



# PARMA SUMMER SCHOOL

28 – 30 SEPTEMBER 2021, Parma

Food Safety Aspects of Integrated Food Systems

## Environmental risk assessment (ERA) of regulated products in EFSA's remit: Current challenges & future directions taken by EFSA

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# On today's menu

**1** | EFSA's remit pertaining  
to ERA

**2** | ERA of genetically  
modified organisms  
(GMOs) – Case study

**3** | Current challenges &  
future directions taken by  
EFSA

# 1 | EFSA's remit pertaining to ERA

# 1 | Role (simplified)



Reference body for **risk assessment** of food/feed in the European Union (EU)

# 1 | Tasks (simplified)

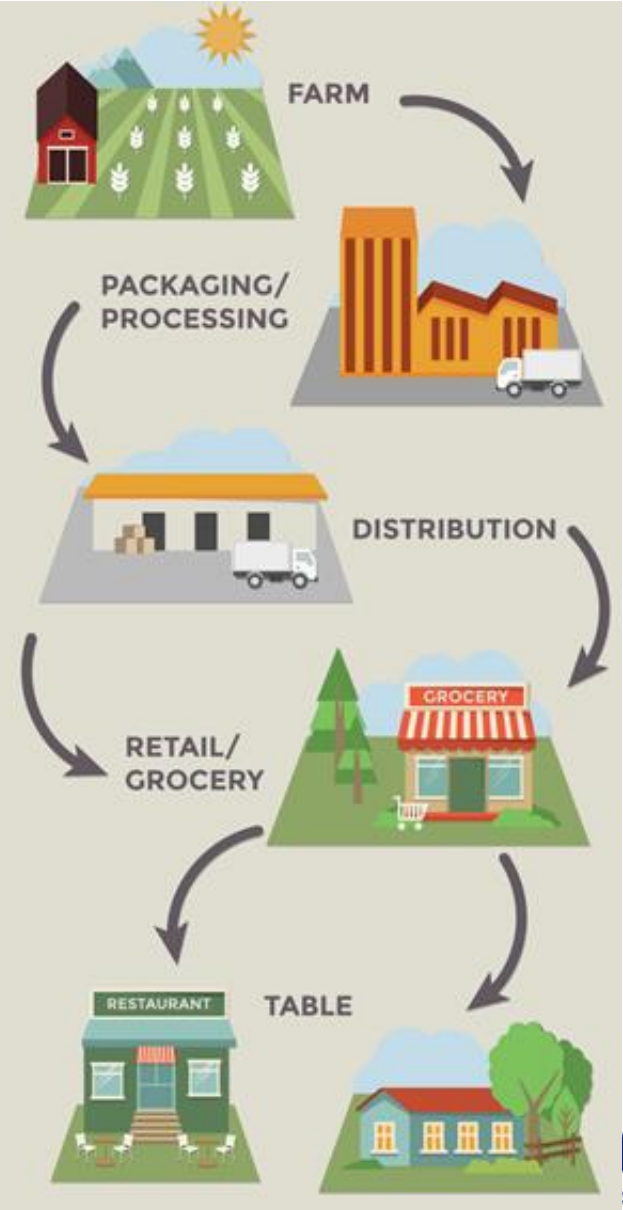


# 1 | Role (simplified)



EFSA's work covers the **entire food chain** –  
from farm/field to fork

# 1 | Remit (simplified)



## Stressors/regulated products (pertaining to food/feed production)

- Animal diseases (zoonotic/non-zoonotic)
- Biological hazards
- Botanicals
- Chemical mixtures
- Food contact materials
- Contaminants
- Food and feed
- Emerging risks
- Endocrine active substances
- Enzymes
- Flavourings

**Feed additives**  
**Genetically modified organisms**

Nanomaterials  
Novel foods/feeds

**Plant protection products (active substances)**

Processing aids  
**Quarantine plant pests**

## Protection goals

- Human health
- Animal health
- Animal welfare
- Plant health

**Environment**  
(biodiversity, ecosystems, ecosystem services, ...)





# 1 | Activities (simplified)



# 2 | ERA of GMOs – Case study (ERA aspects & concepts)

# 2 | Introduction

- **Definition**

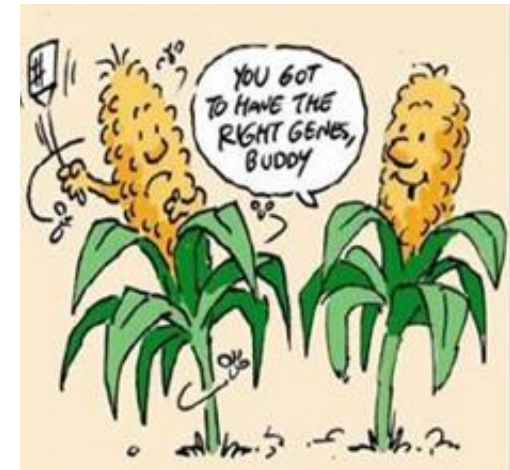
- An organism whose **genetic material** has been changed in a way that does not occur under natural conditions through cross-breeding or natural recombination

- **Regulatory oversight**

- The deployment of products that **are, contain,** or are **produced from** GMOs must have an authorisation prior to entering the market

- **Prospective/pre-market risk assessment**

- EFSA is responsible to perform risk assessment of GMOs
- **Protect** human health, animal health & the environment

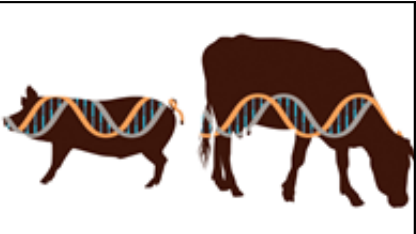
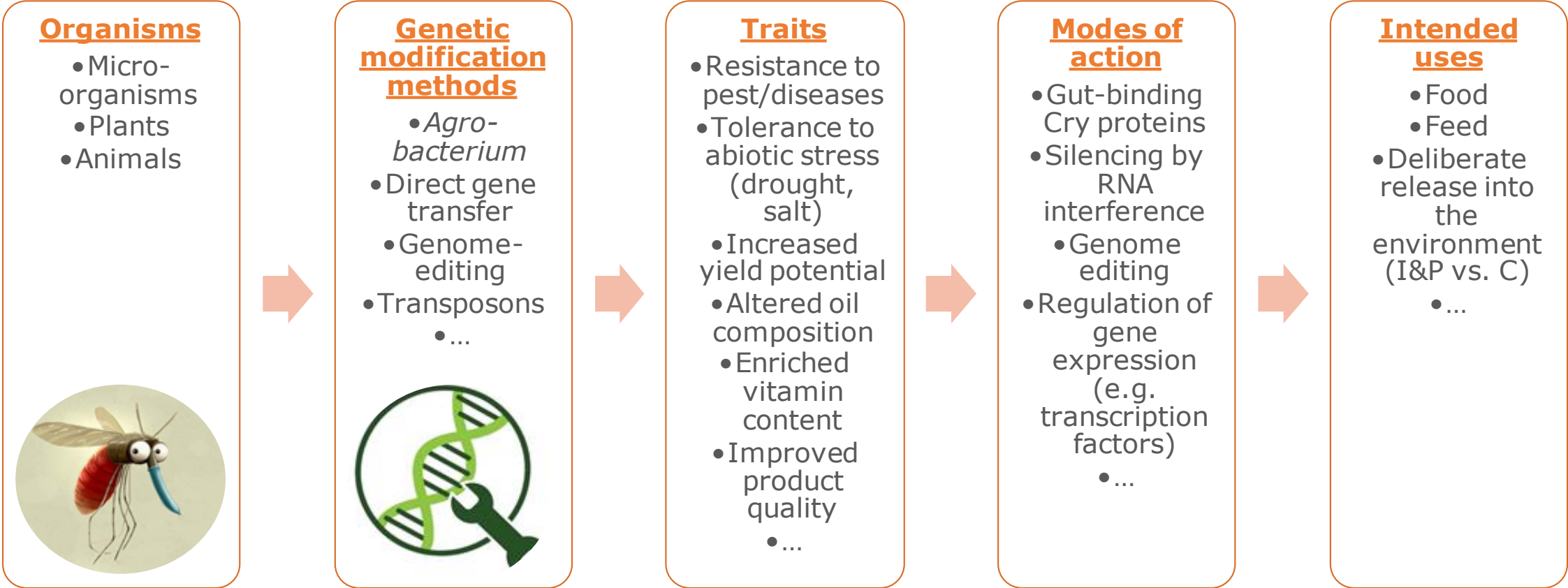


# 2| EU legal framework

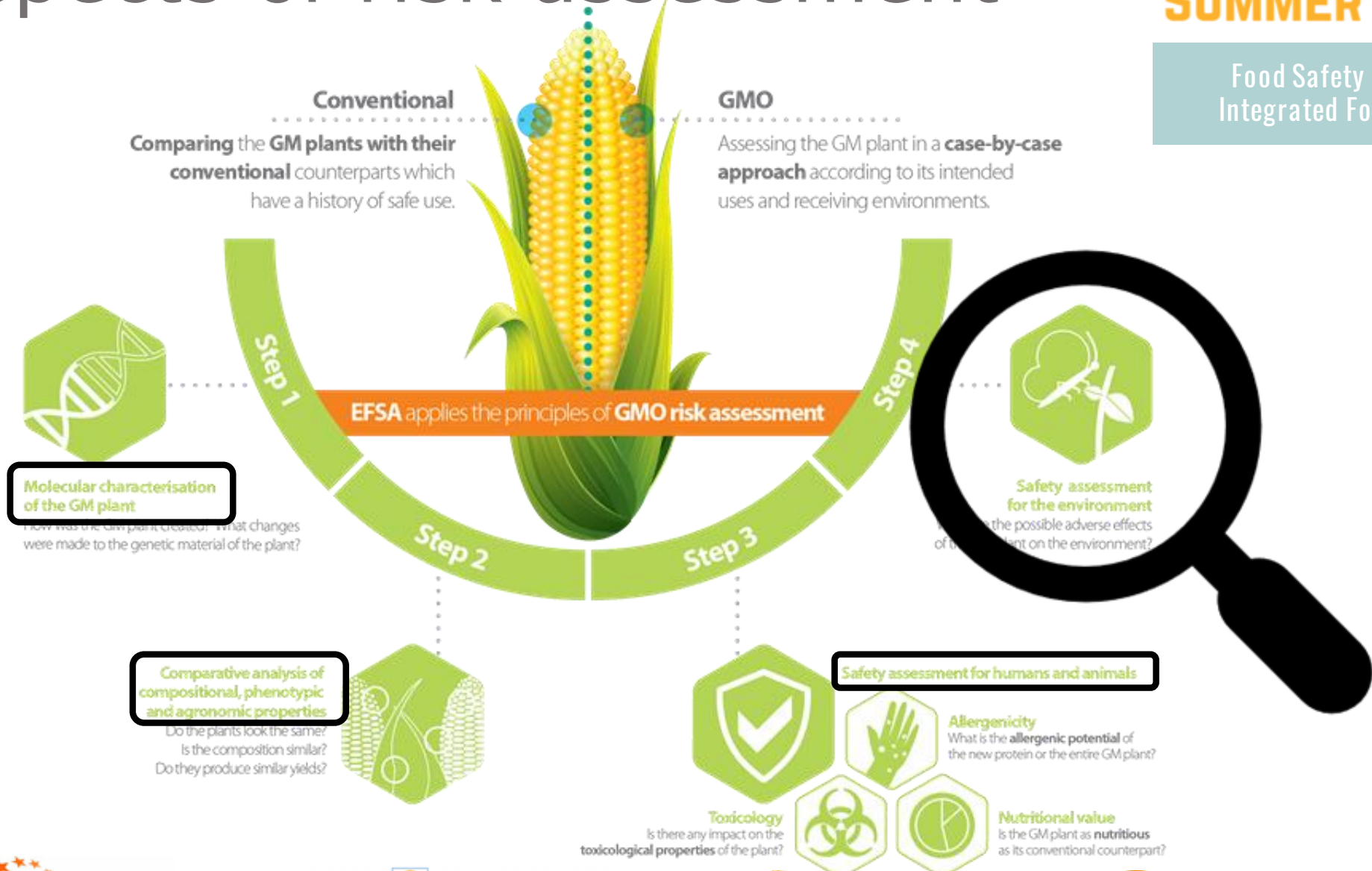
- **High-level overview**

- Contained use
- **Deliberate release into the environment**
- **Food and feed uses**
- Traceability & labelling
- Sampling & detection
- Unique identifiers
- Coexistence
- Transboundary movements
- ...

# 2 | Types of GMOs



# 2 | Aspects of risk assessment



Source:  
<https://www.efsa.europa.eu/en/discover/infographics/risk-assessment-genetically-modified-plants>



# 2| Persistence & invasiveness

- **Risk concerns**

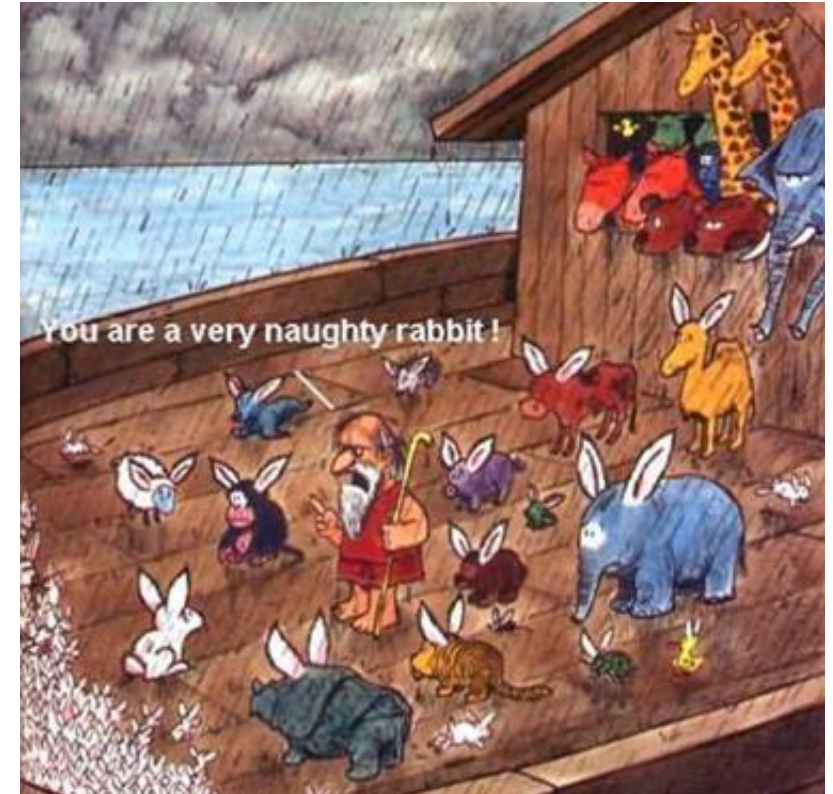
- Will the transgene(s) alter the persistence (weediness) & invasiveness ability of the GMO, compared to its conventional counterpart (fitness costs vs. benefit)?
- If so, under which conditions?



# 2| Vertical gene flow

- **Risk concerns**

- Is vertical gene flow likely?
- If so, will the transgene(s) of the GMO alter the persistence & invasiveness ability of sexually cross-compatible organisms (fitness cost vs. benefit)?

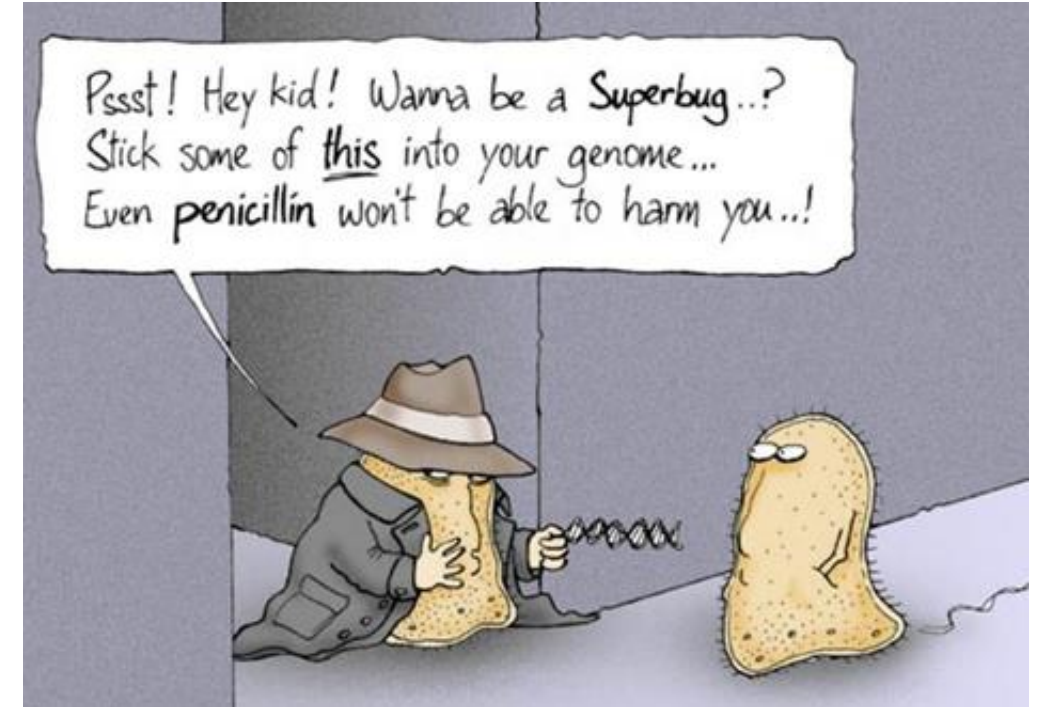




# 2| Horizontal gene flow

- **Risk concerns**

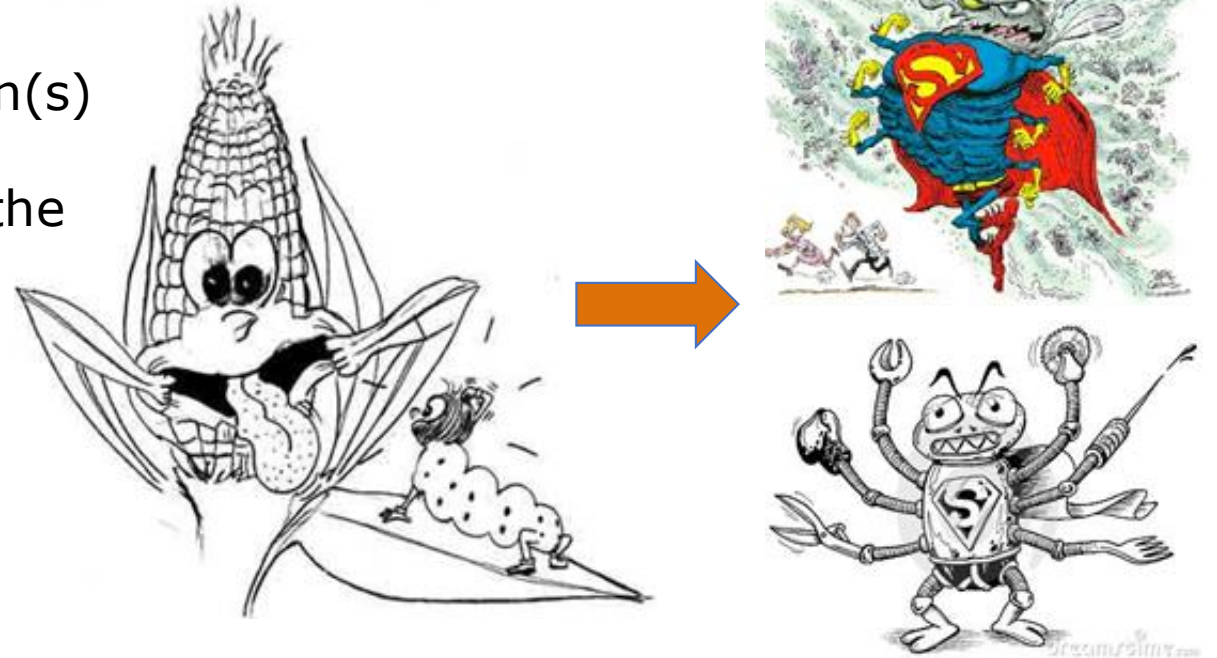
- Is horizontal gene flow likely?
- If so, will the transgene(s) of the GMO give a selective advantage to recipients?



# 2| Target organisms

- **Risk concerns**

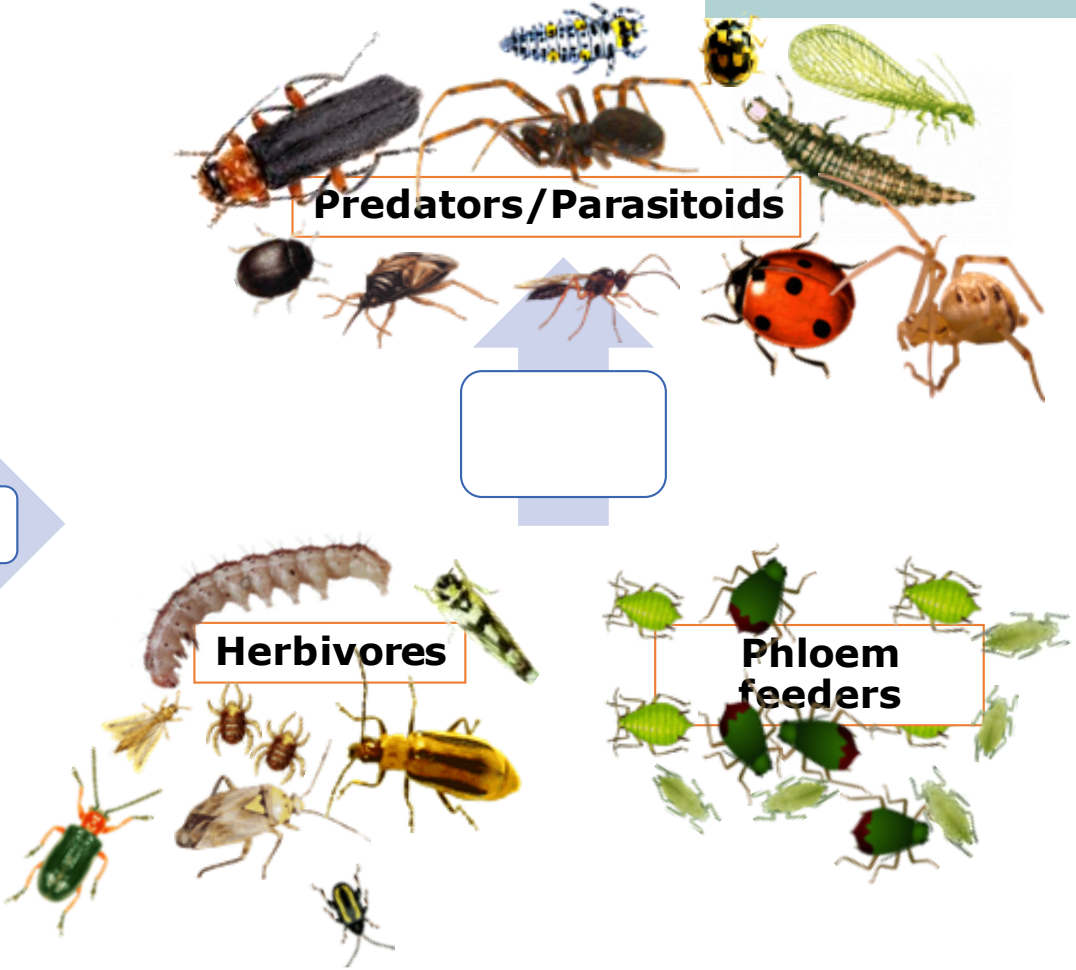
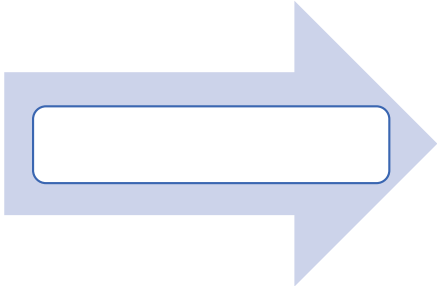
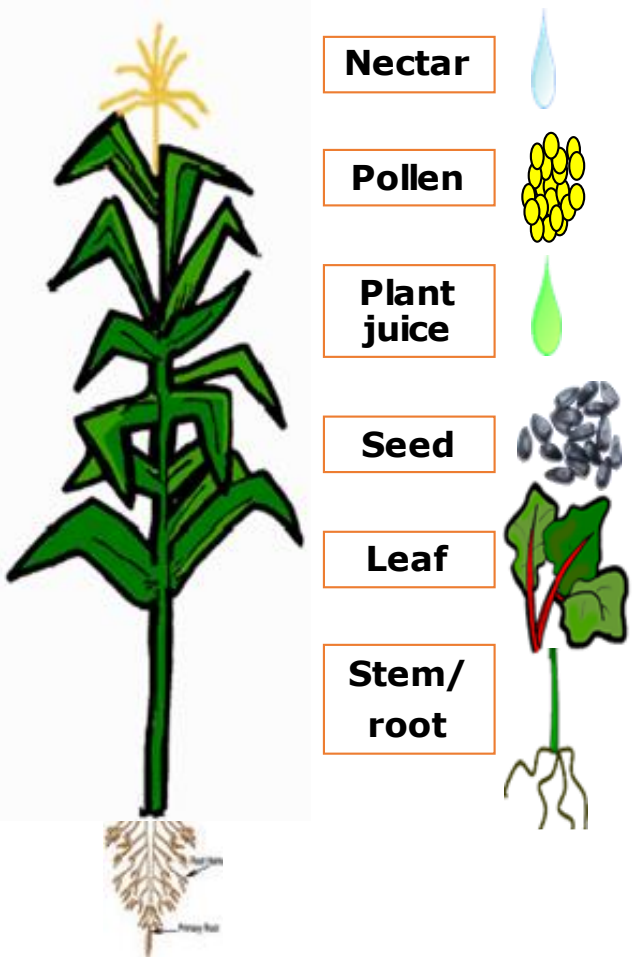
- Will the target organism(s) evolve resistance to newly expressed protein(s) or other novel components (small interfering RNAs, genome editor) of the GMO?





# 2 | Non-target organisms

- Possible routes of exposure**





# 2| Human & animal health

- **Risk concerns**

- Will the accidental intake of or exposure to the GMO, or parts of it, lead to adverse effects on humans & animals?



# 2 | Soil

- **Risk concerns**

- Does the newly expressed protein(s), other novel components of the GMO, & the GMO itself adversely affect biogeochemical processes & the abiotic environment?

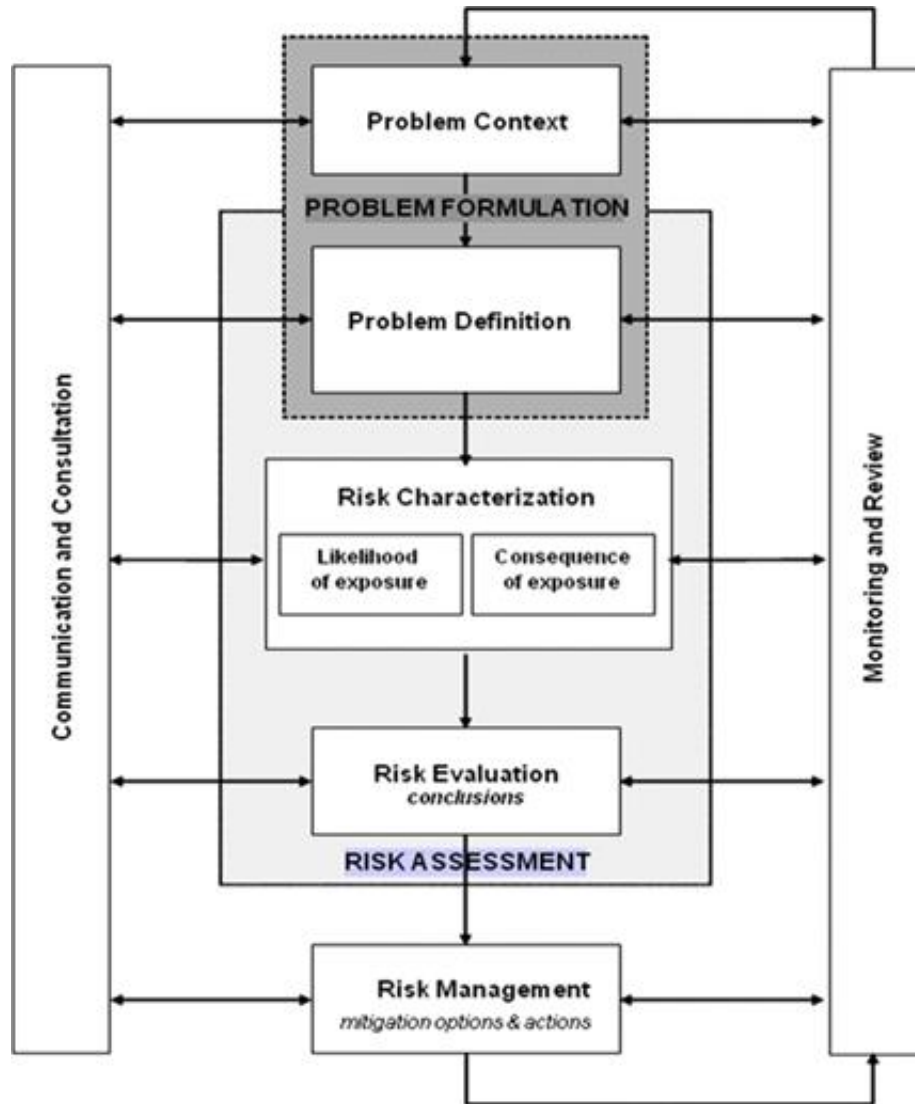


# 2 | Farm management practices

- **Risk concerns**

- Does the GM plant alter farm management practices
- Can altered farm management practices adversely impact the environment?
- Note
  - Pesticide usage is covered by pesticide legislation (out of scope of GMO legislation)

## 2 | Problem formulation



- **Role & purpose**

- First key step of ERA
- Frames ERA
- Helps to focus ERA on those aspects that are relevant for regulatory decision-making

- **Risk context**

- Framed by policy

Figure: Wolt et al. (2010), Transgenic Research,  
<https://doi.org/10.1007/s11248-009-9321-9>



**1| Identify protection goals & make them operational**

**Protection goals (PGs):** Human health | Animal health | Environmental health | Soil health | Water quality

**Operational/specific PGs:** Ecological entity & attribute to protect | Maximum tolerable impact | Spatial & temporal scale of protection

Source: EFSA (2016), EFSA Journal, <https://doi.org/10.2903/j.efsa.2016.4499>

**2| Devise plausible pathways to harm**

**3| Formulate risk hypotheses**

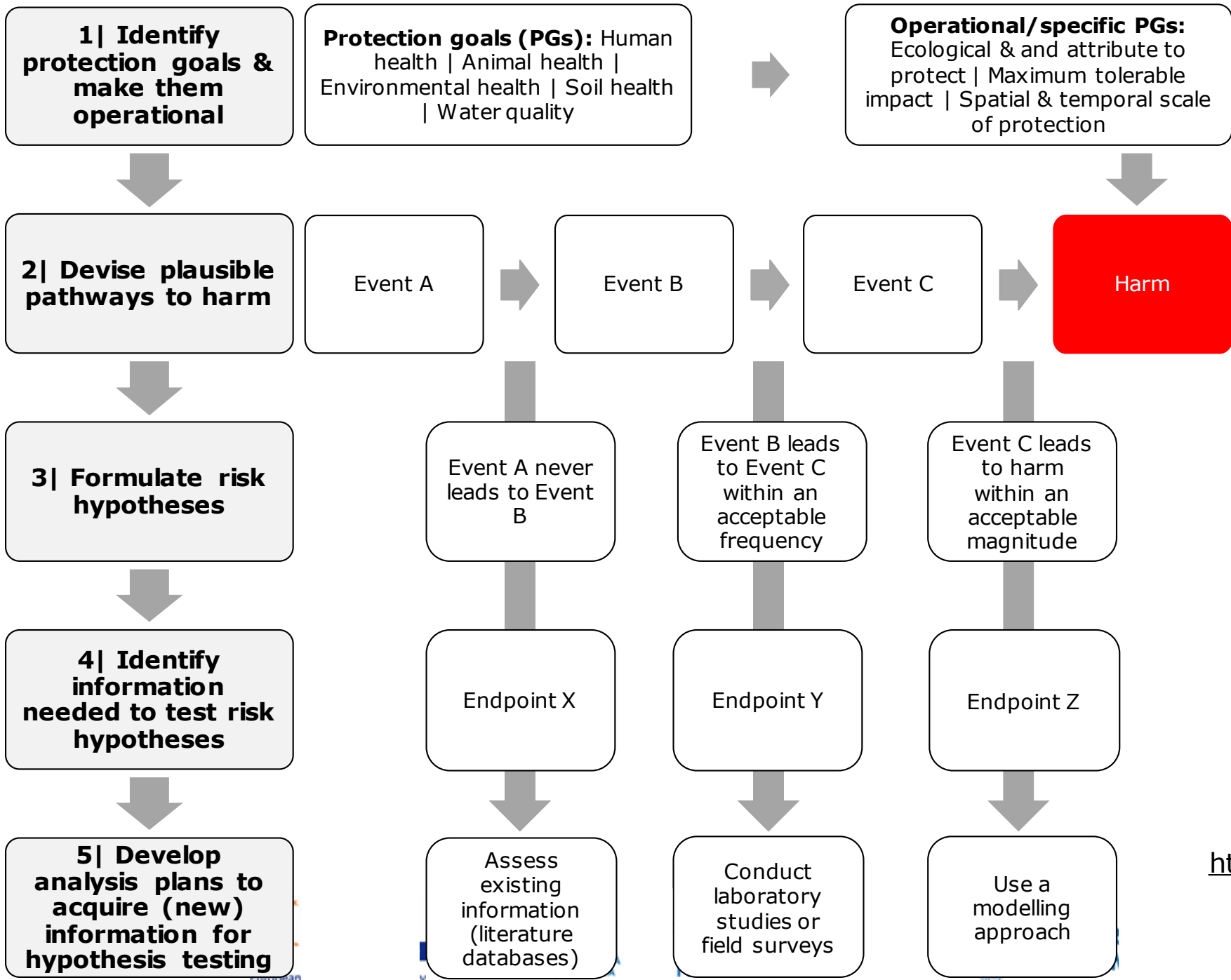
**4| Identify information needed to test risk hypotheses**

**5| Develop analysis plans to acquire (new) information for hypothesis testing**

**Step 1:** To identify relevant **Ecosystem Services (ESs)** using the Millennium Assessment Ecosystem categories

**Step 2:** To identify **Service-Providing Units (SPUs)** for ESs

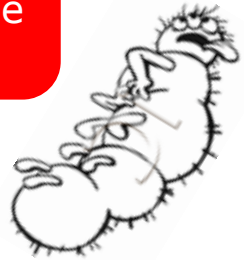
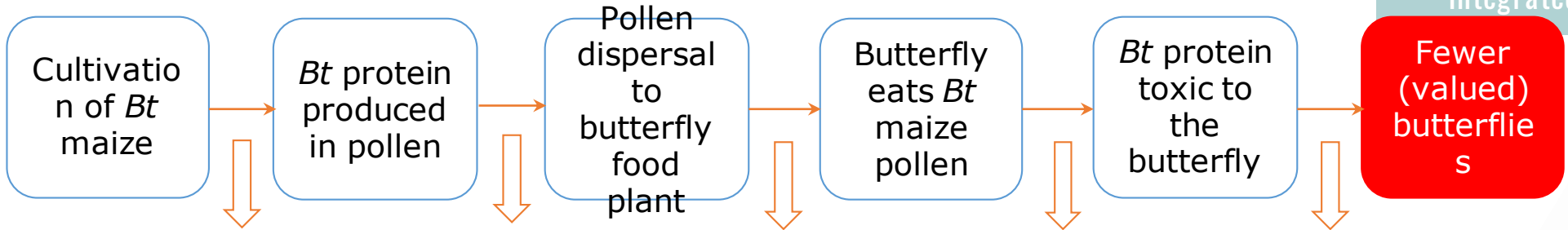
**Step 3:** To specify the **degree/parameters of protection** of SPUs using specific dimensions



Test risk hypotheses with existing information before acquiring new information

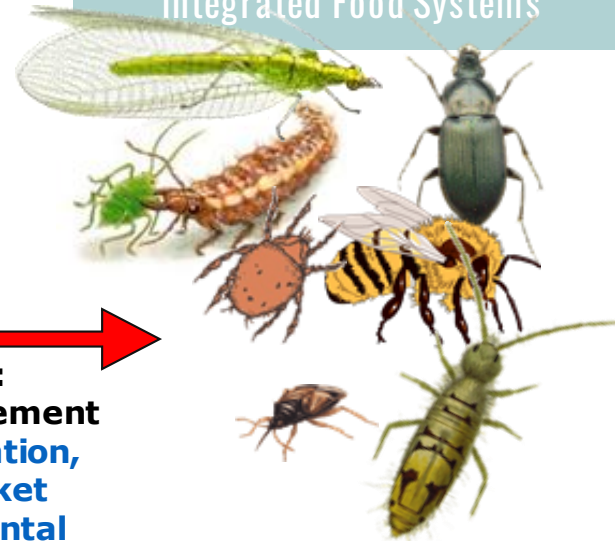
Figure: Devos et al. (2021), *Biotechnology Advances*, <https://doi.org/10.1016/j.biotechadv.2021.107807>

# 2 | Pathway to harm

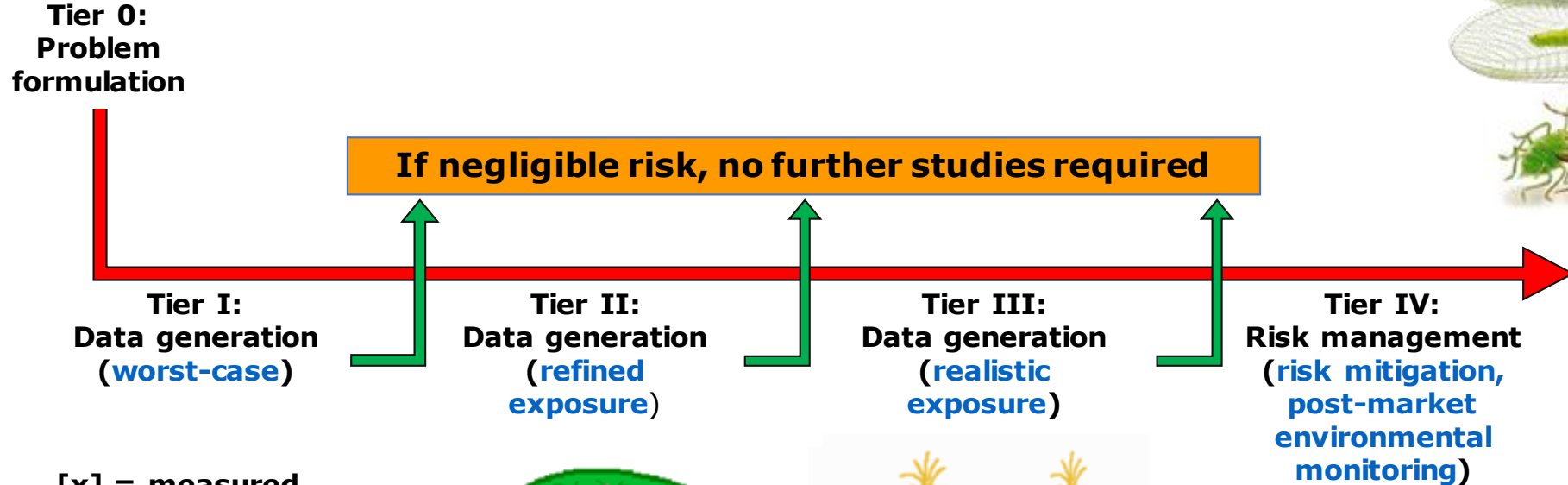


<p><b>H<sub>1</sub></b> <u>No Bt protein in pollen</u></p> <p><b>Testing:</b> Pollen expression study</p>	<p><b>H<sub>2</sub></b> <u>No pollen on food plant</u></p> <p><b>Testing:</b> Food plant distribution Pollen dispersal</p>	<p><b>H<sub>3</sub></b> <u>Pollen not eaten</u></p> <p><b>Testing:</b> Pollen palatability Avoidance behaviour</p>	<p><b>H<sub>4</sub></b> <u>Pollen not toxic to individuals</u></p> <p><b>Testing:</b> Eco-toxicological studies with protein or pollen</p>	<p><b>H<sub>5</sub></b> <u>Toxicity no effect on population size</u></p> <p><b>Testing:</b> Population modelling Diet analysis</p>
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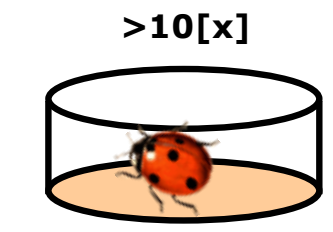
Figure: Adapted from Alan Raybould



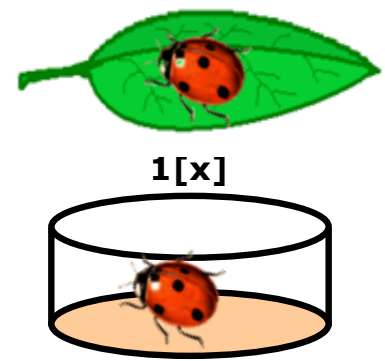
# 2 | Tiered approach



[x] = measured concentration in plant



Laboratory



Laboratory



(Semi-)field



# 2| Risk/uncertainty management

- **Risk mitigation measures**
  - Reduce identified risks to an acceptable level
    - Example: Insect resistance management
- **Post-market environmental monitoring**
  - Case-specific monitoring
    - Resolve remaining scientific uncertainties
    - Check assumptions made in the ERA
  - General surveillance
    - Identify unforeseen/unanticipated adverse effects

# 2 | ERA vs. ecological research

- **Purpose**

- Reduce “science” vs. “policy” uncertainty
  - ERA = policy-led activity to support regulatory decisions (tool for decision-making)
  - ERA ≠ necessarily intended to maximise production of (curiosity-driven) knowledge

- **Sources of problems addressed**

- Risk hypothesis tested
  - “No difference” vs. “unacceptable risk”

- **Methods for testing hypotheses**

- Targeted vs. untargeted (profiling)
  - Indicators of unacceptable risk

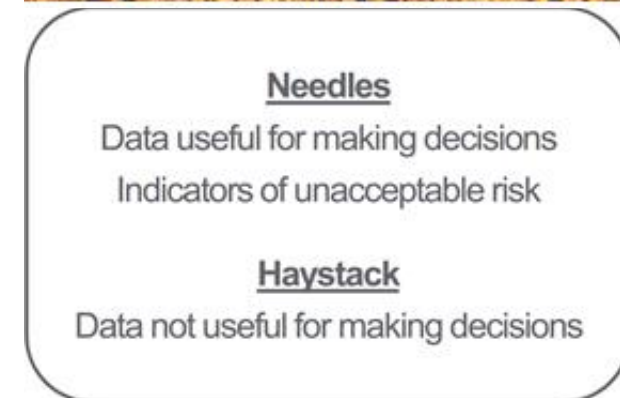


Figure: Alan Raybould

# 3 | Current challenges & future directions

# 2 | ERA paradigm shift needed?

Drivers of change

ERA has fallen out of step of growing body of scientific evidence



Alarming & unprecedented rate of biodiversity loss



Environmental issues



ONE health targets



Societal demands



New policy targets



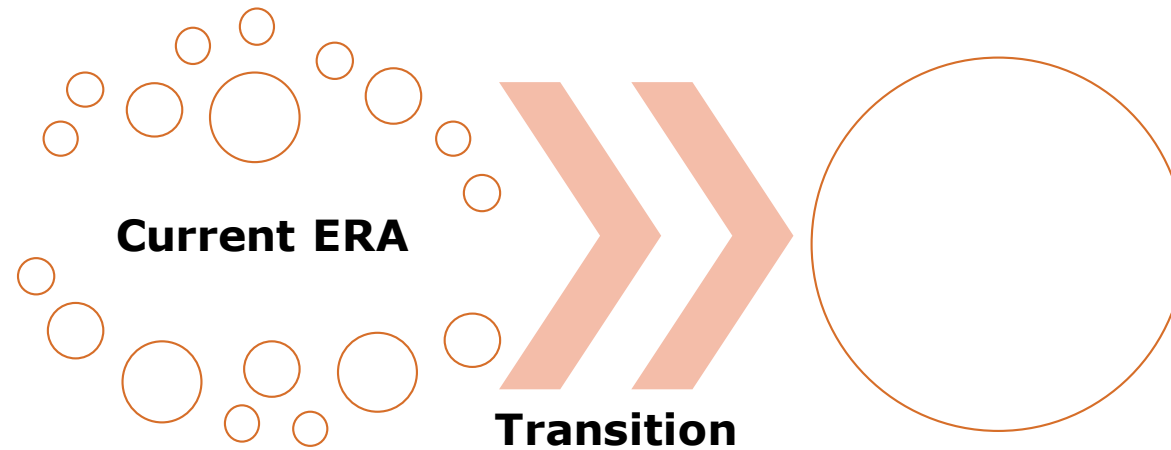
Framing/shaping of **future strategic goals for ERA**  
(EFSA 2027 Strategy)



Preliminary considerations on "**Future of ERA**"



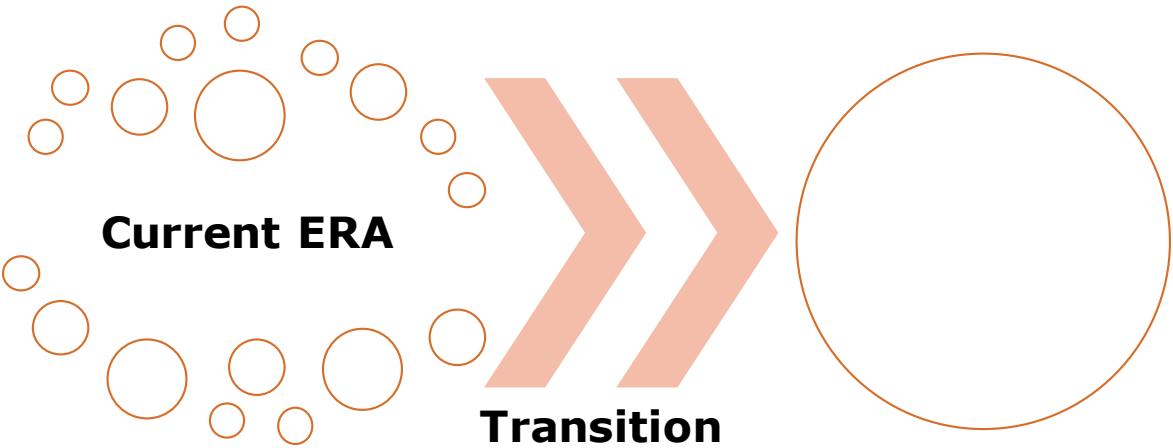
# 3 | New generation ERA



## EU Partnership for next generation, systems-based ERA (PERA)

1. Consider **environmental context** more **realistically** (landscape-scale population-level ERA)
2. Account for multiple regulated products/environmental stressors
3. Improve **feedback loops** through monitoring, vigilance & surveillance (connect prospective & retrospective ERA)
4. Compare impacts with those of **alternative solutions**
5. Foster **cooperation** & data/expertise **sharing**
6. Bridge regulatory silos

# 3 | New generation ERA



## EU Partnership for next generation, systems-based ERA (PERA)

**Step 1**

**Theme paper**

Develop theme paper that outlines vision & goals. Process subject to consultations

☑

**Step 2**

**Roadmap for action**

Develop roadmap for action. Call @EFSA\_EU (OC/EFSA/ED/2020/1) in 3 lots (500 kEuro each):

- 1. **PERA**; 2. NAMs; 3. RACEMiC

**University of Coimbra (PT)**

**Step 3**

**Implementation**

Implement roadmap for action. Outsource tasks through grants & procurements (from 2022 onwards). Promote uptake of new approaches & methods in regulatory ERA

## 3 | EFSA's 2020-2021 themes



# 3 | EFSA's PERA contributors

- **Pesticide Peer Review (PREV) Unit**
  - Domenica Auteri
- **Scientific Evaluation of Regulated Products (REPRO) Department**
  - Guilhem De Seze
- **Scientific Committee and Emerging Risk (SCER) Unit**
  - Yann Devos & Agnès Rortais
- **Science Studies and Project Identification and Development Office (SPIDO)**
  - Julia Fabrega, Claudia Heppner & Kiara Aiello Holden

# 3 | ONE Health conference

**PARMA**  
**SUMMER SCHOOL**

Food Safety Aspects of  
Integrated Food Systems

## ONE PLANET



### TOWARDS A SYSTEMS-BASED APPROACH FOR THE ENVIRONMENTAL RISK ASSESSMENT OF PESTICIDES

The use of regulated products – such as biocides, industrial chemicals, pesticides, pharmaceuticals, feed additives and genetically modified organisms – is subject to an environmental risk assessment (ERA) and regulatory approval in most jurisdictions worldwide. While substantial progress has been made in achieving environmental protection with single product-based assessments, such assessments are perceived to have fallen out of step with scientific knowledge. Moreover, they are not necessarily aligned with modern policy targets and societal demands that call for a cleaner, greener future and a more sustainable food/feed system. Further advancing the ERA of regulated products will be key in supporting the UN SDGs and EU Green Deal ambitions to safeguard the environment (including biodiversity and ecosystems). We will explore: (1) the scientific merits and issues with the current ERA paradigm; (2) the incremental change needed to advance ERA of pesticides; (3) opportunities and challenges associated with the transition to/implementation of a more holistic ERA framework for pesticides that follows an inclusive and integrated systems-based approach; and (4) policy implications. The session will provide feedback to EFSA, other EU agencies, EU Member States and international partners on current challenges and future development opportunities for the transition towards a systems-based approach for the ERA of pesticides.

SUBMISSION OF ABSTRACT  
EXTENDED DEADLINE - 30.09.2021



HEALTH • ENVIRONMENT • SOCIETY

21-24 JUNE 2022, BRUSSELS AND ONLINE



# 3 | Pave the way

## EFSA JOURNAL

Open Access

Editorial |  Open Access |   

### EFSA is working to protect bees and shape the future of environmental risk assessment

Simon J More , Domenica Auteri, Agnès Rortais, Steve Pagani

First published: 05 January 2021 | <https://doi.org/10.2903/j.efsa.2021.e190101>

# Thank YOU for your attention!

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Pictures: Le Jardin de Delphine (Parma)