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EFSA Scientific Colloquium
Summary Report

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BIODIVERSITY AS PROTECTION GOAL IN ENVIRONMENTAL RISK ASSESSMENT FOR EU AGRO-ECOSYSTEMS

27 – 28 November 2013, Parma, Italy

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About EFSA

The European Food Safety Authority (EFSA) was established and funded by the European Community as an independent agency in 2002 following a series of food scares that caused the European public to voice concerns about food safety and the ability of regulatory authorities to fully protect consumers.

In close collaboration with national authorities and in open consultation with its stakeholders, EFSA provides objective scientific advice on all matters with a direct or indirect impact on food and feed safety, including animal health and welfare and plant protection. EFSA is also consulted on nutrition in relation to Community legislation.

EFSA's work falls into two areas: risk assessment and risk communication. In particular, EFSA's risk assessments provide risk managers (EU institutions with political accountability, i.e. the European Commission, European Parliament and Council) with a sound scientific basis for defining policy-driven legislative or regulatory measures required to ensure a high level of consumer protection with regards to food and feed safety.

EFSA communicates to the public in an open and transparent way on all matters within its remit. Collection and analysis of scientific data, identification of emerging risks and scientific support to the Commission, particularly in case of a food crisis, are also part of EFSA's mandate, as laid down in the founding Regulation (EC) No 178/2002 of 28 January 2002.

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I. INTRODUCTION

The 19th meeting in the EFSA Scientific Colloquium Series was dedicated to "*Biodiversity as Protection Goal in Environmental Risk Assessment for EU agro-ecosystems*" and was held in Parma on 27-28 November 2013.

Environmental risk assessment (ERA) considers the potential impact on the environment caused by, for example, regulated products or invasive species. The European Food Safety Authority (EFSA) is responsible for ERA of regulated products/species related to the food/feed chain in all areas falling within its remit. It performs this task in accordance with the various sectorial legislations[1] wherein the **general protection goals** (GPGs) to be considered in ERA are set for each type of regulated product/species[2] and their specific use, for example use in agricultural environments contributing to crop production.

Overall, these GPGs strive for a high level of environmental protection. EFSA is aware that within **agro-ecological landscapes** a whole range of GPGs can be established. The prioritisation of GPGs is difficult and involves trade-off decisions as one cannot protect everything, everywhere, at the same time in agriculture. EFSA is not responsible for trade-off discussions, as those fall under the domain of risk management[3]. The 18th EFSA Colloquium[4] showed that stakeholders interpret and prioritise GPGs that can be set in a given agro-ecosystem differently. For the scope of the 19th Colloquium, EFSA has not prioritised **biodiversity** over other GPGs in agro-ecological landscapes. However, as biodiversity is a common and prominent GPG for all ERAs performed by EFSA, it was identified as the topic that would benefit most from further consideration with regard to making it operational in ERAs.

1 An overview of ERA schemes and the applicable sectorial legislations is given in the "*Review of current practices of environmental risk assessment within EFSA*" (EFSA, 2011). EFSA performs ERA for plant protection products (PPPs), the introduction and spread of non-endemic plant pests, the commercial release into the environment of genetically modified organisms (GMOs), for feed additives, biological hazards and it is envisaged that more Panels (e.g. for food contact materials) will perform ERA on applications submitted to EFSA.

2 Research initiatives have been launched to provide an overview of protection goals (PGs) for a particular type of regulated product/species. For example, in the ongoing AMIGA project, Member States were asked to list PGs applicable in their territory and which of those are applicable to GMOs. Also for chemicals such comparison has been made (see Hommen et al., 2010).

3 Other risk management issues relevant to PGs (but not in the remit of this Colloquium) are risk/benefit analyses, risk mitigation measures and post-market environmental monitoring.

4 See the results of Discussion Group 1 of Colloquium XVIII '*Towards holistic approaches to the risk assessment of multiple stressors in bees*' http://www.efsa.europa.eu/en/events/event/130515.htm).

GPGs, are indeed only broadly outlined in the sectorial legislations, so that a translation of GPGs to **specific protection goals** (SPGs) is required for specific ERA schemes. To be scientifically useful for ERA and regulatory decision-making, it is crucial to define clear SPGs and to make them operational by translating them into **measurable endpoints**. These measurable endpoints are necessary for quantifiable predictions of the probability and seriousness of harmful effects during ERA.

Furthermore, the translation of GPGs to SPGs and measurable endpoints may leave room for different technical interpretations: e.g. each of the EFSA Panels on Plant Health (PLH), Plant Protection Products and their Residues (PPR) and Genetically Modified Organisms (GMO) have developed a number of specific guidance documents wherein their respective ERA schemes (addressing SPGs) are described (EFSA GMO Panel, 2010, 2013; EFSA PLH Panel, 2010, 2011; EFSA PPR Panel, 2009, 2013). In order to explore possible harmonisation of ERA schemes, EFSA experts discussed at EFSA's 10th Anniversary Conference (7-8 November 2012, session "*Having an eye for the environment*"), how a common approach would ensure that environmental SPGs are considered consistently across ERAs, irrespective of the type of regulated product/species. This accounts for the fact that in general the same agro-environment is expected to be exposed to the different types of regulated products/species to be assessed.

Considering the wider implications and the overarching nature of this topic, EFSA recently launched a self-tasking mandate that requested the Scientific Committee to continue previous work on PGs, developed in the area of plant protection products (PPP), and to expand it to a wider range of regulated products, such as GMOs, feed additives, and invasive species. The previous work of the EFSA PPR Panel described how GPGs, as mentioned in the legislative framework for PPPs, could be specified using the ecosystem services concept (EFSA PPR Panel, 2010; Nienstedt et al., 2012). Such work was developed in consultation with the various stakeholder groups involved (EFSA, 2010). In view of the regulatory responsibilities for protection goals (PGs) and their normative status, the further study on SPGs for ERA required a dedicated forum with the organisation of the 19th Scientific Colloquium to convene experts from various stakeholders, including risk managers. This Colloquium offered the opportunity to bring together international experts for an open scientific debate and to collect views on the following topics that were introduced by a keynote speaker in the opening plenary session, presenting the state of knowledge in that area.

- Discussion Group 1 of this Colloquium explored where further harmonisation is possible while considering SPGs in the different ERA schemes at EFSA and while making them operational for EU agro-ecosystems.
- Discussion Group 2 focused on biodiversity as the most common and prominent PG set in all ERA legal frameworks. How to assess and how to measure biodiversity were the specific topics for discussion with risk managers and risk assessors.
- Discussion Group 3 looked at the protection of endangered species that may be impacted by regulated products/species under EFSA's remit.
- Discussion Group 4 discussed the concept of including ecological recovery/resilience of non-target populations in ERA.

II. ABSTRACTS OF SPEAKERS IN OPENING PLENARY SESSION

Objectives of the Colloquium

Theo Brock, *Wageningen University and Research Centre, The Netherlands*

The main objective of the Colloquium is to bring together international experts from different sectors and to facilitate an open debate on topics that are the subject of the Colloquium. The opinions and ideas of different stakeholders are captured and will be used to inform EFSA Panels and Working Groups on environmental PG issues. EFSA is responsible for developing ERA procedures for regulated products and invasive species related to the food/feed chain. The topics addressed by EFSA concern the ERA of plant protection products (PPR Panel), non-endemic plant pests (PLH Panel), genetically modified organisms (GMO Panel), feed additives (FEEDAP Panel), biological hazards (BIOHAZ Panel) and overarching issues (Scientific Committee). A dialogue is required between different stakeholders and between risk assessors and risk managers since there is a trade-off between economic activities and environmental PGs (e.g. the protection of biodiversity in agro-ecosystems). An important question at stake is whether the SPGs should be harmonised or differentiated dependent on the regulated product/species. More specifically, an internal mandate for the EFSA Scientific Committee posed the questions: "For different regulated products/species, and with reference to biodiversity in agro-ecosystems, is there scope for: (1) The use of the ecosystem services concept to define SPGs?, (2) Harmonization of SPGs?, (3) Ecological recovery of non-target populations?, and (4) The protection of endangered species?".

Introduction to protection goals, ecosystem services and the roles of risk management and risk assessment

Lorraine Maltby, *the University of Sheffield, United Kingdom*

Robust and efficient risk assessment procedures require clear PGs specifying what to protect, where to protect it and over what time period. PGs specified in EU environmental regulations indicate, in general, what is to be protected, but are not specific enough to inform an effective risk assessment and hence risk management process. The inherent trade-off between agricultural production and biodiversity, coupled with the fact that not all biodiversity can be protected everywhere all the time, raises the question: what risks to which elements of biodiversity are acceptable? Biodiversity underpins the delivery of ecosystem services (benefits people derive from ecosystems), which include food production, climate regulation, nutrient cycling and the presence of charismatic species.

Specifying PGs in terms of ecosystem service delivery makes the trade-offs between food production and other services transparent and provides a mechanism for protecting species diversity. It also makes the risk assessment more relevant for socio-economic assessments and therefore better informs risk management decisions.

Making protection goals operational for use in environmental risk assessments: an applicant's perspective

Monica Garcia-Alonso, *Estel Consult Ltd, United Kingdom*

In the EU, ERAs are used for decision-making, including decisions on approvals of new plant protection products, on the environmental release of genetically modified organisms and on actions to take to control or eradicate the spread of invasive alien species. To fulfil their purpose, these ERAs must be "fit for purpose", providing relevant information for decision-makers and focussing on the key aspects that the assessments must consider. Therefore, country legislation, general PGs and relevant policy documents outlining data requirements are taken into account. However, typically, GPGs are generic, normative and stated in very broad terms so they are too ambiguous to be directly applicable in ERAs. This means that risk assessors often have to interpret what GPGs are relevant for the ERA. Different stakeholders often have different interpretations of what GPGs are relevant, this leads to difficulties during the review and decision-making process. The need to translate GPGs into SPGs for "fit-for-purpose" ERAs has been identified. An operational translation of GPGs focuses the ERAs, facilitates the selection of relevant assessment endpoints, the formulation of testable hypotheses and the selection of measurement endpoints. Different approaches for translating GPGs into SPGs have emerged in different EU frameworks: plant protection products, invasive alien species and GMOs. These three approaches are based on the use of the ecosystem service concept, as a tool to make GPGs operational for ERAs. The main methods taken in the three approaches were outlined, highlighting the main similarities and differences to use as a basis for discussing potential harmonisation, so SPGs can be developed for agro-ecological landscapes in the EU independently of the product under consideration.

The role of population dynamics in environmental risk assessments to protect biodiversity

Michael Bonsall, *University of Oxford, United Kingdom*

Understanding population dynamics necessitates an appreciation of birth, death and dispersal events. All of these demographic processes drive population change. In this talk modern approaches (based on net growth analysis rather than key-factor analysis) are presented for understanding the contribution of all these demographic processes to population-level patterns and change. Using case studies, the tacit assumption is questioned that ecological processes driving species interactions remain qualitatively unchanged across geographical ranges and the implications this has for ERAs. It is also considered how best to develop analyses for understanding complex species webs and interactions. Finally, population dynamics of rarity and the implications of rarity are discussed for ERAs.

Modeling recovery in risk assessment and management: getting the purpose, limits, uses and partnerships established before you start

Paul Jepson, *Oregon State University, USA*

Population recovery following anthropogenic perturbation is a pre-requisite for maintaining agricultural biodiversity and for sustaining aquatic and terrestrial wildlife within agro-ecosystems. If pesticides were universally of low risk to non-target taxa, then direct effects that limit populations would not occur. We would then be faced with the still significant challenge of reconciling the needs of wildlife with the disturbance regime and landscape simplification brought about by agriculture. Given that pesticides do have impacts on on-target taxa, how can the concept of recovery be built within ecological risk assessment and encompass the uncertainties associated with climate, soil, cropping system practices and pesticide use regimes? The presentation outlines steps that farmers may take to limit pesticide risk and reduce the area of impact of pesticides in agricultural landscapes. In Arizona, partnerships between regulators, educators and farmers have reduced intrinsic risk and the area of impact of programs over 20 years. In Oregon, similar partnerships have limited the frequency of high -risk pesticide exposures for aquatic life in agricultural watersheds. Both of these programs have delivered systems that are conducive to recovery by non-target taxa, and both reinforce the argument that for recovery to be considered, quantifiable goals must be set for limiting the extent and impact of pesticide use. It would then be possible to know whether or not consideration of recovery within ERA is having the desired effect. The presentation shows that this information can have powerful impacts when shared with farmers, who manage the complexities associated with their local context. For ERA to consider recovery, the purpose and scope of this process must be defined, and the degree to which it encompasses all possible systems and uses must be known. The presentation goes on to examine the concept of ecotoxicological recovery time, which falls within the scope of current regulatory capacities, and argues that this may present an effective way forward, supported by modeling. Examples are provided from California (aquatic invertebrate risk in sprayed agricultural landscapes of varying production intensity), Oregon (complex patterns of farmer spray programs), and West Africa (intensive use of high risk pesticides) to illustrate applications of models based upon species sensitivity distributions, combined with maps of impact area[5] .

5 The West African data are now available at:
http://rstb.royalsocietypublishing.org/content/369/1639/20130491.full.pdf

III. SUMMARY OF DISCUSSION GROUPS RESULTS

Following the introductory presentations, participants split into discussion groups to debate specific issues in more detail. Participants were provided with guidance on the remit of the discussion groups via a presentation by Andrea Altieri. Before the Colloquium, all participants had received briefing notes, including selected references for further background, so as to be prepared for an interactive exchange of views and expertise during the discussion. Participants were divided, based on their preferences, into four groups to allow parallel discussion groups. The summaries presented below are structured following the short set of discussion points that had been formulated in the briefing notes for each discussion group.

The final session was dedicated to a presentation and debate on the outcomes of the discussion groups in order to reach the conclusions and recommendations of the Colloquium, as presented in the final chapter of this report. Finally, Theo Brock presented the take-home messages by summarising the main outcomes of the Colloquium.

1. Discussion Group 1 – Translating protection goals into measurable endpoints for use in environmental risk assessments of regulated products and species[6]

Chairs: Robert Luttik and Joe Perry – Rapporteurs: Monica Garcia-Alonso and Reinhilde Schoonjans

1. How to use the ecosystem service concept to identify SPGs, and can the approach already developed for PPPs be applied to define SPGs for other products like GMOs and pest species?

The group first agreed that GPGs for agriculture should be the same regardless of the type of regulated product/species, since the environment under protection is the same. At the same time it was noted that the management decisions regarding these GPGs can differ per type of regulated product/species.

Following this, it was also agreed that the identification of ecosystem services requiring protection, could be the same in all ERA schemes. This means that the group was

6 This covers PPP, GMOs, feed additives, quarantine species and biocontrol agents.

favourable for using the same ecosystem service approach for PPPs, GMO and invasive species. Transparency on the criteria to select ecosystem services that are potentially affected by PPPs, GMO or pest species is necessary. Such selection can start from the full list of ecosystem services of the Millennium Ecosystem Assessment[7] and should be based on the same criteria across all EFSA Panels. While such selection would yield a general list of ecosystem services that are potentially affected, due to case specificity, only subsets of such ecosystem services list may be actually relevant for ERA of certain substances/ organisms.

While further discussing the way to translate GPGs and make them operational for ERA, the approaches to translate GPGs into SPGs as adopted by each of the EFSA Panels were found similar, but using different terminology. The group therefore suggested that a next step for EFSA would be to **harmonise where possible the terminology for SPGs** and to keep it consistent with the different legislations. Examples of harmonisation of terminology included the preference of considering the "in-field" spatial scale rather than "in-crop" and the need for clarification of these terms, e.g. to include field managed/unmanaged margins. Participants suggested that using a clear problem formulation at the start of each case-specific ERA should further enhance transparency and clarity of the relevant SPG. EFSA acknowledged that an ongoing Working Group of the Scientific Committee is exploring the potential harmonisation of terminology (incl. the options for the spatial scale of a SPG) and the role of problem formulation as a critical first step in ERA[8].

When moving towards the subsequent steps of defining measurable endpoints (e.g. selection of test species and test endpoints), there was confusion among participants on "what needs to be protected", "what needs to be assessed" and "what needs to be measured". In the PPP system test species for early tier tests are legally defined and thus mandatory requested for each product prior to ERA. For each GMO the relevant test species are selected on a case-by-case basis. This important difference between both systems is to be considered when trying to harmonise the approaches for specifying PGs. In both cases, however, species are selected to measure effects (measurement endpoints) that are then used to assess impact to a wider range of species or to a particular ecosystem service (assessment endpoints).

In conclusion, the group found that some aspects of the current approaches in PLH, PPR and GMO Panels could be combined to make them workable and harmonised, but this would need careful consideration and adaptation for each area.

7 http://www.maweb.org/en/index.aspx

8 EFSA mandate nr M-2013-0098, requesting an opinion and public consultation on PGs.

2. *How could the six dimensions methodology for defining SPGs, already developed for PPPs, be applied to other products like GMOs and pest species?*

Discussion Group 1 first clarified that the six dimensions followed by EFSA's PPR Panel (i.e. ecological entity, attribute, magnitude, temporal scale, spatial scale and uncertainty) are standard general components of risk assessment and are not specific to the ERA of PPPs. In fact, most of the six dimensions (apart from the "degree of certainty", for which the applicability remains unclear) are already used in the ERA schemes for PPP, GMO and invasive alien species at EFSA, but not always in the same way. The group found it difficult to reach a common interpretation on how these dimensions should be applied in the different ERA schemes. More particularly, there was confusion about choosing an option for each of the dimensions in order to "define what needs protection" or to "define what needs to be tested".

For the dimension of "ecological entity", for example, the group was undecided on what basis to focus a SPG on the functional group level or on the meta-population level. Furthermore, particular terms were missing from the proposed options for ecological entity, such as the "Service Providing Units" as currently used by the EFSA PLH Panel for pest species assessment.

Other dimensions like "spatial and temporal scale" were considered suitable, although further discussions on the options for both dimensions are needed. The spatial scale dimension requires clarifications for the options "in-field"/"in-crop" and requires the inclusion of "edge of field". Choosing the temporal scale dimension for an SPG was considered difficult since that is linked to choosing the dimension for the magnitude of effect. Moreover, the group felt that matching for a SPG the spatial and temporal scales with the magnitude of effect actually defines what is an acceptable effect, and this is considered a risk managers responsibility. Indeed, this Colloquium aimed at hosting risk management – risk assessment discussions to try to make progress in this area. Discussion Group 1, comprising only one risk manager, clearly felt unsure about acceptability criteria of effects.

For the dimension "uncertainty", Discussion Group 1 was divided on whether this should be included in the definition of SPGs or during the risk analysis.

The group concluded that the options for each of the dimensions may need to be adapted for each of the SPGs for ERAs, where the key drivers/focal species may differ. This is the case for GMOs where focal species are selected on a case-by-case basis during problem formulation.

The group also discussed the use of "scenarios" as this was considered useful for the further steps of defining the measurement endpoints, and to determine relevant spatial, temporal and biomass measurements for the assessments. Specific test hypotheses could then be developed for each scenario. The group considered that the selection of measurement endpoints (e.g. mortality or sub-lethal effects for a given test species) depends on the SPG, but some members felt that the full range of possible effects must always be considered in ERA. Reference was made to behavioural endpoints. According to some members of Discussion Group 1, behavioural studies should be conducted in addition to toxicological studies as changes in behaviour may have a relevant effect on populations.

Some group members expressed concern about the representativeness of some measurement endpoints for assessing effects at a larger scale. However, the group seemed to conclude that whatever SPGs are used in the ERA, they should be measurable. It should thus be possible to assess the effect of the stressor to the SPG (e.g. to assess potential adverse effects on pollinators, methods with sufficient power to determine if the effects observed fall within the thresholds established should be used).

During an additional discussion related to quantifying effects, it was questioned how the six dimension approach is compatible with the comparative risk assessment approach as required for GMOs. This triggered a discussion on the importance of the baseline and the choice of the comparator as set by risk managers for GMO ERA, and the group acknowledged that risk assessment can be comparative as well as quantitative. It also triggered the remark, that safety factors and recovery are used in ERAs and are compatible with the comparative approach.

Discussion Group 1 concluded that the six dimensions can be useful to make PGs operational, but noted that the options for each dimension as defined in the PPR approach are not necessarily the best fit for ERAs for pest species and GMOs. Therefore, the options for each dimension require further development.

3. *How can an agreement at EU level on a common approach for specifying protection goals be reached regardless of the type of the regulated product/species?*

This question was clearly designed for a dialogue between risk managers and risk assessors from the different fields. As only a single risk manager attended Discussion Group 1, the discussion focused on the wider interpretation of the question into other sectors that are beyond the remit of EFSA (e.g. those that cover biocides), rather than on how such agreement could be reached. The group felt that a decision on a common approach for specifying PGs regardless of the type of regulated product/species should be made by risk managers as it would require harmonisation between the sectorial legislation for ERA. Regarding the responsibilities of risk assessors under yet other frameworks e.g. legislation for nature conservation or the water framework, the group highlighted the lack of clarity on their interrelationship as well as their relation with the sectorial legislation for regulated products.

a) Who are the bodies to be consulted for GMOs, PPP and pest species and would these include bodies that set environmental protection goals outside agro-ecological landscapes?

The group concluded that the ultimate bodies to be consulted should have decision power and distinguished different scenarios:

(1) if the consultation is "only" about specifying PGs within the context of implementing existing sectorial legislation, then the bodies to consult would be the Standing Committee on the Food Chain and Animal Health (SCFCAH, particularly the sections for PPPs, GMO and PLH) and the Competent Authorities under Directive 2001/18/EC for GMOs

(2) if the consultation refers to setting environmental PGs in general, including PGs for agricultural systems, then this would be out of the remit of EFSA and would require a long legislative process with the involvement of decision bodies that cover a wider remit than the EFSA's. While the group felt that EFSA should adhere to its legal remit to assess regulated products/species, the group exchanged its views on such longer legislative processes. These could include prior discussions with bodies such as:

   a. the network of the heads and directors of Environment Protection Agencies (EPA) and similar bodies across Europe, or the network of the Heads of European

Nature Conservation Agencies (ENCA) which aims to strengthen nature conservation in Europe

b. the wider scientific community and scientific advisory bodies such as the Society of Environmental Toxicology and Chemistry (SETAC) and the European Advisory Committees on Biosafety (MEACB). These wider scientific discussions could focus on the application of ecosystem services to ERAs, more particularly on the anthropocentric character of ecosystem services. It was remarked that since EFSA's remit is for agro-ecological landscapes that are cultivated for the benefit of humans, such discussions are no longer required and scenario (1) applies

It was also discussed how the views of farmers, applicants and other stakeholders (e.g. ECPA) could be incorporated in order to help define the proposals for SPGs (e.g. to define what constitutes environmental harm) and whether DG Agriculture and Rural development should be involved in the discussion about SPGs for agro-ecological landscapes.

b) How can these bodies be approached by EFSA in case a need arises (e.g. for setting an effect size, limits of concern)?

Setting appropriate effect sizes and limits of concern is a prerequisite for ERAs, but this point was not discussed in detail. On the general level again, the group suggested that EFSA could facilitate harmonisation by constructing a proposal, which – depending on the remit of harmonisation see above scenarios (1) and (2) – could be shared with other sectors. EFSA confirmed that sister agencies (ECHA, EMA, and EEA) can be consulted at Working Group level in case needed. The Discussion Group, reminding that the final decision for harmonisation lies with the Member States and the EC, raised further (unanswered) questions whether the EC should facilitate a common approach on GPGs and/or on SPGs; whether the EC would consider outsourcing this activity.

4. ***Provided with the SPG for honeybees exposed to PPP and defined in six dimensions, Discussion Group 1 was asked to define the SPGs for bees in six dimensions also when***

- exposed to a GM crop;
- exposed to a pest species;
- exposed to a GM crop, PPPs and a pest species together.

Ecological entity:	individual - (meta)population - functional group - ecosystem
Attribute:	behaviour - survival/growth - abundance/biomass - process - biodiversity
Magnitude:	negligible effect - small effect - medium effect - large effect
Temporal scale:	days - weeks - months - seasons → 1 year
Spatial scale:	in crop - edge of field - nearby off-crop - watershed/landscape
Degree of certainty:	low - medium - high*

**Legal requirement [for details see section 2.4]*

After discussing the 6 dimensions of the provided example and used by the Bee Working Group when proposing the SPG for bees, Discussion Group 1 members seemed to agree that a SPGs set for agro-ecological landscapes (in this case the protection of bees) should be the same regardless the type of regulated product/species. However, divergences on how to apply the six dimensions using the options described in the PPP approach were apparent, as different group members had different interpretations on what each option within a dimension meant and what should be the focus. Therefore, although the six dimensions could be useful, a more clear definition on what each option means may facilitate their application. As a result, the Group opted not to produce similar figures for other stressors of for multiple stressors acting together.

2. Discussion Group 2 – Protecting biodiversity in agro-ecosystems – How to assess, measure and monitor biodiversity?

Chair: Lorraine Maltby – Rapporteurs: Gabor L. Lövei and Jane Richardson

1. What is the specific protection goal for biodiversity in an agro-ecosystem? Discuss the pros and cons of the ecosystem service concept.

At the beginning, the group discussed the meaning of the terms agro-ecosystem and biodiversity. A major factor which characterises agro-ecosystem is the level of human activity. In Europe, agro-systems include many diverse areas, most of which are actively managed (although at a varying intensity of management) and a small proportion of protected or unmanaged areas. A typical European agro-ecosystem is the result of complex interactions between humans, cultivated crops, domestic animals, wildlife, climate and geographical features. The group felt that the distinction between in-field and off-field areas is important when discussing the meaning of an agro-ecosystem. Additionally, some in the group had the opinion that GPGs should apply both in-field and off-field, stressing that the underlying ecological processes are the same and that there are interactions between the two areas. Therefore, GPGs cannot be considered separately. Others in the group held the view that there should be prioritisation or differentiation of PGs in-field and off-field: they referred to reasons of practicality and differing human requirements from in-field and off-field areas (e.g. yield vs. recreation).

Biodiversity is a very broad term and to support the development of risk assessment frameworks, specific terms would be more suitable. The use of the terms functional biodiversity or structural biodiversity can help hypothesis formulation and the terms genetic, species or landscape biodiversity have been legally defined.

The following pros and cons of the ecosystem services concept were identified:

Cons:

- Differences in legislation within the EU, only some of which refer to ecosystem services;
- The values are anthropocentric and human values may change with time or differ between communities;
- There is uncertainty when weighing the importance of different services;
- Risk of oversight, because services may have been missed based on current knowledge;
- There are knowledge gaps about the drivers of ecosystem services.

Pros:

- Explicit consideration of community values;
- Holistic approach which can be applied to various ecosystems, incl. terrestrial, marine or freshwater;
- Allows explicit communication of trade-offs to risk managers and supports informed decision-making;
- Provides a common foundation, allowing communication between different scientific disciplines and interest groups;
- Aids prioritisation for the development of guidance and frameworks;
- Identifies areas for improvements in mitigation measures;
- Allows a functional approach in the development of study designs (e.g. roles in reduced food webs) and provides alternatives when individual species-based measures are difficult;
- Biodiversity underpins ecosystem service delivery and may in itself be identified as an ecosystem service.

2. How can biodiversity be measured in agro-ecosystems?

2.1 What are the endpoints or tools (and limitations) to assess biodiversity?

Discussion Group 2 addressed this question by referring to the tiered approach currently used in ecological risk assessment for regulated products. In general, the tiered approach is a well-recognized tool for assessing effects of regulated products (e.g. GM crops) and is used among different Regulatory authorities. Since effects can be detected in lower tier studies there is not always the need to go to higher tier studies which suggest performing extended field studies.

The lower tier studies largely measure species sensitivity, for example No Observed Effect Concentration (NOEC) and "Lethal Concentration LC_{50}" endpoints. Since a limited number of species are tested in isolation, it is difficult to extrapolate to biodiversity and to understand indirect effects (e.g. the availability of food for bird nestlings). The selection and number of species to be tested was also discussed. Traditionally, species have been selected based on their suitability for laboratory testing and the availability of approved test guidelines. There is now a move in some areas towards a case-by-case approach with the selection of species based on functional diversity. It is important to note that for some regulated products standard laboratory toxicity tests may not be optimal and

some participants referred for the case of GM plant ERA to tests performed *in planta*. There was some concern over the level of protection due to uncertainty factors and impact of the selection of percentiles for exposure estimates. Overall, there were differing levels of confidence in the group that lower tier endpoints protect biodiversity.

The group also discussed higher tier field and extended field studies as well as the endpoints measured in these studies. Such endpoints can cover population dynamics, responses and recovery at the population level, and the estimated number of species (vs. no. of species collected) at the biodiversity level. For some regulated products, negative effects on biodiversity or on specific functional groups are not acceptable and therefore recovery endpoints are not relevant. One member of the group recommended that all new products deemed safe for authorisation should be subjected to extended field trials. While it was not specified what those trials should measure or what hypotheses they should test, it was claimed that such approach would deliver a rich source of ecosystem data and that as knowledge increases, the design of field trials could be simplified and optimised. This approach could therefore be seen as a broad-based ecological monitoring as part of a publicly funded research rather than responding to a clearly defined regulatory need. For field studies it is important that a statistically robust design is used and that the geographical and spatial scales are appropriate. The selection of comparators or baselines is also a complex issue. In particular, there is a requirement for the definition of conventional/pre-treatment production systems and a need to consider natural cycles and variability in biodiversity endpoints. A number of limitations in using structural biodiversity measures from field trials were identified. These limitations related to differing levels of species sensitivity, pre-adaptation of species to the stressor and variable viable abundance levels. The group concluded that when selecting tools and endpoints to measure biodiversity, it was important not to increase the regulatory burden. Familiarity is expected to reduce regulatory testing, whereas increased ecological knowledge might bring new testing requirements.

The tiered approach is not always applicable in areas other than regulated products (e.g. invasive species). In addition, it is important that methods account for species or functional multiplicity. Therefore, the group identified modelling (e.g. population dynamics models and food web models), mesocosm studies including the estimation and use of NOEC community, diversity indices, species assemblage and functional diversity measures (e.g. decomposition/microbial populations) as important tools in the assessment of effects on biodiversity. It was noted that the use of these tools is dependent on data availability and the validation of models or indices.

2.2 How can it be checked if the measured endpoints are effective in contributing to protecting biodiversity in agro-ecosystems?

Field studies and monitoring were identified as the methods to check if the pre-release risk assessment is effective in protecting biodiversity in agro-ecosystems. Under the EU approval process for GMOs, post-market environmental monitoring, and in particular general surveillance, is mandatory. Use of existing surveillance networks is envisaged as one of the tools to detect anticipated adverse effects that GM crops might have on the receiving environment(s). In general, the group recommended better use of information from other existing monitoring systems (e.g. EU Habitat and Birds Directives, Red List and monitoring regimes for invasiveness and weediness). Inspired by the presentation of the integrated approach used in Oregon, it was concluded that information collected within the primary production sector could be a valuable monitoring tool. Most importantly, the challenge of demonstrating causality via general surveillance was highlighted and therefore a hypothesis-driven approach was recommended when selecting or designing monitoring systems. The group favoured a holistic monitoring approach, accounting for multiple stressors (see point 3, below).

3. What are the tools for taking account of multiple stressors on biodiversity (before/after a given authorisation or measure)?

The group, recognising a potentially bewildering complexity, identified a diverse range of stressors. Due to the large number of possible stressors, it was suggested to use public (does the public care about this particular risk?) and expert opinion or exposure models to rank important interactions for further study.

The group discussed possible options to account for multiple stressors in risk assessment, including: introducing an additional level of precaution in the form of safety and uncertainty factors; the use of ecological thresholds, scenario analysis which can make use of existing knowledge of receiving environments, changes in management practices and ecosystem sensitivities; or empirical studies where biologically relevant combinations of stressors can be tested under controlled conditions.

However, due to the complexity of interactions between multiple stressors generally, the group favoured a modelling approach. It was acknowledged that in other disciplines suitable mechanistic or probabilistic models exist (e.g. landscape and spatial, food web, trophic levels, trait based, ecopathology, hub and spoke and community models). These models can be usefully adapted but it is important that the assumptions, limitations,

precision and accuracy of the selected model are recognised and that appropriate temporal and spatial scales are selected. However, the development of such models can only proceed once accepted biodiversity endpoints/outcomes have been defined.

The risk assessors in the group identified the importance of validating the specificity and sensitivity of models, in particular running tests with positive controls. They also wanted to use a limited set of models rather than case specific models as this would allow them to be sufficiently familiar with the models concepts to interpret the outputs correctly. In terms of interpretation of model outputs, the risk assessor needs to understand that in ecosystems there may be multiple stable states which differ from the original (pre-treatment) state and that the addition of new stressors can magnify the predicted effects and sequential order of addition of stressors may alter the predicted effects.

The group concluded that improved knowledge of interactions between stressors is a way to reduce uncertainty prior to and after authorisation. It was also noted that in field studies and monitoring programmes multiple stressors are naturally present (e.g. natural exposure to diseases, climate, and management practices). Most importantly, the group stressed that risk management, mitigation measures and enforcement action should also be considered when assessing the effect of multiple stressors on biodiversity.

3. Discussion Group 3 – Endangered species – Are endangered species adequately covered in current environmental risk assessment schemes?

Chair: Michael Bonsall – Rapporteurs: Yann Devos and Jörg Romeis

1. Are current risk assessment practices sufficiently robust to cope with endangered species? Should endangered species found in agro-ecosystems (agro-ecological landscapes) be subject to a distinct risk assessment?

The group discussed what is meant by "endangered species" and what criteria are used to define endangerment at a legal and scientific level. Although endangered species are usually defined as species that are at risk of getting extinct, the need to clarify the interrelationships between "endangered", "rare", "vulnerable" and "protected" species was stressed. For instance, it was not clear whether all protected species are necessarily rare and/or endangered. Therefore, a prerequisite when considering endangered species is to understand the compliance conditions for a species to be considered endangered. In this respect, reference was made to Rabinowitz (1981) who defined rarity using the following three criteria: local population size, geographic distribution and habitat specificity.

The availability of up-to-date lists of endangered species was found indispensable for considering them in ERA. As the endangerment status of species may vary at the local, regional, national and European level, lists of endangered species will differ depending on the jurisdictional scale. Therefore, it was discussed whether ERAs pertaining to endangered species performed by EFSA should focus on the European level, and whether such assessments could/should be complemented with national/regional/local risk assessments conducted by EU Member States. This would allow ERAs for endangered species to be in tune with the local conditions of receiving environments. The group highlighted the need to clarify the scientific and legal basis used to define why a species is considered endangered. Likewise, there is a need to clarify the interrelationships between "endangered", "rare", "vulnerable" and "protected" species and, in addition, the legal interplay between the various European/national/regional/local lists of endangered species.

It was indicated that ERA practices for GMOs and plant protection products differ and that these differences should be accounted for.

The strengths and weaknesses of current ERA practices for endangered species were discussed and the following points were raised:

Strengths:

- *Problem formulation*: Problem formulation, which is the critical first step of an ERA, enables a structured, logical approach to identifying harmful effects requiring characterisation, while excluding non-harmful effects as irrelevant. Problem formulation helps to maximise the usefulness of ERA studies for regulatory decision-making. The group concluded that the problem formulation can focus the ERA for endangered species and ensure that relevant questions are considered during the risk characterisation process.
- *Plausible pathways to harm*: As part of the problem formulation, plausible pathways to harm should be identified for endangered species. These pathways describe the successive steps that need to be fulfilled for harm to occur to the endangered species.

  Besides the potential additional adverse effects caused by the stressor under assessment, other stressors contributing to the endangerment of the species should ideally be considered. The group felt that this would enable one to put the additional impact caused by the single stressor under assessment into a broader context. Knowledge is therefore needed on why a species is considered endangered.
- *Unit of protection*: For endangered species, the protection of both aspects of biodiversity (abundance & species richness) is important and required on a legal basis. Depending on the jurisdictional scale, the unit of protection of endangered species may be set either at the level of populations or individuals. Should populations be the unit of protection, then the characterisation of potential risks was considered useful. Some participants of the group argued that harmful effects could be tolerated, as long as the populations would be able to recover. However, not all participants shared this view.

  If each individual of a species is to be protected, then no harmful effects would be tolerated and thoroughly characterising potential risks would not be very helpful. It was considered that risk management rather than risk characterisation would be essential in this latter case.
- *Exposure*: The spatial and temporal coincidence of the stressor and endangered species need to be characterised during the exposure assessment. This would enable one to identify exposure at an appropriate spatial and temporal scale.

Weaknesses:

- *Multiple stressors*: The group indicated that current ERAs are not sufficiently holistic, as they address single stressors in isolation. In reality, endangered species are likely to be exposed to multiple stressors. Therefore, multiple stressors should be accounted for in ERA, which require knowledge on the multiple stressors contributing to why the species is endangered (baseline data). It was also indicated that ERAs should consider both direct and indirect harmful effects. Habitat loss or food web effects may cause indirect harmful effects.
- *Scale*: The need to fine tune ERAs performed at the macro and micro scale was emphasised.
- *Recovery*: Some members of the group did not consider recovery to be an option in the ERA of endangered species and stated that endangered species need protection because they have no or the least possible potential of recovery. Therefore a "precautionary approach" (e.g. by taking the most conservative options during ERA) fits better.

2. *To what extent can ecological data for endangered species and ecotoxicological data from related non-endangered species be used to inform the ERA of endangered species?*

It was noted that, for legal reasons, endangered species may not be appropriate for ecotoxicological tests. The group was of the opinion that the surrogate species concept currently applied in ecotoxicological testing could be applied to inform ERAs of endangered species. There is no scientific evidence suggesting that the sensitivity of endangered species to a specific substance would not fall in the range of the sensitivity distribution of taxonomically-related species. Therefore, extrapolating data generated with related non-endangered species to endangered species was considered feasible.

Given the ecological context of endangered species and because the consequences of a harmful effect to these species may be dramatic, it was recommended to make sufficiently conservative assumptions in ERAs when using surrogate species. These conservative assumptions would come into play at different levels and involve the use of:

- higher safety factors applied to effect/measurement endpoints (e.g. lower trigger values);
- worst-case exposure scenarios;
- specific measurement endpoints (e.g. sublethal endpoints to capture population level effects);

- reduced acceptable levels of scientific uncertainty.

It was also indicated that the surrogate species concept may only be workable if suitable taxonomically-related surrogate species, which are amenable to testing, exist.

3. What risk mitigation measures could be envisaged to prevent endangered species being put at risk resulting from the application of a regulated product?

It was concluded that risk mitigation measures could be envisaged to prevent endangered species being put at risk. Such measures are context-specific and should account for the biology of the endangered species, reasons for its endangerment, and the intended uses of the substance/living organism under assessment, as well as the combination of these characteristics. Therefore, information is needed on:

- hazards;
- exposure;
- spatial and temporal co-occurrence between the stressor under assessment and the endangered species;
- habitats hosting the endangered species.

The main objective of risk mitigation is to reduce the spatial and temporal exposure of the endangered species to the regulated product/species under assessment. This can be achieved through the use of spatial isolation distances or habitat management. In-field mitigation measures should focus on limiting temporal exposure to the product. For example, in the case of PPPs, it was noted that the use of specific active substances could be avoided during the flowering period of specific plants in order to avoid exposure to pollinators. Off-field mitigation measures include buffer zones, isolation distances and nature reserve management. Reference was also made to financial support mechanisms such as subsidies for conservation areas. It was noted that the implementation of suitable risk mitigation measures may be challenging when the occurrence of the endangered species is scattered across the landscape.

In most cases, farmers will be the in-field risk managers. Therefore, it was stressed that communication, education and training of farmers should be developed and emphasised, as these tools will aid farmers to understand the importance of risk mitigation measures. In addition, advisory services and forecasting tools should be made available to farmers so that specific risks can be quantified by them at the local level.

4. *Is monitoring needed to check the efficacy of risk mitigation measures for the occurrence of endangered species? If so, how should such monitoring be implemented?*

The group concluded that post-market environmental monitoring can be a useful tool to generate new data that can feedback into ERAs. However, monitoring entails several challenges which may limit its potential as feedback mechanism.

Three different monitoring objectives were discussed: (1) compliance monitoring; (2) monitoring of endangered species; and (3) supplementary monitoring.

- *Compliance monitoring*: Compliance monitoring was considered to be mainly product/stressor-oriented. The aim would be to check whether farmers implemented the recommended risk mitigation measures. Both regulatory authorities and the product owner would be responsible for compliance monitoring. Farmer questionnaires could be one of the tools to collect the necessary information.
- *Monitoring of endangered species*: The data generated through the monitoring of endangered species should enable the assessment of their status over time. As society considers that specific measures should be undertaken to protect endangered species from harmful effects, it was emphasised that regulatory authorities should bear the responsibility to ensure this type of monitoring. Although relevant data may be collected through existing surveillance and nature conservation networks, it was recognised that the collected data may be not necessarily fit for purpose. In addition, it may be challenging to determine the cause of an observed effect.
- *Supplementary monitoring*: The group was of the opinion that supplementary monitoring could be put in place to assess the efficacy of the implemented risk mitigation measures. Specific experimental monitoring studies could be designed to investigate specific research questions.

  Instead of asking specific research questions only, this type of monitoring could also be directed at generating relevant baseline data needed to confirm ERA assumptions. Supplementary monitoring was considered product/stressor-oriented, and should ideally be conducted by research funders and the product owner.

4. Discussion Group 4 – Ecological Recovery – How to make ecological recovery operational in ERA?

Chair: Paul Jepson – Rapporteurs: Stephanie Bopp and Wopke Van der Werf

The group focused on addressing population recovery since the PG for most organism groups is related to the population level. The group considered resilience as a wider concept related to the whole ecosystem on a long-term. Although resilience was introduced for discussion, the group did not have sufficient time to go into detail about this concept.

1. How to take into account the potential of population recovery in ERA under real field conditions assuming simultaneous or repeated exposure to the same or multiple stressors?

When no effects are elicited by a regulated product or species, recovery does not need to be addressed. However, as soon as some effects of a certain magnitude are allowed to occur, the potential for recovery needs to be considered. It needs to be ensured that allowed effects are reversible and the duration of such effects is acceptable.

The group started by discussing the issue of potential vs. actual recovery as raised in the question. Population recovery was seen as an emergent property of the system, depending on the species traits in combination with the ecosystem characteristics. It was concluded that the concept of potential recovery in agro-ecosystems is useful, but should be applied with caution in a regulatory context, taking into account realistic crop scenarios, agricultural management schemes and landscapes.

In the context of potential vs. actual recovery, the question of the impact of exposure to multiple stressors in agro-ecosystems was discussed. Currently, single regulated products/species are addressed in separate risk assessments, whereas in real agro-ecosystems organisms may be exposed to several products/species at the same time or sequentially. Therefore, the question was raised whether realistic "packages" of such multiple stressors (products/species) should be assessed in the future. It has to be stressed that effects might accumulate in the course of e.g. a pesticide treatment scheme. An overall allowed effect should then be defined in the context of the SPG in order to be considered in ERA. This will be relevant when (and if) implementing the recovery concept in ERA. However, due to the numerous possible combinations and the expected changes of those "packages" over time, this approach may become too complex to be readily implemented in ERA. Nevertheless, it was considered desirable to develop a systems perspective in future ERA.

In order to judge whether the use of regulated products (e.g. GMOs and PPPs) in certain agro-ecosystems is in conflict with the sustainability of populations of non-target organisms, the risk assessment should focus on vulnerable species. Properties relevant to define vulnerability are species traits and characteristics that determine:

Susceptibility to exposure:

- Low ability to avoid exposure in space and time (being at the wrong place at the wrong time);
- Absence of resistant life-stages.

Sensitivity to stressor:

- Poorly developed detoxification and repair mechanisms (if stressors concern toxic substances);
- Presence of sensitive life-stages (that coincide with exposure).

Internal and external (re-colonization) recovery processes:

- Few offspring;
- Long generation time;
- Low dispersal ability;
- Narrow habitat requirement resulting in few source populations for recovery.

If trait-based recovery potential is considered in the ERA, then realistic combinations of traits should be taken into account rather than combining all worst-case traits in a way that would never occur in reality.

The recovery potential might be negatively influenced by the following ecosystem characteristics:

- Large agricultural fields with a low proportion of off-field area; i.e. places with few or distant refuge habitats;
- Spatial distribution and/or separation between in- and off-field areas, e.g. scattered natural habitats;
- Poor quality of refuge/off-field structures.

The group discussed how population modelling could help in addressing the recovery potential of different organism groups. Experimental approaches at a wider spatial scale are costly and might have insufficient statistical power due to the difficulty to replicate. Effect models could be used for synthesising and up-scaling results from smaller scale

experimental trials or for down-scaling from monitoring data. To successfully use population modelling approaches for consideration of recovery in the ERA at an EU level, different realistic agro-ecosystem scenarios are needed that can be linked to the relevant exposure scenarios. Traits affecting recovery potential should be considered, so that representative indicator species, including vulnerable species[9], are covered. Such representative vulnerable species might then act as focal species in the ERA. The group concluded that modelling results and experimental data cannot be evaluated in isolation and should be used as complementary tools in the ERA. A wish list regarding models for use in the regulatory context was drawn up:

- Effect modelling should not introduce additional unnecessary complexity, but give additional confidence and help in reducing the uncertainty in the ERA. It should address specific relevant questions of the ERA in order to support decision-making.
- Effect models should be well tested and robust. The use of realistic and reliable input data for models is essential and should therefore be well documented.
- There is a trade-off between transparency and tractability on the one hand, and biological realism on the other hand: single population models may be criticised for neglecting interactions between species, while community models addressing those interactions are criticised for being too complex and difficult to validate. Criticisms of modelling approaches should be overcome by clearly describing the objectives, limitations and uncertainties related to the modelling. It was noted that similar limitations for experimental data should not be overlooked.
- Effect models should be able to assess different landscape and crop rotation scenarios. There is a need for ecological scenarios to calculate exposure, population level impacts and recovery in different climatic zones and landscape settings.
- Effect models should be able to include mitigation measures. It might be very useful for risk managers to check the comparative efficiency of different mitigation measures supported by modelling. For continuous improvement of models, feedback from regulatory users is needed. Furthermore, an iterative process should be pursued for

9 A definition of "focal species" for clarification can be found in the Guidance of EFSA for Risk Assessment to Birds and Mammals (EFSA, 2009): "A 'focal species' is a real species that actually occurs in the crop when the pesticide is being used. The aim of using a 'focal species' is to add realism to the risk assessment insofar as the assessment is based on a real species that uses the crop. It is essential that the species actually occurs in the crop at a time when the pesticide is being applied. It is also essential that this species is considered to be representative of all other species that may occur in the crop at that time. As a 'focal species' needs to cover all species present in the crop, it is possible that there may be more than one 'focal species' per crop."

model improvement based on monitoring data from retrospective ERA and other relevant studies, such as field experiments.

- GM plant ERA may consider colonisation and persistence of taxa, using data that parameterise recovery models, but the concept of recovery itself may not be relevant if no adverse effects are observed.
- Landscape scale models may assist in interpretation of positive impacts of some crop technologies on biodiversity.

2. What is the spatial/temporal scale that should be taken into account for calculating ecological recovery of populations considering different ecological traits? Which spatial/temporal scale should be considered to sustain a population in the long-term from a scientific point of view?

For different PGs, different spatial scales are relevant. For example, a PG regarding a certain species should not be allowed to become extinct in Europe requires a much larger scale for the assessment than a PG of supporting natural enemies of crop pests (e.g. beneficial arthropods in field). It is a risk management decision as to whether a local impact on biodiversity can be tolerated. In accordance with most PGs, the population of a species should be maintained at the assessed scale relevant to the PG. Specific measures will probably be needed for endangered species (see Discussion Group 3).

Regarding the temporal scale, concerns were raised about long-term effects that might not be directly identified in ERA over short time frames (e.g. looking at one growing season or one year only) and allowing recovery might lead to unwanted long-term shifts in species densities or distribution. It was suggested that parameters of population-related processes may change over time as stress is continued. When considering relevant time scales and long-term impacts, it was discussed to include also significant impacts of external factors such as climate change effects on species distribution.

When selecting the appropriate spatial and temporal scale for recovery considerations, the high variability in European agro-ecosystems and their recovery capacities need also to be taken into account. For example, the spatial connectivity or patchiness of off-field areas plays an important role. This could be addressed by suitable scenarios considering the different landscape structures. Modelling could be used to check how different management options affect the recovery potential of an agro-ecosystem. In view of the temporal scale, also the variability in species traits needs to be carefully taken into account. Due to different climatic conditions across Europe, intrinsic species characteristics such as generation time, relevant for internal recovery, might differ substantially.

3. ***From a regulatory point of view, is there scope for spatial differentiation when implementing the ecological recovery option in the ERA for regulated products, dependent on the species at risk and the ecological properties of the European agro-ecological landscapes of concern?*** (e.g. should some effects with subsequent recovery be allowed in-field, edge-of-field, further off-field /at landscape level?)

The discussion for this question focused on the spatial scale to be considered for implementing recovery. The group concluded that PGs need to be met at local and larger scale, even if some effects at a narrower scale may be allowed. Whenever recovery is considered in the ERA, effects over a wider spatial scale and longer time frames (e.g. more than one growing season or one year) need to be taken into account even if effect at local scale are assessed. There was some reluctance in the group to separate the risk assessment for in- and off-field areas since the habitats are not isolated from each other, i.e. an impact on the in-field area may have a long-term impact on the off-field area. In this context, it was considered, that recovery by re-colonisation from external sources (from areas not affected by the regulated product/species) might lead to a long-term depletion of those external sources over extended periods and have long-term impact on the wider spatial scale (Topping et al., 2014) which has to be avoided.

The group discussed the acceptability of allowing effects on density of a population at a locally restricted scale while the overall landscape population level is maintained. Thus the trade-off depends strongly on the non-target organisms with their different traits, such as e.g. mobility and habitat range and the defined PGs.

Some group members were concerned that feedback between the prospective and retrospective ERA should be strengthened, so that e.g. results of post-market environmental monitoring can be taken into consideration when assessing long-term effects. This also enables considering the actual recovery occurring under field conditions with various stress parameters in contrast to the potential recovery that is expected based on impact by one single regulated product/plant. Examples, where the linking between different legislative frameworks could be improved, were the Regulation (EC) No 1107/2009 on the authorisation of plant protection products with the Water Framework Directive (2000/60/EC).

In conclusion:

- Proper definition and consideration of the concepts of potential and actual recovery were considered to be important. The consideration of the recovery potential has significant consequences for regulatory decision-making.
- Models are certain to play a role, but a deliberative and participatory process is needed to develop and implement them and ascertain that they are used in line with their objectives and limitations. Field experimental data will continue to play a role in decision-making, and these must take into account the sources and mechanisms of recovery of selected taxa, and their habitat/resource needs. Field experimental data are also needed to support and improve models. A flow of information to and from risk management is required if the implications of delayed recovery are to be understood and models could help to assess the impact of different management options.
- Better access to data on life history traits (e.g. in the form of a data base) of ecologically sensitive species (i.e. not necessarily the tested species) is required to enable the consideration of recovery potential in ERA.
- Better feedback is also needed between policy instruments that affect farm sustainability, support for biodiversity and habitat management to render agriculture more conducive to recovery.

IV. FINAL DISCUSSION

In order to implement biodiversity as a PG in ERA for EU agro-ecosystems, a wide range of key issues were identified at this 19th EFSA Colloquium: from what is requested to be protected by law, over the practicalities to measure something as complex as biodiversity, to specialised topics on the SPGs for endangered species in agro-ecosystems, and the possible consequences of adopting the recovery concept in the ERA of individual stressors to protect biodiversity in agro-ecosystems subject to multiple stressors.

While commenting on the feedback from the individual Discussion Groups, the full audience actively contributed to the final discussion as follows.

1. Translating protection goals into measurable endpoints

At present, biodiversity as a common GPG in the sectorial legislations for ERA schemes is not defined by its structural and functional components that require protection. Such a uniform definition could serve as a framework for the ERA of regulated products assessed by EFSA. Each Panel has interpreted its own sectorial legislation to make PGs operational according to the specific characteristics of its area (e.g. PPPs, GMOs or invasive alien species). One of the major aims of the 19th Colloquium was to jointly explore with a range of stakeholders, if a more **common approach to translating GPGs from the legislation into SPGs and measurable endpoints was possible**. The debates were confined to risk assessment for regulatory products/species in agro-ecological landscapes, corresponding to the remit of EFSA.

On the interpretation of GPGs (of which biodiversity is one common example), participants were in general agreement that **the ecosystem services concept for identifying SPGs is a useful tool** to help identify those PGs that the ERA should focus on when considering regulated products that will be used in agro-ecological landscapes. The concern that the ecosystem services concept is anthropocentric was acknowledged and, given the complexity of both the ecosystem services and the complexity of how to measure/assess biodiversity, uncertainty remains as to whether the concept of ecosystem services is protective enough for the level of biodiversity expected in agro-ecological landscapes. This uncertainty is unlikely to be resolved given the dynamics of any particular ecosystem and the changes in land use over time. The ecosystem services concept at present provides a relatively uncomplicated and transparent language for the risk assessment processes and consequent risk management decisions because it allows identifying and addressing the trade-offs between the needs of agricultural production and nature conservation.

On the implementation of the six **dimensions for further defining SPGs**, there were different views on what needs to be protected, what the risk assessment should assess and what effects can be measured. It was underlined that SPGs should be measurable. From the discussion it appeared that further defining SPGs in given dimensions may not have been fully understood and that some practice/training is recommendable before applying them in an operational way. One of the difficulties lies in the fact that ideally SPG should be defined before beginning the ERA (i.e. in the legislation, in guidance documents or in problem formulations) and thus is not an outcome of the ERA. However, understanding and determining what effects should be measured often occurs only during a case-specific ERA. Furthermore, setting the magnitude of acceptability of such a case-specific effect beforehand, is a risk management decision, and is therefore perceived as difficult for risk assessors.

2. Protecting biodiversity: how to assess, measure and monitor

Protecting biodiversity in agro-ecosystems requires an interpretation of biodiversity (by defining SPGs), the formulation of testable risk hypotheses and then a choice of what needs to be measured and tested during the prospective risk assessment of regulated products/species. While the term "protecting biodiversity" can perhaps be meaningfully interpreted only within a **given context (e.g. during the problem formulation step of the ERA)**, participants suggested the need to clarify what is to be protected and where. In addition, the need for a common definition for agro-ecological landscapes and biodiversity was stressed, as well as the identification of a single workable relationship between biodiversity and ecosystem services. For the latter it was emphasised that the balance of evidence for linking biodiversity to ecosystem services is not giving a unique answer: service may increase, decrease or remain the same as diversity increases. However, during the general discussion there was a strong feeling that when services are considered over a longer time scale or at a wider spatial scale, biodiversity should always be assessed to deliver the service, not only by abundance but also by species richness to cover the service provision by alternative species.

Further key aspects when interpreting biodiversity as a GPG and deciding how to measure it, are the consideration of indirect effects and the impact of multiple stressors. These key aspects clearly extend beyond EFSA's legal remit and a way forward for risk assessors from different domains (inside and outside EFSA's remit) is to be determined. Protecting biodiversity may also require the appropriate implementation of **feedback mechanisms between prospective** (largely based on experimentation and modelling) **and retrospective** (for a large part based on monitoring) **ERA approaches**. Suggestions that can help are to look at the use of models, scenario analysis, trait based approaches, foodweb interactions

and prior work on mixtures (e.g. by the European Commission Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)).

Risk mitigation to manage all the factors threatening biodiversity is considered to be of primary and critical importance for the adequate protection of biodiversity. Ideally for risk assessors of regulated products/species, the level of protection should be assessed in monitoring schemes (e.g. by tracing key species) and such knowledge be fed back to the risk assessors to refine their assessments where needed. Currently however, information about the level of protection achieved, and whether or not this is adequate, is lacking for risk assessors.

3. Covering endangered species in ERA

The EFSA Scientific Committee should seek with its newly mandated ERA Working Group clarity on the scientific and **legal basis** for defining endangered species and their common attributes of rarity, vulnerability or protection status.

The strengths and weaknesses of current ERA schemes for covering endangered species were reviewed and the participants underlined that any choice made during **risk assessment should be relatively conservative**, e.g. when setting the trigger value to go to higher tier tests or by selecting individuals as ecological entity for endangered species of vertebrates, and the population, but without the recovery option, for non-vertebrates when defining SPG for endangered species.

One recurrent remark from the audience was that **habitat loss** is the main stressor for endangered species and that this should be part of the baseline description for ERA of regulated products/species with respect to endangered species. Nonetheless, the audience considered it appropriate that applicants and risk assessors of new regulated products/ species take the responsibility not to add any additional stress to the level of stress already existing for endangered species. Moreover, since multiple stressors act upon the environment simultaneously, each sector should regulate its own areas in order to prevent any additional stress. Ultimately, participants emphasised the need to assess multiple stressors together and the need for risk assessment-risk management interaction to provide **feedback from potential monitoring schemes**.

4. Making ecological recovery operational in ERA

The potential of temporal/spatial ecological recovery of a population after impact by a regulated product/species is at present **not a very common element** in ERAs at EFSA or elsewhere in the EU, except for PPPs in the in-field and, under stringent conditions, in the edge-of-field ERA that aims to protect populations of non-target populations of invertebrates and plants. The recovery of a non-vertebrate population after the use of PPPs is now rather implicitly underlying some of the decisions for market authorisation. Participants concluded that the option for recovery, if used, is *a priori* to be considered explicitly (e.g. in consultation with risk managers), and this **will require the specification of scale and the time** in which recovery can be expected.

Such explicit predictions may **demand interactive and adaptive model development** for prospective risk assessment of the regulated product as well as better feedback from observations made in the field after use of the regulated product once allowed onto the market. Risk assessors cannot be expected to produce accurate predictions of recovery for each organism group and for each product. They should be able to refine or verify their modelled predictions once the product is on the market and address the lack of confidence in modelling for risk assessment that some critics may have. One idea was to include **monitoring** in the field, if suitable monitoring schemes were to become available in the future, as an essential tool to validate the models. It was recognised that such feedback mechanisms obviously require regular dialogue between risk assessors and risk managers, but no practical proposals were made. The current separation between risk management and risk assessment in Europe was not considered ideal in this regard. However, it was suggested that the need for feedback from the risk management (i.e. including observations from the field) should be included in the future opinion of the Working Group on recovery.

5. General issues

Repeatedly during the discussions on how PGs for ERA are set, why and by whom, the audience was confronted with the complexity of **policy making at EU level**. Policy making involves intense and iterative consultations between the European Commission, the council of Member States and the European Parliament. An overarching policy document, using **ecosystem services to determine what is an unacceptable risk to the environment,** would be much welcomed by risk assessors. Such a need has, however, not yet been recognised on the active **political agenda**. It was clear to the audience that ecosystem services should not only be used by risk assessors, but also by risk managers to enable **cost-benefit analyses**. Moreover, using the same language would facilitate working

towards a more holistic and systematic approach to environmental protection across the different policy areas. It was noted that the new legislation on Plant health will mention ecosystem services. Regarding the anthropocentric character of ecosystem services, it was recognised that the **cultural services and the ethical ecosystem services** also have to be considered. Such considerations might however require an interdisciplinary approach, e.g. including ecosystem service approaches for nature conservation.

In this context, the audience recognised that EFSA can promote the need for biodiversity protection and can help to achieve this goal in agro-ecosystems. The latter requires the specification of what is to be protected, at a certain time, place and level. The use of scenarios is therefore considered mandatory. While doing this, it should be remembered that ERA is only a small part of protecting biodiversity and that inherently, the regulated products under assessment serve the PG of crop/food/feed production.

Sustainable agriculture is a major PG for our agro-ecosystems and the biodiversity therein. An overarching regulatory framework could help to clarify that the priorities for areas used to crop for human needs cannot be the same as the priorities in other areas.

V. OVERALL CONCLUSIONS

Establishing what is to be regarded as environmental harm is a complex process of analysing and implementing policy objectives. It requires that risk managers define what deserves protection and what level of change is to be regarded as harmful. This is set by the respective legislations, but because of their general formulation and since the determination of environmental harm is subjective, some room for interpretation may remain. However, risk assessors can only use natural sciences to determine whether a certain action is acceptable once "good" and "bad" have been defined. Consequently, risk managers must be explicit about which environmental resources are to be protected, where and over what time period they must be protected, and what level of change is found acceptable. This involves the political process of setting the pertinent baselines for comparison and thresholds when performing ERAs. These normative choices define the framework in which risk assessors have to operate.

In the context of the risk assessment schemes that EFSA Panels have elaborated within their respective legal remits, the 19th EFSA Colloquium convened participants from a wide range of stakeholders to reflect on the process of translating GPGs to make them operational for ERA, i.e. by defining SPGs and measurable endpoints. Furthermore, the purpose was to discuss how this can be done in a more consistent way, regardless of the type of regulated product/species.

The 19th Colloquium was attended by 89 international scientists and stakeholders from 21 countries, including EU Member States, non-EU countries and the USA. Among the participants were representatives from the European Commission, OECD, national governmental organisations, academic institutions and the private sector, such as crop protection and plant biotechnology industry. This mix of stakeholders allowed for a wide range of views on PGs, their normative values and implementation for ERA of regulated products/species in agro-ecosystems.

One of the main conclusions of the 19th Colloquium is that regular risk assessment — risk management dialogues are a prerequisite for the above tasks as they are linked to discussing the level of change that would be regarded as harmful. More generally, such dialogues were seen as needed for effective help in environmental protection through prospective risk assessment.

With respect to the specific scientific topics addressed at the Colloquium, the following conclusions were drawn by the respective Discussion Groups.

Discussion Group 1: Translating protection goals into measurable endpoints

- As a starting point, the group first concluded that GPGs for agriculture should be the same regardless of the type of regulated product/species, since the environment is the same.
- Furthermore, the group agreed on the need for more transparency and consistency while interpreting GPGs across ERAs.
- Making GPGs operational for ERA, by translating them in SPG and measurable endpoints, requires further considerations with the engagement of risk managers and experts from various stakeholder groups in the necessary dialogues. The group concluded that the ultimate bodies that EFSA should engage must have decision power. In the scenario that the consultations are "only" about specifying PGs within the context of implementing existing sectorial legislation, the bodies to consult would be the Standing Committee on the food chain and animal health (SCFCAH, particularly the sections for plant protection products, GMO and PLH) and the Competent Authorities under Directive 2001/18/EC for GMOs.
- To address the GPGs as set broadly in the law, the ecosystem services approach was supported for identifying relevant SPGs, albeit with some reservations concerning its anthropocentricity.
- The practical identification and definition of SPGs for the assessment of potential risks of regulated products/species at different spatial scales could be further addressed, and not solely under the responsibility of risk assessors.
- All participants found the concept of specific dimensions useful to further define the identified relevant SPGs. The kind of dimensions, e.g. entity, attribute, magnitude, spatial scale, temporal scale (and to a lesser extent the level of uncertainty) were generally considered adequate. However, the options currently described for each of those dimensions require refinement and flexibility for the various sectors that EFSA covers in ERA.
- The harmonised translation of GPGs into measurable endpoints for use in ERAs, regardless of the type of regulated products/ species, will only be feasible if face-to-face discussions are ensured between practitioners of the various sectors that EFSA covers in ERA. The first step would be to see where the terminology as currently used in each sector can be harmonised, while keeping it in line with the different legislations.

Discussion Group 2: Protecting biodiversity: how to assess, measure and monitor

- The Discussion Group could not refer to specific biodiversity-related PGs already defined for agro-ecosystems and underlined that since biodiversity is a very broad term, specific terms would be more suitable for supporting the development of risk assessment frameworks. The use of the terms functional biodiversity or structural biodiversity can help problem formulation in ERA and the terms genetic, species or landscape biodiversity have been legally defined.
- The Discussion Group listed several pros and cons of the ecosystem services concept to help identify specific PGs for biodiversity in agro-ecosystem. While the approach could be subject to uncertainty, knowledge gaps and changes, it has the important potential to offer a common and uncomplicated language to work further in this area more explicitly with all parties involved.
- Definitions are needed to clarify specific terms used across the EFSA Panels (e.g. biodiversity, agro-ecosystems). Harmonisation of the approach used to translate biodiversity as GPG, to identify biodiversity-related SPGs and make them operational for ERA procedures by defining measurable endpoints is feasible across regulated products/species, yet flexibility should be ensured.
- Regarding the endpoints or tools (and limitations) to assess biodiversity, there were differing levels of confidence among the participants as to the degree to which current lower tier ERA methods (e.g. the test endpoints and the use of surrogate test species) protect biodiversity. Also for the higher tier field and extended field studies with biodiversity-related endpoints (e.g. population dynamics, responses and recovery at the population level, and the estimated number of species versus the number of species collected), strengths and weaknesses were identified.
- The group concluded that when selecting tools and endpoints to measure biodiversity within ERA for regulated products/biodiversity, it was important not to increase the regulatory burden.
- Field studies and monitoring were identified as the methods to check if the pre-release risk assessment is effective in protecting biodiversity in agro-ecosystems. The group recommended better use of information from existing monitoring systems (e.g. EU Habitat and Birds Directives, Red List and monitoring regimes for invasiveness and weediness).
- Due to the complexity of interactions between multiple stressors generally, the group favoured a modelling approach over other options to account for multiple stressors

in risk assessment. Existing models can be usefully adapted but it is important that the assumptions, limitations, precision and accuracy of the selected model are recognised and that appropriate temporal and spatial scales are selected. However, the development of such models can only proceed once accepted biodiversity endpoints/outcomes have been defined.

- ERA of regulated products/species contributes to the protection of biodiversity in agro-ecosystems, but needs to be complemented with other critical elements such as mitigation and habitat protection.

Discussion Group 3: Covering endangered species in ERA

- A prerequisite when considering endangered species is to understand the scientific and legal basis used to define why a species is considered endangered. Likewise, there is a need to clarify the interrelationships between "endangered", "rare", "vulnerable" and "protected" species.
- The surrogate species concept currently applied in ecotoxicological testing could be applied to inform ERAs of endangered species. Extrapolating data generated with related non-endangered species to endangered species is feasible, provided that the ecological context of the endangered species is accounted for. The surrogate species concept may only be workable if suitable taxonomically-related surrogate species, which are amenable to testing, exist.
- Sufficiently conservative assumptions should be made during ERAs for endangered species (e.g. the trigger value to go to higher tier tests), as the consequences of a harmful effect to these species may be dramatic owing to their ecological context.
- As generally applicable, mitigation can be envisaged to prevent endangered species being put at risk. Risk mitigation aims to reduce the spatial and temporal exposure of the endangered species to the stressor under consideration. Mitigation measures are context-specific and should therefore account for the biology of the endangered species, reasons for its endangerment, and intended uses of the substance/living organism under assessment, as well as the combination of these characteristics.
- As generally applicable, post-market environmental monitoring can be a useful tool to generate new data that can feedback into ERAs for endangered species. However, monitoring entails several challenges which may limit its potential as feedback mechanism.

Discussion Group 4: Making ecological recovery operational in ERA

- The group acknowledged that when no effects are elicited by a regulated product or species, recovery does not need to be considered in ERA. However, as soon as some effects of a certain magnitude are allowed to occur, the potential for recovery needs to be considered. It needs to be ensured that allowed effects are reversible and the duration of such effects is acceptable.
- In order to make ecological recovery operational in ERA, a proper consideration of potential and actual recovery, as well as internal and external recovery, is essential. It was concluded that the concept of potential recovery in agro-ecosystems is useful, but should be applied with caution in a regulatory context, taking into account realistic crop scenarios, agricultural management schemes and landscapes.
- To address the appropriate spatio-temporal scale of recovery processes, the development and selection of agro-ecosystem scenarios, focal species and mechanistic models are required.
    - To successfully use effect modelling approaches for consideration of recovery in the ERA at an EU level, different realistic agro-ecosystem scenarios are needed that can be linked to the relevant exposure scenarios.
    - Traits affecting recovery potential should be considered, so that representative vulnerable species are covered. Such representative vulnerable species would then act as focal species in the ERA.
- The group concluded that modelling results and experimental data cannot be evaluated in isolation and should be used as complementary tools in the ERA.
- There is a need for communication between model developers and regulators to optimise the appropriate use and implementation of models in decision-making.
- Regarding whether some effects with subsequent recovery should be allowed in-field, edge-of-field, further off-field or at landscape level, the group concluded that PGs need to be met at local and larger scale, even if some effects at a narrower scale may be allowed. Therefore, whenever recovery is considered in the ERA, effects over a wider spatial scale and longer time frames (e.g. more than one growing season or one year) need to be taken into account.
- Feedback between the prospective and retrospective ERA should be strengthened, so that e.g. results of post-market environmental monitoring could be taken better into consideration to check for long-term effects and consider the actual recovery occurring under field conditions with various stress parameters in contrast to the potential recovery that is expected based on impact by one single regulated product/species.

VI. ABBREVIATIONS

BIOHAZ	Biological hazards
EC	European Commission
ECPA	European Crop Protection Association
ECHA	European Chemicals Agency
EEA	European Environment Agency
EMA	European Medicine Agency
ENCA	European Nature Conservation Agencies
EFSA	European Food Safety Authority
EPA	Environment Protection Agencies
ERA	Environmental risk assessment
EU	European Union
FEED	Feed additives
GMO	Panel on Genetically Modified Organisms
GPG	General protection goal
LC_{50}	Lethal concentration
MEACB	European Advisory Committees on Biosafety
No	Number
NOEC	No Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PG	Protection goals
PLH	Panel on Plant Health
PPR	Panel on Plant Protection Products and their Residues
PPP	Plant protection product
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SCFCAH	Committee on the Food Chain and Animal Health
SCHER	Scientific Committee on Health and Environmental Risks
SETAC	Society of Environmental Toxicology and Chemistry
SPG	Specific protection goal

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VIII. Annexes

Annex 1 Programme of the Colloquium

Annex 2 Participants at the Colloquium

ANNEX 1 PROGRAMME OF THE COLLOQUIUM

EFSA Scientific Colloquium N°19 Biodiversity as Protection Goal in Environmental Risk Assessment for EU agro-ecosystems

27-28 November 2013 , Parma, Italy

PROGRAMME

Overall chair: Theo Brock, Vice Chair of the Panel on Plant Protection Products of the European Food Safety Authority

Overall rapporteurs: Tony Hardy, Chair of the Scientific Committee of the European Food Safety Authority Reinhilde Schoonjans, European Food Safety Authority
Reinhilde Schoonjans, European Food Safety Authority

Wednesday 27 November

08.30 - 09.00 Registration participants

08.15 - 08.45 Briefing meeting with all chairs and rapporteurs

09.00 - 12.35 SESSION 1: INTRODUCTORY PLENARY SESSION

09.00 - 09.10 Welcome and introduction to EFSA
Tobin Robinson, European Food Safety Authority

09.10 - 09.20 Objectives of the Colloquium
Theo Brock, Vice Chair of Panel on Plant Protection Products and their Residues of the European Food Safety Authority

09.20 - 09.40 Introduction to protection goals, ecosystem services and roles of risk management and risk assessment
Lorraine Maltby, Department of Animal and Plant Science, The University of Sheffield, UK

09.40 - 09.50 Questions

09.50 - 10.10 Making protection goals operational for use in environmental risk assessments
Monica Garcia-Alonso, Estel Consult, London, UK

10.10 - 10.20 Questions

10.10 - 11.00 Coffee / tea break

11.00 - 11.20 The role of population dynamics in ERAs to protect biodiversity
Michael Bonsall, Department of Zoology, University of Oxford, UK

11.20 - 11.30 Questions

11.30-11.50 The role of population modelling in the assessment of recovery in ERA for protecting biodiversity
Paul Jepson, Integrated Plant Protection Centre, Oregon State University Centre, USA

11.50-12.00 Questions

12.00 -12.20 Introduction to Discussion Groups
Andrea Altieri, European Food Safety Authority

12.20 - 13.30 Lunch

13.30 - 18.30 SESSION 2: DISCUSSION GROUPS (DG)

DG1 Translating protection goals into measurable endpoints for use in ERA of regulated products and species
What has been done and are current practices applicable to different types of products/species?

Chairs: *Robert Luttik & Joe Perry, Scientific Committee of the European Food Safety Authority*
Rapporteurs: *Monica Garcia-Alonso, Estel Consult, London, UK*
Reinhilde Schoonjans, European Food Safety Authority

DG2 Protecting biodiversity in agro-ecosystems
How to assess it, how to measure it and how to monitor it?

Chair: *Lorraine Maltby, Department of Animal and Plant Science, The University of Sheffield, UK*
Rapporteurs: *Gabor Lövei, Department of Agroecology Aarhus University Flakkebjerg Research Centre, DK*
Jane Richardson, European Food Safety Authority

DG3 Endangered Species
Are they adequately covered in current ERA schemes?

Chair: *Michael Bonsall, Department of Zoology, University of Oxford, UK*
Rapporteurs: *Joerg Romeis, Agroscope Reckenholz-Tänikon Research Station, CH*
Yann Devos, European Food Safety Authority

DG4 Ecological recovery
How to make it operational in ERA?

Chair: *Paul Jepson, Oregon University, USA*
Rapporteurs: *Wopke Van der Werf, Wageningen University, NL*
Stephanie Bopp, European Food Safety Authority

16.00 Coffee / Tea break

18.00 End of Discussion Groups

Thursday 28 November

09.00 - 10.00	**SESSION 3: CONTINUATION OF DISCUSSION GROUPS** **Concluding discussion of the outcomes and the production of reports to the plenary session**		
10.00 - 10.30	Coffee / Tea break		
10.30-13.30	**SESSION 4: FINAL PLENARY SESSION**		
	10:30-10:50	Report back from Discussion Group 1	*Monica Garcia-Alonso, Estel Consult, London, UK*
	10:50-11:05	Discussion	
	11:05-11:25	Report back from Discussion Group 2	*Gabor Lövei, Department of Agroecology Aarhus University Flakkebjerg Research Centre, DK*
	11:25-11:40	Discussion	
	11:40-12:00	Report back from Discussion Group 3	*Yann Devos, European Food Safety Authority*
	12:00-12:15	Discussion	
	12:15-12:35	Report back from Discussion Group 4	*Paul Jepson, Oregon University, USA*
	12:35-12:50	Discussion	
	12:50-13:20	General discussion	
	13:20-13:30	Take-home messages	*Theo Brock, Vice Chair of the Panel on Plant Protection Products of the European Food Safety Authority*
13.30	**COLLOQUIUM ADJOURNS**		

Organising Committee

Andrea Altieri, *European Food Safety Authority*

Stephanie Bopp, *European Food Safety Authority*

Theo Brock, *Vice Chair of the Panel on Plant Protection Products and their Residues of the European Food Safety Authority*

Sarah Brown, *European Commission*

Yann Devos, *European Food Safety Authority*

Tony Hardy, *Chair of the Scientific Committee of the European Food Safety Authority*

Robert Luttik, *Vice-Chair of the Scientific Committee of the European Food Safety Authority*

Karin Nienstedt, *European Commission*

Joe Perry, *Chair of the Panel on Genetically Modified Organisms of the European Food Safety Authority*

Tobin Robinson, *European Food Safety Authority*

Reinhilde Schoonjans, *European Food Safety Authority*

ANNEX 2 PARTICIPANTS AT THE COLLOQUIUM

Name	Affiliation	Country	Discussion Group (DG)
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Detlef BARTSCH	BVL	DE	3
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Michael BONSALL	University of Oxford	UK	2
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