EESE

EU ENVIRONMENTAL SCENARIOS FOR ERA OF NON-TARGET ORGANISMS

OC/EFSA/PREV/2023/02

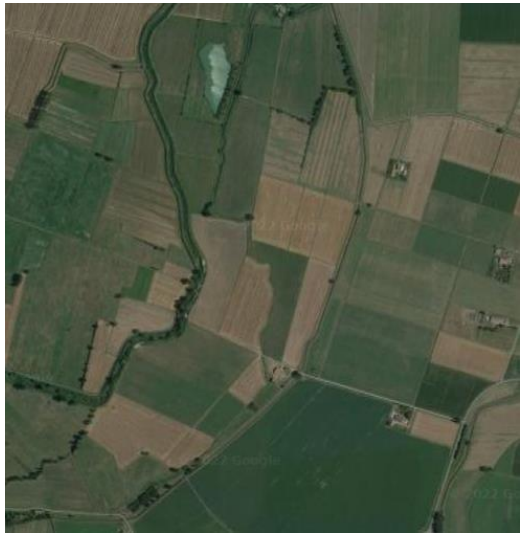
PSN meeting, 29-30 October 2024

EUROPEAN FOOD SAFETY AUTHORITY

BACKGROUND

- ERA performed within the PPP authorisation process should be able to predict risks over large geographical areas (e.g., over an entire country, regulatory zone, or even over the entire EU).
- The nature and the magnitude of environmental risks are very much influenced by several biotic and abiotic factors, which are variable in space and time.

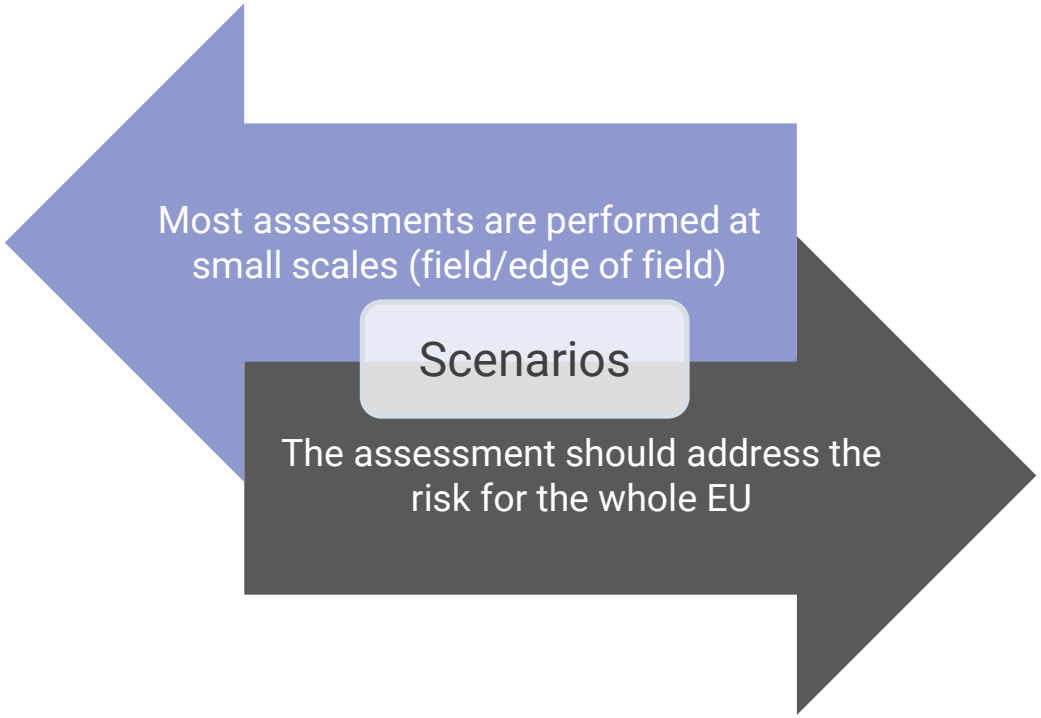
This … is not the same as … This



- Accounting for context-dependent factors is pivotal in developing future methods for ERA.

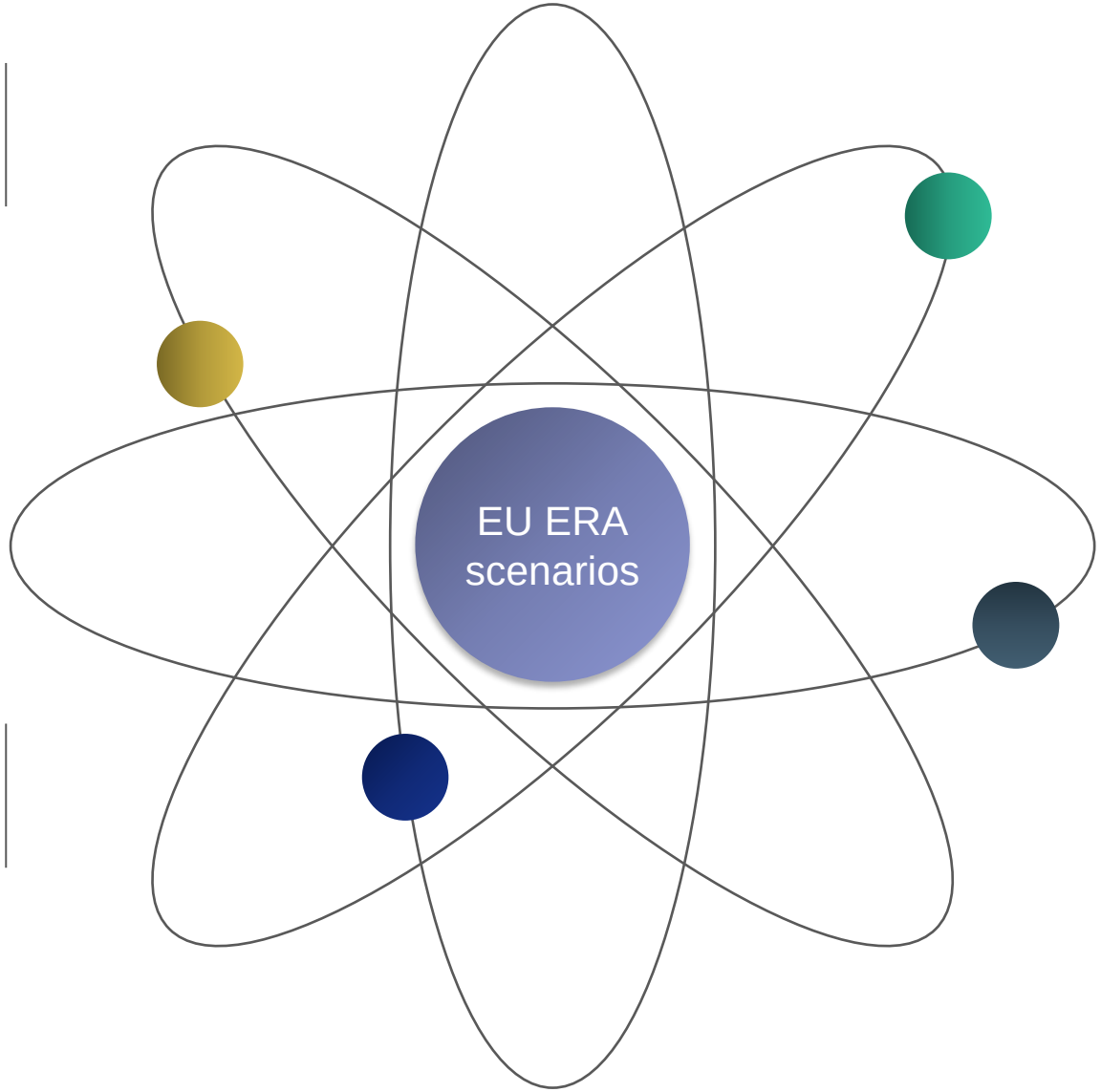
BACKGROUND

- Performing ad-hoc assessments for each specific context in the entire EU does not appear as a convenient solution
- Scenarios help considering the most relevant combinations of drivers without getting into impractical site-specific assessments
- Maximise relevance and realism of PPP risk assessment in the context of EU agriculture
- Focus of the project:
  - Terrestrial environments. Data for aquatic environments will be collected, but aquatic scenarios will not be developed for the time being
  - Cropped areas + field margins + other semi-natural areas in terrestrial agro-ecosystems



OVERARCHING GOALS

Provide context for running simulations with fate/effect/ecological models



Align conditions for the exposure assessment and the risk characterization (spatial, temporal, and ecological aspects)

Representativeness of higher tier studies and extrapolation of findings

Define baseline conditions for specific assessments and for SPG derivation

OBJECTIVES

Objective 1 - Collection of georeferenced data of field margin and other semi-natural landscape elements.

Objective 2 - Characterisation of habitat in agro-ecosystems and vulnerability of biological assemblages in fields and in semi-natural landscape elements

Objective 3 – Definition of environmental scenarios

Objective 4 – State of the art regarding food web/ ecological interaction models and their use in ERA of PPPs.

PROCESS AND STATUS

Climate data

Macroscopic land use

Agronomic stats

Aerial photog.

Satellite images

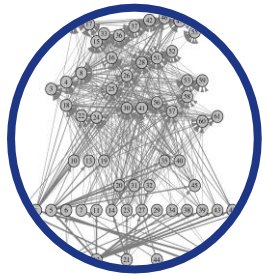
Existing surveys

Regional geodatabases

Field surveys (validation)

Bio-Ecology (Objective 2)

Food web and other ecological interactions (Objective 4)



Tier-1 clusters of similar landscapes → Identify representative locations → High-resolution maps → Tier-2 clusters → Tier-2 clusters communities → Tier-3 clusters → Environmental scenarios ← Food web / ecol. interaction models

Done

Literature review

Citizen science projects

Floral survey (in time)

Faunal survey (in time)

Protocols ongoing

Vulnerability analysis

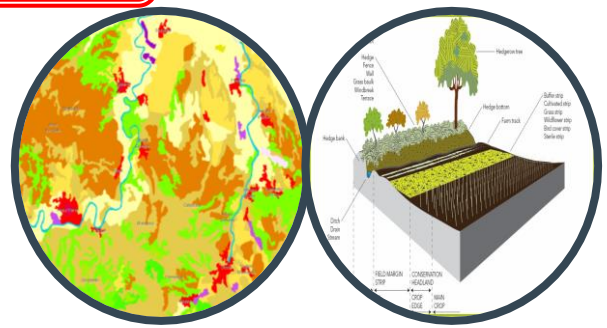
Literature review

Lab testing

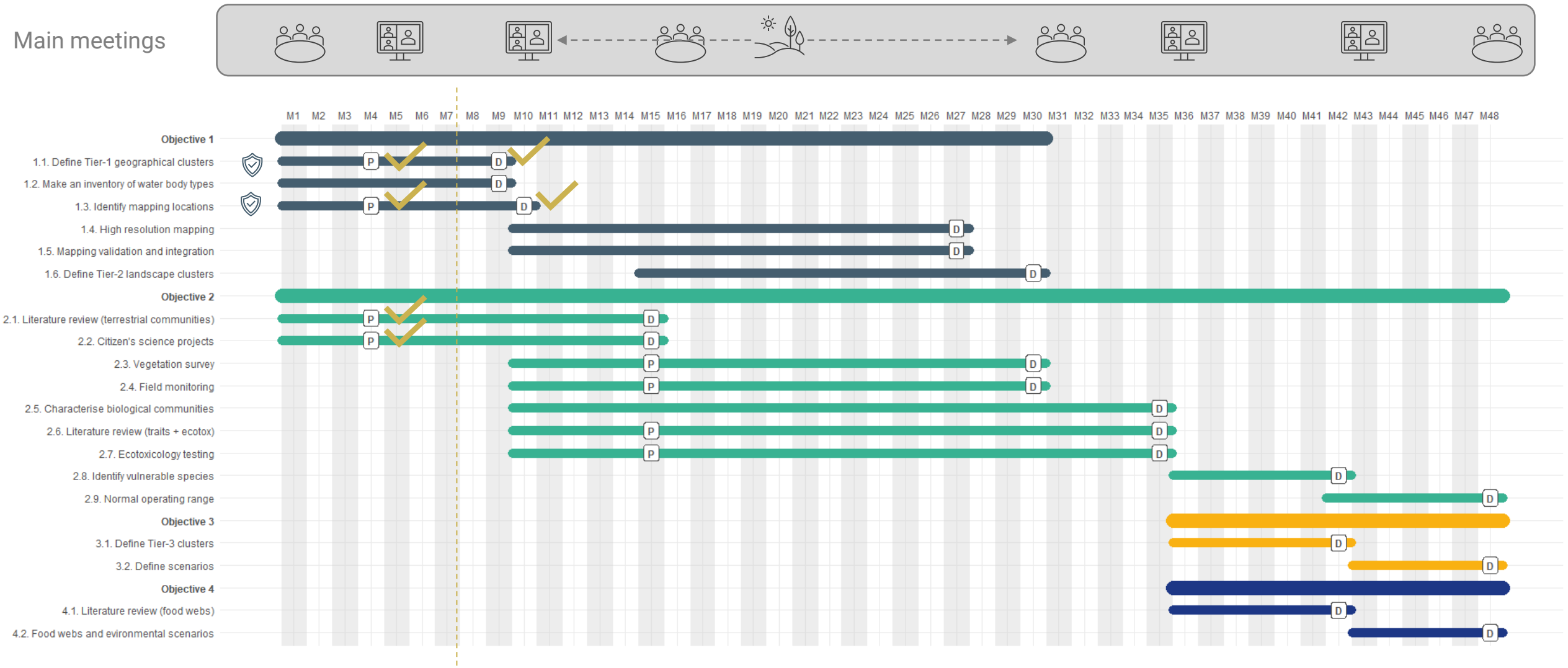
Final scenarios (Objective 3)

Literature review

Landscape structure (Objective 1)



ENVISAGED TIMELINE

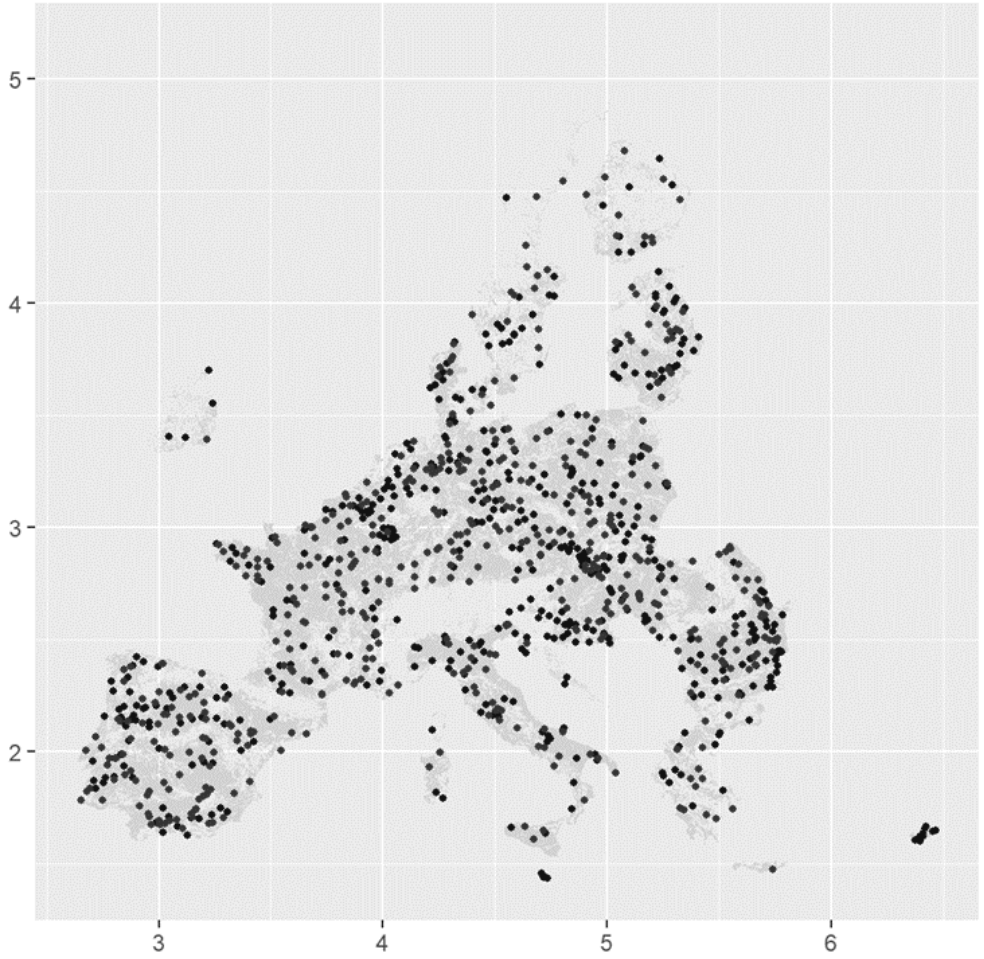


TIER-1 STRATIFICATION OF EUROPE

- The main spatial unit is represented by quadrants of 2x2 km centred in LUCAS points (LUCAS master grid)– the entire EU is covered
- Stratification based on :
  - Land cover classes (from CORINE)
  - Environmental zones classes (from Metzger et al. 2005)
  - Parent material classes (from European Soil Database)
- 240 EESE theoretical strata, 231 ‘real’ strata, further simplification led to 135 strata with sufficient abundance (> 100 2x2 km quadrants)
- 60 strata covers about 94% of agricultural land (sampling will focus on those)

SAMPLING

- 1000 quadrants will be mapped with high resolution
- 60 quadrants will be investigated in the field for collecting primary data on:
  - Habitat types
  - Biological communities
  - Vegetation structure



PERA

ADVANCING THE ERA OF PLANT PROTECTION PRODUCTS TOWARDS A SYSTEM-BASED APPROACH

UBA-EFSA-2023-PLANTS-01

PSN meeting, 29-30 October 2024

EUROPEAN FOOD SAFETY AUTHORITY

PERA FPA - ADVANCING THE ERA OF PLANT PROTECTION PRODUCTS TOWARDS A SYSTEM-BASED APPROACH

FRAMEWORK PARTNERSHIP AGREEMENT - ARTICLE 36 GRANT

AREA 1

Advance the characterisation of **exposure** of **non-target organisms**

AREA 2

Advance on the characterisation of the **hazard** of **non-target organisms**

AREA 3

Investigate the use of **mechanistic effect models**, including population models in ERA

AREA 4

Exploring the **integration** and **interconnection of data** from different sources, methods, tools, and objectives

2024 — **2028**

Work starts in 2024 and will continue until Q4 2027/Q1 2028

1. Characterisation of deposition for relevant environmental matrices
2. Exposure characterisation in-soil organisms
3. Exposure characterisation via plants
4. Refined exposure factors

1. Development of protocols for literature search - hazard characterisation of terrestrial NTOs
2. Gathering/collate data - hazard of active substances for non-target organisms
3. Literature search - exploring the application of NAMs
4. Recommendations - design of new test protocols for terrestrial ecotoxicology

Work is planned to start in Q2 2025 and will continue until Q1 2028

1. Develop a protocol defining criteria for the regulatory evaluation of models
2. Development of a protocol for the systematic retrieval of existing effect models
3. Set up a repository for selected models & evaluate them
4. Training courses on effect models for regulatory ERA of pesticides

1. Exploring & assess stakeholder needs and perceived benefits of an integrated knowledge platform
2. Develop the risk assessment platform

PERA

DEVELOP A STEPWISE APPROACH FOR A FIT FOR PURPOSE RISK ASSESSMENT FOR LOW-CONCERN ACTIVE SUBSTANCES AND USES

GP/EFSA/PLANTS/2023/04

PSN meeting, 29-30 October 2024

EUROPEAN FOOD SAFETY AUTHORITY

PERA A.S. OF LOW CONCERN

MAIN GOAL

- Support the identification of situations where some or all data are not required due to the ‘nature’ of the active substance and its proposed uses or because ‘not scientifically necessary’ (according to point 1.5 in the Annex of Regulations 283/2013 and 284/2013).

- Develop a stepwise approach for a fit for purpose risk assessment for low-concern active substances and uses

FRAMEWORK PARTNERSHIP AGREEMENT ARTICLE 36 GRANT

- Aristotle University of Thessaloniki – Greece (coordinator)
- University of Thessaly - Greece
- Wageningen University and Research - Netherlands
- Agencia Estatal Consejo Superior de Investigaciones Científicias M.P./ CSIC-INIA - Spain
- Dutch Board for the Authorisation of Plant Protection Products and Biocides / Ctgb - Netherlands
- Hellenic Agricultural Organization Demeter - Greece

PERA A.S. OF LOW CONCERN

SCOPE: a.s. Part A of the Data Requirements (Regulation 283/2013)

- Botanicals
- Microorganisms' product
- Inorganics
- Semiochemicals
- Biological materials (animal oils, RNA, peptides…)

TASKS

1. Develop harmonized and science-based criteria for justifying the non-submission of guideline studies
2. Investigate the potential use of alternative methods & develop fit-for-purpose approaches for the exposure and hazard assessment
3. Suggest a step-wise approach, starting from problem formulation, to frame fit-for-purpose risk assessment
4. Develop case-studies
5. Suggest methodology how to perform a proper and fit-for-purpose literature search
6. Identify knowledge gaps to allow for further investigation in the future

TIMELINE

- 18th months project
- Started on the 26/01/2024; end 25/07/2025
- In October, a draft approach was submitted
- A workshop will be organised in January 2025 to get input/feedback from the MS & stakeholders

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