Background and context of the EFSA guidance for soil exposure and stakeholder involvement

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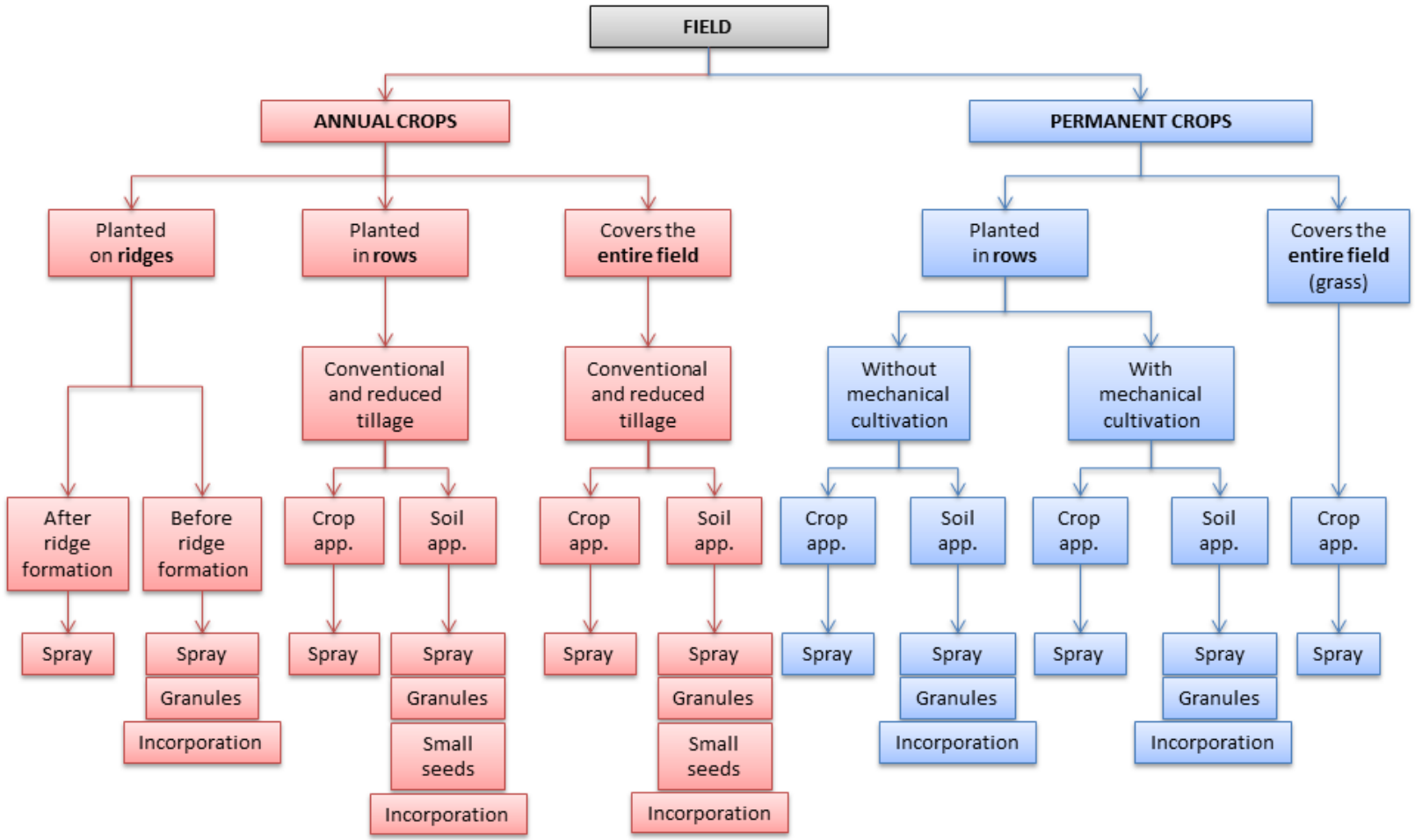
BACKGROUND FOR THE GUIDANCE

- The European Commission tasked EFSA to:
  - **Prepare an EFSA guidance on PECs in soil**
- Take into account
  - Science and methodology proposed by the PPR Panel
  - Different application techniques
  - Metabolites and transformation products
- Involve stakeholders
  - Public consultation and info sessions

MAIN FEATURES OF THE EXPOSURE ASSESSMENT

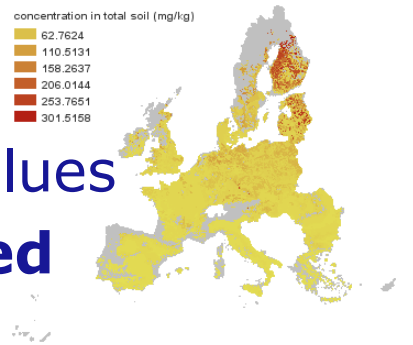
- Two types of **crops**
  - **Annual crops** including row crops (band, strip & spot applications) and crops grown on ridges
    - Ploughing each year to 20 cm, homogenous top soil
  - **Permanent crops** including grassland
    - No or some mechanical cultivation, organic matter gradient in top soil
- Different types of **application techniques**
  - Boom spraying to soil or crop canopy
  - Soil incorporation, granules and small seeds
  - Air assisted broadcast spraying in permanent crops
- Different types of in-field **exposure**
  - E.g. In-row areas vs. between-row areas

THE COMPLETE EXPOSURE ASSESSMENT



MAIN FEATURES OF THE EXPOSURE ASSESSMENT

- **Concentrations**
  - Total soil to be used in line with current procedure
- **Ecotoxicological averaging depths**
  - 5 cm to be used in line with current procedure
- Wide range of **time weighted average PEC values** (TWA)
  - 2 - 56 days
- **Exposure mapping** (Tier-2 and 3B only)
  - High resolution crop maps with calculated PEC/TWA values
  - First step towards **risk mapping** and **landscape based approaches** for compounds



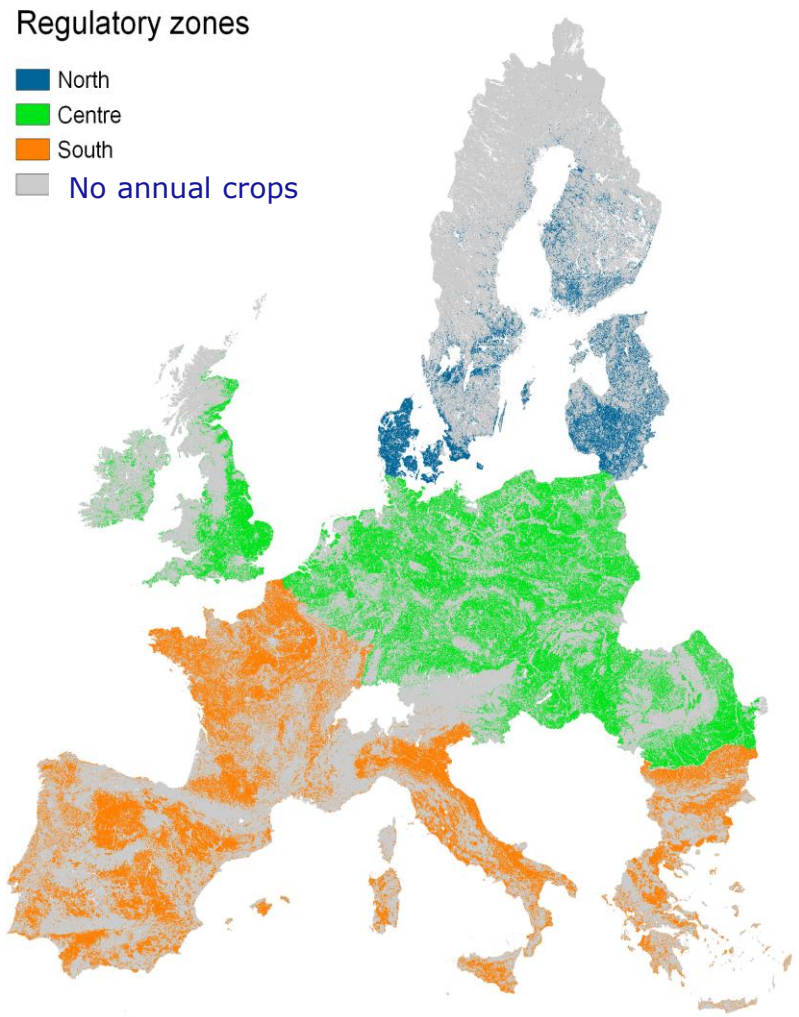
MAIN FEATURES OF THE EXPOSURE ASSESSMENT

- **Tiered approach**
  - 4 levels with increasing realism from lower to higher tier
  - Tier-1 to Tier-3 supported by user friendly software (PERSAM, PEARL & PELMO)
- **Wash-off from crop canopy**
  - Predefined default wash-off at lower tiers
  - Scenario specific wash-off at higher tiers calculated by model
- **Substance properties**
  - **Consistent with ground water and surface water exposure assessment including metabolite parameters**
  - Soil depending substance properties (e.g. *p*H dependent sorption)

THE EXPOSURE ASSESSMENT GOAL

- The exposure concentration should not exceed the regulatory acceptable concentration in **90 % of the area of intended use** of a pesticide in the **three regulatory zones**

- The area of intended use is approximated by **the area of the crop** in which the pesticide is intended to be used



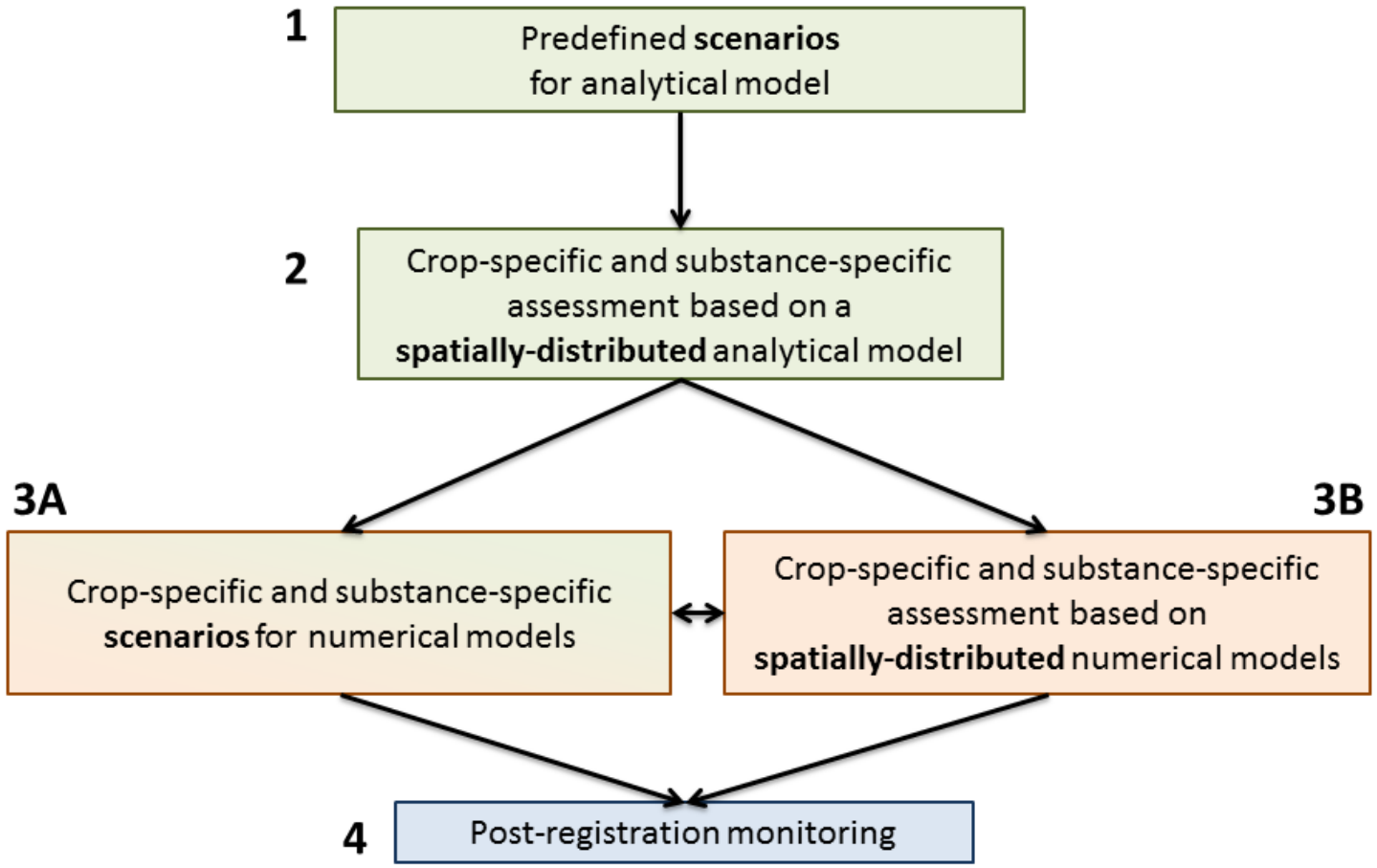
THE TIERED APPROACH

- All tiers aim at the same exposure assessment goal
- Higher tiers are less conservative but require more effort
- Two major routes of refinement
  - Refinement of **processes**
  - Refinement of **spatial detail**
- All tiers are modelling tiers, except Tier-4, which consists of post-registration monitoring
- Strong focus on consistency
  → **not necessary to include different tiers in regulatory submissions**

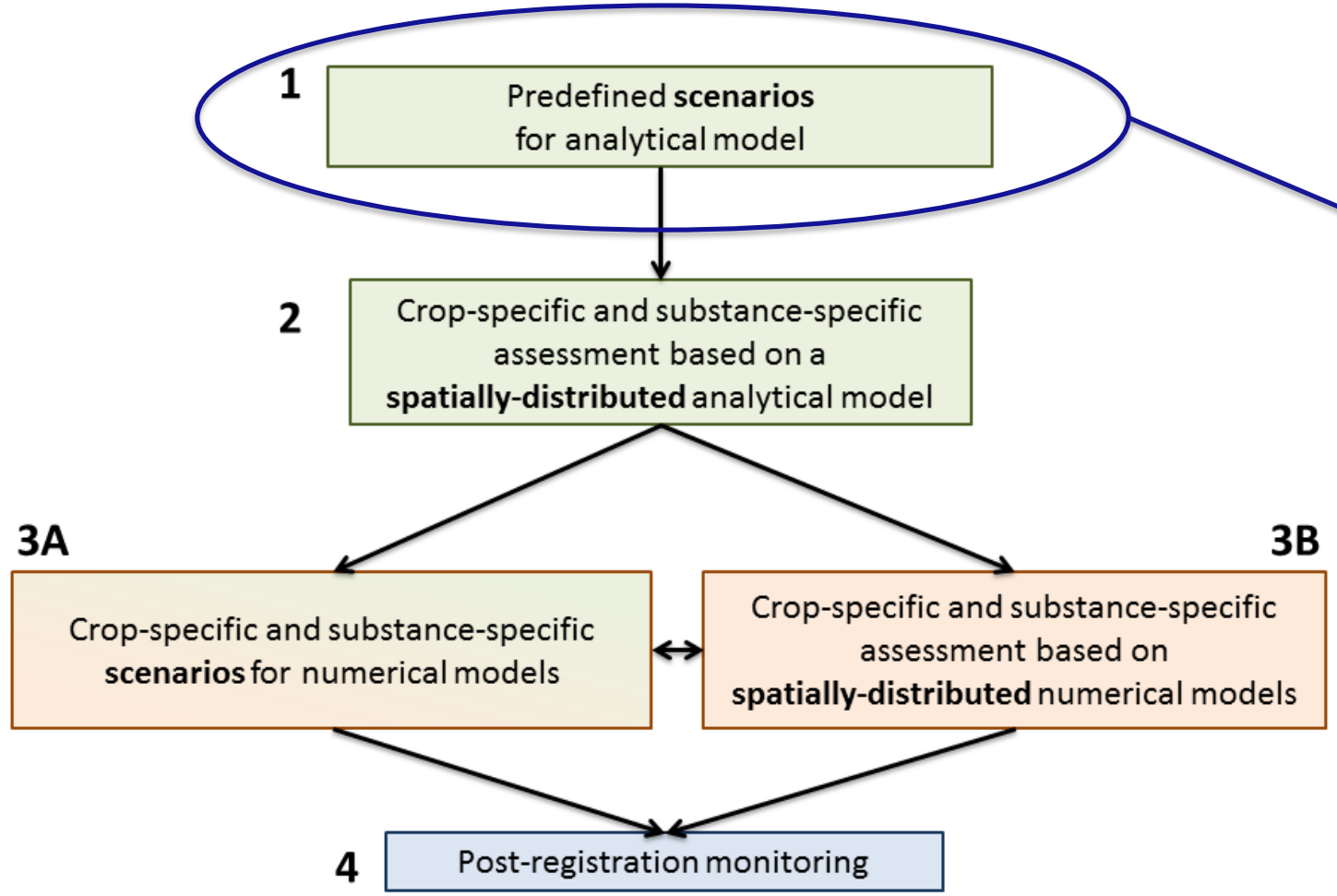
MODELS SUPPORTING THE GUIDANCE

- Currently three models have been updated to support the guidance
  - **PERSAM:** EFSA soil exposure software developed under procurement with contractor for PECs at Tier 1 and Tier 2 and for scenario selection at Tier 3A
  - **PEARL and PELMO:** Groundwater models updated also to be able to be used for soil PECs at higher tier (Tier 3A)
  - All models are in final testing phase
    - PERSAM is being tested through EFSA WG and EFSA
    - PEARL and PELMO were submitted into FOCUS version control

THE TIERED APPROACH



THE TIERED APPROACH

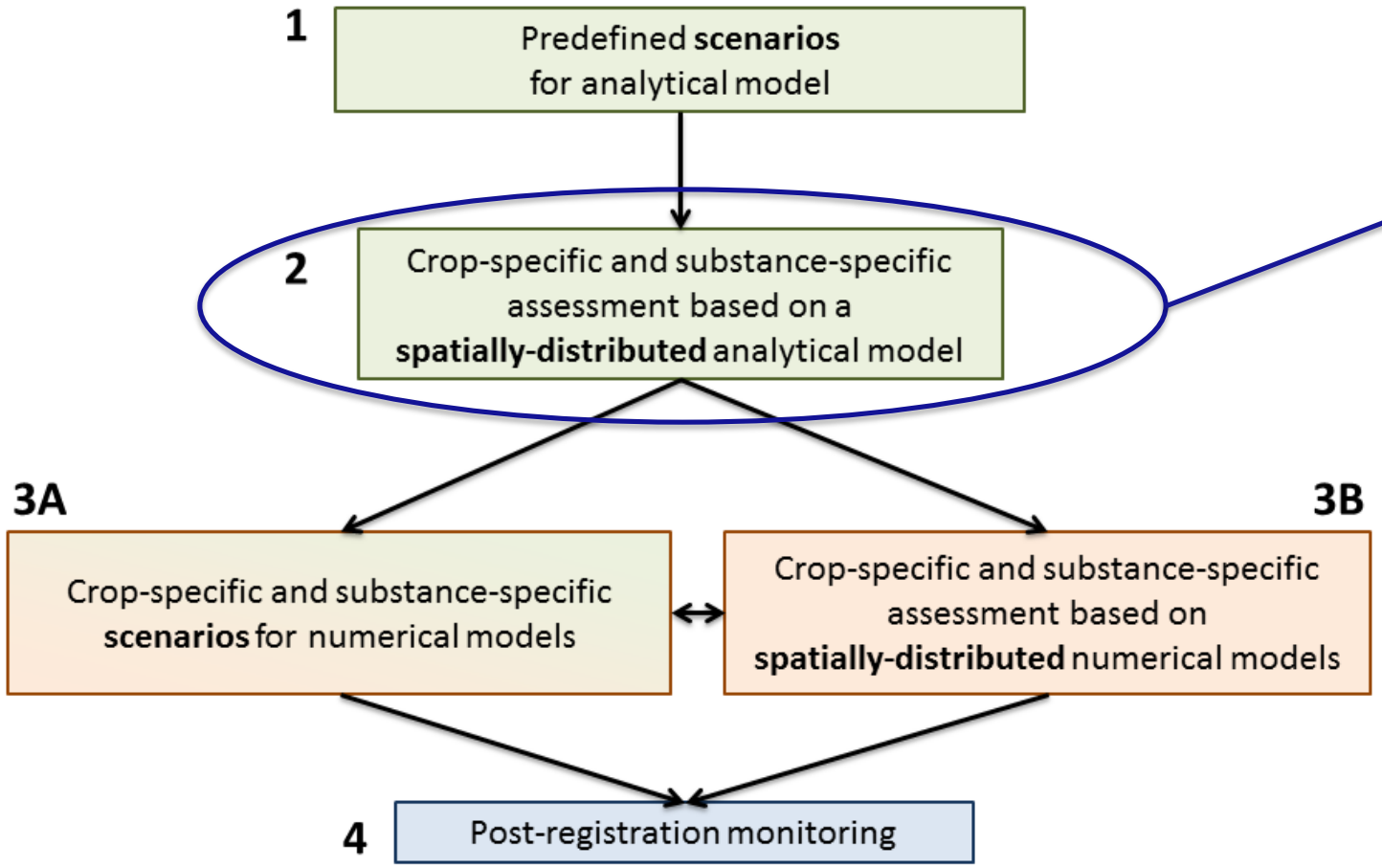


Tier-1:

- PERSAM
- 3 predefined scenarios (TC)
- Crop-independent
- No crop canopy processes

Fast screening tool

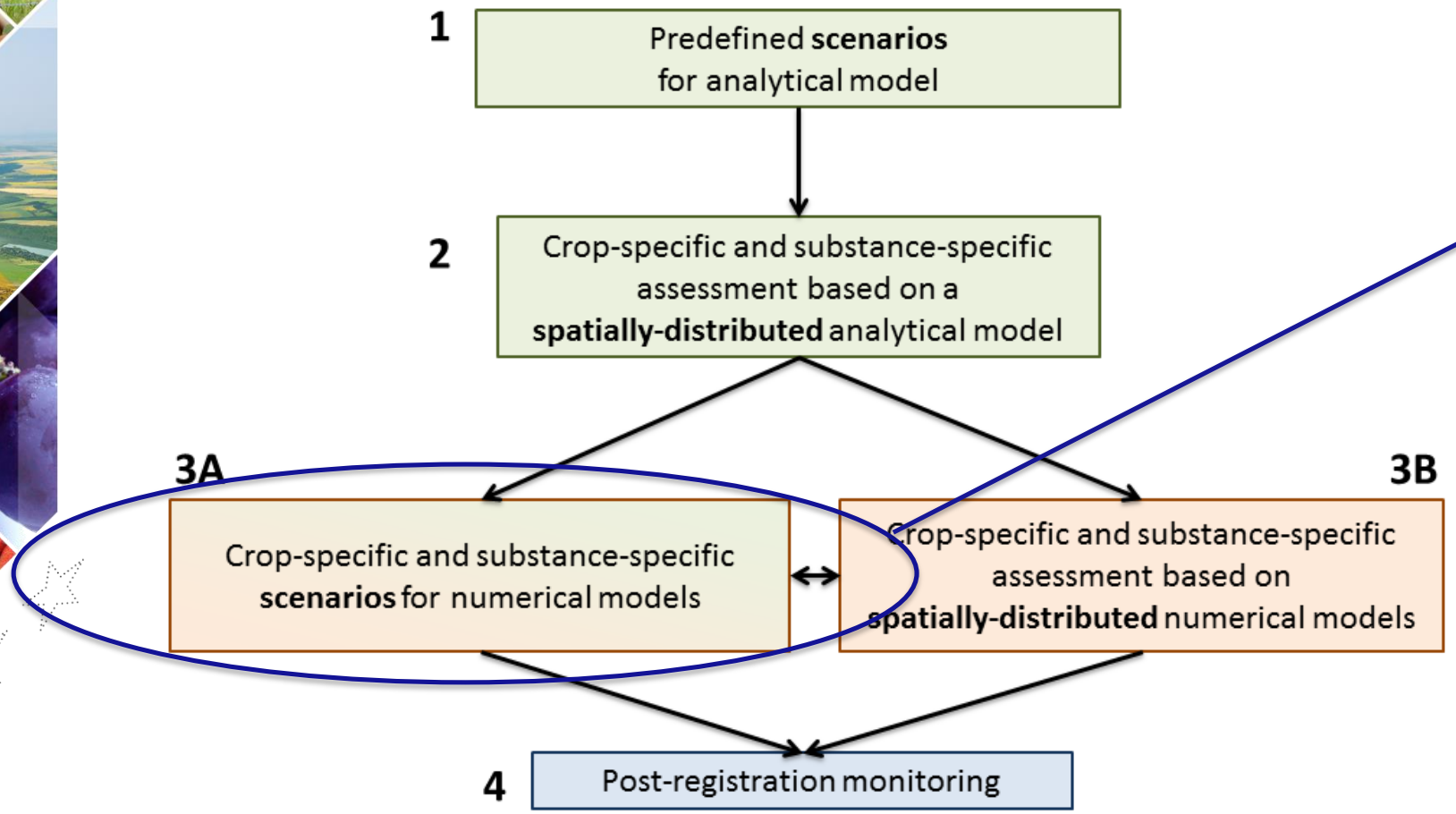
THE TIERED APPROACH



Tier-2:

- PERSAM
- Crop specific scenarios
- Canopy processes included (default wash-off)

THE TIERED APPROACH



Tier-3A:

- PERSAM + PEARL/PELMO
- Crop specific scenarios
- Canopy processes included (modelled wash-off)

FEATURES OF EXPOSURE ASSESSMENT

- Until new effect guidance is available,
  - the **ecotoxicological averaging depth remains 5 cm** and should be continued to be used in soil organism risk assessment
  - **pore water exposure concentrations not to be used in soil organism risk assessment**
    (pore water concentrations may be used as a surrogate for puddles → Birds & Mammals / bee risk assessment)

NEW VS. CURRENT EXPOSURE ASSESSMENT

- Factors leading to **higher PEC values**
  - Shift in bulk soil density to significantly lower values
  - Wash-off from crop canopy included
  - Adjustment factors needed at lower tiers (consistent tiered approach)
- Factors leading to **lower PEC values**
  - Leaching included at all tiers
  - Shift from worst-case *DissT50* to average *DegT50*
- **On average** new assessment (Tier-3A) more conservative for short living substances but less or similarly conservative for persistent substances
- Lower tiers (Tier-1 and 2) always more conservative

PUBLIC CONSULTATION: THE PROCESS

Interaction with stakeholders

- IRIS (EFSA/JRC) workshop at the start of the project
- The PPR Panel took considerations from this workshop into account when developing scientific opinions
- Based on two *fate* and one *in soil effect* PPR opinions EFSA developed a draft **GD PECs in soil for annual crops** (excluding permanent crops and crops grown on ridges)
  - 1st public consultation launched by July 2014
  - ~ 300 comments
- Draft GD published in April 2015

PUBLIC CONSULTATION: THE PROCESS

Interaction with stakeholders – cont.

- Update on draft GD amended with guidance on **permanent crops and crops grown on ridges**
  - 2nd public consultation on new approaches launched by July 2016
  - ~ 180 comments
- The WG gave responses to all comments (EFSA technical reports) and considered the comments for preparing the GD
- Final GD **published in October 2017**

ACKNOWLEDGEMENT

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