



# Appraisal of new approach of Environmental Risk Assessment (ERA) by European Food Safety Agency (EFSA)

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## **Risk assessment strategy for GMOs:**

**CURRENTLY: Divide and evaluate  
as singular components acting in  
isolation!**

# EXAMPLE: HR crops

Developers/supporters claim full credit for the **BENEFITS** of this Integrated Package:

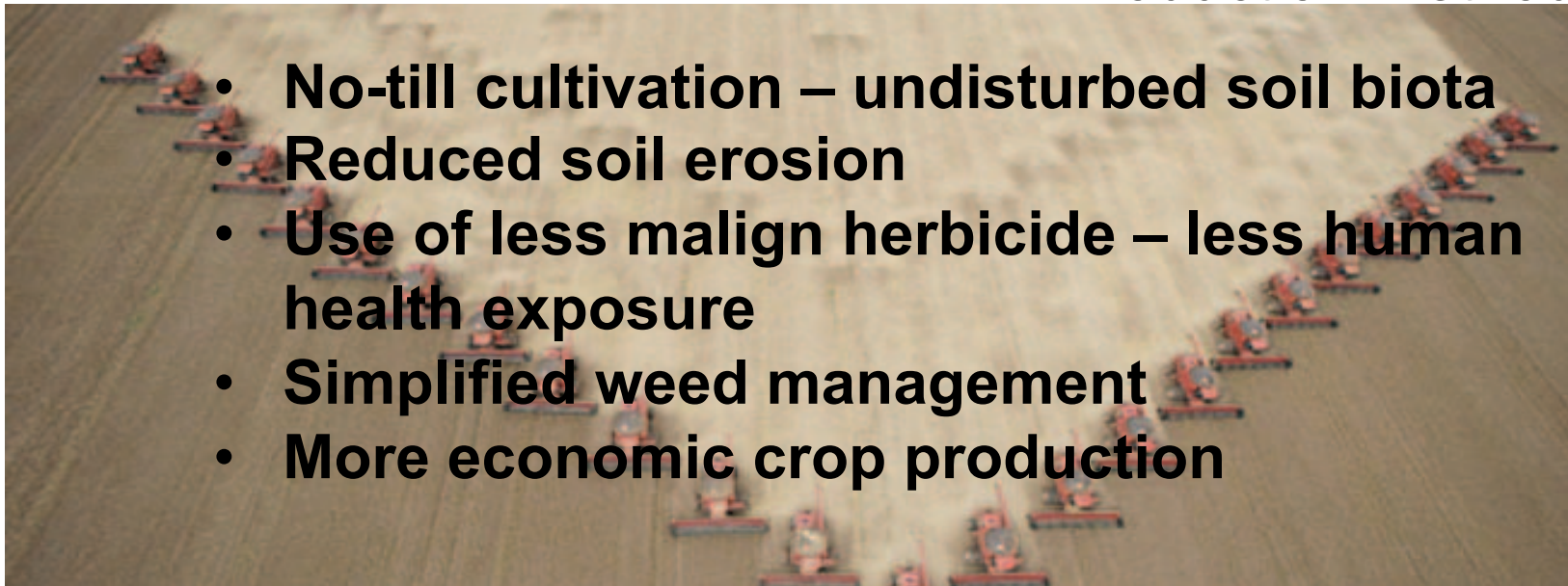


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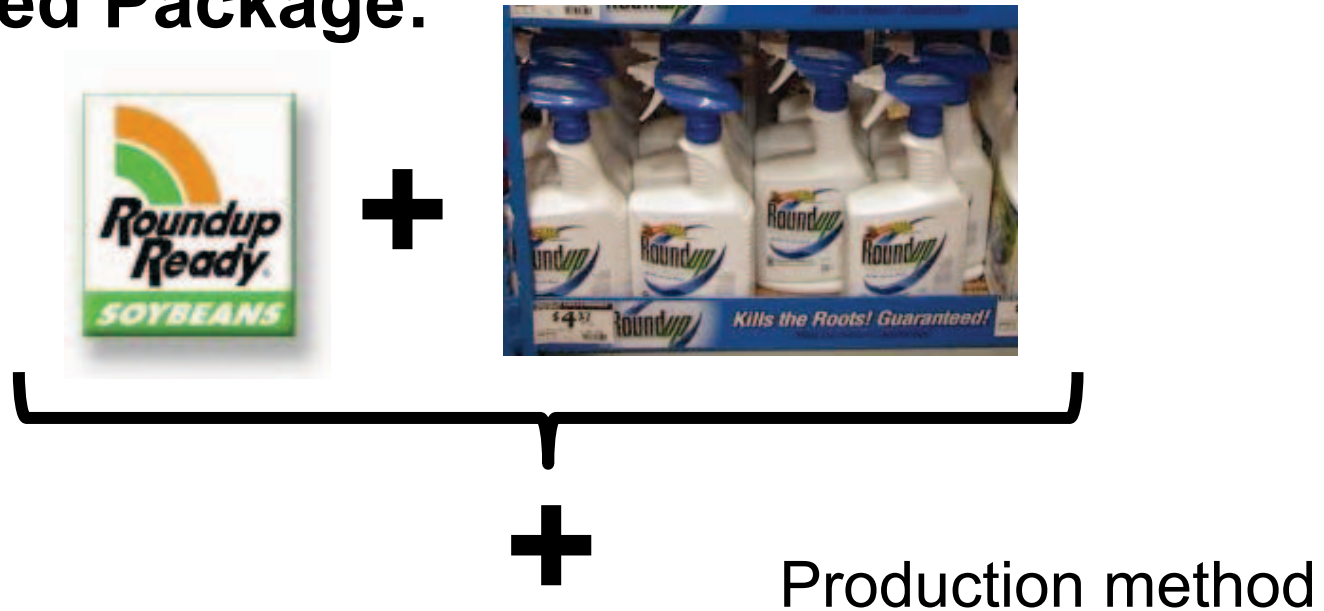
Production method



- No-till cultivation – undisturbed soil biota
- Reduced soil erosion
- Use of less malign herbicide – less human health exposure
- Simplified weed management
- More economic crop production

# EXAMPLE: HR crops

...but deny and reject all **adverse effects** of this Integrated Package:

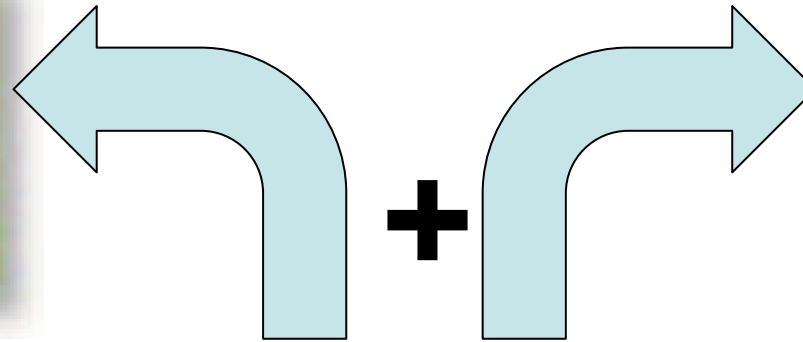


- Weed resistance rampant
- Use of 'old', more toxic herbicides in addition to Roundup
- Health effects of massive use of Roundup (aerial spraying) and residues in foods/feeds
- Environmental problems – reduced soil microbial activity, reduced availability of micro-nutrients, huge non-target biodiversity effects, etc.



# EXAMPLE: HR crops

GM trait product tested in isolation from GM Plant



**Pesticide** testing in isolation from GM Plant

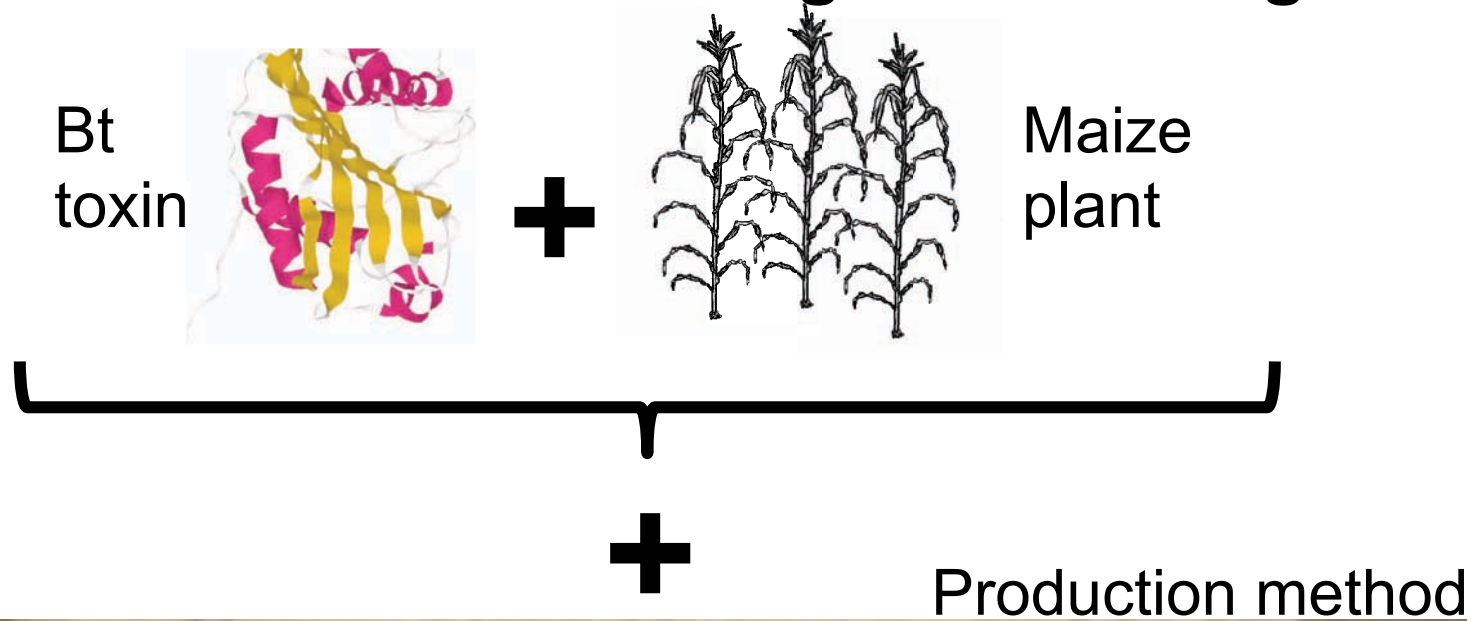


## NO ADVERSE EFFECTS!!

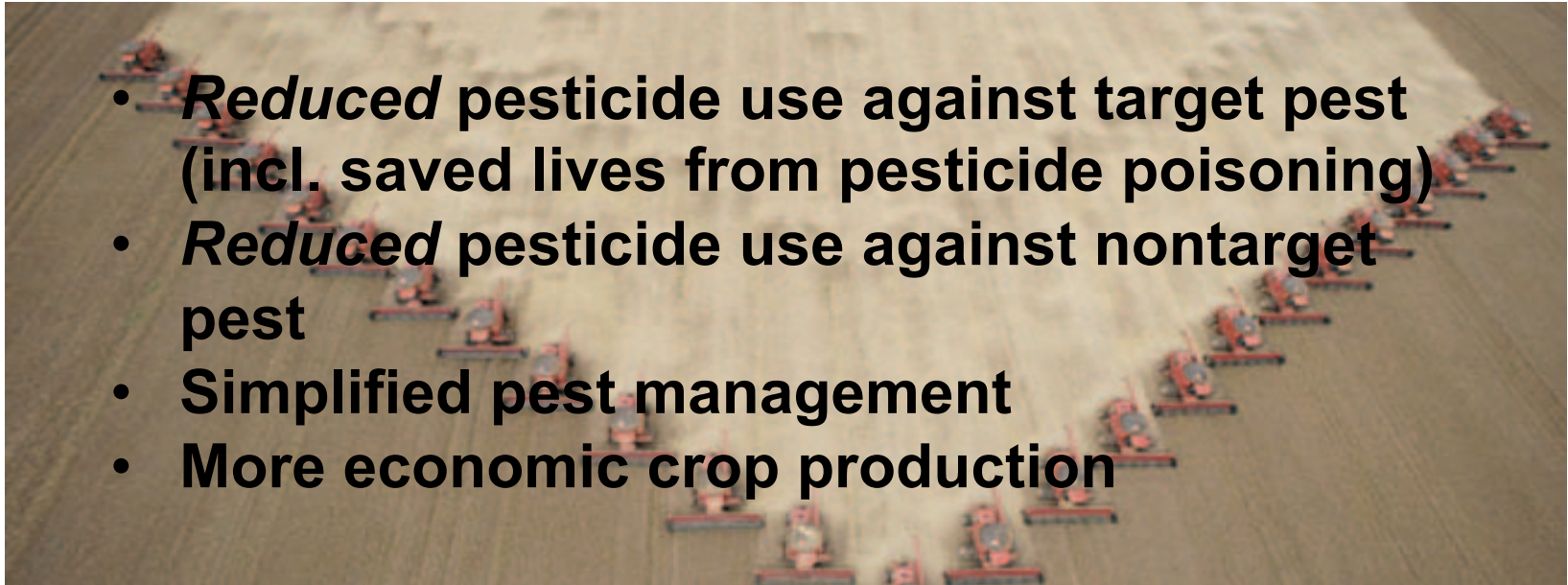
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# EXAMPLE: Bt crops

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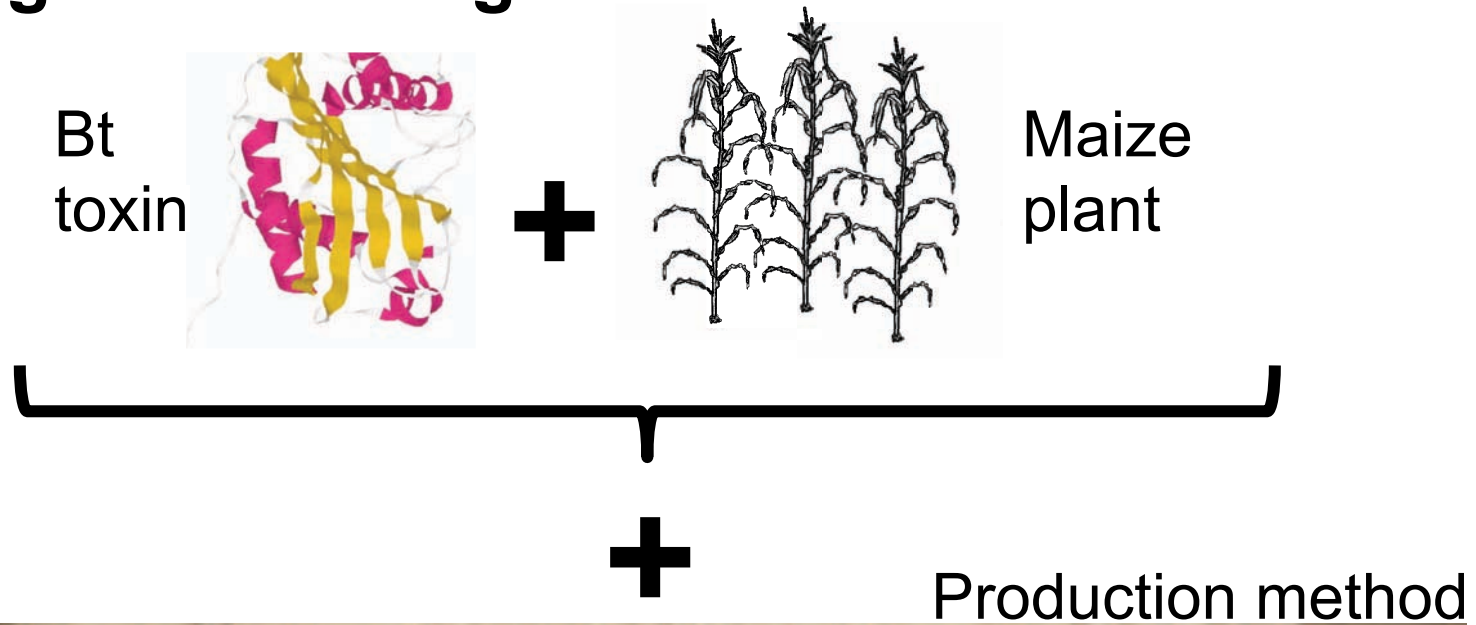


- *Reduced* pesticide use against target pest (incl. saved lives from pesticide poisoning)
- *Reduced* pesticide use against nontarget pest
- Simplified pest management
- More economic crop production



# EXAMPLE: Bt crops

...but deny and reject most **adverse effects** of Integrated Package:

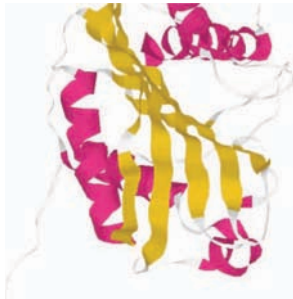


- *Increased* pesticide use against resistant target pest (incl. lost lives from pesticide poisoning)
- *Increased* pesticide use against secondary target pest
- More complex pest management
- Less economic crop production

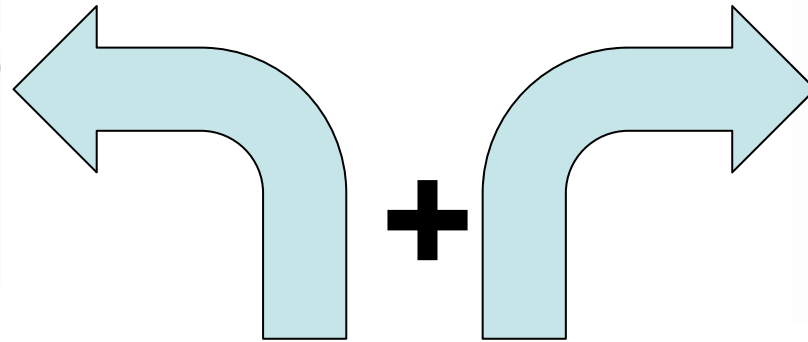


# EXAMPLE: Bt crops

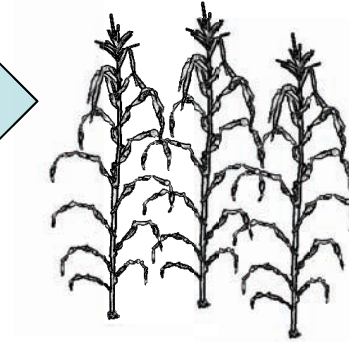
GM trait product tested in isolation from GM Plant



**Bt toxin –**  
microbial protein



GM Plant



**GRAS- generally**  
regarded as safe

**NO ADVERSE EFFECTS!!**

- *Increased* pesticide use against resistant target pest (incl. lost lives from pesticide poisoning)
- *Increased* pesticide use against secondary target pest
- More complex pest management
- Less economic crop production



# What model do we want?



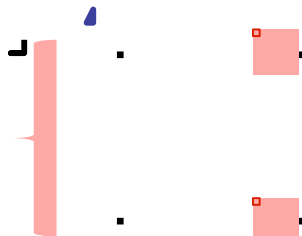
Adverse effects/Risks



Beneficial effects/Benefits

Current

non-precautionary



**Unbalanced –  
biased to *benefits***

**Balanced,  
narrow limits**

**Balanced,  
broad limits**

precautionary



**Unbalanced –  
biased to *risks***



# Mandate of EFSA



1. ERA of potential effects of GM plants on non-target organisms through
  - a) development of **criteria for the selection of non-target organisms** and representative species thereof
  - b) selection and recommendation of **appropriate methods** to study the potential effects



# Mandate of EFSA



2. Development of **criteria for field trials** to assess the potential ecological effects of the GM plants in receiving environments
3. **Identification of the EU geographic regions** where GM plants may be released and the selection of representative receiving environment(s)
4. Selection of appropriate techniques to **assess potential long-term effects** of GM plants



# Legal Status of Guidance

- "as for the guidance presently developed for food and feed, it is our objective that this guidance document on environmental risk assessment will have **regulatory status** and will be **adopted by the Member States** with the support of risk assessors at national level."





# Critical Appraisal



- A number of good steps forward, progress in terms of scientific rigorosity, quality and for environmental safety were made
- Recognized that calls from scientists for such improvements were finally heard – rewarding, confidence building



# 1) Selection of Non-Target Organisms and development of testing methods



- **Greatest progress was made here!**
- Ecological criteria applied to selection of testing species or ecological processes
- Environment considered
- Realistic routes of exposure
- Testing of transgene product & GMO
- Building on and **incorporating concepts developed by wider science circles than is usually considered by EFSA!**

# 2010 Final Draft

# 2009 Draft

## Selection of "focal species"

### Preserving the functional biodiversity

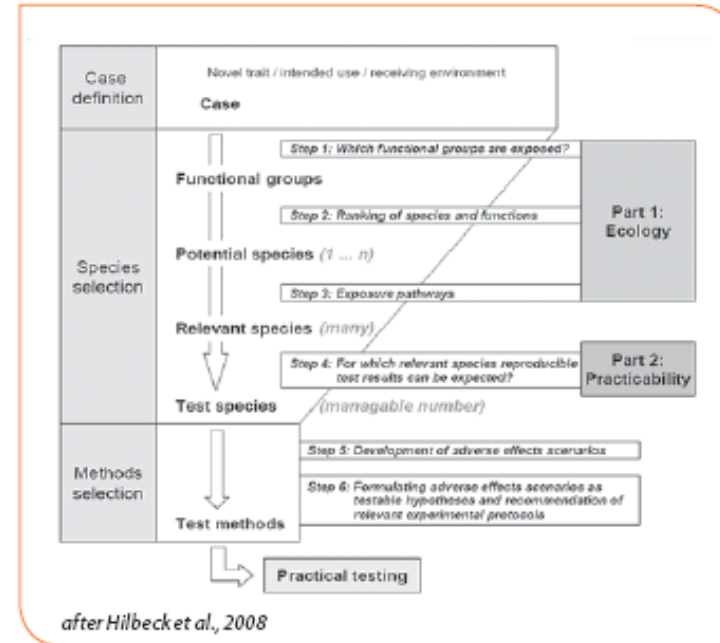
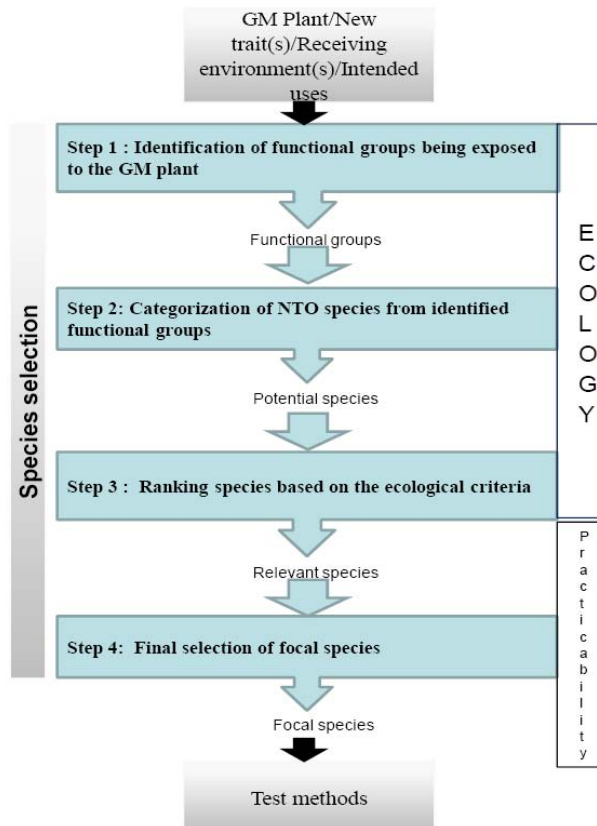
- ▶ Herbivores
- ▶ Predators
- ▶ Parasitoids
- ▶ Pollinators, pollen feeders
- ▶ Decomposers
- ▶ Species of conservation/cultural conc

## EFSA AND GMO RISK ASSESSMENT FOR HUMAN AND ANIMAL HEALTH AND THE ENVIRONMENT

14-15 September 2009, Brussels, Belgium



Self-tasking Working Group on environmental impacts of GM plants on Non-Target Organisms



after Hilbeck et al., 2008



## **While the CURRENT ecotox model is**

prescriptive with regard to species and protocols  
– starts narrow and considers other (e.g. long-term, cumulative) effects only if acute, short-term effects of a plant-produced novel protein occur.

## **The NEW whole-plant ERA Model is**

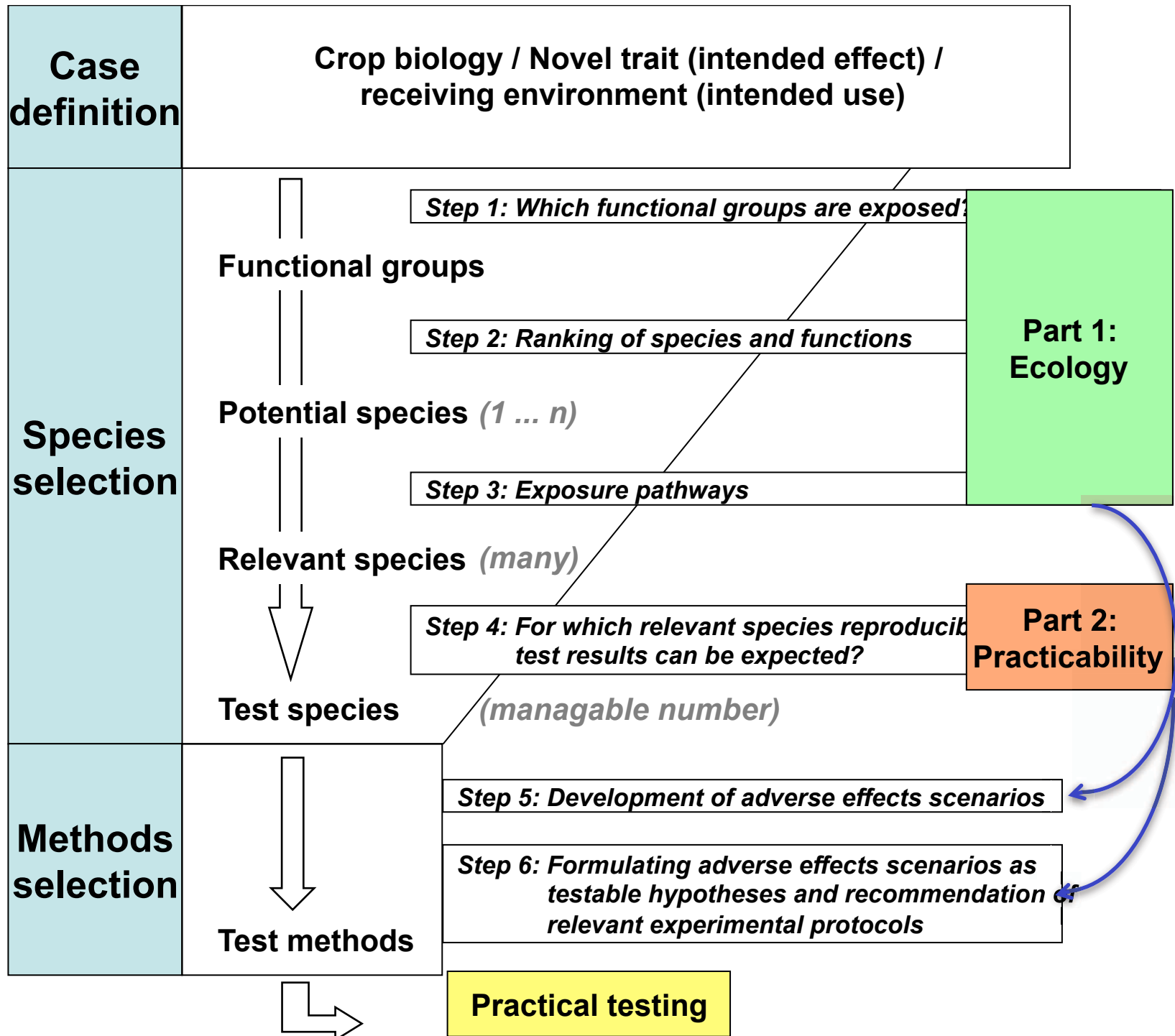
prescriptive with regard to the selection procedure for testing species from the receiving environment ....





## Whole Plant - GMO ERA Model

- Based on a biodiversity function approach
- Starts broad – reducing species number through a transparent process based on ecological criteria like: abundance, phenology, ecological significance, exposure
- Aim: Filtering out those that are associated with highest potential risk (= exposure x ecological significance)
- Selection process informs:
  - potential adverse effect scenarios
  - formulation of risk hypotheses
  - design of proper experiments and protocols



**We can narrow the lists down to numbers of species that are reasonable (20-30)**

**Expert-driven process – takes 3-5 days**

**Open, transparent process builds legitimacy and validation at a later time**

**Information on first steps can be used for same crop plant and receiving environment again – data base building**



## Concerns:



- EFSA introduces „**comparative safety analysis**“ as „general principle“ in a legally binding EU document on ERA
- „Comparative safety analysis“ is a new expression for the **concept of substantial equivalence**
- Used and criticised in the context of GM food safety assessment
- Not accepted as safety assessment in ERA





# In Contradiction With



- **Regulation 1829/2003**: „Whilst substantial equivalence is a key step in the procedure for assessment of the safety of genetically modified foods, it is **not a safety assessment in itself.**”
- **Codex GL 45-2003**: “The concept of substantial equivalence is a key step in the safety assessment process. However, it is **not a safety assessment in itself**; rather it represents the starting point which is used to structure the safety assessment of a new food **relative to its conventional counterpart.**”



## Consequences

- EFSA will be empowered to **take decisions** on the interpretation of data regarding statistically significant differences of unintended effects **prior to the conduct of ERA** on three essential criteria in the “comparative safety analysis”





## New Decision Making Steps prior to ERA



1. determination of the **consistency** of the observed differences;
  2. determination of the **non-transient nature** of the observed differences;
  3. determination of the **biological relevance** of the observed differences
- Unintended effects will only be included in ERA when they pass all three tests



## 1. Introduction

## 2. Strategies for ERA of GM plants

### 2.1 Comparative safety assessment

## 3. Specific areas of risk to be addressed

3.1 Persistence and invasiveness, including plant-to-plant gene flow

3.2 Potential for plant to micro-organisms gene transfer

3.3 Interaction of the GM plant with target organisms

3.4 Interactions of the GM plant with non-target organism

3.5 Impacts of the specific cultivation, management and harvesting techniques

3.6 Effects on biogeochemical processes

3.7 Effects on human and animal health

3.8 Overall risk evaluation and conclusions

## 4. PMEM plan

**Concern: Will function as huge bottleneck filtering out the vast majority if not all of the current GM plants**

## 2.2 Objectives of different ERA steps

2.2.1 Step 1: Problem formulation (incl. hazard identification)

2.2.2 Step 2: Hazard characterisation

2.2.3 Step 3: Exposure characterisation

2.2.4 Step 4: Risk characterisation

2.2.5 Step 5: Risk management strategies

2.2.6 Step 6: Overall risk evaluation and conclusions

## 2.3. Cross-cutting considerations

2.3.1. Choice of comparators

2.3.2 Receiving environment(s)

2.3.3. General statistical principles

2.3.4 Long term effects (including techniques for their assessment)

2.3.5 GM plants containing stacked transformation events

## References

## Appendices

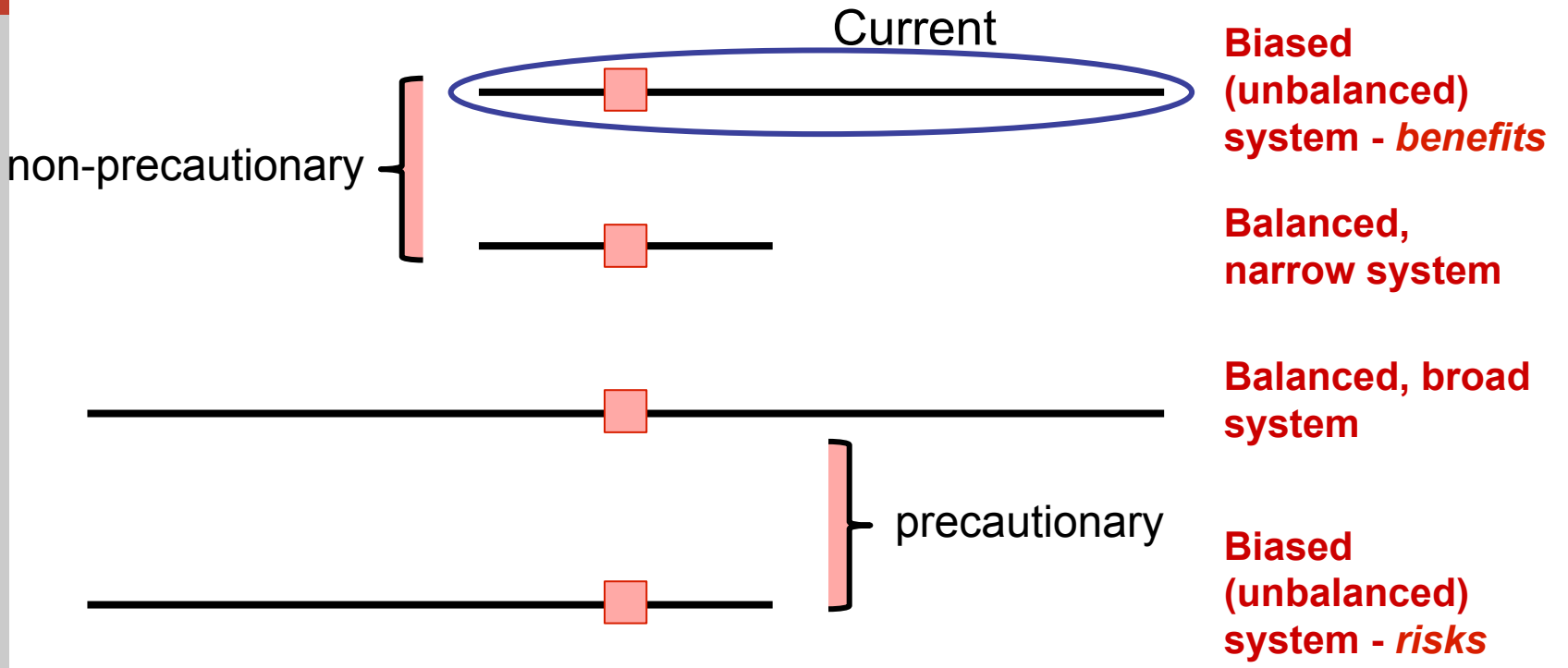
A. Background information for geographical zones in the receiving environment(s)

B. Considerations for long-term effects

# What model do we want?



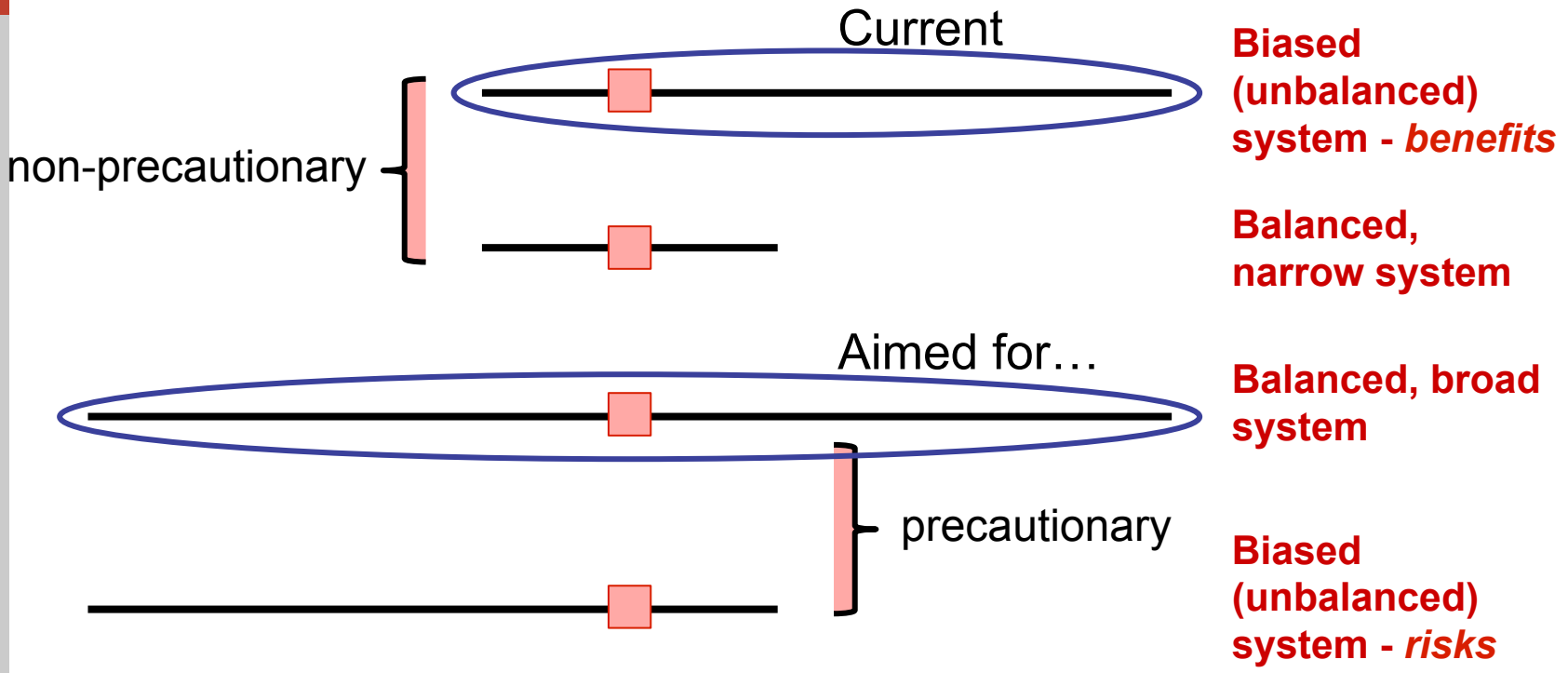
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# What model do we want?



Adverse effects/Risks ■ Beneficial effects/Benefits







**You (should) decide!**