

GP/EFSA/PLANTS/2023/04:

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

WORKSHOP ON THE DEVELOPMENT OF A FIT-FOR-PURPOSE APPROACH FOR ASSESSING THE RISK OF LOW-CONCERN ACTIVE SUBSTANCES



INTRODUCTION TO THE PROJECT AND THE WORKSHOP

Domenica Auteri (EFSA) & Zisis Vryzas (AUTH)



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OF THESSALONIKI

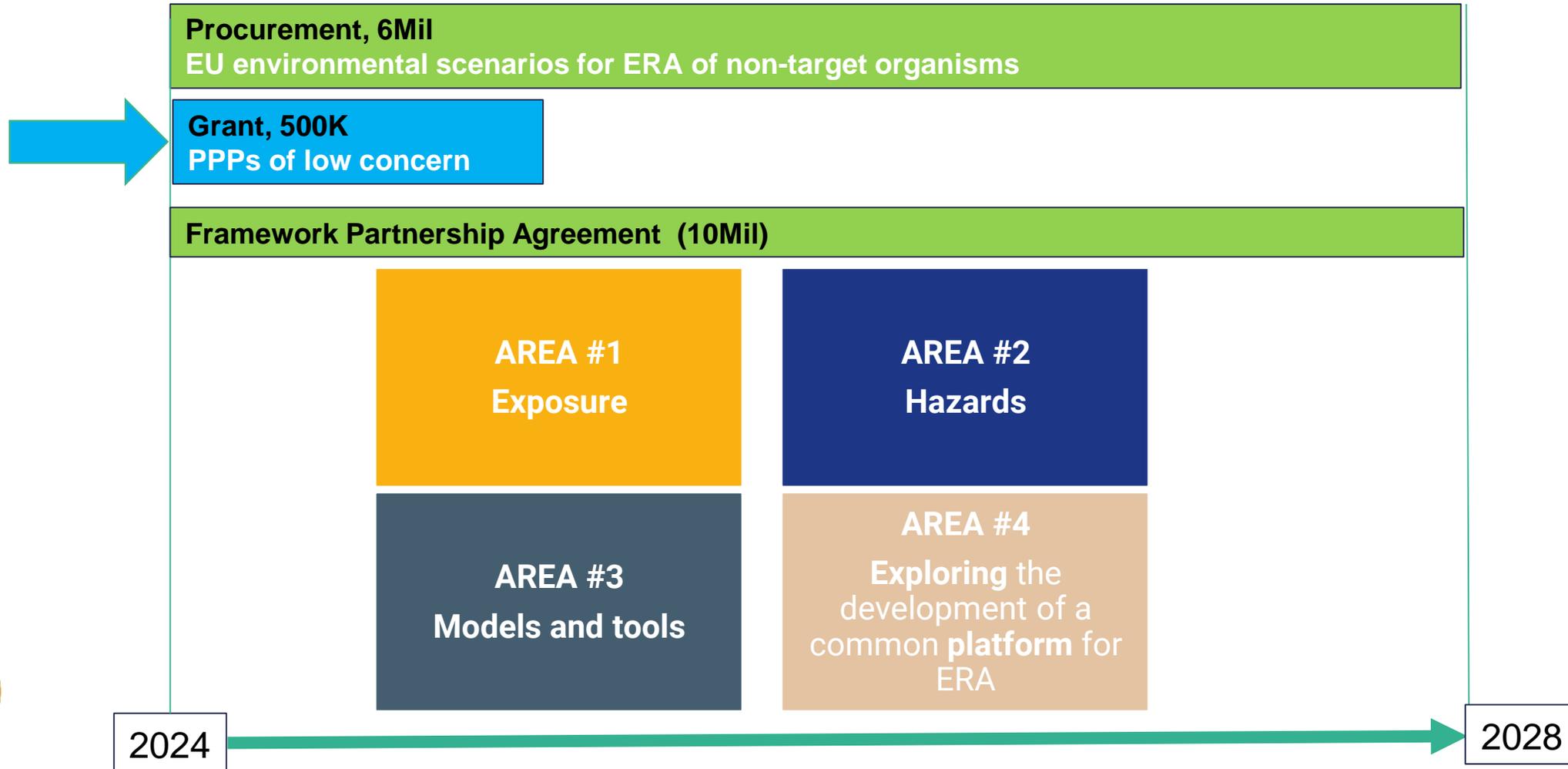


OUTLINE

- PERA project and scope of the Call (Domenica Auteri)
- Presentation of the consortium and progress so far (Zisis Vryzas)
- Scope and agenda of the Workshop (Zisis Vryzas)

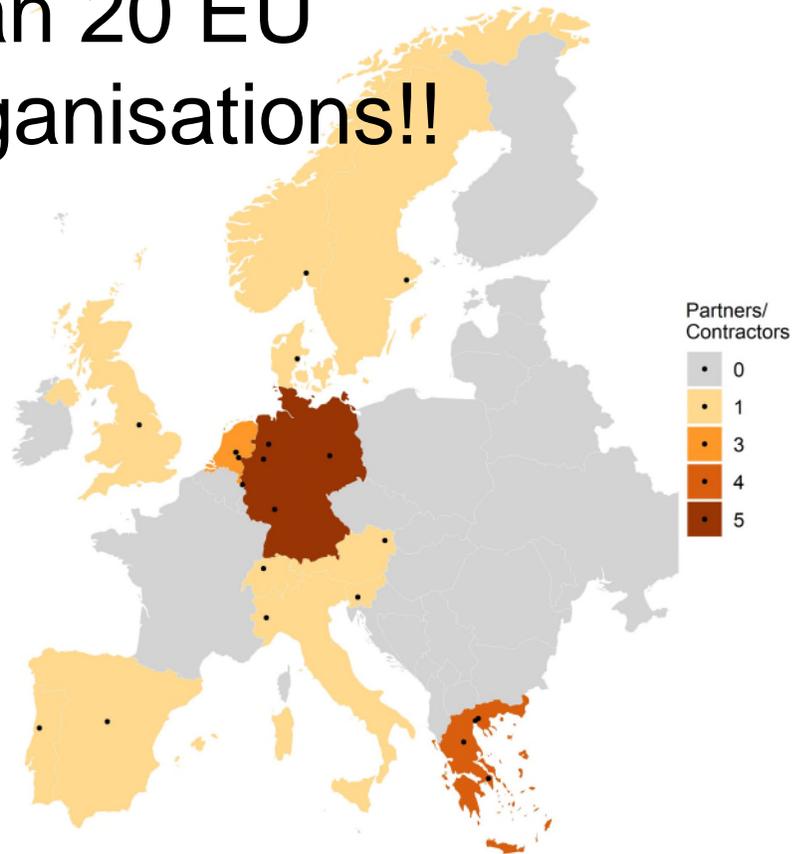


MULTIANNUAL PLAN (PERA PROJECT) - OVERVIEW



PARTNERSHIP

86 experts for more than 20 EU organisations!!



Procurement EU scenarios

- Stichting Wageningen Research (NL) (**coordinator**)
- Wageningen University (NL)
- University of Coimbra (PT)
- EFTAS GmbH (DE)
- Agroscope (SW)

Sub-contractors: University of Sheffield (UK), Institute for Agro-ecology and Biodiversity (DE), University of Natural Resources and Life Sciences (AT), Fraunhofer IME (DE), Aarhus University (DK), and the Norwegian Institute for Water Research (NO)

GRANT PPP low concern

- Aristotle University of Thessaloniki (EL) (**coordinator**)
- University of Thessaly (EL)
- Stichting Wageningen Research (NL)
- INIA (ES)
- CTGB (NL)
- Hellenic Agricultural Organization (EL)



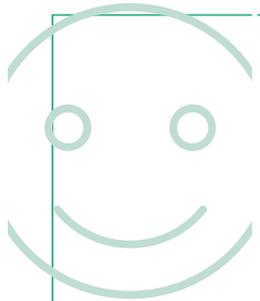
GRANT FPA

- Stichting Wageningen Research (NL) (**coordinator**)
- University of Coimbra (PT)
- Aarhus University (DK)
- KEMI (SE)
- Agricultural University of Athens (EL)
- University of Torino, (IT)
- UBA, (DE)
- National Institute of biology, (SO)

Subcontractors: Osnabruck University, (DE)



LOW CONCERN ACTIVE SUBSTANCES (LCASS): OBJECTIVES



Scope

- Lean, simplify & speed up ERA of PPPs with a ***low toxicological profile*** by focusing on aspects of potential risk only



Goals

- Develop science-based criteria for ***data waiver*** (problem formulation)
- Identify ***alternative methods*** for exposure & hazard assessment for PPPs



A CHALLENGING PROJECT

Necessity for a fit-for-purpose risk assessment scheme of LCASs

Necessity of the call and scope

- Develop a **harmonised** stepwise approach for a **fit-for-purpose** risk assessment of active substances that are falling under Part A of the Data Requirements (Regulation 283/2013) and that are **potentially of low concern**
- The aim is primarily to 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”**, **“it is technically not possible to supply”** (point 1.5 in the Annex of Regulations 283/2013)



Types and Sub-types of Low Concern Active Substances (LCASs)

Definition of the term “Low Concern Active Substances”:

- The term **Low Concern Active Substances** is used to describe potential **Low Risk pesticides**
- Low risk pesticides are pesticides that have already been approved and apply to the specific criteria for low-risk under the pesticide Regulation (EC) No 1107/2009, whereas the concept of the potentially LCASs is broader.
- The project focuses on LCASs

Types and sub-types of LCASs:

- The criteria and fit-for-purpose risk assessment methods to be developed should cover the following types of low-concern a.s: **botanical active substances, semiochemicals, inorganics, peptides, dsRNA, other biological materials (i.e. blood, animal oil, urea, sugars, lipids)...**
- Microorganisms are not included but substances from microorganisms or fermentation (**microbial metabolites**) are included



SUB-OBJECTIVES

Sub-objectives:

- S01: Criteria that would allow to **identify** and **group** low-concern active substances
- S02: Criteria of **non-submission** of guideline studies (Hazard, Exposure)
- S03: Potential use of alternative methods to testing for the **hazard** assessment
- S04: Fit-for-purpose approaches for the **exposure** assessment
- **S05: Fit-for-purpose risk assessment (stepwise approach starting from problem formulation)**
- S06: Literature search criteria (search terms and inclusion/exclusion criteria) EFSA Journal 2011;9(2):2092
- S07: Knowledge gaps identifications (to be covered in the final report)



TIMELINE

Timeline

- 18th months project
- Started on the 26/01/2024; end 25/07/2025



PRESENTATION OF THE CONSORTIUM

Partners



PRESENTATION OF THE CONSORTIUM

Consortium and Expertise

AUTH

Zisis Vryzas, Assoc. Prof. in Pesticide Science

Urania Menkissoglu-Spiroudi, Emeritus Prof. in Pesticide Chemistry

Dr. Emmanouil Nikolaos Papadakis, Research Scientist in Pesticide Science

Dr. Aggeliki Tampoula Research Scientist in Pesticide Science

Dr. Fragkoulis Georgios, e-fate modeler

Dr. Emmanouil Karazafeiris Research Scientist in Pesticide Science

UTH

Dimitrios Karpouzas, Prof. of Environmental Microbiology and Biotechnology

Kalliope K. Papadopoulou, Prof. in Plant Biotechnology

Dimitrios Kouretas, Prof. of Physiology-Toxicology

Dr. Sofia Tsaloumi, Research Scientist in Food Science

WR

Dr. Gertie H.P. Arts, Senior Scientist at Wageningen Environmental Research, Wageningen University

Mechteld Maria Susan ter Horst, Environmental fate researcher and project manager ERA

Dr. Bastian Polst, Research Scientist in Aquatic Ecology and Ecotoxicology

CSIC-INIA

Dr. José-Luis Alonso-Prados, Head of the Plant Protection Unit at INIA

Dr. Belén Guijarro, Regulatory Affairs Specialist on registration of biocontrol agents

Dr. Patino-Ropero María José, Research Scientist in Chemistry

Ctgb

Dr. Anne Steenbergh, Policy advisor in the area of sustainability of plant protection products

Jacobijn E. van Etten, project manager responsible for the process management of biopesticides dossiers

ELGO

Dr. Athanasios Dalakouras, Researcher in Plant Molecular Genetics

Dr. Dimitrios Vlachostergios, Researcher in Plant Breeding



PROGRESS SO FAR !

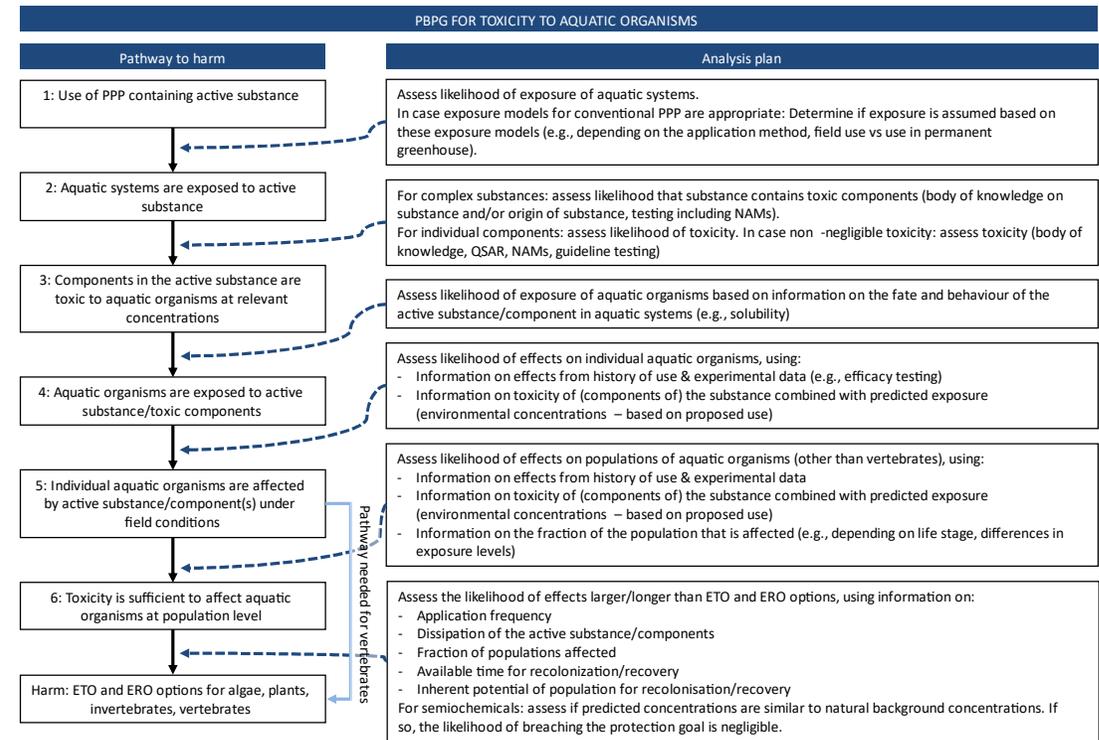
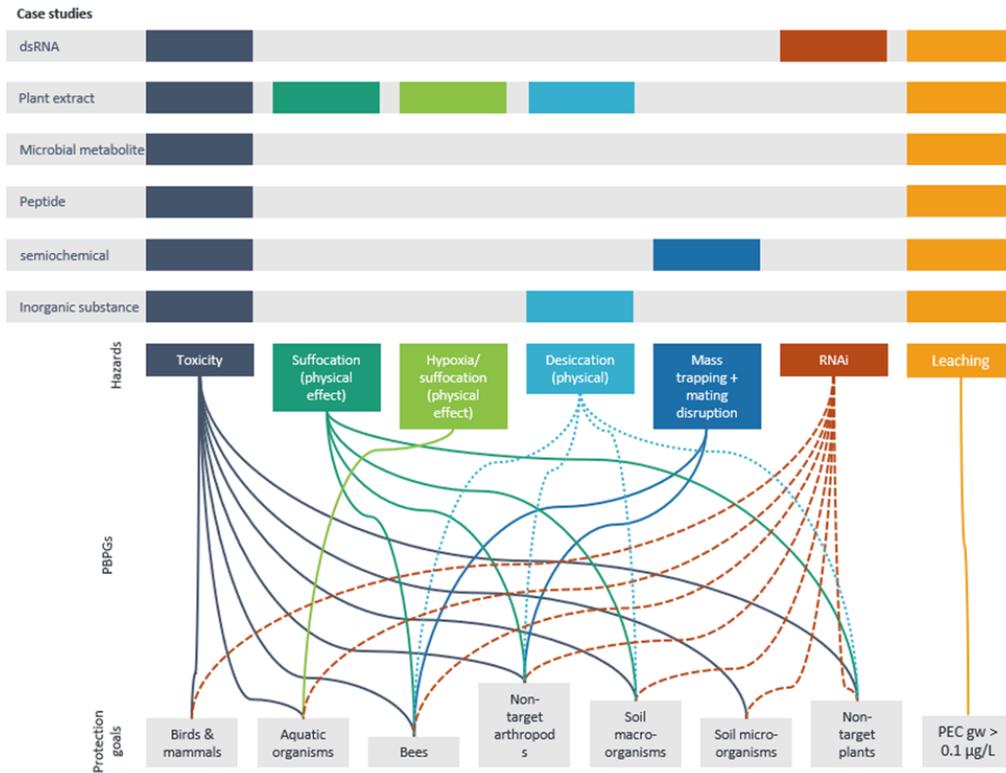
Work Plan and Milestones

Task(s)	Deliverable	2024											2025							
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	#	
		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul
Overarching task: Develop an outline describing the methodology to address SO 2, 3, 4, 5	D0																			
1. Categorisation of substances replaced by Problem formulation using pathways to breach of protection goal	D2X																			
2. Identification of the scientific criteria for non-data submission - Interim report 2	D2A																			
3.1. Identification of alternative methods to in vivo ecotoxicity testing - Interim Report 2	D2B																			
3.2. Alternative in vivo toxicity testing - Interim report 2																				
4. Fit-for-purpose approach for the exposure assessment of LCASs-Interim Report 2	D2C																			
5. Development of fit for purpose risk assessment schemes - Interim Report 2	D2D																			
6. Methodological approach for data collection and collation - Interim Report 2	D2E																			
7. Project management and communication																				
Workshop	D3																			
Interim report 3	D4																			
Final report	D5																			



FROM SUB-OBJECTIVE OUTCOMES TO THE DRAFT PROPOSAL

The application of the Problem formulation approach with the pathways to breach the protection goals methodology



SCOPE OF THE WORKSHOP

The workshop is organised to **present** the Problem formulation approach with the Pathways to Breach the Protection Goals Methodology and **get input/feedback** from the MS and stakeholders on the draft proposal

- Gather feedback from the Member States (MS) regarding the current risk assessment of LCASs and Introduce the use of problem formulation in risk assessment of LCASs
- Present the application of Pathways to Breach the Protection Goals (PBPG) approach in the Low Concern Active Substances (LCASs)
- Facilitate discussions in four break-out groups



WORKSHOP AGENDA



Day 1 – 15 January

Time	No.	Item	Presenter
8.30		Registration	
8:45	1	Welcome Introduction to the project and the workshop	Kostas Koutsoumanis (AUTH), Domenica Auteri (EFSA), Zisis Vryzas (AUTH)
09:10	2	Introduction on the use of problem formulation in risk assessment.	Boet Glandorf
09:30	3	Introduction to PBPG and the stepwise approach to fit-for purpose RA	Anne Steenbergh (Ctgb)
10:00	4	Experience from EC & MS on the assessment of LCAs	Eric Liégeois (EC) Alexandra Miricescu (IE) John Kandris/Evangelos Karanasios (EL)
10:45		<i>Coffee break</i>	
11:15	5	Example of application to LCAs: Case studies presentations	Urania Menkissoglu-Spiroudi & Manolis Karazafeiris, Bastian Polst & Aggeliki Tampoula Belén Guijarro
12:20	6	Introduction to the break-out group	Rachel Sharp (EFSA)
12:30		<i>Lunch break</i>	
13:30	7	Break-out group session 1	
15:00		<i>Coffee break</i>	
15:30	8	Break-out group session 2	
17:00	9	Sum-up in plenary - session 1	Dimitrios Karpouzas (UTH)
17:30		<i>End of the first day</i>	
17:45		<i>Walking guided city tour</i>	
19:30		<i>Networking Cocktail</i>	

Day 2 – 16 January

Time	No.	Item	Presenter
8:30	10	Summary of day 1 – Introduction to day 2	Gertie H.P. Arts (WR)
8:40	11	Experience from Stakeholders	Industry –Edward Pilling & Cedric Bertrand RATION - Dimitrios Karpouzas
9:10	12	Break-out group session 3	
10:40		<i>Coffee break</i>	
11:10	13	Sum-up in plenary - session 2 and 3	Domenica Auteri (EFSA)
11:55	14	Conclusions and next steps – Closing of the meeting	Zisis Vryzas (AUTH), Aude Kienzler (EFSA)
12:00		<i>End of the workshop</i>	

Workshop on the development of a fit-for-purpose approach for assessing the risk of low-concern active substances.

Agenda

15-16 January 2025 08:30-17:30 / 08:30-12:00



Location: Thessaloniki, Mediterranean Palace – Greece

Chair: Aude Kienzler (EFSA)



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