Framework for the environmental assessment of plant protection products
INTRODUCTION
This document concerns the environmental assessment of plant protection products in the transitional scheme, that is to say in cases where an active substance has not been listed in Annex 1 of Directive 91/414/EEC.

As its point of departure, the environmental assessment of plant protection products covers areas considered to be of crucial environmental significance 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 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\(^1\), 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 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\(^2\)).

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

The active substance, any metabolites\(^3\) 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\(^4\).

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2. The Annex shows the Danish requirements on data during the transitional period: the requirements on data for active substances that are authorized pursuant to Council Directive 91/414/EEC can be found in Annex 5.1 of the Statutory Order on plant protection products.
3. 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\(_2\)O and mineral salts.
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 it is present at more than 10 per cent (typically measured as percentage of added radioactivity). If, based on the available documentation, there are indications that metabolites at less than 10 per cent 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.

With respect to products, Directive 91/414/EEC states that as a rule studies must be available, except in the case of simple formulations (e.g. an active substance in a water solution). In practice, however, studies of products are not always available, unless they contain several active substances. It has not hitherto been Danish practice to require studies of the environmental properties of products, unless there has been some indication that the product has had a significantly larger effect than the active substance on non-target organisms. That is why tests of products are seldom available as a point of departure, if only the "old" data set has been submitted in accordance with Annex 5.3 of the Statutory Order on Pesticides. The Danish Environmental Protection Agency carries out ad hoc appraisals of whether or not the data on an active substance also covers the product. To the extent that data on products is available, such data is included in the risk assessment for non-target organisms. In the risk assessment, product data for acute risks will be weighted with a higher value than data on active substances. In the case of chronic risk where product data is not required but has been submitted, the data will be assessed but will not necessarily overrule active substance data. This is because the different components of the product can be degraded differentially or separated in the environment over time.

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.

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4 In connection with the Danish Environmental Protection Agency's assessments of an active substance’s fate or distri-
Fate and distribution/behaviour in the environment: persistence, mobility and bioaccumulation

A plant protection product containing a persistent or bioaccumulable active substance can impact the environment over a long period, whereas a mobile active substance can pollute groundwater. 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's understanding is that it is not at present possible to appraise the long-term consequences of the use of highly persistent products (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 given to products with an active substance that is very persistent 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).

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 a safety factor (also called assessment factor or uncertainty factor), according to which the risk is assessed on the basis of comparing the quotient (TER) with the safety factor (cut-off value).

When determining toxicity or exposure, the quotient method gives no consideration to many cir-

bution/behaviour, the product's composition is not generally considered significant.
cumstances, 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 nature
- the method cannot be used to estimate indirect effects (interactions through the food chain, etc.)
- uncertainties cannot be fully quantified
- the 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.

In light of the above, the specific variation in sensitivity between species and theoretical considerations (cf. the recommendations of Linders et al., 1992), the Danish Environmental Protection Agency finds that the trigger values specified in the Uniform Principles do not reflect sensitivity variations sufficiently in all cases, as well as the other circumstances ignored by the quotient method. To reduce the risk of unacceptable effects on non-target organisms, the Danish Environmental Protection Agency considers it necessary to apply safety factors greater than the triggers specified in the Uniform Principles in the case of aquatic organisms.

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 to be included/are included in Annex 1 of Directive 91/414/EEC. 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.
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 tests, which illuminate the degradation, mobility and bioaccumulation of the active substance and its possible metabolites.
The first round of assessment (Tier 0) is centred on the substances themselves (their intrinsic properties), and not on the use of the product (dose, crop, etc.). If, on the basis of these laboratory tests, it is considered that there is no risk of the active substance or its metabolites exceeding the limit values or cut-off values, products containing the relevant active substance are considered to be acceptable without further investigation, as far as the relevant area is concerned. If, on the other hand, the limit values or cut-off values are exceeded, the procedure continues through higher tiers, where additional investigations (including, e.g., mathematical modelling, lysimeter studies, field tests or monitoring) are included and assessed on the basis of a realistic worst-case situation with respect to the dose used, conditions of use, weather conditions, etc.

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

Fate in air
In Denmark it has not hitherto been specifically required to investigate or document evaporation of pesticides from the soil and treated crops, or degradation of pesticides or their metabolites in air (the atmosphere). However, there have been requirements for tests of a range of physical and chemical properties, including vapour pressure, solubility in various solvents and adsorption properties. Evaporation and distribution in air are, however, qualitatively included in the overall assessment of a substance's fate. The Danish Environmental Protection Agency uses the rule of thumb that substances with a vapour pressure of P < 10^{-3} Pa only evaporate to a modest degree.

In step with the fact that recommendations are drafted internationally on the assessment of evaporation and degradation in air, and that these are included in the Community assessments (FOCUS Air 2005), these items are now also being included in the Danish assessments.

Persistence in soil
Persistent active substances can affect the environment over long periods, 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 polluting groundwater, of bioaccumulation and of unpredictable effects on non-target 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.

This assessment is carried out with a view to minimising the risk of effects. However, effects require that there is bioavailability, i.e. that exposure of biota occurs. Therefore a distinction ought to be made between substances that are persistent because they degrade slowly and substances that are
not bioavailable. It is therefore important to consider which extraction methods are 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 "counted" 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 rough 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) due to the fact that so much knowledge 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 dispensing from the criteria below for assessing persistence.

Therefore, in special circumstances the procedure can be dispensed from 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 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:

- have a DT$_{50}$ > 3 months and/or a DT$_{90}$ > 1 year
- 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 degrading are strongly bound in the soil (e.g. to humus and/or clay particles). This binding strongly reduces bioavailability (Fomsgaard, 2004).

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$^5$ and climatic$^6$ 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

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$^5$ Classifications of Danish soil types can be found in Annex 2.

$^6$ Danish climate data can be found in Annex 3.
substance are not considered to constitute any unacceptable risk to the environment from the standpoint of persistence. 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 $\text{DT}_{50} > 6$ months. Products containing active substances or metabolites that fail to satisfy the above cannot, therefore, 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 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.

**Mobility**

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

The Uniform Principles specify limit values\(^7\) 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\(^8\).

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\(^7\) 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.

\(^8\) To be interpreted as the sum of the active substance and its metabolites.
As more substances are entered in Annex I, limit values will 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.

**Tier 0:** Based on laboratory tests illuminating the substance's *intrinsic properties*, an initial appraisal is made of whether the active substance or relevant metabolites satisfy the following points:

- $< 2\%$ leaching in all soil types in soil column tests
- $K_d > 200$ or $K_{oc} > 2000$
- $R_f < 0.1^9$

If all of the above points are satisfied$^{10}$, the Danish Environmental Protection Agency considers an active substance or a metabolite to have *low mobility* in soil. The background for the cut-off values is a comparison of results from laboratory tests and findings in groundwater for a large number of active substances. These results are also compared to the German BBA's and US Environmental Protection Agency's classification for substances that pollute groundwater.

It should be emphasised that these cut-off values are guiding values and that assessments of the individual active substances must always be conducted. Moreover, the *degradation rate* in soil is included in the assessment, as slow degradation increases the risk of leaching, all other things being equal.

In the Community context column tests are no longer required if reliable adsorption and desorption tests are available. Due to this, mobility is primarily assessed based on model calculations and this principle is also accepted by the Danish Environmental Protection Agency. In addition, $R_f$ values are no longer required in the EU or Denmark, but can be assessed if they are available.

If an active substance and its metabolites have low mobility in soil (cf. the above) and its degradation proceeds at an acceptable rate, and if there is no question of particularly problematic conditions of use (e.g. use on paved areas$^{11}$), the Danish Environmental Protection Agency considers that products containing the relevant active substance do not constitute an unacceptable risk of polluting groundwater. If this is not the case, the procedure continues to Tier 1.

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9 $R_f$ values show the distance travelled by a given substance in thin layer chromatography "relative to front", i.e. how far the substance travels in relation to the solvent used.
10 There is no requirement on studies of $R_f$, but if this value is available the requirement must be satisfied.
11 Special documentation is required for paved areas and a special assessment is carried out, see Annex 4 (cf. Newsletter, Nov. 1999).
**Tier 1:** In the second round, the risk of leaching is assessed with consideration for the *conditions of use*, for which supplementary data is required, e.g. in the form of lysimeter studies, field studies, mathematical modelling\(^{12}\) and monitoring data\(^{13}\). Especially mathematical modelling is used to a growing extent and the Danish Environmental Protection Agency requires model calculations unless the other studies very convincingly demonstrate that unacceptable leaching will not occur in the Danish context.

When evaluating the studies mentioned above, consideration must be given to whether soil\(^{14}\), climate\(^{15}\) and conditions of application (crops, vegetation cover, application method, formulation of the product, its quantity and time of application) correspond to Danish conditions.

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). If this concentration does not exceed the limit values, the product is considered *not to constitute an unacceptable risk of polluting groundwater* in the proposed application. If one or both of the limit values are exceeded, the product cannot be approved for the proposed use.

If, on the basis of laboratory studies of intrinsic properties (Tier 0), it is not possible to clarify that there is no unacceptable risk of polluting groundwater, and if there is no acceptable documentation of the conditions of use (Tier 1), the product cannot be approved for outdoor use.

**Bioaccumulation**

Bioaccumulable 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 bioaccumulable metabolites.

**Tier 0:** Potentially bioaccumulable 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 bioconcentration factor of greater than 1000\(^{16}\), if they are easily degradable\(^{17}\)
- are expected to accumulate in aquatic organisms with a bioconcentration factor of greater than 100, if they are not easily degradable
- are expected to accumulate in birds and/or mammals with a bioconcentration factor (related to fatty tissue) of greater than 1\(^{18}\)

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\(^{12}\) See Annexes 5 and 6 for a more detailed description of the appraisal of lysimeter and field tests or of modelling.

\(^{13}\) See Annex 7 for a more detailed description of monitoring data and assessment of this.

\(^{14}\) Classifications of the Danish soil types can be found in Annex 2.

\(^{15}\) Danish climate data can be found in Annex 3.

\(^{16}\) Assessed on the basis of bioaccumulation studies in fish, in which whole fish are the point of departure.

\(^{17}\) Cf. the OECD guidelines for the testing of chemicals, see Annex 8.

\(^{18}\) To be assessed on the basis of metabolism studies in mammals, in connection with the health-related assessment.
If the above values are not exceeded, products containing the relevant active substance are not considered to constitute any unacceptable risk to the environment with respect to bioaccumulation. If any of the values are exceeded, the procedure continues to Tier 1.

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

**Effects on non-target organisms.**
Plant protection products can present a risk of unacceptable effects on non-target organisms in the aquatic and terrestrial environments. Appraisal of the extent to which these effects are unacceptable is based on laboratory tests in a number of standard organisms. The ratio of the toxicity towards the tested organisms to the expected exposure (which is assessed on the basis of the product's use and dose), is calculated and compared to a safety factor (trigger). A tiered assessment is carried out, in which the toxicity and exposure are gradually refined towards a 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 studies. These will usually have been done for 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 consideration is given to this in the risk assessment.

Risk assessment is carried out for all relevant test organisms. The decision is made on the basis of the most sensitive organism. The assessment includes the short-term (acute) effects and effects over longer periods (subchronic/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 (cf. the guidelines).

However, 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 EC₅₀ 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.

**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.

Firstly (Tier 0), a rough estimate of the initial exposure is made, i.e. the predicted environmental concentration (PEC), on the basis of the product's general area of use/application method (spray product, granulate, etc.).

At Tier 1, the calculations are refined with respect to degradation/disappearance and the product's specific area of use (crops, etc.), so that the PEC approaches a realistic worst case. The information (e.g. laboratory studies of degradation) received in connection with the application for authorization is used as the point of departure for refining the exposure. When adjusting the PEC, 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).

The technical guidance documents under EU auspices propose the use of a time weighted average (TWA) when conducting risk assessments of chronic effects. At the same time, however, it is also emphasised that there is a risk of failing to consider the effects that occur initially (as a result of higher concentrations). In future, the Danish Environmental Protection Agency will carry out an ad hoc assessment of the appropriateness of using TWAs in each individual case. In this context, consideration must also be given to the toxicity profile and fate of the active substance (for more information, see Annex 9).

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 risk assessment for aquatic organisms is based on standard laboratory tests in algae, daphnia and fish and, possibly, sediment-dwelling organisms and aquatic plants. For measurement of concentrations in toxicity tests see the EU Guidance Document on aquatic ecotoxicology (section 2.1.1. - 2.1.4).

As examples of the conditions significant to the concentration of active substances and metabolites in aquatic environments, it is worth mentioning the dimensions and nature of ponds/watercourses, the extent of wind drift, the input of drainage and run-off, rate of mixing, layering on the surface, adsorption to plants, plankton and sediment, evaporation, chemical, biological or photolytic degradation, etc.

In standard laboratory tests for use with risk assessment at Tier 0 and for use in classification, sediment should not be added as this often reduces the bioavailability of the substance and therefore reduces the level of toxicity measured\(^\text{19}\).

When estimating the concentration in the aqueous phase, the point of departure is airborne drift, as this type of exposure is assumed to have the greatest significance for any effects\(^\text{20}\). The PEC is estimated for a realistic worst-case pond with a depth of 30 cm.

Aquatic organisms

**Tier 0:** In the first round, a rough estimate of the exposure is made, which is based on the worst conceivable situation, i.e. where the product is sprayed directly over the water. The PEC is estimated on the assumption that the entire dose (i.e. the dose/unit area) is mixed in a standard pond (see Annex 10 for the calculations). If the product is used several times during a period in which residues from preceding applications will still be present, the PEC is adjusted accordingly (see Annex 10 for a more detailed description).

The toxicity exposure ratio (TER) is estimated on the basis of the toxicity data and the PEC and is compared to the various trigger values (safety factors) as shown below:

<table>
<thead>
<tr>
<th>Organism</th>
<th>Endpoint</th>
<th>TER</th>
<th>DK trigger value *</th>
<th>EU trigger value **</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fish and daphnia</td>
<td>Acute</td>
<td>TER = (\frac{\text{LC}_{50}}{\text{PEC}})</td>
<td>1000</td>
<td>100</td>
</tr>
</tbody>
</table>


\(^{20}\) The Danish Environmental Protection Agency is working on the development of more complete exposure scenarios that include all relevant sources of exposure for both watercourses and lakes. This will be achieved by using new exposure models. The Danish Environmental Protection Agency has developed a watershed-based modelling tool known as “Pestsurf” for calculation of pesticide concentrations in watercourses and lakes and ponds. At present criteria are being developed for using Pestsurf in risk assessments for the aquatic environment. Parallel to this, the EU has developed a modelling tool known as FOCUSsw (surface water) which is used for calculating the PECsw for active substances under examination, cf. “Guidance document on aquatic ecotoxicology”. It is expected that Pestsurf and FOCUSsw will supplement each other in aquatic risk assessments in which the level of protection is gradually adapted to increasing model complexity. The work is expected to be completed in 2007.
Chronic

<table>
<thead>
<tr>
<th>Algae and aquatic plants</th>
<th>Growth inhibition biomass&lt;sup&gt;23&lt;/sup&gt;</th>
<th>TER=</th>
<th>NOEC&lt;sup&gt;21&lt;/sup&gt; or EC&lt;sub&gt;x&lt;/sub&gt;&lt;sup&gt;22&lt;/sup&gt;</th>
<th>PEC</th>
<th>100</th>
<th>10</th>
</tr>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>NOEC&lt;sup&gt;21&lt;/sup&gt;</td>
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<td>100</td>
<td>10</td>
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<td>EC&lt;sub&gt;50&lt;/sub&gt;</td>
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</table>

* Used in the transitional period
** Used after active substance has been included in Annex I to Directive 91/414/EEC

If the quotient is greater than the Danish safety factors used by the Danish Environmental Protection Agency, the product is considered not to constitute any unacceptable risk to aquatic organisms in the proposed use.

If, on the other hand, the quotient is lower than the safety factor, the procedure continues to Tier 1.

**Tier 1:** In order to enable comparison with the effect concentrations derived from the toxicity tests, the adjustment of the PEC must reflect the drop in exposure that would occur as a result of a reduction in the concentration of the substance, for example due to degradation during the test period. In cases where water/sediment studies have been submitted, data on degradation/disappearance from those studies is used for adjusting the PEC (see Annex 10); in all other cases, hydrolytic or photolytic data can be included. If additional laboratory tests have been submitted to clarify the substance's fate or toxicity, they are included in the assessment (in the form of changes to the PEC, the effect concentration or the safety factor).

When assessing the acute risk to fish and daphnia the initial PEC from Tier 0 is kept, because on the basis of the acute toxicity tests which typically run for 48, 72 or 96 hours and in which the concentration of the test substance is held constant<sup>24</sup> (i.e. flow-through test) it is not possible to determine whether any effects would be influenced by the fact that, in nature, the concentration would actually be dropping. The PEC can only be adjusted if special laboratory tests have been conducted to shed light on this problem.

Tests on algae and aquatic plants are usually carried out as static tests, for which reason the PEC from Tier 0 is retained as the point of departure.

---

<sup>21</sup> The primary aim of the test is to examine the sublethal effects on growth and reproduction – as a starting point the endpoint for these effects is used in the risk assessment (NOECpro or NOECgrowth). If there is a case of significant adult mortality for concentrations that lie below the endpoints that are set for sublethal effects, it is then assessed whether this mortality is covered by the acute risk assessment (in relation to timing, extent and dose/response). If this is not the case, then adult mortality is included in the chronic assessment – either in the form of NOECmort or in the form of the establishment of a combined NOEC for mortality and reproduction/growth in relation to potential effect on population level and with consideration for the substance properties and test system.

<sup>22</sup> Cf. the introduction. The NOEC is only used if no effects are actually observed at this concentration. Alternatively EC<sub>x</sub> is used, where x is dependent on which effect is assessed to be acceptable in terms of population for the individual species.

<sup>23</sup> In Denmark the lowest of the two figures ’growth rate’ and ‘biomass’ was previously used for algae. From now on the growth rate measured after 72 hours will be used. The same has been decided for existing substances and biocides (TGD 2003) and is now recommended by the OECD. It should be noted that the USA (presumably for legal reasons) continues to use biomass measured after 96 hours. Likewise inhibition of growth rate is used for aquatic plants (Lemna).

<sup>24</sup> In cases where static tests (i.e. with an inherent drop in concentration) were used, as a rule the toxicity values will be compared to the initial PEC.
Chronic/long-term toxicity tests typically run for 3-4 weeks. When assessing risk on the basis of an adjusted PEC, the problem is in principle the same as described above, i.e. it is not possible to determine how any effects are affected by the fact that under natural conditions the concentration would actually be dropping, however the acute studies do provide knowledge on the risks of short-term exposure to a "high" (initial) concentration. The Danish Environmental Protection Agency will as a starting point use a time weighted average (TWA) over 7 days for fish and daphnia. This applies to substances for which the assessment is based on the standard data set and for which there are no other signs of rapidly occurring chronic effects (see Annex 9). The seven days are judged to be a relatively conservative period in relation to the length of the standard tests and at the same time represent a time interval that is realistic and biologically relevant in relation to the endpoints that are studied in the tests.

The adjusted PEC is compared to the toxicity. If the TER value is greater than the safety factors used by the Danish Environmental Protection Agency, the product is considered not to constitute any unacceptable risk to aquatic organisms in the proposed application. If, on the other hand, the TER value is lower than the safety factors, the procedure continues to Tier 2.

**Tier 2:** The PEC is adjusted on the basis of the standard pond and information on the relationship between distance and wind drift. The PEC is first estimated for spraying to the edge of the no-cultivation zone for agricultural crops (2 metres) by correcting for the percentage drift (see Annex 11). If, after this, the quotient is greater than the safety factor, the product is considered not to constitute any unacceptable risk to aquatic organisms, provided that it is not used within less than 2 metres of aquatic environments. If not, the next step is to determine whether a larger preservation zone (no-spray area) would be sufficient to reduce the PEC to an acceptable level with respect to acute and chronic toxicity. If so, the product must not be used closer to the aquatic environments than the given distance (see Annex 11) (field crops: maximum 20 metres; vegetables, ornamental plants and fruit bushes: maximum 30 metres; orchards and forests: maximum 50 metres). If a maximum preservation zone is not sufficient, the procedure continues to Tier 3.

**Tier 3:** 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.

In connection with the assessment of mesocosm tests, the Danish Environmental Protection Agency has set an acceptable effect level of 10 per cent (at the population level) for aquatic invertebrates with high reproduction potential, if the depleted population recovered quickly during the test. Fast recovery from effects of this order of magnitude is generally expected of these types of organism (see Annex 12 for a definition of fast recovery).

The safety factor associated with this effect level from mesocosm studies is set on the basis of an appraisal of the quality of the tests\(^25\). As the point of departure, however, a minimum safety 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 that may be exposed).

\(^{25}\) For assessment of mesocosm studies see Annex 12.
If several tests of high quality have been submitted that illustrate the difference there can be between the various natural systems, the safety factor can be reduced in accordance with the guidelines in Annex 12. Tests that are different in terms of time and space can be used to lower the safety 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.

*Sediment-dwelling organisms*

The Danish Environmental Protection Agency has not hitherto undertaken a special risk assessment for sediment-dwelling organisms. This area is, however, within the scope of Directive 91/414/EEC, which sets requirements on studies if a substance can accumulate in sediment (see Annex 13). In cases where data is available, the assessment will be carried out in accordance with the guidelines of the Uniform Principles pertaining to "Guidance document on aquatic ecotoxicology" (see also Annex 13).

The exposure can be estimated from the concentration in the aqueous phase or from the concentration in the sediment, depending on the type of test on which the effect concentrations were based. Estimation of the PEC in the aqueous phase is described above. When estimating the PEC in the sediment, the point of departure is the percentage distribution to sediment in water/sediment tests, where the total quantity of active substance is assumed to be mixed in the upper 2 cm (cf. test guidelines). The toxicity data and PEC are compared as has been described for aquatic organisms.

*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 granulates and dressed seeds, the exposure is assessed on the basis of ingestion of these (see Annex 14).
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 guidelines in "Guidance Document on Risk Assessment for Birds and Mammals Under Council Directive 91/414/EEC". For Danish decisions in the transitional period the scenarios for ingestion of plant material, insects and seeds are used, cf. tables 4, 6 and 7 in the Guidance Document.

The scenarios in the Guidance Document are based on exposure via ingestion of food according to daily dose (mg/kg food/day). In the first tier there are selected indicator species for which standard scenarios have been made for acute, short-term and long-term exposure for birds and acute and long-term exposure for mammals. For the acute assessments, exposure is based on realistic worst-case exposure (90 fractile) stated as RUD (residue per unit dose). For short-term exposure an average value is used and for long-term exposure the average value is adjusted by using time weighting (based on a half-life of 10 days over a period of 21 days). For all indicator species a standard food intake rate (FIR – shown as kg related to body weight) is given for the various food categories. The daily intake (ETE: estimated theoretic exposure) is calculated according to

\[
ETE = (FIR/bw) \times C
\]

where C is the concentration in the food, for sprayed products \(C = \text{RUD} \times \text{dose in kg/ha}\).

**Acute toxicity** is assessed based on \(LD_{50}\) found in acute oral tests for birds and mammals.

**Short-term toxicity** is assessed for birds only, based on short-term food-toxicity studies. In this case, the \(LC_{50}\) value from the five-day food toxicity test is used.

The **chronic toxicity** is assessed on the basis of reproduction studies (see Annex 14 for a more detailed description of data selection). Unless there is any question of special conditions (e.g. high persistence in plant material) the effects on avian and mammalian reproduction are only assessed for spring use, as autumn use is not normally considered to be associated with unacceptable effects on the reproduction of wild birds and mammals.

The effect values are converted to daily dose in accordance with the Guidance Document and are compared with the calculated daily intake (ETE) for the relevant indicator animal:

\[
\text{Effect value (daily dose)/ ETE} = \text{TER (Toxicity Exposure Ratio)}
\]

The spreadsheet "Fugle-pattedyr Standardscenarieberegninger.xls" (Birds and mammals standard scenario calculations.xls) can be used to help with calculations.

**Safety factors (trigger values, cf. the Uniform Principles):**

- Birds and mammals, acute: 10
- Birds and mammals, chronic: 5

If the TER value is greater than the specified safety factors, the product is considered not to constitute any unacceptable risk to birds and mammals in the proposed use. If, on the other hand, the TER
value is lower than the safety factor, the procedure continues to the next tier in accordance with the guidelines.

In Tier 1 it is assumed that the worst case is that animals exclusively ingest plant material or insects that are sprayed with the product. For granulates and dressed seeds, the exposure is assessed on the basis of ingestion of these.

In Tier 2 the risk assessment is refined by modifying the ETE (estimated theoretical exposure) so that it takes account of animals’ possible avoidance of sprayed food \((AV = \text{avoidance factor})\), proportion of diet that originates from the treated area \((PT = \text{proportion of diet obtained in treated area})\) and proportion of the food type in diet \((PD = \text{proportion of food type in diet})\). All three factors can be given values between 0 and 1 and thus the TER value in Tier 2 is calculated by:

\[
\text{Effect value (daily dose)}/(\text{ETE} \times AV \times PT \times PD) = \text{TER (Toxicity Exposure Ratio)}
\]

If the substance or product is highly toxic to birds or mammals and/or the exposure is very high and the TER is thus lower than the Danish Environmental Protection Agency’s safety factors, a higher tier study may be necessary.

**Higher-tier studies:** on the basis of possible special laboratory, semi-field or field tests (including the investigation of repelling effects) an assessment is carried out using a realistic worst-case situation. See Annex 14, for an assessment of higher-tier studies.

The Danish Environmental Protection Agency only carries out the refined risk assessments to a limited extent (when data that can be readily included is available)(cf. Newsletter, July 2006). If on the basis of the standard scenarios it is not possible to obtain an acceptable risk assessment or if no safe use can be shown for a given crop/use, the applicant will be given a deadline for supplying further documentation/assessment. If no further assessment is submitted, or if the Danish Environmental Protection Agency does not consider that the new documentation submitted shows that the use is safe, the case will be decided on the information available – i.e. authorization will not be given to the crops/use in question.

Additional material must be relevant for Danish conditions and the uses in question. Reference can be made to higher-tier Community assessments and associated documentation, but in this case it must be argued why these are relevant, and they must be adapted to use in Denmark (crop, doses, time of spraying, number of treatments etc.).

In the assessment of higher-tier studies for birds that have a high reproduction potential \((r\text{-strategists})\), the Danish Environmental Protection Agency has in this context set an acceptable effect level of a 5 per cent reduction in reproduction potential, as there is also a high natural juvenile mortality rate in these species. A 5 per cent effect is therefore not expected to have any significant influence

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26 All bird species the Danish Environmental Protection Agency normally carries out risk assessments for are r-strategists.
on the populations. The safety factors that are associated with this effect level will depend on the quality and extent of the documentation that the assessment is based on.

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 birds and mammals in the proposed use.

If no such documentation is available, or if the reduction in avian reproduction exceeds 5 per cent or the product causes direct mortalities (e.g. ascertained as being the result of acute toxicity in field tests), the product cannot be authorized for outdoor use.

**Arthropods**

The Danish Environmental Protection Agency has not previously required documentation for beneficial arthropods (apart from honey bees). This area is, however, within the scope of Directive 91/414/EEC and will be assessed in cases for which documentation is available. The risk assessment is carried out in accordance with the Uniform Principles, see Annex 15.

**Terrestrial invertebrates**

The assessment is based on standard laboratory tests of earthworms. 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:** The PEC estimate is based on the assumption that the total dose/unit area is mixed into the upper 5 cm of the soil. If the product is used several times during a period in which residues from preceding applications will still be present, the PEC is adjusted appropriately (see Annex 10 for a more detailed description). 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 various safety factors (triggers, cf. the Uniform Principles) as shown below:

\[
\text{Acute toxicity} \quad \frac{\text{PEC}}{\text{PEC}} > 10
\]

---

27 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.

28 Effects on bees are assessed for outdoor use; the assessment is carried out by the DJF.

Chronic toxicity 

\[ \text{TER} = \frac{\text{NOEC or EC}_{30}^{x}}{\text{PEC}} > 5 \]

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

If the quotient is greater than the safety 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 safety factors, the procedure continues to Tier 1.

**Tier 1:** The PEC is adjusted with respect to the vegetation cover (see Annex 16) (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 safety 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 safety 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 per cent 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 safety factors that are associated with this effect level depend on the quality of the toxicity studies. In this context, consideration must be given to the fact that this assessment is not necessarily representative of other terrestrial organisms. For other species, ad hoc assessments of the effect levels are carried out.

If there is not considered to be any question of unacceptable effects and the studies are satisfactory, the product is considered **not to constitute any unacceptable risk to earthworms/soil-dwelling organisms** in the proposed use.

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

**Micro-organisms**

The assessment of effects on micro-organisms 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 micro-organisms is assessed on the basis of the deposition of the substance on soil and the resulting

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30 In relation to the above the NOEC is only used if there are no actual observed effects at this concentration. Alternatively EC, is used, where x depends on which effect is judged to be acceptable in terms of the population of the individual species.
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:** The PEC estimate is based on the assumption that the total dose/unit area is mixed into the upper 5 cm of the soil. If the product is used several times during a period in which residues from preceding applications will still be present, the PEC is adjusted appropriately (see Annex 10 for a more detailed description).

The Uniform Principles' trigger for effects on the microbial metabolisation of N and C (N and C 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 micro-organisms 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 16 for a more detailed description).

If inhibition under field conditions is not considered to exceed 25 per cent, the product is not considered to constitute any unacceptable risk to micro-organisms in the proposed use. If, on the other hand, the inhibition is greater, the procedure continues to Tier 2.

**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 micro-organisms' reproductive capacity (cf. the Uniform Principles).

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 micro-organisms 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**

The Danish Environmental Protection Agency has not previously required documentation for effects on micro-organisms in wastewater sludge. This area is, however, within the scope of Directive 91/414/EEC and will be assessed in cases for which documentation is available and 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 as-
essment will be done on the basis of whether a realistic worst-case PEC can cause unacceptable ef-
ficts.
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Annex 6: Appraisal of mathematical modelling of risk of pollution of groundwater
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Annex 1

**Data requirements on plant protection products**

The following data requirements apply to plant protection products marketed in at least one EU Member State before 26 July 1993, i.e. "old EU substances", and which are not yet included in Annex I (see also Annex 5.3 in the Statutory Order on pesticides). The documentation requirements on plant protection products marketed after that date, i.e. "new EU substances", can be found in the Statutory Order on pesticides, Annex 5.1. In addition an applicant may choose to send the EU data set (Annex 5.1) for substances that have not yet been included in Annex 1.

In the table below, the 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\(^{31}\)  
   Soil disinfection; outdoor use\(^{1}\)

2. Private use in gardens\(^{32}\)  
   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

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\(^{31}\) 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.

\(^{32}\) For private use in gardens data on adsorption/desorption is also required.
### Data requirements on active substance for area of use:

<table>
<thead>
<tr>
<th>Requirement</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>19. Plant metabolism</td>
<td></td>
<td></td>
<td>x</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>21.1. Photolysis on soil</td>
<td></td>
<td>x</td>
<td></td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>21.2. Soil column: a.s. for 3 soil types, aged substance 1 soil type</td>
<td></td>
<td>x</td>
<td></td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>21.3. Adsorption/desorption</td>
<td></td>
<td></td>
<td>x</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Accumulation of active substance and significant metabolites(^3) in soil</td>
<td></td>
<td>x</td>
<td></td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>21.5. Evaporation from soil (only if vapour pressure &gt; 10(^{-3}) Pa)</td>
<td></td>
<td>x</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>22.1. Biological degradation in water/water-sediment studies</td>
<td></td>
<td>x</td>
<td></td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>22.2. Adsorption to sediment and accumulation in sediment</td>
<td></td>
<td></td>
<td></td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>22.3. Effects on water treatment plants</td>
<td></td>
<td></td>
<td></td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>23.1. Acute toxicity in two fish species</td>
<td></td>
<td>x</td>
<td></td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>23.1.1. Acute toxicity in daphnia</td>
<td></td>
<td>x</td>
<td></td>
<td>x</td>
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<tr>
<td>23.1.2. Reproduction test in daphnia</td>
<td></td>
<td>x</td>
<td></td>
<td></td>
<td>x</td>
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<tr>
<td>23.1.3. Acute toxicity in algae</td>
<td></td>
<td>x</td>
<td></td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>23.1.4. Effects on other aquatic organisms</td>
<td></td>
<td>x</td>
<td></td>
<td></td>
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<tr>
<td>23.5. Bioaccumulation (Kow &gt; 1000)</td>
<td></td>
<td>x</td>
<td></td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>24.1. Acute toxicity and other effects in earthworms</td>
<td></td>
<td>x</td>
<td></td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>24.2. Effect on soil respiration</td>
<td></td>
<td>x</td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>24.3. Effect on ammonification</td>
<td></td>
<td>x</td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>24.4. Effect on nitrification</td>
<td></td>
<td>x</td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>25.1. Acute feed toxicity in two bird species with different Diets</td>
<td></td>
<td>x</td>
<td></td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>25.2. Reproduction test in one bird species</td>
<td></td>
<td>x</td>
<td></td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>26. Effect on honey bees</td>
<td></td>
<td>x</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>27. Any information on toxic effects towards other useful species</td>
<td></td>
<td>x</td>
<td></td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>

### Data requirements on product for area of use:

<table>
<thead>
<tr>
<th>Requirement</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.1. Content of substances harmful to honey bees</td>
<td></td>
<td></td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.2. Other ecotoxicological effects</td>
<td></td>
<td>x</td>
<td></td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>6.3. Ecotoxicological effects of inactive components</td>
<td></td>
<td>x</td>
<td></td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>

1. Only degradation in a single standard soil required.
2. Except for photolysis on soil.
3. See p.2 for description of significant metabolites.
The Danish soil types are classified according to the distribution of their particle sizes and humus content:

<table>
<thead>
<tr>
<th>Texture definition for soil type</th>
<th>Symbol</th>
<th>JB No.</th>
<th>Clay less than 2 ( \mu m )</th>
<th>Silt 2-20 ( \mu m )</th>
<th>Fine sand 20-200 ( \mu m )</th>
<th>Sand 20-2000 ( \mu m )</th>
<th>Humus 58.7 % C</th>
<th>Cultivated land in DK*, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coarsely sanded</td>
<td>GR.S.</td>
<td>1</td>
<td>0 - 5</td>
<td>0 - 20</td>
<td>0 - 50</td>
<td>75 - 100</td>
<td>&lt; 10</td>
<td>24</td>
</tr>
<tr>
<td>Finely sanded</td>
<td>F.S.</td>
<td>2</td>
<td>0 - 5</td>
<td>0 - 20</td>
<td>50 - 100</td>
<td>75 - 100</td>
<td>&lt; 10</td>
<td>10</td>
</tr>
<tr>
<td>Coarse clay-mixed sand</td>
<td>GR.L.S.</td>
<td>3</td>
<td>5 - 10</td>
<td>0 - 25</td>
<td>0 - 40</td>
<td>65 - 95</td>
<td>&lt; 10</td>
<td>7</td>
</tr>
<tr>
<td>Fine clay-mixed sand</td>
<td>F.L.S.</td>
<td>4</td>
<td>5 - 10</td>
<td>0 - 25</td>
<td>40 - 95</td>
<td>65 - 95</td>
<td>&lt; 10</td>
<td>21</td>
</tr>
<tr>
<td>Coarse sand-mixed clay</td>
<td>GR.S.L.</td>
<td>5</td>
<td>10 - 15</td>
<td>0 - 30</td>
<td>0 - 40</td>
<td>55 - 90</td>
<td>&lt; 10</td>
<td>4</td>
</tr>
<tr>
<td>Fine sand-mixed clay</td>
<td>F.S.L.</td>
<td>6</td>
<td>10 - 15</td>
<td>0 - 30</td>
<td>40 - 90</td>
<td>55 - 90</td>
<td>&lt; 10</td>
<td>20</td>
</tr>
<tr>
<td>Clay</td>
<td>L.</td>
<td>7</td>
<td>15 - 25</td>
<td>0 - 35</td>
<td>40 - 85</td>
<td>&lt; 10</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Heavy clay</td>
<td>SV.L.</td>
<td>8</td>
<td>25 - 45</td>
<td>0 - 45</td>
<td>10 - 75</td>
<td>&lt; 10</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Very heavy clay</td>
<td>M.SV.L.</td>
<td>9</td>
<td>45 - 100</td>
<td>0 - 50</td>
<td>0 - 55</td>
<td>&lt; 10</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Silt</td>
<td>SI.</td>
<td>10</td>
<td>0 - 50</td>
<td>20 - 100</td>
<td>0 - 80</td>
<td>&lt; 10</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Humus</td>
<td>HU.</td>
<td>11</td>
<td></td>
<td></td>
<td>&gt; 10</td>
<td></td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Special</td>
<td>SPEC.</td>
<td>12</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Sand content, percentage of top soil.</th>
<th>Samples with more than:</th>
<th>Clay content, percentage of top soil.</th>
<th>Samples with more than or equal to:</th>
</tr>
</thead>
<tbody>
<tr>
<td>40 % sand</td>
<td>&gt; 99 %</td>
<td>2% clay</td>
<td>= 99 %</td>
</tr>
<tr>
<td>50 % sand</td>
<td>= 99 %</td>
<td>5% clay</td>
<td>= 70 %</td>
</tr>
<tr>
<td>Sand Percentage</td>
<td>Clay Percentage</td>
<td>Sand Percentage</td>
<td>Clay Percentage</td>
</tr>
<tr>
<td>-----------------</td>
<td>----------------</td>
<td>----------------</td>
<td>----------------</td>
</tr>
<tr>
<td>60 %</td>
<td>97 %</td>
<td>10 %</td>
<td>35 %</td>
</tr>
<tr>
<td>70 %</td>
<td>81 %</td>
<td>15 %</td>
<td>10 %</td>
</tr>
<tr>
<td>80 %</td>
<td>49 %</td>
<td>20 %</td>
<td>2 %</td>
</tr>
<tr>
<td>90 %</td>
<td>9 %</td>
<td>30 %</td>
<td>0.4 %</td>
</tr>
<tr>
<td>95 %</td>
<td>&lt; 1 %</td>
<td>50 %</td>
<td>0.01 %</td>
</tr>
</tbody>
</table>

| 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):

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

* Cappelen (2002)
** Frich et al. (1997)

Average air temperature (°C):

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

* Cappelen (2002)
** Cappelen (1997)

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

<table>
<thead>
<tr>
<th>Year</th>
<th>Jan</th>
<th>Feb</th>
<th>Mar</th>
<th>Apr</th>
<th>May</th>
<th>Jun</th>
<th>Jul</th>
<th>Aug</th>
<th>Sep</th>
<th>Oct</th>
<th>Nov</th>
<th>Dec</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average</td>
<td>2.0</td>
<td>2.0</td>
<td>3.1</td>
<td>7.2</td>
<td>12.2</td>
<td>15.8</td>
<td>17.9</td>
<td>17.4</td>
<td>14.4</td>
<td>10.2</td>
<td>6.1</td>
<td>3.5</td>
<td>9.3</td>
</tr>
</tbody>
</table>

Source: University of Aarhus, Faculty of Agricultural Science

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

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

* Landwirtschaftliche Untersuchungs- und Forschungsanstalt (LUFA) Speyer.
Pavements and similar use areas

Overall it is considered that there is no risk of leaching from paved areas. This is mainly due to the fact that there is no water movement through paved areas, there is often a degradation in the building materials and the removal of topsoil does not in itself necessarily constitute a risk of leaching.

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 topsoil 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 so that a specific evaluation can be made of any deviation from the general conditions above.

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 $<< 0.1 \mu g/l$

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 usually be assessed with respect to their intrinsic properties, lysimeter tests or field studies. Unless the results irrefutably show that no unacceptable leaching will take place under Danish conditions, mathematical modelling must be carried out and included in the overall assessment.

The following requirements on modelling and scenarios must be satisfied:

- Models: a model code, which can indicate preferential transport mechanisms, including macro-pore flow and capillary rise, must be used. The model must be usable for Danish conditions. This means 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. Alternatively the PELMO model and Hamburg scenario from FOCUS can be used.
- 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.
- 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 each individual day of the period in which use of the product is proposed.
- The results must be reported as annual averages.
- 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 to 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 (5 per cent, as the rule), the model runs cannot be used to support authorization for the proposed application.

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.

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*:

<table>
<thead>
<tr>
<th>Test</th>
<th>No.</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOC Die-Away</td>
<td>301 A</td>
<td>70 % (DOC)</td>
</tr>
<tr>
<td>CO₂ Evolution</td>
<td>301 B</td>
<td>60 % (BOD)</td>
</tr>
<tr>
<td>MITI (I)</td>
<td>301 C</td>
<td>60 % (BOD)</td>
</tr>
<tr>
<td>Closed Bottle Test</td>
<td>301 D</td>
<td>60 % (TOD)</td>
</tr>
<tr>
<td>Modified OECD Screening</td>
<td>301 E</td>
<td>60 % (CO₂)</td>
</tr>
<tr>
<td>Manometric respirometry</td>
<td>301 F</td>
<td>70 % (DOC)</td>
</tr>
</tbody>
</table>

* 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 CO₂ and not just primary degradation to possible metabolites or bound residual products.
Annex 9

Use of time weighted averages (TWA)

Time weighted averages have found broad application for estimating more realistic environmental concentrations when calculating risk quotients (TER) for long-term effects. The time weighted average is calculated from the following formula:

$$PEC_t = PEC_0 \times (1 - e^{-kt})/kt$$

in which

$PEC_t$ is the concentration at time $t$, $PEC_0$ is the initial concentration and $k = \ln2/DT_{50}$.

The time weighted averages are used for substances when:
- the assessment is based on the standard data set – i.e. based on tests in accordance with the standard guidelines that are carried out with “fixed” concentrations (e.g. aquatic flow-through test)
- there is no indication that short exposure can lead to chronic effects

If there is information in the available literature or from research projects (e.g. on time to response) that indicates that chronic or delayed effects can occur after short exposures then an ad hoc assessment is carried out. In such cases careful consideration must be given to which $PEC$ would be relevant to compare the endpoint in question with (see Scientific Panel’s statement on dimoxystrobin for proposals on this, EFSA Journal 2005, 178).

Purely from the standpoint of the fate of a substance, the time weighted average can be considered a reasonable estimate of an integrated concentration over a given time (provided that the degradation rates used are representative of the given situation).

From the standpoints of effect/toxicity, however, there are several reasons for doubting how well a time weighted average can express the level of exposure of an organism and the level to which it possibly "reacts". These reservations apply in the same manner both when reducing exposure by using a concentration after a certain time (48 hours or 96 hours) and when using a time weighted average.

The following factors should be considered:

- If a substance causes a toxic effect very quickly (including not only lethal effects but also sub-lethal, which possibly do not appear until later) and, at the same time, degrades rapidly, a time weighted average will underestimate the initial exposure of the organism and, thus, yield a quotient that in fact fails to cover natural conditions.
- Many toxicity tests are carried out as flow-through tests, or as tests in which feeding occurs with a constant concentration. Often, no observations are made during the test. This means that it is rarely possibly to determine how quickly an effect commences. Consideration must be given to any indication that effects can occur after short-term exposure.
• Static tests and one-time exposure tests have an inherent drop in concentration or exposure over time. The extent to which this drop is representative of "natural" conditions should be assessed but, as the point of departure, the effect values from static tests and one-time exposure tests should be compared to the initial value of the exposure.
• Time weighted averages do not include the concentration of any metabolites formed during degradation of the active substance, and metabolites must therefore be assessed independently.
• As a rule, time weighted averages must always be compared to effect values based on measured concentrations.
• If there is a case of multiple applications, this must be included in the calculation of the time-weighted average.
Annex 10

**Calculation and adjustment of PEC**

*Initial PEC in soil*
To be estimated from the dose*/soil volume in the upper 0-5 cm (converted to weight using the soil density, which is set to 1.5 g/cm³).
The following formula is used:

\[
\text{PEC}_s = \frac{(\text{Number of kg a.s./ha} \times 10^6 \text{ mg/kg})}{(10000 \text{ m}^2/\text{ha} \times 10^4 \text{ cm}^2/\text{m}^2 \times 5 \text{ cm} \times 1.5 \text{ g/cm}^3 \times 10^{-3} \text{ kg/g})} \times (\text{Number of kg a.s./ha}/0.75)
\]

where the result is expressed as: mg a.s./kg soil (i.e. ppm).

* the dose for seed dressings is calculated, e.g. as kg a.s./100 kg seed x Number of 100 kg seed/ha (for grain, 200 kg seed/ha is used as the worst case).

*Initial PEC in water*
Estimated from the dose/water volume at a depth of 30 cm (0.3 m)
The following formula is used:

\[
\text{PEC}_w = \frac{(\text{Number of kg a.s./ha} \times 10^6 \text{ mg/kg})}{(10000 \text{ m}^2/\text{ha} \times 0.3 \text{ m} \times 10^3 \text{ l/m}^3)} \times (\text{Number of kg a.s./ha}/3)
\]

where the result is expressed as: mg a.s./l water

*PEC at a given time*
Estimated from the following formula:

\[
\text{PEC}_t = \text{PEC}_0 \times e^{-kt}
\]

in which
PEC\(_t\) is the concentration at time t
PEC\(_0\) is the initial concentration
k = ln2/DT\(_{50}\) and
DT\(_{50}\) is the half-life of the substance.

*Time weighted average (TWA)*
The time weighted average is calculated from the following formula:

\[
\text{PEC}_{twa} = \frac{\text{PEC}_0 \times (1 - e^{-kt})}{kt}
\]
in which
PEC_{twa} is the time-weighted average at time t
PEC_0 is the initial concentration
k = ln2/DT_{50} and
DT_{50} is the half-life of the substance.

Multiple applications
In cases where several applications are made within a season, at such short intervals that residues from previous applications will still persist in the relevant medium (water, sediment, soil, plant material, etc.), a realistic worst-case PEC must allow for this. In the first round, the maximum proportion/concentration of the first application that can possibly be present at the time of the second application (and so on for more applications) is estimated on the basis of the degradation rate and this value is added to the initial concentration for the second application. The calculations are made using the following formulae\(^33\):

Where there is a question of two applications of the same dose:

\[
PEC_{t_{\text{max}}} = PEC_0 \times (1 + 0.5^{t/DT_{50}})
\]

in which
PEC_{t_{\text{max}}} is the total concentration immediately after the second application
PEC_0 is the initial concentration (PEC immediately after the first spraying)
t is the time interval between the first and second applications, and
DT_{50} is the half-life of the substance.

Where there is a question of n applications of the same dose:

\[
PEC_{n} = C_0 \left(1 - e^{-nk}\right)/\left(1 - e^{-k}\right)
\]

in which
PEC_{n} = the total concentration immediately after n applications, and
k = ln2/DT_{50}

In the risk assessment, subsequent adjustments to the PEC at Tier 1 or higher tiers must then be based on the total maximum concentration.

Water/sediment studies
In cases where water/sediment studies have been submitted, the information taken from these stud-

\(^33\) From: Soil persistence models and EU registration. Focus report, 1996
The above formulae can only be applied in cases of first-order degradation kinetics.
ies on degradation/disappearance is used for adjusting the PEC for aquatic organisms. For aquatic organisms, the adjustment should be based on disappearance from the aqueous phase, usually in the form of the DT$_{50}$ for the aqueous phase (disappearance can be due to degradation, evaporation, sedimentation, etc.).

For sediment-dwelling organisms, the adjustment should be made with consideration for the form of toxicity test from which the toxic-effect values are derived. If there is exposure through the aqueous phase, the above adjustment is used. If there is exposure through the sediment, the maximum concentration in the sediment should be used as the point of departure for adjustment, which should in that case include disappearance from the sediment (based on the DT$_{50}$ for the sediment phase) and supply to the sediment (through continued sedimentation).
Annex 11

Non-spraying buffer zones to the aquatic environment

Spray drift values for different types of crop:

<table>
<thead>
<tr>
<th>Distance (m)</th>
<th>Agriculture</th>
<th>Fruit trees</th>
<th>Vegetables, ornamental plants, fruit bushes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Early stage</td>
<td>Late stage</td>
<td>Height &lt; 50 cm</td>
</tr>
<tr>
<td>2</td>
<td>1.41</td>
<td>39.6</td>
<td>25.8</td>
</tr>
<tr>
<td>10</td>
<td>0.29</td>
<td>11.8</td>
<td>3.60</td>
</tr>
<tr>
<td>20</td>
<td>0.15</td>
<td>2.77</td>
<td>1.09</td>
</tr>
<tr>
<td>30</td>
<td>-</td>
<td>1.04</td>
<td>0.54</td>
</tr>
<tr>
<td>40</td>
<td>-</td>
<td>0.52</td>
<td>0.32</td>
</tr>
<tr>
<td>50</td>
<td>-</td>
<td>0.30</td>
<td>0.22</td>
</tr>
</tbody>
</table>

Spray drift values have been investigated by the German authorities (Rautmann et al., 2001). These German 90 percentiles approximately correspond to average values in Denmark because of higher wind speeds in the Danish coastal climate, according to Asman et al. (2003).

"Early stage" in fruit trees corresponds to "during flowering" (until 15 May - 1 June), and "Late stage" corresponds to "after flowering". The terms "during and after flowering" should be used in both the authorization text and the label text.

Non-spraying buffer zones to the aquatic environment of 2, 10 and 20 metres are used in farming. 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.

The following maximum preservation zones are set on the basis of the greatest distance with the spray-drift values of the above table.

<table>
<thead>
<tr>
<th>Crop</th>
<th>Maximum preservation zone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agriculture</td>
<td>20 metres</td>
</tr>
<tr>
<td>Fruit trees</td>
<td>50 metres</td>
</tr>
<tr>
<td>Vegetables, ornamental plants, fruit bushes</td>
<td>30 metres</td>
</tr>
</tbody>
</table>
Annex 12

**Appraisal of mesocosm studies**

In connection with the assessment of mesocosm studies please see OECD Guidance Document on Simulated Freshwater Lentic Field Tests (Outdoor Microcosms and Mesocosms, May 2006), which provides recommendations for test design, analyses, reporting etc. In addition see the reference list at the end of this annex.

Examples of factors that can be included in the appraisal are given below. In the older studies it can not be guaranteed that the recommendations in the newer guidelines are fulfilled. The studies must be judged on the basis of their individual quality and their results used in risk assessment in relation to this (see below).

**Examples of type/size of mesocosms:**
(Source: "Aquatic mesocosm studies in ecological risk assessment" SETAC)
Sediments are included in all of the studies described.

Large pond systems. Artificial ponds of uniform size and depth. Size typically between 0.01 to 0.1 ha and volume between 100 and 1000 m$^3$. The artificial ponds should be colonised with aquatic animals and plants artificially or by natural colonisation (e.g. by flying water beetles and water bugs) 1-2 months prior to the study.

Outdoor microcosms. The size normally varies from 2 to 20 m$^3$. The test container must be large enough to be representative of a small lentic (standing freshwater area) ecosystem and should not be strongly influenced by changing environmental factors such as temperature, light and wind.

Limnocorrals. An artificial column placed in the pelagic zone (upper layers of the open water) in ponds, lakes and the marine environment. These systems typically vary in size from 0.1 to 100 m$^3$ and can both be in contact with and removed from the floor of the sea, lake or pond.

Littoral enclosures. Plastic or steel walls are used to isolate part of the littoral zone of a pond or lake. Such an enclosure can have a volume of up to 50 m$^3$ and a depth of up to 2 meters.

Lotic systems. For example artificial watercourses in metal channels with water recirculated by pumps. The floor of the channels is often covered with gravel and stones as substrate and protection from current.

**Examples of factors that should be included in the appraisal of mesocosm studies**
A mesocosm study should be a diverse test system that is relevant for Danish conditions and which should have "equivalent" representatives for the groups of organisms that have shown themselves to be most sensitive in laboratory tests.
It is important to consider whether the method that is used to apply the pesticide is realistic and gives the expected exposure. For example, mesocosm studies should not be so large so as to prevent the surface being sprayed in one go. Studies of spray drift from one corner of a larger lake to another must be interpreted with care because exposure data cannot necessarily be compared with possible effects. For example, non-exposed organisms can swim into the sprayed zone.

A single exposure/application per dose is preferable because this makes it easier to relate the observed effects to specific exposures. In connection with drift it is most realistic that exposure occurs through spraying of the surface. Other types of application or several types of treatment can be accepted, however they must be assessed in relation to their use in Denmark.

A dose-response design is preferable to a few doses with several replicates. The design should include a concentration that leads to no effect and at least one concentration that does lead to an effect. Furthermore, the study design should include replicates (see OECD Guidance Document on Simulated Freshwater Lentic Field Tests, Outdoor Microcosms and Mesocosm, May 2006 or HARAP, 1999).

Turbidity should be normal in order to avoid significantly reducing the bioavailability of the test substance due to adsorption by particles. Pesticides with a high Koc can adsorb strongly to TOC (Total Organic Carbon) or to DOC (Dissolved Organic Carbon). TOC at 3.5 – 8.0 mg/l and DOC at 3.1 – 7.3 mg/l can be considered as reasonable levels (source: Aquatic mesocosm studies in ecological risk assessment, SETAC).

Species in the mesocosm study should be determined to the lowest taxonomical level possible as this gives the possibility of assessing the individual species’ responses, which is desirable in terms of the diversity perspective. It should therefore be possible to check the collection lists in order to follow the number of the individual species during the study period and to relate possible fluctuations to the determination of the NOEC/NOAEC value and to assess recovery for the most sensitive species.

If recovery is included in the assessment, documentation must be given that shows that recovery occurs within a period of four weeks. It must be ensured that it is a case of real biological recovery and not an artefact (e.g. because of lack of robust statistics or a coincidental reduction in the control).

In relation to the overall assessment of recovery it is important to include dispersal potential for the species in question.

It is recommend that fish are not included in mesocosm studies that focus on effects on zooplankton and macroinvertebrates, because the predatory pressure from fish can complicate the assessment of the tested pesticide’s impact on the size of population of the various invertebrate taxa.
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.

Use of results in risk assessment
The safety 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 safety 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 safety 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 safety 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 safety 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 safety factor if they represent different population mixes or biotopes.

Definitions
NOEC/ECx (e.g 5-10): The NOEC is the highest concentration for which there are no statistically significant effects on organisms or transformation rates in the study in relation to control. An ECx can also be used in which a very low effect (e.g. 5-10 per cent) is extrapolated by linear regression. This avoids some of the uncertainty with the NOEC which is due to the choice of concentration levels in the study design.

Recovery: recovery from a disturbed state to a state that is comparable with the control (i.e. there is no longer a difference for a species/parameter between the relevant exposure concentration
and the control). Determination of the period that recovery covers is limited by the number of measurements that are taken.

NOAEC: 'No Observed Adverse Effect Concentration’ the concentration for which there are only limited effects and recovery has occurred within an acceptable period of time for the most sensitive species/parameter.

EAC: Ecologically Acceptable Concentration – this concept is used in the EU’s aquatic guidance document, and is defined as the concentration at which no ecologically adverse effects are expected. The EAC is based on a NOEAEC (No Observed Ecologically Adverse Effect Concentration) to which a safety factor may be added. The Danish Environmental Protection Agency does not use these concepts due to the fact that we are not of the opinion that it is possible to define ecologically non-adverse effects. Instead we use the NOAEC.

References:


Annex 13

Sediment-dwelling organisms

The data requirements in Annex II of Directive 91/414/EEC stipulate that a requirement to test sediment with sediment-dwelling organisms must be considered when an active substance can be expected to enter and accumulate in the sediment. In this context, consideration must be given to whether or not effects on sediment-dwelling organisms are likely on the basis of the effect values for aquatic organisms and the expected exposure.

In the "Guidance document on aquatic ecotoxicology" more specific guidelines are described. In regard to the possibility of exposure via sediment, the assessment is based on the fact that at least 10 per cent of the applied radioactivity (in the form of the active substance or metabolites) must be recoverable from the sediment after 14 days in water/sediment studies. Furthermore, a NOEC < 0.1 mg/l for daphnia is used as the trigger - but with the reservation that consideration must be given to the exposure. The document also states that, for persistent substances (DT_{50} > 3 months), it can be necessary to require a life-cycle test, to facilitate an assessment of the effects on reproduction.

As stated in the data requirements of Annex II, the test must be conducted with *Chironimus sp.* (gnat larvae) and the endpoints must be survival and development to the adult stage. In regard to this there are two OECD Test Guidelines (TG 218 “Sediment-Water Chironomid Toxicity Using Spiked Sediment” and TG 219 “Sediment-Water Chironomid Toxicity Using Spiked Water”). In both tests newly hatched gnat larvae (*Chironomus sp.* ) are used as the test organism. The tests run over 10 days (range finder, acute test where only survival is measured) or 28 days (final test) where survival, growth, development and hatching to adult are measured.

In the one test (TG 218), the test substance is mixed into the sediment phase after which water is added above the sediment and finally the larvae are added. In the other (TG 219) the test substance is mixed in the aqueous phase after it has established over the sediment and the larvae are added. The two tests result in different forms of exposure and, thus, differing bioavailabilities of the test substance. These two tests have also proven to yield widely different effect values.

In practice, the spiked water test (TG 219) is considered to be most representative of natural exposure when simulation is through spray drift and, therefore, deposition of the substance on the surface of the water. This test also makes it possible to add repeated doses of the test substance, for simulating multiple applications. TG 218 is more comparable to a situation where soil particles with adsorbed substance enter a water body by run off. There are no requirements on which test(s) should be used for specific substances. It is necessary to assess whether the arguments for use of a particular test put forward by the applicant are reasonable.

According to the EU “Guidance document on aquatic ecotoxicology” results from such tests are used as follows: for tests that use the spiked sediment method the effect concentrations are stated based on sediment (dry weight), while results from tests based on the spiked water method are stated according to the concentration in the aqueous phase. Correspondingly the results are compared with PEC values, based on the solid phase and the aqueous phase respectively.

The studies are considered to be long-term tests, therefore NOEC values (or EC_{10} values) are used as a starting point for environmental risk assessment.
The term Toxicity Exposure Ratio (TER) used in EU terminology thus becomes NOEC/PEC and the cut-off value (trigger value) is set at 100. If the TER value is < 100, the risk for unacceptable effects is considered to be too high and the assessment must be refined with higher-tier studies (or a risk reduction must be recommended, e.g. in the form of non-spraying buffer zones around surface water).
Annex 14

**Wild birds and mammals**

**Data selection**
Guidelines are given below on selection of the most relevant endpoints from both acute and chronic standard studies.

The chronic risk assessment can be done with NOAEL (no observed adverse effect level) values instead of NOEL, because for instance, a minor weight loss in mothers is not considered to be an adverse effect. In all cases, it will be necessary to appraise the LOAEL (lowest observed adverse effect level) and the effects that can occur at that dose, so that the effect (endpoint) on which the assessment is based is apparent. If there is a difference in NOAEL for mothers and offspring the biologically most relevant endpoint is used for risk assessment.

**Birds:**
In cases where regurgitation occurs by oral intubation, the LD$_{50}$ is stated as greater than or equal to the highest dose at which regurgitation does not occur. If the trigger value is exceeded in the subsequent risk assessment or if regurgitation occurs at all doses, a test in a bird species that does not regurgitate can be required (cf. Guidance Document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC).

In cases where the test data on birds’ weight and feed intake are not available or where data from the EU guidance document is not sufficient for carrying out any possible refinement of the risk assessment, data from Christensen et al. (1996) can be used.

**Mammals:**
Toxicity input data to the risk assessment for wild mammals is selected from the toxicological (health) part of the documentation.

Acute oral LD$_{50}$ tests with rats and the active substance are used as acute toxicity tests unless special types of products are involved that imply direct exposure to the product itself (e.g. granulates), in such cases product data is used.

In order to assess chronic effects, an endpoint must be found that is biologically relevant and realistic. Foetal development tests (teratogenicity tests) can be used to establish a chronic endpoint, if there are any effects on foetal development. The tests are typically conducted with rats and rabbits, but may also be conducted with hamsters and mice. The endpoint is based on the most sensitive species because adverse effects on foetal development can be very species specific. In the teratogenicity test the substance is administered by gavage, which is not a natural way of exposure, but on the other hand the period of exposure is relatively short (approx. 7-14 days) and will therefore often be relevant for natural exposure of wild mammals. One disadvantage of using the teratogenicity test is, however, that the tests fail to reveal harmful effects on the reproductive capacity. Any reduced sperm quality resulting from exposure to oestrogen-like or anti-androgen substances will not, therefore, be discovered. Therefore multiple-generation/reproduction tests must also be included in the assessment and consideration must be given to whether or not there are any effects on the reproductive capacity for which
further assessment should be carried out for wild mammals. Because the exposure of wild mammals is most often relatively short-term (in relation to multi-generation studies) the effects on the reproductive capacity in F0 and effects on F1 offspring will most often be most relevant. If there is a case of effects on reproduction at concentration levels at which there are also maternal effects (e.g. reduced weight) then an assessment must be made of whether this is a case of direct effects on reproduction or indirect effects through the maternal effects. In the case of the latter, it must be assessed whether the maternal effects would occur as a result of short-term exposure in nature (e.g. based on 28-day studies).

If the test animals' weights at the start of the test and the daily feed intake are not stated in the test report, data from Wolfensohn & Lloyd (1994) can be used.

**Risk assessment for seed dressings**

When sowing seed crops with sowing machines, part of the seed can be expected to remain on the surface of the soil. Preparation of the land for sowing means, moreover, that weed seeds and spilled seed are typically worked into the soil, therefore the seed becomes the dominant food source. Such seed therefore constitutes a potentially large feed supply for birds and, possibly, mammals in the relevant field for a period of about 10 days (until the seeds germinate).

**Tier 1**

Risk assessment for birds and mammals is carried out at Tier 1 in accordance with the guidelines in “Guidance Document on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC” using the same overall model as for spray products.

The PEC is estimated on the basis of the quantity of seed dressing/kg seed (e.g. the PEC for dressed grain is calculated from the dose: 200 ml product/100 kg seed, and from the content of the active substance: 25 g a.s./l product, which yields a concentration of 50 mg a.s./kg seed, corresponding to 50 ppm), which can be directly related to the relevant endpoints through the weight and daily feed intake for the individual bird or mammal species.

Birds are regarded as being more exposed than mammals because birds find their food in newly sown fields to a larger degree.

The Danish Environmental Protection Agency has decided to use the long-tailed field mouse (*Apodemus sylvaticus*) as the model organism for mammals. This is because recent field studies (Johnson, Flowerdew & Hare 1992 and Tew 1994) have shown that the only mouse that is found on newly sown fields to a significant degree is the little seed, insect and plant-eating long-tailed field mouse, which also lives in woodland edges and hedgerows. Voles, for example the field vole, do not usually frequent open fields, and only go into the fields when crops have sprouted.

The risk assessment is otherwise carried out in the normal way for other products and with the same trigger values.

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34 Sowing of pelleted sugar beet and fodder beet seeds is carried out with special sowing equipment that sows the seed in the soil with a band. In this way seeds are sown precisely at a specific depth and at a specific distance from one another. The Danish Environmental Protection Agency has decided that there is no exposure to wild birds and mammals...
Tier 2:
The risk assessments can be refined through the use of specific tests (e.g. repellency or field studies) see below. Alternatively refinement of the risk assessment can be based on "common-sense considerations”, for example about how many dressed seeds need to be eaten in order to reach one tenth LD$_{50}$, which can be compared with how many seeds a bird/mammal can manage to find and eat in one day.

Based on the thousand-seed weight (TSW) for the seed in question, the dose expressed as number of seeds can be calculated, and with knowledge of the sowing distance it is possible to calculate how large an area is needed to find enough seed for one tenth of LD$_{50}$, for example. If this area is relatively small, then the possibility that spillage may occur when seeding machinery is turned should be taken into account.

Such a method requires that the risk assessment is based on specific model species as well as knowledge about the daily food intake and/or foraging areas of these species.

If the risk assessment is refined for a specific indicator species or group of birds or mammals, the fact of whether or not the species/group in question dehusks seeds before ingesting them can be included. In such cases the exposure estimate can be reduced. The degree of reduction must take account of whether the substance that is contained in the seed, germinating plant or roots is systemic.

Certain birds (e.g. chaffinch, greenfinch, goldfinch and bullfinch) normally dehusk seeds, but the Galliformes (gamebirds), bean geese, and pigeons ingest whole seeds and crush them with grit in their crop.

The long-tailed field mouse can dehusk seeds, but the precise extent of this dehusking is not known. Furthermore the long-tailed field mouse can store a reserve of seed food in its nest or another hiding place, which increases the risk of long-term exposure – a long-term assessment would therefore be well founded.

The limit for an acceptable risk is set at a toxicity and exposure that result in the fact that the intake of the normal daily amount of food in the form of seed leads to a dose of pesticide that corresponds to LD$_{50}$ compared with the trigger value. This means that an acceptable intake is set such that it corresponds to one tenth LD$_{50}$.

In future, it may be possible to use toxicokinetic and toxicodynamic calculations for quantification (used in EU pirimicarb risk assessment for birds (EFSA 2006)).

**Risk assessment for granulates**
Granulates that are spread on the surface of the soil will be fully accessible to birds\(^{35}\), which can ingest the granules as grit. Similarly, granules that have been drilled into the soil will be accessible to

\(^{35}\) In relation to seed dressings birds are regarded as more exposed than mammals.
a certain extent on the soil surface (as drilling is not a 100-per-cent effective mechanism). Grit is defined as inorganic particles > 0.5 mm. The number and size of grit vary considerably between species, e.g. from 65 to 21,000 particles and sizes of between 0.5 and 3.5 mm (Christensen et al. 1996). As the absolutely worst case, the point of departure can be taken in the ingestion of granules as feed (cf. seed dressings, the PEC is estimated as the content of the active substance in the granules, e.g. a content of 0.1 per cent active substance yields a PEC of 1,000 ppm). The risk assessment is otherwise carried out in the normal way for other products and with the same trigger values.

If this causes unacceptable risk, the following alternative assessment can be carried out:

- ingestion of granules as grit can be estimated, if the quantity of grit ingested per day for the species in question is known:
  \[
  \text{mg grit/day} \times \frac{\text{mg active substance/mg granulate}}{\text{mg active substance per bird per day, which can be compared to one tenth LD}_{50} \text{ per quail}}^{36}
  \]

- the number of granules/toxic effect can be calculated, e.g. as:
  \[
  \frac{\text{LD}_{50} \text{ [mg/kg]} \times \text{body weight [kg]}}{\text{mg active substance/granule}}
  \]
  The risk of birds being able to ingest the given number of granules under field conditions is then assessed. This assessment can possibly be modified in relation to whether the granulate has a food value and whether it has a repellent effect.

The limit for an acceptable risk is set at a toxicity and exposure that result in the fact that the intake of the normal daily amount of granulate or grit leads to a dose of pesticide that corresponds to LD$_{50}$ when compared with the trigger value. This means that an acceptable intake is set such that it corresponds to one tenth LD$_{50}$.

**Repellent effects of seed dressings (and granulates)**

Because dressed corn or seed (and granulates) could be eaten directly by birds or mammals, it is relevant to investigate the extent to which dressed corn/seeds are avoided by birds and/or mammals so that such behaviour can be included in the exposure assessment. The repellent effect is expressed in the risk assessment as an ”avoidance factor” (AV) which can lie between 0 (complete avoidance) and 1 (no avoidance).

If the repellent effect of a product is to is to be included in the risk assessment, it is a fundamental requirement that the seed dressing/ granulate not be so toxic that the ingestion of only a few seeds/pieces of corn/granules amounts to a lethal dose, i.e. the birds must be able to use their experience of the repellent effect in practice.

Documentation of this is necessary in order to judge the degree of the repellent effect.

No internationally standardised test is available for investigating such avoidance behaviour (avoidance or repellency), albeit in the auspices of the OECD a repellency test for birds is being developed (OECD 2003a). Guidelines for the quality assessment of such tests are lacking, though draft guidelines are available from the OECD (OECD 2003b). The tests that are carried out are usually based on the assumption that animals can distinguish between seed with pesticide (dressed seed or

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36 LD$_{50}$ per bird = LD$_{50}$ [mg/kg] x bodyweight [kg]
granules) and corn without pesticide. This is possible because birds have well developed colour vision whilst small mammals (most of which are nocturnal) have an excellent sense of smell.

Bird behaviour in five-day food toxicity studies can sometimes give an indication of whether birds avoid corn with pesticide (dressed seed or granules) in a situation where there is reduced daily food intake and an increasing dose in relation to the control. Such behaviour may however be due to the fact that birds become "ill" and "loose their appetites". If the only source of food is corn with pesticides, which the birds will not eat, the birds may throw all the corn out of the feeding dish without eating anything.

In the assessment of the quality of the avoidance test, a factor to include is whether the bird has the possibility of seeing or tasting the difference between treated and non-treated seed so that it can learn to associate bad taste/stomach pain with the colour/shape/taste of the food source in question (OECD 2003a). In addition, it must be possible to document that the birds learn to associate the bad taste or nausea with the appearance of the food in question such that they subsequently avoid eating it.

The interpretation of the results must be carried out with care. Partly because it has been shown that substances that are avoided a lot in the avoidance test have been the cause of mortality in the field in cases where hungry birds have eaten dressed corn (ECOFRAM 1999). Furthermore, not all species react in a uniform manner, and the tests are typically based on one species. If the test species is selective ("fussy") or more willing to learn than other species (or hungry animals) that are exposed in the field, then the exposure in the field can be underestimated in calculations that are based on such a test. Finally it should be noted that tests in which birds have the choice between treated/untreated food are much more simple than the situation in the field where there is a lot of choice and the probability of learning is therefore lower.

Assessment of field studies of birds and mammals
Field studies of birds and mammals (higher-tier studies) are usually made available by enterprises when risk assessments at the initial tiers indicate an unacceptable risk for birds or mammals. The high risk can be due to high toxicity of the substance and/or a high dose.

There are no internationally recognised guidelines for field studies of birds and mammals. The study design is different from product to product in order to deal precisely with the (substance-specific) problem areas that have been identified. The quality of such studies varies and examples of factors that should be included in the assessment are given below.

In general, when interpreting information on the percentage of specific types of food in the diet of a species, the fact that this information is based on averages must be taken into account, as well as the fact that the real food intake can vary during the year.
Field studies of birds.
The following three types of field studies of birds are some of the most used:

- **Observation of exposed, naturally occurring foraging behaviour of birds and other behaviour in a period in the area after the application of a product, often in the form of dressed seed.**
  
  In order to be able to assess exposure during the study it is necessary to check whether an assessment of the population density of the birds being observed has been made, i.e. of how many birds could have been exposed to the test substance during the study period. It should also be considered whether the birds that are being observed are able to eat the dressed seed (e.g. larks cannot eat dressed maize; see example in Wolf (2005)). If at the same time there are plentiful food sources in the area that the birds prefer to e.g. the dressed corn (e.g. other seeds, earthworms or insects) then this can mean that the exposure cannot be considered to be a realistic worst case. The assessment should also note whether it has been documented that observed birds have eaten the dressed seed/the treated food, e.g. by examining the contents of captured birds’ gastro-intestinal tracts; see example in Uniroyal Chemicals (1990).

- **Collection of dead birds**
  
  In this case documentation of the relationship between exposure and the condition of the birds can be assessed on the basis of the results of post-mortem examinations performed on any dead birds that may have been collected, in which the intestinal contents are examined for both treated food and alternative sources of food. In addition, in cases where chemical analyses have been performed on bird tissue, the extent to which the methods used have been sufficiently sensitive to detect/measure relevant levels of concentrations should be assessed.

- **Field studies assisted by telemetry**
  
  In these studies small radio transmitters are attached to the birds so that their movements in an area can be followed without the need to observe the birds visually. In this way it is possible to calculate the percentage of time that the birds spend in the exposed area. However, this does not imply that the percentage of food collected by the birds in the area corresponds directly with their time spent in the area. Only if the birds spend nearly 100 per cent or 0 per cent of their time in the area can this time be considered a direct measure of exposure.

Field studies of small, wild mammals.
The "capture-recapture" method is often used for field studies of small mammals, whereby live animals are captured, tagged, released and possibly recaptured. This method is used to assess changes in population density/activity after the application of pesticide. Furthermore baited snap traps are used in cases where a post mortem examination is to be carried out on the animals in order to identify the contents of their gastro-intestinal tracts.

In order to assess exposure during the study and the quality of the study, the following can be considered:

Distance from edge of field to traps could be significant, for example because the long tailed field mouse does not have nests in newly sown fields, but only forages in them. Therefore the traps
should not be placed too close to the edge of a field, because the mice will not manage to forage in
the field before they are trapped.
Identification and reporting of the composition of gastro-intestinal contents provides useful knowl-
edge (e.g. Barber, Tarrant & Thompson 2003). However the timing of when the animals are trapped
plays a role and should be considered in the assessment. This is relevant both in relation to how
quickly after sowing the animals can be observed in the field (i.e. how high possible exposure can
be) and how many hours the animal has been trapped prior to examination of its stomach contents.
The stomach contents of a living mouse can be completely broken down after 12 hours in a trap and
can therefore not be used to document that the mouse has not eaten the dressed seed. Weather con-
ditions during the study also affect exposure, e.g. mice are least active during nights that are rainy,
cold or moonlit.
Annex 15

**Arthropods**

According to Directive 91/414/EEC, laboratory tests for two sensitive standard species, a parasitoid and a predatory mite (such as *Aphidius rhopalosiphi* and *Typhlodromus pyri*) are required. Two additional species must also be tested; these species must be relevant to the crop (with respect to the proposed use of the product). The latter should represent the two other major functional groups: terrestrial predators and predators that dwell on leaves. The following species are recommended by SETAC ("Guidance document on regulatory testing procedures for pesticides with non-target arthropods", 1994):

<table>
<thead>
<tr>
<th>Crop type</th>
<th>Parasitoid</th>
<th>Predatory mite</th>
<th>Terrestrial predator</th>
<th>Leaf-dwelling predator</th>
</tr>
</thead>
</table>
| Fruit farming (greenhouses and forests) | *Aphidius rhopalosiphi*  
*Trichogramma cacoeciae*  
*Leptomastix dactylopri*  
*Drino sp. (forests)* | *Typhlodromus pyri*  
*Amblyseius sp.* | *Pardosa sp.*  
*Poecilus cupreus* | *Orius sp*  
*Episyrphus balteatus*  
*Chrysoperla carnea*  
*Coccinella septempunctata* |
| Field crops | *Aphidius rhopalosiphi*  
*Trichogramma cacoeciae* | *Poecilus cupreus*  
*Pardosa sp.*  
*Aleochara bilineata (vegetables)* | *Episyrphus balteatus*  
*Chrysoperla carnea*  
*Coccinella septempunctata* |}

The initial laboratory studies are carried out on an artificial substrate (e.g. on glass plates or in quartz sand).

Additional studies, in the form of special laboratory tests, semi-field or field tests, should conform to SETAC guidelines ("Guidance document on regulatory testing procedures for pesticides with non-target arthropods", 1994).
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).

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

\(^1\) Values from FOCUS groundwater (2002).
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 \(\sqrt{\text{variance}}\)).

<table>
<thead>
<tr>
<th>Crop</th>
<th>Treatment</th>
<th>Leaf stage</th>
<th>Growth stage</th>
<th>Vegetation cover</th>
<th>Deposition</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Feekes</td>
<td>BBCH</td>
<td>%</td>
<td>% (of sprayed)¹</td>
</tr>
<tr>
<td>Peas</td>
<td>herbicide x 2</td>
<td>Newly germinated</td>
<td>2, 5-7</td>
<td>10-12, 11-75</td>
<td>5-15, 80-100</td>
</tr>
<tr>
<td></td>
<td>insecticide</td>
<td>¹</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Winter rape</td>
<td>herbicide</td>
<td>Before germination</td>
<td>0, 2, 3, 6</td>
<td>0, 13, 16, 60-69</td>
<td>0, 20-40, 90-100</td>
</tr>
<tr>
<td></td>
<td>Autumn herbicide</td>
<td>³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Spring herbicide</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Insecticide</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>³</td>
<td>2, 3, 6, 3, 3-4</td>
<td>13, 30-59, 60-69</td>
</tr>
<tr>
<td>Spring rape</td>
<td>herbicide</td>
<td>³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>insecticide</td>
<td>³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>insecticide</td>
<td>³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

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

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

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

* The value 10 is used for spraying on established grass.
Appendix 17

Abbreviations

ADI – Acceptable Daily Intake, i.e. the daily amount that can be ingested during a lifetime without risk of adverse effects on health.

AF - Assessment Factor, also called an uncertainty factor or safety factor.

AV - Avoidance Factor; if a bird completely avoids the treated food, then the AV= 0 and with no avoidance AV=1.

BBA - Biologische Bundesanstalt für Land- und Forstwirtschaft (The Federal Biological Research Centre for Agriculture and Forestry - a Federal Authority and Federal Research Centre affiliated to Germany's Federal Ministry of Food, Agriculture and Consumer Protection).

DJF - Formerly Danmarks JordbrugsForskning, now Det Jordbrugsvidenskabelige Fakultet (The Faculty of Agricultural Sciences)

DOC - Dissolved Organic Carbon

DT$_{50}$ - Time taken for 50 per cent of the substance to degrade/disappear.

DT$_{90}$ - Time taken for 90 per cent of the substance to degrade/disappear.

EC$_{50}$ - Effective Concentration 50 per cent; the concentration that causes 50 per cent effects in a dose-response test.

EPPO - European and Mediterranean Plant Protection Organization

ETE - Estimated Theoretical Exposure; either as mg/kg bodyweight or as daily dose in mg/kg bodyweight/day.

HARAP - Higher-Tier Aquatic Risk Assessment for Pesticides; international workshop 1998

JB - Jordbundsnummer (soil type number)

Kd - Distribution coefficient between soil and water

K$_{oc}$ - Soil organic carbon - water partitioning coefficient; Kd 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.

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)
<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>SETAC</td>
<td>The Society of Environmental Toxicology and Chemistry</td>
</tr>
<tr>
<td>TER</td>
<td>Toxicity-to-exposure ratio</td>
</tr>
<tr>
<td>TG</td>
<td>Test Guideline</td>
</tr>
<tr>
<td>TOC</td>
<td>Total Organic Carbon</td>
</tr>
<tr>
<td>TSW</td>
<td>Thousand-seed weight, weight of 1000 grains/seeds (g)</td>
</tr>
<tr>
<td>TWA</td>
<td>Time Weighted Average</td>
</tr>
<tr>
<td>US EPA</td>
<td>United States Environmental Protection Agency</td>
</tr>
</tbody>
</table>
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