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SCIENTIFIC OPINION

Scientific Opinion on outline proposals for assessment of exposure of organisms to substances in soil[1]

EFSA Panel of the Plant Protection Products and their Residues[2, 3]

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ABSTRACT

The European Food Safety Authority (EFSA) asked the Panel to prepare a revision of the Guidance Document on persistence in soil (SANCO/9188VI/1997 of 12 July 2000) as scientific knowledge in this field has evolved in recent years. Therefore the Panel started the development of a revised methodology for the assessment of exposure of soil organisms. Based on a previous opinion of the Panel, the methodology is developed both for the concentration in total soil and the concentration in the soil pore water. The aim of the exposure assessment is the spatial 90th percentile of the exposure concentration (maximum in time) in the intended area of use in each of the three regulatory zones. The assessment of this percentile will include the uncertainty of substance and soil properties. The exposure assessment methodology is a function of (i) the type of crop (annual, pasture, permanent or rice), (ii) the tillage system and (iii) the application technique of the plant protection product. Based on statistical data of EU agricultural practice, priority was given to developing a methodology for spray applications to annual crops under conventional or reduced tillage. The Panel considers a mixing depth of 20 cm appropriate for both conventional and reduced tillage in multi-year exposure calculations. The Panel proposes a tiered exposure assessment approach with four tiers. Tier 1 consists of a simple analytical model. Tier 2 consists of three scenarios (one for each of the three regulatory zones) that can be used for any annual crop in a zone. In Tiers 3 and 4, the exposure assessment can be refined considering the specific crops and/or substances with specific properties. The Panel proposes to develop guidance for estimating the degradation rate within the soil matrix from field persistence studies and for estimating wash-off from plants because the estimation procedures used for these degradation and wash-off processes may have a distinct effect on the exposure concentrations.

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KEY WORDS

Exposure assessment, soil, plant protection products, soil organisms, ecotoxic effects, tiered approaches, crop interception.

SUMMARY

The European Food Safety Authority (EFSA) asked the Panel to prepare a revision of the Guidance Document on persistence in soil (SANCO/9188VI/1997 of 12 July 2000) as scientific knowledge in this field has evolved in recent years. Therefore the Panel started the development of a revised methodology for the assessment of exposure of soil organisms. This exposure is needed as part of the effect assessment for soil organisms. To ensure an adequate link between exposure and effect assessment, the Panel had explored the ecotoxicologically relevant types of concentrations to be considered in a previous opinion. As a result, the methodology is developed both for the concentration in total soil and the concentration in the soil pore water.

Development of a scientific methodology for assessment of exposure of organisms to plant protection products and their transformation products in soil requires a detailed definition of the goal of the exposure assessment. This definition is a risk management decision to be taken by EU risk managers.

As a working hypothesis, the Panel suggests that the goal of the exposure assessment is defined as the maximum in time of the spatial 90th percentile PEC_{SOIL} resulting from the use of the plant protection product (assuming 100% market share of the product) and considering the population of agricultural fields (in each of the three regulatory zones) where the crop (or group of crops) is grown in which this plant protection product is applied.

With respect to time, the aim is to assess the all-time-high of the peak concentration or of time-weighted averages concentrations for time windows of 7 to 56 d. With respect to soil depth, the aim is to assess concentrations averaged over the top 1, 2.5, 5 and 20 cm.

The exposure of soil organisms in top soil may be strongly influenced by the type of crop (annual crops, pasture, other permanent crops, or rice); the soil-tillage system (e.g. conventional tillage, reduced tillage, no-tillage, ridge-furrow tillage), the crop management and the application technique (e.g. spray onto bare soil or onto a crop, seed treatment, row treatment). Therefore different exposure assessment methodologies are needed for different combinations of crops, tillage systems and application techniques.

Annual crops cover a larger surface area within the EU than pasture or other permanent crops. Conventional and reduced tillage systems are used much more frequently than other tillage systems in annual crops within the EU. Most plant protection products are applied in annual cropping systems via spray applications. Therefore the development of an exposure assessment methodology for spray applications in annual crops under conventional and reduced tillage has a higher priority than for other combinations of crops, tillage systems and application techniques.

For soils under conventional and reduced tillage, it is defensible to assume that the soil is perfectly mixed up to 20 cm depth periodically in long-term calculations of the concentrations of plant protection products in the top 20 cm of soil.

There may be considerable differences between the crop areas of different crops in each of the three regulatory zones. Therefore the selected scenario may be influenced by the area of intended use (usually a crop or a group of crops). As a consequence, this influence needs to be considered in the development of the exposure assessment methodology for soil organisms.

The proposed exposure-assessment methodology is based on the population of all agricultural fields within a regulatory zone grown with the crop or group of crops that are considered for the plant protection product within the EU registration procedure. So to develop the exposure assessment methodology, the list of possible annual crops for EU registration has to be defined. The Panel recommends that the Commission provides the list of crops to be considered for this purpose.

The Panel recommends basing the exposure-assessment methodology for spray applications in annual crops under conventional and reduced tillage on a tiered approach. Tier 1 is proposed to be based on a simple analytical model. Tier 2 is to be based on simulations with numerical models. To keep the approach as simple as possible, the Panel recommends having within Tier 1 and Tier 2, for each regulatory zone, only one scenario for concentration in total soil and only one scenario for concentration in pore water. These scenarios are used for all annual crops and for all plant protection products in each regulatory zone. Tier 3 is proposed to be again a simple analytical model but in this Tier specific crops and/or plant protection products with specific properties may be considered. Tier 4 is to be based on simulations with numerical models but, as in Tier 3, specific crops and/or plant protection products with specific properties can be considered.

The degradation rate of plant protection products within the soil matrix may play an important role in the exposure assessment of soil organisms. The dissipation rate of plant protection products in field persistence studies may be influenced by processes other than degradation when most of the product is still present in the top millimetres of soil (so in the initial phase of the experiment). Therefore guidance needs to be developed that ensures that the degradation rate coefficients derived from field persistence studies reflect the degradation rate within the soil matrix.

It is not defensible to ignore under all circumstances wash-off of plant protection products from plant surfaces in the exposure assessment of soil organisms. Therefore an approach needs to be developed for incorporating wash-off where necessary in the exposure assessment methodology for soil organisms.

The development of soil exposure scenarios in the proposed Tier 4 is hampered by limitations of existing soil databases at EU level. As a consequence a considerable amount of expert judgement is needed for selection of the soil profiles of the scenarios. Therefore, if a tier similar to Tier 4 would be used at MS-level, the Panel recommends that the notifier and regulators consult national experts.

The development of this exposure-assessment methodology has demonstrated the importance of high-quality databases of soils, crop areas and weather with 100% coverage of the EU-27. To make the guidance operational, the Panel recommends that the Commission ensures access to state-of-the-art databases of soils, crop areas and weather for all stakeholders. To ensure transparency, the Panel further recommends that the description of the structure of the databases and of the data sources is made available publicly.

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BACKGROUND AS PROVIDED BY EFSA

During the review process of the substances of the second list, several concerns were raised regarding the Guidance Document on persistence in soil. A number of Member states have expressed interest in a revision of the current Guidance Document on persistence in soil during the general consultation of Member States on Guidance Documents in answer to the request by the Director of Sciences of EFSA in a letter dated 3 July 2006 sent *via* the Standing Committee on the Food Chain and Animal Health. Furthermore, the EFSA PRAPeR Unit has noted that the Guidance Document needs to be brought in line with the FOCUS degradation kinetics report (SANCO/100058/2005, version 2.0, June 2006).

FOCUS (1997) developed the first guidance at EU level for exposure assessment in soil. This included a simple approach for estimating PEC_{SOIL} but FOCUS (1997) did not develop first-tier scenarios (in contrast to subsequent FOCUS workgroups that developed such scenarios for surface water and groundwater as development of soil scenarios was a lower priority at that time). FOCUS (2006) developed detailed guidance on estimating degradation rate parameters from laboratory and field studies, but did not develop exposure scenarios. Nevertheless there is a need for such scenarios in view of ongoing discussions in PRAPeR experts' groups regarding PEC_{SOIL} as current approaches at EU level just represent the range of climatic conditions covered by available field dissipation and/or accumulation studies and member states would like tools to be able to extrapolate to a wider range of climates present in the EU.

The existing Guidance Document on Persistence in Soil (9188/VI/97 rev 8) published in 2000 did not include scenarios. The intention with the new guidance document is to update the existing Guidance Document on Persistence in Soil to include European exposure scenarios for soil and to provide guidance on best practice for using the results of field experiments and soil accumulation studies in the exposure assessment.

The revision will not include guidance that is in the existing guidance document but has been replaced by newer guidance e.g. in FOCUS (2006). Some parts of the current guidance will not be considered in the revision e.g. for non-extractable residues as these sections are better dealt with separately. The revision will also exclude risk management guidance and hazard cut-offs e.g. PBT classification as this is not within the mandate given to EFSA.

Member States and stakeholders have been and will be consulted through web-conferences and stakeholder workshops to collect comments during the revision of the Guidance Document.

TERMS OF REFERENCE AS PROVIDED BY EFSA

The Scientific Panel on Plant Protection Products and their Residues (PPR Panel) of EFSA was asked in November 2007 by EFSA to prepare a revision of the Guidance Document on persistence in soil (SANCO/9188VI/1997 of 12 July 2000).

ASSESSMENT

1. Introduction

1.1. Background to development of the guidance

FOCUS (1997) developed the first guidance at the EU level for exposure assessment of plant protection products in soil. This included a simple approach for estimating PEC_{SOIL} (Predicted Environmental Concentration in soil) but it did not develop sophisticated first-tier scenarios for numerical models (in contrast to subsequent FOCUS workgroups which developed such scenarios for surface water and groundwater). FOCUS (2006) developed detailed guidance on estimating degradation rate parameters from laboratory and field studies, but also did not develop exposure scenarios. Nevertheless there is need at the EU level for such scenarios in view of ongoing discussions in PRAPeR experts' groups on PEC_{SOIL}. The existing Guidance Document on Persistence in Soil (9188/VI/97 rev 8) published in 2000 did not include scenarios. Therefore the Panel has started a revision of the existing Guidance Document on Persistence in Soil by developing tiered exposure-assessment approaches for soil organisms in which European exposure scenarios play an important role. This will include:

i. development of scenarios representing realistic worst-case conditions for the three regulatory zones North/ Centre/South (Figure 1), as included in Annex 1 of the new regulation concerning the placing of plant protection products on the market (Anonymous, 2009).
ii. definition of the role of results of field persistence and soil accumulation experiments in the tiered assessment approaches

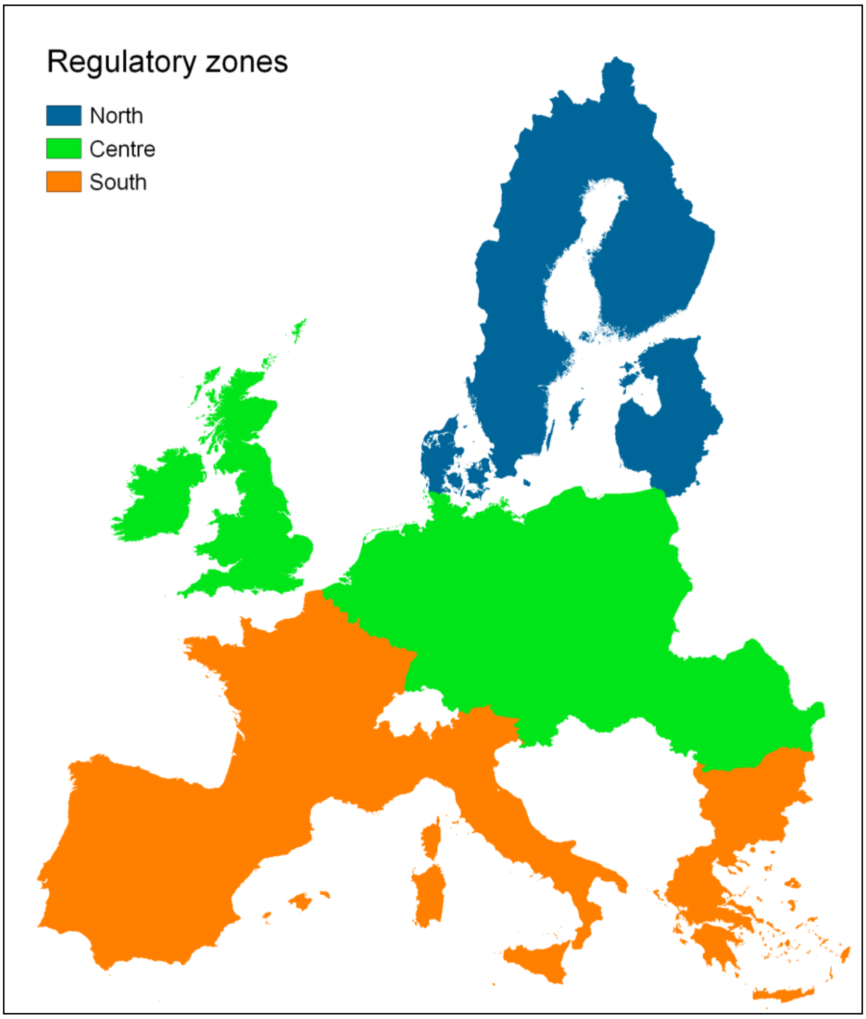

Figure 1. Map of the three regulatory zones used in the registration procedure of plant protection products in the EU.

1.2. General principles of tiered approaches

The Panel considers tiered approaches to be the basis of environmental risk- assessment schemes that support the registration of plant protection products. A tier is defined as a complete exposure or effect assessment resulting in an appropriate endpoint (in this case the PEC_{SOIL}). The concept of tiered approaches is to start with a simple conservative[4] assessment and to only do additional more complex work if necessary (so implying a cost-effective procedure both for notifiers and regulatory agencies).

The general principles of tiered exposure approaches are:

i. lower tiers are more conservative than higher tiers,
ii. higher tiers are more realistic than lower tiers,
iii. lower tiers usually require less effort than higher tiers
iv. in each tier all available relevant scientific information is used
v. all tiers aim to assess the same exposure goal.

[4] In the context of this opinion 'conservative' means 'on the safe side with respect to the risk assessment'.

In short, the tiered exposure assessment needs to be internally consistent and cost-effective and to address the problem with higher accuracy and precision when going from lower to higher tiers. These principles permit moving directly to higher tiers without performing the assessments for all lower tiers.

1.3. Interaction between effect and exposure assessment in the guidance development

The guidance aims to develop exposure assessment methodologies for soil organisms at EU-level. So the exposure assessment is considered to be part of the assessment of terrestrial effects. This assessment requires that the exposure assessment has to consider all kinds of concentration that are considered relevant for assessing these effects. These concentrations are called Ecotoxicologically Relevant types of Concentration, (ERC) and they are determined by the protection goal (see EFSA, 2009). So the risk assessment requires two parallel tiered flow charts, one for the effect assessment and one for the exposure in the field (Figure 2). Only horizontal arrows from F-boxes to E-boxes are shown in Figure 2 to avoid the figure becoming too complicated (the risk-assessment procedure should allow in principle for arrows from all F-boxes to all E-boxes).

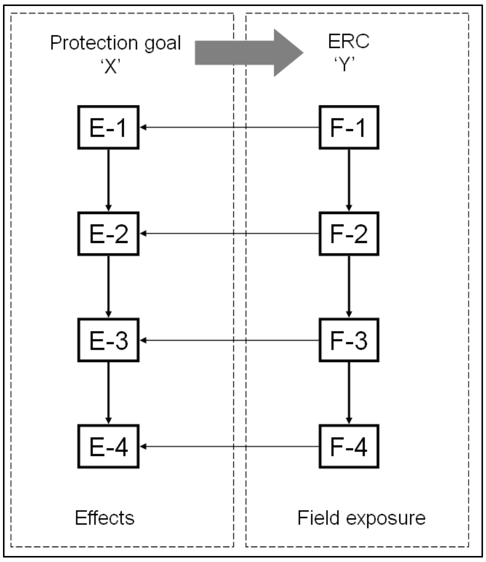

Figure 2. Tiered effect and field-exposure flow charts for a risk assessment addressing a protection goal 'X' which needs field-exposure estimates of an ecotoxicologically relevant concentration (ERC) 'Y' as indicated by the large arrow (taken from Boesten *et al*., 2007). The boxes E-1 to E-4 are four effect tiers and the boxes F-1 to F-4 are four field-exposure tiers ('F' from 'field'). Downward arrows indicate movement to a higher tier. Horizontal arrows from the field-exposure to the effect flow chart indicate delivery of field-exposure estimates for comparison with effect concentrations in the effect flow chart.

An example is given of an arbitrary combination of an effect and a field-exposure tier (Figure 3). The standard procedure in ecotoxicological experiments is to use a range of concentrations to derive a concentration–response relationship. Assessment endpoints within effect tiers have to be expressed in terms of the same type of ERC as the endpoints of the field-exposure tiers. For instance, if the type of ERC was defined as the concentration in the soil pore water then this has to be used in the risk

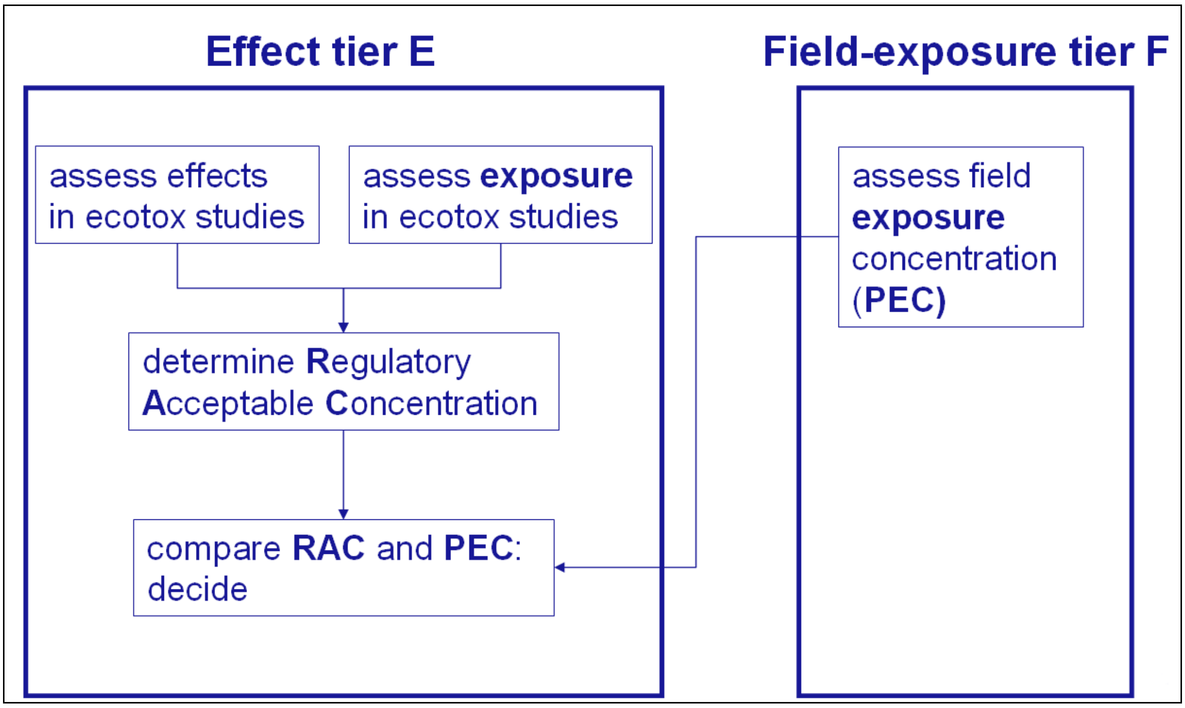

Figure 3. Schematic representation of the two types of exposure assessments which are needed in any combination of tiers of the effect and field-exposure flow charts (taken from Boesten *et al*., 2007).

assessment both for evaluating the results of the ecotoxicological experiment and for estimating the exposure in the field. This implies that there are two equally important types of exposure assessments required for the risk assessment procedure. The first assessment (in the field-exposure box in Figure 3) involves estimating the exposure (in terms of a certain type of ERC) that will occur in the field resulting from the use of the plant protection product in agriculture. This is part of the field-exposure flow chart (Figure 2) and is often referred to as PEC, Predicted Environmental Concentration (we use 'PEC' because this is the most common term but this does not exclude use of measured field concentrations in higher exposure tiers if these measured concentrations are more appropriate). The second exposure assessment (in the effect box in Figure 3) is a characterisation of the exposure (defined in terms of the same type of ERC) to which the organisms were exposed in all ecotoxicological experiments. This second exposure assessment is part of all tiers in the effect flow chart. Both exposure assessments and their interaction with the ecotoxicological activities (Figure 3) require that fate experts and ecotoxicological experts have to co-operate closely for the exposure assessment in the ecotoxicological experiments.

1.4. Targets of the exposure assessment

Currently the protection goal of the assessment effect is to protect the organisms in the field that are important for maintaining soil functions (including fertility).

The development of the FOCUS groundwater scenarios was based on 90^{th} percentile PEC_{GW} values within agricultural areas using the plant protection product in each of nine different climatic zones across the EU (FOCUS, 2000). Based on this, nine groundwater scenarios were developed with each of these being intended to deliver the 90^{th} percentile PEC_{GW} for one of the climatic zones. The development of the FOCUS surface-water scenarios was based on similar considerations but not on a fixed overall percentile of the population of concentrations to be expected (FOCUS, 2001). The Panel checked with risk managers at Member State level (via the consultation of the project plan) whether a 90^{th} percentile exposure concentration should be used here and their response confirmed this.

In their reaction to the project plan, several EU Member States indicated that the exposure assessment procedure should be kept as simple as possible. If scenarios were to be developed for nine different climatic zones (as in the mentioned FOCUS groundwater scenarios), this would lead to a complicated procedure. Therefore the Panel proposes to develop guidance for estimating 90^{th} percentile values of PEC_{SOIL} only for each of the three regulatory zones North/ Centre/South (Figure 1).

The Panel proposes to base the PEC_{SOIL} on the spatial 90^{th} percentile using the all-time high concentration considering time series of application of at least 20 years. This 90^{th} percentile PEC_{SOIL} within each of the three zones has to be based on a distribution of individual PEC_{SOIL} values.
Each of these individual PEC_{SOIL} values is intended to be an estimate of the average value at the scale of individual agricultural fields to which the plant protection product is applied. The assessment procedure will not account for the random spatial variability within an individual field because the Panel considers this level of detail currently not sufficiently relevant for the risk-assessment schemes regarding ecotoxic effects. The assessment procedure will account for systematic spatial variability (eg application of herbicides in orchards in strips below the trees and seed treatments).

Another aspect of the definition of the 90^{th} percentile PEC_{SOIL} is the population of agricultural fields on which the percentile is based. The Panel suggests as a working hypothesis that the definition is based on the population of the intended area of use in a regulatory zone. For example, for a plant protection product that is applied to potatoes, the population of fields is then defined as the fields on which potatoes are grown in a zone.

So the Panel suggests as a working hypothesis that the goal of the exposure assessment is defined as the maximum in time of the spatial 90^{th} percentile PEC_{SOIL} resulting from the use of the plant protection product and considering the population of agricultural fields (in one of the three regulatory zones) where the crop (or group of crops) is grown to which this plant protection product is applied. This goal is further called goal ‘A’ (Figure 4).

An alternative (called goal ‘B’; see Figure 4) would be to define, for any annual[5] crop, the population as all fields within the total area of annual crops in a zone. However, then the fraction of the area on which a crop is grown needs to be considered in the calculation of the 90^{th} percentile. For example, if the plant protection product is used in a crop that grows only on 7% of all fields, then 93% of the fields have zero concentrations by definition, so the 90th percentile concentration is zero. This goal has the consequence that the risk to soil organisms would be considered absent for all plant protection products applied in crops that grow on less than 10% of the area of annual crops in a regulatory zone. This seems difficult to defend on the basis of the Uniform Principles.

Another alternative (called goal ‘C’; see Figure 4) would be to define the population as all fields within the total area of annual crops in a zone but with the additional specification that the exposure assessment has to be based on the hypothetical assumption that the plant protection product is applied to all fields. This is likely to be a confusing option for risk managers because this is a completely hypothetical population. Eg the 90^{th} percentile for potatoes will then be determined considering also soils on which potatoes cannot grow. So this option has the disadvantage that it is not based on the reality. The consequence of selecting such an option would be that it is difficult to define higher tiers because higher tiers are usually based on the principle that they are closer to reality than lower tiers.

[5] Note that here annual crops are considered as an example. The same reasoning applies to eg permant crops.

The last alternative considered here (called goal 'D'; see Figure 4) is to zoom in on e.g. the three areas with the highest density of the crop in a regulatory zone and to consider in each of these areas the population of all fields in the total area of annual crops. This is a modification of option B: the difference is that B considers the scale of the regulatory zone whereas D considers the scale of areas with high crop density (size typically 1000 km^2). The consequence is that for option D the 90th percentile concentration may be strongly influenced by the fraction of the area of annual crops on which a crop is grown. For example, a minor crop like Brussels sprouts, even in the 1000-km^2 area with the highest Brussels-sprouts density within the EU, may be grown on less than 10% of the area of all annual crops. This would lead to a 90th percentile concentration of zero, thus eliminating the need of any terrestrial effect assessment for Brussels sprouts. So the exposure assessment in option D gives a lower 90th percentile concentration for minor crops than for major crops. So option D might be attractive to risk managers wishing for lower protection levels for minor crops than for major crops.

In option A, the fraction of the area of annual crops on which a crop is grown in a regulatory zone has no influence on the 90th percentile because the area on which a crop is grown is defined as the population to be considered (Figure 4). So for minor crops, option A may result in 90th percentile concentrations that are much higher than those of option D. However, for major crops the opposite may be true if the areas with the highest crop densities have climatic and soil properties that lead to higher exposure concentrations than most of the surface area where this crop is grown within the EU.

This option D has some similarity to the landscape-level exposure assessment approach for exposure of aquatic organisms described by FOCUS (2007). This can be illustrated with the case described in Appendix A4 of FOCUS (2007). The case considers the risk to aquatic organisms resulting from use of a plant protection product in citrus orchards. In the case in FOCUS, Step 1, 2 and 3 exposure calculations showed unacceptable risks so a FOCUS Step 4 approach was needed. This Step 4 approach was based on selection of an area of 2600 km^2 around Valencia because this is one of the areas with the highest density of citrus orchards in the EU (FOCUS, 2007). Probability density functions of PEC values resulting from spray drift were estimated for all 3719 water bodies in this 2600-km^2 area showing that over 50% of the water bodies in the area had no drift loadings. The similarity is that both in this example case of FOCUS (2007) and in option D it is considered acceptable to consider a population of which a large part is not exposed at all because the plant protection product is not used in the neighbourhood of these elements of the population. In spite of this similarity, the Panel considers option D difficult to defend for soil organisms because most populations of soil organisms in different agricultural fields show less mobility than aquatic organisms..

A further risk management aspect of the goal is the definition of the market share of the plant protection product. This is defined as the fraction of surface area of a crop area where the plant protection product is used against a certain pest (e.g. for the same pest there may be three different plant protection products each with a market share of 33%). The market share can be prescribed to be 100% or the actual market share may be considered. This is a further choice for options A, B and D but for option C only the market share of 100% seems a consistent choice. The market share may become relevant e.g. if post-registration monitoring is included as a higher tier (and also for other exposure goals such as exposure of surface waters at large distance of treated fields). Some MSs have collected statistical data on market shares (see footnote on p. 29 of EFSA, 2008).

The guidance proposal in this opinion is based on goal A in combination with a market share of 100%. This goal is a working hypothesis that has to be agreed by the EU risk managers. A tiered risk assessment approach is in principle uniquely linked to a certain goal. So it is not appropriate to develop a tiered approach for goal A and e.g. then later add a highest tier based on goal D. So if the EU risk managers were to decide on another specification of the goal, the Panel would need to modify this guidance proposal.

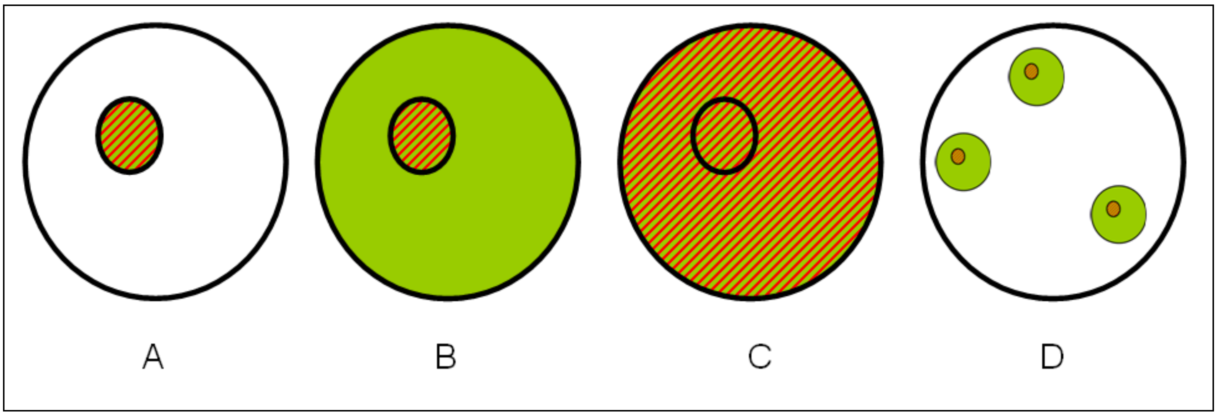

Figure 4. Schematic representation of options A, B, C and D for the goal of the exposure assessment. Each large circle represents the population of fields of all annual crops in one of the three regulatory zones. For A, B, and C each small circle represents the population of fields grown with the crop X considered in the exposure assessment. For D the three green circles indicate areas of high crop density of a size of about 1000 km^2. Green indicates that the area belongs to the population of fields considered in the exposure assessment. The red lines indicate that the plant protection product is applied in the area.

Based on EFSA (2009), tiered exposure-assessment approaches will be developed for the following types of ERC:

1) the concentration in total soil (adsorbed plus dissolved) expressed as mass of pesticide per mass of dry soil (mg/kg) averaged over the top 1, 2.5, 5 or 20 cm of soil for various time windows: peak and time-weighted averages (TWA) for 7, 14, 21, 28 and 56 d
2) pore-water concentration (mg/L) averaged over the top 1, 2.5, 5 or 20 cm of soil for the same time windows

As described above, the maximum value in time (resulting from multiyear applications) will be the target for all types of concentration.

The guidance will be limited to exposure assessment for the assessment of terrestrial effects within the treated field (therefore off-crop exposure assessment will not be provided). It will also not include guidance for assessment of persistence triggers or for PBT (Persistence Bioaccumulation Toxicity) classification.

Release of substance from soil-bound residues will not be included in the exposure assessment because this would require a review of available information thereon and the estimation of release rate coefficients of soil-bound residues. This is considered impossible within the given time frame. Moreover the Panel expects (based on expert judgment) that this would have only small effects on the estimated exposure concentrations in total soil and in pore water.

1.5. Effect of crop management, soil tillage and application technique on the exposure assessment methodology

The exposure assessment for annual crops differs from that for permanent crops because the soil systems of these crops differ; e.g. permanent crops will often have a litter layer whereas this is usually not the case for annual crops. Moreover EFSA (2009) indicated that different types of crop need different types of ERC (see Figures 4 and 5 of EFSA, 2009). The exposure assessment for tillage systems with annual ploughing differs from that for no-tillage systems because the ploughing may have a large ‘diluting’ effect on the concentrations in the top centimetres. The exposure assessment depends also on the application technique of the plant protection product: for instance a seed treatment will lead to high exposure concentrations around the seeds and low concentrations in most of the surrounding soil whereas spraying onto soil will lead to concentrations that are more or less uniform in horizontal direction in soil. Therefore different exposure assessment methodologies are needed for different combinations of crops, tillage systems and application techniques.

1.6. Bird’s eye view of following chapters of the opinion

Chapter 2 gives an overview of the characteristics of soil tillage, crop management and application techniques within EU agriculture and horticulture leading to the selection of the combination of application technique and agricultural system with the highest priority for developing an exposure assessment procedure. Chapter 3 describes the proposed tiered approach for exposure assessment for this selected combination. Chapter 4 gives an outlook on future activities and Chapter 5 describes the usefulness of the proposed approach for Member State level.

2. Overview of characteristics of soil tillage, crop management and application techniques within EU agriculture and horticulture

2.1. Background: conventional versus conservation tillage practices

Most of the tillage literature classifies soil-cultivation systems according to their impact on placement and distribution of previous crop residues in soil and by the different operations of the soil tillage. Although in literature a number of different classifications are found, (see for example the classification reported in Table 1 by the Conservation Tillage Information Centre) most of them distinguish two categories denominated conventional and conservation tillage (El Titi, 2003; Baker & Saxton, 2007; McKyes, 1985; Schjønning, 2004).

Table 1: Systems of soil tillage and effect on crop residues cover on the soil surface (CTIC, 2006).

Soil tillage	Soil surface covered by crop residues (%)	Main implementation
Conventional tillage	< 15 (0-10)	Mouldboard plough Disc plough Spading machine
Conservation tillage:		
- Mulch tillage	> 30 (30-50)	Disc harrow
- Disc-drilling		Chisel plough, harrow
- Drillage	> 50	Seeding drill
- No-tillage	> 50	Seeding drill
- Ridge tillage	> 50	Ridger
- Sod-seeding	> 30 (40-60)	Seeding drill
- Stable seeding	> 30	Seeding drill
- Strip tillage	> 50	Seeding drill
- Sub-soiling	> 30 (40-60)	Strip-till
-Chemical	> 30 (30-60)	Sub-soil, deep ripper, Paratill
Fallow/ploughing	> 10 (depending on weed residue)	Boom/manual sprayer

Conventional tillage, also called intensive tillage, comprises all tillage types that leave less than 15% of crop residue on the soil surface after planting the next crop or before the preparation of the soil seed bed. Generally this technique requires ploughing to 30-40 cm depth or intensive tillage, followed by secondary tillage.

Conservation tillage is any tillage, including cultivation and planting system, that leaves 30% or more of the soil surface covered with crop residues after planting. From the literature search, it appears clear that this category will thus include different techniques, different till depths and agricultural tools although no-tillage is the most well known technique (Figure 5). The most common conservation tillage practices used in Europe can be described as reported below:

(a) No-tillage. The soil is left undisturbed from harvest to planting with the exception of nutrient/sludge injection. The planting or seeding is accomplished in a narrow seedbed or slot created by coulters, row cleaners or disc openers. To increase soil aeration, periodic deep ripping (40-60 cm depth) is required. Crop residues accumulate on the soil (> 50 % cover).

(b) Ridge tillage. The soil is left undisturbed from harvest to planting, which takes place on ridges prepared with sweeps, disc openers, coulters or row cleaners. Residues are left on the soil surface between the ridges (> 30% cover).

(c) Mulch-tillage. The soil is disturbed prior to planting with tools such as chisels, field cultivators, discs, sweeps or blades (> 30% cover).

(d) Strip-tillage or zone tillage. These are considered modifications of the above techniques. Conventional surveys consider this technique to be no-tillage if less than 25 % of the row width is disturbed; more than 25 % is considered to be mulch tillage (> 30% cover).

(e) Reduced tillage and minimum tillage. Any tillage type that leaves 15-30 % cover after planting. For this reason, these terms usually comprise all the conservation tillage with the exclusion of the no-tillage.

(f) Sod-seeding. Refers to the specific no-tillage practice of re-seeding existing pasture swards.

Because we cannot include so many different types of tillage (characterised by high variability in use across Europe) in the assessment scheme, for the purpose of this opinion we consider conservation tillage to be based on the two main tillage sub-categories, viz no-tillage and reduced tillage.

2.1.1. Influence of soil-tillage practices on pesticide exposure

Reduced tillage leads to significant and complex changes in the physical, chemical and biological properties of soil, most often interrelated with each other, thus affecting the fate of the applied pesticides. Understanding the effects of tillage on pesticide fate in soils implies a comprehensive evaluation of all the interactions between the different dissipation processes and of all the different soil factors affected by tillage operations. Some of these interactions are now well known, but most of them are still poorly understood. Conservation tillage increases soil organic C and N concentrations compared with conventional tillage by decreasing oxidation of organic matter and aggregate degradation. Placement of plant residues at the soil surface reduces its contact with soil microorganisms for decomposition, thereby increasing the concentrations of organic C (an average 15 – 35 % increase after three years of practice, depending on the situation), thereby resulting in amelioration of the soil structure. However when the conventional type of tillage management is then performed, as usually occurs, this amelioration is lost quickly.

Locke and Bryson (1997) and recently Alletto *et al*. (2009) reviewed the literature data and found that effects of the tillage on most dissipation processes such as retention, degradation and transfer are highly variable and sometimes contradictory. This variability is partially explained by the multiplicity of processes and contributory factors, by the variety of their interactions, and by their complex temporal and spatial dynamics. The “mulch effect” may increase retention of pesticides in the topsoil layer under conservation tillage due to the crop residue left on the soil surface and it may decrease the availability of the pesticides for biological degradation. This competition between retention and degradation leads to a higher persistence of pesticides in the soil system mainly due to the pesticide residues in the mulch, though this persistence can be partially compensated for by more intensive microbial activity under conservation tillage.

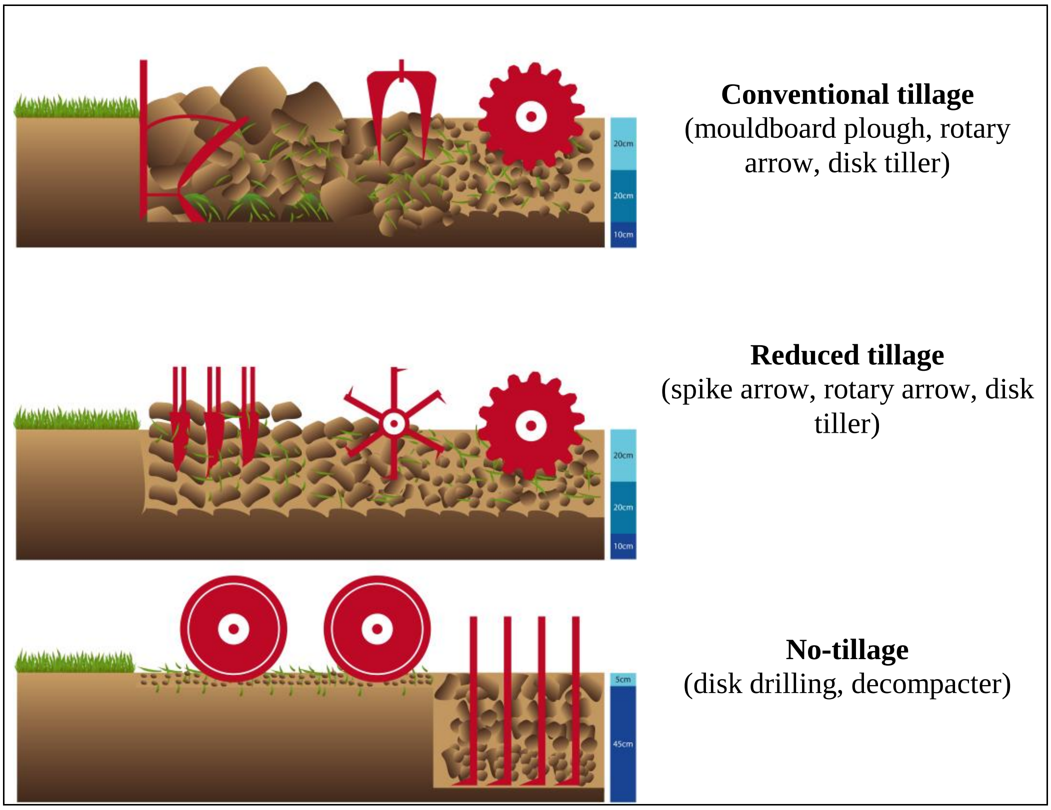

Figure 5. Schematic description of soil tillage, depth of tilling and agricultural tools used for the seed bed preparation of annual crops under long-term management.

Based on these findings, we can conclude that more knowledge is needed to fully understand the temporal and spatial dynamics of pesticides in soil in order to improve the assessment of pesticide risks. As long as this knowledge is not available, the exposure assessment under the different tillage practices has to be based on conservative assumptions.

On the other hand, the accumulation of crop residues on the soil surface could influence the pesticide fate by acting as a 'slow release formulation' of the pesticide thus reducing peak concentrations in soil water.

2.1.2. Agricultural practices across Europe

The question is how and to what extent the different soil tillage systems are used in Europe, and if these follow a geographical pattern. There is not a single official dataset at European level. Furthermore, the absence of a common classification standard produce different outputs in all the surveys carried out. Only two reliable major data sources were found that deliver recent information on tillage practices adopted in Europe and on the extent of the conservation practices:

- the Kassa-Project on Sustainable Agriculture - EU & CIRAD (Lahmar et al., 2007), a European project funded by EU DG research which monitored the Northern EU Member States , and
- the European Conservation Agriculture Federation (2007), the main association on conservation agriculture in Europe.

The extent of reduced tillage ranges from between 4 to 40 % in individual European countries. No-till is used very rarely in Europe (< 0.1 to 3.5 % of the agricultural area in temperate Northern and Eastern Europe, with virtually none in Southern Europe). According to the European Conservation Agriculture Federation (2007), 15% of European agricultural land has reduced tillage which includes crops such as orchards, olives and vineyards.

Table 2 : Proportion (%) of arable land under conservation tillage (which includes no-tillage) and no-tillage in some Member States. ECAF and KASSA used different standard in the survey.

Country	ECAF		KASSA project	
	Conservation tillage	**No-Tillage**	**Conservation tillage**	**No-Tillage**
Belgium	17.2	0		
Denmark	10.1	0	6.8	0
Finland	52.3	6.8		
France	21.0	0.8	4.6	0.2
Germany	21.2	1.7	20	3.0
Greece	15.8	7.4		
Hungary	10.8	0.2		
Ireland	2.5	0		
Italy	76.8	1.0		
Portugal	21.1	4.0		
Slovakia	12.6	2.6		
Spain	18.0	4.4		
United Kingdom	45.6	3.1	7.7	0.1
Norway			15	0.6
Estonia			16	1.0
Czech Republic			18	3.5
Ukraine			24	0.1

At Member State level, some official data have been assessed. In France, for example, the French Ministry of Agriculture (Agreste, 2006) confirms a variable distribution of the practices across the different regions with a very low incidence of no-tillage practices such as direct sowing and much more (7 to 48 %) reduced-tillage operations comprised of differing techniques. For the main arable crops in France (sugar beet, wheat, rape, maize, barley, potato, sunflower), ploughing was the main tillage practice (Figure 6) for all crops in 2006 (from 53 to 95 % by area) but had slightly decreased since 2001: no-till agriculture (direct sowing) and reduced tillage are most important for wheat, rape and barley.

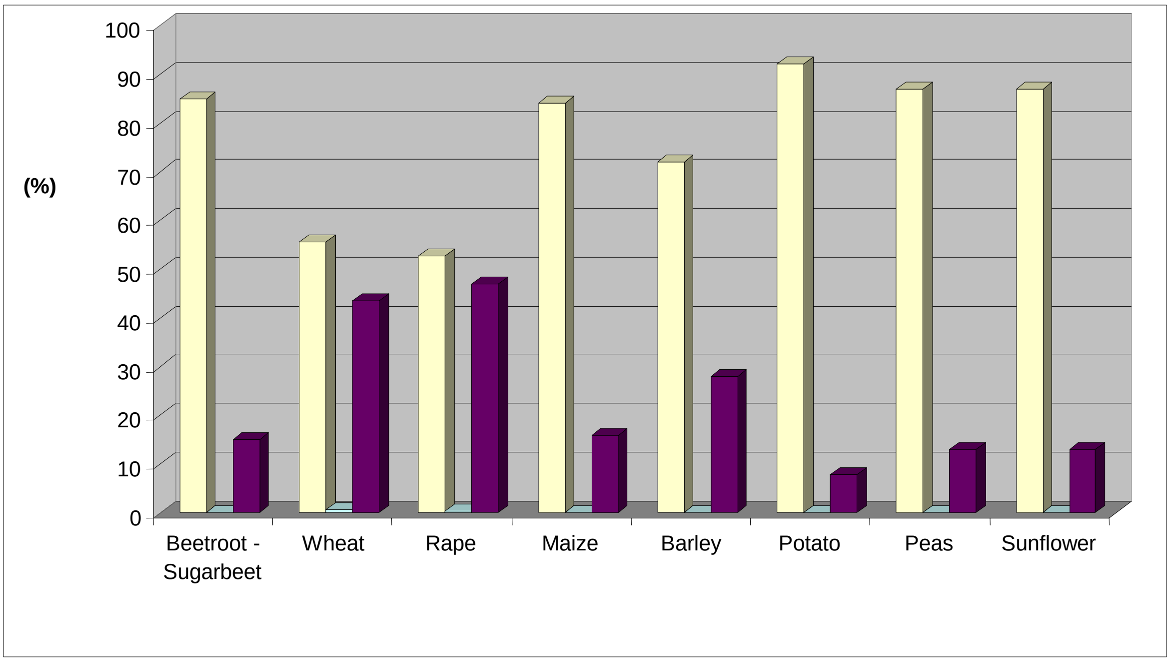

Figure 6. Importance as percentage of the arable land of conventional tillage (white), no-tillage practice such as direct sowing (blue) and reduced tillage (violet) in France (Agreste, 2006).

A similar distribution of reduced tillage has been observed in Germany, where reduced tillage operations are almost non-existent in the South and mostly occur in the East (Kassa project: Lahmar et al., 2007). Mostly there is a general correlation between average farm size and adoption of reduced and no-tillage (small size favours use of conventional rather than reduced or no-tillage). Everywhere in Europe the difference in the adoption of these practices across the climatic zones is also due to differences in water availability and tradition. In regions with sufficient or excess rainfall, no-tillage or reduced tillage in vineyards and orchards may be established to support the transport of excess rainfall that could contribute to also improving the food quality. In regions where natural rainfall is a limiting factor for crop production, the top soil layer will be cultivated in order to reduce the evaporation of water from soil (water conservation).

2.1.3. Handling of effects of soil tillage in the exposure assessment

Regarding pesticide persistence, two main factors are influenced when conventional or reduced tillage or no-tillage is adopted in the farm management: the crop residues and the tillage depth. Different tillage systems produce different amounts of crop residues in space and time, increasing from conventional to conservation tillage, and such field coverage could intercept a discrete amount of pesticide before it reaches the soil. Also, the degradation rate of pesticides in soil may decrease in soils covered with plant litter compared to that in bare soil (Doublet et al., 2009). In addition, different tillage could mix soil layers from different depths leading to differences in the 'dilution' of concentrations of plant protection products.

The Panel carried out the parameterisation based on the available experimental data, the scientific evidence and the good agricultural practices. The Panel decided pragmatically not to consider interception by the crop residue materials, and instead followed a conservative approach.

The decision taken for the tillage depth was more problematic, due to the large variation in the conservation-tillage methods used in Europe. A representative depth at European level was then set for a specific soil-mixing depth per category of soil tillage, 5 cm and 20 cm for no-tillage and reduced/conventional tillage respectively. These assumptions are supported by the more general information in the most recent survey carried out in Europe in the framework of the European Project SOCO (JRC, 2009).

When considering practises in the time frame used for assessing accumulation of more persistent substances, it was concluded that mixing depths of 5 cm for no-tillage and of 20 cm for reduced tillage are conservative enough. Minimum tillage practises are not continued indefinitely for annual crops (Conant et al, 2007). These depths are representative of the mixing depth of the most suitable soils for conservation tillage such as the light soils, the most important crop suitable for conservation tillage management across Europe. These values are considered as a realistic average which is representative of most European soil/crop conditions. Specific pedo-climatic conditions and specific crops could allow a shallower mixing depths but this should be considered on a case by case basis for assessment at regional level.

2.2. Cropping system

To cover as much as possible the characteristics of European agriculture, the Panel considered the main factors of the cropping systems for the development of the soil persistence scenarios to be crop type, crop management, water management and pesticide treatment.

2.2.1. Crop type and management

The crops grown across Europe (the EU-27) vary according to land type and climate (Figure 7). For the remit of this opinion the first distinction to be made is the crop type: we can distinguish annual and perennial crops. Arable crops are annuals planted at any time of year and harvested within a few months (e.g. cereals, vegetable, potato, tomato). Perennial crops, also called permanent crop, remain for several seasons, from 2-4 years for perennial pasture (i.e. grass and alfalfa) to 5-15 years (orchards, hops, citrus, olives and vines).

Perennial crops such as olives, citrus and vines are typically maintained with a cover crop between the rows (although the areas underneath the plants are kept clear to avoid competition for water and nutrients). Cover crops are classified by their temporal occurrence:

- annual, with cropping during winter or summer lasting up to one year. Winter crops are planted during the autumn to provide soil cover during the winter: these are usually legumes, vetches and alfalfa, which are then tilled in spring for nitrogen enrichment. Summer cover is typically grass;
- perennial, which last for at least three years, are common for most of the perennial crops. The cover is usually a grass mix which, after the first year, becomes dominated by the local weed population.

2.2.2. Water management

Annual crops may be heavily irrigated by sprinkler, furrow and flooding irrigation. Perennial crops, such as olives, citrus, vines, and industrial and horticultural crops, such as tomato and melons, are typically irrigated by drip systems running along the rows (soil surface or shallow subsoil). For scenario development, we can categorize the different irrigation operations as either overall irrigation or localized such as drip and strip irrigation.

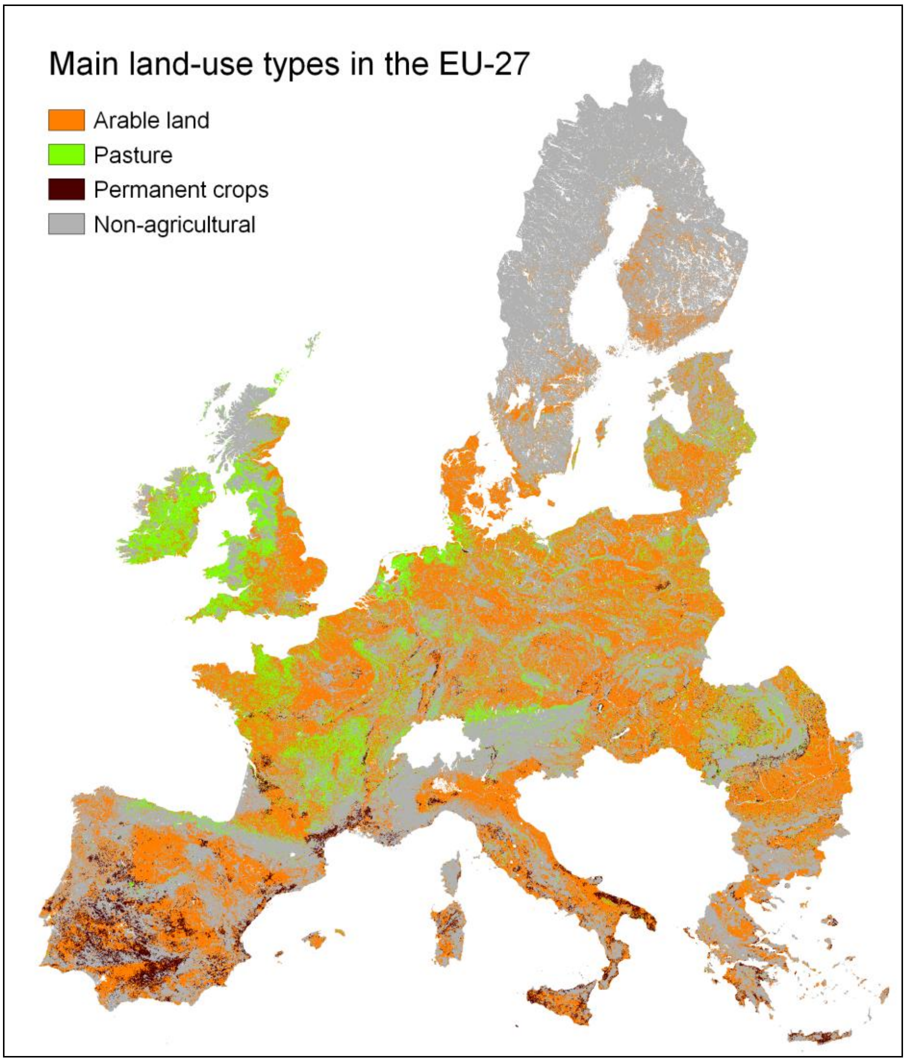

Figure 7. Dominant land-use types at the scale of 1 km^2 in the EU-27.

2.2.3. Pesticide management

Fungicides and insecticides are usually sprayed directly onto the plants. However there may be spray drift deposition onto soil between the crop rows (where applicable) as well as deposition beneath the plants depending on the growth stage of the crop. Herbicides in arable crops may be sprayed onto the soil surface (pre-emergence) or directly onto the plant (post-emergence of the weeds). In perennial crops (e.g. orchards and vines), herbicide may be applied directly underneath the plants.

In any of the above situations, the plant canopy may play an important role by intercepting the pesticide spray, resulting in differing amounts of pesticide drift and plant deposition with possible subsequent wash off to the soil surface. This factor must be taken into consideration in the parameterisation of the scenarios.

Seeds and tubers may be treated with insecticide or fungicide prior to planting, or granular formulations may be applied as a row or banded treatment into the open furrow during planting (e.g. potatoes).

2.3. Selection of the combination of application and agricultural system with the highest priority

As described in the introduction, the Panel considers that the exposure assessment for the PEC_{SOIL} may depend strongly on (i) the type of crop (annual crops, pasture, other permanent crops or rice), (ii) the tillage system, and (iii) the application technique of the plant protection product. The different crops types are more or less spatially separated (Figure 7) and will utilise varying tillage systems and pesticide-application techniques. Many combinations of tillage systems and application techniques occur for annual crops in EU agriculture (see Figure 8). For permanent crops there are probably also many possible combinations.

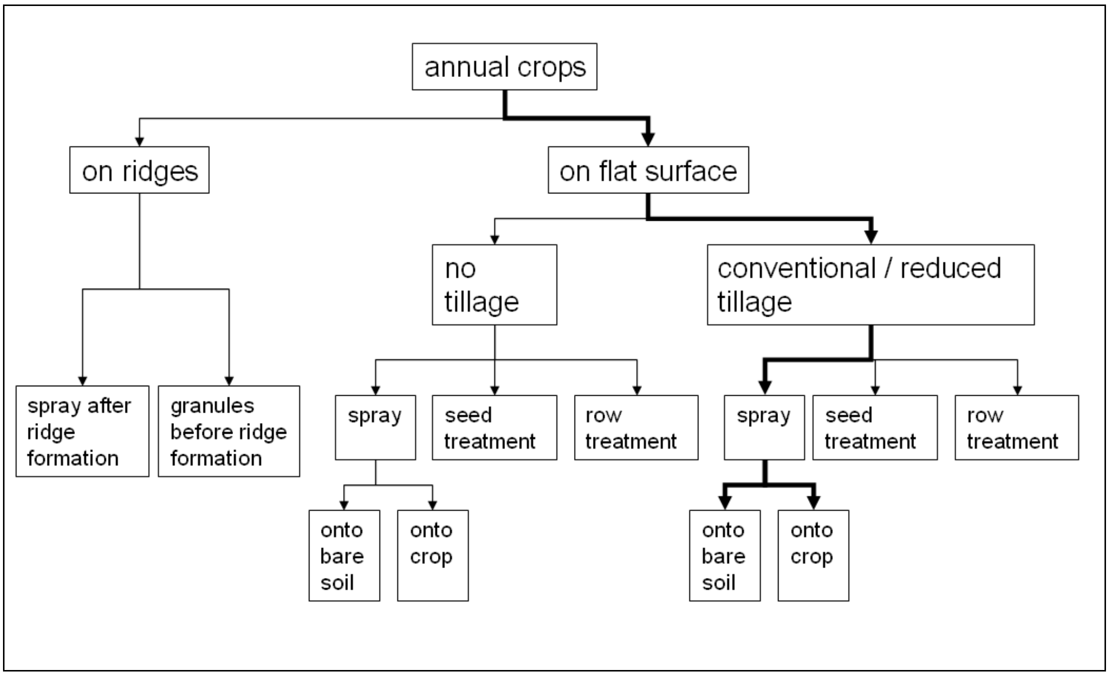

Figure 8. Overview of tillage systems and application techniques for annual crops. The bold lines indicate the selected combinations for the development of the exposure assessment methodology. The box 'on flat surface' indicates that the tillage does not lead to ridges and furrows.

In principle, different exposure-assessment methodologies have to be developed for each combination of crop type, tillage system and application technique. Therefore the Panel proposes to phase this guidance development as follows: firstly guidance will be developed for the combination of annual crops, conventional or reduced tillage and spray applications. This is the most important combination of application of plant protection products within EU agriculture and horticulture as it comprises the largest surface area and most usage of plant protection products. As described before, the Panel considers it defensible to assume within the exposure assessment methodology that this combination is mixed up to 20 cm depth.

The soil-tillage and crop-management techniques for rice differ of course strongly from those for the other arable crops and so rice is not further considered in this Opinion.

3. Tiered approach for spray applications in annual crops with reduced or conventional tillage

3.1. Overview of the tiered assessment scheme

As described in Section 1.4, the purpose of the exposure assessment is the spatial 90th percentile concentration resulting from the use of the plant protection product (assuming market share of 100%) and considering the population of agricultural fields (in one of the three regulatory zones) where the crop (further called 'crop X') is grown in which this plant protection product is applied. To achieve this goal, the Panel proposes a tiered assessment scheme (Figure 9) both for the assessment of the concentration in the pore water and for the concentration in total soil. The schemes for the two types of ERCs (the concentration in total soil and the concentration in pore water) are identical but the contents of the tiers differ so there are two parallel tiered assessment schemes. The tiered scheme applies to spray applications to annual crops under conventional or reduced tillage but may also be useful for other types of application or other tillage systems.

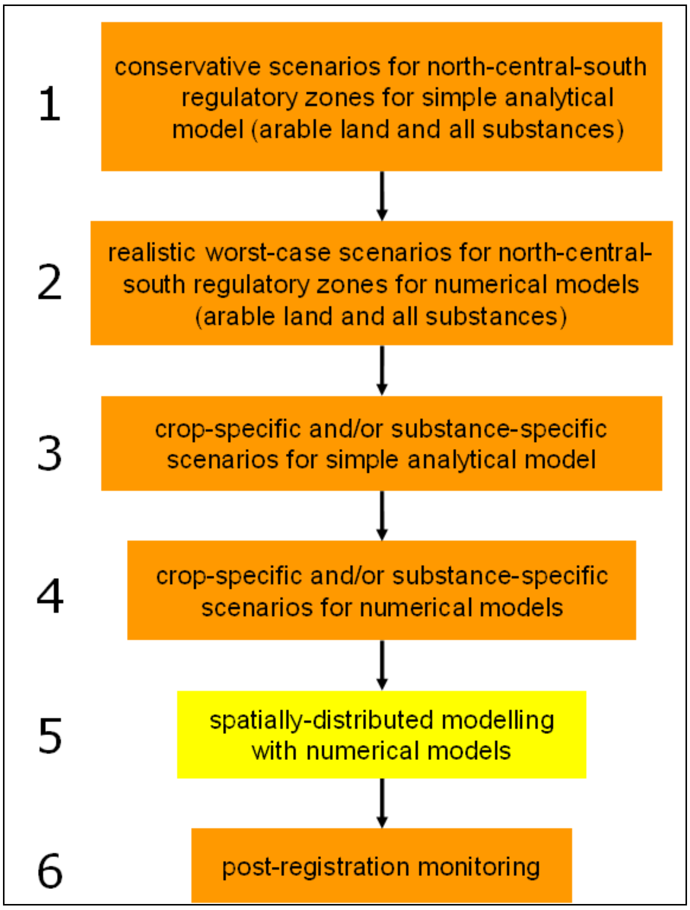

Figure 9. Tiered scheme for the exposure assessment for annual crops with conventional or reduced tillage and spray application. The yellow colour of the Tier-5 box indicates that this tier cannot be made operational in the near future.

Tiers 1 and 2 are based on one scenario per zone for each of the two types of ERC, (i) considering the total surface area of annual crops within a zone and (ii) assuming that substance parameters such as the *DegT50* and the K_{OC} are not related to soil properties (e.g. soil pH). Tier 1 is based on scenarios for a simple analytical model whereas Tier 2 is based on scenarios for numerical models. In Tiers 3 and 4, the area of use can be restricted to specific crops and relationships between the K_{OC} and/or *DegT50* and soil properties can be included. Similarly to Tier 1 and Tier 2, Tier 3 is based on scenarios for a simple analytical model whereas Tier 4 is based on scenarios for numerical models. The Panel has some doubts whether Tier 4 is feasible at EU level in view of limitations of existing soil databases (however it may be feasible at regional level if sufficient data are available). Tier 5 is planned to be an agreed spatially distributed modelling software tool at the EU level that should be seen as a desirable future development. The Panel will consider the inclusion of a sixth Tier which would offer the possibility of post-registration monitoring in agricultural practice.

The scenario-selection procedures in Tiers 1 and 2 are based on the total surface area of annual crops because this is expected to result in a robust procedure. The area of the selected crop (or combination of crops) will have an effect on the scenario selection, so it will be necessary to include safety factors within Tiers 1 and 2 to ensure that these tiers are conservative enough for all crops.

The scenario-selection procedures in Tiers 1 and 2 assume that the K_{OC} and the *DegT50* do not depend on soil properties. However, these tiers should also be conservative for substances whose K_{OC} and/or the *DegT50* do depend on soil properties. This will be assured by using conservative values of the K_{OC} and/or the *DegT50* of such substances in Tiers 1 and 2.

3.2. Approach to the development of Tier 1

Tier-1 calculation procedures will be developed based on the Tier-2 scenarios using the single rule that the Tier-1 scenarios have to be more simple and conservative than the corresponding Tier-2 scenarios (see Section 1.2). As a consequence, Tier 2 will act as the yardstick for Tier 1, and so the Panel will first develop Tier 2 and thereafter Tier 1.

Tier 1 will consist of a simple analytical model (‘back-of-the-envelope’) that will be parameterised for the three zones (North/Centre/South). A tier can only be simple in practice if the input data are limited. Therefore the input to be provided by the user will be restricted to:

i. half-life for degradation in top soil at 20^{o}C and a moisture content corresponding to field capacity,
ii. the organic-carbon/water distribution coefficient (K_{OC}),
iii. the annual rate of application (i.e. the sum of the application rates within one growing season in case of multiple applications),
iv. whether application takes place every year, every second year or every third year.

Tier-1 calculations will be based on the following conceptual model:

i. no crop interception is assumed,
ii. the substance is applied to the soil surface,
iii. the only loss process from the soil is degradation,
iv. soil properties such as moisture content and temperature are constant in time,
v. the effect of tillage is accounted for by assuming complete mixing over the tillage depth at the moment of tillage (each year in autumn or winter),
vi. adsorption is described by a linear isotherm,
vii. the average exposure concentration over a certain depth is calculated from the sum of the concentration just before the last application and the dose divided by this depth.

The Tier-1 calculations will include calculation of concentration in total soil and in pore water. Both peak values and TWA-values for windows up to 56 days will be calculated. Tier 1 will include calculation of concentrations of metabolites based on the conservative assumption that each metabolite is applied at the application time of the parent at a dose that is corrected for the kinetic formation fraction (using procedures in FOCUS, 2006) and the molar mass of the metabolite.

The results of calculations following the above procedure will be compared to results of Tier-2 calculations for some 20 plant protection products. It will be ensured that Tier 1 is more conservative than Tier 2 by introducing safety factors as necessary.

As described in Section 3.1, conservative values of K_{OC} and the *DegT50* will be used in Tier 1 for substances whose K_{OC} and/or *DegT50* depend on soil properties. Conservative means here that the calculated exposure concentrations are higher than the actual concentrations. So conservative implies here that the K_{OC} is low and the *DegT50* is high. A low K_{OC} is conservative because degradation is the only loss process, so the K_{OC} influences only the distribution over solid phase and pore water. The K_{OC} has thus no effect on the concentration in total soil and a low K_{OC} gives the highest concentration in the pore water.

If K_{OC} and/or *DegT50* depend on soil properties, relationships have to be established between K_{OC} and/or *DegT50* and these soil properties. The conservative values to be used in Tier 1 (and similarly those to be used in Tier 2) will be based on a statistical analysis of these relationships.

3.3. Approach to the development of Tier 2

Tier 2 consists of three times two scenarios (one for each of the three zones) that have been parameterised for numerical models such as PELMO and PEARL. The scenarios will be defined with the detail necessary to be able to run these models (including input files for a few of these models for a few crops and a few model substances).

Development of the Tier-2 scenarios consists of two phases: firstly the scenarios will be selected and secondly they will then be parameterised. In the public consultation, Member States pointed to the need to provide guidance as to whether median or worst case *DegT50* values should be used as input. Regarding the role of substance properties in scenario development, the Panel has concluded that the input values for the most important substance parameters such as *DegT50* and K_{OC} have to be part of the selection procedure for the Tier-2 scenarios.

As described in Section 3.1, Tier-2 scenarios will be selected assuming that the 90th percentile is based on the population of all fields within the total area of annual crops in a zone. As described before, the aim of the exposure assessment is to consider the population of agricultural fields in a regulatory zone where a certain crop X is grown. So the population used for the selection of the Tier-2 scenarios is a simplification of the desired population. Such a simplified approach may not be conservative enough for part of the crops in a zone: the 90th percentile of all fields where crop X grows, may be larger than the 90th percentile of the population of all fields within the total area of annual crops in a zone. Therefore in the final stage of the definition of the Tier-2 scenarios, the magnitude of the effect of these different populations on the 90th percentile concentrations will be assessed systematically and safety factors will be introduced into the Tier-2 calculation procedures as necessary. To estimate these safety factors accurately, scenario selections and scenario calculations will be needed for some 20 model substances for all the relevant different crops in the three zones and the results of these hundreds of calculations will have to be analysed carefully. These scenario selections and calculations will be based on the methods proposed for Tier 3. So Tier 3 acts as a reference tier in the tiered assessment scheme.

The Panel will also consider basing first conservative estimates of these safety factors on the difference between the 90th and 100th percentile concentrations for the total area of annual crops within a regulatory zone for some 20 substances. Such conservative estimates will require much less effort and their magnitude will indicate the degree of urgency for the more refined and laborious procedure. The Panel does not exclude that this conservative approach will be based on a percentile slightly below the 100th percentile in view of recently discovered uncertainties in the underlying datasets for dataset elements that are close to the 100th percentile.

To achieve a realistic description of the long-term behaviour of plant protection products in soil, the Tier-2 scenarios will be based on a time series of 20 years of daily meteorological data such as rainfall and temperature. From these 20 years of data, 66 years of data will be generated using the procedure reported in FOCUS (2000). This procedure allows for applications:
- every year (simulation period of 26 years and 26 application years),
- every two years (simulation period of 46 years and 23 application years),
- every three years (simulation period of 66 years and 22 application years).

The Tier-2 scenarios will also be parameterised for a range of annual crops (typically 15 crops for each scenario). This can be done fairly easily because the crop-growth parameters for different climatic regions within the EU have already been collected (FOCUS, 2000; 2001). Recently additional crop-growth parameters have been collected within the FOOTPRINT project (Centofanti et al., 2008) and these will also be considered for utilisation.

As described in Section 3.1, conservative values of K_{OC} and *DegT50* will be used in Tier 2 for substances whose K_{OC} and/or the *DegT50* depend on soil properties. In this context, conservative means a high *DegT50*. With respect to the $K_{OC,}$ conservative means a high value for the concentration in total soil (because such a value leads to less leaching and thus higher concentrations in the top soil). For the concentration in the pore water, there is no general guidance possible as to whether a high or a low K_{OC} is conservative (high K_{OC} leads to high concentration in total soil but also to low concentration in pore water). So for the concentration in pore water, it is recommended to perform Tier-2 calculations using for the full range of K_{OC} values and to use the highest exposure concentration considering this range.

3.4. Approach to the development of higher tiers

As described in Section 3.1, Tiers 1 and 2 are based on one scenario per zone for each ERC considering the full surface area of arable land within a zone and assuming that the K_{OC} and *DegT50* of the PPP do not depend on soil properties. The Panel proposes to also include higher tiers in which the area of use can be restricted to specific crops or dependencies between K_{OC} and/or *DegT50* on soil properties may be included in the scenario-selection procedure.

Specific crops may be relevant, in cases such as e.g.:
- crops that cannot be grown in the whole zone because of climatic reasons (e.g. tomatoes in the central zone),
- crops that cannot be grown in the whole zone because they need special soil types.

For these, it may be meaningful to change the standard Tier-2 scenario to a more realistic location, which will become specific for the selected crop.

The assumption that substance parameters such as the *DegT50* and the K_{OC} are not related to soil properties is not defensible for all plant protection products and their metabolites in soil. Therefore higher tiers are included should these substance parameters be a function of soil properties.

For these cases, Tiers 3 and 4 are proposed (Figure 9). At Tier-3 level, scenarios for a simple model are used (similar to Tier 1) and at Tier-4 level scenarios for numerical models are used (similar to Tier 2). Tier 3 is included because a better selection of the 90^{th} percentile scenario may have more effect than more sophistication of the description of the processes in the numerical models and because derivation of such a scenario is relatively easy to do (provided that all necessary databases are made available publicly). The Panel is currently performing the scenario selection for Tier 2. The selection of adequate soil profiles appears to require considerable expert judgement in view of limitations of existing soil databases at EU level. Therefore the Panel doubts whether Tier 4 is feasible in regulatory practice at the EU level.

As indicated in Figure 9, the applicant may choose to consider only crop-specific scenarios or only substance-specific scenarios or a combination of the two. A crop-specific scenario is in principle possible for all plant protection products whereas a substance-specific scenario is only possible for substances whose K_{OC} or *DegT50* is related to soil properties.

Because there are many different possibilities for the nature of the relationships between K_{OC} or *DegT50* and soil properties (e.g. the K_{OC} may either increase or decrease with pH), and because there are many different crops, Tiers 3 and 4 will consist only of a description of the procedures to be followed (so not of parameterised scenarios for all relevant cases).

A further tier may be considered (Tier 5, Figure 9) which would consist of spatially distributed modelling with numerical models. This tier will have to be based on:

i. a database of soil profiles which covers the whole agricultural area within the EU with sufficient reliability,
ii. a database of weather stations that covers the whole agricultural area within the EU,
iii. a map of all the relevant crops within the EU,
iv. at least one numerical model for simulation of the behaviour of plant protection products in the soil,
v. a GIS environment that enables a few hundred runs with this model for any combination of plant protection products and crop to be considered.

Such a system has the advantage that the system itself can select appropriate scenarios for any combination of PPP and crop without the need of simplifying assumptions (including relationships between K_{OC} or *DegT50* and soil properties in the scenario-selection procedure). Such a system is in principle feasible on the basis of current knowledge, e.g. such a system has been in use for leaching assessment in the Netherlands since 2004 and also in other Member States such systems are in use or being developed. However, considerable efforts will be needed to get such a system agreed and operational for use in the EU exposure assessment. So Tier 5 should be seen as a desirable future development.

The Panel considers the possibility to include post-registration monitoring as Tier 6. As described in Section 1.2, one of the principles of tiered approaches is that all tiers aim to assess the same protection goal. In the context of the tiered approach of Figure 9, this means that all tiers aim to assess the spatial 90^{th} percentile PEC_{SOIL} resulting from the use of the plant protection product for a market share of 100% and considering the population of agricultural fields (in one of the three regulatory zones) where the crop (further called 'crop X') is grown in which this plant protection product is applied. For Tier 6 this implies that this percentile has to be assessed via one of the following procedures:

i. random sampling in combination with appropriate statistical assessment of the 90^{th} percentile
ii. some form of modelling combined with geostatistical analysis that enables a more targeted sampling strategy to assess this percentile (this also includes the use of existing data that are analysed afterwards).

The Panel expects that statistical analysis will show that it is impossible to assess the 90th percentile with sufficient accuracy on the basis of a few soil accumulation studies. Such studies are likely to be more useful for a better estimation of the degradation half-life in top soil (see next section).

Post-registration monitoring is likely to be meaningful only for plant protection products that show build up of residues at a time scale of at least 5 years. Using results of post-registration monitoring studies may imply that the market share of a product may have an effect on the results. Thus this market share may become part of the exposure assessment. If the results of the post-registration monitoring are obtained for a market share of e.g. 50%, then the resulting 90th percentile concentration has to be corrected via some procedure to obtain the 90th percentile concentration corresponding to a market share of 100%.

3.5. Approach for handling the use of results of field persistence and soil accumulation experiments within the tiered assessment scheme

For the exposure assessment in soil, the degradation half-life (*DegT50*) in topsoil at 20^{o}C and field capacity is a very important input parameter of the simple and numerical models used in the tiered approach (Figure 9). The Panel proposes to base this parameter on a stepped approach (Figure 10) for all tiers: (i) only considering values from laboratory studies, (ii) also including values from field persistence studies and (iii) including additional values from soil accumulation studies. This is done because field persistence studies and soil accumulation studies may provide more realistic estimates of this half-life than the laboratory studies and because such studies are available in many dossiers.

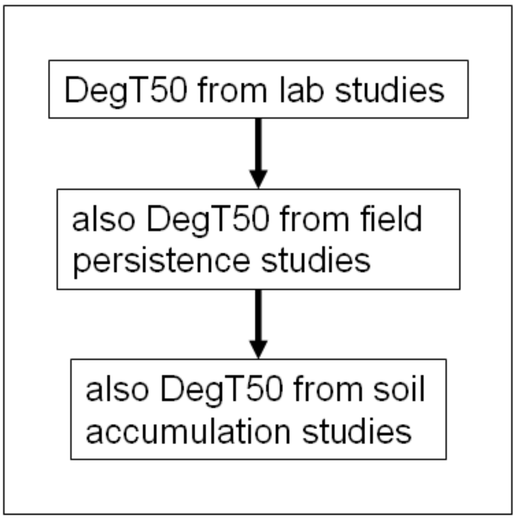

Figure 10. Schematic representation of stepped approach for estimating the *DegT50* in the soil to be used in the exposure assessment in the different tiers (Figure 9).

However, there is a complication with respect to the estimation of the *DegT50* values from field persistence studies. These *DegT50* values will be used to simulate long-term accumulation of plant protection products with ploughing up to 20 cm depth every year. So they have to reflect the degradation rate within the soil matrix. Field dissipation studies regularly show a fast initial decline (Walker *et al.*, 1983). Immediately after application, the plant protection product is concentrated in the top millimetres of the soil. In this top layer, processes other than degradation within the soil matrix may take place (volatilisation, photochemical degradation, runoff etc.). Therefore a procedure will be developed that ensures that the *DegT50* derived from field persistence studies reflects the degradation rate within the soil matrix (and not initial loss processes from the top millimetres of soil).

Similarly, there are also complications with respect to the estimation of the *DegT50* values from soil accumulation studies. Such studies may contain only two samplings per year and the plant protection product may have been sprayed on a full-grown crop. In such a situation it may be difficult to estimate the fraction of the dose that eventually reached the soil. This may complicate an accurate estimation of the *DegT50* within the soil matrix from soil accumulation studies. A procedure will be proposed to overcome this problem.

In view of these complications in estimating *DegT50* values from field persistence studies and soil accumulation studies, the Panel considers it still a point of debate whether the stepped approach for estimating the *DegT50* should be indeed part of Tier 1 or only apply to higher tiers.

3.6. Approach for handling crop interception of plant protection products within the tiered assessment scheme

Crop interception may have a large influence on the exposure in soil of plant protection products that are sprayed onto the crop. This process will be handled differently in the different tiers (Figure 9).

In Tier 1, it will be assumed that crop interception does not occur. This is a simple and conservative approach which is in line with the level of sophistication of this tier.

In Tier 2, crop interception will be estimated from the crop-interception tables proposed by FOCUS (2000) because this is the best information that is currently available. FOCUS (2000) recommended ignoring wash-off from plant surfaces which led to the procedure that the application rate is corrected for the crop interception. This procedure has become common practice in the EU risk assessment procedures since 2000. The Panel contacted the authors of FOCUS (2000) and asked for clarification whether the estimation procedures of the interception figures presented by FOCUS (2000) included the consideration that wash-off was ignored. This appeared to not be the case (Van der Linden & Resseler, personal communication, 2009). The Panel considers the maximum interception fraction of 90% in the FOCUS tables accounts to some extent for the exclusion of wash-off. However, the Panel considers the approach by FOCUS (2000) not defensible because there is insufficient evidence that wash-off can be ignored under all relevant circumstances (Leistra, 2005). Instead the Panel proposes to let the numerical models simulate dissipation on the plant surfaces and wash-off to soil. The Panel will develop conservative estimation procedures for the model parameters describing loss from plant surfaces due to uptake and degradation and also for the parameters describing the wash-off to the soil. In this context, conservative means high wash-off fractions of the intercepted substance (so slow loss due to plant uptake and degradation and rapid loss due to wash-off). However, the Panel considers it also acceptable that these conservative estimation procedures are overruled by experiments with plants under a range of relevant conditions.

Tier 3 uses a simple analytical model similar to the one used in Tier 1. The Panel currently considers two options for crop interception in Tier 3. The first option is to assume no crop interception (as in Tier 1). So the total applied amount is assumed to penetrate into the soil. The advantage of this approach is that it is conservative enough. However, if crop interception has a major effect on the exposure concentrations, Tier 3 may give higher concentrations than Tier 2 which is in general undesirable in a tiered approach. At the same time, the appropriateness of this simple Tier 3 may be questioned if crop interception is such a dominant process that it has more effect than the effect of the crop area or the substance-specific parameters. So it may be a workable solution to assume no crop interception in Tier 3 because Tier 3 is expected to require much less effort for the notifier than Tier 4.

The second option for crop interception in Tier 3 is to use the results of Tier-2 calculations with the numerical models to estimate the fraction of the dose that will reach the soil surface by wash-off. As described before, the soil exposure concentrations in Tier 2 will be based on the all-time maximum value considering 20 years of application. Therefore it seems appropriate to base this estimation of the wash-off fraction on the application year with the highest wash-off. It is possible that using this highest wash-off year leads again to concentrations that are higher than those in Tier 2 because the all-time high is not only driven by wash-off but also by other factors such as soil temperature. However, this will happen much less often than when no crop interception is assumed.

For Tiers 4 and 5, the Panel proposes to use the same approach for crop interception as for Tier 2.

3.7. Phasing of the guidance development for spray applications to annual crops with reduced or conventional tillage

This Opinion describes the outline of the proposed tiered approach. The next step will be to develop the scenario-selection procedure for Tier 2, followed by the scenario selection and the parameterisation of the selected Tier-2 scenarios. Subsequently, scenario calculations will be carried out for some 20 model substances to illustrate how the scenarios work. The results of these calculations will be used to develop Tier 1 (to ensure that Tier 1 is more conservative than Tier 2). Thereafter the guidance for the Tier-3 and Tier-4 scenarios will be developed. The resulting tiered system together with the calculation results for about 20 model substances both for Tier 1 and Tier 2 will be described in a future Opinion.

As described in Section 3.3, the Panel considers two options for developing the safety factors for the possible effect of the difference between the total area of annual crops and the area of the intended crop within a zone: a simple conservative procedure based on the difference between 90th and 100th percentile concentrations in each of the zones and a sophisticated and more accurate procedure based on scenario selections and calculations for all relevant crops in each of the zones. The Panel expects to include the safety factors based on the simple procedure in this Opinion on the resulting tiered system but not the safety factors based on the accurate procedure. This accurate procedure is very laborious. Therefore the Panel proposes to outsource this work and to describe the resulting safety factors in a later opinion. The advantage of this sequence is that the Panel first gains experience with the methodology of the selection and parameterisation of the scenarios before outsourcing the scenario selection for the different crops in the different zones. This will ensure that the Panel can prescribe the methodology in sufficient detail for the outsourcing.
In parallel to the guidance development of the tiered exposure assessment (in another Opinion), guidance will be developed for the stepped approach for estimating the *DegT50* considering laboratory studies, field persistence studies and soil accumulation studies (as shown in Figure 10).

As a further step, the guidance described in these three Opinions will be tested by applying it to about five plant protection products whose Draft Assessment Reports are available. This application will not be performed by the Panel but via outsourcing. Based on the experience gained from this testing procedure, the guidance will be revised as necessary.

Guidance for post-registration monitoring will be included only if this is feasible with a limited amount of resources because such monitoring will be performed in very exceptional cases. It cannot be excluded that this guidance will take a considerable amount of resources because of the statistical complications resulting from the requirement that a 90th percentile has to be estimated with sufficient accuracy.

4. Outlook to future activities

The development of the exposure assessment for the immediate future will be restricted to the combinations of annual crops, conventional or reduced tillage and spray application. In the longer term, exposure assessment procedures need to be developed for other combinations in EU agriculture and horticulture (Figure 8 and EFSA, 2009).

As follows from the above, the development of the exposure assessment will be restricted to the exposure in the field and no development of the exposure assessment in the ecotoxicological studies is foreseen in the immediate future (Figure 3). The Panel acknowledges that this exposure assessment in the ecotoxicological studies is an essential part of the effect assessment procedure that has to be tackled in the longer term. This will be handled as an exposure issue in the revision of the guidance document on terrestrial ecotoxicology.

5. Usefulness of proposed methodology at Member State level

These exposure assessment approaches are developed to assist in decision making for Annex I listing in the EEC/91/414 (so EU level). However, the Panel considers the proposed procedure, models and databases for the scenario development also useful at the level of the Member States if Member States agree to use a spatial percentile similar to the one used in this proposal. However, following this procedure, the selected scenarios at the level of a Member State will of course differ from those selected at EU level. This will only work if Member States have access to the databases of soils, crops and weather used by the Panel or equivalent or better datasets. Harmonisation of the exposure assessment methodology within the EU will therefore be stimulated strongly by making these databases available to all Member States. The Panel considers the proposed definition of the role of results of field persistence and soil accumulation experiments in principle applicable to the exposure assessment in all Member States.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

1. Development of a scientific methodology for assessment of exposure of organisms to plant protection products and their transformation products in soil requires a detailed definition of the goal of the exposure assessment. This definition is a risk management decision.

2. The exposure of soil organisms in top soil may be strongly influenced by the type of crop (annual crops, pasture, other permanent crops, or rice); the soil-tillage system (e.g. conventional tillage, reduced tillage, no-tillage, ridge-furrow tillage), the crop management and the application technique (e.g. spray onto bare soil or onto a crop, seed treatment, row treatment). Therefore different exposure assessment methodologies are needed for different combinations of crops, tillage systems and application techniques.

3. Annual crops cover a larger surface area within the EU than pasture or other permanent crops. Conventional and reduced tillage systems are used much more frequently than other tillage systems in annual crops within the EU. Most plant protection products are applied in annual cropping systems via spray applications. Therefore the development of an exposure assessment methodology for spray applications in annual crops under conventional and

reduced tillage has a higher priority than for other combinations of crops, tillage systems and application techniques.

4. For soils under conventional and reduced tillage, it is defensible to assume that the soil is perfectly mixed up to 20 cm depth periodically in long-term calculations of the concentrations of plant protection products in the top 20 cm of soil.

5. There may be considerable differences between the crop areas of different crops in each of the three regulatory zones. Therefore the selected scenario may be influenced by the area of intended use (usually a crop or a group of crops). As a consequence, this influence needs to be considered in the development of the exposure assessment methodology for soil organisms.

6. The degradation rate of plant protection products within the soil matrix may play an important role in the exposure assessment of soil organisms. The dissipation rate of plant protection products in field persistence studies may be influenced by processes other than degradation when most of the product is still present in the top millimetres of soil (so in the initial phase of the experiment). Therefore guidance needs to be developed that ensures that the degradation rate coefficients derived from field persistence studies reflect the degradation rate within the soil matrix.

7. It is not defensible to ignore under all circumstances wash-off of plant protection products from plant surfaces in the exposure assessment of soil organisms. Therefore an approach needs to be developed for incorporating wash-off where necessary in the exposure assessment methodology for soil organisms.

RECOMMENDATIONS

1. The proposed exposure-assessment methodology is based on the population of all agricultural fields within a regulatory zone grown with the crop or group of crops that are considered for the plant protection product within the EU registration procedure. So to develop the exposure assessment methodology, the list of possible annual crops for EU registration has to be defined. The Panel recommends that the Commission provides the list of crops to be considered for this purpose.

2. The Panel recommends basing the exposure-assessment methodology for spray applications in annual crops under conventional and reduced tillage on a tiered approach. Tier 1 is proposed to be based on a simple analytical model. Tier 2 is to be based on simulations with numerical models. To keep the approach as simple as possible, the Panel recommends having within Tier 1 and Tier 2 only one scenario for concentration in total soil and only one scenario for concentration in pore water. These scenarios are used for all annual crops and for all plant protection products in each regulatory zone. Tier 3 is proposed to be again a simple analytical model but in this Tier specific crops and/or plant protection products with specific properties may be considered. Tier 4 is to be based on simulations with numerical models but, as in Tier 3, specific crops and/or plant protection products with specific properties can be considered.

3. The development of soil exposure scenarios in the proposed Tier 4 is hampered by limitations of existing soil databases at EU level. As a consequence a considerable amount of expert judgement is needed for selection of the soil profiles of the scenarios. Therefore, if a tier similar to Tier 4 would be used at MS level, the Panel recommends that the notifier and regulators consult national experts.

4. The development of this exposure-assessment methodology has demonstrated the importance of high-quality databases of soils, crop areas and weather with 100% coverage of the EU-27. To make the guidance operational, the Panel recommends that the Commission ensures access to state-of-the-art databases of soils, crop areas and weather for the stakeholders. To ensure transparency, the Panel further recommends that the description of the structure of the databases and of the data sources is made available publicly.

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ABBREVIATIONS

DegT50	Half-life resulting from transformation of substance in the soil matrix
ERC	Ecotoxicologically Relevant Concentration
FOCUS	Forum for Co-ordination of pesticide fate models and their USe
K_{oc}	organic-carbon/water partition coefficient
MS	Member State
PBT	Persistence Bioaccumulation Toxicity
PEC	Predicted Environmental Concentration
PEC_{SOIL}	Predicted Environmental Concentration in soil
PPP	Plant Protection Product
PPR Panel	Scientific Panel on Plant Protection Products and their Residues
RAC	Regulatory Acceptable Concentration
TWA	Time-Weighted Average