SCIENTIFIC OPINION

Scientific Opinion on the development of specific protection goal options for environmental risk assessment of pesticides, in particular in relation to the revision of the Guidance Documents on Aquatic and Terrestrial Ecotoxicology (SANCO/3268/2001 and SANCO/10329/2002)[1]

EFSA Panel on Plant Protection Products and their Residues (PPR)[2, 3]

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ABSTRACT

General protection goals are stated in European legislation but specific protection goals (SPGs) are not precisely defined. These are however crucial for designing appropriate risk assessment schemes. Here a process for defining SPG options is presented, which uses the ecosystem services approach as an overarching concept and could be used in consultation processes with risk managers and stakeholders. SPGs are defined in 6 dimensions: biological entity, attribute, magnitude of effect, temporal and geographical scale of the effect, and the degree of certainty that the specified level of effect will not be exceeded. SPG options are presented for 7 key drivers (microbes, algae, non target plants (aquatic and terrestrial), aquatic invertebrates, terrestrial non target arthropods including honeybees, terrestrial non-arthropod invertebrates, and vertebrates), covering all ecosystem services which could potentially be affected by the use of pesticides. To ensure ecosystem services, taxa representative for the key drivers identified need to be protected at the population level or higher. However, for aesthetic reasons (cultural ecosystem services) it may be decided to protect vertebrates at the individual level. To protect biodiversity, impacts at least need to be assessed at the scale of the watershed/landscape. The Panel also emphasizes the importance of a tiered approach for risk assessment, the essential linking of exposure and effect assessments in terms of spatial and temporal scales, and the relevance of ecological scenarios for appropriate pesticide risk assessments. It intends to use the presented concepts as input for the dialogue between risk managers and risk assessors during the next steps of the revision of the Ecotoxicology Guidance Documents.

KEY WORDS

protection goals, ecosystem services, environmental risk assessment, pesticides, plant protection products, guidance documents, ecotoxicology

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SUMMARY

Following a request from EFSA, the Panel on Plant Protection Products and their Residues (PPR) was asked to deliver a scientific opinion on the development of specific protection goal options for environmental risk assessment of pesticides, in particular in relation to the revision of the Guidance Documents on Aquatic and Terrestrial Ecotoxicology (SANCO/3268/2001 and SANCO/10329/2002).

The aim of the PPR Panel is to develop robust environmental risk assessment (ERA) procedures which provide the highest achievable protection to human health and the environment. At the same time the ERA procedures should be scientifically sound, efficient, and minimize cost for society (in particular to industry and regulators), enable transparent risk management decisions, and allow at the same time for refinements of the risk assessments if applicable or if more data or tools become available. For the development of robust and efficient ERA procedures it is crucial to define clear specific protection goals. Risk assessors need to know ***what*** to protect, ***where*** to protect it and over ***what time period***.

The Panel considers it necessary to derive specific protection goal options that can be agreed with risk managers and other stakeholders via a consultation process in order to provide the framework within which appropriate risk assessment methodology can be developed for pesticides. In particular clarifications are needed to define specific protection goals with respect to ecological, temporal and spatial scales, in-crop versus off-crop situations, multiple stress, and uncertainties.

Given the diversity and range in general protection goals mentioned in the legal framework, the PPR Panel applied the ecosystem services concept as an overarching concept, used elsewhere in European policy setting, which helps systematically to identify specific protection goal options for key drivers covering all environmental compartments. Based on the ecosystem services identified by the Millennium Ecosystem Assessment (2005) the PPR Panel identified those ecosystem services which could potentially be directly or indirectly (e.g. via trophic interactions) affected by the normal agricultural use of plant protection products and identified the groups of organisms which constitute the most important key drivers for those ecosystem services to address the potential environmental risks of plant protection product use resulting from normal agricultural practice. Specific protection goals for each of the key drivers identified in the previous step were defined and summarised in 7 groups of organisms (microbes, algae, non target plants (aquatic and terrestrial), aquatic invertebrates, terrestrial non target arthropods including honeybees, terrestrial non-arthropod invertebrates, and vertebrates). Plant protection products are applied primarily in fields where crops are grown, and can cause effects in adjacent elements in the agricultural fields, such as field margins, hedges, non-crop patches (e.g. small woods), groundwater, ditches, streams and lakes, also in areas far away due to long range transport of pesticides, and this is considered in the development of the specific protection goals.

Although it can be assumed that the existing environmental risk assessment procedure for plant protection products is implicitly and partly based on the protection of ecosystem services, the Panel has identified and suggested a clearer, explicit framework for deriving specific protection goals.

It is important to recognise that final decisions on the choice of specific protection goals involves risk management judgements, which are outside the remit of EFSA and the PPR Panel, and therefore need to be made in consultation with risk managers. In order to facilitate this essential consultation, for some cases a range of alternative options for the specific protection goals is developed in this opinion, representing alternative levels of protection. This requires specifying the following 6 dimensions or aspects of a specific protection goal: the ecological entity that is to be protected (individuals, (meta)populations, functional groups or ecosystems), the attribute(s) or characteristic(s) of that entity that must be protected (behaviour, survival/growth, abundance/biomass, processes, biodiversity), the magnitude of effect that can be tolerated for the attributes to be measured (biological scale), the temporal scale of effect (e.g. the maximum time on an annual basis over which single or repeated exposure/effect events are expected to exceed the critical level that can be tolerated), the spatial scale of the effect (e.g. the distance from the sites of application where the exposures and critical effect level to be tolerated are expected to occur), and the degree of certainty that the specified level of effect will

not be exceeded. These dimensions are interdependent, and when considering the spatio-temporal dimensions of risk it is important to consider both exposure and effects and their spatio-temporal dimensions.

To ensure ecosystem services, taxa representative for the key drivers identified need to be protected at the population level or higher. However, for aesthetic reasons (cultural ecosystem services) it may be decided to protect vertebrates at the individual level. To protect biodiversity, impacts at least need to be assessed at the scale of the watershed/landscape.

Given that most of the services under the selected specific protection goals are performed by populations or groups of populations, development of appropriate population models for use in risk assessment is needed. There is no lack of population models available in the literature and some of these have been used for decision making in, for example, fisheries management, conservation, etc. However, challenges remain to develop a suite of standard models, incorporating the necessary level of ecological complexity, which can be broadly accepted for use in risk assessment by regulators and the regulated.

The Panel also emphasizes the importance of a tiered approach for risk assessment, the essential linking of exposure and effect assessments in terms of spatial and temporal scales, and the relevance of ecological scenarios for appropriate pesticide risk assessments and its further work on the update/development of Ecotoxicological Risk Assessment Guidance Documents. The tiered system as a whole needs to be (i) appropriately protective, (ii) internally consistent, (iii) cost-effective and (iv) address the risk assessment with greater accuracy and precision when going from lower to higher tiers. For all tiers or levels within a risk assessment scheme that addresses a certain key driver the same specific protection goal applies. The PPR Panel proposes to identify for each key driver (taxonomic group or other ecological entity) a reference tier, based on the most sophisticated experimental or modelling risk assessment method that addresses the specific protection goal, and then use this reference tier to calibrate lower tiers using simpler methods that are practical for routine use.

The PPR Panel intends to use the specific protection goal options for each key driver as well as the general concept presented in this Opinion as input for the dialogue between risk managers and risk assessors during the problem formulation phase during the next steps of the revision of the Guidance Documents (GDs) Aquatic Ecotoxicology and Terrestrial Ecotoxicology for which the Panel received the mandates in 2009 (EFSA-Q-2009-00001 and EFSA-Q-2009-00002, respectively).

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BACKGROUND AS PROVIDED BY EFSA

EFSA's Panel on Plant Protection Products and their Residues (PPR) received early 2009 the mandates for the revision of the Guidance Documents (GDs) Aquatic Ecotoxicology SANCO/3268/2001 and Terrestrial Ecotoxicology SANCO/10329/2002 (EFSA-Q-2009-0001 and EFSA-Q-2009-0002, respectively). In this context, the Panel aims to develop/update Guidance Documents that:

- achieve the general and specific aims of the EU legislation for protecting the environment
- provide risk assessment procedures that enable risk management decisions to be reached with minimum cost and effort for both industry and the regulatory authorities, but allowing refinement of the assessments if more data are made available
- harmonize, as much as possible, the risk assessment procedures for the different ecological compartments

Considering the previous experience of the PPR-Panel with the mandates EFSA-Q-2006-064 and EFSA-Q-2009-00223 related to the Guidance Document on Risk Assessment for Birds and Mammals, the PPR-Panel agreed that it would be crucial to develop and agree with the respective risk managers on the protection goals for the respective environmental compartments in an early step of the process. The rationale for this is that this procedure will smooth and improve the efficiency of the update of the risk assessment schemes.

TERMS OF REFERENCE AS PROVIDED BY EFSA

The Scientific Panel on Plant Protection Products and their Residues (PPR Panel) of EFSA is asked to:

- prepare and adopt a scientific opinion on protection goal options for environmental risk assessment (ERA) of pesticides in the context of EFSA-Q-2009-00001 and EFSA-Q-2009-00002
- consult risk managers regarding the appropriate protection goals for ERA of pesticides
- consult relevant stakeholders regarding the appropriate protection goals for ERA of pesticides

1. Introduction

EFSA's PPR Panel received the mandate EFSA-Q-2009-00861 to issue a scientific opinion on the development of protection goals for Environmental Risk Assessment (ERA) of pesticides[4] in the context of EFSA-Q-2009-00001 and EFSA-Q-2009-00002, which asked for the revision of the Guidance Documents (GDs) Aquatic Ecotoxicology and Terrestrial Ecotoxicology (SANCO/3268/2001[5] and SANCO/10329/2002[6] , respectively).

The aim of the PPR Panel for fulfilling these mandates is to develop robust environmental risk assessment (ERA) procedures which provide the highest achievable protection to human health and the environment. At the same time the ERA procedures should be scientifically sound, efficient, and minimize cost for society (in particular to industry and regulators), enable transparent risk management decisions, and allow at the same time for refinements of the risk assessments if applicable or if more data or tools become available. For the development of robust and efficient ERA procedures it is crucial to define clear protection goals. Risk assessors need to know ***what*** to protect, ***where*** to protect it and over ***what time period***.

Protection goals are broadly defined in the EU legislation, with Regulation (EC) No 1107/2009[7], which repeals Directive 91/414/EEC[8], being the most relevant legislative document for this opinion. Other legislative documents may also be relevant because they regulate either the use of the same substances in other contexts or the use of similar substances (e.g. Directive 98/8/EC on Biocides[9] and Regulation (EC) No 1907/2006 (REACH)[10]); or because they regulate the protection of environmental compartments in general (e.g. draft Soil Framework Directive (EC, 2004), Habitats Directive 92/43/EEC[11], Water Framework Directive 2000/60/EC[12]).

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[4] The terms "pesticides" and "plant protection products" are used as synonyms throughout this scientific opinion, including active substances, safeners, synergists and co-formulants covered under the new regulation concerning the placing of plant protection products on the market (Regulation (EC) 1107/2009).

[5] Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC (SANCO/3268/2001) rev.4 final, 17.11.2002, p. 1 - 62.

[6] Guidance Document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC (SANCO/10329/2002) rev.2 final, 17.10.2002, p.1 - 39.

[7] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309/1, 24.11.2009, p. 1 - 50.

[8] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1 - 32.

[9] Directive 98/8/EC of the European Parliament and of the council of 16 February 1998 concerning the placing of biocidal products on the market. OJ L 123/1, 24.4.1998, p. 1 - 63.

[10] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. OJ 396/1, 30.12.2006, p. 1 - 849.

[11] Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora. OJ L 206 , 22.07.1992 p. 7 - 50.

[12] Directive 2000/60/EC of the European parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy. OJ L 327, 22.12.2000, p. 1 - 73.

Since the protection goals are defined in broad terms in the EU legislation, they should be interpreted as **general protection goals.** For the purpose of this document general protection goals are defined as ***overall goals to be achieved as required by the EU legislation to protect human health and the environment from unacceptable impacts of pesticides.*** However, due to the variety of ways and the general terms in which the general protection goals are expressed in the legislation a "translation" into precise goals for Risk Assessment (RA) in terms of method development or risk assessment routine application is difficult. It is thus necessary to define specific protection goals for the purpose of designing risk assessment procedures. Obviously, the existing developed risk assessment schemes and data requirements in the context of Regulation (EC) No 1107/2009 should be considered in this process.

This opinion aims at developing specific protection goal options for the environmental risk assessment of pesticides. **Specific protection goals** are in this opinion defined by ***the entities that need to be protected, the attributes and/or functions of those entities, as well as the magnitude, temporal and spatial scales of effects on these attributes and/or functions that can be tolerated without impacting the general protection goal and the required degree of certainty with which the protection goal defined should be achieved.***

The definition of specific protection goal used in this opinion is in accordance with the definition of generic ecological assessment endpoint (GEAE) as used by the U.S. Environmental Protection Agency. GEAEs are based on US-environmental legislation and US-EPA's policies and precedents and can be considered and adapted for specific ecological risk assessments. An assessment endpoint is defined as an explicit expression of the environmental value to be protected, operationally defined as ecological entity and its attributes (US-EPA, 2003).

The process for developing specific protection goals based on the available general protection goals is part of the problem formulation in the ecological risk assessment framework and it is based on the goals set by risk managers (Figure 1). In the context of defining the protection goals and level of protection in this Opinion, the PPR Panel considers **risk managers** as ***those who decide what level of effect for which protection goal is acceptable in the context of product authorisation***. Risk managers base the granting of marketing authorisations for individual plant protection products on the work of the risk assessors, who do the assessment under Regulation (EC) No 1107/2009 according to the EFSA Guidance. The PPR Panel prepares the Guidance Documents to be used by risk assessors, and bases its methodology on the protection goals and levels of protection set by risk managers.

Stakeholders were consulted on this opinion via a stakeholder workshop *"Protection goals for environmental risk assessment of pesticide: What and where to protect?"* held in Parma the 15th and 16th of April, 2010 (EFSA, 2010b). Additionally, risk managers from European Member States were consulted via a risk manager consultation organised in co-operation with the European Commission (Directorate General for 'Health and Consumers') in Brussels the 11th and 12th of May. The feedback obtained in both consultations was considered in the finalisation of this opinion.

The process followed by the PPR-Panel started with a comprehensive review of the European legislation relevant to pesticides, chemicals and/or to environmental protection objectives, looking for references to protection goals, in order to identify the key words and concepts to be further used after consultation with risk managers and other relevant stakeholders. In parallel key publications in the area of biodiversity and environmental protection and related assessment tools were considered in order to identify the relevant criteria that could be used practically to describe the entities to be protected and their functions. On the basis of this information the protection of biodiversity together with the protection of the services that are brought by ecosystems or by parts of ecosystems were identified as two important axes in defining specific protection goals. The definition of specific protection goals based on this reasoning was performed for each group of organisms as listed in Council Directive 91/414/EC (Annex II and III, data requirements) and amended by the key groups of organisms that were missing in this list according to an analysis based on the ecosystem services concept. The first implications for risk assessment were then discussed.

This Opinion is structured as follows:

- The need to define specific protection goals for the ERA of pesticides, based on an overview of the most relevant general protection goals with respect to the ERA of pesticides in the current relevant European legislation (Section 2).

- A framework developed by the PPR-Panel to derive specific protection goal options based on the ecosystem services concept that can be used in our dialogue with risk managers (Section 3).

- An outlook for the next steps to be followed in order to develop robust and efficient risk assessment procedures based on the specific protection goal options developed (Section 4).

- Conclusions and Recommendations

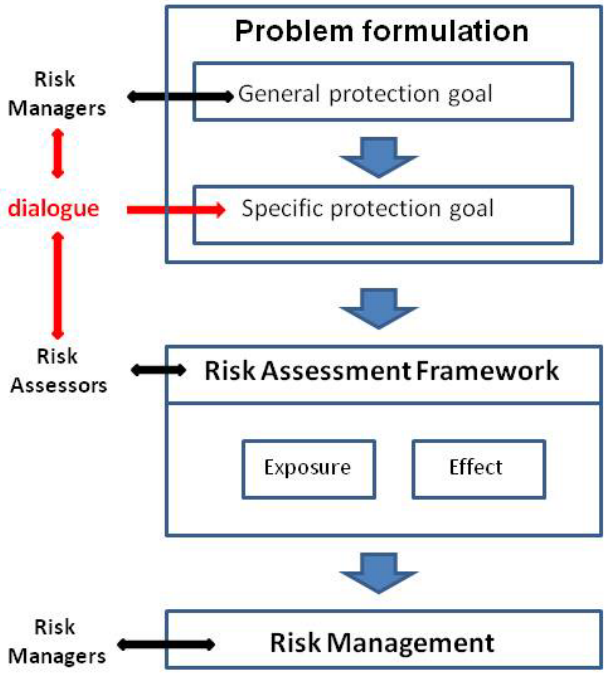

Figure 1: Relation between problem formulation, protection goals, risk assessment framework, and risk management in the process of developing specific protection goals. Please note that this figure focuses on the interaction between risk assessment and risk management as defined in this Section. However, the involvement of stakeholders is also needed in the definition of protection goals.

2. The need to define specific protection goals for ERA of pesticides

As mentioned before, for the development of robust and efficient ERA procedures it is crucial to know ***what*** to protect, ***where*** to protect it and over ***what time period***. The PPR Panel followed a systematic approach in its current mandate on the development of ERA guidance documents on pesticides, and examined the European legislation (the EU *acquis communautaire*) in order to identify environmental protection goals that are particularly relevant to the risk assessment and regulation of pesticides. However this is not a legal review or priority comparison of the different legislative documents and approaches, but is intended to assist the refinement of protection goals as practical targets for the development of appropriate risk assessment methods.

There are no specific protection goals defined in any of the legislation, rather the protection goals are often very broadly described (i.e. general protection goals). However, in the context of the current Panel mandate, it is important that risk assessors understand what risk managers[13] want to protect under the different regulations and identify any potential conflicts or discrepancies that may impact on the risk assessment of pesticides. Our analysis includes the EU- Consolidated Version of the Treaty [14], the new Regulation (EC) No 1107/2009 on plant protection products, the Annexes to the Directive 91/414/EEC, the Sustainable Use of Pesticides Directive 2009/128/EC[15], the Directive 92/43/EEC (Habitat Directive), the Directive 2000/60/EC (Water Framework Directive), policy documents on soil protection, the Directive 2006/118/EC[16] (the Groundwater Directive) and the Directive 2008/56/EC[17] (Marine Strategy Framework Directive). The Directive 98/8/EC on Biocides and Regulation (EC) No 1907/2006 (REACH) have not been considered in this analysis because the general aims and the processes proposed in general are similar to the pesticide legislation.

2.1. General protection goals in the Treaty on the European Union

The **EU Treaty** has set, as a principle, a goal of a high level of protection of the environment (article 2):

> *"The Community shall have as its task, […] a high level of protection and improvement of the quality of the environment, […]".*

This principle is reflected in article 174 on community policy for the environment and in articles 94 and 95 for the approximation of laws establishing an internal market. Community policy on the environment shall (article 174) take into account the diversity of situations in the various regions. All current product legislation aiming at harmonizing the internal market (founded on article 95) refers to the principle of achieving the high level of protection in the requirements for an environmental risk

[13] Refer to Section 1 for a definition of risk managers in the context of this Opinion.

[14] European Union-Consolidated Versions of the Treaty on European Union and of the Treaty establishing the European Community; article 2. OJ, C 321 E, 29.12.2006, p. 1 - 331.

[15] Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides. OJ L 309/71, 24.11.2009, p. 71 - 86.

[16] Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration. OJ L 372 , 27.12.2006, p. 19 - 31.

[17] Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (Text with EEA relevance) OJ L 164, 25.6.2008, p. 19 - 40.

assessment of chemicals or products (examples of current product legislation are Chemicals (REACH), Biocides, Veterinary Medicines, Medicines, Feed additives, Sludge, Fertilizers, Genetic Modified Organisms, Dangerous Substances).

2.2. General protection goals in European pesticide legislation

Plant production is particularly important in the Community. The use of plant protection products is seen as one of the most important ways to protect plants and their products against harmful organisms, including weeds and of improving agricultural production. Against this background, the most relevant legislation for pesticides is the new **Regulation (EC) No 1107/2009 on plant protection products** which repeals Council Directives 79/117/EEC[18] and 91/414/EEC. In its Article 4.3 criteria for the approval of plant protection products (hereafter referred to as pesticides) are specified, of which those referring to the environment are quoted below (complementary criteria for the residues of pesticides are in article 4.2).

> *A plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements:*
> *[…]*
> *(b) it shall have no immediate or delayed harmful effect […] on groundwater;*
> *[…]*
> *(e) it shall have no unacceptable effects on the environment, having particular regard to the following considerations where the scientific methods accepted by the Authority to assess such effects are available:*
> > *(i) its fate and distribution in the environment, particularly contamination of surface waters, including estuarine and coastal waters, groundwater, air and soil taking into account locations distant from its use following long-range environmental transportation;*
> > *(ii) its impact on non-target species, including on the ongoing behaviour of those species;*
> > *(iii) its impact on biodiversity and the ecosystem;*

Regulation (EC) No 1107/2009 defines 'environment' in article 3(13):

> *"waters (including ground, surface, transitional, coastal and marine), sediment, soil, air, land, wild species of fauna and flora, and any interrelationship between them, and any relationship with other living organisms."*

and 'biodiversity' in article 3(29):

> *"variability among living organisms from all sources, including terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this variability may include diversity within species, between species and of ecosystems;"*

It should also be noted that Article 3(18) defines Good Plant Protection Practice (GPP) as:

> *"Practice whereby the treatments with plant protection products applied to given plants or plant products, in conformity with the conditions of their authorised uses, are selected, dosed*

[18] Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances. OJ L 33, 8.2.1979, p. 36 - 40.

and timed to ensure acceptable efficacy with the minimum quantity necessary, taking due account of local conditions and of the possibilities for cultural and biological control;"

From the definitions of environment and biodiversity as well as the provisions in article 4.3(e) it follows that the general protection goal is comprised of the following:

1. Soil, land
2. Air
3. Groundwater and transitional water
4. Surface water
5. Fresh water
6. Estuarine and coastal water
7. Marine water
8. Wild species of flora and fauna (in particular non-target species) including their diversity
9. Any interrelation amongst and between the things listed above (which seems to be covered again by the mentioning of the ecosystem) and other living organisms.

In other words, the general protection goals concern all terrestrial and aquatic ecosystems, regardless of their proximity to the points of emission of pesticides, including their relationships with other living organisms. "*Other living organisms*" seem to be those that are not classifiable as wild species of flora and fauna or as non-target organisms: e.g. target organisms, man, domestic species of flora and fauna, and taxonomically speaking, all other kingdoms (e.g. bacteria, fungi, yeasts). However, the definition of biodiversity includes all living organisms and it is here understood that the reference to flora and fauna is not intended in the strict taxonomical sense. This definition implies that the goal is to protect all species, in all habitats. When it comes to choosing protection goals for risk assessment and risk management in agricultural landscapes, however, trade offs between production and biodiversity need to be considered and not all biodiversity can be protected in every location all the time (see Section 3 for further discussion).

The Regulation (EC) No 1107/2009 reflects the principle of high level of protection of the Treaty in its preambles and articles (e.g. 1.1 and 4.3). A high level of protection is here transformed into:

1. *no unacceptable effects* on the environment (preambles 8, 10, 24; article 4.3) where it concerns plant protection products and
2. *no serious risk* to the environment where it concerns treated seeds (preambles 33 and 48; article 49).
3. The phrase (no serious risk as used for treated seeds) is also used in relation to emergency measures for approved substances (preamble 48) which means that a 'serious risk' equals 'unacceptable effects'.
4. Concerning groundwater, article 4.3 quotes *no immediate or delayed harmful effects* and Annex II (3.10) refers only to article 29(6) which itself refers to the Annex VI of the Directive 91/414/EEC. Groundwater takes a special position since it is both part of the environment and addressed separately from the environment. The use of plant protection products shall neither lead to 'unacceptable effects' on the groundwater (including its ecosystems according to the definition of the environment), nor to 'immediate or delayed harmful effects', as further addressed in the Uniform Principles, which means that 'immediate or delayed harmful effects' equals 'unacceptable effects'.
5. Finally, substances shall *not have endocrine disruptive properties that may cause adverse effects unless exposure of non-target organisms is negligible* (Annex II 3.8.2).

Regulation (EC) No 1107/2009 (Article 8) defines the data requirements on which risk assessments are based as those set out in the Annexes II and III to Directive 91/414/EEC, but subsequent amendments of these data requirements are possible according to Regulation (EC) No 1107/2009, Article 78.1.

The Regulation (EC) No 1107/2009 in its Article 4.3(e) (ii) specifies the 'ongoing behaviour of non-target species'. Although it is not defined what 'ongoing behaviour' is, the qualification makes clear that behaviour is a relevant protection goal, as are other impacts on non-target species (which could include individual mortality and population decline). It should be noted that the mentioning of 'ongoing behaviour' does not, in the legal sense, limit the assessment to that potential effect only. Annex II to the new Regulation provides several specifications to Article 4.3.

- Annex II 3.8.3 specifies "*acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour*"
- Annex II 3.8.2 specifies *adverse effects caused by endocrine disruption.*
- Annex II 3.8.1 refers to Directive 97/57/EC[19] (Annex VI to Directive 91/414/EEC) for further specifications. There, in the Specific Principles of Evaluation, for birds and other vertebrates, aquatic organisms, honey bees and for earthworms and other non-target soil macro-organisms it is stipulated: "evaluate the extent of the *short-term and long-term risk* to be expected". For beneficial arthropods the wording is *lethal and sublethal effects* and *activity*.

In the Regulation (EC) No 1107/2009 the article 29(6) refers to the Uniform Principles (Annex VI to Directive 91/414/EEC):

> *"Uniform principles for evaluation and authorisation of plant protection products shall contain the requirements set out in Annex VI to Directive 91/414/EEC and shall be laid down in Regulations adopted in accordance with the advisory procedure referred to in Article 79(2) without any substantial modifications."*

Annex VI of Directive 91/414/EEC has been adopted in Directive 97/57/EC. This Directive contains:

- General and Specific Principles of Evaluation;
- General Principles of Decision making;
- Specific Principles of Decision making.

In its introduction, point 1 re-iterates the high level of protection, stating:

> *"The principles developed in this Annex aim to ensure that evaluations and decisions with regard to authorization of plant protection products, …, results in the implementation of the requirements of Article 4 (1) (b), (c), (d) and (e) of this Directive by all the Member States at the high level of protection of human and animal health and the environment."*

Section 2.5.2. of the Specific Principles on Evaluation ("Impact on non-target species") lists in Points 2.5.2.1 to 2.5.2.6 specific principles for evaluation for different organisms groups. For every group, it is specified that:

[19] Council Directive 97/57/EC of 22 September 1997 establishing Annex VI to Directive 91/414/EEC concerning the placing of plant protection products on the market. OJ L 265, 27.9.1997, p. 87 - 109.

"This evaluation will take into consideration the following information:

> …
> *(iii) where relevant, other authorized uses of plant protection products in the area of envisaged use containing the same active substance or which give rise to the same residues;"*

For birds and other vertebrates, aquatic organisms, honey bees and for earthworms and other non-target soil macro-organisms it is stipulated to:

> *"evaluate the extent of the short-term and long-term risk to be expected"*

For beneficial arthropods it is stipulated to evaluate:

> *"lethal and sublethal effects on these organisms to be expected and the reduction in their activity".*

In the General Principles on Decision Making point 5 states:

> *"Since the evaluation is to be based on data concerning a limited number of representative species, Member States shall ensure that use of plant protection products does not have any long-term repercussions for the abundance and diversity of non-target species."*

The Specific Principles on Decision Making formulate hazard and risk based thresholds for the organism groups. They also specify an unless-clause that specifies "*no unacceptable impact*" or "*no unacceptable effects*" or "*not at risk*" when assessed "*under field conditions*". Directive 97/57/EC contains no specification of the qualification "*unacceptable*" for effects. Decision making criteria thus associate acceptability/unacceptability of effects with impacts/effects that could occur in the field – i.e. under realistic exposure conditions, as observed on multiplication (micro organisms), growth, development and behaviour within colonies (honeybees), at the population level specifically (earthworms, aquatic predatory species), and including the possibility for indirect effects at the food chain/community level (birds and other terrestrial vertebrates).

Additionally, the assessment of multiple stress by the use of multiple plant protection products, being applied at the same time (e.g., tank mixtures) or in sequence, seems to be required in order to prevent additive impact on the abundance and diversity of non-target species. This appears to be required by the above mentioned point 5 in the General Principles on Decision Making, which states "*Member States shall ensure that use of plant protection products does not have any long-term repercussions for the abundance and diversity of non-target species*" (note this refers to plant protection products in the plural and "use" in the singular, which implies they are being referred to collectively). This also may imply a need to define the spatial and temporal dimensions of use and hence of agro-ecological scenarios (including possible refuges).

Article 3(18) of Regulation (EC) No 1107/2009 defines Good Plant Protection Practice (GPP) as:

> *"Practice whereby the treatments with plant protection products applied to given plants or plant products, in conformity with the conditions of their authorised uses, are selected, dosed and timed to ensure acceptable efficacy with the minimum quantity necessary, taking due account of local conditions and of the possibilities for cultural and biological control;"*

Furthermore, the Regulation clarifies in Article 4 that the protection goals implied are to be met consistent with Good Plant Protection Practice (GPP) and having regard to Realistic Conditions of Use (RCoU). This juxtaposition (approval when the application is done under GPP and RCoU, meets the general protection goals) implies that definitions and/or assumptions of GPP and RcoU are basic for assessing the risk from use and emission of the pesticide.

The Panel recognises the importance of GPP and Good Agricultural Practice (GAP). Both the level of compliance with GPP and the (variation in) realistic conditions of use at the local scale are sources of uncertainty within the risk assessment approach, and depend on several factors:

- It is not possible to always and everywhere control the timing of application vs. the occurrence of the next rainfall event, or change in wind speed, overcast, and smoothness of the field.

- Operational conditions like investment in equipment or lack of (access to) information and training, lack of expertise or skills to make the correct decision or to execute the application correctly.

- Good plant protection practice (GPP) implies that plant protection products may be mixed during application (EPPO, 2003). Therefore GPP may lead to multiple stress due to plant protection product use which occurs simultaneously and consecutively in crop protection programs.

Therefore, in order to meet the protection goals consistent with good plant protection practice (GPP) and having regard to realistic conditions of use, the risk assessment methodology should account for some degree of non-compliance to label instructions, for simultaneous use of products, and for variability in local conditions. This can be accounted for in agricultural scenarios for pesticide programmes (that reflect GPP) and realistic conditions of use (that reflect ecological, landscape and climate aspects). These scenarios would picture a realistic worst case cropping system against which the use of the product according to the proposed label instructions is assessed.

Also of relevance is the new **Directive 2009/128/EC on the sustainable use of pesticides**, which establishes in each European Member State and after the authorisation phase a framework to achieve the sustainable use of pesticides. The targets may cover different areas of concern including protection of the environment. The objectives of the Directive should be achieved through the national transposition into law of plans for risk reduction and reduction of impacts of pesticide use on human health and the environment. Member States are required to adopt National Action Plans (NAP, Article 4) to set up their quantitative objectives, targets, measures and timetables to reduce risks and impacts of pesticide use on human health and the environment. The NAPs should be developed with the contribution of different stakeholders and end-user groups, and a variety of authorities and organizations including those endorsing the responsibility to protect the environment and human health, beside agronomical, social and economical sectors. The relation to protection goals discussed in this opinion is clearly stated in Article 12 requiring risk management measures in any treated areas used by the general public and vulnerable groups, in protected areas, and in agricultural treated areas. For these measures risk managers and decision makers are asked to take decisions based on the margin of safety assessed mainly per Pest Control Strategy at the scale of the farm and, possibly landscape/basin level.

2.3. General protection goals in other European environmental legislation

Other European legislation may also have particular relevance to the use and potential environmental distribution of pesticides. The **Directive 92/43/EEC (Habitat Directive)** details what is considered a ‘significant negative impact’ on animal and plant species of community interest in need of strict protection. In order to protect any legally protected species (Annex 2 of the Habitat Directive) it deals with site specific rather than generic risk assessment. The Habitat Directive states in article 12, point 4:

> *"Member States shall establish a system to monitor the incidental capture and killing of the animal species listed in Annex IV (a). In the light of the information gathered, Member States shall take further research or conservation measures as required to ensure that incidental capture and killing does not have a significant negative impact on the species concerned."*

The European Commission has formulated an integrated vision on soil protection in the **Thematic Strategy for Soil Protection (**EC, 2006a; EC, 2002a). The overall objective is the protection and sustainable use of soil. When soil acts as a receptor, action has to be taken at the source.

A definition of soil is given in the Commission's proposal for a Soil Framework Directive:

> *" [soil] forming the top layer of the earth's crust situated between the bedrock and the surface, excluding groundwater[…]."*.

The following functions are defined:

a) biomass production, including in agriculture and forestry;

b) storing, filtering and transforming nutrients, substances and water;

c) biodiversity pool, such as habitats, species and genes;

d) physical and cultural environment for humans and human activities;

e) source of raw materials;

f) acting as carbon pool;

g) archive of geological and archaeological heritage.

From the policy documents on soil quality described above, it is clear that the general European approach to soil is that of general protection of environmental, economic, social and cultural functions.

Among the other European legislations, perhaps the most relevant to the impact of plant protection products is the **Directive 2000/60/EC (Water Framework Directive, WFD)**. According to its preamble, this Directive aims at "*maintaining and improving the aquatic environment in the Community*". Member States should aim to achieve the objective of at least a "*good ecological status*" and a "*good chemical status*" by defining and implementing the necessary measures. Where good water status already exists, it should be maintained. The biological, hydromorphological and physico-chemical parameters that determine the ecological status are presented in Annex V to the Directive. For a good status the Directive 2000/60/EC (Water Framework Directive) requires that Environmental Quality Standards (EQSs) are met, without prejudice to Directive 91/414/EC (Annex V, section 1.2). Within the context of the Directive 2000/60/EC (Water Framework Directive), EQSs are thus one of the instruments to evaluate water quality. They serve as a benchmark to decide whether or not specific measures are required. The EQSs are compared with data from chemical monitoring programmes and two types of EQSs are distinguished to cover both long-term and short-term exposure to a chemical:

i. an annual average environmental quality standard (AA-EQS) to protect against the occurrence of prolonged exposure, and

ii. a maximum acceptable concentration environmental quality standard (MAC-EQS) to protect against possible effects from short term concentration peaks.

According to the Directive, EQSs for priority (hazardous) substances (including some pesticides) should always be derived. The geographical unit under consideration in the Directive 2000/60/EC

(Water Framework Directive) is the river basin, which is defined as "*the area of land from which all surface run-off flows through a sequence of streams, rivers and, possibly, lakes into the sea at a single river mouth, estuary or delta*". Within each river basin, the water bodies should be identified for which the Directive 2000/60/EC (Water Framework Directive) requirements (including chemical and ecological status) should be reported to the EC. These reports not only concern the priority (hazardous) substances but also additional substances (including several pesticides) that potentially are of concern in a specific river basin.

According to the Technical Guidance Document currently underlying the Directive 2000/60/EC (Water Framework Directive) (EC, 2003), it is generally accepted that protection of the most sensitive species will protect structure, and hence function. It is assumed that:

- ecosystem sensitivity depends on the most sensitive species, and
- protecting ecosystem structure protects ecosystem function.

The Water Framework Directive 2000/60/EC, Directive 2006/118/EC on the protection of groundwater against pollution and deterioration, Directive 91/676/EEC[20] concerning the protection of waters against pollution caused by nitrates from agricultural sources, Directive 99/31/EC[21] on the landfill of waste, as well as the proposed Soil Framework Directive (EC, 2006a; EC, 2006b) provide means to protect groundwater aquifers from pollution and deterioration. The legislation intends to safeguard groundwater resources while maintaining important land-use such as agriculture, forestry, urban development and industry. In Directive 2006/118/EC (ground water directive), maximum limits of pollutant concentrations have been set for nitrate and pesticides in groundwater bodies. Actions must be taken i) not to exceed these limits, ii) reverse trends in pollution iii) prevent completely emission of hazardous pollutants. The criteria set should provide groundwater for human consumption as well as for ecosystems depending on groundwater.

In Annex I of the Directive 2006/118/EC (ground water directive), limit values have been set for single pesticides and for the total amounts (sum) of pesticides or nitrates. These values should not be exceeded. For some pesticides also environmental quality standards (EQS) have been set for surface waters as required in the Water Framework Directive. These include limits for single pesticides.

Additionally, **Directive 2008/56/EC (Marine Strategy Framework Directive)** establishes a framework for marine environmental policy. European Member States shall take the necessary measures to achieve or maintain good environmental status in the marine environment by the year 2020 at the latest, including the prevention and reduction of pollution inputs in the marine environment, so as to ensure that there are no significant impacts on or risks to marine biodiversity, marine ecosystems, human health or legitimate uses of the sea. Pollution includes in this context direct or indirect introduction of substances (e.g. pesticides) which results or is likely to result in deleterious effects in the marine environment, as a result of human activity and impairing, in general terms, the sustainable use of marine goods and services.

[20] Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources. OJ L 375 , 31.12.1991 p. 1 - 8.

[21] Council Directive 99/31/EC of 26 April 1999 on the landfill of waste. OJ L 182 , 16.07.1999 p. 1 - 19.

2.4. Conclusion

The Panel concludes that the EU *acquis communautaire* has described general protection goals, but clear definitions on specific protection goals are lacking, and there is variation across the different regulations and directives that may be relevant to the use of plant protection products. The protection goals are often very broadly described (i.e. general protection goals) by *unacceptable effects*, *risk*, *serious risk*, *adverse effects*, *harmful effects* or *long-term repercussions*. The current EU plant protection product legislation does not define these qualifications any further nor does it define the level of certainty implied by the phrases such as *clearly establish*, *shall have*, *ensure*, *not expected*, or *demonstrates*.

In particular, clarifications are needed to define specific protection goals with respect to the following issues:

Ecological, temporal and spatial scales:

The specific protection goals should address terrestrial and aquatic ecosystems and take into account long-range environmental transport to locations distant from where the plant protection products are applied. The risks of long-range transport of pesticides are explicitly included, but no limitations are set on the spatial and temporal scale of the risk assessment. Both short-term and long term risks are in scope.

In-crop versus off-crop situation:

No clear distinction is made between (and hence no restriction to) in-crop or off-crop risk assessment (see Figure 2); but a distinction is made between target and not-target species and between non-target wild species and other living organisms. Although from a legal point of view a distinction between in-crop and off-crop risk assessment for non-target organisms is not made, it is considered practical to make this distinction in the risk assessment because of differences in the socio-economic and ecological functions of in-crop and off-crop areas. As a consequence, the PPR-Panel defines in-crop as the area where a crop is grown, which could be rather homogeneous showing natural spatial variability but no systematic spatial variability (e.g. cereals); or showing a systematic spatial heterogeneity (e.g. crops planted in rows, orchards; see also EFSA, 2009) . Off-crop is defined as the area outside the edges of the area where the crop is grown. See further details on Sections 3.2 and 3.3).

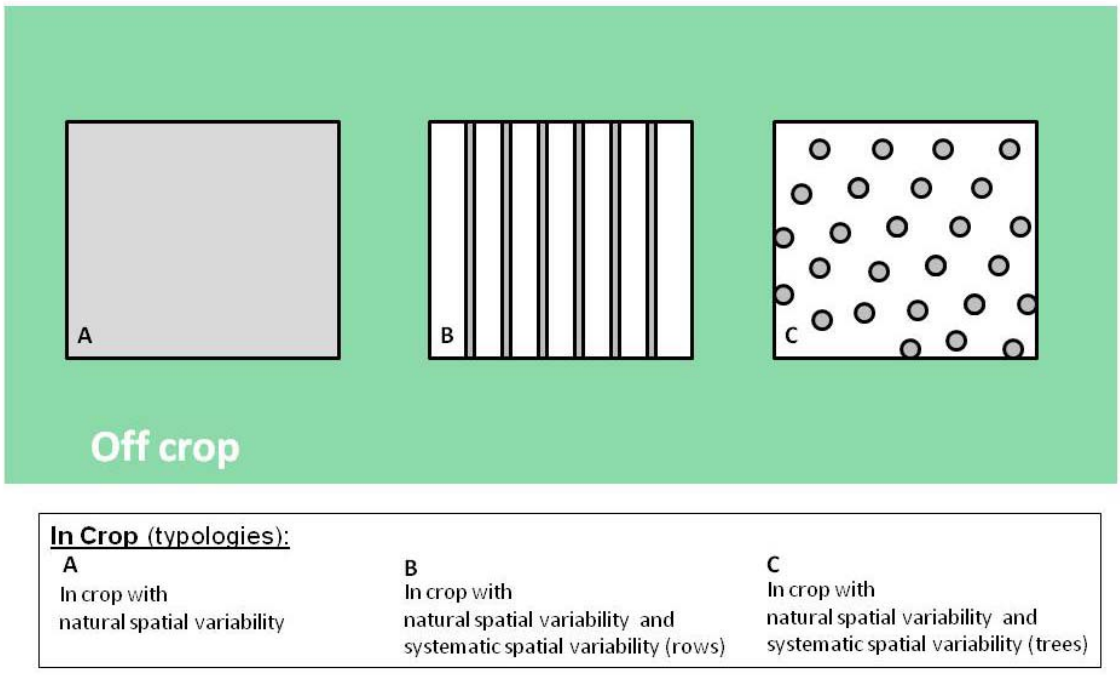

Figure 2 In-crop and off-crop areas as defined in the context of this Opinion.

Multiple stress:

Multiple stress by the use of multiple plant protection products, being applied at the same time (e.g., tank mixtures) or in sequence, should be assessed to identify 'similar residues' in the area of envisaged use. Multiple stress from pesticides should also be considered to prevent additive impact on the abundance and diversity of non-target species. This appears to be required by point 5 in the General Principles on Decision Making, which states "*Member States shall ensure that use of plant protection products does not have any long-term repercussions for the abundance and diversity of non-target species*" (note this refers to plant protection products in the plural and "does" in the singular, which implies that their use is being referred to collectively). This may imply that the risk assessment of individual plant protection products needs to be more conservative for products used in crops with an intensive multiple plant protection product use than for crops with low plant protection product input. It also may imply a need to define the spatial and temporal dimensions of use and hence of agro-ecological scenarios (including possible refuges), which is currently not done. Consequently, the tools (that will be) developed under the umbrella of both the Plant Protection Product Regulation (1107/2009) and the Sustainable Use of Pesticides Directive (2009/128/EC) are required to solve the multiple stress problem.

Uncertainties:

Annex II of the new Regulation (EC) No 1107/2009 states that the assessment should take into account the "uncertainty of the data". This implies that explicit consideration of uncertainty is appropriate, both by the PPR-Panel when developing the revised guidance documents, and during the assessment of specific risks. One option for addressing this is to use a tabular approach to documenting and evaluating uncertainties, as in the PPR opinion on risk assessment for birds and mammals (EFSA, 2008). Also, in order to meet the protection goals consistent with good plant protection practice (GPP) and having regard to realistic conditions of use, the risk assessment methodology should account for some degree of non-compliance to label instructions, next to simultaneous use of products, and for variability in local conditions.

The legislation requires a high level of certainty that unacceptable effects will not occur, as indicated by the use in many places in the texts of phrases such as: *clearly establish*, *shall have*, *do not have any*, *ensure*, or *demonstrates*. This has implications for the degree of certainty or strength of evidence required (especially in higher tier assessments), and for the degree of conservatism required (especially in lower tier assessments).

In the light of the information reviewed above, the Panel considers it necessary to derive specific protection goal options in consultation with risk managers and stakeholders in order to develop appropriate risk assessment methodology to apply to plant protection products. The concepts and process used to derive these specific protection goals are explained in the following sections.

3. How to develop specific protection goals for the environmental risk assessment (ERA) of pesticides

In the previous section, general protection goals defined in the EU legislation concerning protection of the environment, in particular against effects of pesticides, were summarized. There the Panel concluded that, in order to implement these general protection goals within a risk assessment methodology, it is necessary to define specific protection goals (SPGs) that identify and justify the attributes of the specific environmental entities that have to be protected. These SPGs will then be used as basis for developing or updating risk assessment schemes and methods.

For defining SPGs the Panel followed a procedure with the steps shown in Box 1. This opinion has its focus on steps 1 to 4. Step 5 needs to be addressed at the start of the process of updating the ecotoxicological GDs, while Step 6 is the core of the GDs to be developed. Introductions to steps 5 and 6 are given in Section 4.

Box 1 Stepwise approach adopted by the PPR Panel for developing the proposed specific protection goals and the revision of the Ecotoxicology GDs

1) Choose the ecosystem services as an overarching concept for deriving specific protection goals (see Section 3.1.1).

2) Identify the ecosystem services relevant in the European agricultural landscape from Table 1 (Section 3.2). Identify those ecosystem services that are most likely to be impacted by pesticides.

3) Identify the key drivers through which impacts on relevant ecosystem services could occur (key drivers are defined as the major taxonomic or functional groups that provide the ecosystem service)

The results of steps 1 to 3 are shown in **Table 2** (Section 3.2).

4) Specify dimensions of the specific protection goal options for each ecosystem service and key driver combination (Section 3.3)

    a) Take the key drivers for relevant ecosystem services from Table 2.

    b) Identify the tolerable effect range on each of the dimensions for each key driver under consideration, taking into account the relevant requirements from the legislation.

    c) Record the emerging definition of the specific protection goal in narrative form. Ensure that the emerging definition is potentially capable of being either measured in laboratory or field studies, or estimated by modelling.

    d) Consider the extent to which a specific protection goal for a certain key driver may be "covered" by those for other key drivers. Focus attention on the most important key drivers and minimise the number of protection goals that need to be specified (and subsequently assessed)*.

The result of step 4 is shown in **Table 3**.

Further step in the problem formulation phase with risk managers: *Identify together with risk managers the options for each specific protection goal that needs to be addressed in the Guidance Documents*

5) Identify and focus on "vulnerable" representatives for each key driver (Section 4.1.1)

6) Develop protective risk assessment schemes (based on the SPGs, the vulnerable representatives, appropriate and already available testing endpoints and species, etc.) (Section 4.1.2)

* ***Example****: the specific protection goal for fish may cover the protection of the aquatic stages of amphibians or the specific protection goal for honey bees may cover the protection of other pollinators like bumblebees*

3.1. Step 1. Choose a suitable concept for deriving specific protection goals

The general protection goals defined in EU pesticide legislation imply the protection of all species in all habitats (Section 2.2). However, when defining SPGs for risk assessment and risk management in agricultural landscapes it is necessary to consider trade-offs between, for example, production and biodiversity conservation and to acknowledge that not all biodiversity can be protected in every location all the time. The Panel identified the need for a conceptual framework that could be used to identify key drivers and to prepare the basis for taking decisions on what, where, and at which scale to protect the different key drivers. The ecosystem services concept was chosen for this purpose as it encompasses all environmental compartments (aquatic and terrestrial systems) and covers the potential consequences of different human uses of ecosystems (e.g. production and conservation).

3.1.1. What is the ecosystem services concept?

Ecosystem services are the benefits humans receive from ecosystems and include the production of goods (i.e. provisioning services e.g. food production), life support processes (i.e. regulating and supporting services) and life fulfilling conditions (i.e. cultural services) (Figure 3, Daily et al., 2000). The concept illustrates the dependency of mankind on ecosystems (see Figure 3).

Depending on the scope and application of the ecosystem services concept, many classifications and interpretations exist (e.g. Daily 1997; De Groot et al., 2002; Millennium Ecosystem Assessment, 2005; Vandewalle et al., 2008). In general, four categories of ecosystem services are distinguished: provisioning, regulating, cultural and supporting services (Table 1). Supporting services underpin all other services. The descriptions of ecosystem services show that a complete set of ecosystem services covers, in principle, all species and all environmental compartments in ecosystems.

An ecosystem can provide multiple services at the same time and place, although human society, operating through for example land users and water managers, tends to optimise certain ecosystem services in certain places. Ecosystem services are highly interconnected and interdependent and, therefore, the management or optimisation of one service may have negative consequences for others (Rodriquez et al., 2006). Optimisation of particular ecosystem services is considered to be more sustainable when the trade off against other services is limited as much as possible. Guidelines for the sustainable use of ecosystem services and for balancing benefits of optimising one service against the effects this may have on other services, are given below:

- The use of an ecosystem service should not lead to its exhaustion or destruction locally
- In optimising a specific ecosystem service, other services should as far as possible remain intact.
- The recovery capacity of the ecosystem services should remain intact; this means that impacted services must be able to return to the normal operating range.
- All ecosystem services must have the requisite space. This means that all ecosystem services are needed to a certain extent which limits the scale at which optimizing of certain services can occur. For instance, food production can not be optimized everywhere since space for other services is also needed and it is not possible to optimise all ecosystem services at the same place.
- The exploitation of the ecosystem services must not harm its surroundings, e.g. other contiguous ecosystems.

It has also been recognised that the original characteristics of an ecosystem are crucially important for the success of the optimisation of an ecosystem service (TCB, 2003). For instance, agriculture on poor

soils needs more input in the form of nutrients, organic matter and plant protection products compared with agriculture on richer soils.

Table 1: Ecosystem services categorised according to the MEA (Millennium Ecosystem Assessment, 2005)

MEA category	Ecosystem service
Provisioning services	Food
	Fiber
	Genetic resources
	Biochemicals, natural medicines, pharmaceuticals
	Ornamental resources
	Fresh water
Regulatory services	Air quality regulation
	Climate regulation
	Water regulation
	Erosion regulation
	Water purification and waste treatment
	Disease regulation
	Pest regulation
	Pollination
	Natural hazard regulation
Cultural services	Cultural diversity
	Spiritual and religious values
	Knowledge systems
	Educational values
	Inspiration
	Aesthetic values
	Social relations
	Sense of place
	Cultural heritage values
	Recreation and ecotourism
Supporting services	Soil formation
	Photosynthesis
	Primary production
	Nutrient cycling
	Water cycling

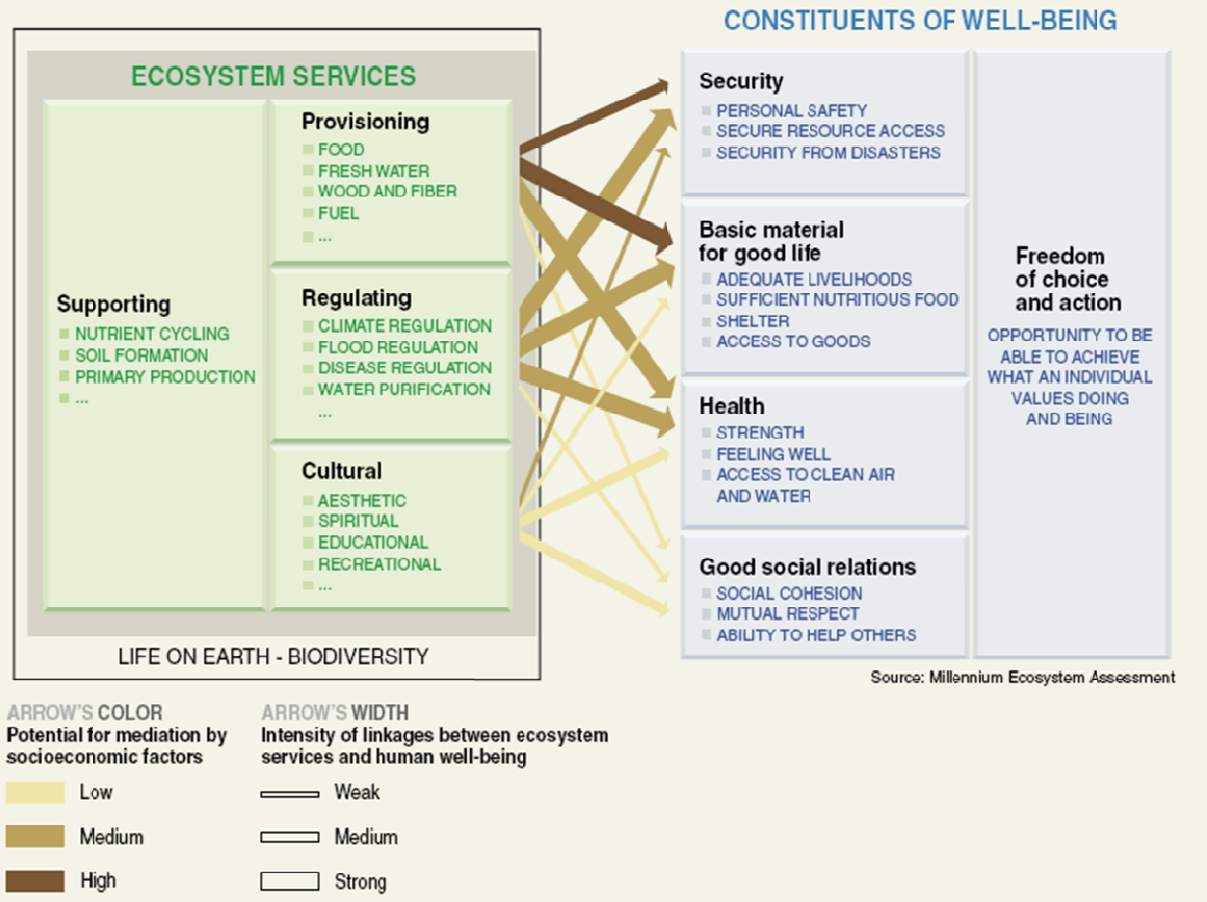

Figure 3 Relationship between ecosystem services and constituents of well-being (source: Millennium Ecosystem Assessment, 2005).

3.1.2. Why use the ecosystem services concept for developing specific protection goals?

Increased human population size and economic development have led to a rapid change in the composition, structure and functioning of ecosystems so that their capacity to provide necessary services has been either compromised or overwhelmed (Foley et al., 2005; Millennium Ecosystem Assessment, 2005). The global population is forecast to increase to 9 billion by 2050 resulting in a projected doubling in global food demand, posing major challenges for the sustainability of food production and the other services provided by terrestrial and aquatic ecosystems (Tilman et al., 2002). It has been argued that the causal relationship between inadequate ecosystem services and low levels of human wellbeing is bidirectional and reinforcing (Butler and Oluoch-Kosura, 2006) and that the ecosystem services approach provides a vehicle for integrating social and environmental sustainability (Hodgson et al., 2007). Against this background of increasing global food demand and decreasing availability of high quality agricultural land, it is evident that the delivery of ecosystem services should be protected.

As stated above, it is recognized that the ideal situation when optimizing one ecosystem service over others is to reduce the effects on the other services as much as possible. However, in most cases some potential effects need to be considered. The acceptance or otherwise of these effect requires decisions at social, political, and risk management levels. The ecosystem services concept can aid efficient communication between the different stakeholder groups, in particular when defining specific protection goals: an advantage recognized by the participants of the EFSA stakeholder workshop in

April 2010 (EFSA, 2010b). The issue of trade offs in relationship to specific protection goals will be further addressed in section 4.2.

The ecosystem services concept can be applied to all ecosystems, used across environmental compartments and applied at a range of spatial and temporal scales. Additionally, already "formally fixed" protection goals, like for instance legal requirements to protect particular species could be included in the ecosystem services concept by considering these entities to be protected under cultural ecosystem services. A recent study comparing conservation projects that focus on promoting only biodiversity with projects that focus on promoting ecosystem services, indicated that ecosystem service projects are as effective at addressing threats to biodiversity as their biodiversity counterparts (Goldman & Tallis, 2009). Furthermore, it has been argued that the ecosystem services concept may lead to more integrative approaches in environmental policies and could facilitate addressing these policies at different spatial and temporal scales (Van Wensem, 2009).

3.1.3. Current use of the ecosystem services concept in the context of environmental policy

The ecosystem services concept is widely recognised as a useful framework for policy makers, as stated in the Millennium Ecosystem Assessment (MEA, 2005), and The Economics of Ecosystems and Biodiversity (TEEB) report (EC, 2008). The MEA considered the current status and trends in services provided by terrestrial, marine and freshwater ecosystems, including cultivated systems. The concept is gaining prominence in European environmental policy making (e.g. Ecosystem Services Special Issue, *Science for Environmental Policy* news alert, Issue 20 May 2010) and is being integrated in the latest developments of European policy (e.g. "Halting the loss of biodiversity by 2010 and beyond" (EC, 2006c)). Furthermore, the proposed legal implications of the European Soil Strategy, the draft Soil Framework Directive (EC, 2006b), aim at establishing "*a framework for the protection of soil, its sustainable use and the preservation and, where appropriate, sustainable restoration of the capacity of soil to perform as many as possible of [….] environmental, economic, social, scientific and cultural functions"*. Given the definition of ecosystem services, the functions stated in the draft Soil Framework Directive may be considered as ecosystem services.

The ecosystem services concept has also been discussed– and adopted for different purposes – by environmental bodies such as the United States Environmental Protection Agency, Environment Canada, United Nations Environment Programme and The Organisation for Economic Co-operation and Development (http://www.epa.gov/ecology/index.htm, http://www.cbin.ec.gc.ca/jib-ibd/ecosystemiques-ecosystem.cfm?lang=eng, http://www.oecd.org/dataoecd/16/35/ 38331999.pdf, http://www.ipbes.net/). For example the science advisory board of the USA-EPA published a report on valuing the protection of ecological systems and services (USA-EPA, 2009). In this report it is stated that the federal Insecticide, Fungicide and Rodenticide Act is a policy context were valuation on basis of ecosystem services is required.

Further, the present data requirements under Regulation (EC) No 1107/2009 and the linked environmental risk assessment procedure for plant protection products are implicitly based on the protection of ecosystem services. Examples include: soil non target invertebrates and litter decomposition (ecosystem services: soil formation, nutrient cycling), beneficial arthropods (ecosystem service: pest control) and honey bees (ecosystem service: pollination). The range of ecosystem services provided by agricultural landscapes is considered further in section 3.2.

3.1.4. The role of biodiversity in the context of ecosystem services

The new plant protection product Regulation (EC) No 1107/2009 states the aim to not have unacceptable effects on biodiversity as one of the general protection goals. The definition of biodiversity adopted in Regulation (EC) No 1107/2009 includes variation in genes, species and

ecosystems, although protection of biodiversity is often associated with protecting areas with a high ecological value or protecting specific (rare, threatened or otherwise highly valued) species.

Biodiversity is mostly seen as the provider of ecosystem services (see Altieri, 1999; Munns Jr et al., 2009 and references cited therein) and is addressed specifically under the ecosystem services 'genetic resources' (in general terms) and 'cultural services' (e.g. rare or highly valued species). When it comes to choosing protection goals for risk assessment and management of cultivated areas, it becomes clear that trade offs between ecosystem services need to be accepted and that not all biodiversity can be protected everywhere. The ecosystem services concept allows us to identify what to protect, what the trade offs are and provides the basis for taking decisions on what, where, and at which scale to protect.

Despite the necessity of accepting trade offs between, for example, production and biodiversity conservation, it has been recognised that cultivated areas within the agricultural landscape, are important for biodiversity (e.g. Davies et al., 2008). In many countries, the relative area of land allocated to agricultural landscapes is large compared to that of other landscape elements, in which threats other than plant protection product use may be present. The projected rise in global demand for agricultural products has led some authors to argue that the traditional approach of segregating agricultural production from areas managed for biodiversity conservation should be replaced by more integrated 'ecoagriculture' landscapes. Ecoagriculture landscapes are defined as mosaics of native habitat and agricultural production in which biodiversity is conserved within productive agricultural landscapes to generate benefits for production, biodiversity and local people (Scherr and McNeely, 2008). The guidelines given in Section 3.1.1 (page 21) indicate that combining multiple ecosystem services in the same landscape element contributes to the sustainability of the use of ecosystem services.

Biotic and abiotic processes and the ecosystem functions they drive, underpin the delivery of ecosystem services. Biodiversity is essential for ecosystem functioning, but the precise relationship between them is an area of considerable scientific debate (Loreau, et al., 2002; Naeem et al., 2009). Some species (i.e. keystone species and ecosystem engineers) contribute to ecosystem functioning in ways that are unique and hence their addition or loss from a community causes detectable changes in functioning. Most species, however, are at least partly substitutable for the ecosystem functioning and their loss can be compensated for by other species. The rivet hypothesis (Ehrlich and Ehrlich, 1981) assumes that communities are comprised of specialised species with limited capacity to compensate for each other, the loss of each additional species having an increasingly critical effect (cf. rivets in an airplane wing) (Lawton, 1994). The redundancy hypothesis (Walker, 1992), however, assumes a greater degree of functional redundancy in that more than one species plays a given role in a community and can therefore compensate if some species are lost. For example, if species sensitive to a particular stressor suffer a decrease in population density, they could be replaced by other resistant species having a similar function, thereby maintaining the delivery of the service. In communities with high functional redundancy, functional diversity (functional dissimilarity in the community) is more important than taxonomic diversity (species richness) in the delivery of ecosystem services (overview in Munns Jr et al., 2009). However, functional redundancy may be exhausted if too many species are lost (e.g. Schäfer et al., 2007) and taxonomic diversity within functional groups plays a crucial role in fluctuating environments by enabling ecosystems to cope with adverse effects originating from different stressors (i.e. insurance hypothesis, Yachi and Loreau, 1999). It should also be noted that species typically contribute to more than one service in an ecosystem, and that the degrees of functional redundancy may vary for different services.

3.2. Step 2 and 3: Identify ecosystem services in agricultural landscapes affected by plant protection products and their key drivers (i.e. representative taxa or functional groups)

Agricultural landscapes provide a number of important ecosystem services, which support the production of food and other raw materials as well as contributing to regulatory (e.g. water regulation and climate regulation) and cultural (e.g. aesthetic value and recreation) services (Zhang et al., 2007; Sandhu et al 2010). In terms of Table 1 the most important services for production are: provision of food, fibre, fuel, genetic resources, biochemicals & natural medicines, and the regulation of pollination, seed dispersal, pests, diseases & water, as well as the underlying supporting services. Due to the large relative area of agricultural landscapes there is a societal demand for other services to be delivered by them. Regulation of climate, of air quality, and of erosion, water purification, as well as cultural services such as recreation and ecotourism, cultural heritage and aesthetic values are examples of these. With good management of agricultural land the number of services that may be provided by the land (including water regulation, climate regulation and habitat for many species) could be much higher than it often is.

Plant protection products are applied primarily in fields where crops are grown, and can cause effects in adjacent elements in the agricultural fields, such as field margins, hedges, non-crop patches (small woods), groundwater, ditches, streams and lakes, also in areas far away due to long range transport of pesticides (Figure 4). The adjacent landscape elements also provide partly different, ecosystem services. It should be kept in mind that taxa related to important ecosystem services are not (always) present all the time in a landscape element, but may originate from other areas. Examples are pest predator species or natural pollinators that colonize crop fields from field margins, hedgerows and natural patches. These elements are also important resources for recovery of certain species. Therefore the same approach for choosing protection goals may be used for other elements in the agricultural landscape, besides the crop fields. When doing this the basic rules for balancing the trade offs caused by plant protection product use (in order to optimise crop production) against the benefits we receive from other ecosystem services apply. Again, what counts is the protection of all ecosystem services though not all at the same time and at the same place.

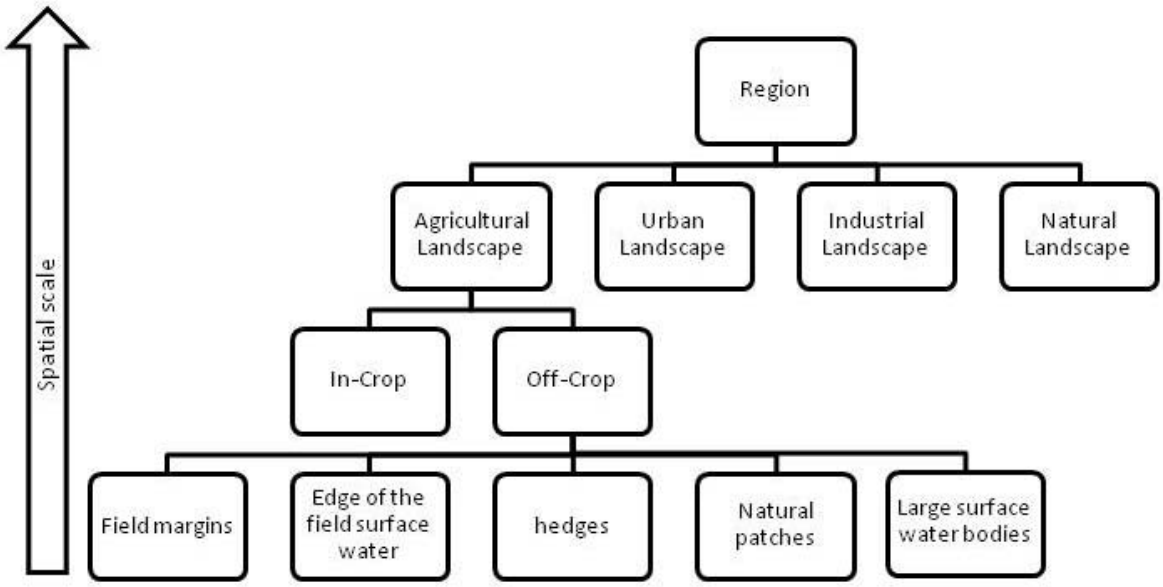

Figure 4: Schematic representation of landscapes and their elements

Based on the above considerations, the Panel has assessed the importance of ecosystem services in the agricultural landscape, and the likelihood that these ecosystem services will be affected by plant protection products. In order to derive specific protection goals the Panel identified key drivers for the affected ecosystem services. The assessment of affected ecosystem services and the identification of key drivers was based on the expertise of the Panel and its working group members. The results of these two steps are given in Table 2 at the end of this Section. The most important ecosystem services in agricultural landscapes which are potentially affected by pesticides are listed below:

Ecosystem Service category	In crop areas	Off crop areas
Provisioning	Food Fibre & fuel	Food Genetic resources Fresh water
Regulating	Pollination Pest & disease regulation	Pollination Pest & disease regulation Water regulation Erosion regulation Water purification
Cultural	Education & inspiration Recreation & ecotourism Cultural heritage	Education & Inspiration Recreation & ecotourism Cultural heritage Aesthetic value
Supporting	Primary production Photosynthesis	Primary production Photosynthesis Habitat provision Soil formation and retention Nutrient cycling Water cycling

Table 2: Ecosystem services in different spatial areas, their importance in these areas (+ small; ++ intermediate; +++ large), and the potential impact of pesticides (due to normal agricultural use) on them. The ecosystem service list is based on the Millennium Ecosystem Assessment Report (2005), but some categories are added, adapted or deleted.

Ecosystem service		In crop	Off Crop				Strongly impacted by pesticides (direct or indirect effects via trophic interactions)	Potentially impacted taxa
			Small edge of field margins	More remote terrestrial areas (e.g. hedges, natural areas)	Small edge-of-field surface waters (agricultural landscapes)	Large surface waters + wetlands + marine ecosystems		
Provisioning services	Food	+++	+	++	+	+++	Yes	crop species, cattle, small game and other consumable vertebrates, fungi and berries (wild fruits), consumable fish, crayfish, molluscs, algae
	Fibre & fuel	+++	+	++	+	++	Yes	crop plants (fibres/biofuel), trees (wood/biofuel), emergent macrophytes (thatched roofs), aquatic primary producers and peat (biofuel)
	Energy (hydroelectric and cooling water)				+	+++	No	fouling organisms
	Transport (waterways, e.g. boat traffic)				+	+++	No	fouling organisms
	Genetic resources/ biodiversity	++	++	+++	++	+++	Yes	all species
	Biochemical/ natural medicines	++	+	++	+	+	No	organisms used for medicinal or personal care products
	Ornamental resources	++	++	++	++	++	No	ornamental species and landscape elements
	Fresh water	+	++	+++	+++	+++	Yes	microorgansims, algae, etc

Ecosystem service		In crop	Off Crop				Strongly impacted by pesticides (direct or indirect effects via trophic interactions)	Potentially impacted taxa
			Small edge of field margins	More remote terrestrial areas (e.g. hedges, natural areas)	Small edge-of-field surface waters (agricultural landscapes)	Large surface waters + wetlands + marine ecosystems		
Regulatory services (beneficial regulations)	Pollination	+++	+++	+++	+	+	Yes	bees and other pollinator species (particularly insects)
	Seed/propagule dispersal	+	++	++	++	++	Yes	insects, birds, mammals, fish and water
	Pest & disease regulation	+++	+++	+++	+++	+++	Yes	non target arthropods (beneficials, natural enemies), invertebrate and vertebrate predators and fungal species
	Climate regulation	++	+	+++	+	+++	No	Several species (wild and domestic)
	Air quality regulation	++	+	+++		+++	No	plants
	Water regulation (quantitative aspects)	++	++ (acting as buffer zones)	+++ (acting as buffer zones)	+++	+++	Yes	plants, micro-organisms, soil fauna and beavers (dams)
	Erosion regulation		++	+++	+	++	Yes	rooted plants soil fauna (ecosystem engineers)
	Natural hazard regulation (other than water regulation, e.g. avalanches and landslides)	+	+	+++	?	?	No	rooted plants (shrubs and trees)
	Invasion resistance		+	++	+	++	Yes	autochthonous species with a similar niche than invasive species
	Water purification/soil remediation/waste treatment	+	++	++	+++	+++	Yes	plants, fauna, macrofauna bacteria and fungi

Ecosystem service		In crop	Off Crop				Strongly impacted by pesticides (direct or indirect effects via trophic interactions)	Potentially impacted taxa
			Small edge of field margins	More remote terrestrial areas (e.g. hedges, natural areas)	Small edge-of-field surface waters (agricultural landscapes)	Large surface waters + wetlands + marine ecosystems		
Cultural services	Spiritual and religious values	++	++	++	++	++	Yes	all species
	Education and inspiration	+++	+++	+++	+++	+++	Yes	all species
	Recreation and ecotourism	++	++	+++	++	+++	Yes	fish (sport fishing), attractive plants and vegetation, vertebrates (bird watching, hunting) and attractive invertebrates
	Cultural heritage	+ to+++ (in traditional landscapes)	+ to +++ (in traditional landscapes)	+++	+++	+++	Yes	preservation of structures constructed and/or modified by man and their typical biota
	Aesthetic values	++	++	+++	++	+++	Yes	all species, in particular plants, vertebrates, attractive invertebrates and red list species
	Sense of place	++	++	++	++	++	No	trees, patches of vegetation and ecosystems as landscape features

Ecosystem service		In crop	Off Crop				Strongly impacted by pesticides (direct or indirect effects via trophic interactions)	Potentially impacted taxa
			Small edge of field margins	More remote terrestrial areas (e.g. hedges, natural areas)	Small edge-of-field surface waters (agricultural landscapes)	Large surface waters + wetlands + marine ecosystems		
Supporting services (to produce other ESS)	Primary production	+++	+++	+++	+++	+++	Yes	algae and vascular plants
	Photosysthesis	+++	+++	+++	+++	+++	Yes	algae and vascular plants
	Provision of habitat	++	+++	+++	+++	+++	Yes	ecosystem engineers (e.g. beavers, earthworms, plants) and larger plants and animals that provide surfaces for periphytic organisms (e.g. shells of mussels)
	Soil formation and retention	++	+++	+++	+	++	Yes	soil fauna (mainly ecosystem engineers e.g. earthworms, ants) plants (e.g. organic matter and peat formation)
	Nutrient cycling	++	+++	+++	+++	+++	Yes	microorganisms, primary producers, grazers, detritivores, consumers, predators
	Water cycling	++	+++	+++	+++	+++	Yes	plants and terrestrial and aquatic ecosystems

3.3. Step 4: Identify specific protection goal options in terms of dimensions for each of the key drivers

3.3.1. The process

The Panel proposes the systematic formulation of specific protection goal (SPG) options for each of the key driver/ecosystem services combinations that may be affected by pesticides as identified in the previous steps (see Table 2). In this process the organism groups that are already requested under the data requirements of Regulation (EC) No 1107/2009 and Directive 91/414/EEC are considered and particular attention is given to organism groups which are, so far, not included in the standard data requirements of the European legislation.

After the process of deriving SPGs for each key driver /ecosystem service combination, those combinations leading to similar SPGs have been pooled. The results of this work are summarized in Table 3 (pooled table) in the end of this Section.

Based on the summarised data in Table 3, the PPR Panel suggests defining SPGs for 7 key drivers: microbes, algae, non-target vascular plants, aquatic invertebrates, terrestrial non-target arthropods (including honey bees), terrestrial non-arthropod invertebrates and vertebrates (covering fish, amphibians, reptiles, birds and mammals). Thus, the key drivers for SPGs that the PPR-Panel derived on the basis of the data requirements in European PPP regulation and the ecosystem services concept do not deviate substantially from the current taxonomic groups used in European ERA procedures for plant protection products. It is important to note that some ecosystem services such as genetic resources (biodiversity), education & inspiration and aesthetic value apply to all these taxonomic groups.

For each of the 7 key drivers identified, SPGs have been formulated on the basis of the criteria and considerations described below.

The SPGs are recognised as having a multi-dimensional nature. They must be expressed at a level of biological organisation (e.g. individuals, populations, functional groups, ecosystems) that is capable of being addressed by a practical regulatory risk assessment procedure using the current state of the science. For example, it would not be useful to express a SPG at a biological level that either is not practical to measure under realistic conditions, e.g. semi-field or field, or cannot be estimated with reasonable certainty by modelling. In addition, the SPG needs to be specified in terms of temporal and spatial scales that are precise enough to be assessed. Finally, the legislation includes a requirement for a high degree of certainty that effects of concern will be prevented (Section 2). This requires specifying the following dimensions or aspects of the SPGs (see also Figure 5):

- The **ecological entity** (level of biological organisation) of the key driver that is to be protected (e.g. individual birds, populations of earthworms).

- The **attribute(s) or characteristic(s)** of that entity that must be protected such as behaviour, survival, reproduction/growth, population density, processes (e.g. primary productivity, grazing efficiency, nutrient cycling) and biodiversity.

- The **magnitude of effect** that can be tolerated for the attributes to be measured (biological scale), which may include decreases and increases due to indirect effects.

- The **temporal scale of effect** that can be tolerated for the attributes to be measured in terms of duration of the effect, frequency of effects, and interval between effects (within and across years).

- The **spatial scale of the effect**, i.e. maximum area over which an effect exceeding the critical level can be tolerated in terms of the distance from the site of application where the effect can be observed and the spatial configuration and extent of affected sites in the landscape.

- The **degree of certainty** required that the effects will not exceed the specified levels.

These dimensions are likely to be interdependent: e.g. a magnitude of effect that is acceptable over a short time scale may not be acceptable if it continues over a long time scale, or small effects on population density could be allowed at a local scale for a medium period of time, as long as on a regional scale the population is not affected (Figure 6). The formulation of the SPGs needs to consider, therefore, the scales at which they should be applied, and this relates both to the effects and exposure assessment. Consequently, the Panel defines SPGs by the entities that need to be protected, the attributes and/or functions of those entities, as well as the magnitude, temporal and spatial scales of effects on these attributes and/or functions that can be tolerated without impacting the general protection goal (see Section 1). Note that some of the dimensions (entity, attribute) are statements about the nature of the endpoint to be assessed, while others are statements about the maximum tolerable effect (magnitude, and temporal and spatial scale) or how likely it is to be exceeded (degree of certainty).

When defining the dimensions of the SPGs for each key driver (see Figure 5) both the effect and exposure assessment should be considered. In addition, the spatio-temporal scale of the exposure needs not to be the same as the spatio-temporal scale of the effects and should also consider migration of exposed organisms to unexposed areas, migration of unexposed organisms to previously exposed sites (external recovery) and related "action at a distance" (see e.g. Spromberg et al., 1998). As a consequence, the Ecotoxicologically Relevant Concentration (ERC) may be different for the different group of organisms that co-occur in the same ecosystem due to habitat selection and differences in territory and activity (see also EFSA, 2009). In this context it is important that the relevant ERC, including its spatio-temporal scale, is defined for all the key drivers of a specific protection goal.

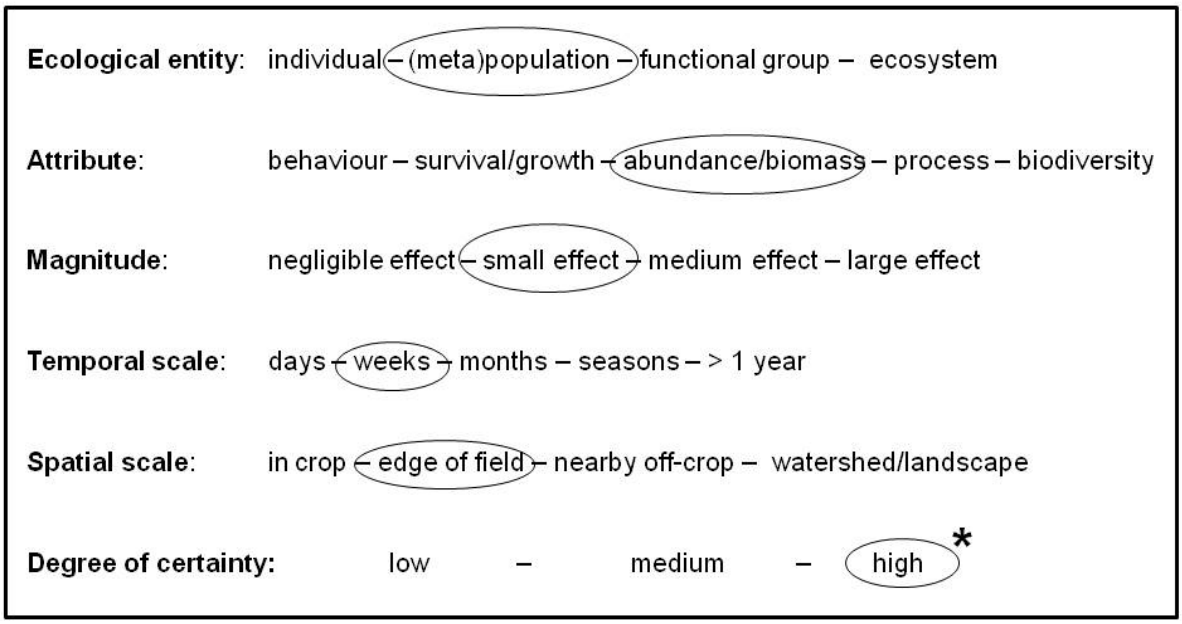

Figure 5: Example of development of a specific protection goal definition. For each specific protection goal option one (range of) point(s) on each dimension must be chosen, and then defined in precise enough terms to be measurable (e.g. abundance). The protection goal defined prevents (positive or negative) effects to the right of any of the circled points. Refer to the text for details.

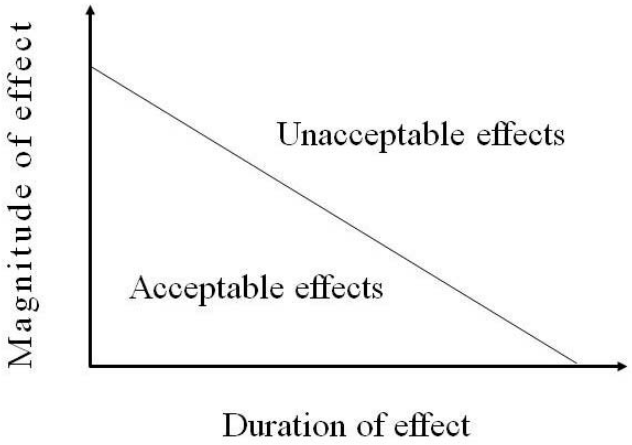

Figure 6: Example of interdependency of the dimensions of specific protection goals: the acceptable limit in one dimension depends on the limit selected in another dimension (Note that the exact shape of the relationship is unknown and other (nonlinear) relationships are possible. In this Opinion the simplest relationship is given as an example). Larger effects are acceptable provided they are short-lived.

3.3.2. The specific protection goal options identified

On the basis of the process described in the previous section, the range in proposed SPG options for different key drivers that may be followed for the ERA of plant protection products is summarized. The emerging definition of the specific protection goal (SPG) for each key driver is presented as well in narrative form in Table 3.

The specific protection goals that the PPR-Panel identified in Table 3 usually concern the maintenance of a diverse range of ecosystem services in the (agricultural) landscape/watershed of concern by allowing temporary effects on local field or edge-of-field populations only. For the majority of key drivers presented in Table 3 the ecological entities to be protected are (meta)populations[22]. However, the ecological entity may also be individuals when it concerns vertebrates and species harvested for human consumption (e.g. shellfish), or functional groups when it concerns provisioning and supporting services by algae, some invertebrate groups and microbes, as summarised below:

Key driver	**entity**		
	individuals	**(meta)populations**	**functional groups**
Microbes			x
Algae (freshwater and marine)		?	x
Non target plants (aquatic and terrrestrial)		x	
Aquatic invertebrates (freshwater and marine)		x	
Terrestrial invertebrates (non-target arthropods and non-arthropods)		x	
Bees		x	
vertebrates	x (lethality)	x	

[22] A metapopulation is a "population of populations" of the same species connected through immigration and emigration (Hanski and Gyllenberg, 1993).

For the majority of key drivers, SPGs are at the level of the population or higher in accordance with the publications of USA-EPA (2003), Delorme et al. (2005) and Hommen et al. (2010) in which it is stated that most ecological protection goals aim at preserving populations of non-target organisms rather than individuals. In these reports, however, the ecosystem services concept was not explicitly used to derive SPGs. As stated already, the advantage of using the ecosystem services concept is that it enables a systematic and transparent assessment of all possible SPG options and thus is very helpful as a communication tool with risk managers, stakeholders and the public at large.

Adopting the population level as the ecological entity means that effects on individual survival, reproduction and/or growth are only of concern for risk assessment if they result in impacts at the population level. For some key drivers temporary impacts on population size or structure resulting from plant protection product use may be considered acceptable if the impacts are temporary and local. The rate of recovery of populations from impacts depends on such factors as age-specific survival and reproduction as well as dispersal ability. Judgements about whether and to what extent impacts of pesticides at the population level are acceptable thus need to consider the life-history traits of the impacted species, the duration of exposure to the pesticides and the spatial scale over which the exposure occurs (see for further discussions on this topic section 4.1.1).

It is important to recognise that final decisions on the choice of specific protection goals involves risk management judgements, which are outside the remit of EFSA, and therefore need to be made in consultation with risk managers. In order to facilitate this consultation, in this opinion for some cases a range of alternative options for the specific protection goals are developed, representing alternative levels of protection. This opinion aims to provide a framework to derive specific protection goal options that can be used in the dialogue between risk managers and risk assessors during the problem formulation phase when starting the revision of the Guidance Documents. An advanced draft of this opinion has been consulted with both stakeholders and risk managers via consultations performed in April and May 2010 (see Section 1 and EFSA, 2010b). The feedback obtained in these consultations was considered during the Panel's finalisation of the opinion.

3.3.3. Further considerations

The ecological entities and attributes selected for each key driver (and vulnerable representatives for these key drivers) should be informed, where possible, by ecological information, while the intensity of the acceptable effects (magnitude, duration, spatial scale) should be informed by knowledge on the normal-operating range of the assessed attribute for undisturbed ecological entities.

Factors to consider when choosing the range for the dimensions to be used in deriving SPG options (see Figure 5) include the importance of the ecosystem service to humans, the contribution made to this service by the key drivers (and their representative vulnerable species, see more details in Section 4.1.1) under consideration (e.g. importance as key species or ecological engineers), and the resilience of the service (i.e. its potential for and speed of recovery after an impact due to pesticide effects on the key driver under consideration). Thus the degree of protection that is appropriate varies between key drivers, depending on the importance (to human society) of the ecosystem services they provide. This will be further discussed in Section 4.2.

On the basis of feedback obtained at the stakeholder workshop (Parma 15-16 April, 2010) and risk manager consultation (Brussels, 11-12 May 2010) the PPR Panel agrees that different specific protection goals for in-crop and off-crop areas are needed for several key drivers (e.g. terrestrial non-target vascular plants, non-target arthropods and non-target invertebrates). The PPR Panel proposes to consider the field margin and buffer strip of agricultural fields as areas to which the in-crop specific protection goals apply (keep it simple). It needs to be further discussed with risk managers what will be the specific protection goal status of off-crop areas like hedgerows and drainage furrows (that periodically fall dry) and that are owned by the farmer.

The derivation of SPGs can be assisted additionally by focussing on a small number of major options based on different combinations of these dimensions. For instance Brock et al. (2006) defined a number of "principles" which distinguish between prevention of effects on individuals, prevention of effects on populations, acceptance of effects on populations subject to recovery within a specified period, acceptance of structural effects on ecosystems provided ecological functions are maintained (functional redundancy). These simplified characterisations may be helpful in discussions with risk managers and stakeholders.

3.4. Conclusions

The Panel has chosen the ecosystem services concept as an overarching concept for developing specific protection goals (SPGs). The concept enabled the diverse range of general protection goals mentioned in the legislation to be addressed, while allowing for a more systematic and transparent approach for identifying SPGs. The use of the concept is in line with international environmental policy and research developments.

The PPR Panel identified 7 key drivers for the ecosystem services potentially impacted by pesticides in agricultural landscapes: microbes, algae, non-target vascular plants, aquatic invertebrates, terrestrial non-target arthropods (including honey bees), terrestrial non-arthropod invertebrates and vertebrates (covering fish, amphibians, reptiles, birds and mammals). The PPR Panel then developed a framework to derive SPG options for each of these key drivers, in which SPGs are defined in terms of 6 dimensions: ecological entity (individuals, (meta)populations, functional groups, ecosystems), attributes (behaviour, survival/growth, abundance/biomass, processes, biodiversity), the magnitude of the effects, the temporal and spatial scale of the effects and the degree of certainty required that the specified level of effects will not be exceeded.

For the majority of key drivers, SPG options are at the level of the population or higher. Judgements about whether and to what extent impacts of pesticides at the population level are acceptable need to consider the life-history traits of the representative species for the key driver, the duration of effects caused by exposure to the pesticides and the spatial scale over which the effects occur.

The key drivers for SPGs that the PPR-Panel derived on the basis of the data requirements in European PPP regulation and the ecosystem services concept do not deviate substantially from the current taxonomic groups used in European ERA procedures for plant protection products. For the further development/update of the ecotoxicological risk assessment guidance documents, it needs to be critically evaluated whether the SPGs for microbes, amphibians and reptiles are covered by those for other taxonomic groups.

The Panel concludes that both agricultural and societal demands need to be considered when identifying specific protection goals, both in crop and off crop. The PPR Panel intends to use the specific protection goal options for each key driver as well as the general concept presented in this Opinion as input for the dialogue between risk managers and risk assessors during the problem formulation phase during the next steps of the revision of the Guidance Documents.

Table 3: Specific protection goals for the most important key drivers of ecosystem services potentially impacted by the agricultural use of pesticides (see Table 2) considering the legal requirements as formulated in European legislation and specified in terms of ecological entity, attribute, magnitude of impact and the spatio-temporal scale of the tolerable impact. The level of certainty required is not shown in the table, but the review of legislation in section 2 suggests that, in general, a high level of certainty is required that protection goals will not be breached. *(Note that this table was written by scientists as informers of the acceptability debate).*

key driver	ecosystem service	legal requirement	specific protection goal	ecological entity	attribute	scale		
						magnitude of impact	spatial scale of impact	temporal scale of impact
Microbes	- nutrient cycling - water purification/ soil remediation/ waste treatment - soil formation and retention	no unacceptable effects	no unacceptable effects on functions of microbial communities	functional groups	functions	negligible effects to medium effects	field to landscape	weeks in fields to days in off crop areas
Microbes	- pest and disease regulation - genetic resources - education and inspiration - food	no unacceptable effects	no decrease of biodiversity	metapopulation	species diversity and abundance	small to large effect to negligible effects	field to landscape	weeks in fields and edge of field to no to days in other off-crop areas
Algae (freshwater and marine)	- primary production - photosynthesis - nutrient cycling - water purification	no unacceptable lethal and sublethal effects	no to short-term effects on densities/biomass of functional groups and communities	functional groups and communities	function and biomass	negligible effects to small effect	edge of field to watershed	days to weeks in edge of field to days in protected areas and watershed

key driver	ecosystem service	legal requirement	specific protection goal	ecological entity	attribute	scale		
						magnitude of impact	spatial scale of impact	temporal scale of impact
algae (freshwater and marine)	- genetic resources - education and inspiration	no decrease in biodiversity	no decline in biodiversity in the watershed/ landscape	metapopulation	diversity and abundance (population density)	locally small to large effect but negligible effects in protected areas and watershed	edge of the field to watershed	days to weeks in edge of field to no to days in protected areas and watershed
non target plants (aquatic and terrestrial)	- primary production - nutrient cycling - water regulation - provision of habitat -food	no unacceptable lethal and sublethal effect	no to short term effect on biomass of functional groups and keystone species	population to functional groups	biomass as affected by survival and growth	negligible to small effect (population dependent)	edge of field to landscape/ watershed	days to weeks in edge of field to no to days in protected areas and watershed
non target plants (aquatic and terrestrial)	- genetic resources - education and inspiration - recreation and ecotourism - aesthetic values	no decrease in biodiversity	no decline in biodiversity in the watershed/ landscape	metapopulation to community	diversity and population abundance/ biomass, visible phytotoxic effects	locally small to medium effect but negligible effects in protected areas and landscape / watershed	field to landscape / watershed	days to weeks in fields and edge of field to no to days in protected areas and landscape/ watershed

key driver	ecosystem service	legal requirement	specific protection goal	ecological entity	attribute	scale		
						magnitude of impact	spatial scale of impact	temporal scale of impact
aquatic invertebrates (mainly marine)	food	no unacceptable lethal and sublethal effect no unacceptable effect on ongoing behaviour	no to short-term effects on densities/biomass of consumable species	population	abundance and biomass as affected by impacts on survival and reproduction	negligible to small effects	patches of aquatic environment used for collection/ production	no to days
		acceptable human health risks	no secondary poisoning by food consumption	individual to population	internal concentrations	negligible to small effect	patches of aquatic environment used for food collection / production	variable depending on life cycle of species
aquatic invertebrates (freshwater and marine)	- water purification - nutrient cycling, - pest and disease regulation-	no unacceptable lethal and sublethal effect no unacceptable effect on ongoing behaviour	no to short-term effects on densities/biomass of functional groups	functional groups	abundance and biomass	negligible to small effect (population dependent)	edge of field to watershed	days to weeks in edge of field and no to days in protected areas and watershed
aquatic invertebrates (freshwater and marine)	- genetic resources - education and inspiration	no decrease in biodiversity	no decline of biodiversity in the watershed/ landscape	metapopulation	diversity and abundance (population density)	locally small to large effect but negligible effects in protected areas and watershed	edge of field to watershed	days to weeks in edge of field and no to days in protected areas and watershed

key driver	ecosystem service	legal requirement	specific protection goal	ecological entity	attribute	scale		
						magnitude of impact	spatial scale of impact	temporal scale of impact
honey bees	food	no unacceptable acute or chronic effects on colony survival and development, taking into account honey bee larvae and honey bee behaviour	no significant effect on colony survival and development and on production of honey, pollen, etc.	colonies per apiary	survival and function	negligible to small effect	edge of the field and other non-crop areas	no to days
non target arthropods (terrestrial) including honey bees	pollination	no unacceptable lethal and sublethal effects no effects on ongoing behaviour	no to small effect on biodiversity, abundance and behaviour	populations	abundance and foraging behaviour	negligible to small effects (depends on life cycle of species)	in crop to off crop	no to days during the crop flowering period days to weeks in edge of field areas (depends on period of foraging)
		no unacceptable acute or chronic effects on colony survival and development, taking into account honey bee larvae and honey bee behaviour	no significant effect on survival and foraging behaviour on bees foraging in flowering crop	forager populations		negligible to medium effects on forager population within the colonies, no significant impact on foraging behaviour		no to days during the crop flowering period weeks to months in off crop areas (depends on period of bee foraging)

key driver	ecosystem service	legal requirement	specific protection goal	ecological entity	attribute	scale		
						magnitude of impact	spatial scale of impact	temporal scale of impact
non target arthropods (terrestrial)	pest and disease regulation	no unacceptable lethal and sublethal effects no effects on ongoing behaviour	no to temporary impacts on density of functional groups	functional groups	abundance/ function	small to medium effect in agro-ecosystems	field to edge of the field	weeks to months in field and edge of field
non target arthropods (terrestrial, soil organisms)	- soil formation and retention - nutrient cycling,	no unacceptable lethal and sublethal effects, no effects on ongoing behaviour	no to temporary impacts on density of functional groups	functional groups	abundance/ function	small to medium effect in agro-ecosystems, negligible effects in other off-crop areas	Field to landscape	weeks to months in field and edge of field , no to days in other off-crop areas

key driver	ecosystem service	legal requirement	specific protection goal	ecological entity	attribute	scale		
						magnitude of impact	spatial scale of impact	temporal scale of impact
non target arthropods (terrestrial) and honeybees	- genetic resources - education an inspiration - aesthetic values	no decrease of biodiversity	no decrease of biodiversity in the landscape, temporary impact on local populations	metapopulation	species diversity, species abundance	Locally small effects but negligible effects in protected areas and landscape	Field to landscape	weeks in field and edge of field no to days in protected areas and landscape
		no unacceptable acute or chronic effects on colony survival and develop-ment, taking into account honey bee larvae and honey bee behaviour	no significant effect on colony survival and development	colonies per apiary	survival, foraging behaviour	no decrease of colonies per apiary and negligible to small effects on foraging behaviour	landscape	no to days
non-arthropod invertebrates (terrestrial), including earthworms	- food - genetic resources - education an inspiration	no decrease of biodiversity	no decrease of biodiversity in the landscape, temporary impact on local populations	metapopulation	species diversity, species abundance (survival and reproduction)	locally small effects but negligible effects in protected areas and landscape	field to landscape	weeks in field and edge of field and no to days in protected areas and landscape

key driver	ecosystem service	legal requirement	specific protection goal	ecological entity	attribute	scale		
						magnitude of impact	spatial scale of impact	temporal scale of impact
non-arthropod invertebrates (terrestrial), including earthworms	- soil formation and retention - nutrient cycling, - provision of habitat	no unacceptable lethal and sublethal effects no unacceptable effects on ongoing behaviour	no to short-term effects on densities/biomass of functional groups	functional group to community	abundance, biomass	small to medium effect in agro-ecosystems and negligible effects in other off-crop areas	field to landscape	weeks in field and edge of field and no to days in other off-crop areas
vertebrates (aquatic and terrestrial)	food	no unacceptable lethal and sublethal effects no unacceptable effects on ongoing behaviour	negligible effect on population structure of harvestable species	population	abundance, biomass, demographic structure	negligible to small effects	(edge of) field to watershed/ landscape depending on the home range of species	days to weeks acceptable locally (if caused by avoidance behaviour)
			healthy appearance of individuals used for human consumption	individual to population	frequency of tumours and other abnormalities in harvested individuals	negligible effect		not applicable
		acceptable human health risks	no secondary poisoning by food consumption	individual to population	internal concentrations	negligible to small effect	(edge of) field to watershed/ landscape depending on the home range of fish species	variable depending on life cycle of fish species

key driver	ecosystem service	legal requirement	specific protection goal	ecological entity	attribute	scale		
						magnitude of impact	spatial scale of impact	temporal scale of impact
vertebrates (aquatic and terrestrial)	- genetic resources - education and inspiration - aesthetic values	no unacceptable lethal and sublethal effect no unacceptable effects on ongoing behaviour	no decline in biodiversity species: negligible effects on population structure negligible visual unacceptable effects on behaviour	individual to population	behaviour and abundance (as affected by survival, growth and reproduction)	negligible to small effects	(edge-of) field to watershed/ landscape depending on the home range of species (special attention should be paid to spawning and nursery sites)	only if caused by avoidance behaviour temporal effects (days to weeks) acceptable

4. Next steps after deriving specific protection goals

4.1. Roadmap for the further update of the ecotoxicological risk assessment guidance documents

In the previous Section, the Panel proposes a framework for defining specific protection goals (SPGs) that identify and justify the attributes of the specific environmental entities that are to be protected. These SPGs will be used as the basis for developing and updating risk assessment schemes and methods.

After SPGs have been clearly defined and set for risk assessors (which requires discussing the options with risk managers), the following additional steps are needed for the development/update of risk assessment Guidance Documents:

- Step 5 – Identify and focus on "vulnerable" representatives for each key driver
- Step 6 - Develop protective risk assessment schemes (based on the SPGs, the vulnerable representatives of the key drivers identified, appropriate and already available test endpoints and species, etc.)

In this Section, these additional steps and some basic concepts are explained, which the PPR-Panel recommends and intends to use when working on its mandates on updating the Guidance Documents on Aquatic and Terrestrial Ecotoxicology (SANCO/3268/2001 and SANCO/10329/2002, respectively). It is emphasised that the PPR-Panel expects the exercise of defining SPGs and vulnerable key drivers for them to be performed once, prior to revising the GDs. The main aim of the exercise is to identify which kinds of tests need to be included in the revised GDs so that an adequate level of environmental protection can be achieved in connection with pesticide use.

4.1.1. Step 5 - Identify and focus on vulnerable representatives for each key driver

In this step representative species for the key drivers of each SPG need to be identified. Because it is not possible to study or model all species that could occur in the environment and which may be exposed to pesticides, vulnerable key drivers will be defined for each specific protection goal. These are not necessarily standard test species.

One way of defining vulnerable key drivers is to use model species that may be more vulnerable because they are more exposed than other species. In addition, toxicological sensitivity as well as life-cycle traits that would limit the species' potential for recovery (e.g., low fecundity, long life cycle, and limited dispersal) would be important to consider (De Lange et al, 2009, 2010). Additionally, the approach described in the guidance document for birds and mammals (EFSA, 2008) could be adopted. There three categories of species have been defined: indicator species, generic focal species and focal species (see for more details EFSA, 2008).

Identifying vulnerable representatives needs to be done and represents the next step for the update of the Ecotoxicology Guidance Documents.

4.1.2. Step 6 - Develop protective risk assessment schemes

The development of protective risk assessment schemes will be done by other EFSA Working Groups in the near future in the context of the received mandates of updating the Aquatic and Terrestrial Ecotoxicology Risk Assessment Guidance Documents (EFSA-2009-Q-00001 and EFSA-2009-Q-

00002). There are however some basic principles which we would like to draw attention to here and which will be considered by these Working Groups when working on the mandates referred to above.

4.1.2.1. Tiered risk assessment approach

Tiered approaches are the basis of environmental risk assessment schemes that support the registration of plant protection products, as stated in the Guidance Documents SANCO/3268/2001 and SANCO/10329/2002 (EC, 2002b; EC 2002c). The concept of tiered approaches is to start with a simple conservative assessment and only to do additional and more complex work if necessary (thus it implies a cost-effective procedure both for industry and regulatory agencies). In short, the tiered system as a whole needs to (i) be appropriately protective, (ii) be internally consistent, (iii) be cost-effective and (iv) address the problem with an increasing accuracy and precision when going from lower to higher tiers. Note that for all tiers or levels within a risk assessment scheme that address a certain key driver, the same specific protection goal applies (including the options proposed by the risk assessors).

In most cases, assessing directly whether the use of a plant protection product complies with the specific protection goals would require refined experimental or modelling methods that would not be practical for routine use in a Tier 1 risk assessment procedure. Equally, in general, the standardised studies or models used at Tier 1 level do not measure the specific protection goals directly. The PPR Panel's solution to this is to identify for each key driver (taxonomic group or other ecological entity) a reference tier[23], based on the most sophisticated experimental or modelling risk assessment method currently available that addresses the specific protection goal. This reference tier will then be used to calibrate lower tiers using simpler methods that are practical for routine use. The concept of this approach is illustrated in Figure 7 and Figure 8.

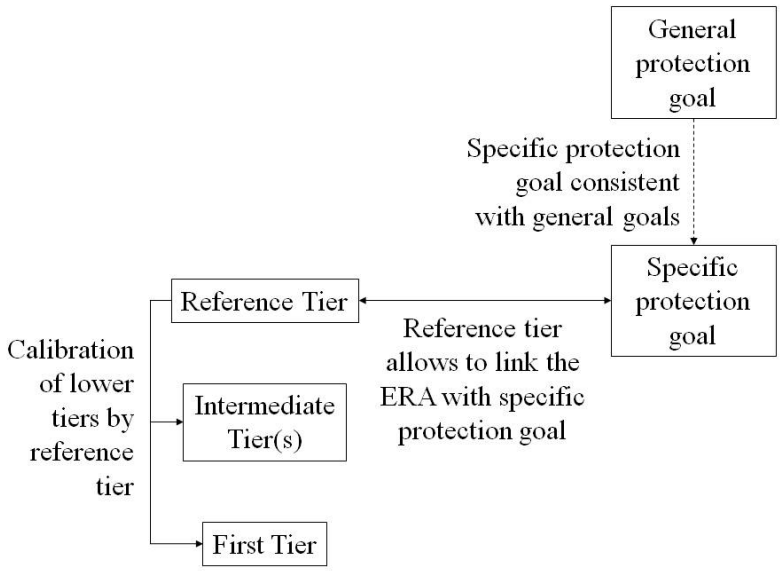

Figure 7: Illustration of the relationship between tiers of the risk assessment process and protection goals, in the approach used by the PPR Panel.

[23] Reference tier is defined as a sophisticated experimental system or model that is practical for higher tier use. A more advanced tier than the reference tier should be possible to assess risks in specific cases.

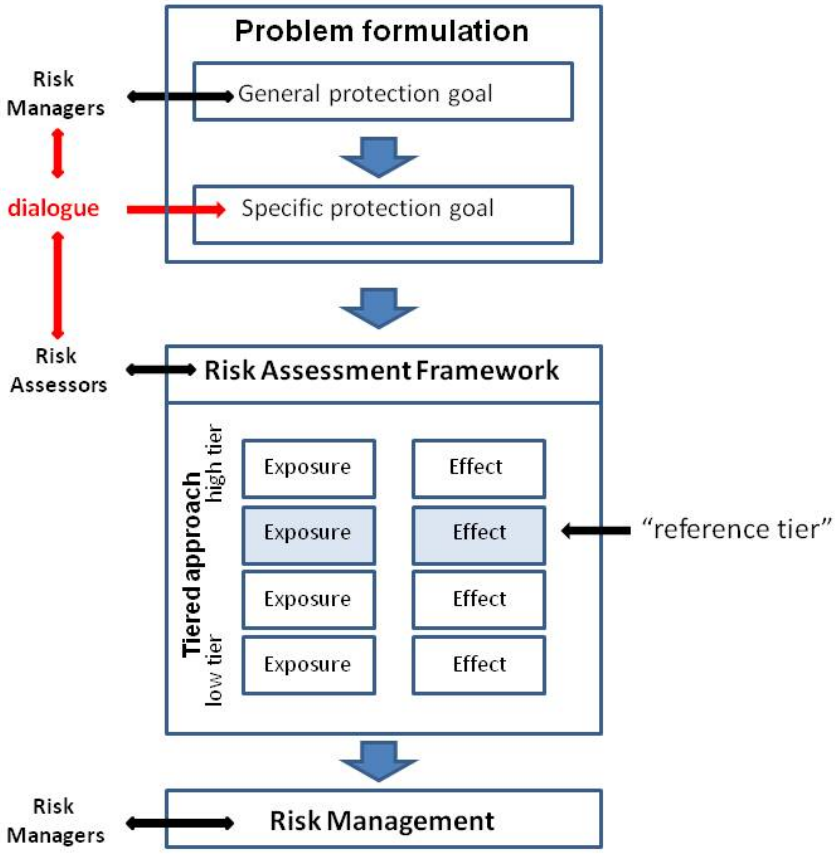

Figure 8: The tiered approach used in a risk assessment framework and its relationship to problem formulation, protection goals, and risk management in the process of developing specific protection goals and developing risk assessment guidance. Please note that this figure focuses on the interaction between risk assessment and risk management as defined in Section 1. However, the involvement of stakeholders is also needed in the definition of protection goals.

As a consequence, having derived the specific protection goals in this opinion, the next logical step in the process of updating the Ecotoxicology GDs (EFSA-2009-Q-00001 and EFSA-2009-Q-00002) would be first to identify the corresponding reference risk assessment tiers for each key driver (taxonomic group or other ecological entity). Then to construct a tiered risk assessment approach and a reference tier and to develop the lower tiers by calibrating them via the reference tier (Figure 7). Obviously, the existing risk assessment schemes and data requirements in Regulation (EC) No 1107/2009 should be considered in this process. Additionally, it might happen that the emerging definition of the specific protection goal is not capable of being measured or modelled with existing methods. In that case, emphasis should be placed on developing appropriate modelling or experimental approaches that can more directly assess the specific protection goal that has been agreed by risk managers. While these new approaches are under development, surrogate specific protection goals should be used, but there should be an opportunity to revisit a specific protection goal when more appropriate methods to assess it are developed.

4.1.2.2. Link between exposure and effect

When linking exposure to effects for assessing risks, the same ecotoxicologically relevant exposure concentrations (ERC) should be used for both field exposure estimates (expressed in terms of predicted environmental concentrations) and effect estimates (expressed in terms of regulatory acceptable concentrations). Also, when addressing the spatio-temporal dimensions of risk it is important to consider both exposure and effects and their spatio-temporal dimensions (see e.g. the proceedings of the ELINK workshop; Brock et al., 2010). For example, in exposure estimates according to FOCUS surface water scenarios a 50^{th} percentile year (different weather conditions that affect pesticide fate) is used in combination with e.g. a 97^{th} spatial percentile (e.g. based on the population of edge-of-field ditches considered relevant) (FOCUS, 2001). Ideally, in implementing specific protection goals also the spatio-temporal dimensions of the related effects estimates need to be defined and consistently used within the tiered risk assessment scheme. This process needs interactions between environmental fate and effect experts and between risk assessors and risk managers (decision makers). For all tiers or levels (see Section 4.1.2.1) within a risk assessment scheme the same specific protection goals (including the related spatio-temporal dimensions of the related exposure estimate) need to be used.

A common, cost-effective approach in the prospective exposure assessment is the development of exposure scenarios representative for relevant landscape elements (e.g. in-crop or edge-of-field habitats). Such scenarios are defined as representative combinations of crop, soil, climate, and agronomic parameters to be used in modelling. The assumptions underlying these exposure scenarios are based on knowledge of the physical, chemical and biological characteristics of the landscape element of concern and on prevailing weather conditions, and usually a "realistic worst-case" approach is adopted to parameterise these scenarios (see e.g. FOCUS, 2001). This "realistic worst-case" implies that a worst-case exposure concentration is not assessed but instead some selected percentile of the probable concentration expected (see also EFSA, 2010a). As a consequence, as part of the spatial and temporal dimensions of the protection goal, the following questions need to be answered:

i. What spatial unit should be considered? This should be based on the type of spatial unit (e.g. macrophyte-dominated ditches or all ditches, soils with communities dominated by mesofauna or soils with communities dominated by endogeic and anecic earthworms) and on the dimension 'spatial scale' (e.g. an agricultural field or one square metre of such a field).

ii. What spatial statistical population of these units should be considered? (e.g. all ditches within 10 m distance of treated fields in a specific regulatory area or all ditches in 1000 km^2 areas with a high use intensity of the product in a specific regulatory area; all potato fields in a certain regulatory area).

iii. What multi-year temporal statistical population of concentrations should be considered?

iv. What value of the percentile should be used and how should it be determined from the resulting combined spatio-temporal statistical population?

v. Should the fraction of the target crop that is treated be included in the risk assessment and if so how?

These are essential specifications of the protection-goal dimensions because the risk is only assessed for the spatio-temporal variability of the systems that are included (so for the remaining systems even extreme effects are considered acceptable).

4.1.2.3. Development of ecological scenarios

In addition to exposure scenarios, it seems logical also to develop ecological scenarios for the landscape elements we intend to protect by the risk assessment performed, as proposed both in the proceedings of the ELINK workshop (Brock et al., 2010) and by the PPR Panel (EFSA, 2009). An ecological scenario is defined as a representative abstraction of the biological, physical and chemical parameters for the ecosystem of concern; the biological parameters relate to the assembly of populations of different species and the way in which they interact with each other and their abiotic environment. Collecting ecological field data (including physical and chemical characteristics) of the landscape elements that we intend to protect is important in developing and improving the tiered risk assessment approach by incorporating representative ecosystem properties (including their variability) in the scenarios and tools for both the exposure and the effects assessment. In this way, ecological datasets may be particularly useful in higher-tier risk assessments derived either from model ecosystems (e.g. mesocosms) or ecosystem models. They may also be useful at earlier steps of the risk assessment, since ecological data may provide useful information about the relevant ecosystem properties that affect pesticide fate (e.g. pH, light, organic matter content), the relevant species to be tested (e.g. to construct SSDs), the relevant focal species to select, or about ecologically relevant experimental conditions to use in refined fate and effects studies.

All prospective approaches to assessing ecological risks in relevant landscape elements rely heavily on the proper linking of predicted exposure concentrations to ecotoxicological and ecological data. The ecotoxicological data usually consist of dose/concentration–response relationships derived from controlled experiments with standard and additional test species or (semi-)field tests. The ecological data usually relate to the 'target image' of the relevant community in the landscape elements of concern, including ecological traits of the vulnerable species at risk. Uncertainty factors and/or modelling approaches, are used to extrapolate the experimental dose/concentration–response relationships in space and time, e.g. to estimate the threshold concentrations for toxic effects in the field or the potential for recovery of affected populations.

4.1.2.4. Addressing uncertainties

Approaches to assess exposure and effects are both characterised by uncertainties. These uncertainties need to be considered when developing the assessment scenarios and approaches, so that they can be designed to provide the desired level of certainty that effects of concern will be prevented. A practical approach for evaluating uncertainties affecting the level of protection was developed by the PPR Panel in the guidance on risk assessment for birds and mammals (EFSA, 2008). The level of certainty required will have been defined as part of the specific protection goals.

When developing the risk assessment approach, it is important to consider the level of certainty required (as defined in the SPG), for example, when deciding what level of statistical significance should be used when interpreting effects in regulatory studies, or what confidence intervals should be selected for statistical estimates (e.g. for the HC_5). Additionally, the degree of certainty should also take account of unquantified uncertainties affecting the risk assessment as such and any ecological, spatial or temporal extrapolation.

4.2. The use of the ecosystem services concept for further decision making on SPGs

In the context of the further work to develop guidance documents, it is important to recognise that final decisions on the choice of specific protection goals involve risk management judgements, which are outside the remit of EFSA and the PPR Panel. Therefore this needs consultation among risk assessors, risk managers, and other stakeholders. Additionally, it needs to be kept in mind that when making these choices, in most cases some effects need to be accepted because it is not possible to optimize all ecosystem services at the same time and place. Rather one ecosystem service will often be

optimized over others, keeping however the effects on the other services to a minimum. This is the moment when decisions at social, political, and risk management levels are needed. Here the ecosystem services concept can help to quantify and communicate trade offs involved in environmental management options between the different stakeholder groups involved, in particular when defining specific protection goals. For example, the "costs" of pesticide impacts on pollination (and other services) can be valued against the benefits of the pesticide use in terms of increased food production (the service being optimised in agricultural landscapes). Trade offs among services can be expressed in different value systems (monetary, moral values, scarcity, etc). An important advantage of the ecosystem services concept is that it makes trade offs among ecosystem services transparent and explicit. These features should facilitate a more informed debate and ensure a more balanced use of ecosystems that ensures their long term sustainability.

4.3. Further considerations and research needs

The proposed approach outlined in this opinion provides a means for developing and communicating risk assessments that are more directly relevant for protecting the ecosystem services on which society depends. Defining specific protection goals on the basis of ecosystem services should help to facilitate the development of methods and models that more directly assess relevant impacts of pesticide use, thereby reducing the uncertainties associated with extrapolating from test results to protection goals.

Given that most of the specific protection goals are performed by populations or groups of populations, development of appropriate population models for use in risk assessment is needed. There is no lack of population models available in the literature, and some of these have been used for decision making in, for example, fisheries management, conservation, etc. However, challenges remain to develop a suite of standard models, incorporating the necessary level of ecological complexity that can be broadly accepted for use in risk assessment by regulators and the regulated.

In this opinion the PPR Panel developed a framework for the derivation of specific protection goal options to allow a transparent and adequate risk assessment within the registration procedure of (individual) plant protection products. Although this framework does not directly solve mixture toxicity and multiple-stress caused by realistic packages of plant protection products used in different crops and agricultural landscapes, the PPR Panel is of the opinion that this framework based on the ecosystem services concept clearly illustrates that this aspect cannot be ignored when considering pesticide risks at a wider spatio-temporal scale. As mentioned already, the tools that will be developed under both the PPP new regulation and the Sustainable Use of Pesticides Directive (2009/128EC) may be required to solve the multiple stress problem. Within the context of Regulation (EC) No 1107/2009 an option might be to adopt more stringent specific protection goal options for those individual plant protection products used in crops characterised by an intensive multiple plant protection product use than for an individual product used in crops with low plant protection product input.

CONCLUSIONS AND RECOMMENDATIONS

From a detailed review of the current legal texts relevant to the regulation of plant protection products and their possible impact on the environment, the PPR Panel concludes that the EU *acquis communautaire* has set out general high-level protection goals, but clear and precise definitions are lacking. In particular, clarifications are needed to define specific protection goals with respect to the following issues:

- The specific protection goals should address terrestrial and aquatic ecosystems and take into account long-range environmental transport to locations distant from where the plant protection products are applied. No limitations are set on the spatial and temporal scale of the risk assessment, and both short-term and long term risks are in scope.

- A distinction in the risk assessment should be made because of differences in the socio-economic and ecological functions of what are named in-crop and off-crop areas.

- Multiple stress by the use of multiple plant protection products, being applied at the same time (e.g., tank mixtures) or in sequence, should be assessed to identify 'similar residues' in the area of envisaged use. Multiple stress from pesticides should also be considered to prevent additive impacts on the abundance and diversity of non-target species.

- The legislation requires a high level of certainty that unacceptable effects will not occur. This has implications for the degree of certainty or strength of evidence required (especially in higher tier assessments), and for the degree of conservatism required (especially in lower tier assessments).

The PPR Panel considers it necessary to derive specific protection goal options that can be agreed with risk managers and other stakeholders via a consultation process in order to provide the framework within which appropriate risk assessment methodology can be developed for pesticides. In particular clarifications are needed to define specific protection goals with respect to ecological, temporal and spatial scales, in-crop versus off-crop situations, multiple stress, and uncertainties.

Given the diversity and range in general protection goals mentioned in the legal framework, the PPR Panel applied the ecosystem services concept as an overarching concept, used elsewhere in European policy setting, which helps systematically to identify specific protection goal options for key drivers covering all environmental compartments. Based on the ecosystem services identified by the Millennium Ecosystem Assessment (2005) the PPR Panel identified those ecosystem services which could potentially be directly or indirectly (e.g. via trophic interactions) affected by the normal agricultural use of plant protection products and identified the groups of organisms which constitute the most important key drivers for those ecosystem services to address the potential environmental risks of plant protection product use resulting from normal agricultural practice. Specific protection goals for each of the key drivers identified in the previous step were defined and summarised in 7 groups of organisms (microbes, algae, non target plants (aquatic and terrestrial), aquatic invertebrates, terrestrial non target arthropods including honeybees, terrestrial non-arthropod invertebrates, and vertebrates). Plant protection products are applied primarily in fields where crops are grown, and can cause effects in adjacent elements in the agricultural fields, such as field margins, hedges, non-crop patches (e.g. small woods), groundwater, ditches, streams and lakes, also in areas far away due to long range transport of pesticides, and this is considered in the development of the specific protection goals.

Although it can be assumed that the existing environmental risk assessment procedure for plant protection products is implicitly and partly based on the protection of ecosystem services, the Panel has identified and suggested a clearer, explicit framework for deriving specific protection goals.

It is important to recognise that final decisions on the choice of specific protection goals involves risk management judgements, which are outside the remit of EFSA and the PPR Panel, and therefore need to be made in consultation with risk managers. In order to facilitate this essential consultation, for some cases a range of alternative options for the specific protection goals is developed in this opinion, representing alternative levels of protection. This requires specifying the following 6 dimensions or aspects of a specific protection goal: the ecological entity that is to be protected (individuals, (meta)populations, functional groups or ecosystems); the attribute(s) or characteristic(s) of that entity that must be protected (behaviour, survival/growth, abundance/biomass, processes, biodiversity); the magnitude of effect that can be tolerated for the attributes to be measured (biological scale); the temporal scale of effect (e.g. the maximum time on an annual basis over which single or repeated exposure/effect events are expected to exceed the critical level that can be tolerated); the spatial scale of the effect (e.g. the distance from the sites of application where the exposures and critical effect level to be tolerated are expected to occur), and the degree of certainty that the specified level of effect will not be exceeded. These dimensions are interdependent, and when considering the spatio-temporal

dimensions of risk it is important to consider both exposure and effects and their spatio-temporal dimensions.

To ensure ecosystem services, taxa representative for the key drivers identified need to be protected at the population level or higher (see table below). However, for aesthetic reasons (cultural ecosystem services) it may be decided to protect vertebrates at the individual level. To protect biodiversity, impacts at least need to be assessed at the scale of the watershed/landscape.

Key driver	**entity**		
	individuals	**(meta)populations**	**functional groups**
Microbes			x
Algae (freshwater and marine)		?	x
Non target plants (aquatic and terrrestrial)		x	
Aquatic invertebrates (freshwater and marine)		x	
Terrestrial invertebrates (non-target arthropods and non-arthropods)		x	
Bees		x	
vertebrates	x (lethality)	x	

Given that most of the services under the selected SPGs are performed by populations or groups of populations, development of appropriate population models for use in risk assessment is needed. There is no lack of population models available in the literature, and some of these have been used for decision making in, for example, fisheries management, conservation, etc. However, challenges remain to develop a suite of standard models, incorporating the necessary level of ecological complexity, which can be broadly accepted for use in risk assessment by regulators and the regulated.

The PPR Panel also emphasizes the importance of a tiered approach for risk assessment, the essential linking of exposure and effect assessments in terms of spatial and temporal scales, and the relevance of ecological scenarios for appropriate pesticide risk assessments and its further work on the update/development of Ecotoxicological Risk Assessment GDs. The tiered system as a whole needs to be (i) appropriately protective, (ii) internally consistent, (iii) cost-effective and (iv) address the risk assessment with greater accuracy and precision when going from lower to higher tiers. For all tiers or levels within a risk assessment scheme that addresses a certain key driver the same specific protection goal applies. The PPR Panel proposes to identify for each key driver (taxonomic group or other ecological entity) a reference tier[24], based on the most sophisticated experimental or modelling risk assessment method that addresses the specific protection goal, and then use this reference tier to calibrate lower tiers using simpler methods that are practical for routine use.

The PPR Panel intends to use the specific protection goal options for each key driver as well as the general concept presented in this Opinion as input for the dialogue between risk managers and risk assessors during the problem formulation phase during the next steps of the revision of the Guidance Documents (GDs) Aquatic Ecotoxicology and Terrestrial Ecotoxicology for which the Panel received the mandates in 2009 (EFSA-Q-2009-00001 and EFSA-Q-2009-00002, respectively).

[24] Reference tier is defined as a sophisticated experimental system or model that is practical for higher tier use. A more advanced tier than the reference tier should be possible to assess risks in specific cases.

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GLOSSARY AND ABBREVIATIONS

EEC	European Economic Community
EFSA	European Food Safety Authority
ELINK	Linking Aquatic Exposure and Effects in the Registration Procedure of Plant Protection Products
EPPO	European Plant Protection Organisation
EQs	Environmental Quality Standards
ERA	Environmental Risk Assessment
ERC	Ecotoxicologically Relevant Concentration
EU	European Union
EQS	Environmental Quality Standards
FOCUS	FOrum for the Co-ordination of pesticide fate models and their USe
GAP	Good Agricultural Practice
GEAE	Generic Ecological Assessment Endpoint
GD	Guidance Document
GMO	Genetically Modified Organisms
GPP	Good Plant Protection Practices
HC_5	Hazardous concentration for 5 % of the species of a SSD
MEA	Millennium Ecosystem Assessment
NAP	National Action Plan
PPP	Plant Protection Product
PPR	EFSA Panel/Unit on Plant Protection Products and their Residues
RA	Risk Assessment
RCoU	Realistic Condition of Use
REACH	Registration, Evaluation, Authorization and Restrictions of Chemicals
SANCO	Directorate General for Health and Consumer Affairs (European Commission)
SPG	Specific Protection Goal
SSD	Species Sensitivity Distribution
TCB	Technische commissie bodem, "the Dutch Soil Protection Technical Committee"
WFD	Water Framework Directive