

GLYPHOSATE & BIODIVERSITY



*Bayer Distinguished Fellow
Global Regulatory Scientific Affairs*



*Bayer Glyphosate Environmental Safety
Manager & GRG Ecotoxicology TWG
Chair*

AGG pre-submission telecon meeting;
- April 16th, 2020

Objectives

To engage and get feedback from the AGG on the scope and nature of the biodiversity assessment for glyphosate considering how it used.

- Brief overview of the environmental safety profile of glyphosate.
- Get feedback on specific protection goals (SPGs) for the glyphosate biodiversity assessment (e.g., aquatic and terrestrial).
- Present a risk-based framework and methodology to conduct a “biodiversity” assessment that informs risk mitigation and risk management options.
- Leave plenty of time for questions and discussion during and after the presentation.

Questions for Discussion

- We have not tried to develop a “new” approach for the biodiversity assessment. In the AGG’s opinion, is the general approach using the core data and lines of evidence clear and fit-for-purpose?
 - The proposed Specific Protection Goals (SPGs) largely draw from existing EFSA guidance and the EFSA protection goal workshops. Are the proposed SPGs for the biodiversity assessment fit-for-purpose and if not are there recommendations for how to revise one or more of the SPG’s?
 - Are there any areas the AGG feel have not been sufficiently covered in the proposed approach?
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Questions for Discussion

- A strength of the aquatic assessment is that the different trophic levels (e.g., primary producers / consumers and secondary consumers) were tested and show negligible risk. Does the AGG agree that we can follow the approach outlined in the EFSA Aquatic Guidance (Option 1) to address indirect effects through trophic interactions?
 - Considering the exposure and effects assessment for bees, is there any additional information that should be considered to address indirect effects to bees?
 - Based on the exposure and effects assessment for soil organisms, should anything else be considered to address the indirect effects assessment to soil organism functional and compositional biodiversity?
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Questions for Discussion

- Considering the current in-field and off-field protection goals for nontarget arthropods, and meeting those protections goals with the existing assessment is there anything else to consider to maintain relevant nontarget arthropod functions in-crop and protecting species abundance and richness (i.e., insect biodiversity) off-crop?
 - Currently, there are no in-crop protection goals for nontarget terrestrial plants. Therefore, comprehensively addressing indirect effects from in-crop weed control, is best addressed outside the PPP framework and under other policies (e.g., common agricultural policy (CAP)). Does the AGG agree that the best solution to address indirect effects from in crop weed control is best handled by risk management options under other policies (e.g., CAP)?
 - For example, does the AGG agree that protecting farmland birds, from indirect through trophic interactions that may result from in-crop weed control, can be addressed independently by MS via risk management options and using the provisions of the new CAP?
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Glyphosate's Environmental Profile Informs the Biodiversity Assessment
GLYPHOSATE

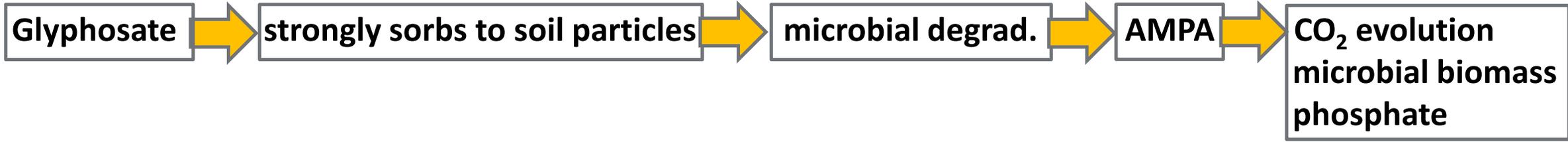
| Parameter | Value |
|--------------------------------|---|
| High water solubility | 10.5 g/L (pH2, 20°C) |
| Log pow (octanol-water coef.): | - 3.2 at 25°C → low bioaccumulation potential. <i>BCF = 1.1 (bluegill sunfish)</i> |
| Sorption coefficient | 884-60000 mL/g, n=20 (EFSA, 2015); → low mobility to immobile, low leaching potential |
| Persistence in soil | maximum of 37.75/38.3 d → low to moderate persistence in soil |
| Persistence in sediment | 61.4% in sediment after 14 days – but not biologically available – strongly sorbed |

AMPA

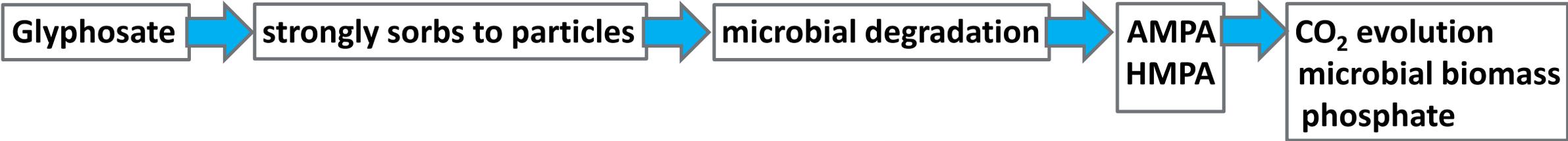
| | |
|--------------------------------|---|
| High water solubility | >100 g/L |
| Log pow (octanol-water coef.): | -1.43 (Synthon Lab) / -2.17 (Kowwinv 1.67) → low bioaccumulation potential |
| Sorption coefficient | 1119-45900 mL/g, n=16 (EFSA, 2015) / [new values (2020), range 1160 – 8248] |
| Persistence in soil | maximum of 633 d → moderate to high persistence in soil |
| Persistence in water | 58-456 d (system), 2-16 (water), sediment: no values |

Glyphosate Environmental Profile

FATE IN SOIL



FATE IN WATER



Principal route to SW is drift (run-off / ground water entry negligible to non)

- Phosphate contribution to surface water is negligible compared to fertilizer and industrial sources.

Biological activity of both metabolites is within the risk profile of the parent

[HMPA: forms at very low levels (<3-5%); moderately persistence (10-128 d)]

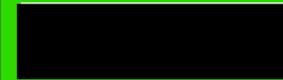
Anticipated Outcome of Ecotoxicology Direct Effects Risk Assessment

| | |
|---|--|
| Avian acute and chronic risk | Acute & chronic bird risk assessment - Pass at Tier II (+ dietary res. decline refinement) |
| Mammal acute and chronic risk | *Acute & chronic mammal risk assessment - Pass at Tier II (+ dietary res. decline + endpoint refinement) |
| Fish acute and chronic risk | Acute & Chronic PASS at FOCUS Step 2 or 3 |
| Aquatic Invertebrate acute and chronic risk | Acute & Chronic - PASS at FOCUS Step 2 |
| Pollinator Risk Assessment | Risk assessment PASS at first Tier (EPPO) + EFSA GD Appr. |
| Arthropods other than bees | Risk assessment PASS at Tier II (in and off-field) |
| Aquatic plants algae and macrophytes | Acute & Chronic PASS at FOCUS Step 2 |
| Soil organisms including soil microbes (N-trans) | Chronic risk assessment PASS at first Tier |
| Non-Target Terrestrial Plants (NTTPs) | Risk assessment PASS with 5 or 10 m in-field buffer / shorter buffer applicable at MS level + DRT + shielded sprayer etc... |

Summary of Water Monitoring Data

- FOCUS Step 3 gives acceptable acute and chronic risk for direct effects at each trophic level.
- A summary of monitoring data from the 2015 RAR, surface water levels for glyphosate (n =75000) and AMPA (n =56700) were <RAC and the monitoring data in peer reviewed publications does NOT modify the assessment.
- In our recent analysis >250,000 samples analyzed with 99.99% of the glyphosate environmental monitoring data were <RAC (Hughes, 2020)

PROBLEM FORMULATION FOR THE GLYPHOSATE BIODIVERSITY ASSESSMENT



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The Most Significant Effect on Biodiversity has been Caused by Changes in Land Use

- Recently, the European Parliamentary Research Service commented on the role of PPPs in securing global food production and preserving biodiversity (EPRS, 2019).
- **Key conclusions from their assessment were:**
 - Increases in biodiversity are marginal from organic farming and because organic farming is approximately 25% less productive than conventional farming more land is needed at the expense of biodiversity.
 - There is a need for efficient farming practices to reduce the agricultural footprint and support biodiversity.
 - The most significant effect on biodiversity has been caused by land use changes since the 1950s (40 - 50% of the land is used for ag).

Glyphosate Enables Environmental Benefits that Support Biodiversity

- Recently, head of EFSA, Dr. Bernhard Url stated the next time regulators assess glyphosate, they should look at how not re-registering glyphosate would impact *“biodiversity, water, farmers’ income, food prices, availability of foods”*. He went on to state, *“This was what we missed in the previous glyphosate discussion”*.

https://www.euractiv.com/section/agriculture-food/interview/efsa-boss-next-time-we-should-also-assess-consequences-without-glyphosate/?utm_source=POLITICO.EU&utm_campaign=1443c835f5-EMAIL_CAMPAIGN_2019_05_22_01_19&utm_medium=email&utm_term=0_10959edeb5-1443c835f5-190128733

- Benefits to ag productivity that can be realized from glyphosate in a conservation tillage program include improved nutrient cycling, improved soil and water conservation, decreased demand for external inputs, increased functional soil biodiversity to improve soil and crop health, cover crop management, improved carbon sequestration, decreased erosion leading to improved water quality.

Glyphosate is Important for Conservation Agriculture

French Ag Minister Didier Guillaume stated *"My position is clear: we will continue soil conservation agriculture with glyphosate. If there is no glyphosate, soil conservation agriculture, a virtuous agro-ecological practice, cannot be done."*

"If we want to protect the soil, keep the carbon in the soil and fight against global warming, we need soil covers, we must stop these large empty plowed fields to capture nitrogen and carbon," explained the minister. "You need soil cover, it is recognized in the agroecological transition, to do that, there is a need for glyphosate"

<https://www.lefigaro.fr/flash-eco/l-agriculture-de-conservation-des-sols-pourra-continuer-a-utiliser-du-glyphosate-selon-didier-guillaume-20200221>

Biodiversity is a New Protection Goal in 1107

- Regulation (EC) No. 1107/2009 Article 4 (3e) introduced biodiversity as a new protection goal: *“impacts on biodiversity and the ecosystem must be avoided”*.
- However, there is no specific and comprehensive guidance for a biodiversity assessment.
- **Biodiversity** is defined in the EU regulations as variability among organisms and the ecological complexes of which they are a part.
- The diversity among living organisms that provide ecological functions has been termed **“functional biodiversity”**, which differs from **“compositional biodiversity”** that refers to species richness and **“structural biodiversity”** that refers to habitat structure.

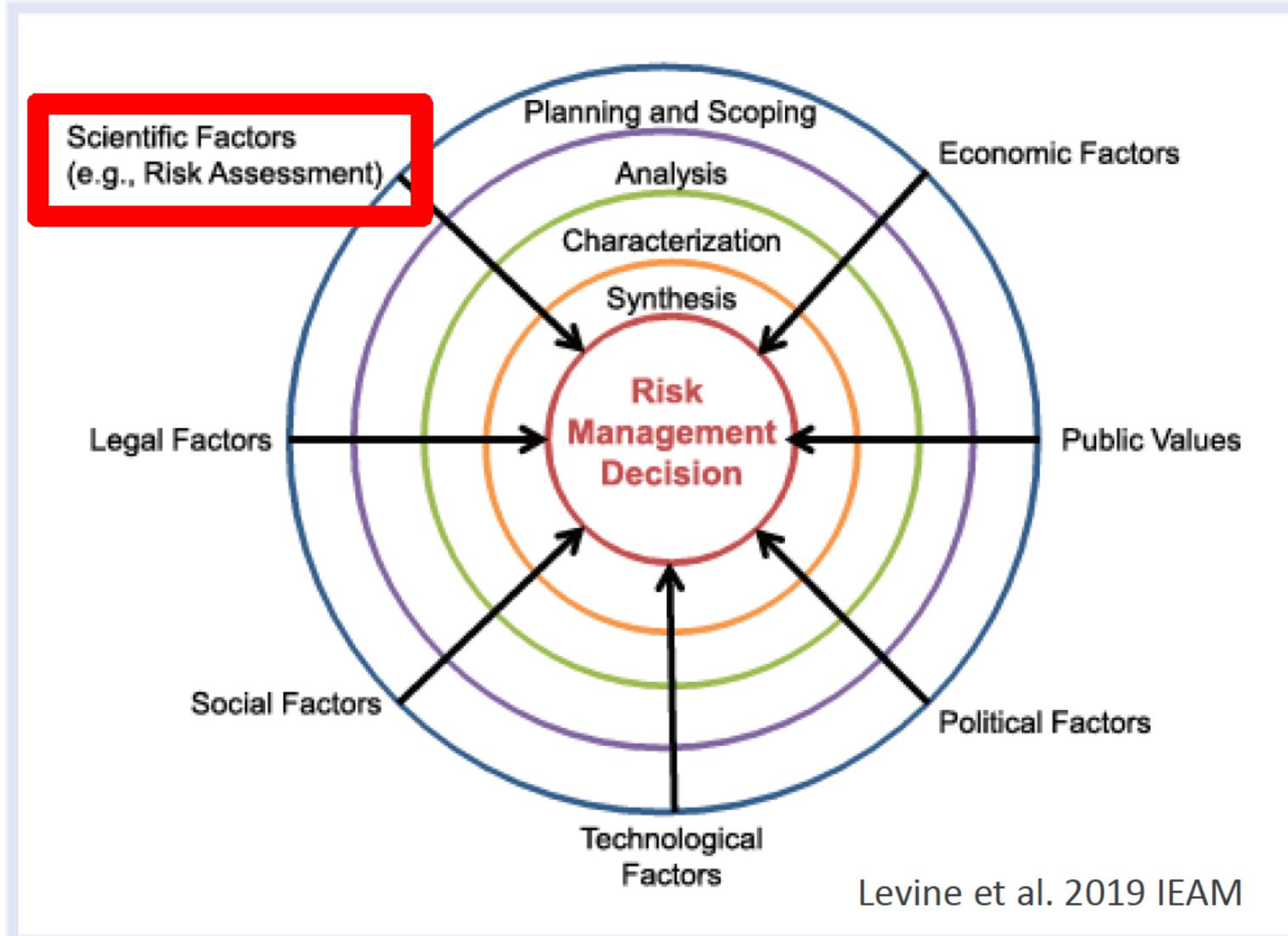
Biodiversity was Commented on in the Glyphosate Annex 1 Renewal Assessment Report (2015)

- In addition to the standard ERA, the RAR had a Biodiversity section (B.9.9.1.6 and B.9.1.7.7) discussing indirect effects via trophic interactions on farmland birds from in-field weed control.
 - The RMS presented a discussion of indirect effects of herbicides including glyphosate on farmland birds and mammals.
 - The RMS advocated for the need for regulating indirect effects under 1107/2009.
 - However, the RMS acknowledged that not re-registering glyphosate was not an option, and advocated that attention is given to the issue by MS during product registration and offered **risk management** options for biodiversity preservation.

Risk Management

Risk managers are the decision makers within the regulatory agency, sometimes in a different branch than risk assessors.

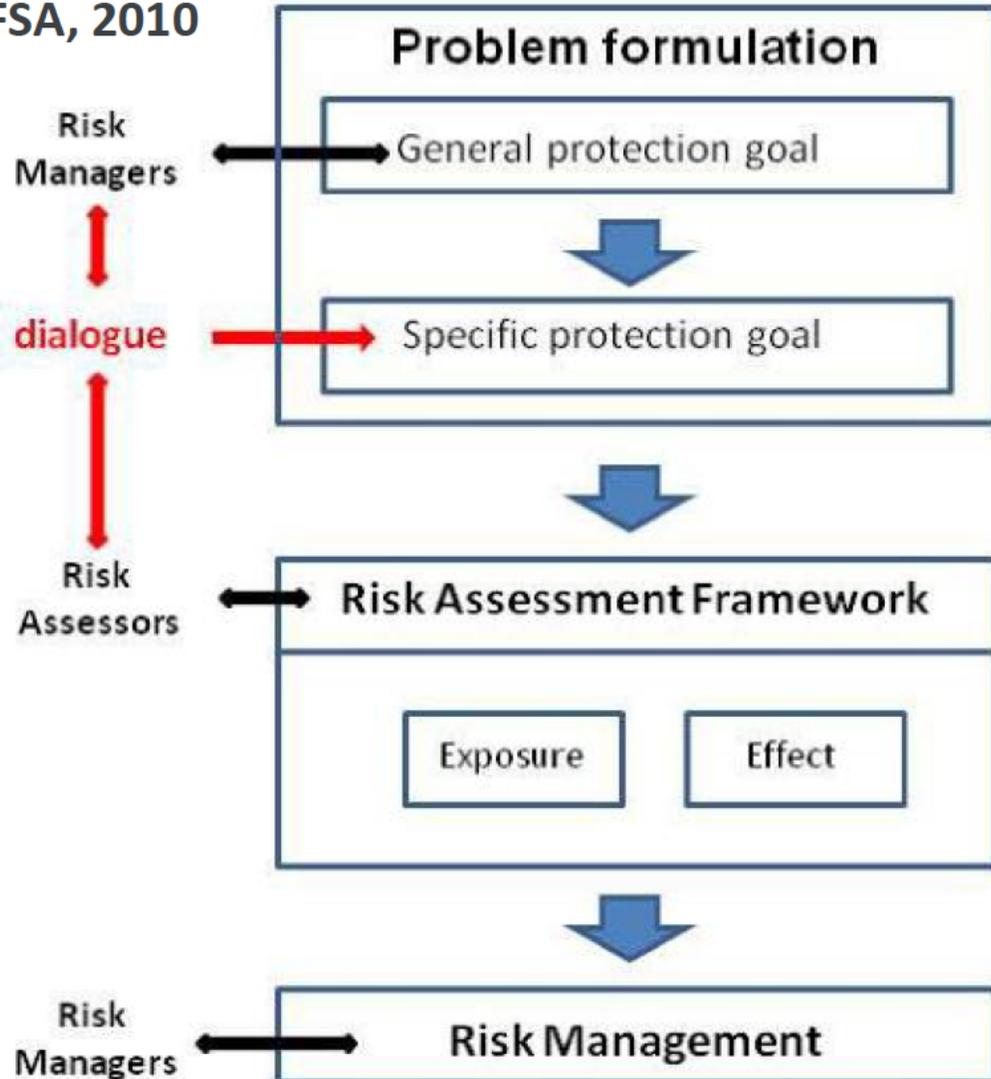
*Risk Management takes the scientific risk assessment and incorporates **social, economic, political and legal factors** that impinge or influence the final decision and selects regulatory actions.*



The risk assessment is only one component of risk management and many other factors need to be considered.

There is a relationship between problem formulation, general protection goals, risk assessment and risk management in the process of developing specific protection goals.

EFSA, 2010



- For this process to work there needs to be an interaction between risk assessors and risk managers.
- Therefore, a goal for the call is to present SPGs for discussion with the AGG to align on the scope of the assessment approach.

How does EFSA Guidance for Birds & Mammals Address Indirect Effects Through Tropic Interactions?

- The GD only provides methods to assesses direct effects for birds and mammals.
- However, the GD stated that it is *arguable* that indirect effects to birds and mammals should be assessed - but indirect effects was looked at as a risk management issue and not within EFSA's and the PPR Panel's remit.
- Therefore, the Panel adopted a two-stage approach first preparing the existing GD.
- In the second stage, representatives from EFSA, EC and RMS have committed to address risk management issues in revised guidance.
- It was acknowledged in the GD, while risk assessment schemes exist to assess indirect effects, they are developmental and not considered appropriate for regulatory use until further work has been done to develop suitable schemes and risk mitigation measures.

Results from the EFSA questionnaire to MS to seek their views on the appropriate scope of the Birds & Mammal Guidance Document

Question 4: Should risk assessment [in the new birds and mammal guidance document] take account of indirect effects, i.e. effects on birds due to pesticide removing its food supply or habitat?

Should risk assessment [in the new birds and mammal guidance document] take account of indirect effects, i.e. effects on birds due to pesticide removing its food supply or habitat?

| No. | Question | What the current Guidance Document says on this issue | Factors to consider | Implications for revision of the Guidance Document | Please insert your opinion on each question in this column |
|-----|--|---|---|--|--|
| 4. | Should risk assessment take account of indirect effects, i.e. effects on birds due to pesticide removing its food supply or habitat? | Indirect effects are not mentioned. The current approach assesses only direct toxic effects. | <p>Indirect effects are potentially within the scope of the definitions of ecological effects in Directive 91/414/EC and its Annex VI.</p> <p>The current draft revision of the Directive includes a reference to impacts on biodiversity.</p> <p>There are a number of ecological studies showing statistically significant indirect effects of pesticides on birds.</p> <p>Many experts believe indirect effects are more likely and important than direct effects.</p> <p>There are no established approaches for regulatory assessment of indirect effects on birds and mammals. The research literature contains models of indirect effects for some specific scenarios.</p> | <p>Adding new guidance on approaches to estimate indirect effects would require involving additional experts and probably could not be completed within the deadline.</p> <p>Other options would be to view this as an issue for research or develop a separate guidance document.</p> <p>It may be preferable to manage indirect effects through mechanisms other than pesticide approvals, e.g. farmland management, conservation schemes.</p> | |

Slides 22 - 24 Included as PRE READ

Results from the EFSA questionnaire to MS to seek their views on the appropriate scope of the Birds & Mammal Guidance Document

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| | |
|-------------------|---|
| Commission | Dealing with indirect effects is certainly not feasible on short term perspective. Importance of indirect effects might be different for different species and depend on various other factors. Therefore, there is clearly a need for further research to answer the questions in which cases and how indirect effects should be considered. This would certainly trigger the need for new guidance. |
| Austria | We are aware that indirect effects probably are more important than direct effects. However, in the framework of regulatory assessment of single plant protection products it appears very challenging to take account of indirect effects. We would like to see this as an issue for research. |
| Czech Rep | Yes, we believe that indirect effects are important and should be taken into account. |
| Denmark | Whether indirect effects should be taken in is a difficult question to answer. In the real world this obviously is important. However, the indirect effects of the use of pesticides can in principle be caused by many other means (e.g. mechanical weed removal). It could therefore be argued that indirect effects belong in the realm of general agricultural politics. Thus it should be established through general politics how agriculture should be managed in order to obtain the diversity that is desired. However if alternative assessments are to be part of the approval procedure in the future it would be useful to develop tool (e.g. population models) that took into account indirect effects. Also if population modelling on a larger (e.g. regional) scale were to be performed it would be important to take into account indirect effects as well as other stress factors. |
| Finland | In Finland, it seems that indirect effects are more important than direct effects. It is realistic to explore these effects with advanced modelling and using the detailed GIS based bird population monitoring data which are available in Finland, but this is a project demanding a lot of working-months (a guess estimate: two highly skillful experts for 1–2 years). |

Question 4 Should risk assessment take account of indirect effects

| | |
|-----------------|--|
| France | <p>From the open literature there is strong evidence that indirect effects does matter. Before the input of additional human and technical means, one way to guarantee an acceptable level of protection for birds would be that consistent conclusion are reached for the different group of organisms considered under Annex VI of Directive 91/414/EC. A conclusion for acceptable risk to non target plants, non target insects, earthworms and other soil organisms, relying on consistent and robust hypothesis, may limit potential indirect effects of the PPP under assessment. That means that an overview of risk assessment hypothesis among groups of organisms should be done before a definite conclusion is reached for birds. A specific chapter may be included in revised document that would harmonize the assessment of indirect effects to birds and mammals (e.g. consider recovery of non target organisms only if appropriate/relevant regarding consequence of indirect effects for birds and mammals population, it is not to reject recovery in risk assessment but to use them in a suitable way to ensure a low occurrence of indirect effects).</p> |
| Portugal | <p>Risk assessment of indirect effects should be assessed, however it may be more appropriate to manage indirect effects through mechanisms other than pesticide approvals e.g. impacts on biodiversity, conservation schemes, etc.</p> |
| Ireland | <p>No. The consideration of indirect effects on behaviour and survival would be extremely difficult to deal with in risk assessment. The availability of insect prey within the crop canopy at the time of crop treatment with an insecticide is obviously very low. Such short term knock down can only be replenished by adjacent hedge row refuges. Appropriate conservation measures can provide the mechanism for alleviation of these short term effects and risk management options are the appropriate response.</p> |

Question 4 Should risk assessment take account of indirect effects

| | |
|------------------------|--|
| United Kingdom | <p>Agriculture is important to the UK and maintaining a healthy and plentiful supply of quality food is a priority. However, all possible steps are taken to avoid or lessen any demonstrated impacts on wildlife and the UK has implemented a wide range of measures to reduce the impact of farming on the environment and promote wildlife. These include specific support to environmental measures and organic farming practices, which still require the removal of pests and weeds. National research has suggested that indirect effects have a much lower impact on bird numbers than direct effects. But most of these impacts can be managed through crop and farm management practices. The new guidance could usefully include any examples for when an assessment of direct toxic effects is not required.</p> |
| Sweden | <p>We believe that modern agriculture is likely to have profound indirect impact on biodiversity, e.g. on bird populations by depletion of food sources by use of plant protection products against herbs, insects etc. However, the draft regulation (as the current directive) does not provide the means to evaluate and take into account in decision making such indirect effects. Even if the intention of the requirement is to assure biodiversity to be maintained in the surrounding of the treated areas (fields, orchards, etc.) this regulation is not the proper legislation to address this issue. Natural populations and species are exposed to and respond to mixtures of stressors and xenobiotics. But under the draft regulation (as the current directive) active substances and PPPs are regulated individually, independent of the properties of and use of other substances and PPPs. Therefore SE considers that the requirement to ensure that plant protection products have no unacceptable influence on biodiversity should be deleted in order not to give the message that this regulation can properly address the task of maintained biodiversity.</p> |
| The Netherlands | <p>Please take into account If a robust risk assessment method can be identified. Otherwise indeed issue for further research before including into risk assessment. Concentrate on direct effects. A discussion on policy goals for indirect effects will be difficult</p> |

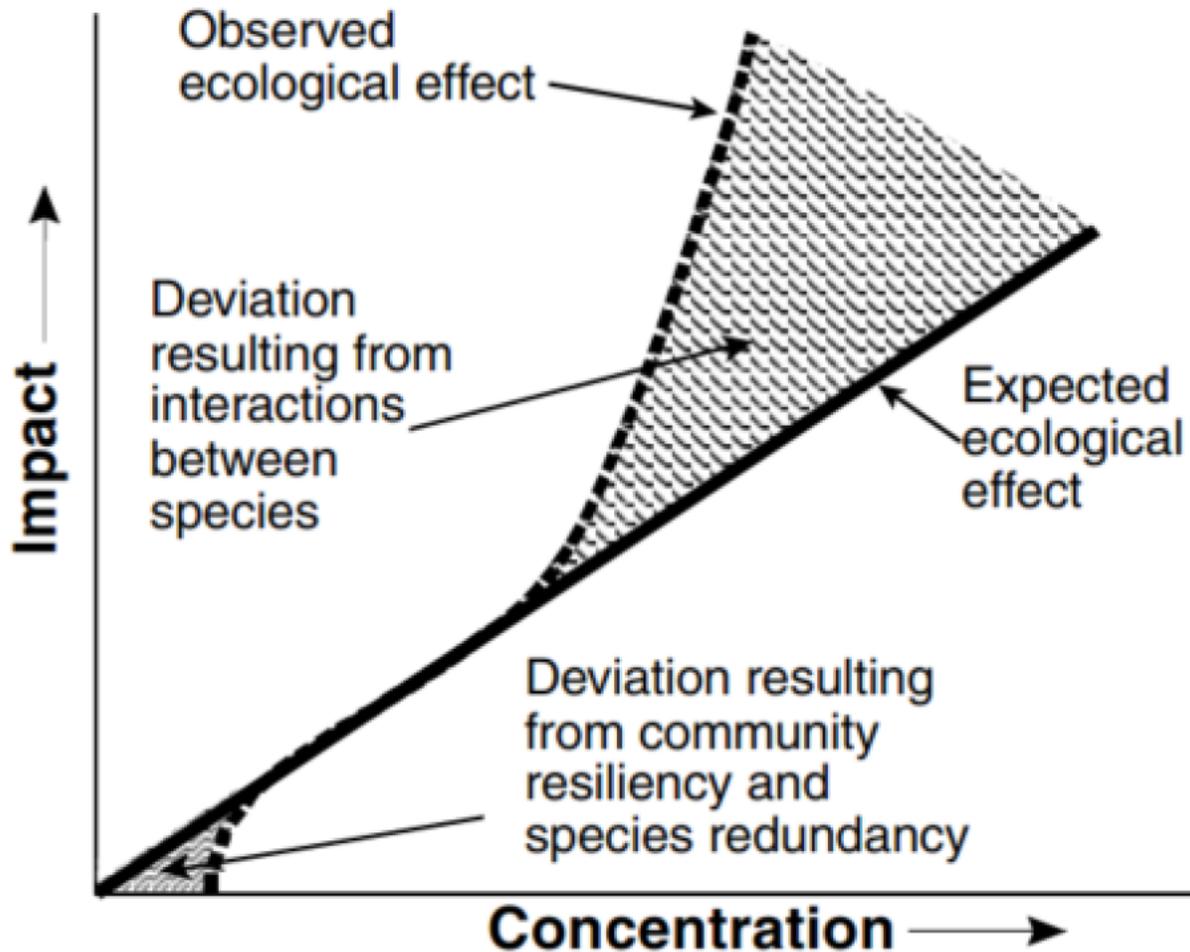
Previous Feedback from the AGG Will be Considered in the Biodiversity Assessment

- .. Provide a comprehensive evaluation of the impact of glyphosate on biodiversity and include a proposal(s) for mitigations to protect biodiversity.
- The assessment in the dossier will consider the following:
 - Existing nontarget organism assessment guidance
 - In-field and off-field habitats
 - The relevant peer-reviewed literature
 - Monitoring data within the context of biodiversity (water detects <Regulatory Acceptable Concentration (RAC))
 - Environmental mixtures (glyphosate monitoring data will inform this assessment)
 - Discussion on how to manage biodiversity (e.g., EU and MS level for the local situation)
 - Ecosystems Services Approach – recommended by EFSA to inform the development of Specific Protection Goals (EFSA, 2010)

Ecosystem Services Inform the Development of Specific Protection Goals

- **Ecosystem Services** are generally defined as ecological processes and functions that sustain and improve human well-being.
- Biodiversity plays a role in the provisioning of ecosystem services.
- Ecosystem services are grouped into four categories (Millennium Assessment Report, 2005):
 - Provisioning: food, fiber, timber, fresh water, etc. (historically the highest priority)
 - Regulating: soil and water conservation, pollination, pest control, nutrient cycling, carbon sequestration
 - Supporting: soil formation and fertility, water purification, etc.
 - Cultural: aesthetic and recreational
- The Ecosystem Service Approach considers **trade-offs** as well as spatial and temporal scales and ecological functional redundancies.
- The concept of **Functional Redundancy** assumes that more than one species performs a given role within an ecosystem.

Functional redundancy and resiliency, is considered by the Ecosystem Services approach and can compensate for indirect effects in ecosystems



It has been recommended that the Ecosystem Services approach is used to inform the development of Specific Protection Goals and considers functional redundancy (EFSA, 2010; ECETOC, 2015).

From: [REDACTED] 2002. Probabilistic risk assessment using species sensitivity distributions. In: Species sensitivity distributions in Ecotoxicology. Lewis publishers.

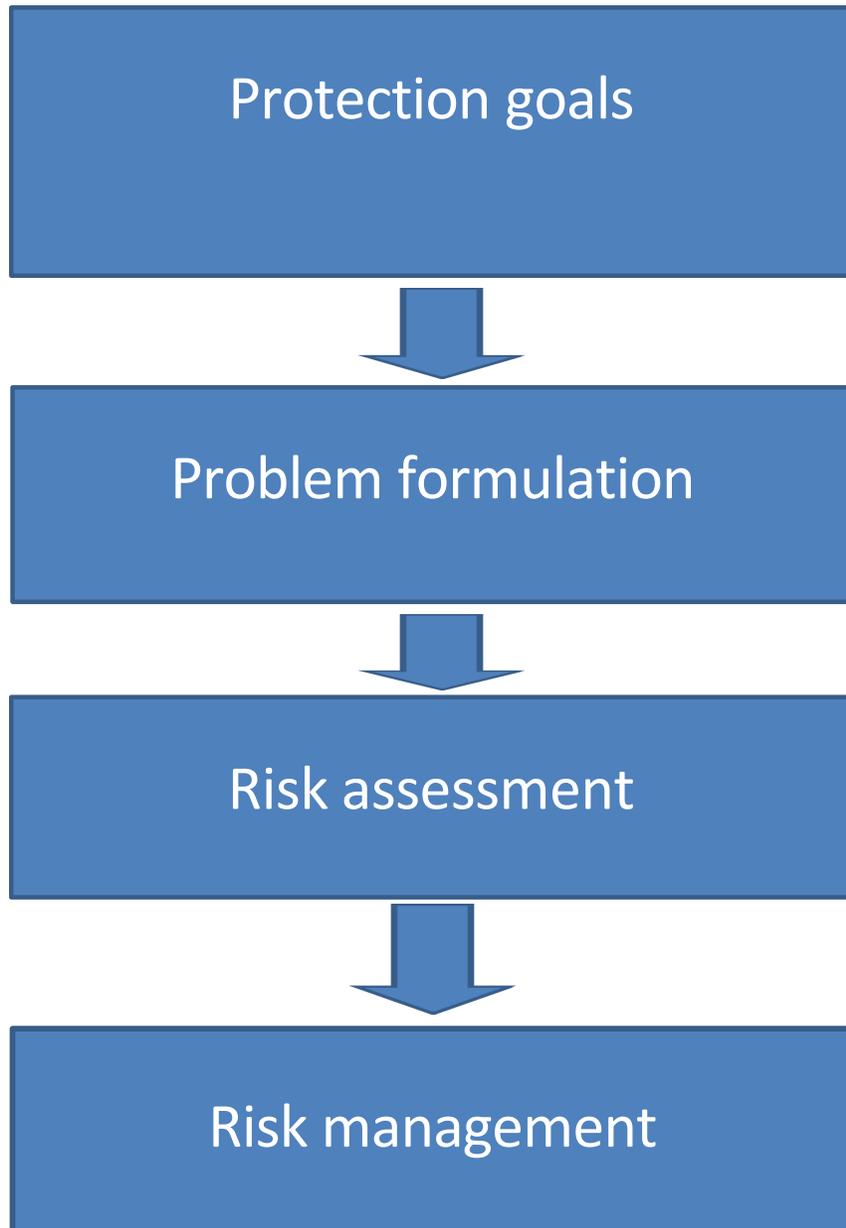
PPR Stakeholder Workshop on Protection Goals for ERA of Pesticide: What and where to protect?

When it comes to choosing protection goals for risk assessment and management of cultivated areas, it is clear that trade offs need to be accepted and that not all biodiversity can be protected always, everywhere and all the time. **The ecosystem services concept allows us to identify what to protect, what the trade offs are and to prepare the basis of taking decisions on what, where, and at which scale to protect.** Whereas it is desirable to protect all ecosystem services, it may not be essential to protect them all at the same time in the same place.

The Ecosystem Services approach was chosen by the Panel as the overarching concept for deriving SPGs because it helps to identify what to protect, dimensions* of the SPGs and trade offs as a basis for practical regulatory decision making.

* ecological entity, attribute, magnitude of effect, spatial and temporal scale, degree of certainty

Developing Specific Protection Goals (SPGs) for a Biodiversity Assessment

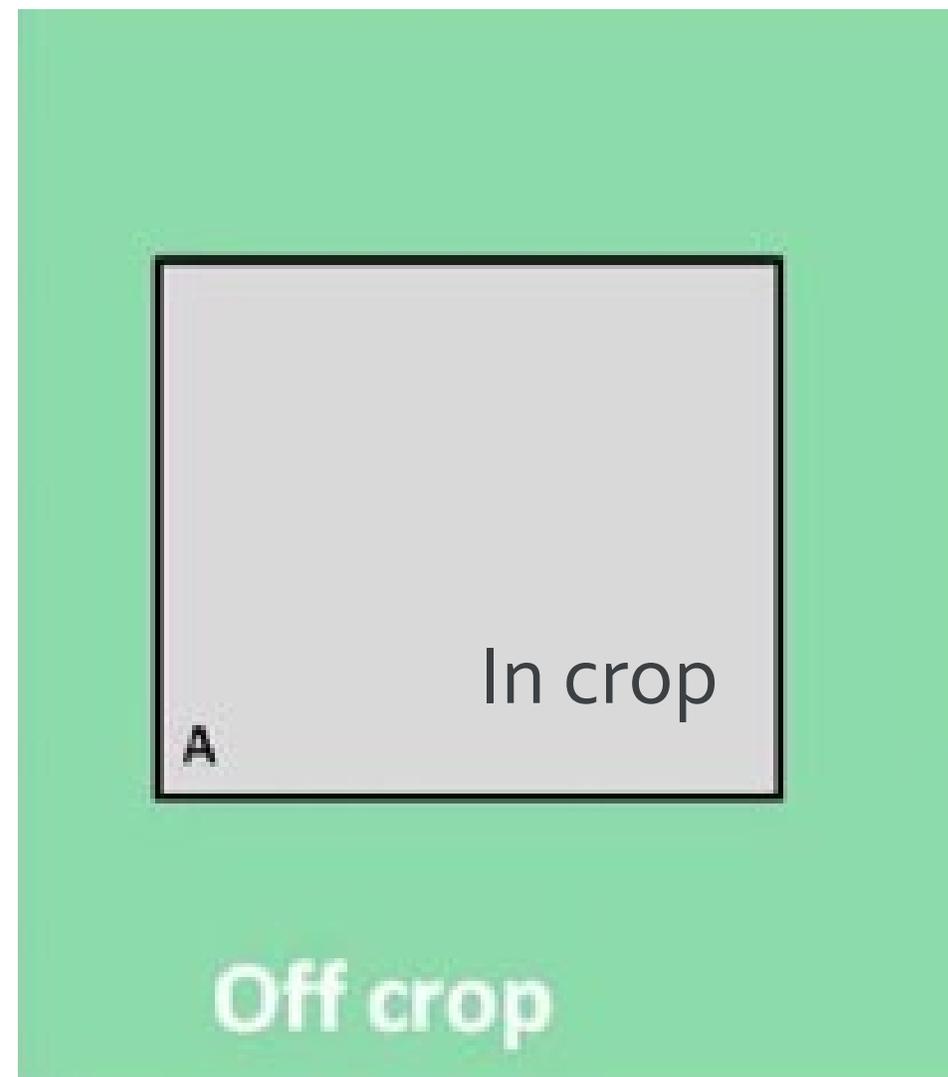


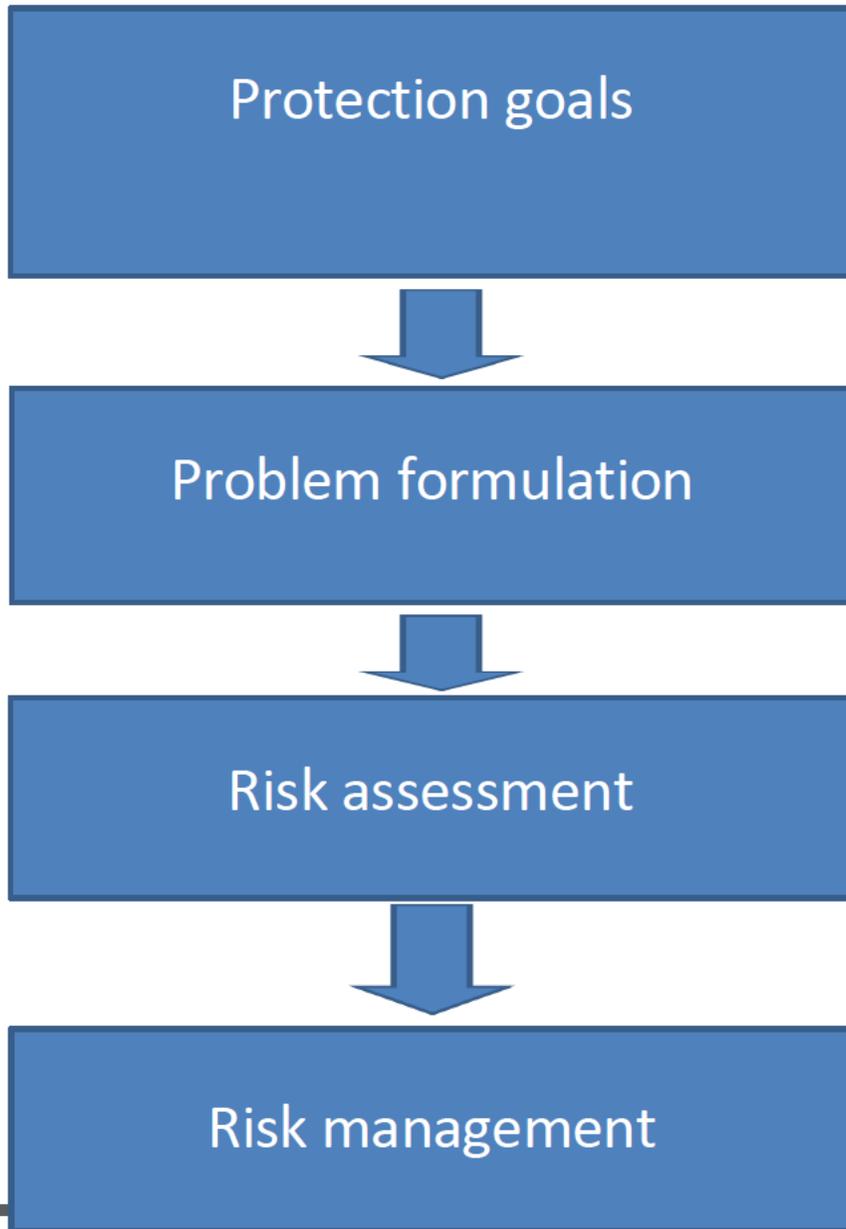
- An ecological assessment requires Specific Protection Goals specifying **what** to protect, **where** to protect it, the **level of protection** and over what **time period** (EFSA, 2010).

- For some taxa there are justifiably different protection goals as well as different protection goals for in-crop and off-crop.

In-Crop vs Off-Crop Protection Goals

- In the legal framework, no clear distinction is made between in-crop or off-crop risk assessments.
- It was considered practical by the EFSA PPR-Panel to make a distinction between in-crop and off-crop risk assessments because of differences in the socio-economic and ecological functions of in-crop and off-crop areas (EFSA, 2010).
- Similar considerations were made while developing ESCORT2/3 NTA guidance.





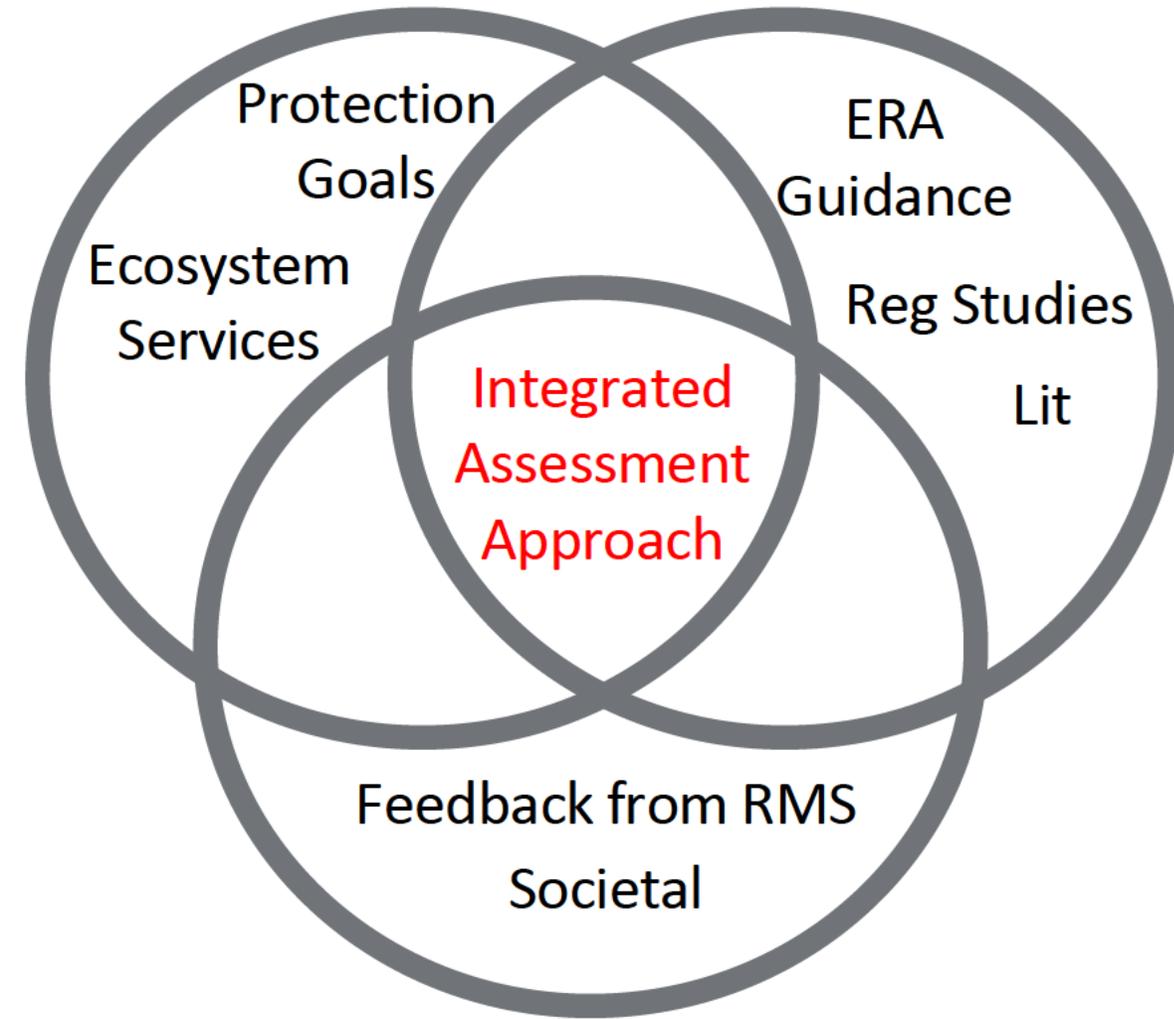
- EC 1107/2009 only provides a generic Protection Goal: No unacceptable effect to the environment [including biodiversity]

- The existing ERA procedure for PPPs is already largely based on the protection of populations and communities which provide the ecosystem services.
- Therefore, the expectation is that the SPGs relevant for a biodiversity assessment can be largely met with the existing ERA guidance.

- However, the SPGs for a biodiversity assessment should involve consultation with AGG and MS risk managers.

Proposed Specific Protection Goals for the Biodiversity Assessment

Considerations Taken for the Biodiversity Assessment



- The purpose of the biodiversity assessment is to evaluate the potential for direct and indirect effects to biodiversity and propose risk mitigations to inform risk management options.
- Breaking the assessment up into smaller components will streamline the assessment and allow us to identify taxa and services which are most at risk.
- SPGs need to be transparent and defensible.
- For each taxonomic group, a framework is presented that shows the relationship between Specific Protection Goals, Assessment Endpoints and Measurement Endpoints and provides rationale why the SPG are protective of biodiversity or inform mitigations and/or risk management options.

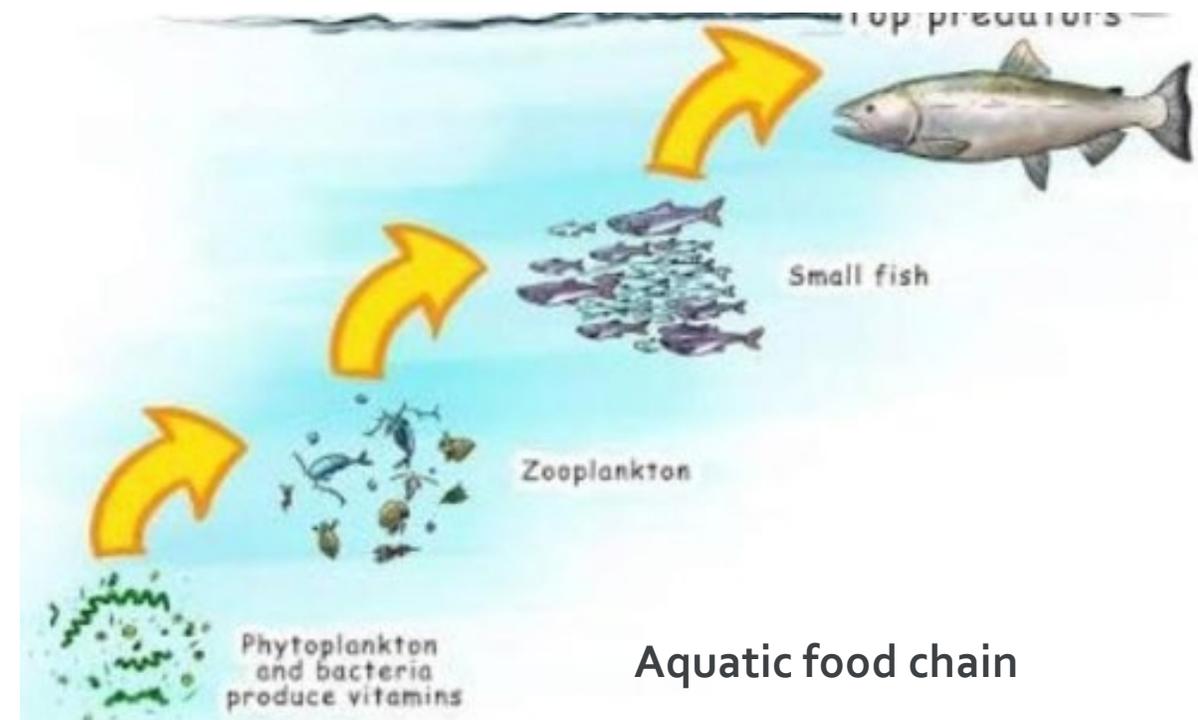
The relationship between specific protection goals, assessment endpoints and measurement endpoints for aquatic systems (wetlands, rivers and lakes) exposed by runoff and/or spray drift.

| Proposed Specific Protection Goals | Assessment Endpoints | Measurement Endpoints | Study Types |
|--|--|--|---|
| Negligible acute and long-term effects to aquatic plant and animal populations from direct and indirect effects. | Survival, growth and reproduction of aquatic populations | Acute and chronic toxicity to aquatic plants and animals and bioaccumulation | Algal toxicity Vascular plant toxicity Acute <i>Daphnia</i> <i>Daphnia</i> life-cycle Chironomid emergence Acute fish Fish ELS Fish repro screening Fish Full Life-cycle Amphibian metamorphosis Bioconcentration |

Protecting against direct effects on representative sensitive populations is protective of indirect effects through trophic interactions at the community, ecosystem and landscape levels (Option 1: EFSA aquatic guidance, 2013).

Protecting against direct effects is protective of indirect effects

- Protecting against direct effects at each trophic level is protective of indirect effects at the community, ecosystem and landscape levels (i.e. protective of the interaction between taxa groups within a food chain)
- A summary of monitoring data from the 2015 RAR and the recently analyzed environmental monitoring data is <RAC. does not modify the assessment.



Discussion Question

A strength of the aquatic assessment is that the different trophic levels were tested and showed negligible risk. Does the AGG agree that we can follow the approach outlined in the EFSA Aquatic Guidance (Option 1) to address indirect effects through trophic interactions?

The relationship between specific protection goals, assessment and measurement endpoints for bees from contact and dietary exposure.



| Proposed Specific Protection Goals | Assessment Endpoints | Measurement Endpoints | Study Types and data to assess specific protection goals |
|--|--|-------------------------------------|---|
| No significant effect on honeybee colony survival, development and production of hive products | Population size and stability of managed bees and quantity and quality of honeybee hive products | Adult survival and larval emergence | Adult honeybee acute contact & oral Adult Bumble bee acute Adult solitary bee acute Adult honeybee chronic Larval honeybee emergence Honeybee semi-field and field brood studies |
| Pollination services | Population size and stability of native and commercially managed bees | | |
| Bee biodiversity | Species richness of native bees | | |

Negligible acute and chronic risk to larval and adult bees from direct effects considering both EPPO and EFSA approaches

Negligible Risk of Direct and Indirect Effects to Bees

- Measured levels of glyphosate in honey from monitoring studies indicate low colony exposure and spray buffers required for NTTPs should be protective of off-crop forage.
- Importantly, control of in-crop flowering weeds should not result in indirect effects since they are not a major source of nectar and pollen (ERM, 2019).

ERM. 2019. Regulatory report on the occurrence of flowering weeds in agricultural fields.

Sponsored by the European Crop Protection Association. Authors [REDACTED]

- Required label language¹ should largely address the concern for indirect effects to pollinators e.g., *“To protect aquatic organisms/non-target plants/non-target arthropods/insects respect an unsprayed buffer zone of (distance to be specified) to non-agricultural land/surface water bodies.”*

¹ Commission Regulation (EU) No 547/2011

Discussion Question

Considering the exposure and effects assessment for bees, is there any additional information that should be considered to address indirect effects to bees?

The relationship between specific protection goals, assessment and measurement endpoints for **soil macro and micro-organisms from foliar applications.**

| Proposed Specific Protection Goals ¹ | Assessment Endpoints | Tier 1 Measurement Endpoints | Tier 1 Study Types |
|---|--|--|--|
| Protection of structure (biodiversity) and function of soil macro-organism communities and function of soil micro-organism communities. | Structure and function of soil macro-organism communities Long-terms effects on the function of soil micro-organism communities | Survival and reproduction N-transformation rate $\leq 25\%$ difference from control at ≥ 28 days | Earthworm chronic Collembola chronic Predatory mite chronic N-transformation rate |
| Protection of soil services (e.g., supporting services of decomposition, nutrient cycling and water regulation) | Long-terms effects on the function of soil micro-organism communities (i.e., Nitrogen cycling) | Survival and reproduction N-transformation rate $\leq 25\%$ difference from control at ≥ 28 days | |

As there is negligible risk to the structure and function of soil organism communities (EFSA, 2015), risk of indirect effects to supporting/regulating services related to soil processes and soil community biodiversity are expected to be negligible.

Discussion Question

Based on the exposure and effects assessment for soil organisms, should anything else be considered to address the indirect effects assessment to soil organism functional and compositional biodiversity?

The relationship between specific protection goals and associated assessment and measurement endpoints for NTAs.

| Proposed Specific Protection Goals ¹ | Assessment Endpoints | Tier 1/2 Measurement Endpoints | Tier 1/2 Study Types |
|---|--|--|---|
| <u>In-field</u> Maintenance of ecological function of beneficial NTA populations (not to exceed the ability to recover). | Maintaining relevant functions (e.g., bio control, food resource, pollination) (@Tier 1, at the maximum use rate achieve an assessment factor of ≥ 2 with mortality @Tier 2, at the maximum use rate no significant mortality and <50% effect on reproduction.) | Survival (LR ₅₀) and if appropriate, assess reproduction effects | Primary: <i>Typhlodromus pyri</i> (predatory mite) and <i>Aphidius rhopalosiphi</i> (parasitic wasp) Secondary: <i>O. laevigatus</i> , <i>C. carnea</i> , <i>C. septempunctata</i> , |
| <u>Off-field</u> Maintenance of NTA abundance, species richness (biodiversity) and the ability to support in-field recovery. | Insect community biodiversity (@Tier 1, at the MUR achieve an assessment factor of ≥ 2 with mortality @Tier 2, at the MUR no significant mortality and <50% effect on reproduction.) | Survival (LR ₅₀) and if appropriate, assess reproduction effects | |

The standard in-field and off-field assessments pass at Tier 1 or Tier 2 meeting the current protection goals.

Discussion Question

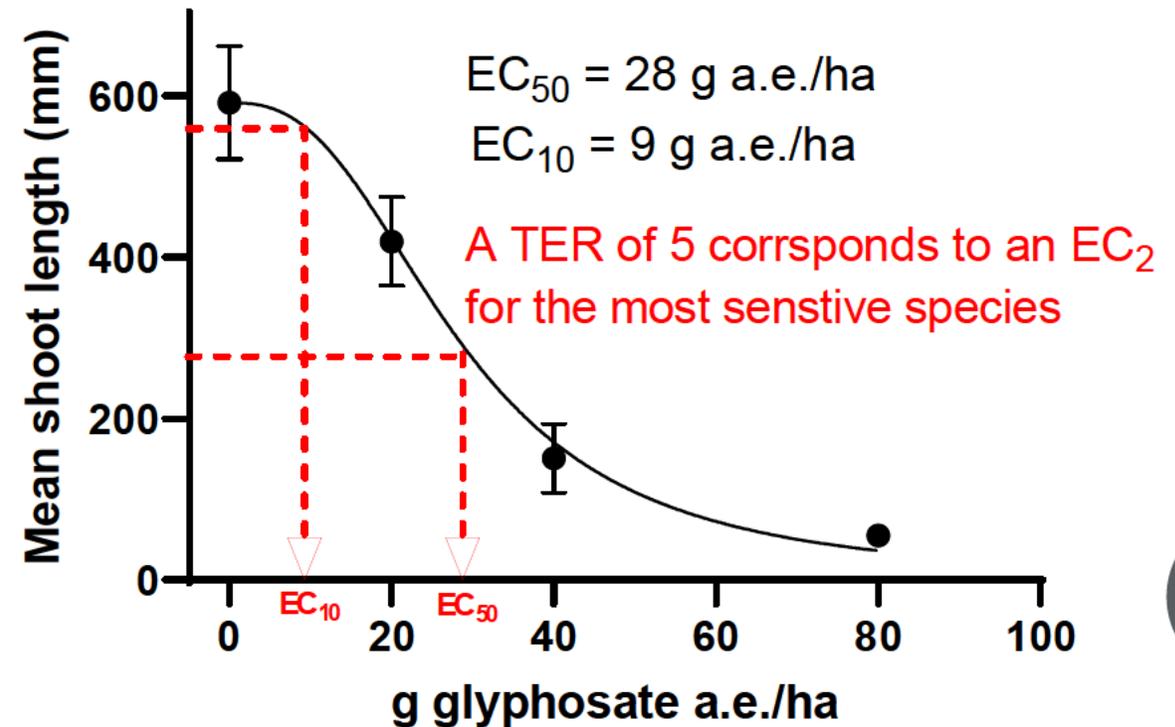
- Considering the current in-field and off-field protection goals for nontarget arthropods, and meeting those protections goals with the existing assessment is there anything else to consider to maintain relevant nontarget arthropod functions in-crop and protecting species abundance and richness (i.e., insect biodiversity) off-crop?

The relationship between specific protection goals and associated assessment and measurement endpoints for **non-target terrestrial (NTTP) plants from spray drift.**

| Proposed Specific Protection Goals | Assessment Endpoints | Measurement Endpoints | Study Types |
|--|--|--|--|
| Negligible risk to off-field NTTP communities to support nutrient cycling, water regulation, food web, aesthetic values and genetic resources (biodiversity) | Protect 95% of the NTTP populations in 90% of the cases. | EC ₅₀ values for plant survival, height and weight. | Tier 2 Vegetative vigor Tier 2 Seedling emergence |

- The NTTP assessment is driven by the most sensitive species (cucumber data - graph to the right) or an HC₅ from a SSD.

- Off-field non-target plant communities can be protected with a buffer and/or drift reduction technology.



Discussion Question

- Currently, there are no in-crop protection goals for nontarget terrestrial plants. Therefore, comprehensively addressing indirect effects from in-crop weed control, is best addressed outside the PPP framework and under other policies (e.g., common agricultural policy (CAP)). Does the AGG agree that the best solution to address indirect effects from in crop weed control is best handled by risk management options under other policies (e.g., CAP)?
 - For example, does the AGG agree that protecting farmland birds, from indirect through trophic interactions that may result from in-crop weed control, can be addressed independently by MS via risk management options and using the provisions of the new CAP?

Please see following two slides summarizing the new CAP proposed revision 2022.

New CAP Aims to protect biodiversity, enhance ecosystem services and preserve habitats and landscapes

VOLUNTARY for farmers

- Farmers will be **rewarded** for going beyond mandatory requirements in relation to agri-environment and/or climate commitments undertaken

- Each Member State will **develop eco-schemes** to support and/or incentivise farmers to observe agricultural practices beneficial for the climate and the environment, beyond their mandatory requirements

MANDATORY for farmers

- All direct payments will be conditional to enhanced environmental and climate requirements. In line with the EU's ambitious environmental and climate objectives, the mandatory requirements with which farmers have to comply will be further strengthened.

New obligations include

- **preserving carbon-rich soils** through protection of wetlands and peatlands
- **obligatory nutrient management tool** to improve water quality, reduce ammonia and Nitrous oxide levels
- **crop rotation** instead of crop diversification

- Obligation for Member States to reserve part of the direct payments to farmers for those participating in **specific eco-schemes**
- **Improved synergies** with other EU policies and programmes on climate action and the environment, such as the LIFE programme

A layer of payments within the CAP's system of "greening payments" is highly relevant to biodiversity and landscapes



- Farmers receive their green payments when they:
 - Maintain a certain level of crop diversity on their arable land
 - Maintain permanent grassland
 - Devote a certain portion of their arable land (labelled "ecological focus area" or "EFA") to biodiversity friendly practices or features.
- The list of possible EFA elements includes (among others) fallow land, buffer strips, terraces and other landscape features.

The relationship between specific protection goals, associated assessment and measurement endpoints for **birds and wild mammals**.

| Proposed Specific Protection Goals ¹ | Assessment Endpoints | Measurement Endpoints | Study Types |
|--|---|--|--|
| No visible mortality and long-term impacts on abundance and diversity to avian populations | No reduction in survival, growth, development, reproduction of avian populations. | Survival, growth, development and reproduction | Acute oral avian and rat Avian reproduction Rabbit teratology Rat 2-gen |

* ERA includes secondary poisoning considerations e.g., earthworm, fish, drinking water but not habitat.

The standard ERA shows negligible risk of direct acute and long term effects to birds and mammals for proposed uses and rates.

National research from the UK suggests that indirect effects have a much lower impact on bird populations than direct effects and indirect effects can be managed through crop and farm management practices.

Discussion Question

- Does the AGG agree that protecting farmland birds, from indirect through trophic interactions that may result from in-field weed control, can be addressed independently by MS via risk management options and using the provisions of the new CAP?

Additional Discussion Questions

- We have not tried to develop a “new” approach for the biodiversity assessment. In the AGG’s opinion, is the general approach using the core data and lines of evidence clear and fit for purpose?
 - The proposed SPGs largely draw from existing EFSA guidance and EFSA protection goal workshops. Are the proposed SPGs for the biodiversity assessment fit for purpose and if not are there recommendations for how to revise one or more of the SPG’s?
 - Are there any areas the AGG feel have not been sufficiently covered in the proposed approach?
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