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Framework for the Assessment of Plant Protection Products

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Editing log - Framework for the Assessment of Plant Protection Products

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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
2019-11-27	1.7	Clarification of human toxicological evaluation of groundwater metabolites to include persistent metabolites. Update of requirements for PPP for non-professionals use to exclude most concentrated products. Further specifications on requirements to alternatives to vertebrate studies as well as potential endocrine disrupting in-door products. Update of the persistency assessment, and clarification of how to perform groundwater modelling and assess results from groundwater modelling	NANHU/ANL GI	Already in force/ 2020-05-01*
6	2.0	Addition of requirements for co-formulants. Clarification of physical chemical assessment, human toxicological evaluation of metabolites concerning endocrine disrupting (ED) effects, PPP use in private homes and regarding worker RMM for trees and bushes. Minor clarifications on assessment of potential ED effects for greenhouse worker, for acute inhalation toxicity, and seed treatment. Clarification of requirements for groundwater modelling (Annex 6) and requirements for metabolites of no toxicological concern (Annex 16). Criteria for low-risk products (Annex 18). Clarification regarding the evaluation of the relevance of soil types for Denmark, persistency in soil and crop interception. Update of the soil types in Denmark (Annex 2), climatic conditions in Denmark (Annex 3), paved areas (Annex 4), vegetation cover and deposition on soil (Annex 11), crop rotation (Annex 13). Update of the environmental risk assessment for non-target organisms, especially for aquatic organisms B&M (including Annex 17).	LOLUN/KILSA/PIAHU/MAHOK/NIHJO/NIGIV/AAA/STNSC/ANXNI	2027-01-01

* 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 May 2018 for version 1.6, December 2019 for version 1.7, and October 2026 for version 2.0.

Contents

INTRODUCTION	5
PURPOSE OF THIS DOCUMENT	5
LEGAL FRAMEWORK.....	5
FRAMEWORK FOR IDENTITY, PHYSICAL-CHEMICAL RISK ASSESSMENT AND ANALYTICAL METHODS.....	7
BACKGROUND	7
GENERAL APPROACH TO IDENTITY, PHYSICAL-CHEMICAL RISK ASSESSMENT AND ANALYTICAL METHODS.....	7
Identity.....	7
Part B2: Physical and chemical properties	8
Part B4: Further information	8
Packaging.....	8
Analytical methods.....	8
FRAMEWORK FOR THE HUMAN HEALTH RISK ASSESSMENT	8
BACKGROUND	8
LEGISLATIVE USER RESTRICTIONS	9
GENERAL APPROACH TO HUMAN HEALTH RISK ASSESSMENT.....	9
HAZARD IDENTIFICATION – classification	9
Acute Inhalation toxicity when PPP is applied by spraying.....	10
Endocrine disrupting properties.....	10
HAZARD CHARACTERISATION – setting of the AOEL and AAOEL.....	11
EXPOSURE ASSESSMENT.....	11
Dermal absorption.....	12
Operators.....	12
Workers.....	12
Bystanders	12
Residents.....	12
Out-door treatment - fields, lawns, orchards.....	13
In-door treatment - greenhouse	13
Tunnel-use	14
Home and Garden – non-professionals	14
Seed treatment	14
RISK CHARACTERISATION	15
Out-door Treatment - fields, lawns, orchards.....	15
In-door treatment – greenhouses	19
Metabolites of no concern.....	21
RISK MANAGEMENT – Decision making	21
FRAMEWORK FOR THE ENVIRONMENTAL ASSESSMENT	22
BACKGROUND.....	22
FATE AND DISTRIBUTION/BEHAVIOR IN THE ENVIRONMENT: PERSISTENCE, MOBILITY AND BIOACCUMULATION.....	23
EFFECTS ON NON-TARGET ORGANISMS: AQUATIC AND TERRESTRIAL ORGANISMS	24
ENVIRONMENTAL RISK ASSESSMENT AND DECISIONS.....	25
FATE AND BEHAVIOUR/DISTRIBUTION IN THE ENVIRONMENT	25
Fate in air	25
Persistence in soil	25
Predicted environmental concentrations in soil	27
Predicted environmental concentrations in groundwater.....	27
Predicted environmental concentrations in surface water	28
BIOACCUMULATION.....	29
EFFECTS ON NON-TARGET ORGANISMS AND RISK ASSESSMENT.....	29
Aquatic organisms	31
Bees.....	32
Arthropods.....	32
Non-target soil meso- and macrofauna	32
Microorganisms.....	32
Biological methods of wastewater treatment.....	32
Non-target terrestrial plants.....	33

LIST OF ANNEXES.....	34
ANNEX 1: DATA REQUIREMENTS FOR PLANT PROTECTION PRODUCTS	35
ANNEX 2: SOIL CLASSIFICATIONS IN DENMARK.....	36
ANNEX 3: CLIMATE CONDITIONS IN DENMARK.....	37
ANNEX 4: PAVEMENTS AND SIMILAR USE AREAS.....	38
~~ANNEX 5: APPRAISAL OF FIELD STUDIES AND LYSIMETER TESTS FOR POLLUTION OF GROUNDWATER.....~~	~~39~~
ANNEX 6: APPRAISAL OF MATHEMATICAL MODELLING OF RISK OF POLLUTION OF GROUNDWATER	40
ANNEX 7: GROUNDWATER MONITORING DATA	42
~~ANNEX 8: DEFINITION OF READILY BIODEGRADABLE.....~~	~~44~~
ANNEX 9: NON-SPRAYING BUFFER ZONES TO THE AQUATIC AND TERRESTRIAL ENVIRONMENT.....	45
~~ANNEX 10: ASSESSMENT FACTOR IN MESOCOSM STUDIES~~	~~46~~
ANNEX 11 VEGETATION COVER AND DEPOSITION ON SOIL	47
~~ANNEX 12: ENVIRONMENTAL RISK ASSESSMENT OF CUMULATIVE EFFECTS FOR COMBINATION PRODUCTS~~	~~52~~
ANNEX 13: CROP ROTATION - NORMAL CULTIVATION PRACTICES IN DENMARK	53
ANNEX 14: CRITERIA FOR PESTICIDES THAT CAN BE USED BY AND SOLD TO NON-PROFESSIONAL USERS	54
ANNEX 15: BENEFICIAL ORGANISMS (OTHER THAN BEES).....	55
ANNEX 16 - DANISH REQUIREMENTS FOR GROUNDWATER METABOLITES AND PERSISTENT METABOLITES OF NO TOXICOLOGICAL CONCERN	57
ANNEX 17: GUIDANCE NOTE ON HIGHER TIER BIRDS & MAMMALS RISK ASSESSMENT IN DENMARK.....	61
ANNEX 18: LOW RISK PLANT PROTECTION PRODUCT	65
ANNEX 19: ABBREVIATIONS	66
REFERENCES	68

Introduction

Purpose of this document

The aim of this document is to provide the framework for the assessment of plant protection products for national authorisation in Denmark. The document may serve as guidance to applicants 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.

In addition to the present Danish framework, applicants must also ensure that applications comply with the Northern Zone (NZ) Guidance document (GD), which facilitates harmonised assessments in the NZ. For the core assessments the NZ GD should be consulted. In some areas, Denmark has specific Danish requirements due to political or geographical reasons. Hence, for the national assessment in DK the present framework is an addition to the NZ GD.

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 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 set out 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.

The individual implementing regulations for approval of active substances contain specific provisions to which Member States must pay particular attention if appropriate. These provisions must be addressed for the product applications and assessments when relevant.

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 that plant protection products may have on human and animal health and of the impact on the environment. The

document applies to all plant protection products which are to be authorized 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 identity, physical-chemical risk assessment and analytical methods

Background

This part of the document concerns identity, technical properties and physical-chemical risk assessment of plant protection products (PPP) as well as validation of analytical methods in accordance with Regulation (EC) No 1107/2009.

General approach to identity, physical-chemical risk assessment and analytical methods

In general, PPPs should be fully characterized in regard to identity of the components of the PPP. Risk assessment of physical-chemical properties and assessment of technical properties of the PPP is performed in order to identify any physical or chemical hazards as well as to assess if the properties of the PPP is acceptable for the uses of the PPP and don't indicate a potential risk to users of the PPP.

Identity

Reference should be made to the Northern Zone Guidance Document (newest version) for general required information on co-formulants and details on assessment of alternative co-formulants. More specifically, the following information is required for co-formulants that are substances or mixtures:

- Name of all ingredients, including impurities (e.g. residual monomers in polymer co-formulants), additives etc. This includes impurities ≥ 0.1 % (also components < 0.1 % must be reported if (eco)toxicologically relevant.
- Content of all ingredients in weight % accounting for 100 %. For intervals, only very narrow ranges are accepted.
- CAS and/or EC numbers

Additional information required for co-formulants that are UVCBs¹:

- Irrespective of concentration, all known components should be specified by their IUPAC name and CAS no.
- All components present in a concentration >10 % in the UVCB should be specified with IUPAC name and preferably CAS no.
- Unknown components present in a concentration <10 % in the UVCB should be identified by a generic description of their chemical nature as far as possible.
- Components which cannot be identified individually shall be described in groups based on chemical nature.
- All components contributing to the classification of the UVCB should be specified.

In case the information is confidential and not available to the applicant, the information should be submitted from the supplier directly to the Danish EPA.

Furthermore, if alternative co-formulants are included in the application, equivalency must be demonstrated. For polymers and other substances that cannot necessarily be identified solely by the CAS no., information should be provided that demonstrate physical-chemical equivalence (e.g. for polymers: chain length (e.g. degree of ethoxylation and propoxylation where relevant), polydispersity, mass-based molecular weight (M_w), number-based molecular weight (M_n), physical-chemical properties etc. For UVCBs: e.g. performance specification, physical-chemical properties etc.).

¹ Guidance for identification and naming of substances under REACH and CLP, version 3.0, 2023

Part B2: Physical and chemical properties

In accordance with 2.11 of Commission Regulation (EU) No 284/2013, all classification categories must be addressed including whether the PPP is corrosive to metals. A study compliant with Regulation (EC) No 1272/2008 shall be submitted unless a reasoned case in accordance with Guidance on Application of the CLP Criteria can be made as to why a study is not needed and a classification is not warranted. It is noted that corrosivity is a complex endpoint and, therefore, information on corrosive properties of the individual components cannot be extrapolated to the PPP. Guidance on the Application of the CLP Criteria, Part 2 lists criteria for considering a substance or mixture for classification where no test data is available. If any of these criteria are fulfilled, a test should be performed in order to conclude on the classification of the PPP.

Part B4: Further information

All sections of Part B4 (4.1-4.5) in accordance with Regulation (EU) No 284/2013 must be included in the registration report.

Packaging

Where available, pictures of packaging before and after storage should be submitted, especially in cases where changes to the packaging after storage has been observed.

For guidance on extrapolation of packaging material and container sizes, reference should be made to Guidance Document for the Generation and Evaluation of Data on the Physical, Chemical and Technical Properties (SANCO/10473/2003 (newest revision)). However, Denmark do not by default accept extrapolation from smaller sizes (e.g. 1 L) to bulk containers (> 50 L). If extrapolation from small to large containers is applied for, a reasoned case should be presented demonstrating that the smaller volume is representative for the larger volume container. In general, Denmark accepts extrapolation from 0.5 to 50 times the tested size without further data. In case larger or smaller sizes are applied for, additional stability data in representative container sizes must be submitted.

Extrapolation from larger to smaller containers should be done with caution, as larger containers in general is not considered representative for smaller containers due to higher interaction between packaging and content in smaller volume packaging.

Analytical methods

Validation of all analytical methods used in the risk assessment (e.g. in aquatic studies for ecotox assessment), should always be presented and assessed in Part B5 with reference to the relevant section where the study is evaluated (e.g. Part B9). Validation of analytical methods used for quantification of active substance and relevant impurities in the PPP in stability studies must be presented and evaluated separately in Part B5 if different from the methods included under Part B5 section 5.2.1.1 and 5.2.1.2 (5.1.1).

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 updates on the human health assessment in this version 1.8 relate to assessment of home and garden products used indoor in private homes, worker RMM for trees and bushes, and Annex 16 where the requirements for assessment of endocrine disrupting properties have been elaborated. Minor clarifications were added to sections on acute inhalation toxicity, greenhouse worker assessment with regard to active substances that are potential endocrine disruptors, and seed treatment.

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.

From 1 July 2020 sale of concentrated products to non-professionals by retailers is banned (authorisations are withdrawn 31 December 2019)². Only concentrated products containing the following active substances can remain authorised for non-professional use:

- insect soaps
- fatty acids
- sulphur or iron
- microbiological agents
- pheromones for insect confusion

Furthermore, the Ministry of Environment's Statutory Order on pesticides³ 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 Regulation⁴, 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 **as well as information on the co-formulants**.

The data requirements are provided in Commission Regulation (EU) No 283/2013 for the active substance and Commission Regulation (EU) No 284/2013 for the PPP. The criteria for classification of the

² In accordance with the supplementary agreement from January 2019 to the 2017-2021 Pesticide Strategy.

³ Statutory Order no. **961 of 26 June 2023** on Pesticides as amended

⁴ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures amending and repealing 67/548/EC and 1999/45/EC and amending Regulation (EC) No 1907/2006

adverse effects are described in the CLP Regulation 1272/2008. The approach for assessment of acute toxicity including skin and eye irritation and skin sensitisation should be applied in accordance with the Northern Zone Guidance Document (newest version).

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. For PPPs containing active substances fulfilling data requirement 7.1.3 a-h, the pre-evaluation method described in the Northern Zone Guidance Document (newest version) cannot be used.

The pre-evaluation method is used to decide how to proceed with the assessment of acute inhalation toxicity in cases where the acute inhalation toxicity is not known for all ingredients in the PPP. Less detailed information can be acceptable in certain cases where the spray dilution is assessed not to be hazardous.

The pre-evaluation method should be applied as described in the Northern Zone Guidance Document (newest version).

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, with some exceptions⁵. From 10 November 2018 the new criteria⁶ and EFSA/ECHA guidance⁷ on endocrine disrupting properties came into force. Before this date the endocrine disrupting properties were evaluated according to the interim criteria in Regulation 1107/2009 and for earlier approved active substances endocrine disrupting properties were not evaluated consistently.

In Denmark, the potential endocrine disrupting properties will be included in the hazard identification of the PPPs used in greenhouses. Active substances (re-)evaluated in the EU before the new criteria where the (re-)evaluation resulted in one of the following outcomes will be considered: 1) Endocrine disrupting properties were indicated, 2) endocrine disrupting properties could not be ruled out (e.g. due to data gaps) or 3) the end-point was not evaluated. Furthermore, substances with a wide documentation in the open literature can also be included.

The ED properties of active substances evaluated in the EU in accordance with the new criteria and guidance⁸ will also be included in the evaluation of new greenhouse-uses.

The concern is focused on the in-door worker scenario as the spraying and other work tasks performed

⁵ In some cases where negligible exposure can be demonstrated, it can be approved (see Annex II paragraph 3.6.5 and 3.8.2 of Regulation 1107/2009)

⁶ Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties.

⁷ Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009

⁸ Documentation based on either a clear conclusion in the minutes from the EFSA expert meeting or a published EFSA conclusion.

in-door give rise to higher and longer-term exposures than out-door use and **because** Danish green-houses employ 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 set⁹.

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 Danish EPA applies the AOEL and the AAOEL determined in the EU. The AOEL is determined in the EU by the following approach:

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 UFs¹⁰ 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 calculator¹¹. Guidance on the setting of an acute AOEL is not finalised 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).

⁹ See the later paragraph about 'Endocrine disrupting properties' below

¹⁰ 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.

¹¹ 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. Updated version: EFSA (2022) Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products. EFSA Journal 2022;20(1):7032

Usually exposure assessment and comparison to the AOEL or the AAOEL 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).

Dermal absorption

For operators, workers, bystanders and residents dermal exposure of pesticides is considered as being the major route of exposure. Therefore, an estimate of the dermal absorption of the concentrated PPP and the in-use dilution(s) 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 and loading of 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 **greenhouse and storage** 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. 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 on operator, worker, bystander and resident exposure assessment 2022¹² (EFSA GD (2022)) and EFSA OPEX online calculator is used for the exposure estimation of operator (professional), worker, bystander (child and adult) and resident (child and adult). Application techniques used outdoors 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. The approach outlined in the Northern Zone Guidance Document (newest version) should be followed.

In-door treatment - greenhouse

EFSA GD (2022) and EFSA OPEX online calculator is used for the exposure estimation of operator (professional), worker, bystander (child and adult) and resident (child and adult)

Spraying techniques in greenhouses are manual e.g. lance sprayers or knapsack or automated application e.g. roof fogger or low-volume mist sprayer. The EFSA GD (2022) has introduced the possibility to include trolley sprayers in the exposure assessment. This is a specific piece of equipment (please see INSST, 2020, in the EFSA GD (2022)), and thus it should be ensured that the trolley is appropriate for the crop in which it is to be used. It is currently unclear, if trolley sprayers as described in the EFSA GD (2022) are used in Danish green houses.

The EFSA GD (2022) has introduced “rain suits” as a possible risk mitigation measure for operators in greenhouses. According to EFSA OPEX online calculator, this type of PPE reduces the exposure significantly compared to certified coveralls. However, it should be noted that according to the data on which the EFSA GD (2022) is based, the rain suits were uncertified clothing consisting of PVC-coated nylon. This does not in itself comprise PPE according to regulation (EU) 2016/425. Indeed, “rain suit” does not adequately describe any type of chemically resistant PPE. Therefore, if an applicant wishes to use rain suit as a risk mitigation measure, it should be ensured that the garment complies with regulation (EU) 2016/425 and that the SDS thoroughly describes what PPE is to be used. ECHAs Guidance on the Compilation of Safety Data Sheets, ver. 4.0 (or newest version) should be consulted for

¹² EFSA (2022) Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products. EFSA Journal 2022;20(1):7032

information on what constitutes an adequate description of PPE. DEPA requires the garment to be a chemically resistant and waterproof, two piece garment.

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

In the EFSA OPEX online calculator, task specific factors are used for the worker exposure assessment (see Table 11 in EFSA GD (2022)). 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 or modelling will 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 (newest version) when the in-door spray scenarios, used in EFSA OPEX online calculator, do not take the inhalation contribution into consideration.

In general, the approach outlined in the Northern Zone Guidance Document (newest version) should be followed.

Tunnel-use

In DK tunnels are normally 8-9 metres wide and could be 100 metres or more long. The tunnels can open and close in the ends often electronically, which is important for temperature regulation. 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 possibility to better control climate and pests.

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

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

Home and Garden – non-professionals

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 PPPs. For products used in private homes, an evaluation of the risk to children should be included. In general, the approach outlined in the Northern Zone Guidance Document (newest version) should be followed.

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).

Usually seed treatment is authorised for closed industrial plants. This shall be stated on the label. If other uses are applied for, documentation for the specific use is required.

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 are 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 is more 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 authorized.

Risk characterisation is determined on two levels – acute risk and longer 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 OPEX online calculator](#), e.g. seed treatment, 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.

Longer term risk

Comparison between the exposure assessment and the AOEL should be done for operators, workers, bystanders and residents. However, longer term exposure of bystanders is essentially the resident scenario and thus covered by the resident risk assessment in the [EFSA OPEX online 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 [assessment](#) can be conducted taking PPE into consideration:

Tier 1 – 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 and RPE during mixing and loading

Tier 4 – workwear and gloves during mixing and loading and application

Higher Tier – e.g. head protection, respiratory PPE, closed cabin, or drift reducing equipment¹³.

Workers:

The availability and use of chemically resistant gloves during pre-harvest activities and manual harvest activities are considered a realistic RMM. However, note that work with PPPs must always be carried out in accordance with the rules from the Danish Working Environment Authority.

Crop inspection tasks for all crops: Use of chemical resistant gloves is considered realistic.

Pre-harvest activities (maintenance, searching, reaching and picking): Use of chemical resistant gloves is considered realistic.

Manual harvest activities: Use of chemical resistant gloves is considered realistic.

Worker tasks can be performed at all times in the crop specific season (crop inspection, pre-harvest activities and manual harvest activities). Therefore, if exposure assessment requires RMM, this should always be indicated on the label.

RMM shall be considered in a tiered manner.

Workwear is always assumed (coverall or long-sleeved shirt and trousers), however it may not be required if the assessment of potential exposure is presented and shows acceptable exposure.

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 following the tiered approach below can be considered.

Use of re-entry interval, chemical resistant gloves and reduced work rate can be considered as RMM. The use of a re-entry interval is considered as tier 2, however, in cases where the re-entry interval becomes too long compared to what is practically possible (this will be crop specific and also dependent on time of treatment and worker tasks), the next tier can be used e.g. if the re-entry interval becomes unrealistically long, when no gloves are used, the use of gloves can be considered and so on.

A reduced work rate can be accepted in special cases, but a work rate less than 2 hours per day is considered unrealistic.

Tiered approach:

Tier 1: No gloves

Tier 2: Re-entry and no gloves

Tier 3: Gloves

Tier 4: Re-entry and gloves

Tier 5: Reduced work rate and no gloves

Tier 6: Reduced work rate and gloves

Re-entry is calculated with the updated EFSA OPEX online calculator.

Table 1: RMM for outdoor worker scenario

¹³ In the EFSA calculator drift reducing nozzles reduces the drift by 50%.

Tasks	Crop type (or group)*	Chemical resistant gloves accepted	Re-entry (days)	Reduced work rate (hours/day) (in special cases)
Crop handling (pre-harvest) and harvest (8 hours)**	Low vegetables (bulb, fruiting, legume, root, tuber), low berries (e.g. strawberries)	Yes	Number of days until re-entry without or with chemical resistant gloves in a tiered manner	Reduced number of working hours/day until re-entry for 8 hours/day is possible. Less than 2 hours/day is not considered realistic
	Low vegetables - brassica	Yes		
	Pome and stone fruit, high berries/bush berries	Yes		
	Ornamentals (low and high (e.g. trees and shrubs))	Yes		
Irrigation and inspection (2 hours)	All crops	Yes		-

*list not exhaustive

**Worker tasks of pre-harvest and harvest activities are not relevant exposure scenarios after herbicide application.

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 metres. It is possible to reduce the buffer strip by the use of drift reducing equipment from 10 metres to 5 metres and from 5 metres to 2 metres if this is confirmed in the exposure assessment. The buffer strip in orchards is per default 5 metres and can similarly be increased to 10 metres and be reduced from 10 to 5 metres with the use of drift reducing equipment. However, it cannot be reduced from 5 to 2 metres because of lack of data. If a 10 metres buffer strip is not sufficient, drift reducing equipment can be applied in combination with either to 2, 5 or 10 metres buffer strip depending on the exposure assessment.

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. must be indicated on the label, in one of the following cases:

1) Based on hazard:

- a. If the product is acute toxic category 1, 2 or 3.
- b. If the product is STOT SE category 1.
- c. If an ARfD, but no AAOEL, is set for the active substance¹⁴.

A default buffer strip of 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.

¹⁴ If an AAOEL is set, then the acute toxic effect will be covered by the risk assessment in the EFSA calculator, and the ARfD shall not trigger a 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 metres and should be stated on the label. This cannot be reduced as no data are available below 5 metres.
 - b. In fields the default buffer strip is 2 metres. 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 metres 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.
- 4) A buffer strip is not required if the application method does not produce fine droplets and therefore does not cause drift (e.g., application using EasyRoller).

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

If the sentence is required based only on the risk assessment for bystanders the label sentence is as follows: ”Må ikke anvendes nærmere end x meter fra veje og offentlige arealer for at beskytte forbipasserende”

If the sentence is required based only on the risk assessment for residents the label sentence is as follows: ”Må ikke anvendes nærmere end x meter fra boliger og institutioner for at beskytte beboere.”

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 and a working day of 1 hour should be assumed. The size of packaging should fit the size of treated area. Hence, the packaging can 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 Annex 14 Criteria for pesticides that can be used by and sold to non-professional users.

For PPPs to be used in private homes, the following statement must be included on the label if children are likely to have access:

- Keep pots treated with the product away from children.

For rodlets the following sentence must be included as well:

- During application in pots, the rodlet has to be pushed into the soil deep enough and well covered with soil to be out of sight of children.

For other uses, specific RMM may be required.

In-door treatment – greenhouses

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 assessment can be conducted taking PPE into consideration:

Tier 1 – 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 and RPE during mixing and loading

Tier 4 – workwear and gloves during mixing and loading and application

Higher Tier – e.g. respiratory PPE, rain suit, head protection or certified coveralls.

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 chemical resistant gloves or a consideration of a realistic re-entry interval is appropriate – referring to RMM in worker section – out-door treatment. Worker tasks can be performed at all times in the crop specific season (crop inspection, pre-harvest activities and manual harvest activities). Therefore, if exposure assessment requires RMM, this should always be indicated on the label.

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

Re-entry is calculated with the EFSA OPEX online calculator.

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 than 1% of the AOEL a waiting period is relevant. The reason is that the data set behind the model is from 16 hours after application. If the greenhouse should be closed for all access for more than 8 hours after application, such a waiting period should be indicated on the label.

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

Tasks	Crop type (or group)*	Chemical resistant gloves accepted	Re-entry (days)	Reduced work rate (hours/day) (in special cases)
Crop handling (pre-harvest) and harvest	Low and high vegetables (edible crops)	Yes	Number of days until re-entry without or	Number of working hours/day until re-entry

(8 hours)	low berries	Yes	with chemically resistant gloves in a tiered manner.	for 8 hours/day is possible. Less than 2 hours/day is not considered realistic
	Strawberries	Yes		
	Ornamentals (low and high)	Yes		
Irrigation and inspection (2 hours)	All crops	Yes		-

*list not exhaustive

Endocrine disrupting properties

In case PPPs contain one or more active substances that are potentially¹⁵ 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 required.

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

- If the concern is founded on a proposed classification as both Repr 2 and Carc 2¹⁶ then new calculated AOELs based on the effects on reproductive toxicity (UF=300) and carcinogenicity (UF=500) should be compared to the original AOEL.
- If the concern is founded on a proposed classification as Repr. 2 and a toxic effect on an endocrine organ¹⁶, then a new calculated ED AOEL based on the most sensitive endocrine mediated effect level (UF=300-500 depending on the data package) should be compared to the original AOEL.
- If the concern is founded on specific ED effects¹⁷, then a new calculated ED AOEL based on the most sensitive endocrine mediated effect level (UF=300-500 depending on the data package) 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 required. 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 greenhouse worker until endocrine disrupting properties according to the new criteria and guidance are included in all EU (re-)evaluations. The in-door worker should therefore not re-enter the greenhouse until a minimum of 10 days after spraying, and gloves should always be worn during handling of crops and soil regardless of the stage of the production. Gloves, re-entry interval and, if relevant, the spraying-picking interval should be stated on the label.

Bystanders and residents:

Bystander/resident exposure is now included in the EFSA OPEX online calculator and must be addressed. A justification must be provided if waived.

¹⁵ See paragraph about 'Endocrine disrupting properties' above.

¹⁶ The interim criteria were used for identification of Endocrine disrupting properties before November 2018

¹⁷ Specific ED effects may result from 1) EU-evaluation according to new ED criteria and GD based on minutes from experts meeting, 2) EU-evaluation highlighting ED in EFSA conclusion, or 3) ED effects known from substantial open literature including US EPA Tox Cast, DEPA research projects, and DAR/RAR.

Metabolites of no concern

It must be demonstrated that groundwater metabolites and persistent metabolites without pesticide effects are of no toxicological concern.

The criteria that trigger the need of toxicological assessment of metabolites are (see section on Persistence in soil):

- Metabolites in groundwater with concentrations $> 0.1 \mu\text{g/L}$ to $0.75 \mu\text{g/L}$.
- Metabolites that are persistent according to the criteria listed in the section "persistence in soil".

See Annex 16 for guidance on the specific Danish requirements for the toxicological assessment of metabolites.

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.

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, bioaccumulation and 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 Principles¹⁸, assessment of the fate and distribution/behaviour in the environment must consider all parts of the environment. To the extent possible the assessment should, therefore, 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 areas considered relevant to a given use are assessed (requirements on data for the different areas of use are shown in Annex 1)¹⁹.

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 acceptable the assessment stops at this tier. If not, the assessment continues to higher tiers, where the assessment is gradually made more realistic 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 metabolites²⁰ 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 very broad in the Uniform Principles,

¹⁸ Laid down in Regulation 546/2011 (see Article 29(6) in The Regulation), which was former Annex VI of Directive 91/414/EEC.

¹⁹ 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 Plant Protection Regulation (EC) No. 1107/2009/EEC.

²⁰ Metabolites are defined here as all degradation, reaction and transformation products of pesticides that differ from the ultimate mineralisation products, i.e. CO₂, H₂O and mineral salts.

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. In 2003, subsequent to the Uniform Principles, 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. According to the Danish Environmental Protection Agency this guidance 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 "Groundwater/Mobility" below) 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: Metabolites, which a) 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 the maximum of formation is not yet reached **at the end of soil degradation studies**. If, based on the available documentation, there are indications that metabolites accounting for lower levels could prove problematic (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 sections.

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.

These properties are assessed to determine whether there is any risk of exceeding the limit values or cut-off values (called "triggers" in the Uniform Principles) 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 finds that it is not possible to appraise the long-term consequences of the use of highly persistent substance (i.e. with half-lives of more than six months **in soil**) at present.

According to the Danish Environmental Protection Agency authorization cannot be granted to products with an active substance that is very persistent ($DT_{50} > 6$ month **in soil**), if the products will be used in a way that involves exposure of the external environment.

Concerning pollution of groundwater, there is no actual "unless clause" in the Uniform Principles, as reference is only made to **compliance with** 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 risk assessment **of non-target organisms the starting point in general** 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)²¹.

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. 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)²².

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

- Extrapolation is done from only a few species to all species
- 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.

A risk assessment based on the quotient method can therefore 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). However, the Uniform Principles do not offer a more specific definition of how this should be proven.

EU guidance documents are drafted on an on-going basis and are used in the EU assessments when

²¹ 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.

²² 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.

substances are approved for the European marked (Regulation (EC) No 1107/2009) in order to clarify the unless clauses in the Uniform Principles. 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 often 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 be emphasised that each individual decision will be based on an overall assessment of the risk constituted by the product taking into account all available information.

Assessment of cumulative ecotoxicological effects of products containing chemical mixtures is 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 **Northern zone GD**).

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 issues 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. If three or more valid field studies, representative of Danish conditions, are available then most emphasis will be placed on the field data. The persistency is assessed from **laboratory modelling endpoints (half-lives normalised to 20°C and pF2) and field** trigger endpoints (non-normalised half-lives). Assessment of persistency should not be based on average or percentiles of the data. Instead, data are assessed by considering the soil types used with a focus on soil

types representative of Danish conditions (see Annex 2 regarding Danish soil types). If in general these soils have a DT₅₀ above 180 days, products containing the active substance cannot be authorised for outdoor use. If only some of the soil DT₅₀ values are above 180 days, an ad hoc assessment is performed to decide if these data constitute the majority of data and if it is likely that DT₅₀ 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 are considered to be of no concern regarding persistence if the following requirements are met:

- The metabolite fulfils 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 have a DT₅₀ < 180 days they do **not constitute an unacceptable risk to the environment, from the standpoint of persistence.**

If a metabolite which fulfils the three requirements listed above ~~of no concern~~ has a DT₅₀ > 180 days it does **not constitute an unacceptable risk to the environment, from the persistence standpoint.**

If the active substance or metabolites of concern have a DT₅₀ > 180 days they do **constitute an unacceptable risk to the environment**, and products containing such an active substance cannot be authorised for outdoor use in Denmark.

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

The Danish Environmental Protection Agency decided to change its practices in 2002 (cf. meeting of the Pesticide Advisory Board 7 March 2002) because sufficient information is available on some substances where 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 exemption from the persistence criteria.

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.

Predicted environmental concentrations in soil

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

Predicted environmental concentrations in groundwater

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 values²³ for the pollution of groundwater. These values are:

- 0.1 µg/l for each individual substance.
- 0.5 µg/l for the sum of substances²⁴.

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.

For metabolites without pesticide effect that fulfil the Danish requirements for no concern (see section on human health risk assessment and Annex 16) and that do not constitute a risk to non-target soil 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 limit values set out above for groundwater.

The risk of leaching is initially assessed by mathematical modelling based on a tiered approach. Tier 1 PEC_{gw} values must be calculated as described in the Northern Zone guidance document. Tier 2 simulations are triggered in Denmark when any tier 1 PEC_{gw} value is > 0.001 µg/L for the active substance or any metabolite. The Danish Environmental Protection Agency's requirements for mathematical modelling of tier 2 PEC_{gw} values are listed in Annex 6. The most important requirements are:

²³ 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.

²⁴ To be interpreted as the sum of the active substance and its metabolites.

- The latest version of the PELMO model (or comparable model) with the Hamburg scenario should be used. In addition MACRO 5.5.4 with the Danish scenarios (Karup and Langvad) can be used. If both models are used then the results of both models must fulfil the limit values.
- Substance specific parameters: 80th percentiles of degradation rates and sorption ratios ($1/n$) and 20th percentiles of K_{OC} values must be used²⁵.
- Separate model runs must be executed for at least three individual days of the period in which use of the product is proposed. In each set of three model runs, only the application dates may vary. All other input values (e.g. crop interception) must be the same. Separate models runs must be performed for each season.
- Use every 2nd, 3rd, 4th and 5th year can only be used as a refinement option if the crop can only be grown in the 2nd, 3rd, 4th and 5th year. A list of crops where this refinement option can be used is available in Annex 13.
- The results must be reported as annual averages. This also applies if the substance is used every 2nd, 3rd or 4th year. All input and output files must be submitted.
- An exceedance of the limit value of 0.1 µg/L is allowed in 1 out of 20 annual averages. The result of the modelling should therefore be reported as maximum annual average concentrations and number of exceedances of the limit value (not as 95th percentile).

This ensures that 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 authorised 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 (see Annex 7 for further guidance). Data from the Pesticide Leaching Assessment Programme²⁶ (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 areas²⁷). 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).

Predicted environmental concentrations in 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

²⁵ Formation fractions and DT₅₀ values should be from the same tier (i.e. lab or field) if data are available. If data are not available, worst case default values should be used.

²⁶ <https://www.vap.dk/?lang=en>

²⁷ Special documentation is required for paved areas and a special assessment is carried out, see Annex 4 (cf. Newsletter, Nov. 1999).

(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. Step 2 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 described 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 are 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 metres has to be added on the label in order to cover the FOCUSsw Step 3 model assumptions for field crops. For orchards and other tall crop (e.g. wine) a no-spray zone of 5 metres has to be added on the label. 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 account for possible higher PEC values at FOCUSsw Step 3), a 2 metres 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 applied²⁸. 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

The assessment of bioaccumulation follows EU- and Northern Zone GD.

Effects on non-target organisms and risk assessment.

The Danish risk assessment for non-target organisms follows the Northern Zone GD with a few exceptions. The specific Danish requirements and exceptions from the Northern Zone GD are described in the following sections.

²⁸ 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.

General considerations

Geometric mean

Geometric mean effect endpoints are accepted in line with the Northern Zone GD.

Formulation toxicity data

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.

Use of time weighted average

Possible use of a time weighted average (TWA) exposure when conducting risk assessments of *chronic effects* should follow the recommendations in the EFSA (2013) and the Northern Zone GD i.e. addressing all concerns regarding use of TWA.

Drift reducing equipment

DEPA does not accept drift reducing equipment as a risk mitigation measure in the ecotoxicological risk assessment. However, in accordance with statutory order No. 1750 of 14/12/2015 and the associated guidance document on use of drift reducing equipment²⁹, DEPA accepts the use of drift reducing equipment as a mean to reduce the buffer zones stated on the product label.

Birds and mammals

The Danish risk assessment for birds and mammals generally follows the Northern Zone GD that again follows EFSA (2023), Guidance on the risk assessment for Birds and Mammals, specific national requirements and exceptions to the Northern zone GD are given below.

Higher tier risk assessment

If higher tier refinements are required to address the risk to birds and/or mammals, guidance is given 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”. In addition, an associated calculation tool is provided in the form of an Excel spreadsheet³⁰.

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

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

²⁹ Available on the Danish EPA website <https://mst.dk/erhverv/sikker-kemi/pesticider/anvendelse-af-pesticider/sproejtetechnologi/reduktion-i-vindafdrift>

³⁰ Available on the Danish EPA website <https://eng.mst.dk/chemicals/pesticides/applications-for-authorisation-after-14-june-2011/cooperation-in-the-north-zone/>

If needed, further higher tier refinements, accepted by Denmark, are set out in Annex 17 “Guidance Note on Higher Tier Birds & Mammals Risk Assessment in Denmark”. This Guidance Note describes a number of options for refinement of the risk assessment for birds and mammals, which apply to national registrations of plant protection products in Denmark. Such refinements include:

- Exceptions regarding Scenarios and Focal Species
- Introduce both acute and long-term PD refinements
- Ad-hoc assessment of RUD values
- Refinement of DT50
- Interception and PT.

Cumulative risk assessment:

For cumulative risk assessment follows EFSA (2023), Guidance on the risk assessment for Birds and Mammals.

Aquatic organisms

The Danish risk assessment for aquatic organisms generally follows the Northern Zone GD, specific national requirements and exceptions to the Northern zone GD are given below.

Endpoint and Assessment Factor from higher tier studies

ERO-RAC derived from mesocosm studies:

The Danish EPA accepts use of the Ecological Recovery Option (ERO) (to derive a Regulatory Acceptable Concentration (RAC)) derived from mesocosm studies. Assessment shall follow EFSA’s Aquatic GD (2013), except from the following Danish requirements:

- The recovery period may not exceed 4 weeks.
- Mesocosm studies with invertebrates may be considered representative of fish, if data on the specific substance does not indicate that fish are more sensitive than invertebrates.
- 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.

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.

Refinement of the assessment factor, AF for ERO-RAC

It is possible to lower the AF e.g., if:

- Several studies of high quality are submitted and the studies illustrate 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.
- Other higher-tier studies that support the NOAEC (No Observable Adverse Effect Concentration) are available.
- Other single species laboratory studies conducted with the most sensitive organisms, or with the most sensitive stages of these organisms (e.g. newly hatched larvae), are available.

Accepted risk mitigation measures

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 crops.

Cumulative risk assessment

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

Bees

The Danish risk assessment for bees follows the interim risk assessment procedure in the NZ GD.

Arthropods³¹

The Danish risk assessment for arthropods generally follows the Northern Zone GD, specific national requirements and exceptions to the Northern zone GD are given below.

Accepted risk mitigation measures:

If relevant, buffer zones can be considered to mitigate exposure in off-field areas (specifically protect §3-habitats). Please refer to Annex 9 for specifications.

Beneficial arthropods:

The assessment of beneficial arthropods is described in Annex 15.

Non-target soil meso- and macrofauna

The Danish risk assessment for soil meso- and macrofauna generally follows the Northern Zone GD, specific national requirements and exceptions to the Northern Zone GD are given below.

Field studies:

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, that recovery occurs within one season/within the intervals between spraying (cf. EPPO Bulletin). If it is documented that no unacceptable effects are expected and the studies are satisfactory, the product is considered not to constitute an unacceptable risk to earthworms/soil-dwelling organisms for the proposed use.

If no such documentation has been presented, or if the available documentation is not sufficient to ascertain that no unacceptable effects can occur in earthworms and other soil-dwelling invertebrates, the product cannot be approved for outdoor use.

Cumulative risk assessment:

For cumulative risk assessment of combination products, where product effect data are not available, follow the Northern Zone GD.

Microorganisms

The Danish risk assessment for microorganisms follows the Northern Zone GD.

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 the use can cause exposure of the wastewater treatment plant (e.g.,

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.

for greenhouse products and post-harvest use). There are no specific guidelines for risk assessment of this area, and therefore an ad hoc assessment can be done on the basis of whether a realistic worst-case PEC can cause unacceptable effects.

Non-target **terrestrial** plants³²

The Danish risk assessment follows the Northern zone GD. 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)).

Accepted risk mitigation measures

If relevant, buffer zones can be considered to mitigate exposure in off-field areas (specifically protect §3-habitats). Please refer to Annex 9 for specifications.

³² Non-target plants are considered to be non-crop plants located outside the treatment area.

List of Annexes

Annex 1: Data requirements for plant protection products

Annex 2: Soil classifications in Denmark

Annex 3: Climate conditions in Denmark

Annex 4: Paved areas

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

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

Annex 7: Monitoring data

~~Annex 8: Definition of readily biodegradable~~

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

~~Annex 10: Assessment of mesocosm studies~~

Annex 11: Vegetation cover and deposition on soil

~~Annex 12: Environmental risk assessment of cumulative effects for combination products~~

Annex 13: Crop rotation - normal cultivation practices in Denmark

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

Annex 15: Beneficial organisms (other than bees).

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

Annex 17: Guidance Note on Higher Tier Birds & Mammals Risk Assessment in Denmark

Annex 18: Low risk plant protection product

Annex 19: Abbreviations

Annex 1: Data requirements for 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).

Specific requirements are mentioned in the individual sections in this National Framework and in the Northern Zone GD. For uses in open greenhouses the requirements in the National supplementary framework for “Environmental risk assessment of plant protection products used in open greenhouses³³” must be addressed.

For outdoor uses in Denmark a proper active substance dossier, that has been assessed at EU level, addressing all basic environmental fate and ecotoxicological data requirements must be submitted. If the active substance dossier assessed at EU level does not support outdoor uses, such uses will be rejected.

³³ <https://eng.mst.dk/chemicals/pesticides/applications-for-authorisation/evaluation-framework>

Annex 2: Soil classifications in Denmark

The relevance of field studies for Danish conditions, must consider whether soil types used in the studies correspond to soil types found in cultivated land in Denmark (see below). Particle size definition (defined by mesh sizes used in sieves) can, however, vary from one country to another and texture classification used in studies conducted in other countries do not necessarily fit the Danish soil texture definitions. As an example, the USDA soil texture classification recommended in the US EPA field study guideline (OPPTS 835.6100 Terrestrial Field Dissipation) does not correspond to the Danish definitions as it uses different sieve mesh sizes. This makes it difficult to compare the study soils with Danish soils. To minimize such difficulties, applicants are encouraged to consider using additional mesh sizes for soil analysis or to try to compare available data with Danish soil types (see below).

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

JB No.	Symbol	Texture definition for soil type	Clay less than 2 µm	Silt 2-20 µm	Fine sand 20-200 µm	Sand, total 20-2000 µm	Organic carbon (%)	Cultivated land in DK, %
1	GR.S.L.	Coarsely sanded	0–4.9	0–19.9	0–49.9	65–100		5
2	F.S.	Finely sanded	0–4.9	0–19.9	50–100	65–100		1
3	GR.L.S.	Coarse clay-mixed sand	5–9.9	0–25	0–39.9	55–95		18
4	F.L.S.	Fine clay-mixed sand	5–9.9	0–25	40–95	55–95		28
5	GR.S.L.	Coarse sand-mixed clay	10–14.9	0–30	0–39.9	45–90		2
6	F.S.L.	Fine sand-mixed clay	10–14.9	0–30	40–90	45–90		37
7	L.	Clay	15–24.9	0–35		30–85		6
8	SV.L.	Heavy clay	25–44.9	0–45		0–75		0
9	M.S.L.	Very heavy clay	45–100	0–50		0–55		-
10	SL.	Silt	0–50	20–100		0–80		-
11	HU.	Humus					≥ 6 ⁽¹⁾	4
12	SPEC.	Special soil types ⁽²⁾						-

¹⁾ Over 6% organic carbon corresponds to ≥10.3% humus. Humus is assumed to be $1.72 \times$ organic carbon.

²⁾ Over 10% clay and over 6% organic carbon.

Source: Landsforsøgene 2025, SEGES innovation (2025) – table 1 page 439

Annex 3: Climate conditions in Denmark

Average precipitation (mm):

Normal	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Year
1991-2020 ¹	65	50	46	39	47	64	66	82	75	83	70	71	759
1971-00 ²	53	34	43	35	42	55	54	59	70	69	65	59	641
1961-90 ³	57	38	46	41	48	55	66	67	73	76	79	66	712
1931-60 ³	55	39	34	39	38	48	74	81	72	70	60	55	664

¹ Rubek et al. (2022)

² Cappelen (2002)

³ Frich et al. (1997)

Average air temperature (°C):

Normal	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Year
1991-2020 ¹	1.6	1.5	3.3	7.2	11.4	14.5	16.9	16.9	13.6	9.4	5.5	2.8	8.7
1971-00 ²	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 ³	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

¹ Rubek et al. (2022)

² Cappelen (2002)

³ 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

The National Statutory Order on Pesticides requires that:

On paved or highly permeable areas, it is not permitted to use plant protection products if the active substances or degradation products of the active substances are not readily degradable according to the statutory order.

With a few exemptions:

- 1) On and around public or private airfields, including military airfields and other aviation facilities.
- 2) On and around tracks and rails on public and private urban and railways.
- 3) On motorway sections with New Jersey concrete barriers. By 'New Jersey concrete barrier' is meant a concrete barrier which may, among other things, be made of reinforced concrete, where the deflecting part has a special geometric design throughout the height of the structure.
- 4) Protected ancient monuments and heritage sites subject to management obligation.

With the following definitions:

Paved areas: Areas where the topsoil or humus layer has been removed and replaced with asphalt, concrete, or similar materials, ensuring that precipitation is directed in a specific direction.

Highly permeable areas: Areas where the topsoil or soil layer has been removed, and where surfaces have been established with paving, tiles, tracks, gravel roads, or similar, which ensure the infiltration of precipitation through the area or a surface runoff to soakaways, surface water, or sewer systems.

Readily degradable: Substances which have a half-life in soil of 10 days or more, where the half-life is the time taken for half of the active substance to be degraded are not readily degradable.

For products that fulfill the above-mentioned requirement the Danish Environmental Protection Agency will perform on an ad hoc basis a specific evaluation based on available data.

References:

Statutory Order on Pesticides (Bekæmpelsesmiddelbekendtgørelsen) latest version³⁴.

³⁴ <https://www.retsinformation.dk/eli/lt/2025/1516>

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

Covered by other sections and Northern Zone Guidance Document.

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

The leaching of active substances and metabolites can 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 and the MACRO model **with the Danish scenarios can be used.** 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, **if field studies are used,** a refinement can be made by selecting the **field** studies that are relevant/representative for Danish conditions e.g. with respect to soil texture, pH **and climate.** **If less than three endpoints are 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 and deposition: The worst case situation regarding soil deposition must be modelled. This situation is identified by combining pesticide dose with the BBCH dependent soil deposition. **Crop interception as required by PELMO in the Danish groundwater modelling approach must be derived from soil deposition values from annex 11 (not EFSA values). If no value for a specific crop is available in annex 11, the EU agreed interception values must be used for this crop (EFSA, 2014).**
- Application dates: 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. If the period, in which use of the product is proposed (GAP use), is for more than 1 season, 3 additional separate model runs must be conducted for every season. The **three** separate model runs should be evenly distributed within the period, and should all be based on the same set of input values (pesticide specific parameters, BBCH, interception etc.). If split application is intended the use must be covered by the model runs.
- The results must be reported as annual averages. This also applies if the substance is used every second, third or fourth year.
- Results of the modelling must be reported as **maximum annual average concentrations and** number of exceedances of the limit value (not as 95th percentile).

- All input and 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, all relevant monitoring data must be included in the assessment. There is currently no adopted EU-guidance on how to assess groundwater monitoring data, but the publication “Conducting groundwater monitoring studies in Europe for pesticide active substances and their metabolites in the context of Regulation (EC) 1107/2009”³⁵ gives direction for assessing groundwater monitoring studies and data and should be consulted.

For the assessment of the leaching risk in Denmark results from the Danish national monitoring programmes (groundwater monitoring, the Agricultural Watershed Catchment Areas), drinking water abstraction wells and the Danish Pesticide Leaching Assessment Programme (PLAP) are used. Data, e.g. from GEUS, open scientific literature or monitoring studies from other countries, which could be relevant and representative for Denmark, should also be included/assessed.

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. 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 **detections**, this must be reported **to show** that the issue has been investigated.

Assessment of results from the Danish Pesticide Leaching Assessment Programme (PLAP)

The results can be obtained either from the PLAP website or by contacting GEUS.

The assessment should contain an introduction which gives an overview of the uses in PLAP. The introduction must present the fields used, the crops, application timing and the dose rates.

When assessing the risk of leaching to groundwater in PLAP only data from the groundwater installations should be used. Hence, data from drains or suction cups are not used.

The assessment of results from PLAP includes a consideration of whether the substances occur in a few individual samples in a short time period in concentrations above the limit value, or if there are many samples below the limit value and many without detections. In these cases the Danish Environmental Protection Agency considers that, although the substance has sometimes exceeded the limit value, the overall picture does not show an unacceptable risk of leaching.

³⁵ Gimsing et al. (2019): Conducting groundwater monitoring studies in Europe for pesticide active substances and their metabolites in the context of Regulation (EC) 1107/2009. Journal of Consumer Protection and Food Safety, July 2019, Volume 14. Open access at <https://link.springer.com/article/10.1007/s00003-019-01211-x>

If many samples exceed the limit value in the groundwater installations over longer time periods, then the risk of leaching is considered to be unacceptable.

The following points should be considered in the overall assessment.

Some substances have been tested several times or for several years. In these cases all data should be included in the assessment. For some substances the first years may not show unacceptable leaching, but after use for a number of years the leaching may become more pronounced. It is, therefore, important to assess the change in findings over time. Most substances have been used on more than one PLAP site, and the different sites may exhibit different patterns in leaching. Leaching may be minimal at one site but more pronounced at another site. The assessment must take into account the results from the most vulnerable site.

All results should be presented, however, the assessment should pay particular attention to the specific uses in PLAP. Some uses (crops, dose rates, application timing, BBCH) may present a higher risk of leaching than others. This should be carefully compared to the intended use.

In PLAP, wells are installed both up-stream and down-stream. Measurements from the up-stream wells give an indication of the leaching from the neighbouring up-stream fields and are hence not directly linked to use of pesticides on the PLAP fields. Measurements from the down-stream wells can be directly related to the use of pesticides on the PLAP fields and hence gives an indication of the leaching potential related to the specific use on the PLAP fields.

When assessing the results from PLAP the weather data should also be included in the assessment. If the weather deviates significantly from the normal weather, then this can affect leaching, e.g. a very dry summer can lead to less leaching and a very wet autumn can lead to more leaching. Description of the weather is presented in the PLAP reports.

Monitoring data from other sources

Data from other monitoring programmes in Denmark and other countries can also add information about the risk of leaching. For information about how to evaluate publicly available monitoring data please consult chapter 7 in Gimsing et al. (2019): Conducting groundwater monitoring studies in Europe for pesticide active substances and their metabolites in the context of Regulation (EC) 1107/2009.

The final assessment of the risk of leaching to groundwater must take into account all relevant information using a weight of evidence approach. This includes knowledge about patterns of use and possible changes in the pattern of use over time.

If available 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~~

Covered by CLP.

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).

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

No-spraying buffer zones to the aquatic environment of 2, 5, 10, 20, 30, 40 and 50 metres are used³⁶.

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, specific drift values for repeated application can be found 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 (90 th percentiles)									
Dis- tance	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			

³⁶ A standard, 2 or 5 metres buffer zone for field crop and orchards respectively 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~~

Covered by section on Aquatic Organisms above and Northern Zone Guidance Document.

Annex 11 Vegetation cover and deposition on soil

The proportion of a spray product deposited on the soil beneath a crop 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 reported by Jensen and Spliid (2003) – see table A11-1. 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) reported in Becker et al (1999). The equation from Olofsdotter and Streibig (1997) is applied to these values to calculate crop interception factors (Oilseed rape, peas, and maize see table A11-2, A11-3, and A11-4 respectively³⁷). Values for crops that are not covered by the above two reports are taken from FOCUS (2002) the EU agreed interception values currently in force must be used (EFSA, 2014).

Regarding interception values calculated based on data from Becker et al (1999), the following rule was applied in order to avoid excessive growth stage intervals for regulatory assessments: if between two growth stage intervals (BBCH stages) there was an increase of $\leq 5\%$ in crop interception, the lowest value was applied across the whole interval (i.e. no new incrementation was created); otherwise if there was an increase of more than 5% crop interception, a new interval was created. When using values, 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.

For potatoes at BBCH 90-99, no measured data is reported in Jensen and Spliid (2003). Five estimated values are available in Becker et al. (1999), but this dataset is too small, and with too high a variability, to use with the equation from Olofsdotter and Streibig (1997). Instead, the EU agreed value is used, in this case (50% crop interception) C.f. footnote 2 under table A11-1. If a desiccant herbicide is used in combination with mechanical flailing of the potato plants, interception by the crop at application of the desiccant on flailed potatoes must be set to 0% as a worst-case unless the applicant can submit data which can reliably demonstrate that another value can be used.

For oilseed rape, DEPA considers that the same deposition values can be applied for winter oilseed rape (WOSR) and spring oilseed rape (SOSR). Becker et al (1999) only contains data on winter oilseed rape (WOSR), which constitutes the large majority of cultivated oilseed in Denmark. The area cultivated with spring oilseed rape (SOSR) was <1% of the total area with oilseed rape in 2021 (SEGES, 2022). Moreover, it is a common practice in Denmark to use a higher seeding rate and plant count per square metre of SOSR compared to WOSR³⁸, hence deposition values for WOSR can be considered conservative compared to that for SOSR at the same growth stage (BBCH).

³⁷ Tables from previous versions have been updated or deleted when covered by EFSA GD.

³⁸ Recommended plant counts are 30-40 plants per square meter in WOSR, and 75-100 plants per square metre in SOSR, respectively - C.f. Danish agronomic guidances on cultivation of winter and spring oil seed rape (SEGES dyrkningsvejledninger).

Table A11-1 Deposition of spray product on soil beneath various crops. The table shows averages, 95 per cent upper and lower confidence intervals, and approximated 80 per cent upper confidence intervals¹ for each growth stage intervals (based on data from Jensen & Spliid, 2003). Extrapolated values *in italic* are added to fill gaps in the growth stage intervals.

Crop	Growth stage	Deposition (% of sprayed)				Crop interception value to be used in groundwater assessments in Denmark (% of sprayed)
Winter cereals	BBCH	95 % lower	Average	95 % upper	80 % upper	
	<i>0-10</i>					<i>0</i>
	11-13	41.1	59.6	86.7	77	23
	<i>14-22</i>					<i>23</i>
	23-28	38.5	50	65.3	60	40
	<i>29</i>					<i>40</i>
	30-32	30.6	36.9	44.7	42	58
	33-34	14.5	18.4	22.9	21	79
	<i>35-37</i>					<i>79</i>
	38-45	6.4	8.2	10.2	10	90
	<i>46-50</i>					<i>90</i>
	51-57	2.7	3.4	4.2	4	96
	<i>58-60</i>					<i>96</i>
	61-71	3.5	4.1	4.7	4	96
	87	11.3	14.7	19.1	18	82
	<i>88-99</i>					<i>82</i>
Crop	Growth stage	Deposition (% of sprayed)				
Spring cereals	BBCH	95 % lower	Average	95 % upper	80% upper	
	<i>0-10</i>					<i>0</i>
	11-13	53.7	65.1	79.8	75	25
	<i>14-19</i>					<i>25</i>
	20-24	41.7	49	57.5	55	45
	<i>25-27</i>					<i>45</i>
	28-32	34.2	38.9	44.7	43	57
	33-35	19.7	23.8	28.8	27	73
	<i>36-48</i>					<i>73</i>
	49-50	13.0	15.8	19.5	18	82
	<i>51-58</i>					<i>82</i>
	59-68	14.1	17.3	21.3	20	80
	<i>69-86</i>					<i>80</i>
	87-89	16.6	20.4	24.9	23	77
	<i>90-99</i>					<i>77</i>

Crop	Growth stage	Deposition (% of sprayed)				
Sugar beet	BBCH	95 % lower	Average	95 % upper	80% upper	
	0-10					0
	11	84.3	99.8	100	100	0
	12	84.1	99.3	100	100	0
	13-14	81.3	93.1	100	98	2
	15-18	69.2	76.4	84.1	81	19
	19					19
	20-22	36.6	42.7	49.9	47	53
	23-29					53
	30-35	24.7	28.9	33.7	32	68
	36-38					68
	39	6.4	7.6	8.9	8	92
	40-99					92
Crop	Growth stage	Deposition (% of sprayed)				
Potatoes	(BBCH)	95 % lower	Average	95 % upper	80% upper	
	0-10					0
	10-19	-	100	-	100	0
	19-25	67.6	90.4	100	97	3
	26-29					3
	30-32	56	74.6	99.5	91	9
	33-34					9
	35-40	40.3	48.5	58.4	55	45
	41-58					68 ³
	59-79	5	6.4	8.2	8	92
	80-90					92
	91-99					50/0 ²

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).

² For the last interval senescence/ripening (BBCH >90), the EU agreed interception value is used. If the application is done on flailed potatoes (i.e. in combination with mechanical flailing), the crop interception must be set to 0%.

³ Since there is a gap in the experimental data in the original study between BBCH 40 and 59, and a large difference in deposition between the two growth intervals, the arithmetic mean of the two deposition values (45 and 92) is used for the interval in between.

Table A11-2: Vegetation cover and calculated crop interception for oilseed rape (based on data from Becker et al, 1999). Values *in italic* are added to fill gaps in the growth stage intervals.

Crop	BBCH code	Mean vegetation cover (%) ¹	Deposition (% of sprayed) ²	Crop interception (% of sprayed)	Crop interception value to be used in groundwater assessments in Denmark (% of sprayed)
Winter and spring oilseed rape	0-9	0	100	0	0
	10-13	6.6 - 9.8	94-91	6-9	6
	14	19	82	18	18
	15-17	33.7 - 38.8	63-68	32-37	32
	18-19	53.8-55.9	47-49	51-53	51
	20-29	61.2	42	58	58
	30				58
	31-39	67.6	36	64	64
	40-50				64
	51-69	77.1 - 79.9	24-27	73-76	73
	70				73
	71-92	88.9 - 90.5	14-16	84-86	84
	93-99				84

1 Data from Becker *et al* (1999), table 8.

2 Calculated on the basis of the following formula: percentage of spray product on soil = 100 - (0.95 x percentage mean vegetation cover).

Table A11-3: Vegetation cover and calculated interception for peas (based on data from Becker et al, 1999). Values *in italic* are added to fill gaps in the growth stage intervals.

Crop	BBCH code	Mean vegetation cover (%) ¹	Deposition (% of sprayed) ²	Crop interception (% of sprayed)	Crop interception value to be used in groundwater assessments in Denmark (% of sprayed)
Peas	0-9	0	100	0	0
	10-15	18.8	82	18	18
	16-21	29	72	28	28
	22-29				28
	30-39	37.8	64	36	36
	40-50				36
	51-59	51.1	51	49	49
	60				49
	61-85	67.7-70.3	36-33	64-67	64
	86-99				64

1 Data from Becker *et al* (1999), table 11

2 Calculated on the basis of the following formula: percentage of spray product on soil = 100 - (0.95 x percentage mean vegetation cover).

Table A11-4: Vegetation cover and calculated interception in maize (based on data from Becker et al, 1999). Values *in italic* are added to fill gaps in the growth stage intervals.

Crop	BBCH code	Mean vegetation cover (%) ¹	Deposition (% of sprayed) ²	Crop interception (% of sprayed)	Crop interception value to be used in groundwater assessments in Denmark (% of sprayed)
Maize	0-11				0
	12-15	7.1-11.9	89-93	7-11	7
	16-18	16.5-22.7	78-83	16-22	16
	19-33	29.8-31.9	70-72	28-30	28
	34-39	41.7	60	40	40
	40-49				40
	50-59	61.1	42	58	58
	60				58
	61-69	76.3	28	72	72
	70				72
	71-89	82.4	22	78	78
	90-99				78

¹ Data from Becker *et al* (1999), table 11.

² Calculated on the basis of the following formula: percentage of spray product on soil = 100 - (0.95 x percentage mean vegetation cover)

~~Annex 12: Environmental risk assessment of cumulative effects for combination products~~

Covered by Northern Zone Guidance Document.

Annex 13: Crop rotation - normal cultivation practices in Denmark

DK only accepts modelling for applications every 2, 3, 4 and 5 years if it is in accordance with the normal crop rotation period of the specific crop i.e. if the crop is grown with such interval in practice, in accordance with the table below:

Crop rotation period in Denmark - The numbers in the table indicate 1: every year. 2: every second year. 3: every third year etc.

Crop	Crop rotation period in years
Potatoes	3/4*
Sugar beets	3
Cereals (winter, spring), maize	1
Beans, peas	5
Carrots	5
Cabbage, Oil seed rape (winter, spring)	4
Onions	5

* Crop rotation every fourth year is for certified seed potatoes only

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

- Products may not be classified for health effects³⁹. This means that the label must not include any human health hazard statements, not even those listed in Table 1.
- 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

Only concentrated products containing the following active substances can be authorised for non-professional use⁴⁰: insect soaps, fatty acids, sulphur or iron, microbiological agents and pheromones for insect confusion or **approved as a low-risk pesticide**.

And

- Products may not be classified for health effects **listed in PPPR Annex II, point 5.1.1 (a)**. 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.
- Based on the risk assessments, safe use must be demonstrated without specific risk mitigation measures. Personal protective equipment is acceptable if they are needed based on the classification of the product, see annex 18.**
- 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 m² (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
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 ⁴¹

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 In accordance with the supplementary agreement from January 2019 to the 2017-2021 Pesticide Strategy.

⁴⁰ In accordance with the supplementary agreement from January 2019 to the 2017-2021 Pesticide Strategy.

⁴¹ The relevance of labelling dilutions with EUH066 should be made on a case by case basis. 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. *Amblyseius* 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 and persistent metabolites of no toxicological concern

It must be demonstrated that groundwater metabolites without pesticide effect ($> 0.1 \mu\text{g/L}$ and below $0.75 \mu\text{g/L}$) and persistent metabolites (see section on persistency) are of no toxicological concern.

The metabolites are considered to be of toxicological concern if they 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 SE1 or RE1 according to Regulation (EC) No 1272/2008, or
- Are considered to potentially have endocrine disruptive properties.

The limit of $0.75 \mu\text{g/L}$ 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) can also contribute to the occurrence of a metabolite these should be counted in the sum.

The data requirements for the assessment for groundwater metabolites $> 0.1 \mu\text{g/L}$ and below $0.75 \mu\text{g/L}$ 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 QSAR⁴² 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. For (Q)SAR assessment for a given endpoint, the most recent version of OECD (Q)SAR model reporting formats (QMRF), and (Q)SAR prediction reporting format (QPRF) and (Q)SAR result reporting format (QRRF) shall be submitted if needed according to the (Q)SAR Assessment Framework (QAF)⁴³. 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 three *in vitro* tests⁴⁴. A combination of an Ames test, an *in vitro* Mammalian Cell Gene Mutation Test (tk or hprt locus) and an *in vitro* micronucleus test fulfils the requirements to cover gene mutations and structural and numerical⁴⁵ alterations⁴⁶. Any alternative study batteries must fully cover these endpoints.

Grouping may be proposed which should be justified for example based on profiling based on (Q)SAR (see also EFSA Guidance on the establishment of the residue definition for dietary risk

⁴² Read-across and QSAR of genotoxicity and end points covered by *in vitro* endocrine disruption endpoints are not necessary.

⁴³ (Q)SAR Assessment Framework: Guidance for the regulatory assessment of (Quantitative) Structure - Activity Relationship models, predictions, and results based on multiple predictions, OECD Series on Testing and Assessment, No. 386 and OECD (2024), (Q)SAR Assessment Framework: Guidance for the regulatory assessment of (Quantitative) Structure Activity Relationship models and predictions - Second edition, OECD Series on Testing and Assessment No. 405

⁴⁴ *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.

⁴⁵ 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).

⁴⁶ Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under

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 testing 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 (EFSA 2017).

Endocrine disrupting (ED) 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 Disrupting Chemicals (as revised in 2017)⁴⁷. As a minimum, EATS-modalities (estrogen, androgen, thyroid, steroid synthesis) should be covered. See table below with an overview of required OECD CF level 2 studies. Assays should be documented according to OECD guidance document (GD) 211 if no standardized test methods are available. In addition, The OECD GD GIVIMP⁴⁸ (2018) should be consulted and compliance with best practices obtained where possible to facilitate regulatory acceptance. A scientific justification is needed if metabolic systems are not included in the assay.

Currently, no validated *in vitro* thyroid assays are included in the OECD Conceptual Framework. Consequently, metabolites suspected to disturb the thyroid axis or metabolites of active substances with effects on the thyroid axis are not acceptable. Alternatively, additional toxicity studies covering the T-modality can be considered on a case-by-case basis but should be described according to OECD GD 211.

Metabolites which potentially may have ED properties determined by screening from OECD CF level 1 and 2 data could be followed up by relevant *in vivo* testing according to OECD GD 150 (2018). The outcome and further testing strategy should be discussed with the Danish Environmental Protection Agency.

If level 2 studies and a thyroid assessment of the metabolites according to the table below is negative (not showing ED properties) the metabolites are considered to be sufficiently investigated, and no further ED assessment is necessary.

Overview of required OECD CF level 2 studies:

Level 2: E modality: ToxCast ER Bioactivity Model or OECD TG 455, OPPTS 890.1300 If ToxCast ER Bioactivity Model is not available
Level 2: S modality: OECD TG 456, OPPTS 890.1200, OPPTS 890.1550, EU B.57
Level 2: A modality: OECD TG 458

regulation (EC) No 1107/2009 (Sanco/221/2000 – rev.11, October 2021).

⁴⁷ the OECD Conceptual Framework for Testing and Assessment of Endocrine Disrupting Chemicals is described in Revised OECD Guidance Document 150 on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption (2018)

⁴⁸ OECD (2018), Guidance Document on Good In Vitro Method Practices (GIVIMP), OECD Series on Testing and Assessment, No. 286.

Level 2:

T modality: no validated tests available.

To consider the T modality as “sufficiently investigated”, ToxCast information/relevant *in vitro* tests and/or Level 4 studies (e.g. OECD TG 408) could be adequate if they are addressing thyroid parameters.

See also “Guidance for the identification of endocrine disruptors in the context of Regulation (EU) No 528/2012 and (EC) No 1107/2009 (EFSA journal 2018;16(6):5311) for completeness and further information on the studies.

If conclusion of the toxicological ED assessment for metabolites is ‘not ED’, then an eco-toxicological ED assessment is required. Eco-toxicological OECD CF level 1 and 2 studies should be included in the assessment if available. New studies may be required if there are indications of effects in the OECD CF level 1 and 2 studies. It must be adequately justified if no OECD CF level 1 and 2 eco-toxicological studies are provided.

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

The metabolites should be tested or addressed by a justified read across⁴⁹ for their subchronic toxicity. For subchronic toxicity testing, a 28-day **rat** study (OECD TG 407) or a 90-day rat study (OECD TG 409) are suggested. However, the choice of study must always be justified on a case-by-case basis taking into consideration the nature of the **possible** alerts (e.g. indications from available data). In regard to potential ED properties, relevant follow-up studies should be according to OECD GD 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)⁵⁰.

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.

Risk assessment:

A risk assessment should be conducted to ensure no unacceptable risk is to be expected for the consumer. The risk assessment should cover both children and adults (WHO (2011)⁵¹, EFSA (2012)⁵²) and take into account exposure from relevant sources e.g. from residues or other active substances. To account for data inadequacy and extrapolation for duration of exposure, uncertainty factors should be applied according to ECHA (2012)⁵³, WHO (2011)⁵⁴ or EFSA (2012)⁵⁵.

⁴⁹ ECHA, 2017. Read-Across Assessment Framework (RAAF). ECHA-17-R-01-EN

⁵⁰ OECD (2014). Guidance on Grouping of Chemicals, SECOND EDITION Series on Testing & Assessment No. 194.

⁵¹ WHO (2011). Guidelines for Drinking-water Quality. Fourth edition. Latest updated version available

⁵² 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. [32 pp.] doi:10.2903/j.efsa.2012.2579.

⁵³ ECHA (2012). Guidance on information requirements and chemical safety assessment. Chapter R.8: Characterisation of dose [concentration]-response for human health.

⁵⁴ WHO (2011). Guidelines for Drinking-water Quality. Fourth edition. Latest updated version available

⁵⁵ 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. [32 pp.] doi:10.2903/j.efsa.2012.2579.

Exceptions or metabolites which need specific considerations:

Where the active substance is classified or suggested to be classified as specific target organ toxic, then the metabolites should be assessed on a case-by-case basis with respect to the toxicological profile of the active substance to assess if the metabolites possess the same hazard. 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.

Background and purpose

This Guidance Note describes a number of options for refinement of the risk assessment for birds and mammals, which apply to national registrations of plant protection products in Denmark.

The Guidance Note shall be viewed in the context of the following documents:

- Guidance Document on Work-sharing in the Northern Zone in the Authorization of Plant Protection Products (latest version)
<https://eng.mst.dk/chemicals/pesticides/applications-for-authorisation/evaluation-framework>
- Guidance of EFSA: Risk Assessment for Birds and Mammals. EFSA Journal 2023; 21(2):7790
<https://doi.org/10.2903/j.efsa.2023.7790>
- 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, Version 2.2, March 2026.
<https://eng.mst.dk/chemicals/pesticides/applications-for-authorisation/evaluation-framework>
and the accompanying Calculation Tool (version 2.2)
<https://eng.mst.dk/chemicals/pesticides/applications-for-authorisation/evaluation-framework>

Tier 1 risk assessments for birds and mammals within the Northern Zone are performed in accordance with Guidance of EFSA (2023) with a few amendments as described in section 4.6.3 of the Guidance Document on Work sharing in the Northern Zone.

Higher tier risk assessments are performed according to the Northern Zone Guidance Document “Pesticide Risk Assessment for Birds and Mammals”. The list of refinement options provided in this Guidance Document is considered to be exhaustive, i.e. no further refinements are generally accepted for the Core assessment.

In Denmark, however, some further refinements of the risk assessment may be applicable. The aim of this Guidance Note is to provide an overview and a short description of these refinement options. Higher tier risk assessments making use of these options shall be presented in the Danish national addendum.

The Guidance Note is intended to serve as guidance to applicants and shall also facilitate a standardised assessment by the Danish Environmental Protection Agency.

All refinement options described in the following tables may be implemented using the Northern Zone Calculation Tool.

Summary of Danish mandatory deviations from the Core assessment

	Northern Zone Core assessment	Denmark
Endpoints	<u>Acute LD50 (birds and mammals):</u> Geometric mean approach is accepted, cf. EFSA (2009) section 2.4.1	<u>Acute LD50 (birds and mammals):</u> Geometric mean approach is <u>not</u> accepted; worst case LD50 is used*
	<u>Reproductive endpoint (birds):</u> Geometric mean LD50/10 is used if lower than NOAEL	<u>Reproductive endpoint (birds):</u> Geometric mean LD50/10 is used if lower than NOAEL (i.e. no deviation from Core assessment)

* Cf. Footnote 9 in the Guidance Document on work sharing

Summary of Danish refinement options

(NZ GD = Northern Zone Guidance Document “Pesticide Risk Assessment for Birds and Mammals”)

	Northern Zone Core assessment	Denmark
Pelleted beet seeds	Follows EFSA GD for birds and mammals risk assessment (only relevant for birds as mammals eating pelleted beet seeds (wood mouse) crack and discard the pellet with most of the residue before ingesting the seed)	Sowing of pelleted sugar beet and fodder beet seeds is carried out with special sowing equipment that sows the seed in the soil with a band. In this way seeds are sown precisely at a specific depth and at a specific distance from one another. The Danish Environmental Protection Agency finds that there is no exposure to wild birds and mammals for this use
Focal species	<u>Whinchat <i>Saxicola rubetra</i>:</u> Focal species in cereals (BBCH 40-89 and pre-harvest desiccation) <u>Willow warbler <i>Phylloscopus trochilus</i>:</u> Focal species in maize (BBCH 30-39)	Whinchat and Willow warbler are not considered relevant focal species in agricultural fields ¹ For all other focal species, the Summary Tables in chapter 7 of the NZ B&M GD apply
Proportion of diet (PD)	<u>Acute risk:</u> No refinement of the Tier 1 diets (EFSA 2023) is accepted	<u>Acute risk:</u> The crop and growth stage specific PD values in the NZ B&M GD can be used; see chapter 5 (sections “Risk assessment”) and appendices 3 & 4 in the GD TER values must be calculated for all relevant combinations of growth stage and month; worst case TER is used
	<u>Long-term (reproductive) risk:</u> The crop and growth stage specific PD values in the NZ B&M GD can be used; see chapter 6 (sections “Risk assessment”) and appendices 3 & 4 in the GD	<u>Long-term (reproductive) risk:</u> The crop and growth stage specific PD values in the NZ B&M GD can be used (as in the Core assessment) TER values must be calculated for all relevant combinations of growth stage and month; <u>geometric</u> mean RUD is used for each focal species
Residues (RUD)	Standard RUD values (EFSA 2023) may be supplemented (<i>not</i> replaced) by	The assessment follows the same principles as described for the Core

	residues from relevant studies. The recommendations in EFSA 2023 are followed (cf. section 4.3 of the NZ GD)	assessment. New additional data will be evaluated on a case-by-case basis and <i>may</i> replace the standard values if they are considered more representative² The evaluation of the representativeness of new data is based on: • Number of sites • Relevance of sites in relation to Danish conditions Any decision on replacement of the standard RUDs will also depend on the amount of data on which the standard RUD values are based³
Residue decline (DT50)	Refinement of the standard DT50 (10 days) is accepted if based on data from at least 4 sites, which are considered relevant for Northern Zone conditions⁴ • 4 to 6 sites: worst case DT50 is used • > 6 sites: arithmetic mean DT50 is used	Refinement of the standard DT50 (10 days) is accepted if based on data from at least 2 sites, which are considered relevant for Danish conditions and for the crop in question • 2 or 3 sites: worst case DT50 is used • ≥ 4 sites: arithmetic mean DT50 is used
Interception	Interception factors can be included in accordance with EFSA 2023, as described in the NZ B&M GD <u>Tiered approach:</u> <u>Step 1:</u> Interception factors in Table 4.2 of the NZ GD are used; no interception is considered at earlier growth stages <u>Step 2:</u> Interception factors in Tables 4.3 and 4.4 of the NZ GD are used⁵; however country specific restrictions to the use of these values apply for Norway, Sweden, Finland and Latvia (see NZ GD section 4.5)	<u>Use of the following values is accepted:</u> • Interception factors in Tables 4.3 and 4.4 of the NZ B&M GD⁵ or • Deposition factors tabulated in Annex 11 (above); upper limit of the 80 percent confidence interval is used if available⁵
Proportion of Time (PT)	<u>Acute risk:</u> No refinement of PT is accepted; PT = 1	<u>Acute risk:</u> PT may be refined if estimates for the species and crop scenario in question are available (from NZ B&M GD chapter 6 or from case-specific studies). Some read-across between structurally similar crops is acceptable but must be duly justified in each case The 90th percentile of the PT distribution for “consumers” is used
	<u>Long-term (reproductive) risk:</u> PT may be refined if estimates for the species and crop scenario in question are available (from NZ B&M GD chapter 6 or from case-specific studies). Some read-across between structurally similar crops is acceptable but must be duly justified in each case	<u>Long-term (reproductive) risk:</u> PT may be refined if estimates for the species and crop scenario in question are available (as described for the Core assessment) Mean PT for “consumers” is used

	The 90 th percentile of the PT distribution for “consumers” is used ⁶	
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¹ Willow warbler would still be relevant for use in energy crops (f.x. energy crops like willow or poplar).

² Even if EFSA peer review expert meetings have confirmed new RUD values, their validity under Danish conditions has to be assessed.

³ Standard RUDs for plant shoots and leaves, and to some extent also for foliar and ground-dwelling arthropods, are considered more reliable than the standard RUDs for other food items.

⁴ In cases a lower number of data, which indicate a very rapid decline, are available, other relevant information may be used a supporting data (e.g. data on hydrolysis or volatilisation).

⁵ It is important to consider that these interception/deposition factors are intended to describe the amount of pesticide that reaches the soil surface and that the deposition on weeds and ground-dwelling arthropods may in some cases be higher. For instance, although an interception factor of 90 % is stated as applicable for spraying on established turf, deposition on ground-dwelling arthropods will most probably be higher than 10 % of the applied dose.

⁶ The 90th percentile for “all birds/mammals” may be used if all of the tracked individuals were caught within (or in close proximity to) the target crop, cf. EFSA (2023).

Annex 18: Low risk plant protection product

Products may not be classified for health effects listed in PPPR Annex II, point 5.1.1 (a). Products can be considered low-risk PPP provided that no specific risk mitigation measures (SRMM) are needed following a risk assessment (according to article 47 in EU regulation 1107/2009).

In general, all risk mitigation measures (RMM) are considered Specific RMMs (SRMM) with a few exceptions mentioned below.

Mammalian toxicology

SRMMs are interpreted as RMMs triggered by exceedance of the (A)AOEL in the exposure assessment, e.g., requirements for personal protective equipment (PPE) or buffer strip zones greater than the default buffer strip for residents and bystanders. However, professional users must wear gloves when applying a PPP, therefore gloves are exempt from being considered a SRMM, regardless if they are required due to an exposure assessment or classification.

PPE triggered by the hazard assessment (CLP-classification) is not considered a specific RMM and is therefore accepted for low-risk PPPs, provided that the classification(s) for the PPP (where co-formulants contribute to the classification) comply with the classification(s) accepted for a low-risk active substance.

Ecotoxicology

Default buffer zones based on built-in model limitations are not considered as SRMM, e.g. when the aquatic risk assessment requires exposure assessment using FOCUSsw Step 3, where there is a built-in buffer zone of 2 m for field crops, or when the default spray drift values from ESCORT 2 for apples include a distance of 3 m.

Residues

If the EU Commission has set a PHI of 1 day for all edible crops, and the active substance is on annex IV (Reg. (EC) No. 839/2008) the PHI is not considered a SRMM.

Phys/chem

Most risk mitigation measures for Phys/chem are not considered specific e.g. “an in-tank antifoaming agent must be used to avoid excessive foaming” or “must be stored in a dry place at or below room temperature”.

Annex 19: Abbreviations

ADI	Acceptable Daily Intake, i.e. the daily amount that can be ingested during a lifetime without risk of adverse effects on health.
AOEL	Acceptable Operator Exposure Level
AAOEL	Acute Acceptable Operator Exposure Level
AF	Assessment Factor, also called an uncertainty factor or safety factor.
BBCH	Biologische Bundesanstalt, Bundessortenamt und CHemische Industrie (growth stage scale)
DEPA	Danish Environmental Protection Agency
ECHA	European Chemicals Agency
DJF	<i>Formerly</i> Danmarks JordbrugsForskning, <i>now</i> 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.
ED	Endocrine Disrupting
EFSA	European Food and Safety Authority
EPPO	European and Mediterranean Plant Protection Organization
ERO	Ecological Recovery Option
FOCUS	Forum for the coordination of pesticides fate models and their use
JB	Jordbundsnummer (soil type number)
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.
LD ₅₀	Lethal dose 50 per cent; dose that kills 50 per cent of test organisms.
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.
OECD	Organisation for Economic Co-operation and Development
OPPTS	Office of Prevention, Pesticides and Toxic Substances (US EPA test guideline prefix)
PD	Proportion of a food type in diet (between 0 and 1)
PEC	Predicted Environmental Concentration
PLAP	Pesticide Leaching Assessment Programme
PT	Proportion of food that is found in the treated area (between 0 and 1)
RAC	Regulatory Acceptable Concentration
RMM	Risk mitigation measure
RPE	Respiratory Protective Equipment
SETAC	The Society of Environmental Toxicology and Chemistry
STOT	Specific target organ toxicity

TER	Toxicity-to-exposure ratio
TG	Test Guideline
TWA	Time Weighted Average
UF	Uncertainty factor
US EPA	United States Environmental Protection Agency

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