Making protection goals operational for use in environmental risk assessments.

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INTRODUCTION

Environmental risk assessments (ERAs) are a key tool for decision-making

- In the EU ERAs are used for decision-making, including decisions on
  - Approvals of new plant protection products (PPPs)
  - Approvals on the environmental release of genetically modified organisms (GMOs)
  - Actions to take to control or eradicate the spread of invasive alien species (IAS).
- ERAs must be "fit for purpose"
  - Providing relevant information for decision-makers
  - Focussing on the key aspects that the assessments must consider;
    - Country legislation, protection goals and relevant policy documents outlining data requirements are taken into account.

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INTRODUCTION

Environmental risk assessments (ERAs) take into account policy protection goals

General protection goals (GPGs)

- Defined by regulations as part of environmental policy.
- GPGs are often formulated in legal terms using normative concepts such as “sustainability, integrity, acceptability,…”

GPGs in the EU

- Relevant GPGs to take into account in ERAs are often difficult to select by risk assessors.
  - GPGs are spread over a number of Directives and official documents.
  - Different EU countries may take different approaches with respect to GPGs.
  - Different frameworks (PPP, GMO, PLH) have different interpretations on the relevant GPGs and different approaches for their implementation.

MAKING PROTECTION GOALS OPERATIONAL FOR USE IN ERAs

Operational translation of GPGs for ERAs

- The operational translation of GPGs focuses the ERA, facilitating the selection of relevant assessment endpoints, the formulation of testable hypotheses and the selection of measurement endpoints.

- The need to translate GPGs into OPGs for "fit-for-purpose" ERAs has been identified. Approaches to address this have emerged in different frameworks: PPPs, IAS, GMOs.
- The proposal is to use the Ecosystem Service (ES) concept
  - The idea is to explain the choices made in ERA to assess the impact of new stressors on ES (provisioning, regulating, cultural and supporting).
  - This methodology allows the identification of the most relevant SPGs for a particular ecosystem focussing on the key ES to protect in that ecosystem.

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MAKING PROTECTION GOALS OPERATIONAL FOR USE IN ERAs

What are the relevant GPGs for agricultural landscapes?

- There are many GPGs that can be considered. Often, not all GPGs can be protected at the same level at the same time: Trade-offs and prioritisation may be necessary.
- Different stakeholders interpret and prioritise GPGs for agricultural landscapes in different ways (18th EFSA Colloquium).
- GPGs often considered are: Biodiversity, crop productivity, food security, air, water and soil quality.
- There is a spatial component to consider: different areas in the agricultural landscape provide different ES (crop, margins, natural areas,…).
    - The level of human management in these areas has a great impact on ES.
    - Crops are planted for the provision of food, fiber or fuel. Their management focuses on optimising production but in a way that the system is not damaged so it remains productive (sustainable production).
- There is also a temporal component as agricultural landscapes can be fluid (crop-rotation, land management) and management input may also change with time.

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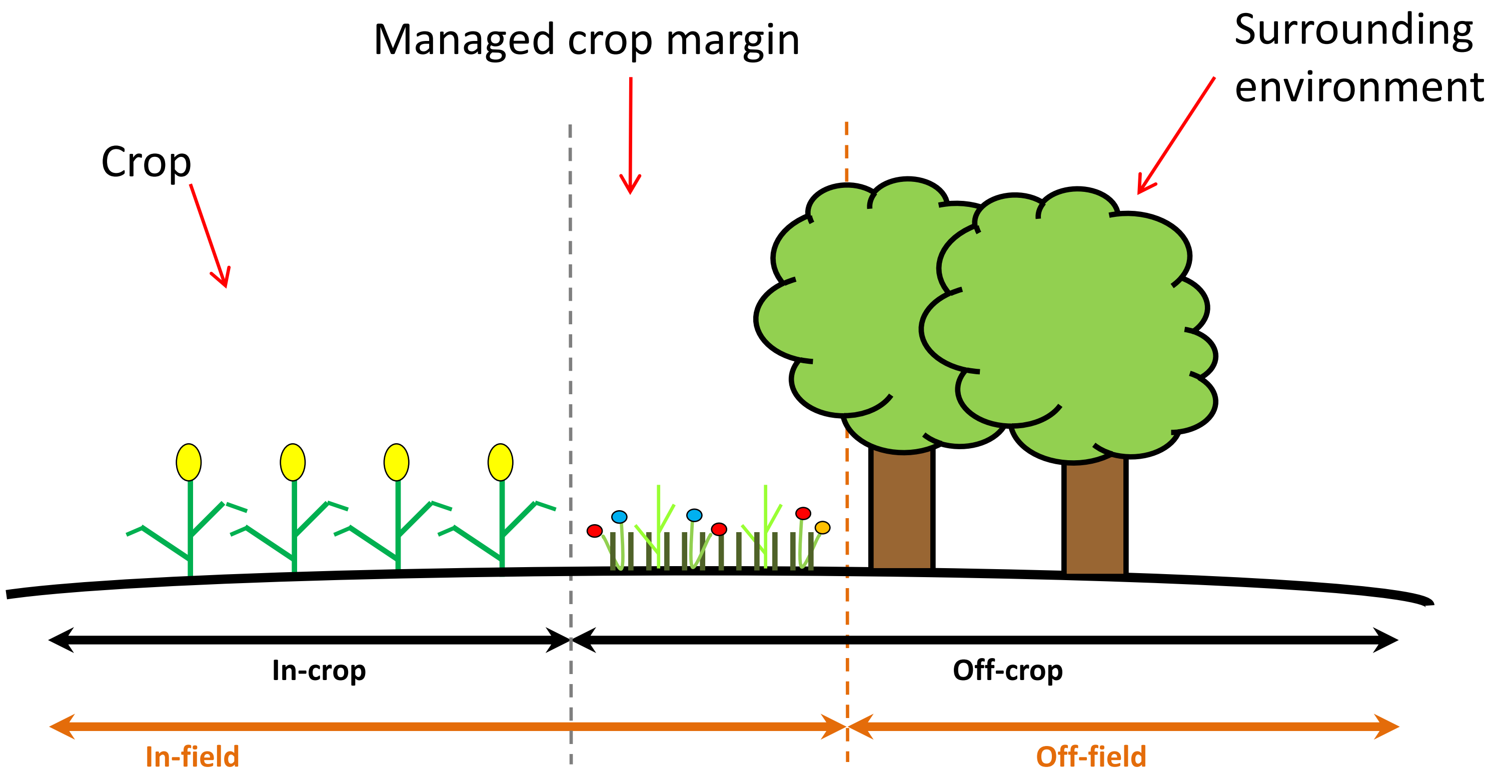
Agricultural landscapes

Agricultural landscapes contain a mixture of ecosystems that receive different levels of human management and provide different ES.

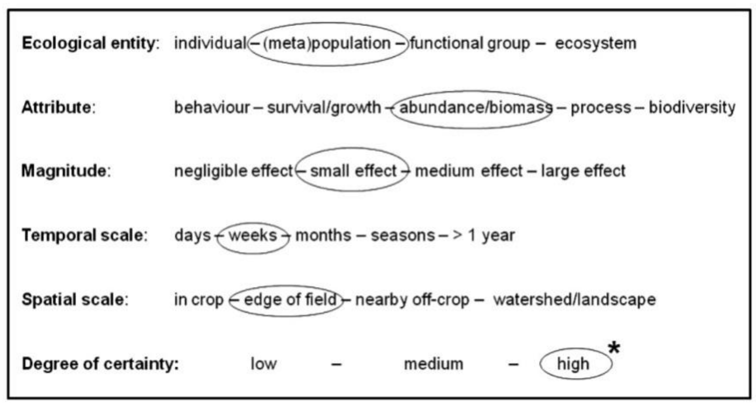


MAKING PROTECTION GOALS OPERATIONAL FOR USE IN ERAs

PLANT PROTECTION PRODUCTS

- In the regulatory framework for Plant Protection Products (PPPs), the EFSA's PPR panel has been working on developing specific protection goals (SPGs) for ERAs for aquatic and terrestrial ecotoxicology performed under Regulation (EC) No 1107/2009 (Scientific Opinion of the PPR Panel (2010) and Nienstedt *et al* (2012)).
- The approach is based on the Ecosystem Services (ES) concept and describes the steps to follow to develop specific protection goals.
- A discrimination between ES in-crop and off-crop is made.
- SPGs are developed in 4 steps, applying six dimensions:

- Ecological entity
- Attribute
- Magnitude
- Temporal scale
- Spatial scale
- Degree of certainty



From Nienstedt et al., 2012

- Once SPGs are defined, guidance on measuring the magnitude of the effects and thresholds are provided.

MAKING PROTECTION GOALS OPERATIONAL FOR USE IN ERAs: PLANT PROTECTION PRODUCTS

List of ecosystem services

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Identification of ES potentially affected by the PPP

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Identification of key drivers for each ES

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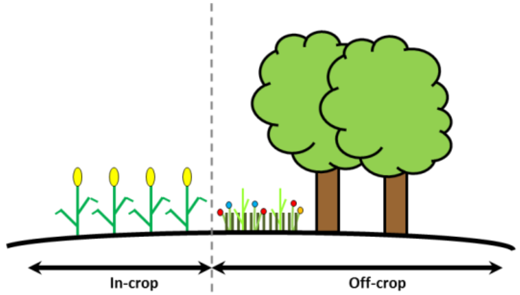
Formulation of SPGs

List of ES from MA (Provisioning, regulating, cultural and supporting)



Ecosystem Services Category	In-crop	Off-crop
Provisioning services	Food and fiber, fuel.	Food, genetic resources, fresh water.
Regulating services	Pollination, pest and disease regulation.	Water regulation, erosion control, water purification.

Key drivers for a given ES are major taxonomic or functional groups that support the ES.

SPGs are defined using six dimensions: ecological entity, attribute, magnitude, temporal scale, spatial scale and degree of certainty.

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MAKING PROTECTION GOALS OPERATIONAL FOR USE IN ERAs: PLANT PROTECTION PRODUCTS (EXAMPLE)

List of ecosystem services

Relevant ES: Pollination

Key drivers: Honeybees

SPG: Colony viability (Colony size)

The magnitude of the impact is categorised in 4 classes

Effect	Magnitude (reduction in colony size)
Large	>35%
Medium	15% to 35%
Small	7% to 15%
Negligible	3.5% to 7%

MAKING PROTECTION GOALS OPERATIONAL FOR USE IN ERAs: INVASIVE ALIEN SPECIES

INVASIVE ALIEN SPECIES (IAS)

In the IAS area, the EFSA's PLH panel has been working on developing a method to conduct ERAs in a consistent and transparent way in the context of a PRA (pest risk assessment process) (Gilioli et al., 2013).

- The approach is based on the ES concept.
- Impact is evaluated by estimating how an IAS modifies structural (biodiversity) and functional (ES) traits of an ecosystem.
- The assessment is based on a scenario analysis with defined spatial and temporal resolution.
- Includes the concept of "Service providing units" (SPUs), linking ecosystem components (individuals, species or communities) to the ES they provide.
- Takes into account the impact of human management of ecosystems on the overall risk evaluation.
- Guidance for qualitative categorisation of measures of the magnitude of the impact and uncertainty is provided.

MAKING PROTECTION GOALS OPERATIONAL FOR USE IN ERAs: INVASIVE ALIEN SPECIES

Scenario development and assumptions

- Temporal scale of the invasion
- Spatial scale of the invasion
- Resistance of the ecosystem at risk
- Resilience of the invaded ecosystem
- Existing management measures

Scenarios are developed to explore future environmental impact of the pest. They take into consideration the temporal and spatial scale, the ecosystem resilience and capacity to resist invasion and existing management measures.

Analysis of the impact (ES losses)

- Information available on environmental impacts caused by the pest in areas of invasion.
- Identification of service providing units (SPUs).
- Identification of functional traits in the SPUs that can be affected.
- Trait service clusters

Evaluation of changes in ES provision: magnitude of the impact and level of uncertainty.

The analysis is focussed through ES, considering SPUs and Functional traits.

The magnitude of the impact is categorised in 5 classes

Rating	Magnitude of the impact (%)
Minimal	Zero or negligible
Minor	0 to 5%
Moderate	5% to 20%
Major	20 to 50%
Massive	>50%

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MAKING PROTECTION GOALS OPERATIONAL FOR USE IN ERAs: INVASIVE ALIEN SPECIES (EXAMPLE)

Scenario development and assumptions

- Temporal scale of the invasion: Slow spread expected.
- Spatial scale of the invasion: <20% of suitable area.
- Resistance of the ecosystem at risk: Low.
- Resilience of the invaded ecosystem: Low, expected to increase with natural enemies
- Existing management measures: eradication measures exist.

Anoplophora chinensis

Analysis of the impact (ES losses)

- Polyphagous pest species.
- SPUs: urban landscapes, orchards, forests.
- Functional traits that can be affected: individual trees, tree populations. No selection of tree species expected at community level.
- Trait service clusters:
  - Provisioning: fiber, ornamental and primary production.
  - Regulating and supporting: regulation of air quality, climate, water and erosion. Nutrient cycling.

Evaluation of impact in ES:
- Provisioning: high
- Supporting and regulating ES: moderate.

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MAKING PROTECTION GOALS OPERATIONAL FOR USE IN ERAs: GENETICALLY MODFIED PLANTS

GENETICALLY MODIFIED PLANTS

In the regulatory framework for GMOs the EFSA GMO panel recommends the application of the GPGs set in 2001/18/ EC in the ERAs (EFSA Guidance on the ERA of genetically modified plants, 2010). The Guidance provides a list of policy documents from which GPGs can be drawn

Applicants are asked to specify which GPGs goals are considered in the ERA as well as which assessment endpoints and measurement endpoints have been used. Some examples are available through recent scientific opinions published by the GMO panel.

Given the case-by-case nature of the ERA for GM plants and the potential for different interpretations of GPGs and assessment and measurement endpoints, applicants, through the EuropaBio platform, developed a proposal to ensure a harmonized approach.

- The proposal is based on the ES concept.
- Considers the impact of the cultivation of GM plants on ES.
- The proposal is based on a conceptual framework.
- Spatial and temporal considerations are included.

MAKING PROTECTION GOALS OPERATIONAL FOR USE IN ERAs: GENETICALLY MODFIED PLANTS

GENETICALLY MODIFIED PLANTS

- The ERA follows a comparative approach using the conventional crop as a comparator.

- The two main GPGs proposed by applicants are:

  - **Sustainable agricultural production**; this includes the impact of the GM plant on ES while the plant is cultivated, but also considers the impact on key ES that are essential for the productivity and health of the system for future cropping seasons (impact on NTOs that contribute to the regulating ES service; persistence and invasiveness of the GM plant; impact on biogeochemical processes and impact of management practices associated with the GM plant).

  - **Biodiversity**; the impact of cultivating the GM plant on biodiversity is considered for in-field and off-field. In-field it focusses on regulating ES (and therefore considered as sustainable agricultural production). Off-field it focusses on biodiversity “as a good” (conservation approach).

- The selection of assessment endpoints and measurement endpoints is done case-by-case, depending on the crop/trait combination (herbicide tolerant, insecticidal, output trait, etc).

- The measure of the magnitude of the impact is quantitative where possible (e.g. NTOs), but mainly qualitative. Thresholds or definitions of harm have not been established. Categorical qualitative measures have not been defined, although the qualitative measures used in other regulatory frameworks are often used (Office of the gene technology in Australia) .

MAKING PROTECTION GOALS OPERATIONAL FOR USE IN ERAs: GENETICALLY MODFIED PLANTS

Policy protection goals

Protection goals set by policy

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Operational protection goals

Identification of the most relevant ecosystem services in order to establish the level of protection.

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Assessment endpoints

"Specific entities and their attributes that are at risk and that are expressions of a management goal". Specify: entity to be protected, attribute or function, unit of protection, spatial scale, temporal scale.

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Risk hypotheses

Driven by the outcome of problem formulation (case-by-case).

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Measurement Endpoints

Selected case-by-case to provide the best test of the hypothesis. Specify which measurement endpoints will be used to assess impact on the Identified SPGs.

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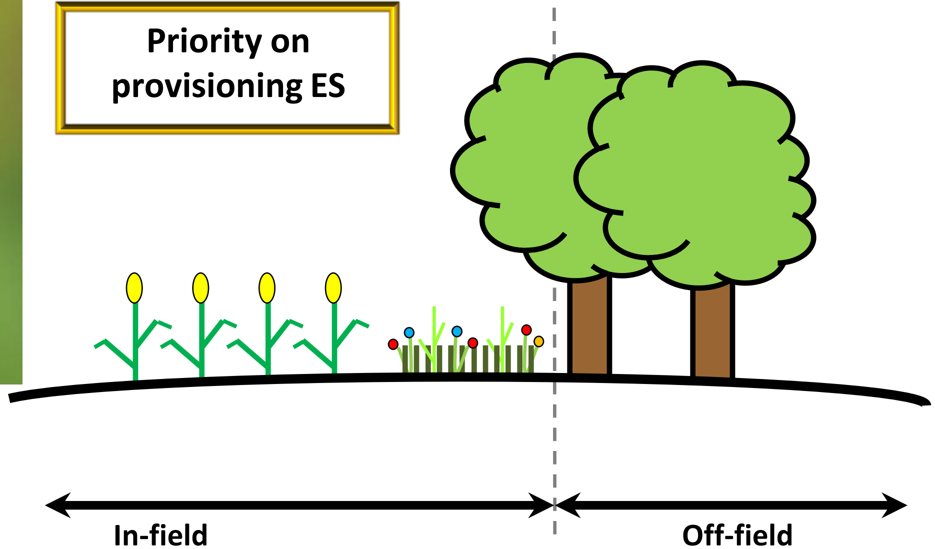
MAKING PROTECTION GOALS OPERATIONAL FOR USE IN ERAs: GENETICALLY MODFIED PLANTS (EXAMPLE: NON-TARGET ORGANISMS)

Priority on provisioning ES



Adverse effects on NTOs as providers of important ecological functions
(Biodiversity as a regulator of ecosystem services).

SUSTAINABLE AGRICULTURAL PRODUCTION

Adverse effects on NTOs of conservation value
(Biodiversity as a "good")

BIODIVERSITY

MAKING PROTECTION GOALS OPERATIONAL FOR USE IN ERAs: GENETICALLY MODFIED PLANTS (EXAMPLE: NON-TARGET ORGANISMS)

POLICY PROTECTION GOALS	OPERATIONAL PROTECTION GOAL	ASSESSMENT ENDPOINTS	CONSERVATIVE TEST HYPOTHESIS	MEASUREMENT ENDPOINTS
Protection of sustainable agricultural production	The cultivation of GM crop X in country Y should not result in adverse effects on regulating ES provided by NTAs in managed crop areas (in-field) compared with cultivation of non-GM varieties of this crop.	Adverse effects on regulating ecosystem functions provided by NTAs (e.g. pollination, decomposition, pest control) in managed crop areas during cultivation of the GM crop or in the following season.	Exposure to insecticidal protein A produced by GM crop X does not have adverse effect on ecological function N (e.g. predation, pollination) relative to the cultivation of non-GM varieties of the crop.	Direct measurement of the ecosystem function (e.g. rate of predation).
		Adverse effects on populations of NTAs that provide regulating ecosystem functions (e.g. pollination, decomposition, pest control) in managed crop areas during cultivation of the GM crop or in the following season.	Exposure to insecticidal protein A produced by GM crop X does not have a greater adverse effect on the population size of NTA Y (e.g. ladybird) than the cultivation of non-GM varieties of the crop.	Increased mortality of ladybird beetles after exposure to high concentrations of protein A relative to unexposed controls in laboratory studies.
Protection of Biodiversity	The cultivation of GM crop X in country Y should not result in adverse effects on NTAs of key conservation value in off-field areas compared with cultivation of non-GM varieties of this crop.	Population decline of valued NTAs in off-field areas during cultivation of the GM crop or in the following season.	Exposure to insecticidal protein A produced by GM crop X does not have a greater adverse effect on the population size of protected species of NTA P (e.g. monarch butterfly) than the cultivation of non-GM varieties of the crop.	Potential exposure (temporal and spatial overlap and levels of exposure) of NTA P to protein A.

From Garcia-Alonso & Raybould, 2013

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MAKING PROTECTION GOALS OPERATIONAL FOR USE IN ERAs

COMPARING THE DIFFERENT METHODS

The methods proposed to make GPGs operational for ERAs to support decision-making for PPPs, IAS and GMOs display many similarities, but there are also differences.

Main similarities between the three methods:

- Based on the ES concept.
- Take into account spatial and temporal considerations to facilitate the selection and prioritisation of relevant ES for the assessment.
    - All address the protection of provisioning (fuel, fiber and fuel) and regulating (e.g. pest and disease regulation, pollination, soil erosion, etc.) ES in agricultural or production landscapes.
- Address impacts on functional and structural biodiversity.

MAKING PROTECTION GOALS OPERATIONAL FOR USE IN ERAs

COMPARING THE DIFFERENT METHODS: TERMINOLOGY

- Main differences between the three methods
  - The language and nomenclature used in the different methods is different
    - PPP: “specific protection goals”, “key drivers”
    - IAS: “service providing units”, “functional traits”, “service clusters”, “structural biodiversity”
    - GMO: “operational protection goals”, “assessment endpoints”, “measurement endpoints”, “focal species”.
  - SPGs in the PPP method are referred to as “assessment endpoints” in the GMO method (defined using the six dimensions: ecological entity, attribute, magnitude, temporal scale, spatial scale and degree of certainty).
  - Measures of the magnitude of the impact are defined in the PPP and IAS approach. However the terms differ:
    - PPP: large, medium, small and negligible.
    - IAS: massive, major, moderate, minor, minimal. For IAS, in addition three descriptors are used for structural biodiversity (minor, moderate and major) that are then quantified through a probability distribution and integrated with the uncertainty component.

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COMPARING THE DIFFERENT APPROACHES: CONCEPTS

- Main differences:
  - The way in which the spatial scale is considered for agricultural landscapes in the PPP and GMO methods is different
    - PPP: differentiates between in-crop and off-crop areas.
    - GMO: differentiates between in-field and off-field areas.
  - The SPGs in the PPP approach define the species to test, the measurement endpoints and the thresholds to assess the impact. This is not the case for GMOs, where species to test and measurement endpoints are selected case-by-case.

Could the methods be harmonized?
- Using the same terminology
- Using the same SPGs, test species, thresholds and measures of magnitude

How?
- Who could drive this harmonization?

MAKING PROTECTION GOALS OPERATIONAL FOR USE IN ERAs

SUMMARY

- ERAs are conducted to facilitate decision-making. Therefore ERAs consider the relevant GPGs set in the legislation.
- GPGs are usually generic and normative and too vague to be scientifically assessed in the ERA. They must be translated into SPGs or OPGs for practical implementation to ensure fit-for-purpose ERAs. A common understanding between risk assessors and risk managers of the SPGs to use in ERAs is essential.
- Methods for making EU GPGs operational for use in ERAs have been developed independently for different types of products.
  - The methods are similar in that all use the ES concept, but there are also differences in the approach taken, the terminology used and the level of detail they provide.
  - Opportunities exist for harmonization.

FURTHER READING

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Thank you for your attention!