Example of application to LCAS: case studies presentations

A botanical oily insecticide with physical mode of action

BACKGROUND INFORMATION

- One or more components found in plants and obtained via processing parts of this plant without intentionally altering/modifying these chemical components
- Botanical substances cover a range of mode of actions (toxic and physical)
- Non coherent physical properties: aqueous extracts, **plant oils**, volatile essential oils
- “Guidance Document on botanical active substances used in plant protection products” (SANCO/11470/2012– rev. 8 20 March 2014) stating they fall under the same EU regulatory frame works as the chemical plant protection products and the data requirements for chemicals in the current Commission Regulations 283/2013 and 284/2013.

BOTANICAL OILY INSECTICIDE WITH PHYSICAL MODE OF ACTION

- Physical mode of action:
  - Loss of functionality of the **protective layers** exposes the pests to loss of fluids, leading to their eventual demise.
  - Penetrates the **respiratory system** of insects, thus releasing the active ingredient internally, while at the same time inhibiting the entrance of air containing oxygen.

BOTANICAL OILY INSECTICIDE WITH PHYSICAL MODE OF ACTION

- Application: Foliar spray
- Efficacy on soft-bodied insects (on larva of insects, on mites, aphids, instars of thrips etc.) and eggs of insects.
- E-fate of oily substances:
  - low mobility
  - rapid degradation
  - low water solubility
- EcoTox:
  - Low toxicity of the active ingredient for Birds, Mammals, Bees (assessed with product only) and NTAs, but **many data gaps remain esp. for the physical Mode-of-Action**

GENERIC PBPGs FOR BOTANICAL PESTICIDE

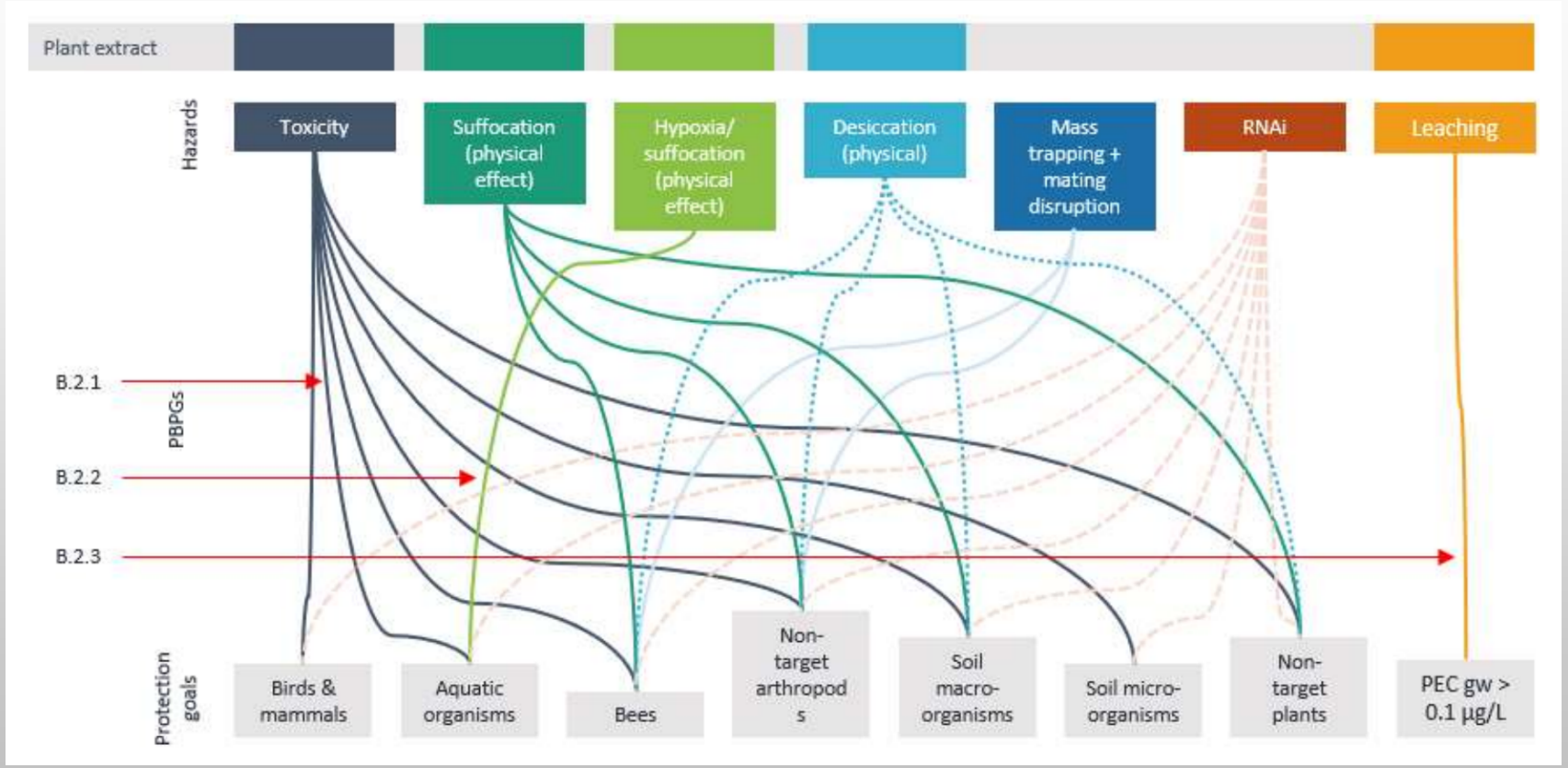

Figure 1: Overview figure of all PBPGs relevant for a botanical oil. In this case study we focus on 1) Toxicity to aquatic organisms, 2) Hypoxia/Suffocation of aquatic organisms, and 3) Leaching to groundwater.

PBPG FOR TOXICITY TO AQUATIC ORGANISMS

- Event 2: Highly **likely** that aquatic systems are *per se* exposed due to the representative use
- Event 3: Toxicity at relevant concentration **highly unlikely** based on available toxicity data
- Event 4: Exposure to active substance is **likely** due to absorbance to particles in the water
- Event 5 & 6: Toxicity at field conditions **highly unlikely** due to exposure conditions and available toxicity data
- Harm: **Negligible**

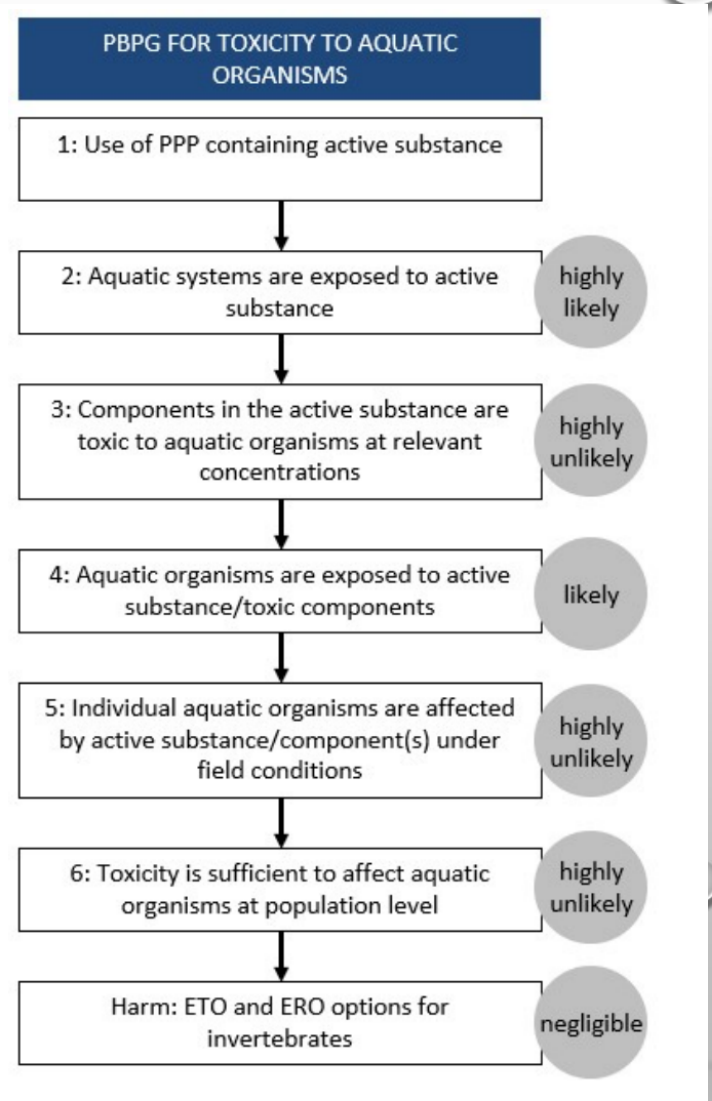

Figure 2. PBPG toxicity to aquatic organisms.

PBPG FOR HYPOXIA/SUFFOCATION OF AQUATIC ORGANISMS

- Event 2: Highly **likely** that aquatic systems are *per se* exposed due to the representative use
- Event 3: Formation of a layer of the active substance on top the the water is h**ighly likely** due to insoluble properties
- Event 4: An oil layer **likely** depletes oxygen in the underlying water column

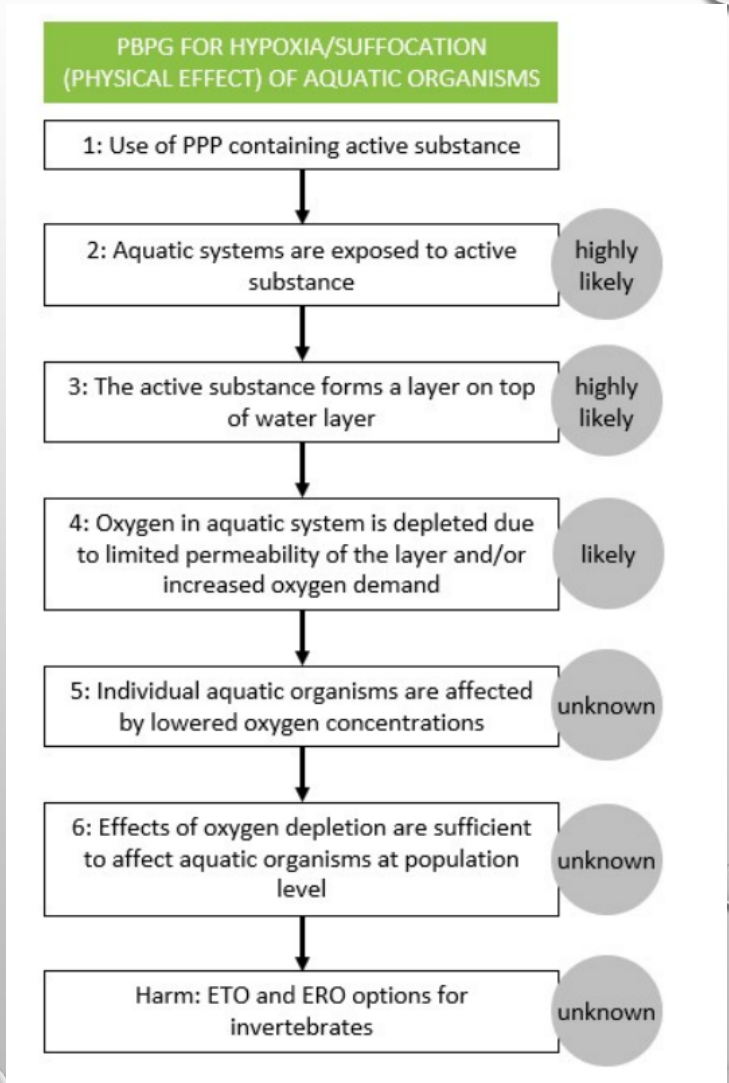

Figure 2. PBPG for hypoxia/ suffocation of aquatic organisms.

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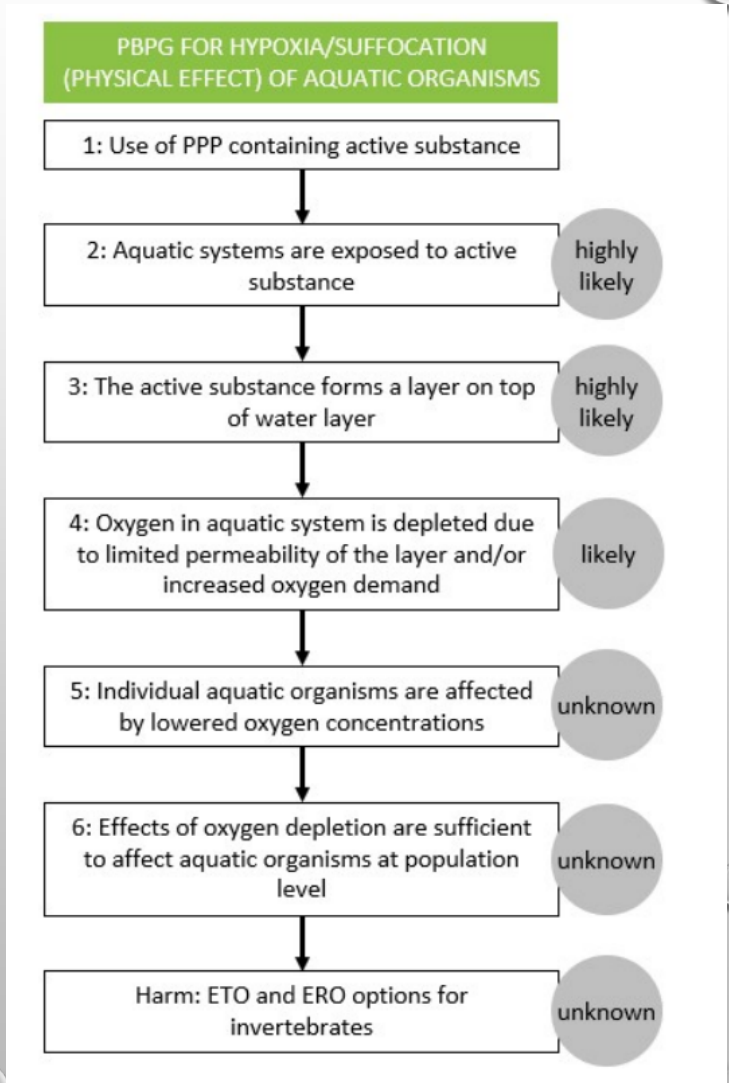
- Event 5: **Unknown**. Analysis plan required



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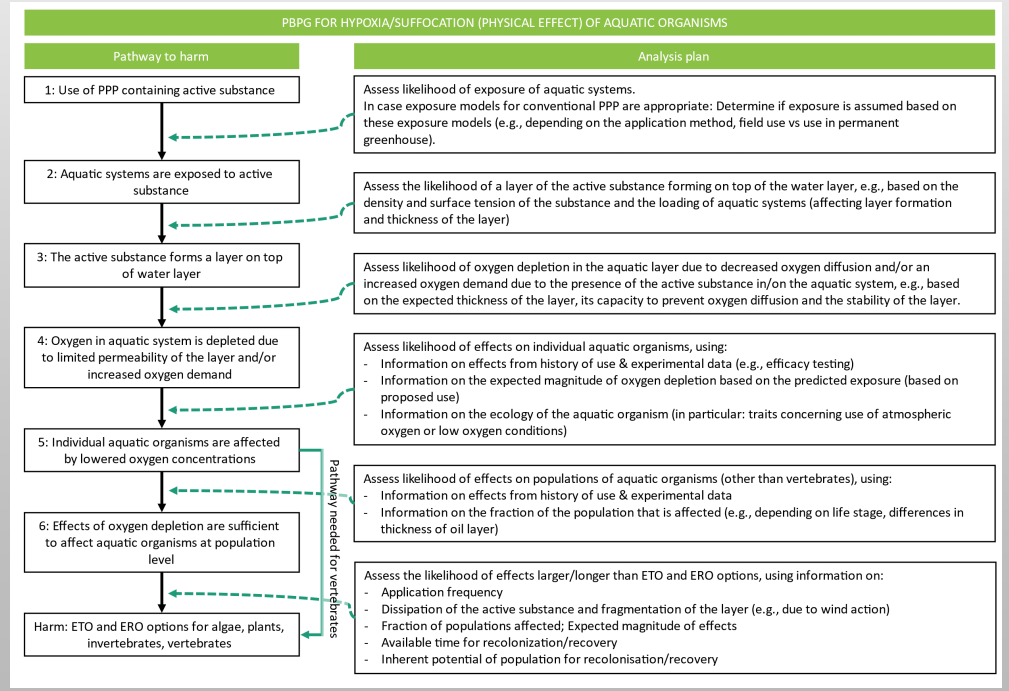

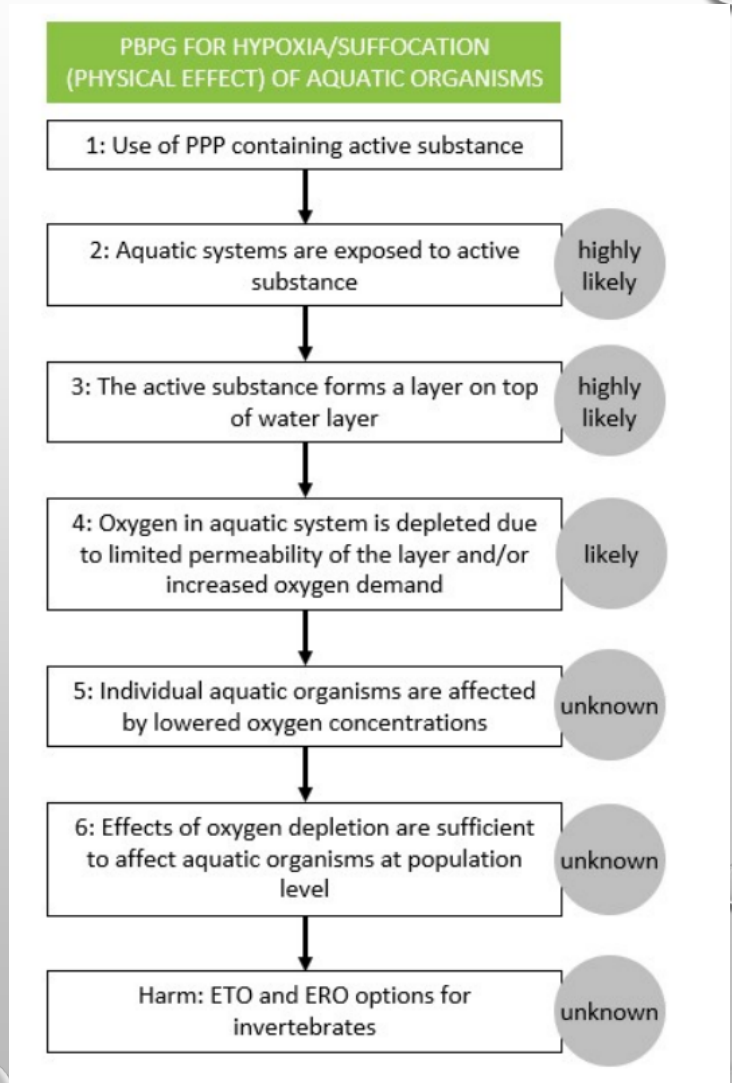

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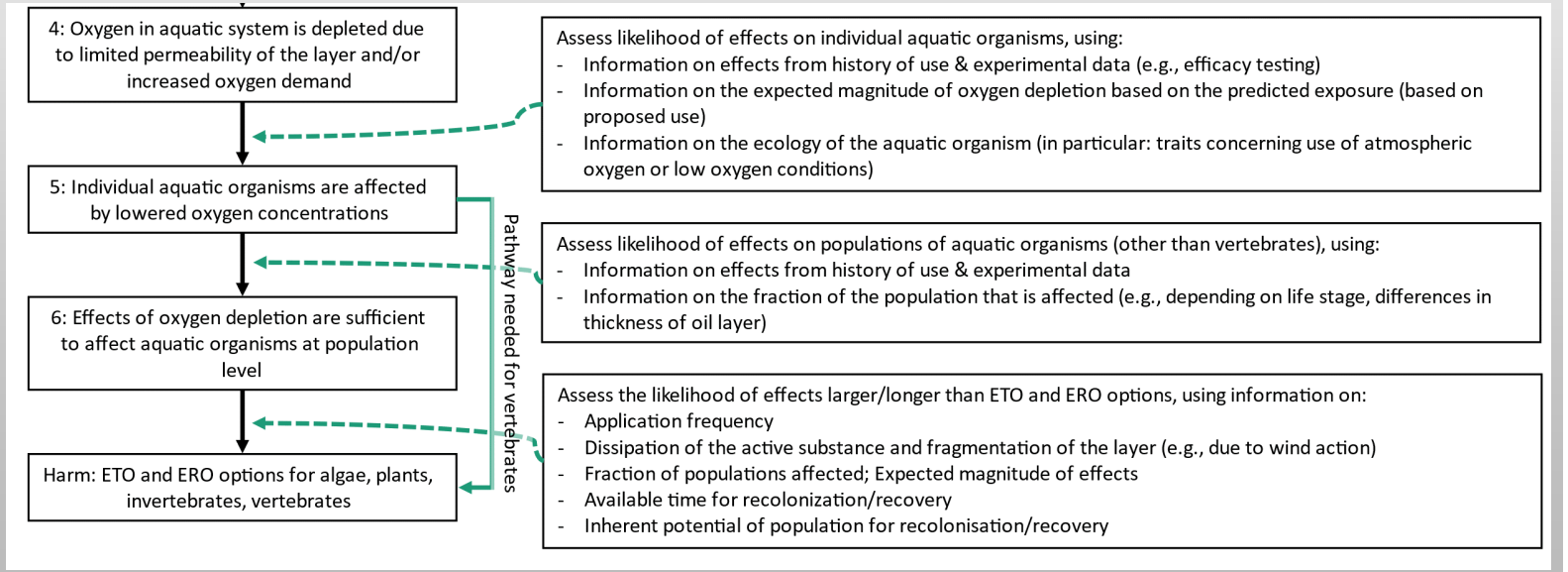
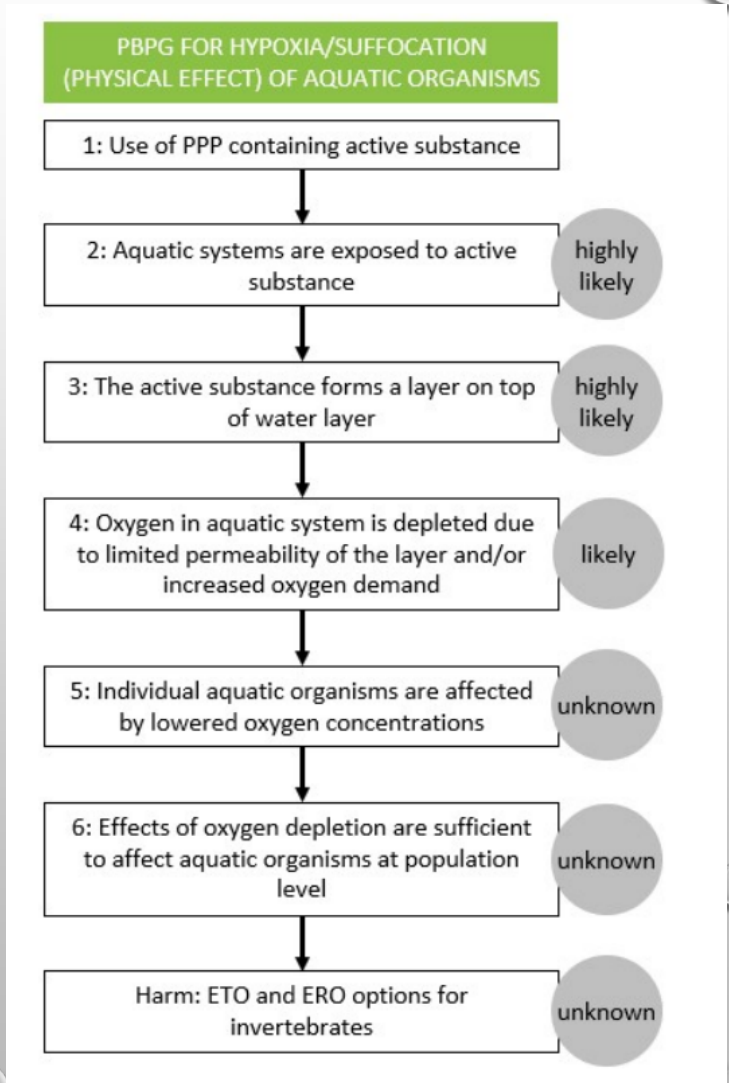


Figure 3. Analysis plant for PBPG for hypoxia/ suffocation of aquatic organisms.



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- Event 5: **Unknown**. Analysis plan required
- Event 6: **Unknown**. Analysis plan required
- Harm: **Unknown.**

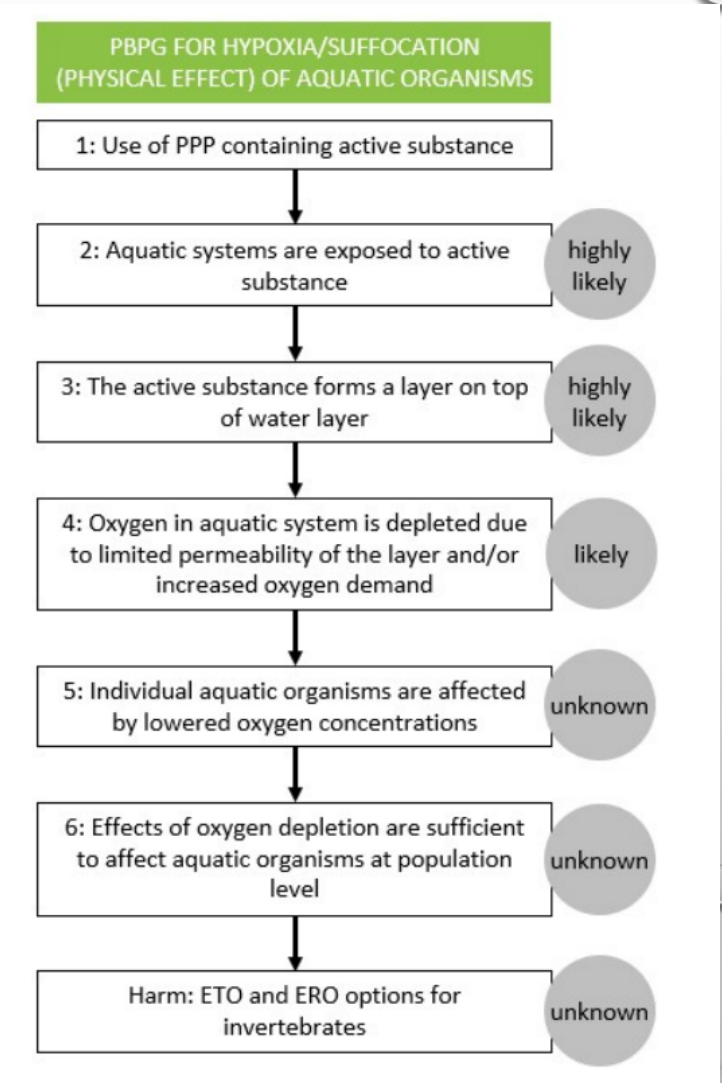

Figure 2. PBPG for hypoxia/ suffocation of aquatic organisms.

PBPG FOR LEACHING TO GROUNDWATER

- Event 2: Soil exposure **highly likely** due to representative use
- Event 3a: **Negligible** due to immobility, high absorption and poor solubility.
- Event 3b: **Highly likely** to form more mobile degradation products
- Harm: **Negligible** due to immobility (Event 3a) resp. **not relevant** (Event 3b) due to food grade quality of the botanical oil.

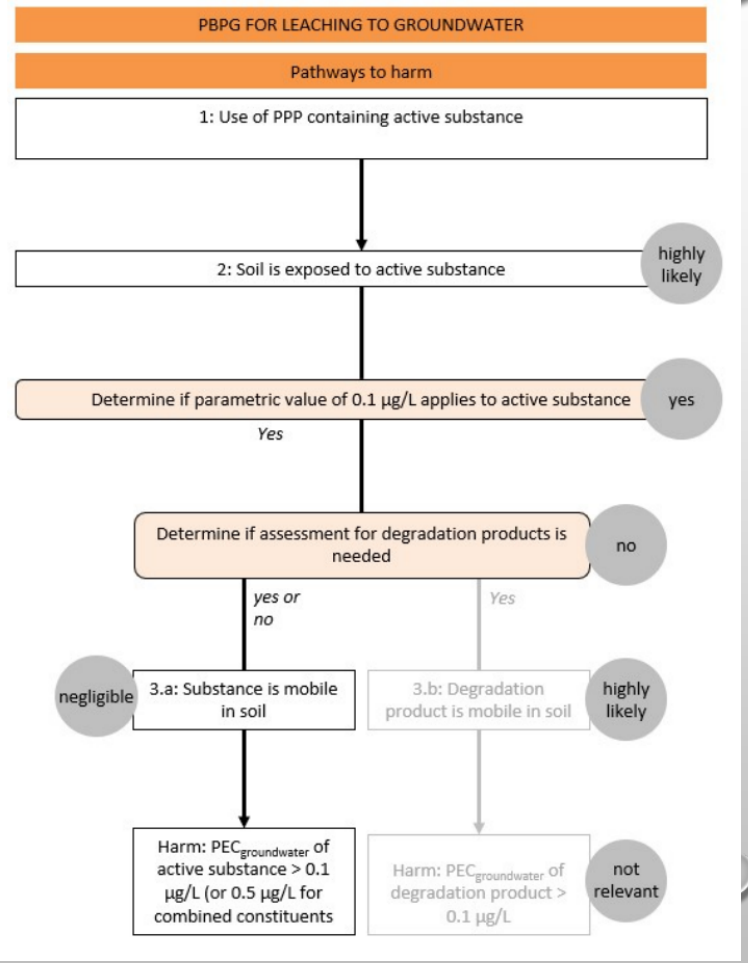

Figure 4. PBPG for leaching to groundwater.

CONCLUSIONS AND FUTURE PROSPECTS

- Botanical active substances require assessment of several PBPGs (toxic and physical effects)
- Currently no guideline exists for the physical effects. There is the need to develop adequate low- and higher tier testing protocols and models for oily substances.
- PBPGs can limit data required *a priori*, e.g. for leaching to groundwater or E-fate in soil
- PBPGs can be used to waive requirement of irrelevant data while highlight the requirement of additional data at the same time, e.g. for suffocation/hypoxia of aquatic organisms.

- The PBPG approach **structures** assessment of botanical substances accounting for their varying physicochemical properties

PBPG FOR SUFFOCATION OF BEES

- Event 2: The active substance spreads **likely** over the body of the NTO due to surface tension
- Event 3: Application **likely** takes place during flowering season when bees are present in orchards
- Event 4: Susceptibility of adult bees currently **unknown** due to differences in tracheal system compared to larvae and other NTAs
- Event 5: **Unknown**
- Event 6: **Unknown** due to data gap but could be extrapolated based on individual experimental data
- Harm: **Unknown** due to Event 4-6

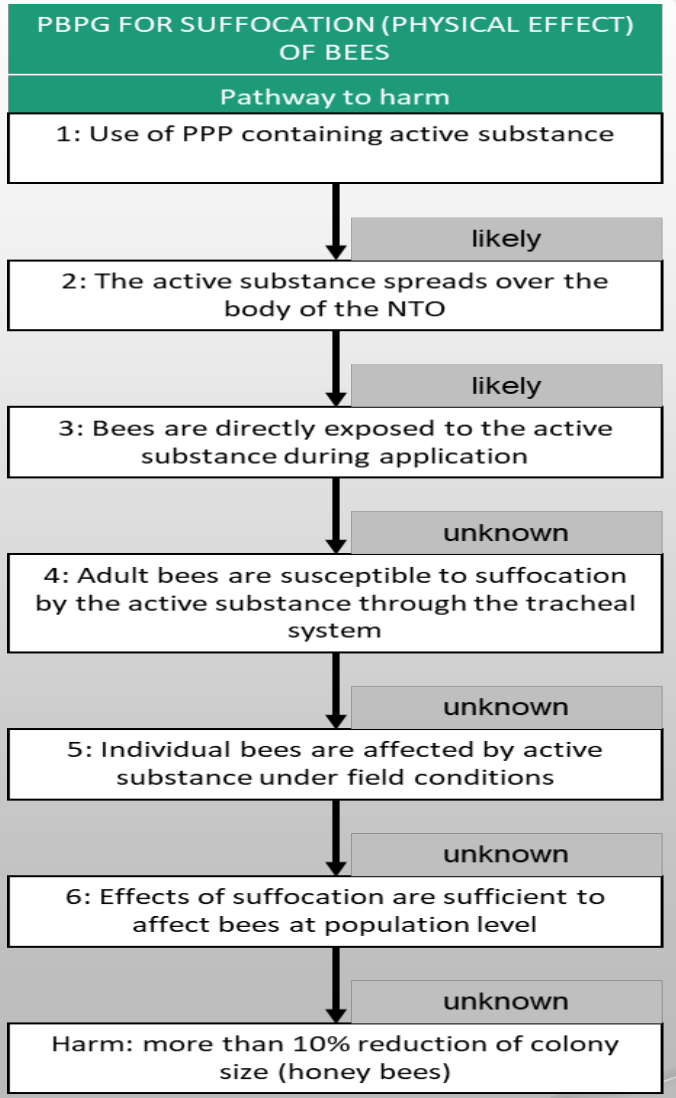

Figure 5. PBPG for suffocation of bees.

PBPG FOR SUFFOCATION OF EARTHWORMS

- Event 2: The active substance **likely** spreads over the body of the NTO due to surface tension
- Event 3: Direct exposure **unlikely** due to low mobility of active substance resulting in earthworms unlikely to come in contact with the active substance.
- Harm: **Unlikely** due to Event 3 and the rest of the PBPG can be skipped

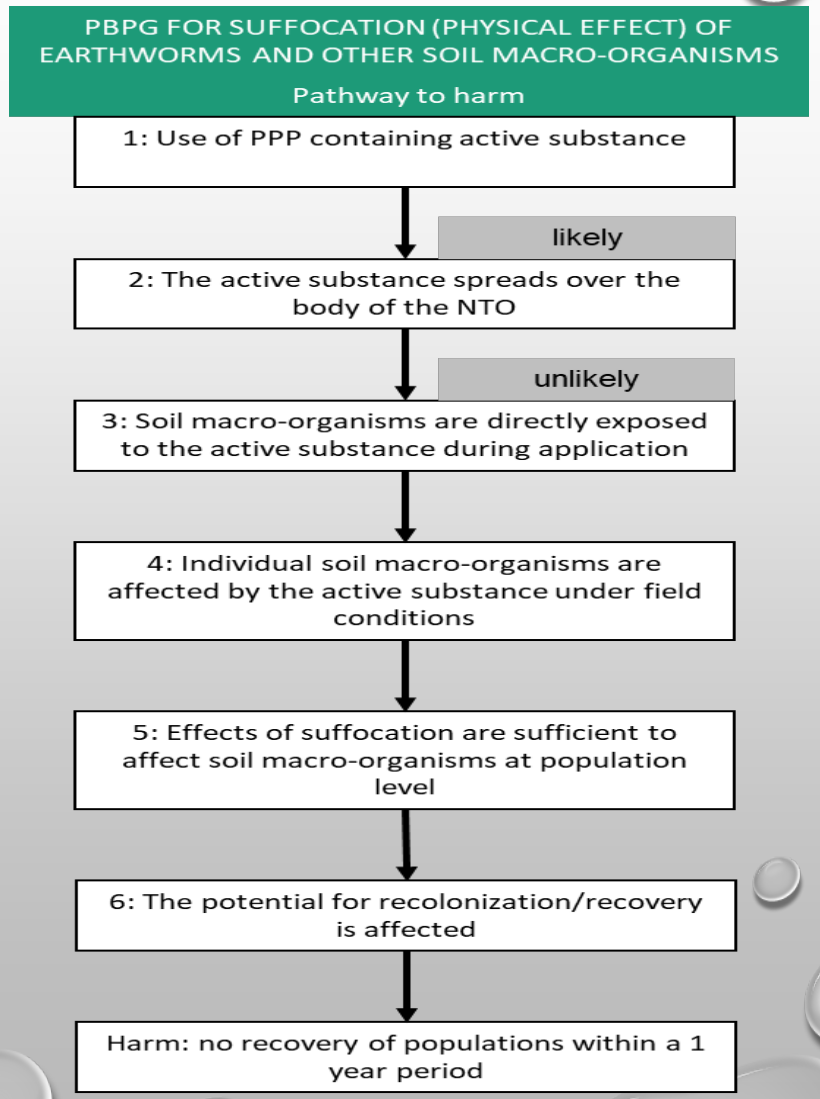

Figure 6. PBPG for suffocation of earthworms.