Danish Ministry of the Environment
Environmental Protection Agency

Framework for the Assessment of Plant Protection Products

Department of Pesticides and Gene Technology
Danish Environmental Protection Agency

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Editing log - Framework for the Assessment of Plant Protection Products

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

		ment as in NZ GD.		
2016-05-04	1.4	Editorial corrections in ERA	AAA	2016-05-04

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

Contents

Introduction

Purpose of this document

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

Legal framework

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

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

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

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

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

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

Framework for the human health risk assessment

Background

This part of the document concerns the human toxicological assessment of plant protection products (PPP) in accordance with Regulation (EC) No 1107/2009. The main toxicological related updates in this version 1.4 of 2016 are: Harmonisation within the EU and/or Northern Zone on the following matters 1) Estimation of operator, worker, bystander and resident exposure, including recreational residential exposure, using the EFSA calculator, 2) no special safety factors for establishing AOEL (e.g. cancer) unless decided in the EU, 3) no special protection factors for PPE, 4) cumulative risk assessment irrespective of similar effects of active substances, 5) Seed treatment as in NZ GD.

LEGISLATIVE USER RESTRICTIONS

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

General approach to human health risk assessment

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

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

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

HAZARD IDENTIFICATION – classification

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

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

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

HAZARD CHARACTERISATION – setting of the AOEL

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

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

After determining the relevant NOAEL a default uncertainty factor (UF) of 100 is usually applied. This factor is made up of a 10-fold factor for interspecies variability and a 10-fold factor for intra-human variability. The 10-fold factors for variability cover toxicokinetics as well as toxicodynamics. Sometimes additional UFs[3] 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 for oral absorption if it is less than 80 %.

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

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

EXPOSURE ASSESSMENT

Exposure assessment is the estimation of the exposure to the active substance when applying the PPP. The estimation takes the dermal absorption, the worst-case use and the possible use of personal protective equipment (PPE) 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 2016.

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

Exposure assessments should be conducted for the operator, worker, bystander, and resident. For the two latter both child and adult exposure are considered. The exposure assessments should be performed for each active substance present in the PPP.

Exposure assessments are performed according to the Northern Zone Guidance Document 2016.

Dermal absorption

For operators, workers, bystanders and residents dermal exposure of pesticides is considered being the

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Regulation (EC) No 1907/2006

[3] EFSA Scientific Committee; Guidance on selected default values to be used by the EFSA Scientific Committee, Sci-

major route of exposure. Therefore, an estimate of the dermal absorption of the concentrated PPP and the in-use dilution of the PPP is necessary to refine the estimate of the exposure (See Northern Zone Guidance Document, 2016).

Operators

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

Workers

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

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

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

Bystanders

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

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

Residents

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

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

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

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entific Panels and Units in the absence of actual measured data. EFSA Journal 2012;10(3):2579.

Out-door Treatment - fields, lawns, orchards

EFSA Guidance Exposure Calculator (EFSA calculator) is used for the exposure estimation of operator (professional), worker, bystander (child and adult) and resident (child and adult). EFSA calculator does not apply to non-professional operators. Hence, the Northern Zone has agreed on acceptable models for this exposure assessment (see Northern Zone Guidance Document 2016).

Recreational resident exposure on lawns 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.

In-door Treatment - greenhouse

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

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

In the EFSA calculator task specific factors are used for the exposure assessment related to worker re-entry into greenhouses approximately 8-16 hours after treatment (see Table 14 in the EFSA GD[4]). The factors are depending on the application method. In addition, task specific factors are used for handling ornamentals after application. Be aware, that none of these task specific factors apply to volatile pesticides or products applied as vapours. In such cases additional data may be required.

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

Seed treatment

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

RISK CHARACTERISATION

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

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

Risk characterisation is determined in two levels – acute risk and long term risk. In addition, cumula-

[4] 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.

tive risk should be assessed if more than one active substance is present in the PPP (see Northern Zone Guidance Document 2016).

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.

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

Long term risk

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

Operators:

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

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

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

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

Higher Tier – for instance head protection, respiratory PPE.

Workers:

PPE for workers can only be included as risk mitigation measure when the risk assessor can be reasonably confident that it would be used. Gloves can for instance be assumed in greenhouses and usually for field workers.

As a first tier the estimated exposure with normal working clothing, but no gloves is compared to the acceptable operator exposure level (AOEL). If the level of exposure is greater than 100% of the AOEL, then a second tier with normal working clothing and gloves can be taken into consideration. Specification of a re-entry interval could only in some cases be used as refinement.

Bystanders and residents:

Bystanders and residents are not likely using PPE. However, a risk mitigation measure could be to increase the buffer strip from the default 2-3 meter to either 5 or 10 meters.

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.

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.

These are for example;

- use of personal protective equipment
- specification of the application methods
- specification of whom and where the product is to be used
- increasing of buffer zones
- specification of re-entry intervals
- reduced work rate, i.e. by limitation of the area sprayed/day

Framework for the environmental assessment

Background

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

This document was major revised in June 2011 in order to accommodate the new Regulation and facilitate more harmonized risk assessments in the Northern zone. The main change in this revision of the framework for environmental risk assessment includes use of FOCUSsw modelling tools to predict surface water exposure, inclusion of the Non Target Arthropods and Not Target Plants in the environmental risk assessment. It is noted, that it is a living document with continues need for updates. The basis of an environmental risk assessment is the data requirements provided in Commission Regulation (EU) No 545/2011 for the active substance and Commission Regulation (EU) No 544/2011 for the product.

As its point of departure, the environmental assessment of plant protection products covers areas considered to be of crucial environmental importance and on which sufficient knowledge for an assessment is available. This particularly applies to persistence and mobility in soil, to bioaccumulation and to effects on terrestrial and aquatic plant and animal species considered not to be pests (non-target organisms). In order to carry out risk assessment of the effect of plant protection products on the environment, information on the products' effects on plants and animals must be available as well as adequate information to calculate exposure, i.e. expected concentrations in soil, water, sediment and relevant animal food items. According to the Uniform Principles[5], assessment of the fate and distribution/behaviour in the environment must consider all parts of the environment. To the extent possible therefore, the assessment should also cover dispersal to other parts of the environment, such as air.

The assessment of the individual products in Denmark is based on their areas of use, so that only the subordinate areas considered relevant to a given area of use are assessed (requirements on data for the different areas of use are shown in Annex 1)[6].

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

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

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

[6] 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 inclusion of an active substance in Annex I of Council Directive 91/414/EEC.

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

The active substance, any metabolites[7] and the product must all be considered in the risk assessment.
The requirements on data (and, thus, on the areas to be covered by the assessment) for the active substance are clearly defined. The concept of metabolite is defined very broadly in the Uniform Principles, where the concept of "relevant metabolites, degradation and reaction products" is used. The Uniform Principles also place metabolites on the same footing as active substances, when the metabolites are "of toxicological or environmental significance". Thus, there are no precise guidelines for this assessment in the Uniform Principles. Subsequent to the Uniform Principles, in 2003 the Commission published a guidance document on relevant metabolites which focuses on groundwater and discusses the criteria that are relevant for metabolites and sets limits for the occurrence of relevant metabolites in groundwater. In the opinion of the Danish Environmental Protection Agency this document does not deal with the problem in accordance with the intentions of the Directive, especially in regards of contamination of groundwater (for more details see the section “Mobility”) and consequently this document is not used by the Danish Environmental Protection Agency in its national evaluations. The Danish Environmental Protection Agency carries out ad hoc appraisals of the extent to which metabolites are significant with respect to health and the environment. As a rule, a metabolite is included in the assessment (either in the form of considerations based on studies of the active substance or on the basis of independent studies of the metabolite) if one of the following conditions apply: a) Metabolites, which account for more than 10 % of the amount of active substance added in soil at any time during the degradation studies; or b) which account for more than 5 % of the amount of active substance added in soil in at least two sequential measurements during the studies; or c) for which at the end of soil degradation studies the maximum of formation is not yet reached. If, based on the available documentation, there are indications that metabolites accounting for lower levels could prove problematical (e.g. in relation to groundwater pollution), they must also be assessed. The Danish Environmental Protection Agency has decided that metabolites that occur commonly in nature (for example pyrimidine) or which are simple substances such as saccharine are not to be considered as relevant.

The environmental assessment is divided into two main areas:

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

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

Fate and distribution/behaviour 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.

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

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

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

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

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

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

Effects on non-target organisms: aquatic and terrestrial organisms

Plant protection products may constitute a risk of unacceptable impact on aquatic and terrestrial non-target organisms. For the effect area, the risk assessment's point of departure is the so-called quotient method, in which the toxicity towards a given organism is compared to the level to which that organism can be expected to be exposed (i.e. the Toxicity Exposure Ratio, TER, cf. the Uniform Principles)[8].

Assessment is done for relevant areas (soil, water, sediments etc.), with the point of departure in the (few) species tested in connection with the application for authorization. There is, however, great variation in sensitivity to different substances between individuals within a species and, especially, between species within the same taxon/in different taxa. In order to protect more species than just the species tested, the risk assessment includes an assessment factor (also called safety factor or uncertainty factor), according to which the risk is assessed on the basis of comparing the quotient (TER) with the assessment factor (cut-off value)[9].

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

- extrapolation is done from only a few species to all species
- no compensation is made for differences between laboratory tests and the actual conditions in na-

[8] 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.

[9] An assessment factor is incorporated in the RAC. I.e. the RAC can be directly compared to a use specific PEC value.

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- the method cannot be used to estimate indirect effects (interactions through the food chain, etc.)
- uncertainties cannot be fully quantified
- exposure is often estimated on the basis of uncertain assumptions.

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

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

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

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

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

ENVIRONMENTAL RISK ASSESSMENT AND DECISIONS

Fate and behaviour/distribution in the environment

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

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

Fate in air

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

Persistence in soil

Persistent active substances can affect the environment over long periods of time, as such substances can be distributed and accumulated within and outside the areas in which they are used. Persistent substances constitute a long-term and difficult-to-quantify risk of spreading in the environment and effects on organisms. Persistent substances can also cause effects on and lead to residues in subsequent crops. This also applies to the metabolites of an active substance.

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

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

Tier 0: Based on laboratory tests of degradation in soil, an appraisal of whether an active substance or its relevant metabolites fulfil one or both of the following:

- have a $DT_{50} > 90$ days and/or a $DT_{90} > 365$ days
- form bound residues (cf. the definition in the Uniform Principles, 2.5.1.1) in quantities in excess of 50 per cent of the initial dose after 30 days, or 70 per cent after 100 days, in combination with a mineralisation of less than 5 per cent over a period of 100 days.

Bound residues are part of the active substance which instead of being degraded are strongly bound

in the soil (e.g. to humus and/or clay particles). This binding strongly reduces bio-availability (Fomsgaard, 2004).

Assessment of persistency of laboratory soil data for DT_{50} should not be based on average or percentiles of the data. Instead data are assessed by considering the soil types used and focusing on soil types representative for Danish conditions. If these soils have a DT_{50} above 90 days, this calls for tier 2 field studies (see below). If only some of the lab soil DT_{50} values are above 90 days, it needs to be assessed if these data constitute the major part of data and if it is likely that DT_{50} for Danish soils is above 90 days. DT_{50} lab values should always be normalised to 20 degrees and moisture content at field capacity (pF2).

If the above values are not exceeded, products containing the relevant active substance are not considered to constitute any unacceptable risk to the environment from the standpoint of persistence. The procedure continues to Tier 1, if any values are exceeded.

Tier 1: An appraisal, with the inclusion of relevant field tests (i.e. tests conducted under conditions considered representative of Danish use, soil[10] and climatic[11] conditions, and which use an active substance or a formulation of the active substance that corresponds to the proposed application), is made of whether or not the above values would be exceeded under the proposed conditions of use. If the above values are not exceeded under field conditions, products containing the relevant active substance are not considered to constitute any unacceptable risk to the environment from the standpoint of persistence. The assessment must be based on non-normalised field DT_{50}. The procedure continues to Tier 2, if any values are exceeded.

Tier 2: Based on the available studies, an appraisal of whether the active substance or relevant metabolites:

- are not, on the basis of their intrinsic properties, expected to be transported away from the target area, i.e. vegetation/soil, e.g. by evaporation or leaching (ad hoc appraisal)
- have a half-life of between 3 and 6 months.

It is not considered possible to undertake a realistic risk assessment if these conditions are not satisfied, as it would not be possible to limit exposure (and, thus, to restrict the studies to the soil environment) and would not be possible to clarify the long-term consequences of substances that have a $DT_{50} > 6$ months. Products containing active substances or metabolites that fail to satisfy the above cannot be approved.

If the conditions are satisfied, an assessment of whether or not there are any unacceptable effects is made on the basis of long-term studies of the direct and indirect effects on selected groups of organisms in the field (an overall framework for such studies is described by Kjær, 1997). If it is considered that there are no unacceptable effects and if the study is considered satisfactory, products containing the relevant active substance are assessed as **not constituting any unacceptable risk to the**

[10] Classifications of Danish soil types can be found in Annex 2.
[11] Danish climate data can be found in Annex 3.

environment, from the standpoint of persistence.

If no such study is available, or if the study is considered unsatisfactory, or if the substance is considered to cause unacceptable effects, products containing the relevant active substance cannot be approved for outdoor use.

PEC_{soil}

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

Groundwater/Mobility

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

The Uniform Principles specify limit values[12] for the pollution of groundwater. These values are:

- 0.1 µg/l for each individual substance
- 0.5 µg/l for the sum of substances[13].

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

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

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

- The PELMO 5.5.3 model (or comparable model) with the Hamburg scenario or MACRO 5.5.3 with the Danish scenarios. If both models are used then the results of both models must fulfil the limit values.
- Substance specific parameters: 80 percentiles for degradation rates and sorption ratios (1/n) must be used and for K_{OC} 20 percentiles must be used[14].
- Separate model runs must be executed for at least three individual days of the period in which use of the product is proposed.

[12] 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.

[13] To be interpreted as the sum of the active substance and its metabolites.

[14] Formation factions and DT50 values should be from same tier (i.e. lab or field) if data are available.

- Use every 2nd, 3rd and 4th year can only be used as a refinement option if the crop can only be grown 2nd, 3rd og 4th year. A list of crops where this refinement option can be used can be found in Annex 13.
- The results must be reported as annual averages. This also applies if the substance is used every second, third or fourth year. All output files must be submitted.

In this way the assessment is done for a realistic worst-case situation, based on the annual average concentration in the water that percolates to the ground water. If this concentration does not exceed the limit values in more than 1 of 20 years, the product is considered **not to constitute an unacceptable risk of polluting groundwater** for the proposed use. If one or both of the limit values are exceeded, the product cannot be approved for the proposed use, unless other studies (lysimeter studies, field studies, and/or monitoring data) very convincingly demonstrate that unacceptable leaching will not occur in the Danish context. When evaluating such studies, consideration must be given to whether soil, climate and conditions of application (crops, vegetation cover, application method, formulation of the product, its quantity and time of application) correspond to Danish conditions. Data from the Pesticide Leaching Assessment Programme[15] (PLAP) can be used in the assessments. When evaluating risk of leaching to groundwater only data from the groundwater installations in PLAP are used and not samples from drains or suction cups. Considerations may also be given to conditions of use (e.g. use on paved areas[16]). 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).

Surface water

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

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

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

FOCUSsw Step 3: Scenarios D3 (sandy soil, Vredepeel, Netherlands) and D4 (loamy soil, Skousbo, Denmark) are considered to be the relevant scenarios representing geological and climate conditions of Danish agricultural soil, i.e. only inputs from spray drift and drainage are considered relevant for Danish conditions. The highest PECsw derived from D3 and D4 is used in the aquatic risk assessment. Noted that FOCUSsw Step 3 operates with default crop specific distances between crops and

[15] http://pesticidvarsling.dk/om_os_uk/uk-forside.html

[16] Special documentation is required for paved areas and a special assessment is carried out, see Annex 4 (cf. Newslet-

the top of the bank that defines the edge of the water body (0.5-3m). If the aquatic risk assessment is based on FOCUSsw Step 3, a no-spray zone of 2 meters has to be added on the label in order to cover the FOCUSsw Step 3 model assumptions. It is noted, however, that if a FOCUSsw Step 3 risk assessment is requested to ensure a FOCUSsw Step 2 risk assessment where the TER value is not 10x the required trigger (to take account of possible higher PEC values at FOCUSsw Step 3), a 2 meter buffer zone is not required. Step 4: Risk mitigation measures can be applied at this step. Drift reduction based on no spray buffer zones can be applied[17]. Crop type specific maximum acceptable no spray buffer zones are provided in Annex 9. Mitigation of drainage contributions shall follow the recommendations in the FOCUS Landscape and Mitigation report (2007) i.e. maximum 90% reduction of drain contributions (e.g. prohibit application to drained soil).

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

Metabolites are modelled in accordance with FOCUS surface water guidance.

Bioaccumulation

Bio-accumulating active substances entail a risk of accumulation in organisms. Accumulation can occur when aquatic organisms absorb the active substance from water and accumulate it in tissue in a concentration higher than the concentration in the water. Similarly, an active substance can accumulate in the food chain, so that the highest levels of the chain receive higher concentrations in tissue than the lower levels (biomagnification). The same applies to bio-accumulating metabolites.

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

- can be expected to accumulate in aquatic organisms with a bio-concentration factor of greater than 1000[18], if they are easily degradable[19]
- are expected to accumulate in aquatic organisms with a bio-concentration factor of greater than 100, if they are not easily degradable
- are expected to accumulate in terrestrial food chains with a biomagnification factor (BMF) of greater than 1[20], [21]

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

Tier 1: The active substance or its metabolites are evaluated to determine whether the elimination rate for the organ from which elimination is slowest has a $DT_{50} < 3$ days and a $DT_{90} < 14$ days (the

ter, Nov. 1999).

[17] 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.

[18] Assessed on the basis of bioaccumulation studies in fish, in which whole fish are the point of departure.

[19] Cf. the OECD guidelines for the testing of chemicals, see Annex 8.

[20] See EFSA guidance on Risk Assessment for Birds and Mammals (EFSA, 2009).

[21] Biomagnification and food chain behaviour for birds and mammals are addressed in the section on risk assessment for birds and mammals.

latter trigger is used in the Uniform Principles). If this is the case, products containing the relevant active substance are considered not to constitute any unacceptable risk to the environment, from the standpoint of bioaccumulation. If these elimination rates are exceeded, products containing the relevant active substance cannot be authorized for outdoor use.

Effects on non-target organisms and risk assessment.

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

Assessment of toxicity

The toxicity assessment is initially (Tier 0) carried out on the basis of the available laboratory endpoint. These endpoints will in many cases have been derived and agreed during the EU process of the active substance; in such case, the studies are appraised to determine whether they are representative of the metabolites and product. In the cases for which studies of the active substance and metabolite, or studies of the product, are available, assessments are made for each of the subordinate areas to determine whether it is most likely that exposure will be to the active substance and/or metabolite or to the product (e.g. birds will be exposed to the product, where seed dressings/granulated formulations are concerned and non-target arthropods are exposed to sprayed formulations) and consideration is given to this in the risk assessment.

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

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

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

expert assessment for each individual species).

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

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

Assessment of exposure

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

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

Additional information (in the form of specific laboratory, semi-field or field studies of the substance's fate) can be included at higher tiers in a realistic worst-case estimate of the PEC.

The following section describes risk assessment and decision making for each individual subordinate area in more detail.

Aquatic organisms

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

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

Mesocosm and Assessment Factor

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

is given in the EFSA Aquatic GD (2013).

The assessment factor (AF) is associated with an ERO[22] from a mesocosm studies. As the point of departure, a minimum assessment factor of 5 will be used (as individual tests cannot be expected to be representative of all of the organisms or biotopes in the landscape at any time that may be exposed). Further advice regarding application of AF is given in annex 10.

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

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

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

Accepted mitigation
Risk mitigation of spray drift should follow the specifications in Annex 9 and it must not exceed the given maximum no spray buffer zones for different types of crop. Please also note, the drift mitigation may not exceed 95%.

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

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

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

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

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

[22] The Ecological Threshold option (ETO) is used by all other MS in the Northern zone and the AF is set in accordance with the Northern zone GD (2016) for this option.

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

Terrestrial organisms

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

Birds and mammals

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

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

If higher tier refinements are required in order to address the risk to birds and/or mammals from an applied use of a product, guidance is give in the Northern zone guidance document "Pesticide risk assessment for birds and mammals - Selection of relevant species and development of standard scenarios for higher tier risk assessment in the Northern Zone in accordance with Regulation EC 1107/2009" and an associated calculation tool is provided in the form of an Excel spreadsheet[23].

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

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

If needed, further higher tier refinements, accepted by Denmark, are given in "Guidance Note on Higher Tier Birds & Mammals Risk Assessment in Denmark"[24]

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

[23] Available on the Danish EPA webside
[24] Available on the Danish EPA webside

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

For cumulative risk the assessment shall follow the Bird and Mammal Guidance Document (EFSA, 2009).

Bees

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

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

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

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

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

Arthropods[25]

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

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

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

Mitigation:

[25] 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.

In order to reduce effects in off-field areas, Danish EPA considers that buffer zones, as described in Annex 9, specifically to protected paragraph3-habitats[26] must be considered in order to mitigate exposure to non-target arthropods.

In-soil organisms

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

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

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

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

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

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

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

Tier 2:
If relevant data is available in the form of specially designed laboratory, semi-field or field tests, an ad hoc assessment of a realistic worst-case situation is carried out. In this connection, the Danish Environmental Protection Agency has set an acceptable effect level of a 50 percent reduction in earthworm populations ("Probable high risk", in the classification proposed in "Earthworms as ecotoxicological test organisms", Christensen & Mather, 1994), on condition, however, that recovery occurs within one season/within the intervals between spraying (cf. EPPO Bulletin). The assessment factors that are associated with this effect level depend on the quality of the toxicity studies. In this context, consideration must be given to the fact that this assessment is not necessarily representative of other terrestrial organisms. For other species, ad hoc assessments of the effect levels are carried out.

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

If there is not considered to be any question of unacceptable effects and the studies are satisfactory, the product is considered not to constitute any unacceptable risk to earthworms/soil-dwelling organisms in the proposed use.
If no such documentation has been presented, or if the available documentation does not make it possible to ascertain that no unacceptable effects can occur in earthworms and other soil-dwelling invertebrates, the product cannot be approved for outdoor use.

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

Microorganisms

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

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

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

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

Biological methods of wastewater treatment

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

Non-target plants (NTP)[27]

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

In order to reduce effects in off-field areas, DEPA considers that buffer zones, as described in Annex 9, specifically to protected paragraph 3-habitats[28] should be considered in order to mitigate exposure to non-target plants.

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

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

List of Annexes

Annex 1: Data requirements on plant protection products

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

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

1. Agriculture; outdoor use
   Forestry; outdoor use
   Fruit growing; outdoor use
   Nursery gardens, market gardening; outdoor use[29]
   Soil disinfection; outdoor use[1]

2. Private use in gardens[30]
   Greenhouses
   Soil disinfection; indoor use
   Products for controlling algal growth; indoor use
   Products for controlling algal growth; outdoor use

3. Seed dressings

4. Granulates

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

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

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

Data requirements on active substance for area of use:	**1**	**2**	**3**	**4**	**5**
Plant metabolism	x		x	x	
Metabolisation in 1 soil type	x	x	x	x	
Degradation, 3 soil types, aerobic	x		x	x	
Photolysis on soil	x			x	
Adsorption/desorption	x		x	x	
Accumulation of active substance and significant metabolites[31] in soil(if DT50 > 3 months)	x		x	x	
Evaporation from soil (only if vapour pressure > 10^{-3} Pa)	x			x	
Biological degradation in water/water-sediment studies	x		x	x	
Effects on water treatment plants	x	x	x	x	
Acute toxicity in fish	x	x	x	x	
Long-term toxicity in fish	x		x	x	
Acute toxicity in daphnia (and additional species for insecticides)	x	x	x	x	
Reproduction test in daphnia	x		x	x	
Acute toxicity in algae (and macro-algae for herbicides)	x	x	x	x	
Effects on other aquatic organisms	x			x	
Bioaccumulation (Kow > 1000)	x	x	x	x	
Long-term effects in earthworms	x		x	x	
Effect on soil micro-organisms	x		x	x	
Acute toxicity in one bird and mammal species	x		x	x	
Reproduction test in one bird and mammal species	x		x	x	
Effect on honey bees	x		x	x	
Any information on toxic effects towards other useful species	x	x	x	x	

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

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

Annex 2: Soil classifications in Denmark

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

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

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

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

Percentage content of sand and clay in Danish soils:

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

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

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

Annex 3: Climate conditions in Denmark

Average precipitation (mm):

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

* *Cappelen (2002)*

** *Frich et al. (1997)*

Average air temperature (°C):

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

* *Cappelen (2002)*

** *Cappelen (1997)*

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

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

Source: University of Aarhus, Faculty of Agricultural Science

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

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

* Landwirtschaftliche Untersuchungs- und Forschungsanstalt (LUFA) Speyer.

Annex 4: Pavements and similar use areas

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

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

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

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

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

References:

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

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

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

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

The following requirements on scenarios and tests must be satisfied:

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

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

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

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

The following requirements on modelling and scenarios must be satisfied:

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

The appraisal is done on the basis of the average annual leaching below the root zone (a depth of about one metre). The number of occasions when leaching exceeds the limit values 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: Monitoring data

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

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

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

The monitoring results are presented with the data on the case. The results start by specifying which monitoring programmes include the substance, how many filters or boreholes have been examined, how many finds have been made (with the detection limit stated) and the number of results over the limit value of 0.1 µg/L.

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

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

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

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

Annex 8: Definition of readily biodegradable

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

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

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

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

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

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

Aquatic environment

Non-spraying buffer zones to the aquatic environment of 2, 10, 20, 30 and up to 50 metres are used. Maximum no spray buffer zones are set in relation the type of crop (see table below)[32].

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 spray types.

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

Terrestrial environment

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

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

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

Annex 10: Assessment factor in mesocosm studies

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

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

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

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

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

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

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

Annex 11 Vegetation cover and deposition on soil

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Limitation

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

Methods

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

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

Method for risk assessment

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

- Test with the product
- For areas where there is no test of the product, cumulative risk for ecotoxicological effects for relevant groups of organisms will be calculated based on the model of CA using the following equation:
  "TriggerA"-value/TERA + "TriggerB"-value/TERB + ….= SUM
  If SUM < 1 the risk assessment is acceptable

  Where:
  "Trigger"-value represent the uncertainty factor of chemical A, B etc.
  TER is the Toxicity Exposure Ratio calculated from the effect concentration (EC50, NOEC) divided by the Predicted Environmental concentration (PEC).

  For aquatic organisms SUM is calculated for the same taxonomic group (i.e. fish, crustaceans, algae and aquatic plants) for the most sensitive organisms.

Annex 13: Crop rotation - normal cultivation practices in Denmark

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

Crop type and maximum and years between cultivation:

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

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

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

1. Ready-to-use products:
   a. Products may not be classified for health effects[33]. This means that the label must not include any of the risk sentences as stated in Table 1.
   b. It must not be necessary to use personal protective equipment to demonstrate safe use. However, if applicants recommend gloves on the label for reasons of routine hygiene it is permitted.

2. Concentrated products
   a. Products which are not classified for health effects or at the most are classified as local irritant or as contact allergenic with the related risk sentences which are marked with an asterisk (*) in Table 1.
   b. Products must be apportioned in dosage bags or have a dosage device or similar which enables easy measurement of the correct amount and ensures that contact with the concentrated product is restricted (stating the correct dosage on the bottle is not sufficient; it must also be ensured that the product can be poured or apportioned without the user coming into direct contact with the product).

In both cases, when ready for use, the solution must comply with requirements a. and b. under point 1.

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

Table 1

Risk phrases relating to human health[1)]	**Hazard statements with respect to human health[2)]**
R22 Harmful if swallowed	Acute Tox. 4, H302: Harmful if swallowed
*R37 Irritating to respiratory system	*STOT SE 3, H335: May cause respiratory irritation
*R38 Irritating to skin	*Skin Irrit. 2 H315: Causes skin irritation
R65 Harmful: may cause lung damage if swallowed	Asp. Tox. 1, H304: may be fatal if swallowed and enters airways
*R66 Repeated exposure may cause skin dryness or cracking	*EUH066: Repeated exposure may cause skin dryness or cracking
R20 Harmful by inhalation	Acute Tox. 4, H332: Harmful if inhaled
R21 Harmful in contact with skin	Acute Tox. 4, H312: Harmful in contact with skin
*R36 Irritating to eyes	*Eye Irrit.2 H319: Causes serious eye irritation
*R43 May cause sensitisation by skin contact	*Skin sens. 1 H317: May cause an allergic skin reaction.
R33 Danger of cumulative effects R67 Vapours may cause drowsiness and dizziness	STOT SE 3, H336: May cause drowsiness or dizziness
R42 May cause sensitisation by inhalation	Resp. Sens. 1 H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled
R64 May cause harm to breastfed babies	Lact., H362: May cause harm to breast-fed children

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

Risk phrases relating to human health[1)]	**Hazard statements with respect to human health[2)]**
R34 Causes burns	Skin Corr. 1B H314: Causes severe skin burns and eye damage
Carc. Cat. 3: R40 Limited evidence of a carcinogenic effect	Carc. 2, H351: Suspected of causing cancer (possible route of exposure)
R41 Risk of serious damage to eyes	Eye Dam. 1 H318: Causes serious eye damage
Xn; R48 Harmful: danger of serious damage to health by prolonged exposure	STOT RE 2, H373: May cause damage to organs through prolonged or repeated exposure (possible specific organs/route of exposure)
Rep. 3; R62 Possible risk of impaired fertility Rep. 3; R63 Possible risk of harm to the unborn child	Reper 2, H361 (possibly f and/or d): Suspected of damaging fertility or the unborn child (possible specific effect/exposure route)
Xn; R68 Harmful: possible risk of irreversible effects	STOT SE 2, H371: May cause damage to organs (possible specific organs/route of exposure)
Mut. 3; R68 Possible risk of irreversible effects	Mut. 2, H341: Suspected of causing genetic defects (possible route of exposure)
R35 Causes severe burns	Skin Corr. 1A, H314: Causes severe skin burns and eye damage

1) Directive 67/548/EC
2) Regulation no 1272/2008 (EC) of the European Parliament and of the Council

Annex 15: Abbreviations

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

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

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