Jornada
Productos fitosanitarios: uso seguro y sostenible

23 DE SEPTIEMBRE DE 2025 | 09:00-14:00

SALA ERNEST LLUCH MINISTERIO DE SANIDAD

Evaluación de plaguicidas más allá de las sustancias quimicas

Marco Regulatorio y nuevos requisitios de datos de productos fitosanitarios basados en microorganismos

MARCO REGULATORIO Y NUEVOS REQUISITOS DE DATOS DE LOS PRODUCTOS FITOSANITARIOS BASADOS EN MICROORGANISMOS

JOSE LUIS ALONSO PRADOS

VICEDIRECTOR TÉCNICO - INIA-CSIC

prados@inia.csic.es

MINISTERIO DE CIENCIA, INNOVACIÓN Y UNIVERSIDADES

CSIC Consejo Superior de Investigaciones Científicas

INIA Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria

MARCO REGULATORIO

ENVIRONMENT
(soil, water, air, biodiversity)

SUSTAINABLE AGRICULTURE

ECONOMIC VIABILITY
(Food supply, farmers incomes; sustainable food products)

SOCIETY
(Food safety & quality; farmers skills; rural, social and economic conditions)

Regulation EC 1107/2009

Main objectives

- Place Plant Protection Products on the EU market;
- Ensuring a high level of protection of both human and animal health and the environment
- Safeguard the competitiveness of Community agriculture;
- Increase the free movement and availability of PPP.
- Speed up approval of a.s. and authorization of PPP.

MARCO REGULATORIO

- **COMMISSION REGULATION (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market amended by COMMISSION REGULATION (EU) 2022/1439 of 31 August 2022**
- **COMMISSION REGULATION (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market amended by COMMISSION REGULATION (EU) 2022/1440 of 31 August 2022**
- **COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products amended by COMMISSION REGULATION (EU) 2022/1441 of 31 August 2022**
- **Annex II of REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market amended by COMMISSION REGULATION (EU) 2022/1438 as regards specific criteria for the approval of active substances that are micro-organisms**
- **Explanatory notes for the implementation of the data requirements on micro-organisms and plant protection products containing them in the framework of Reg. (EC) No 1107/2009 (PAFF-PPL-October 2023-Doc.A.07.01 12 October 2023)**

SCOPE - Art 2. Regulation EC 1107/2009

- This Regulation shall apply to **products**, in the form in which they are supplied to the user, consisting of or containing **active substances, safeners or synergists**, and intended for one of the following uses:
  - a) **protecting plants or plant products against all harmful organisms** or preventing the action of such organisms, unless the main purpose of these products is considered to be for reasons of hygiene rather than for the protection of plants or plant products;
  - b) **influencing the life processes of plants**, such as substances influencing their growth, other than as a nutrient;
  - c) **preserving plant products**, in so far as such substances or products are not subject to special Community provisions on preservatives;
  - d) **destroying undesired plants or parts of plants**, except algae unless the products are applied on soil or water to protect plants;
  - e) **checking or preventing undesired growth of plants**, except algae unless the products are applied on soil or water to protect plants.

- **This Regulation shall apply to substances, including micro-organisms having general or specific action against harmful organisms or on plants, parts of plants or plant products, referred to as 'active substances'.**

CRITERIOS DE APROBACIÓN DE SUSTANCIAS ACTIVAS

ARTÍCULO 4 DEL REGLAMENTO EC 1107/2009 – ANNEX II (MODIFICADO POR REGLAMENTO (EU) 2022/1438)

CUT OFF CRITERIA

FOR MICROORGANISMS

- ✓ **Strain of the micro-organism is not pathogenic to humans**
- ✓ **Isolate of the virus is not infective to humans**
- ✓ **Strains of bacteria do not have any known, functional and transferrable gene coding for resistance to relevant antimicrobial agents.**

CRITERIOS DE APROBACIÓN DE SUSTANCIAS ACTIVAS

ARTÍCULO 4 DEL REGLAMENTO EC 1107/2009

- The **residues** of the plant protection products, **consequent on application consistent with good plant protection practice** and having regard to realistic conditions of use, shall meet the following requirements:
  a) they **shall not have any harmful effects on human health**, including that of vulnerable groups, or animal health, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available, or on groundwater;
  b) they **shall not have any unacceptable effect on the environment**.

CRITERIOS DE APROBACIÓN DE SUSTANCIAS ACTIVAS

ARTÍCULO 4 DEL REGLAMENTO EC 1107/2009

- A **plant protection product**, consequent on application consistent with **good plant protection practice and having regard to realistic conditions of use**, shall meet the following requirements:

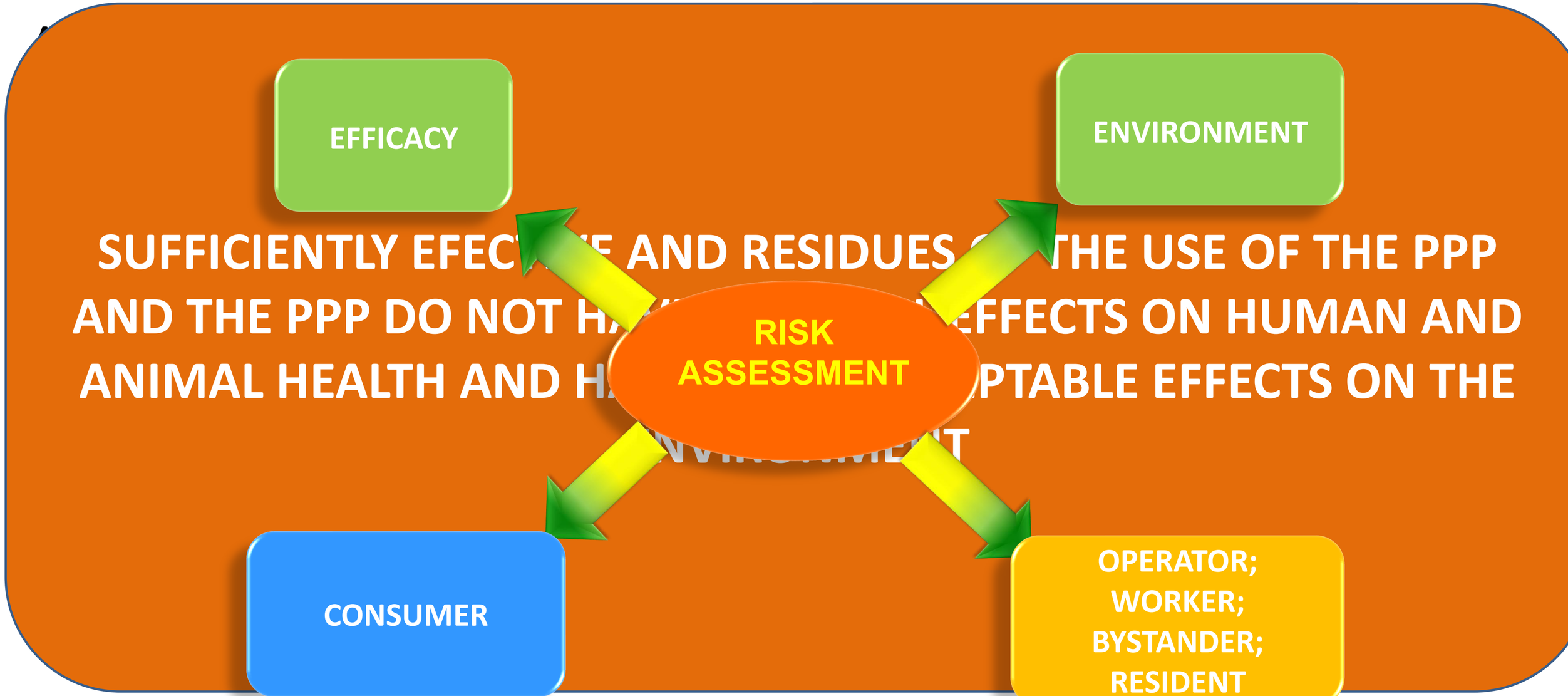
  a) it shall be **sufficiently effective**;

  b) it **shall have no immediate or delayed harmful effect on human health**, including that of vulnerable groups, **or animal health**, directly or through drinking water (taking into account substances resulting from water treatment), food, feed or air, or consequences in the workplace or through other indirect effects, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available; or on groundwater;

  c) it **shall not have any unacceptable effects on plants or plant products**;

  d) it **shall not cause unnecessary suffering and pain to vertebrates to be controlled**;

CRITERIOS DE APROBACIÓN DE SUSTANCIAS ACTIVAS



CRITERIOS APROBACIÓN DE SUSTANCIAS ACTIVAS BAJO RIESGO

Annex II Regulation EC 1107/2009 (Amended by Regulation (EU) 2017/1432 ; 2022/1438)

- **Active substances other than micro-organisms:** An active substance, other than a micro-organism, shall not be considered as being of low-risk

a) it is or has to be classified in accordance with Regulation (EC) No 1272/2008 as any of the following:
   - carcinogenic category 1A, 1B or 2,
   - mutagenic category 1A, 1B or 2,
   - toxic to reproduction category 1A, 1B or 2,
   - skin sensitiser category 1,
   - serious damage to eye category 1,
   - respiratory sensitiser category 1,
   - acute toxicity category 1, 2 or 3,
   - specific Target Organ Toxicant, category 1 or 2,
   - toxic to aquatic life of acute and chronic category 1 on the basis of appropriate standard tests,
   - explosive,
   - skin corrosive, category 1A, 1B or 1C;

b) it has been identified as priority substance under Directive 2000/60/EC;
c) it is deemed to be an endocrine disruptor;
d) it has neurotoxic or immunotoxic effects.

- it is persistent (half-life in soil is more than 60 days) or its bio-concentration factor is higher than 100. However, a **naturally occurring active substance which does not correspond to any of points (a) to (d)** may be considered as being of low-risk, even if it is persistent (half-life in soil is more than 60 days) or its bio-concentration factor is higher than 100.
- Substances emitted and used by plants, animals and other organisms for communication, shall be considered as being of low- risk **where it does not correspond to any of points (a) to (d).**

CRITERIOS APROBACIÓN DE SUSTANCIAS ACTIVAS BAJO RIESGO

- **Micro-organisms**

- 5.2.1. An active substance that is a **micro-organism** other than a virus may be considered a **low-risk active substance unless its susceptibility to at least two classes of antimicrobial agents has not been demonstrated.**

- 5.2.2. **An active substance that is a virus may be considered a low-risk active substance unless it is:**

  (a) a baculovirus with demonstrated adverse effects on non-target insects; or
  (b) a non-virulent variant of a plant pathogen with demonstrated adverse effects on non-target plants.'

DATA REQUIREMENTS ACTIVE SUBSTANCE
Regulation (EU) 283/2013 Amended by Regulation (EU) 2022/1439

PART A – DR FOR CHEMICAL

- a chemical substance (including both semiochemicals and extracts from biological material), or
- a metabolite produced by a micro-organism where:
  - the metabolite is purified from the micro-organism; or
  - the metabolite is not purified from a producing micro-organism which is no longer capable of replication or of transferring genetic material.

PART B – DR FOR MICROORGANISM

- (a) a micro-organism, **either as a single strain or as a qualitatively defined combination of strains** as they occur naturally or by manufacture, or
- (b) a micro-organism, either as a single strain or as a qualitatively defined combination of strains, **and one or more metabolites produced by the microorganism that are claimed to be part of the plant protection action** (i.e. when the application of the metabolite(s) purified from the micro-organism would not cause the claimed plant protection action).

MICROBIAL CONSORTIUM:
all strains must be identified and deposited in a culture collection

- a
  s
  b
- a
  o
  - the metabolite is purified from the micro-organism; or
  - the metabolite is not purified from a producing micro-organism which is no longer capable of replication or of transferring genetic material.

PART B – DR FOR MICROORGANISM

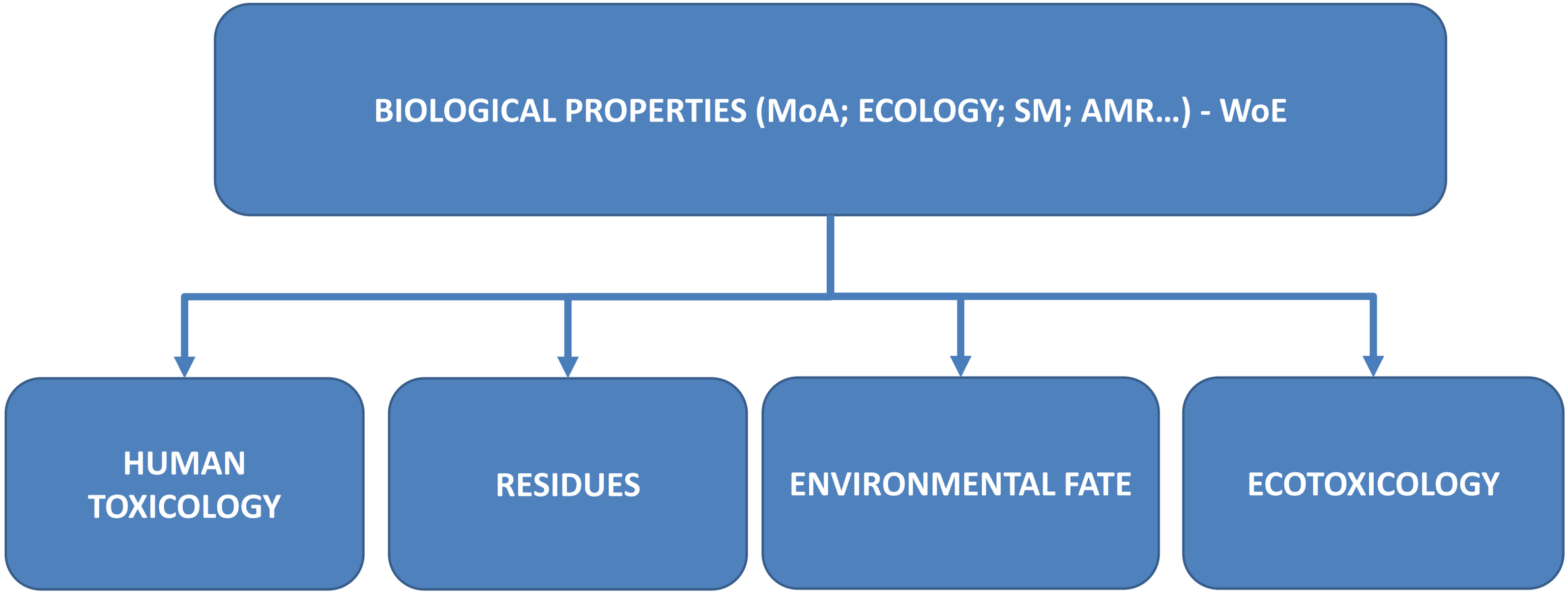
micro-organism, **either as a single strain or as a qualitatively defined combination of strains** as they occur naturally or by manufacture, or

- (b) a micro-organism, either as a single strain or as a qualitatively defined combination of strains, **and one or more metabolites produced by the microorganism that are claimed to be part of the plant protection action** (i.e. when the application of the metabolite(s) purified from the micro-organism would not cause the claimed plant protection action).

FORESEEABLE RISK

- Point 1.1 of Regulation (EU) No 283/2013 and No 284/2013 submitted dossier should contain information which is sufficient to evaluate the **FORESEEABLE RISKS** which the active substance or PPP may entail.
- Risk depends on hazard and the exposure to this hazard
- For living MO a quantitative risk assessment is often not applicable
- Qualitative-based approach and weight of evidence are more appropriate

DATA REQUIREMENTS



DATA REQUIREMENTS “Identity of the microorganism”

1.1 Applicant

1.2 Producer

1.3 Identity, taxonomy and phylogeny of the microorganism: Phylogenetic tree

1.4. Specification of the microbial pest control agent as manufactured

- 1.4.1. Content of the active substance
- 1.4.2 Identity and quantification of additives, relevant contaminating micro-organisms and relevant impurities
- 1.4.3 Analytical profile of batches

1.5. Information on manufacturing process and control measures for the active substance

DATA REQUIREMENTS “Identity of the microorganism”

1.1 Applicant
1.2 Producer
1.3 Identit
tree
1.4. Specification of the microbial pest c
1.4.1. Content of the active substanc
1.4.2 Identity and quantification of
micro-organisms and relevant impuri
1.4.3 Analytical profile of batches
1.5. Information on manufacturing proce
active substance

Microorganisms shall be defined at strain level Information & whether the microorganism is wild type (relevant for natural exposure of humans and the environment), mutant or genetically modified.
Strain deposited at an internationally recognized culture collection.

DATA REQUIREMENTS “Biological properties of the microorganisms”

2.1 Origin, occurrence, and history of use
2.1.1. Origin/isolation source
2.1.2 Occurrence
2.1.3 History of use
2.2 Ecology and life cycle of the microorganism
2.3 Mode of action on the target organism and host range
2.4 Growth requirements
2.5 Infectivity to the target organism
2.6 Relationship to known human pathogens and to pathogens to non-target organisms
2.7 Genetic stability and factors affecting it
2.8 Information on metabolites of concern
2.9 Presence of transferrable antimicrobial resistance genes

DATA REQUIREMENTS “Biological properties of the microorganisms”

2.1 Origin, occurrence, and history of use
2.1.1. Origin/isolation source
2.1.2 Occurrence
2.1.3 History of use
2.2 Ecology and life cycle of
2.3 Mode of
2.4 Growth requirements
2.5 Infectivity to the target organism
2.6 Relationship to known human pathogens and
organisms
2.7 Genetic stability and factors affecting it
2.8 Information on metabolites of concern
2.9 Presence of transferrable antimicrobial resistance genes

All available information on mode(s) of action against the target organisms need to be provided

- **Direct and/or indirect**
- **Pathogenecity**
- **Parasitism**
- **Toxigenicity**
- **Production of antimicrobial agents**
- **Competition for nutrients or space**
- **Plant defence induction**
- **……..**

Single or a combination

DATA REQUIREMENTS “Biological properties of the microorganisms”

2.1 Origin, occurrence, and history of use
2.1.1. Origin/isolation source
2.1.2 Occurrence
2.1.3 History of use
2.2 Ecology and life cycle of
2.3 Mode of
2.4 Growth requirements
2.5 Infectivity to the target organis
2.6 Relationship to know
human pathogens and
organisms
2.7 Genetic stability and factors affecting it
2.8 Information on metabolites of
2.9 Presence of transferrable antimicrobial resistance genes

All available information on mode(s)

Only for non-virulent variant of a plant pathogen virus. Likelihood of regaining virulence through mutation after application under the proposed conditions of use shall be reported

- Production of antimicrobial agents
- Competition for nutrients or space
- Plant defence induction

Only for bacteria
WGS

DATA REQUIREMENTS “Biological properties of the microorganisms”

2.1 Origin, occurrence, and history of use
2.1.1. Origin/isolation source
2.1.2 Occurrence
2.1.3 History of use
2.2 Ecology and life cycle of
2.3 Mode of
2.4 Growth requirements
2.5 Infectivity to the target organism
2.6 Relationship to known human pathogens and organisms
2.7 Genetic stability and factors affecting it
2.8 Information on metabolites of
2.9 Presence of transferrable antimicrobial resistance genes

All available information on mode(s)

Only for non-virulent variant of a plant pathogen virus. Likelihood of regaining

List of metabolites of concern produced by the microorganism, summary information point 5.5.1, 8.8.1, 6.1, 7.2.1 and 7.2.2
No for viruses

- Plant defence induction

Only for bacteria
WGS

SECONDARY METABOLITES

IDENTIFICATION OF METABOLITES OF CONCERN (CONECTED WITH ALL SECTIONS)

- **IDENTITY (Manufacturing process) – ¿active substance or impurity?)**
- **ANALYTICAL METHODS (Technical ; PPP; residues)**
- **HUMAN TOXICOLOGY**
- **RESIDUES**
- **ENVIRONMENTAL FATE**
- **ECOTOXICOLOGY**

DATA REQUIREMENTS “Further information”

3.1 Function and target organism
3.2 Field of use envisaged
3.3. Crops or products protected or treated
3.4 Information on possible development of resistance in the target organism(s)
3.5 Literature data

DATA REQUIREMENTS “Analytical methods” ”

4.1. Methods for the analysis of the MPCA as manufactured

4.2. Methods to determine the density of the micro-organism and quantify residues

The methods used to determine and quantify:

— the density of the micro-organisms, where relevant, as required in points 5.3, 5.4, 6.1 and 7.1.4 and in Section 8,

— the residues of metabolites of concern, where relevant, as required in points 2.8, 5.5 and 8.8 and Section 6;

DATA REQUIREMENTS “Analytical methods” ”

4.1. Methods for the analysis of the MPC

4.2. Methods to determine the residues

The methods used to determine and qua

— the density of the micro-organisms, w

5.3, 5.4, 6.1 and 7.1.4 and in Section 8,

— the residues of metabolites of concern

points 2.8, 5.5 and 8.8 and Section 6;

- **Methods for unequivocal identification of the micro organism (genotypic and/or phenotypic)**
- **Methods for the characterisation of the micro-organism (at specie level and for the phylogenetic tree)**
- **Methods for providing information on possible variability of seed stock / micro organism and its storability**
- **Methods to differentiate a spontaneous or induced mutant from the parent wild strain**
- **Methods to determine the content of the micro organism which is the active substance,**
- **and methods to detect relevant contaminating micro organisms**

DATA REQUIREMENTS “Effects on human health”

5.1. Medical data

5.1.1 Therapeutic and first aid measures

5.1.2. Medical surveillance

5.1.3. Information on sensitisation and allergenicity

5.1.4. Direct observation

5.2 Assessment on potential pathogenicity of the microorganism to humans

5.3. Infectivity and pathogenicity studies on the micro-organism

5.3.1. Infectivity and pathogenicity (oral; intratracheal/intranasal; intravenous, intraperitoneal or subcutaneous)

5.3.2. Cell culture study

5.4. Specific pathogenicity and infectiveness studies on the microorganism

5.5 Information and toxicity studies on metabolites (scientific literature; additional studies)

DATA REQUIREMENTS “Effects on human health”

5.1. Medical data

5.1.1 Therapeutic and first aid m

5.1.2. Medical surveillance

5.1.3. Information on sensitisa

5.1.4. Direct observation

5.2 Assessment on potential pathog

5.3. Infectivity and pathogenicity st

5.3.1. Infectivity and pathogeni

intravenous, intraperitoneal or sub

5.3.2. Cell culture study

5.4. Specific pathogenicity and infe

5.5 Information and toxicity studies

additional studies)

- Information on Identity and biological properties of MO – ASSESMENT OF PATHOGENICITY AND INFECTIVENESS POTENTIAL based on a WoE approach
- Expert judgment: Need of further studies and type of studies on a case by case basis
- MOs are considered as <u>potential</u> sensitizers until a validated test would be available
- Metabolites of concern additional tox studies required for setting reference values. Qualitative assessment and TTC approach are accepted.

DATA REQUIREMENTS “Effects on human health”

5.1. Medical data

5.1.1 Therapeutic and first a

5.1.2. Medical surveillance

5.1.3. Information on sensitisa

5.1.4. Direct observation

5.2 Assessment on potential pathog

5.3. Infectivity and pathogenicity st

5.3.1. Infectivity and pathogeni

intravenous, intraperitoneal or s

5.3.2. Cell culture

5.4. Specific pathogenicity and infe

5.5 Information and toxicity studies

additional studies)

A list with antimicrobial agents with effectiveness against the micro-organism must be provided , to ensure the availability of sufficient therapeutic measures in the event of opportunistic infections

- Informa
- properties of MO – ASSESMENT OF PATHOG
- POTEN
- Expert
- and ty
- MOs a

For those secondary metabolites produced by the micro-organism for which a hazard to human or animal health is identified, information on human exposure should be provided as described under points A.6 (residues in or on treated products, food and feed) and A.7.2 (fate and behaviour of metabolite(s) of concern).

studies required for setting reference values. Qualitative assessment and TTC approach are accepted.

DATA REQUIREMENTS “Residues in or on treated products, food and feed”

Shall be provided unless:

Based on WoE approach metabolites of concern are not hazardous to humans

Estimation of consumer exposure to residues of metabolites that the risk is acceptable

The microorganism is a virus

6.1. Estimation of consumer exposure to residues .

An estimation of consumer exposure shall be provided for metabolites for which a hazard to human health was identified.

6.2 Data generation on residues

Conditional requirement: For those metabolites for which it was not adequately demonstrated that the risk to consumers is acceptable based on the information provided in sections 6.1, residue trials as provided in section 6 of Part A of the data requirements may shall be required

DATA REQUIREMENTS “Residues in or on treated products, food and feed”

Shall be provided unless:

Based on WoE approach metabolites of concern are not hazardous to humans

Estimation of consumer exposure to residues of metabolites that the risk is acceptable

The microorganism is a virus

6.1. Estimation of consumer exposure to residues .

An estimation of consumer exposure shall be provide

which a hazard to human health was identified.

6.2 Data generation on residues

Conditional requirement: For those metabolites for

adequately demonstrated that the risk to consumers is acceptable based on the information provided in sections 6.1, residue trials as provided in section 6 of Part A of the data requirements may shall be required

Conditional DR

Conditional DR

DATA REQUIREMENTS “Residues in or on treated products, food and feed”

Shall be provided unless:

Based on WoE approach metabolites of concern are not hazardous to humans

Estimation of consumer exposure to residues of metabolites that the risk is acceptable

The microorganism is a virus

6.1. Estimation of consumer exposure to residues

An estimation of consumer exposure shall be prov

which a hazard to human health was ident

6.2 Data ge

Conditional requirement: For those metabolites for

adequately demonstrated that the risk to consumers is acceptable based on the information provided in sections 6.1, residue trials as provided in section 6 of Part A of the data requirements may shall be required

If the metabolite of potential concern is present in the MCPA-AM, a consumer risk assessment should be provided based on the maximum level at which the secondary metabolite may be present in the product

Conditional DR

DATA REQUIREMENTS “Fate and behaviour in the environment”

7.1. Environmental occurrence of the micro-organism

7.1.1 Predicted environmental density of microorganisms

7.1.1.1 Soil

7.1.1.2. Water

7.1.2 Exposure to microorganisms known to be patho

organisms. For micro-organisms not occurring in the relevant European environments at the relevant highest taxonomic level and which are known to be pathogenic either for plants or for other organisms

7.1.3 Qualitative exposure assessment of the micro-organism

7.1.4 Experimental exposure data of the micro-organism

If a potential risk is identified for humans or non-target organism(s) and the information provided is not sufficient to conclude on it

7.2 Fate and behaviour of metabolite(s) of concern

7.2.1 Predicted environmental concentration

7.2.2 Qualitative exposure assessment

7.2.3 Experimental exposure assessment

Unless it is properly justified absence of hazard under Section 8

DATA REQUIREMENTS “Effects on non-target organisms”

Infectivity an pathogenicity of the MO to the different NTO shall be provided

8.1. Effects on terrestrial vertebrates

8.2. Effects on aquatic organisms

- **8.2.1. Effects on fish**
- **8.2.2. Effects on aquatic invertebrates**
- **8.2.3. Effects on algae**
- **8.2.4. Effects on aquatic macrophytes**

8.3. Effects on bees

8.4. Effects on non-target arthropods other than bees

8.5. Effects on non-target meso- and macro-organisms in soil

8.6. Effects on non-target terrestrial plants

8.7. Additional studies on the microorganism

8.8. Additional studies on metabolites of concern

DATA REQUIREMENTS “Effects on non-target organisms”

Infec

8.1

8.2

8.3

8.4

8.5

8.6

8.7.

8.8. Additional studies on metabolites of concern

Special attention should be paid to microbial species which are not known to occur in normal conditions of use in the EU agricultural environment. A comparison with occurring densities of the MO may concern the “relevant taxonomic level”

CONDITIONAL

Not required if one of the following is applicable:

− Exposure is expected to be none **(FOR TERRESTRIAL VERTEBRATES IS REQUIRED)** , or

− Significant information is available for the microorganism that supports and demonstrates the absence/lack of negative effects

− Studies and/or existing information on toxicity, infectiveness and pathogenicity

Different routes of exposure shall be taken into account (*infected insects)*

Special attention to entomopathogenic microorganisms for NTA

Additional studies on relevant metabolites related to PART A Reg 283/2013

EU COMMISSION ACTIONS - REFIT

PROMOTE A SUSTAINABLE PLANT PROTECTION, LOW RISK SOLUTIONS AND EFFICIENT RISK MITIGATION MEASURES

- Update of the data requirements and uniform principles for microorganisms and update the risk assessment methodologies

BIOPESTICIDE WG/OECD - 2014

- Improve training to strengthen Member States' expertise in assessing applications for micro-organisms and other biological pesticides.

BTSF Course 2021-2025

- Accelerate the availability of low risk substances and products

BIOPESTICIDE WG /PAI WG

- Funding under the research framework programmes

RATION HE ; LOW CONCERN A.S. (EFSA)

RATION PROJECT HE

MINISTERIO
DE CIENCIA, INNOVACIÓN
Y UNIVERSIDADES

CSIC
CONSEJO SUPERIOR DE INVESTIGACIONES CIENTÍFICAS

INIA
Instituto Nacional de Investigación
y Tecnología Agraria y Alimentaria

Who are we…

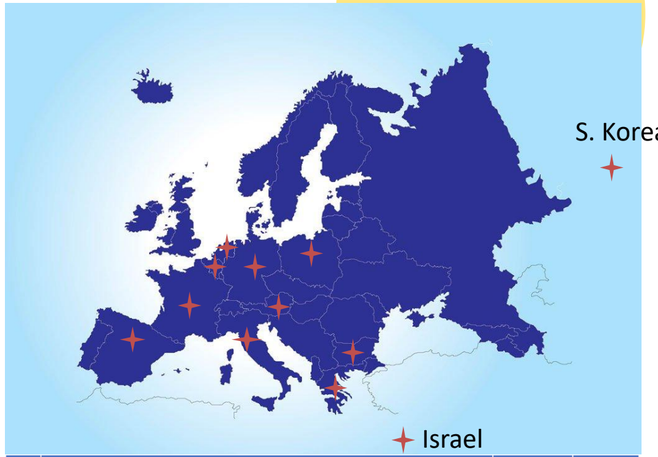
Risk AssessmenT InnOvatioN for Low-Risk Pesticides

Funded by the European Commission

1 **Duration:** 4 years (1.11.2022 – 31.10.2026)

2 ***7* million euros**

3 **21 partners + 1 associated partner**



No	Participant organisation name	Acronym	Country
1	**University of Thessaly (Coordinator)**	**UTH**	**GR**
2	Université Catholique de Louvain	UCL	BE
3	AIT Austrian Institute of Technology GmbH	AIT	AT
4	Helmholtz Centre for Environmental Research GmbH - UFZ	UFZ	DE
5	Biobest	BBEST	BE
6	CBC EUROPE Srl	CBC	IT
7	Weizmann Institute of Science	WI	IL
8	Julius-Kühn-Institut	JKI	DE
9	Hellenic Agricultural Organization – Demeter	HAO	GR
10	Genosolution	GENO	KR
11	Metabolic Insights ltd.	MI	IL
12	Institute of Soil Science and Plant Cultivation	IUNG	PL
13	AEIFORIA HELLAS LTD	AFA	BG
14	Wageningen University	WU	NL
15	ECT Oekotoxikologie GmbH	ECT	DE
16	Foundation for Research and Technology - IMBB	FORTH	GR
17	Syngenta Agro	SYN	DE
18	Bayer Crop Science	BAYER	DE
19	International Biocontrol Manufacturers Association	IBMA	BE
20	INRAE	INRAE	FR
21	Euroquality	EQY	FR
22	CSIC - INIA	INIA	ES

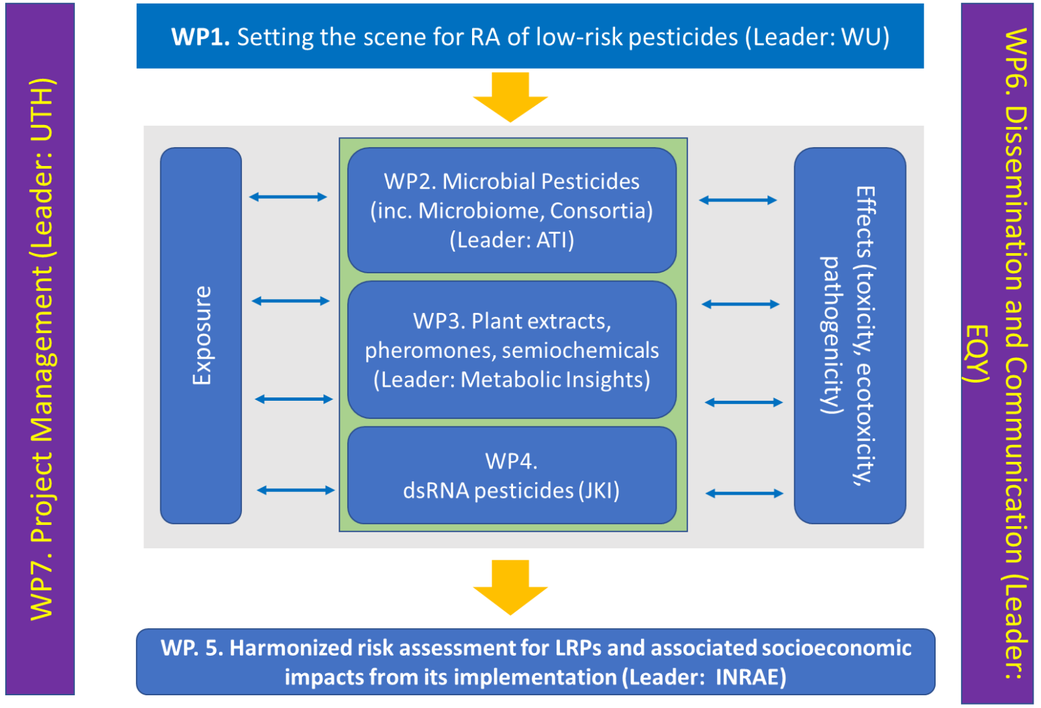
RATION Main Goal

To develop a novel risk assessment scheme for <u>Low-Risk Pesticides (LRP) of biological origin</u>* supported by the necessary guidance, methods, and tools for its implementation

1. **Microbials and New Microbiome Solutions**
2. **Plant extracts, semiochemicals, pheromones**
3. **ds-RNA**

* ***Low-concern substances*** *a term coined from EFSA to describe those products*

Workplan of RATION



Workplan of RATION

WP2, 3 and 4

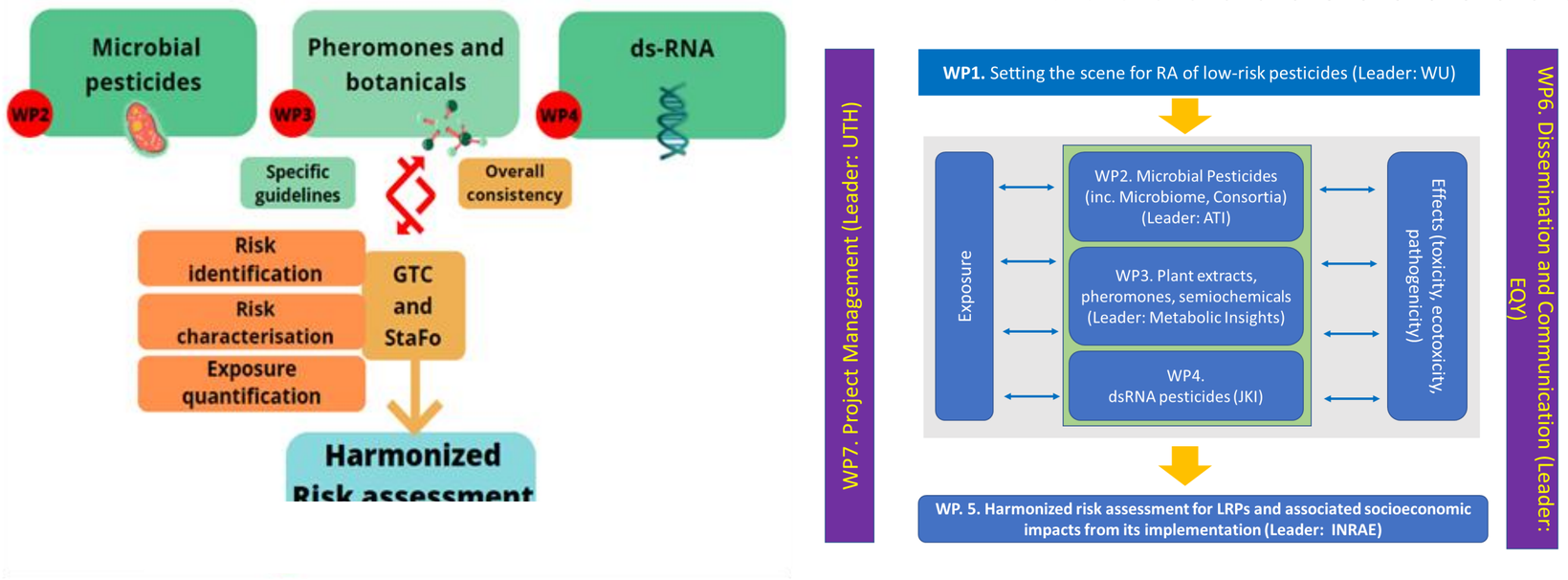


Fig. 4. How RATION will reach from group-specific RA to a harmonized RA strategy for all LRP

EFSA PROJECTS (ART 36)

MINISTERIO
DE CIENCIA, INNOVACIÓN
Y UNIVERSIDADES

CSIC
CONSEJO SUPERIOR DE INVESTIGACIONES CIENTÍFICAS

INIA
Instituto Nacional de Investigación
y Tecnología Agraria y Alimentaria

GP/EFSA/PLANTS/2023/04

Objective: Develop a stepwise approach for a fit for purpose risk assessment, in particular for low-concern active substances and uses (26/01/2024 – 25/07/2025)

Consortium partners

- Co-ordinator: Aristotle University of Thessaloniki, AUTH
- Wageningen Environmental Research (WENR)
- University of Thessaly (UTH)
- Dutch board for the Authorisation of Plant Protection Products and Biocides (Ctgb)
- Agencia Estatal Consejo Superior de Investigaciones Científicas – Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria (CSIC-INIA; UPF-PV)
- Hellenic Agricultural Organization (ELGO)

GP/EFSA/PLANTS/2023/04

Sub-objective 1 : Propose specific criteria that would allow to identify and **group LCASs.**

Sub-objective 2: Identify harmonized and science-based criteria for justifying the **non-submission** of guideline studies specified in both active substance and PPP data requirements to characterize hazard and exposure.

Sub-objective 3 : Investigate, in conjunction with SO2, the potential use of **alternative methods to testing for the hazard assessment** of the substance expected to be of low-concern

Sub- objective 4 : investigate, in conjunction with SO2, the potential use of **fit-for-purpose approaches for the exposure assessment of LCASs**, when the standard exposure assessment is not applicable.

Sub-objective 5 : suggest, based on SO1 to SO4, a **stepwise approach starting from problem formulation**, for fit-for-purpose risk assessment methodologies.

Sub-objective 6 : Describe how to perform a **proper and fit-for-purpose literature search** to support the scientific justification considering SO2, 3 and 4 when searching for available literature data for the different group of LCASs e.g., by indicating fit for purpose search terms and inclusion/exclusion criteria.

Sub-objective 7 : Identify **knowledge gaps** that would be put forward for **further investigation in future**