

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

35th PSN meeting  
12th May 2026



# SET THE SCENE

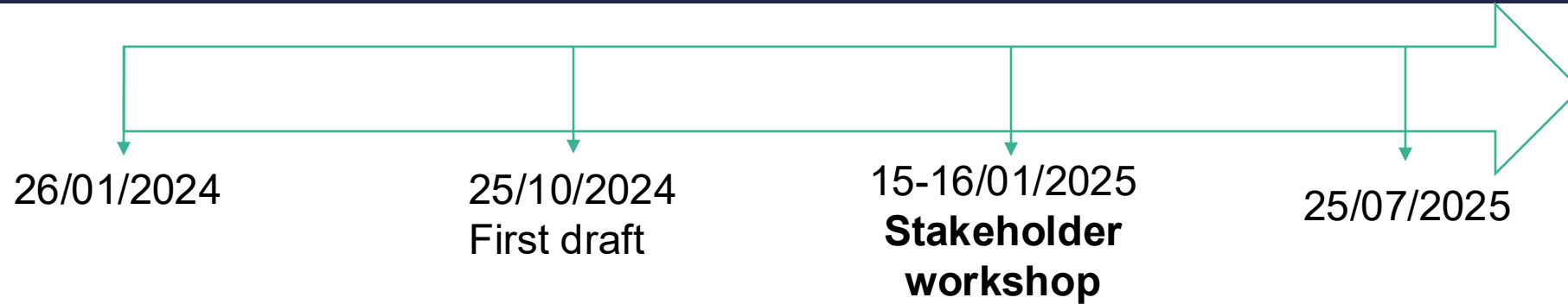
- Increasing number of submission of biopesticides or pesticides of “low concern”
- Current RA methodology not suitable; assessment of such active substances quite challenging
  - No/little data
  - Data requirement not always needed
  - Consider only toxicity, not the other potential MOA
  - Currents 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.*

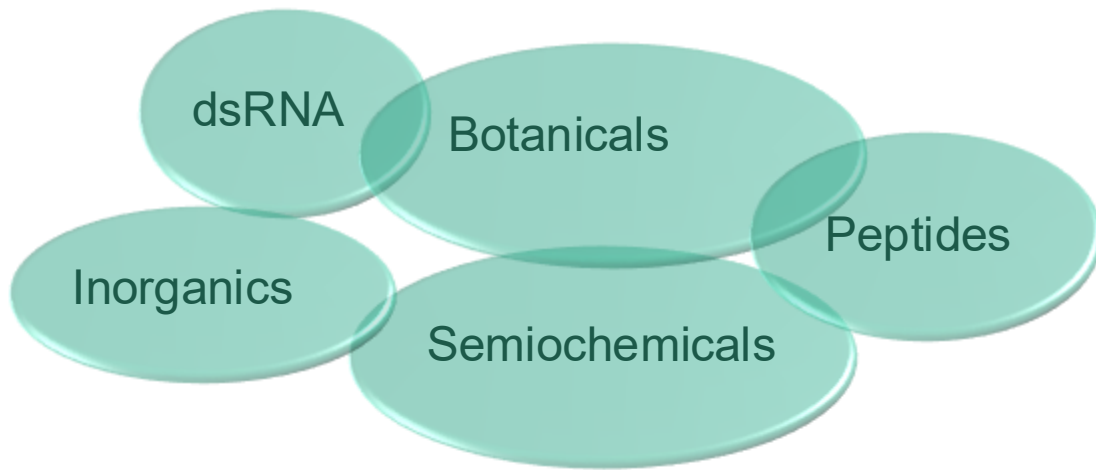
EFSA’s call GP/EFSA/PLANTS/2023/04 launched in 2023: “Develop a stepwise approach for a fit for purpose risk assessment for low-concern active substances and uses”



# 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*

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

Vryzas Zisis<sup>1</sup>, Arts Gertie H.P.<sup>3</sup>, Dalakouras Athanasios<sup>6</sup>, Fragkoulis Georgios<sup>1</sup>, Guijarro Belén<sup>5</sup>, Karazafeiris Emmanouil<sup>1</sup>, Karpouzas Dimitrios<sup>2</sup>, Menkissoglu-Spiroudi Urania<sup>1</sup>, Papadakis Emmanouil Nikolaos<sup>1</sup>, Papadopoulou Kalliope K.<sup>2</sup>, Patino-Ropero María José<sup>5</sup>, Polst Bastian<sup>3</sup>, Alonso-Prados José Luis<sup>5</sup>, Steenbergh Anne<sup>4</sup>, Tsaloumi Sofia<sup>2</sup>, Tsampoula Aggeliki<sup>1</sup>

<sup>1</sup>Aristotle University of Thessaloniki

<sup>2</sup>University of Thessaly

<sup>3</sup>Wageningen Environmental Research

<sup>4</sup>Dutch board for the Authorisation of Plant Protection Products and Biocides

<sup>5</sup>National Centre National Institute for Agricultural and Food Research and Technology

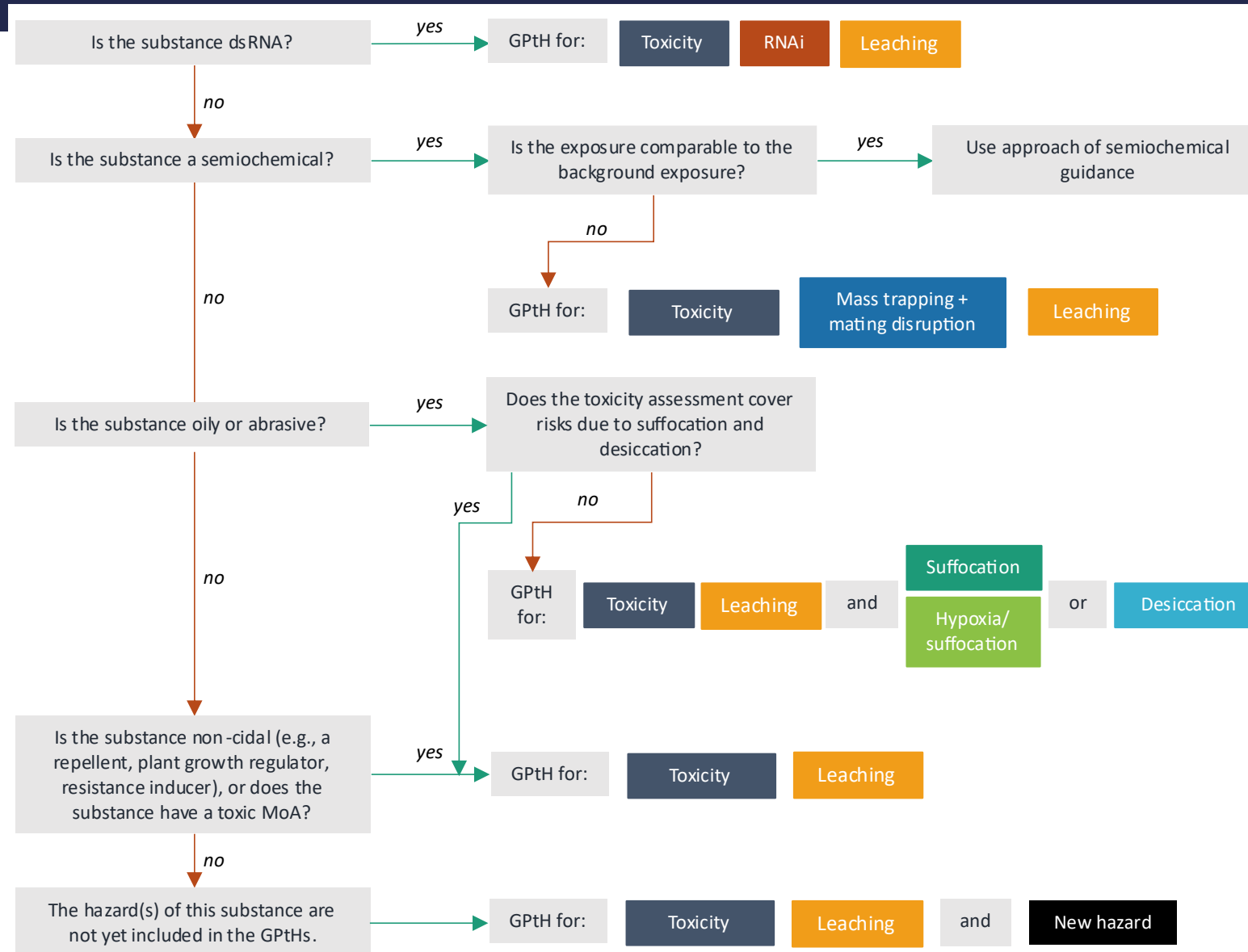
<sup>6</sup>Hellenic Agricultural Organization – Demeter

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



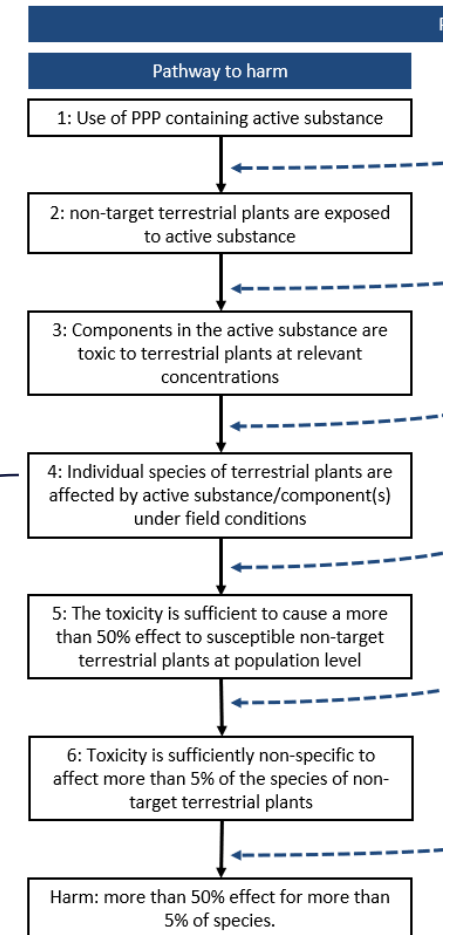
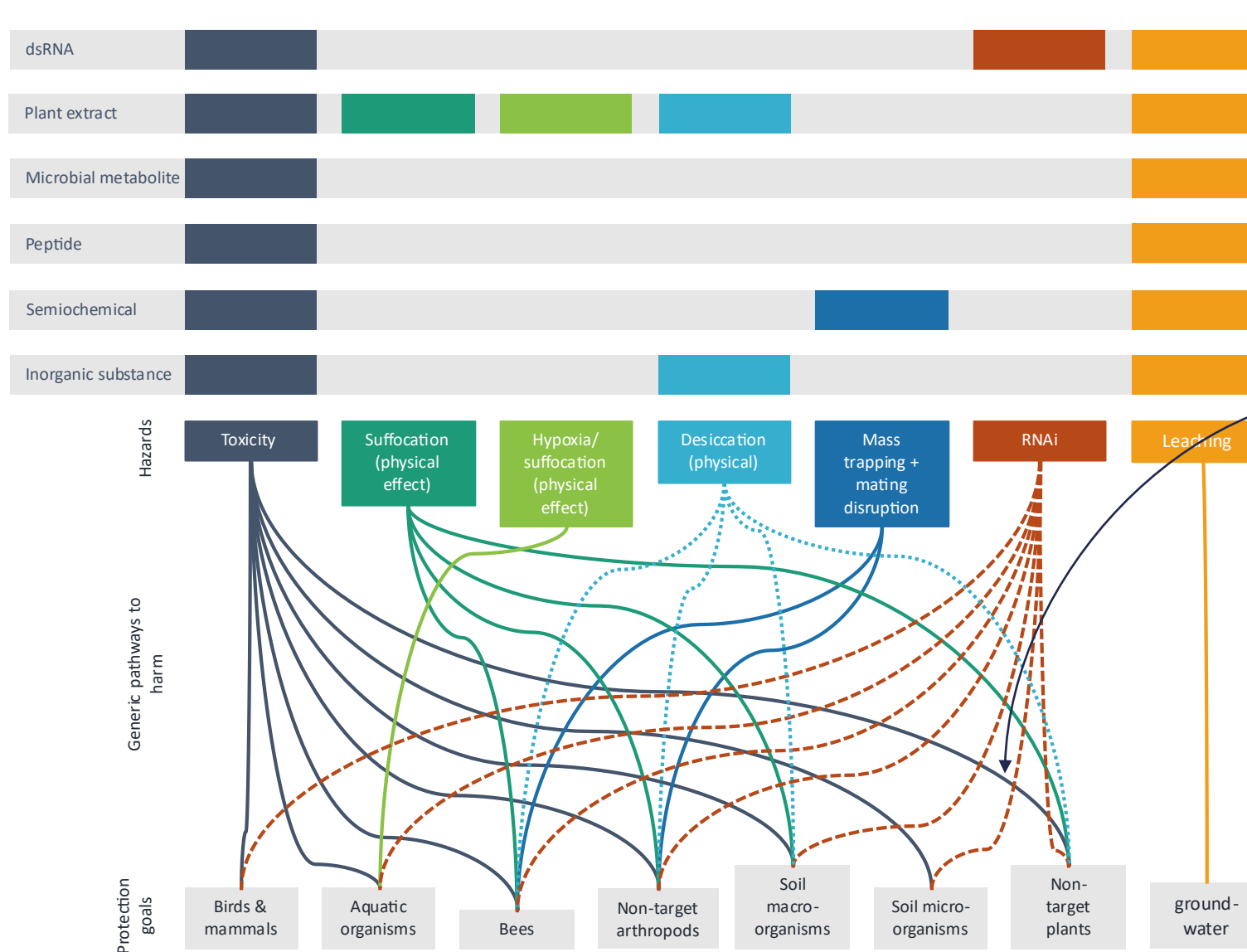
# WHICH HAZARDS SHOULD BE CONSIDERED ?

Identify the hazards



# PTH FOR EACH COMBINATION OF HAZARD & PROTECTION GOAL

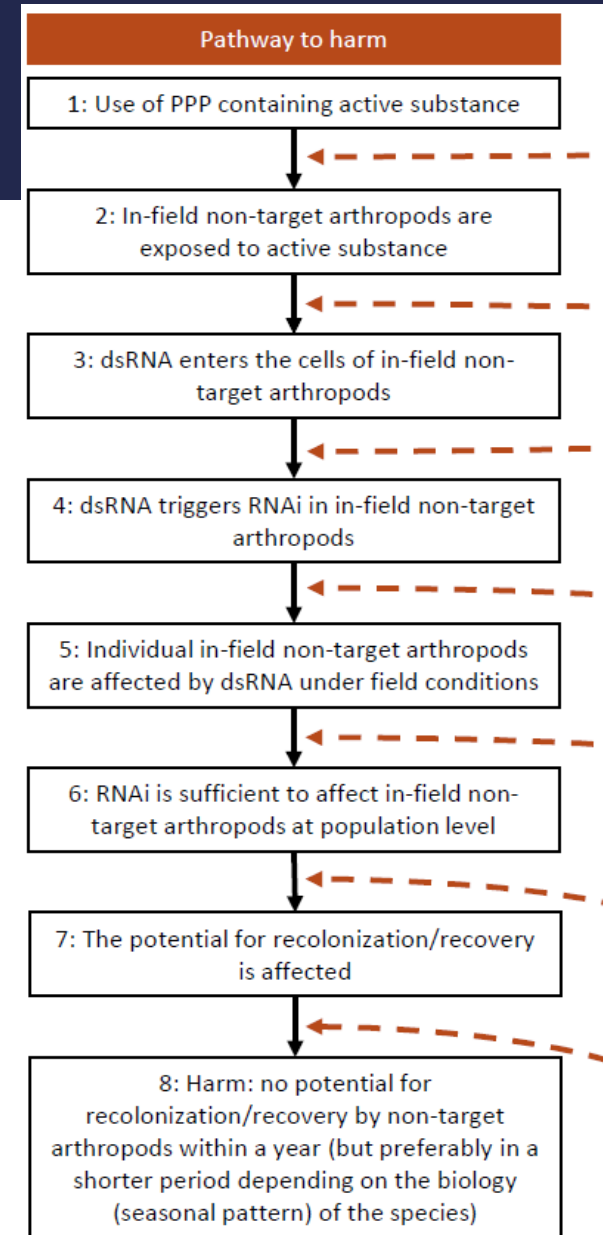
Identify the NTOs



One line = one generic Pth 7

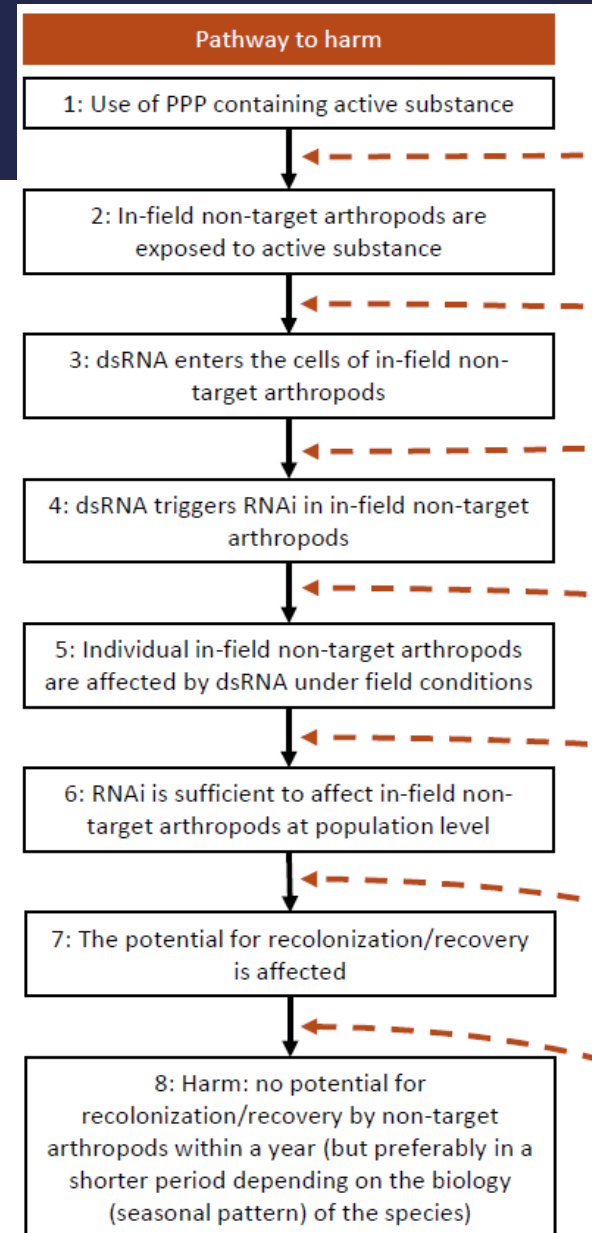
# CORE: THE GENERIC PTH

- 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

## GENERIC PATHWAY TO HARM FOR RNAi TO IN FIELD NON-TARGET ARTHROPODS OTHER THAN BEES

### Pathway to harm

### Analysis plan

1: Use of PPP containing active substance

Assess likelihood of exposure of arthropods.  
Determine if exposure is assumed for the proposed use (e.g., depending on the application method, field use vs use in permanent greenhouse; in case exposure scenarios for conventional PPP are appropriate, these can be used to determine if no exposure is assumed).

2: In-field non-target arthropods are exposed to active substance

Assess likelihood of dsRNA entering cells of arthropods.  
- In general, both naked dsRNAs and, to a greater extent, formulated dsRNAs are taken up by arthropods, provided they have a minimal size of 60 bp.

3: dsRNA enters the cells of in-field non-target arthropods

Assess likelihood that the dsRNA triggers RNAi in arthropods.  
- In silico prediction of possible RNAi in arthropods: bioinformatic analysis search for sequence identity (at least 20 nt) between dsRNA and arthropod.

4: dsRNA triggers RNAi in in-field non-target arthropods

Assess likelihood of RNAi effects on individual arthropods:  
- Assessing occurrence of gene downregulation by methods such as RT-qPCR or transcriptomic sequencing.  
- Assessing effects using laboratory testing (e.g., LC50/LD50/EC50).

5: Individual in-field non-target arthropods are affected by dsRNA under field conditions

Assess likelihood of effects on populations of arthropods, using:  
- Information on effects from history of use & experimental data  
- Information on magnitude of effects of RNAi combined with predicted exposure (environmental concentrations – based on proposed use and including information on degradation rate)  
- Information on the fraction of the population that is affected (e.g., depending on life stage, differences in exposure levels)

6: RNAi is sufficient to affect in-field non-target arthropods at population level

Assess the likelihood of effects on the recolonization/recovery potential, using information on:  
- Application frequency  
- Dissipation of the active substance/components  
- Fraction of population affected

7: The potential for recolonization/recovery is affected

Assess the likelihood of insufficient colonization/recovery potential within a year for non-target arthropods, using information on:  
- Available time for recolonization/recovery  
- Inherent potential of population for recolonisation/recovery  
For all substances other than dsRNA or sRNA the likelihood of breaching the protection goal is negligible.

8: Harm: no potential for recolonization/recovery by non-target arthropods within a year (but preferably in a shorter period depending on the biology (seasonal pattern) of the species)

- 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 contain several options
- Reflects the best option available at that time : might evolved in time!

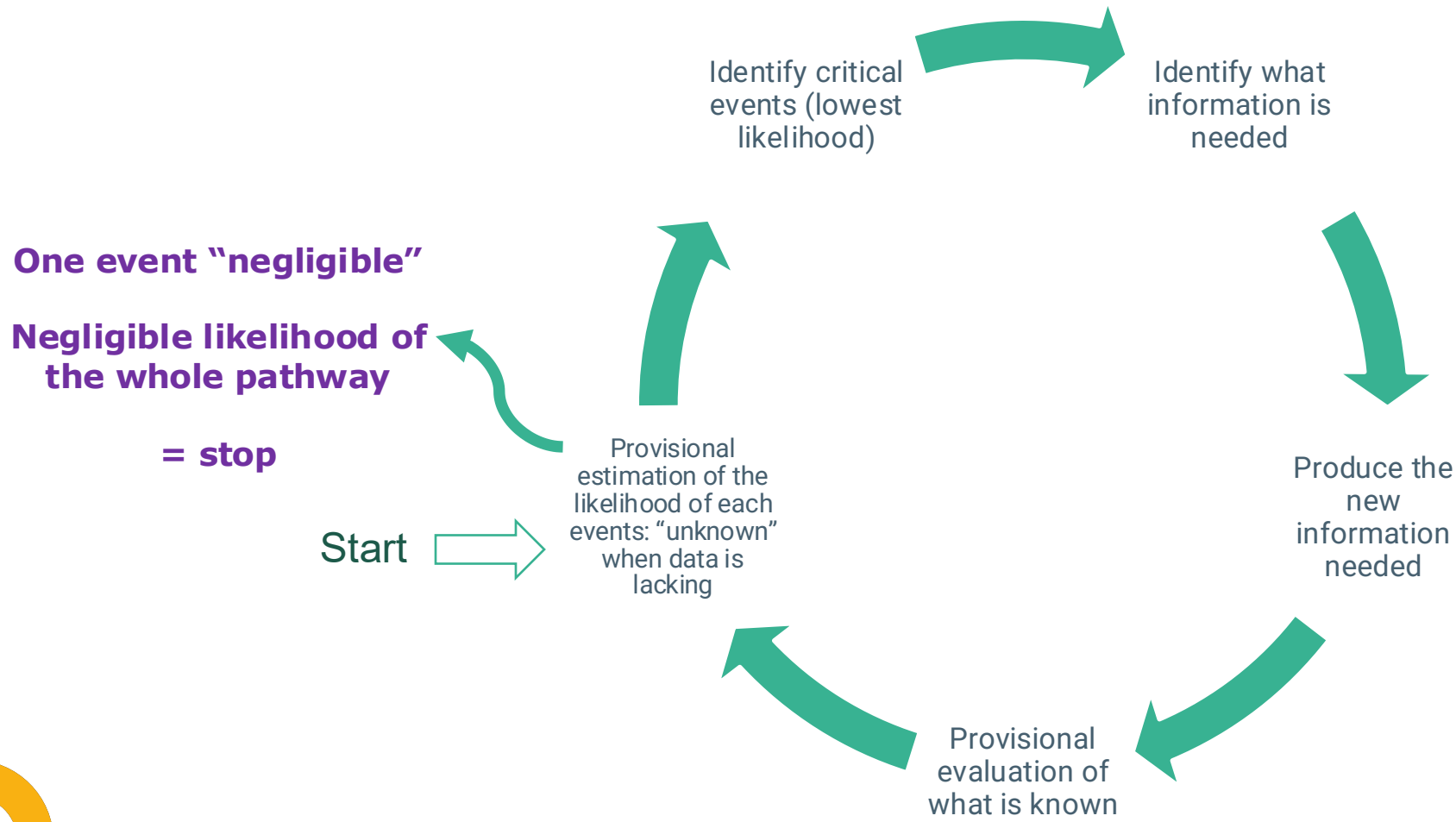


# LIKELIHOOD DESCRIPTORS

<b>Descriptor</b>	<b>Definition</b>	<b>Subjective probability range</b>
<b><i>Certain</i></b>	Is certain to occur.	100%
<b><i>Extremely likely</i></b>	Is expected to occur in almost all circumstances; almost certain.	95 – 100%
<b><i>Likely</i></b>	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%
<b><i>Unlikely</i></b>	May occur, but less probable than not.	10 – 33%
<b><i>Very unlikely</i></b>	Not expected to occur; may occur only in exceptional circumstances.	0 – 10%
<b><i>Negligible</i></b>	Likelihood not distinguishable from zero.	0%
<b><i>Unknown</i></b>	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



# STAY CONNECTED

## SUBSCRIBE TO

[efsa.europa.eu/en/news/newsletters](https://efsa.europa.eu/en/news/newsletters)

[efsa.europa.eu/en/rss](https://efsa.europa.eu/en/rss)

[Careers.efsa.europa.eu](https://careers.efsa.europa.eu) – job alerts



## FOLLOW US ON TWITTER

[@efsa\\_eu](https://twitter.com/efsa_eu)

[@methods\\_efsa](https://twitter.com/methods_efsa)

[@plants\\_efsa](https://twitter.com/plants_efsa)

[@animals\\_efsa](https://twitter.com/animals_efsa)



## FOLLOW US ON INSTAGRAM

[@one\\_healthenv\\_eu](https://www.instagram.com/one_healthenv_eu)



## LISTEN TO OUR PODCAST

Science on the Menu – Spotify, Apple Podcast and YouTube



## FOLLOW US ON LINKEDIN

[Linkedin.com/company/efsa](https://www.linkedin.com/company/efsa)



## CONTACT US

[efsa.europe.eu/en/contact/askefsa](https://efsa.europe.eu/en/contact/askefsa)

