Risk assessment of plant protection products for non-target terrestrial plants

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Non target terrestrial Plant RA

The EFSA has tasked the Pesticides Unit and the PPR Panel on the following activities:

- **Opinion addressing the state of the science to be delivered by the PPR Panel by July 2014**
- **Guidance of EFSA to be delivered by September 2015**
- **Public consultation on the draft Guidance of EFSA**

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Non target terrestrial Plant RA

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- **Protection goal**
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Protection goals

- **The protection goal for higher terrestrial plants aims to protect the biodiversity of plant species in an agricultural area.**
- **It is assumed that the biodiversity is maintained when most of the plant populations will not be affected by the use of plant protection products.**
- **It is also assumed that this goal will be reached when the plant populations are immediately be protected in the off crop area, the edge of the field.**

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Protection goals

- **The risk assessment scheme aims at protecting 95% of the populations in 90% of the case.**
- **Therefore, the assessment is based on the 5th percentile of the species sensitivity distribution (SSD) and on the 90th percentile of the exposure distributions.**
- **It is possible that plant populations can be protected in another way in an agricultural area, but no methods are available for proposing a more landscape scale approach assessment.**
- **Therefore, it is possible that this approach is too conservative.**

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Protection goals

Specific protection goals for off-field NTTPs as key drivers for nutrient cycling, water regulation, food web support, aesthetic values and genetic resources (biodiversity)

Ecological entity:	population
Attribute:	survival/growth/reproduction, abundance/biomass
Magnitude:	negligible
Temporal:	not applicable
Spatial scale:	edge of field
Degree of certainty:	high

Protection goals

Specific protection goals for in-field NTTPs as key drivers for food web support (primary production, provision of habitat and food for other non-target organisms, e.g. arthropods, birds)

Ecological entity:	functional group food web support (e.g. leafy crops, grass, seeds)
Attribute:	biomass for food web support
Magnitude:	negligible (landscape) to medium effects (field)
Temporal scale:	weeks (no to few days during breeding/chick phase)
Spatial scale:	field/landscape
Degree of certainty:	high

Protection goals

Specific protection goals for in-field NTTPs as key drivers for aesthetic values and genetic resources

Ecological entity:	population/meta population
Attribute:	survival/growth/reproduction, abundance/biomass
Magnitude:	medium (meta-population), large effects (population) (both in-field), negligible (landscape)
Temporal:	not applicable/day to weeks
Spatial scale:	field/landscape
Degree of certainty:	high

Protection goals

Endangered species

In situations where endangered species are living in certain areas (including in fields) special measures have to be taken.

Ecological entity:	individuals/population
Attribute:	survival/growth/reproduction, abundance/biomass
Magnitude:	no effects
Temporal:	not applicable
Spatial scale:	field
Degree of certainty:	high

Ecosystem service	Type of endpoints used in risk assessment[10]		Remarks
(A) Specific protection goals for off field			
Biodiversity	Reproductive (long term)	Reproductive endpoint:[11] HC_5 $ER_{repro10}$	Negligible effects on reproduction at the edge of the field
	Vegetative (short term)	Biomass: HC_5 for ER_{veg10}	Negligible to small effects on biomass at the edge of the field Maintenance of plant species diversity may be hampered by direct impairment of reproduction (sexual and vegetative) as well as by indirect effects owing to competitive interactions in the field resulting from effects on growth, which is not covered by the reproductive endpoint
Nutrient cycling	Biomass and/or reproductive (long term)	Biomass (HC_5 for ER_{veg10}) and/or reproductive endpoint (HC_5 $ER_{repro10}$)	Some species are very important for nutrient cycling, e.g. legumes Mycorrhizas are important and therefore a wide variety of plants should be available Different plants have different chemical composition of their leaves and stem, etc., and decompose at different rates, which influences nutrient cycling Remark: it is generally not known which species are the key drivers for nutrient cycling, but the most abundant species are likely to be critical. Therefore, as a starting point, a conservative approach (HC_5 of a species sensitivity distribution calculated on a sensitive endpoint, e.g. $ER_{repro10}$) could be used. The risk assessment could be refined if more information becomes available. The risk assessment could then be focused on the relevant species and biomass impacts on these species

Ecosystem service	Type of endpoints used in risk assessment[10]		Remarks
Water regulation	Vegetative (short term)	Biomass: HC_5 for ER_{veg50}	Small to medium effects could probably be tolerated before affecting water regulation Large changes in plant cover are likely to influence water regulation and in some cases there could be severe long-term effects if the topsoil layer is washed away. This will also adversely affect water courses
Food web support	Vegetative (short term)	Biomass: HC_5 for ER_{veg10}	No effects at the edge of field No data are available to suggest magnitude of effects and to make a quantitative link to effects on food web
	Reproductive endpoint (long term)	Reproductive endpoint:[10] HC_5 $ER_{repro10}$	No effects at the edge of field Probably not applicable to all plants but important for specific plant species. Species on which other animals depend on for food or reproduction
Aesthetic values	Visual effects (e.g. chlorosis)	Visual endpoint: HC_5 $ER_{visual50}$	Slight and temporary chlorosis (bleaching) may be considered acceptable as long as they do not last longer than a few days
	Reproductive endpoint (long term)	Reproductive endpoint from appropriate tests:[10] HC_5 $ER_{repro10}$	Small and temporary effects may be considered acceptable. Probably not applicable to all plants but important for specific plant species
Genetic resources	Reproductive endpoint (long term)	Reproductive endpoint:[10] HC_5 $ER_{repro10}$	Small and temporary effects at the edge of field could be tolerated but there is not enough information available to make a quantitative link between effects at the edge of field and landscape level

(B) Specific protection goals for in field (see SPG chapter SPG B–D)			
Food web support	Vegetative (short-term and/or reproductive endpoints)	Biomass and/or reproductive endpoints	The use of herbicides and/or compounds with herbicidal activity will influence the food web in fields. Information on how much of the food web should be maintained has to come from other risk assessment schemes (e.g. arthropods, birds, etc.) Appropriate solutions could be set aside areas, untreated buffer strips or other types of in-field strips
Aesthetic values	Visual endpoints (e.g. chlorosis or bleaching) or reproductive endpoint (long term)	Visual endpoints (e.g. chlorosis or bleaching) HC_5 for visual endpoint $ER_{visual50}$, reproductive endpoint[10] HC_5 for $ER_{repro10}$	Slight and temporary chlorosis may be considered acceptable as long as they do not last longer than a few days Small and temporary effects on reproduction endpoints may be considered acceptable
Genetic resources	Reproductive endpoint (long term)	Reproductive endpoint:[10] HC_5 $ER_{repro10}$	Small and temporary effects could be tolerated. This part of the table is particular important for rare species that are mainly living in the treated agricultural areas
Endangered species	Reproductive endpoint (long term) and in particular cases it could be necessary to protect individuals of the species	Reproductive endpoint and when necessary any endpoint that will be needed to protect the species as such	In the case of endangered species living in certain areas (including arable land), special measurements should to be taken More guidance will be provided by a working group of the Scientific Committee of the EFSA in 2015

Weeds and rare species

- The PPR Panel recommends for the RA for non-target terrestrial plants growing within crops cannot afford the same level of protection from pesticide application than off-crop plants.
- This is because the aim of herbicide use in agriculture is to control weeds in order to optimize crop productivity.
- Thus, non-crop species growing in-crop includes both weed species that interferes with crop yield but also some rare species that may be of conservation value.

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Weeds and rare species

- Many arable weeds have become rare due to agricultural intensification in several European countries, including the UK, The Netherlands, France, Spain, Germany, Denmark, Sweden and Turkey.
- Herbicide use has been identified as one the main factors for this decline.
- Rare arable weeds are usually annual species that need regular soil disturbance and are preferably found in crop edges of conventional farming as well as in field centre and edges of organic fields.
- Management practices that favour rare arable weeds have been identified, e.g., uncropped tilled field edges with no herbicide spray.

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Selection of species

- **Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 lay down the data requirements that need to be provided as basic data set for the authorisation of active substances and plant protection products, respectively. Tests are mostly conducted with crop species and requirements are very rigid.**
- **Several experiments have demonstrated that crops are suitable surrogates for wild species (herbaceous and woody) when tested at juvenile stage under similar conditions. However some woody and herbaceous species are very sensitive when sprayed at the reproductive stage (e.g. with sulfonyl urea herbicides).**

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Selection of species

- **Many non-crop species can germinate readily and uniformly under greenhouse conditions with minimum requirements, and are deemed suitable for phytotoxicity testing.**
- **Annual and perennial species do not consistently differ in their sensitivity to herbicide.**
- **Disparity in herbicide susceptibility among crop cultivars and wild species ecotypes has been confirmed in a number of studies.**
- **There is a paucity of data on herbicide effects on ferns, mosses and lichens. Limited studies showed that they are quite sensitive.**

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Effect assessment

Types of information available:

Two OECD guidelines (2006) are available for testing pesticide effects on plants under greenhouse or growth chamber controlled conditions:

- **The Seedling Emergence and Seedling Growth Test**
- **The Vegetative Vigour Test**

The USEPA provide four documents (2012) which describe testing of pesticides under controlled and field conditions:

- **Seedling Emergence and Seedling Growth**
- **Early Seedling Growth Toxicity Test**
- **Vegetative Vigor**
- **Background document which provides general information and overall guidance on test procedures, equipments, statistical analyses and reporting**

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Effect assessment

Types of information available:

Plant screening data (efficacy and crop margin of safety data) can be used in pesticide risk assessment, even though testing is not conducted under GLP.

Plant pre-screening data can provide valuable information and easily accessible data on a wide range of species on effects of herbicides (and other pesticides) on non-target plants that are constituent of wildlife habitats.

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Effect assessment

Drawback

The vegetative endpoints are expressed in an EC50 (NOEC would also be possible when dose respons tests are available)

The endpoints do not cover reproductive information.

Protection goal is biodiversity by means of protecting plant populations.

<u>Posible solution</u>:

The use of reproductive endpoints

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Side step

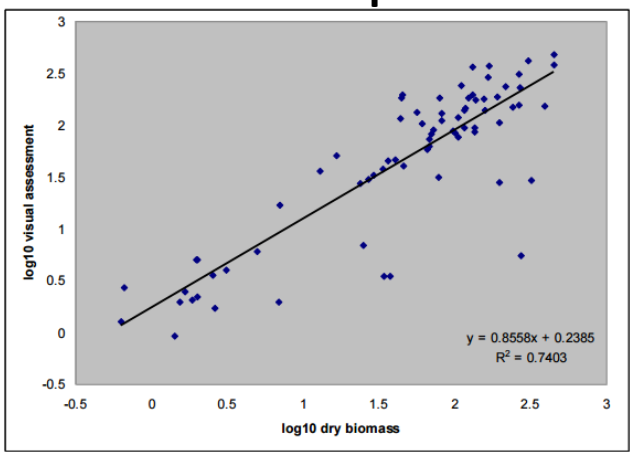

Figure 2: Comparison of effect rates (ERs) calculated using aboveground dry biomass or visual assessment ($n = 73$). Data were available for seven studies from four herbicides: ER_{20} (two studies), ER_{25} (three studies) and ER_{50} (two studies). (From Boutin, Carpenter, Allison, Parsons, Ellis and Casey, unpublished.)

Effect assessment

- In the risk assessment for higher plants the protection goal is to maintain the biodiversity of the higher plant community in agricultural areas.
- This is assumed to be achieved when 95% of the plant populations will be protected from the use of plant protection products.
- The standard endpoint from the higher plant toxicity tests is an EC50 value for vegetative endpoints.

- Because it is intended to protect plant populations it is advisable to use reproductive endpoints instead and it is also advisable not to use EC50 value because than still 50% of the tested species will be affected by the plant protection product, but to use a No Effect Concentration (NOEC).
  It is proposed to use an EC10 value as the surrogate value.

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Effect assessment

For eleven herbicides (2,4-D, chlorimuron ethyl, dicamba, glufosinate ammonium, glyphosate, mechloprop, metsulfuron methyl, primisilfuron, sulfometuron, tepraloxydim and tribenuron) first the standard EC50 for a vegetative endpoint was assessed and thereafter the study was prolonged to achieve an EC50 for a reproductive endpoint.
In total 96 tests (42 different species) were available for which as well a vegetative endpoint was available as a reproductive endpoint.

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Effect assessment

- Not in all cases the reproductive endpoint is lower than the vegetative endpoint, when comparing EC50 values for a vegetative endpoint with an EC50 for a reproductive endpoint 15 out of the possible 35 combination show a lower vegetative endpoint than for reproduction.
- When comparing EC10 values for a vegetative endpoint with an EC10 for a reproductive endpoint 19 out of the possible 46 combinations provide a lower vegetative endpoint than for reproduction.
- When comparing an EC50 for a vegetative endpoint with an EC10 for a reproductive endpoint the latter is besides 4 out of 83 combinations always lower.

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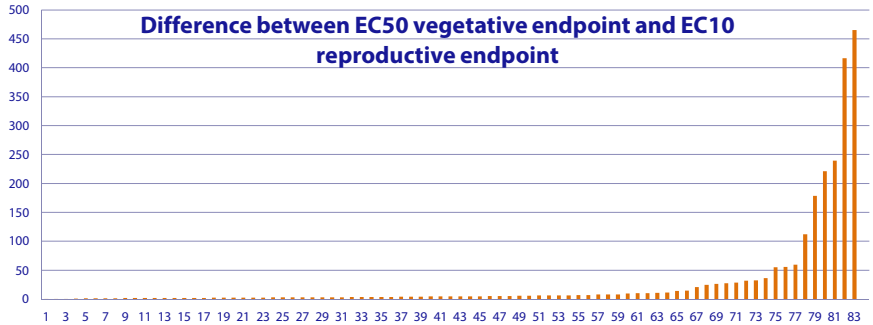
Effect assessment



Percentile	EF
50th	5
75th	11
90th	52
95th	172
Average	28

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Effect assessment

- **For active substances that exhibit herbicidal or plant growth regulator activity, vegetative vigour and seedling emergence concentration/response tests shall be provided for at least six species representing families for which herbicidal/plant growth regulatory action has been found.**
- **If more than 6 species are tested with the vegetative vigour testing protocol or with the seedling emerging protocol all data should be made available for risk assessment.**

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Effect assessment

SSD approach (5th percentile)

Using the EC50 values for 6 or more different species, calculate the 5th percentile of the log-logistic or the log-normal distribution according to Aldenberg and Slob (1993) or Wagner and Løkke (1991) depending on the most likely shape of the toxicity distribution curve (see Note 7) and use this calculated toxicity value in the risk assessment.

5th percentile of SSD = $10^{(AVG - E * STD)}$

in which:
AVG = the mean of the $\log_{10}$ transformed EC50 values
STD = the standard deviation of $\log_{10}$ transformed EC50 values
E = Extrapolation factor dependent on sample size (see Table 1).

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Effect assessment

Extrapolation factors for the lower, median and upper percentiles (5%, 50% and 95%) for estimating the 5th percentile and the 90% confidence interval of a normal SSD and the median percentiles for a logistic SSD (after Aldenberg and Slob, 1993; Aldenberg and Jaworska, 2000)

Sample size	Log-normal			Log-logistic
	Lower	Median	Upper	Median
6	3.71	1.75	0.87	1.81
7	3.40	1.73	0.92	1.78
8	3.19	1.72	0.96	1.76
9	3.03	1.71	0.99	1.75
10	2.91	1.70	1.02	1.73
11	2.81	1.70	1.04	1.72
12	2.74	1.69	1.06	1.72
13	2.67	1.69	1.08	1.71
14	2.61	1.68	1.10	1.70
15	2.57	1.68	1.11	1.70

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Effect assessment

The Ecological Relevant Endpoint (ERE) is the 5th percentile divided by an extrapolation factor for going from an EC50 vegetative endpoint to an EC10 including reproductive effects.

ERE = 5th percentile of SSD / EF
= 5th percentile of SSD / 5

Which EF has to be used is in principle a risk managers decision.

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Different exposure that will be taken into account:

- **Droplet drift/deposition**
- **Vapour drift**
- **Particulate drift**

Scheme will provide methods for calculating buffer zones, which could be situated in the crop or outside the crop.

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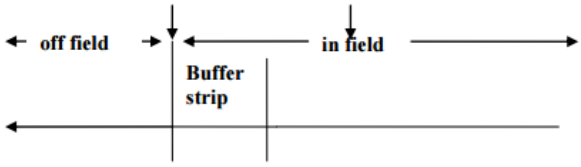

Again this is a risk managers decision to be made

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http://www.efsa.europa.eu/en/efsajournal/doc/3800.pdf

Thanks !

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