FIT FOR PURPOSE RISK ASSESSMENT APPROACH FOR ACTIVE SUBSTANCES OF LOW CONCERN

35th PSN meeting

12th May 2026

EUROPEAN FOOD SAFETY AUTHORITY

SET THE SCENE

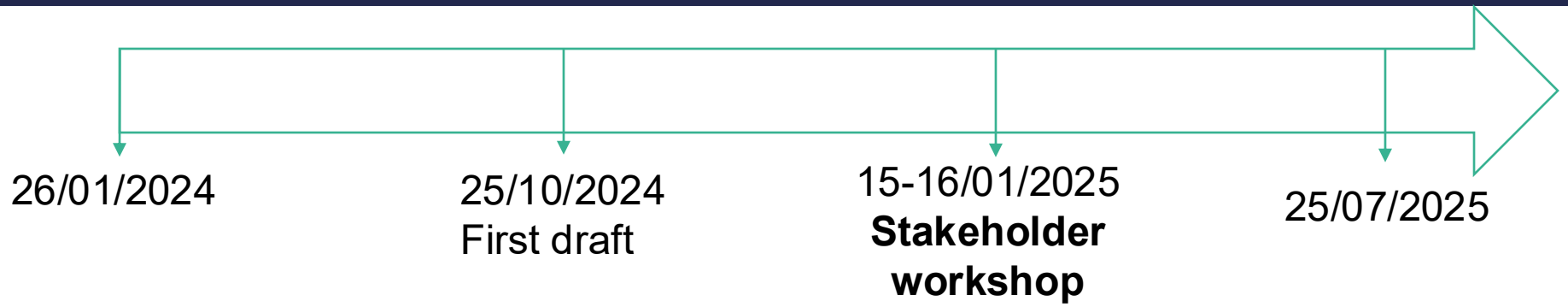
- Increasing number of submission of biopesticides or pesticides of “low concern”

- Current RA methodology not suitable; assessment of such active substances quite challenging
  - No/little data
  - Data requirement not always needed
  - Consider only toxicity, not the other potential MOA
  - Currents tools/TGs do not allow to capture the effects
  - No agreed RA methodologies for RNAs, peptides…

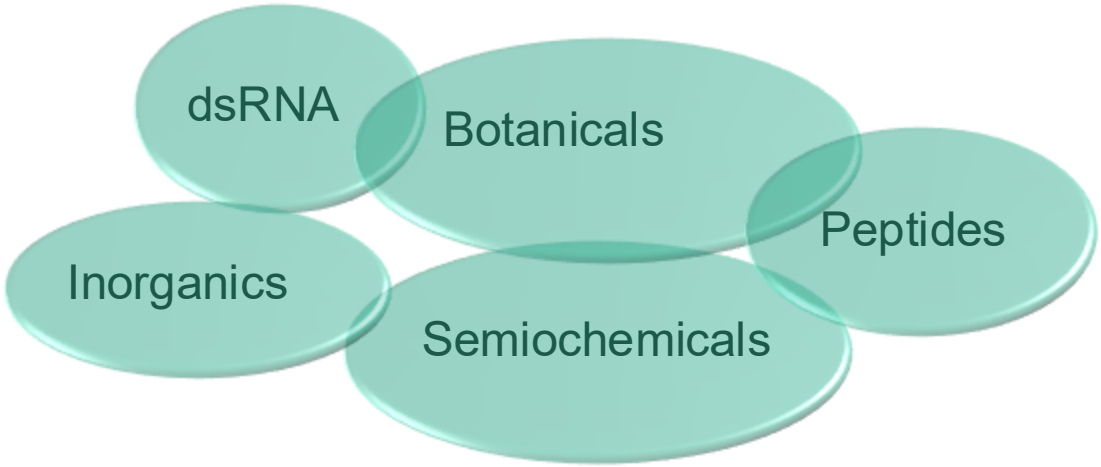
Need to develop a more fit-for-purpose environmental RA approach for low-concern a.s.

EFSA’s call GP/EFSA/PLANTS/2023/04 launched in 2023: “Develop a stepwise approach for a fit for purpose risk assessment for low-concern active substances and uses”

SET THE SCENE



- **Scope**:



- Which generally have lower risk profiles than conventional a.s.
- Microbials not included in the context of this project

THE APPROACH AT A GLANCE

- Based on problem formulation
- Consider hazards other than conventional toxicity
- Facilitate integration of all information relevant for the assessment (such as hazard, e-fate, effects)
- Supports both qualitative and quantitative assessments
- Help identify DR that might not be necessary, or additional data that might be necessary (Iterative process)
- Flexible approach (also suitable for new types of a.s.)

Protection goals are the same as for conventional substance

Pathway-to-harm

THE APPROACH AT A GLANCE

- Final report including “problem formulation toolbox”:

Generic pathway to harm

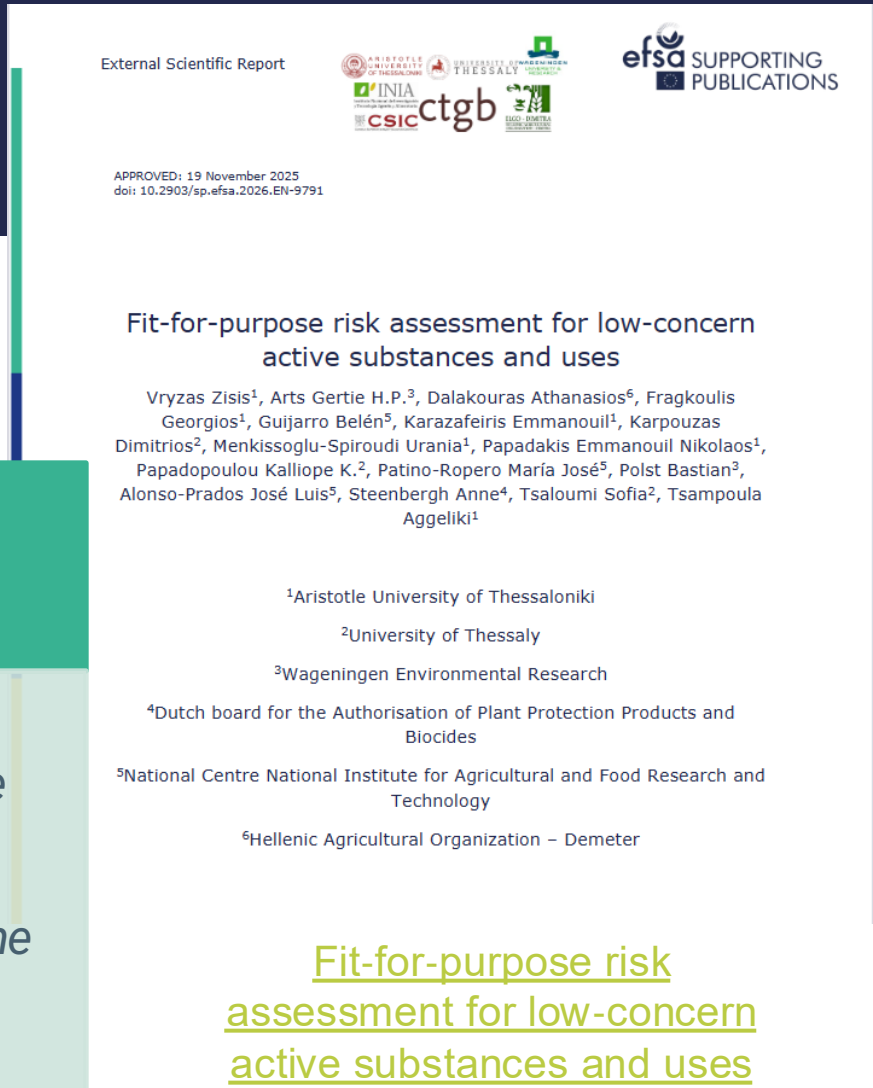
- *Number of events which all must take place in order to breach the protection goal*
- *To assess the likelihood of breaching the protection goal*

Generic Analysis plans

- *Which analyses may be used to assess the likelihood of the individual events*

Likelihood assessment guidance

- *How to assess the likelihood of individual events; how to combine the information within and across the generic pathways*



External Scientific Report

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Fit-for-purpose risk assessment for low-concern active substances and uses

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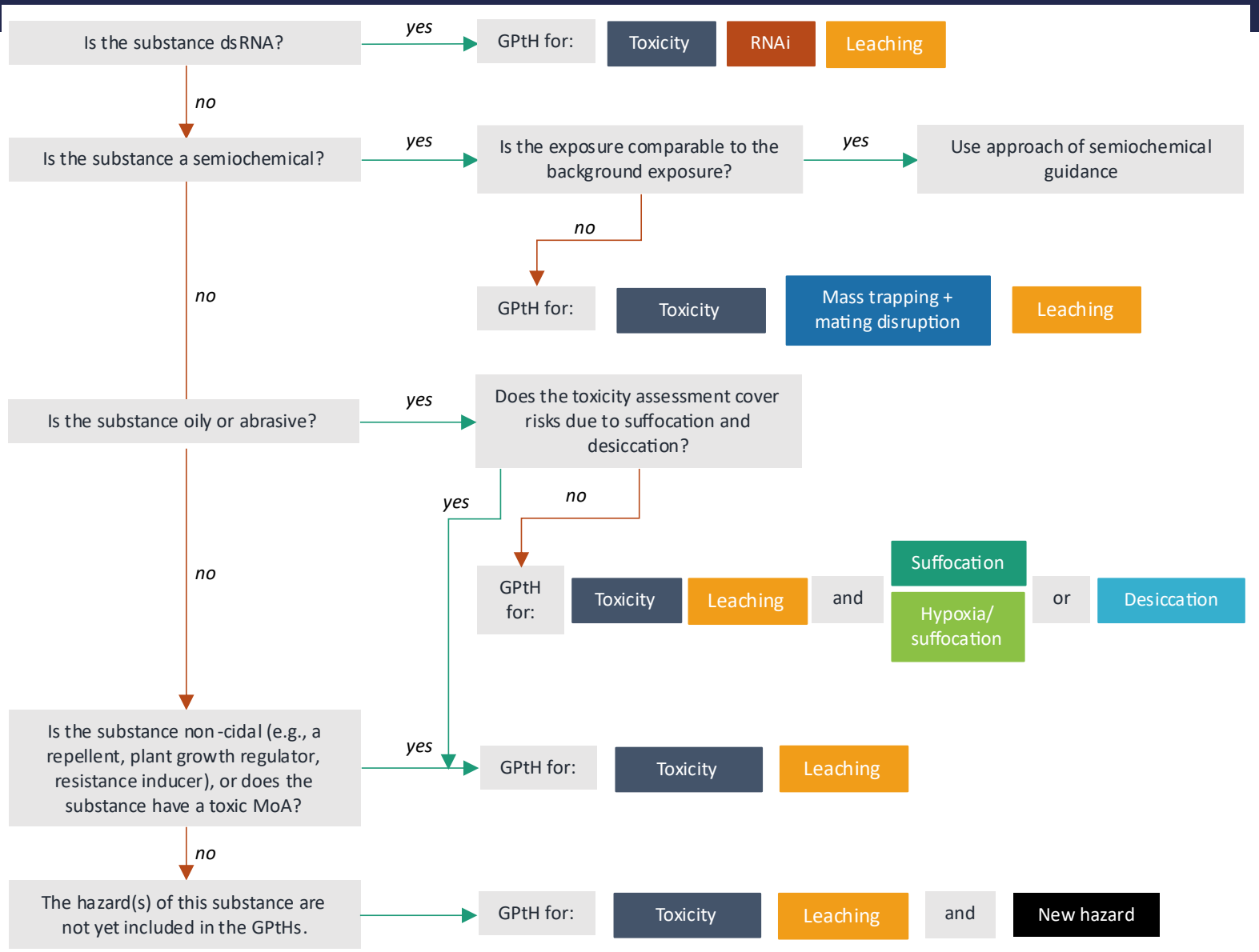
Fit-for-purpose risk assessment for low-concern active substances and uses

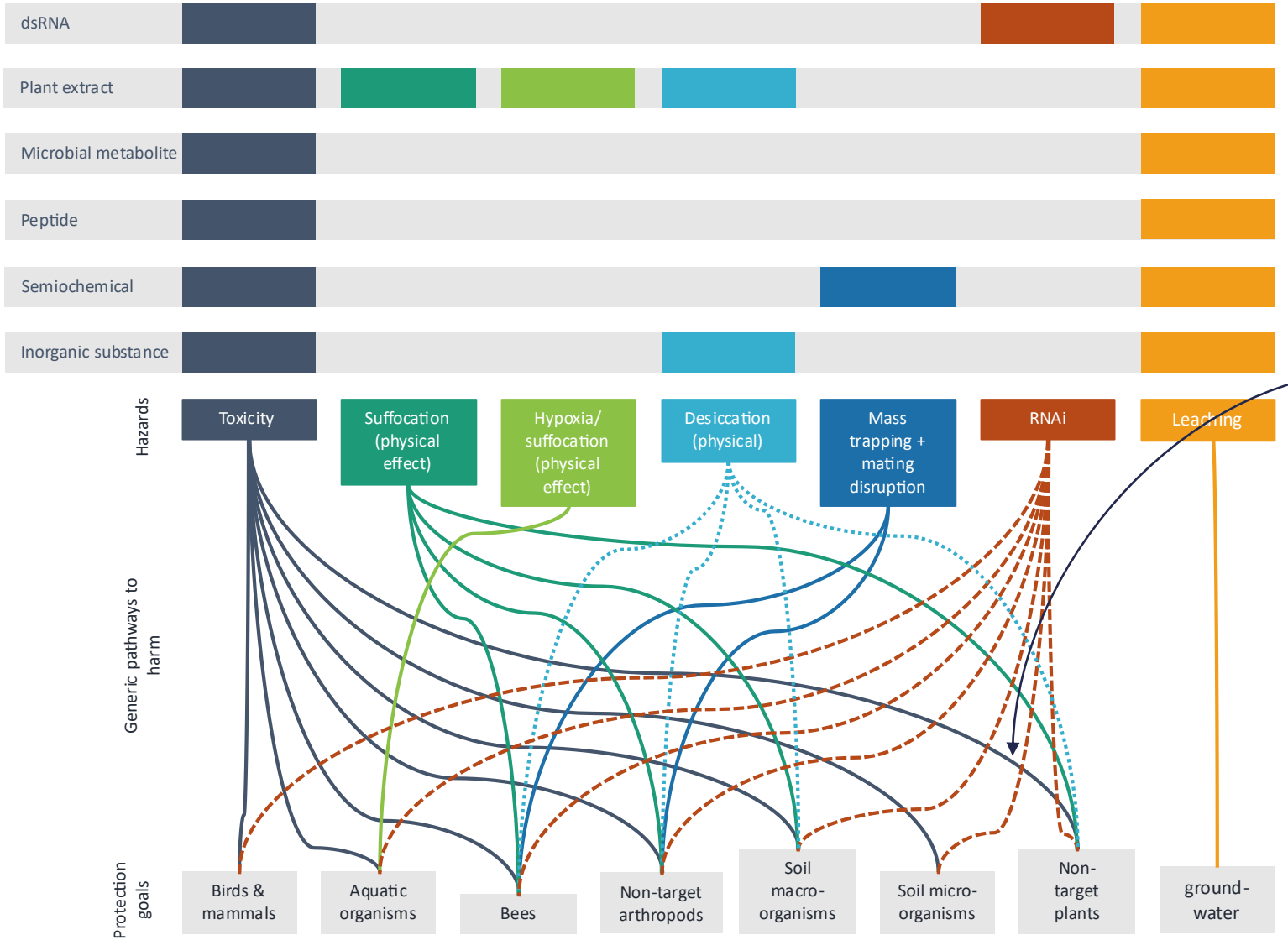
WHICH HAZARDS SHOULD BE CONSIDERED ?

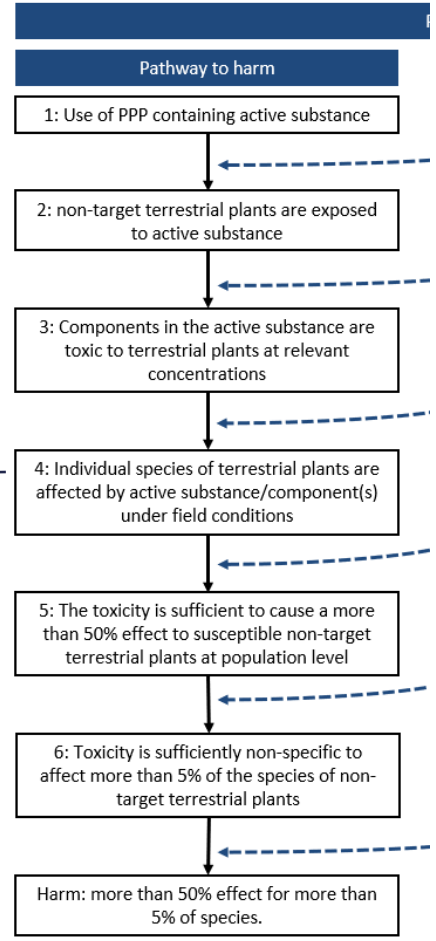
Identify the hazards



PTH FOR EACH COMBINATION OF HAZARD & PROTECTION GOAL

Identify the NTOs

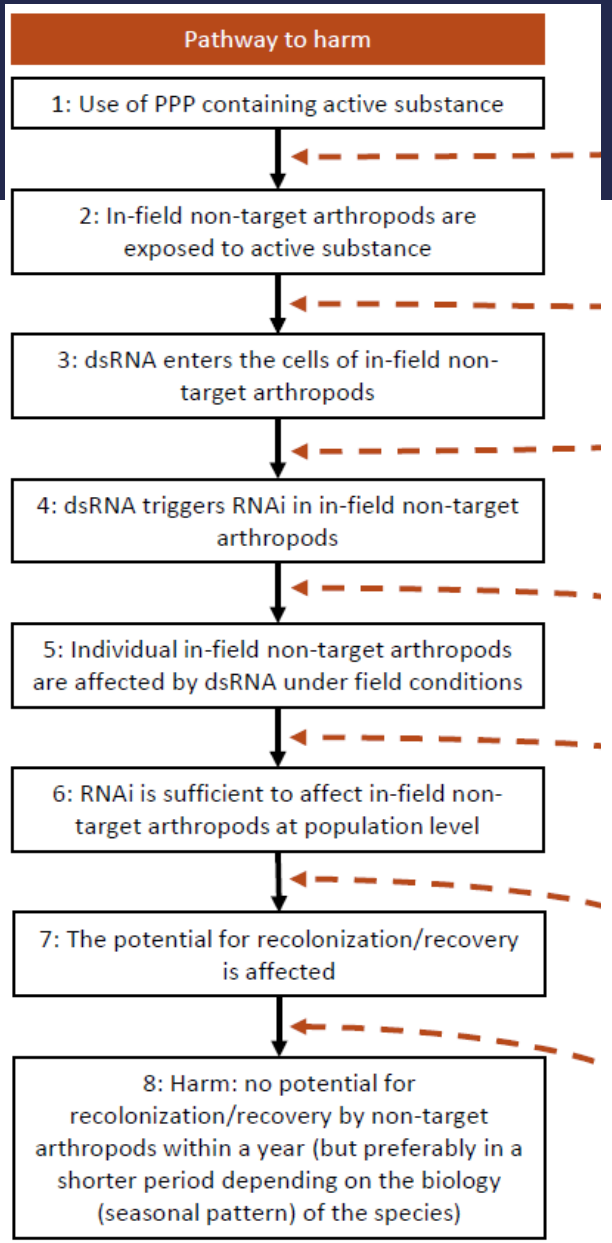




One line = one generic PtH

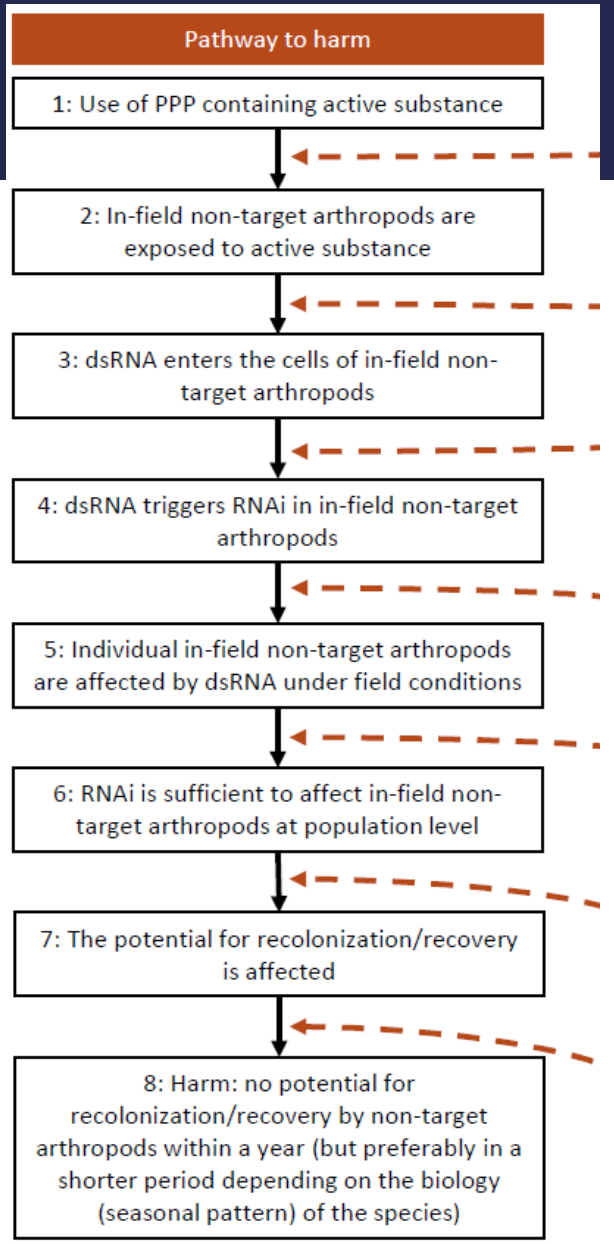
CORE: THE GENERIC PTH

- 1 pathway for each combination of hazard & PG
- Structured sequences of events starting with the use of the PPP and leading to the harm = breaching the PG
- All events need to take place for harm to occur
- Integrates all available information
- Allows qualitative and quantitative assessment



PRINCIPLE OF USING PTH

- No fixed order: no need to start at the beginning
- One event can be demonstrated not to occur > likelihood of breaching the PG is negligible
- None of the events can be demonstrated not to occur : assess the overall likelihood of breaching the PG
- Iterative: Process can be repeated after new data has been generated

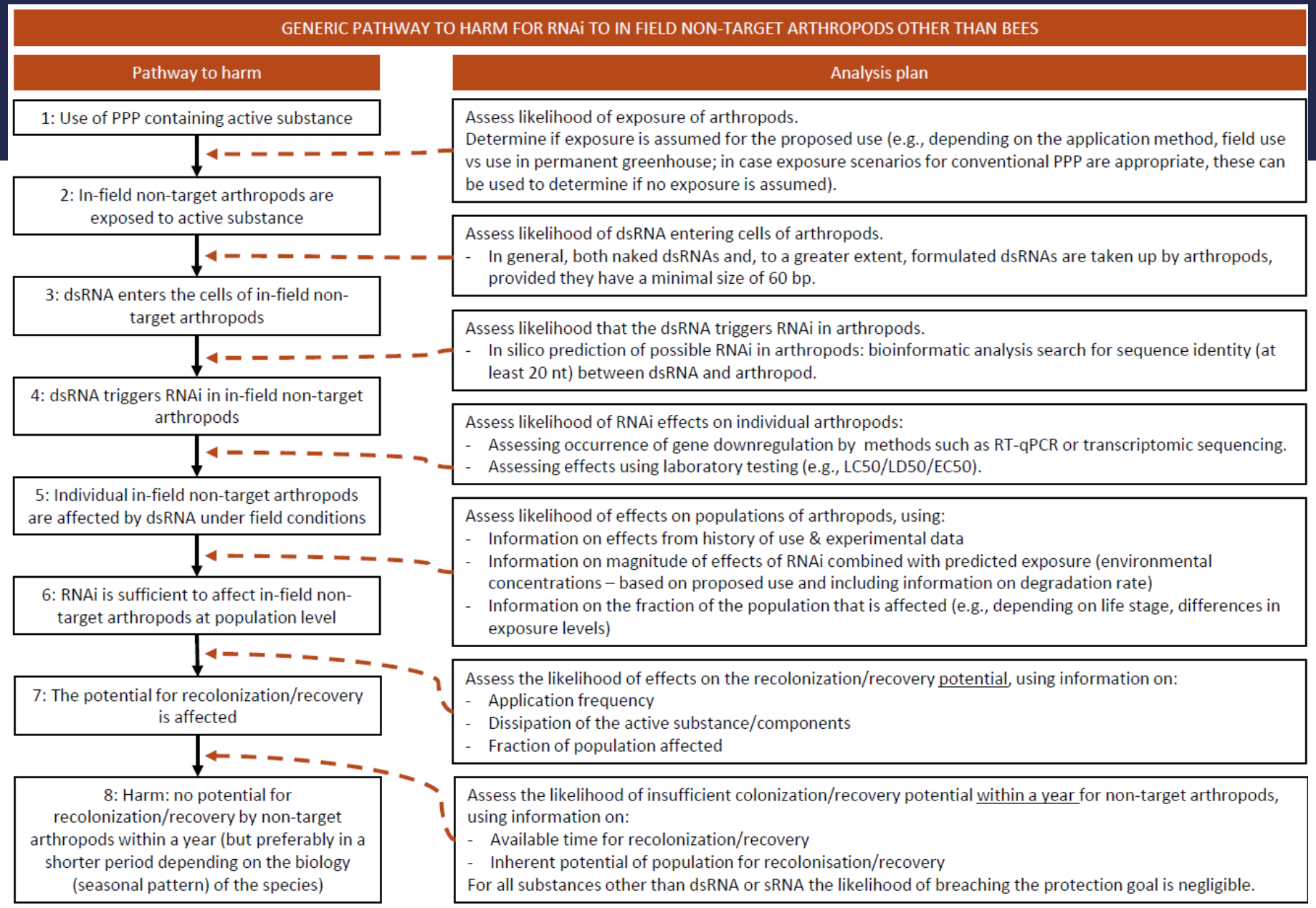


How likely is each events?

Analysis plan and likelihood descriptors

ANALYSIS PLAN

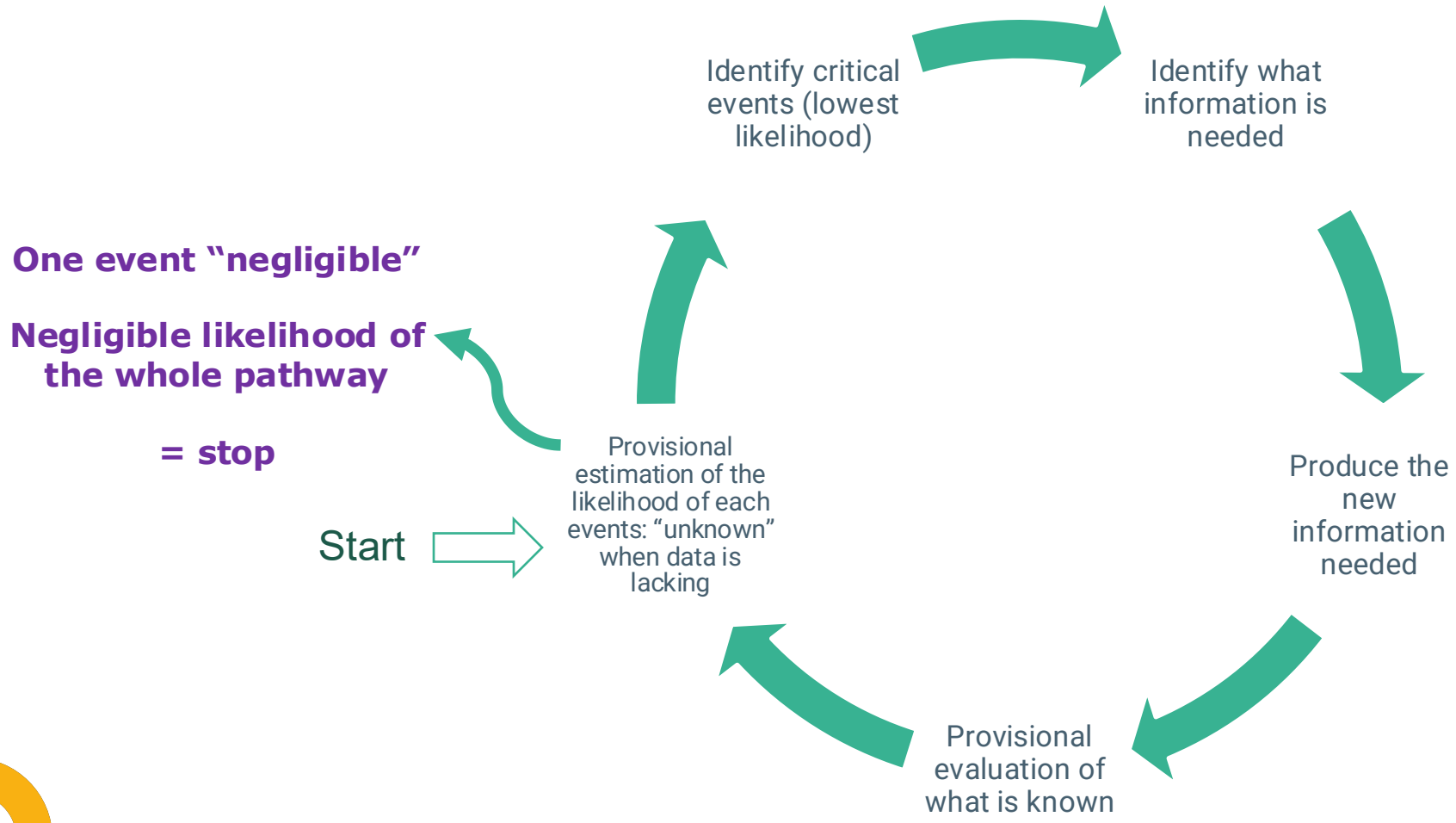
- Provide information on which analyses can be used
- …are not intended as guidelines to prescribe a specific approach and are not exhaustive
- Contains at least one analysis option/event; may contains several options
- Reflects the best option available at that time : might evolved in time!



LIKELIHOOD DESCRIPTORS

Descriptor	Definition	Subjective probability range
Certain	Is certain to occur.	100%
Extremely likely	Is expected to occur in almost all circumstances; almost certain.	95 – 100%
Likely	A reasonable to high probability of occurring; covering a wide range of probabilities from events that might occur or should occur at some time to those that will probably occur in most circumstances.	33 – 95%
Unlikely	May occur, but less probable than not.	10 – 33%
Very unlikely	Not expected to occur; may occur only in exceptional circumstances.	0 – 10%
Negligible	Likelihood not distinguishable from zero.	0%
Unknown	Not sufficient information available to assess the likelihood with sufficient certainty.	0 – 100%

LIKELIHOOD ASSESSMENT



The assessment of the likelihood of each event should consistently be substantiated with appropriate data or information.

OUTCOME OF THE ASSESSMENT

✓More than one generic PtH is relevant : the likelihood of all these pathways should be considered to assess the likelihood of breaching the PG

✓Which level of probability of breaching the PG may be considered as acceptable is a RM decision:

Proposal: when the likelihood of breaching the PG is assessed as "very unlikely" or "negligible" : a low risk may be concluded.

CONCLUSION

- Expectations:
  - Help the applicant/the reviewer to :
    - Better identify which hazard might be relevant for which LCAs
    - Determine which data is needed : complete dossiers, less data gaps
    - Determine which data is NOT needed - *justify and better substantiate data waiving*
  - Better interpret and communicate the outcome of the assessment
  - Flexible enough to include upcoming new type of substances
- Rely mainly on expert judgement !
- Missing tools and TGs to capture MOA other than toxicity

NEXT STEPS

- Published as an EFSA External Report
- Will be consolidated with the outcome of other ongoing projects (RATION, OECD…)
- Wait for the outcome of the Food & Feed OMNIBUS

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