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Mutual recognition: crucial points for environment

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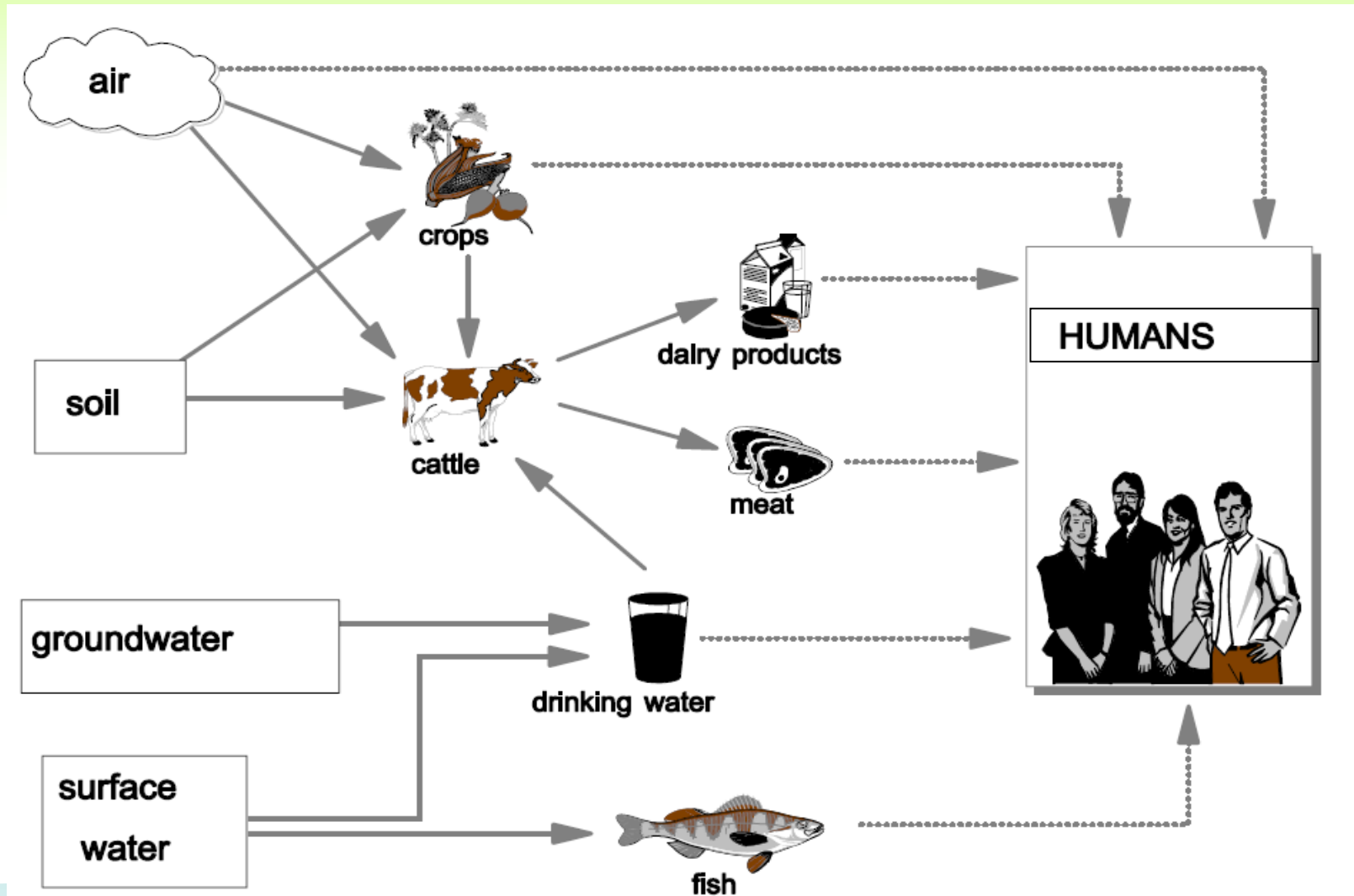
Centro Internazionale per gli Antiparassitari e la Prevenzione Sanitaria
International Centre for Pesticides and Health Risk Prevention (ICPS)



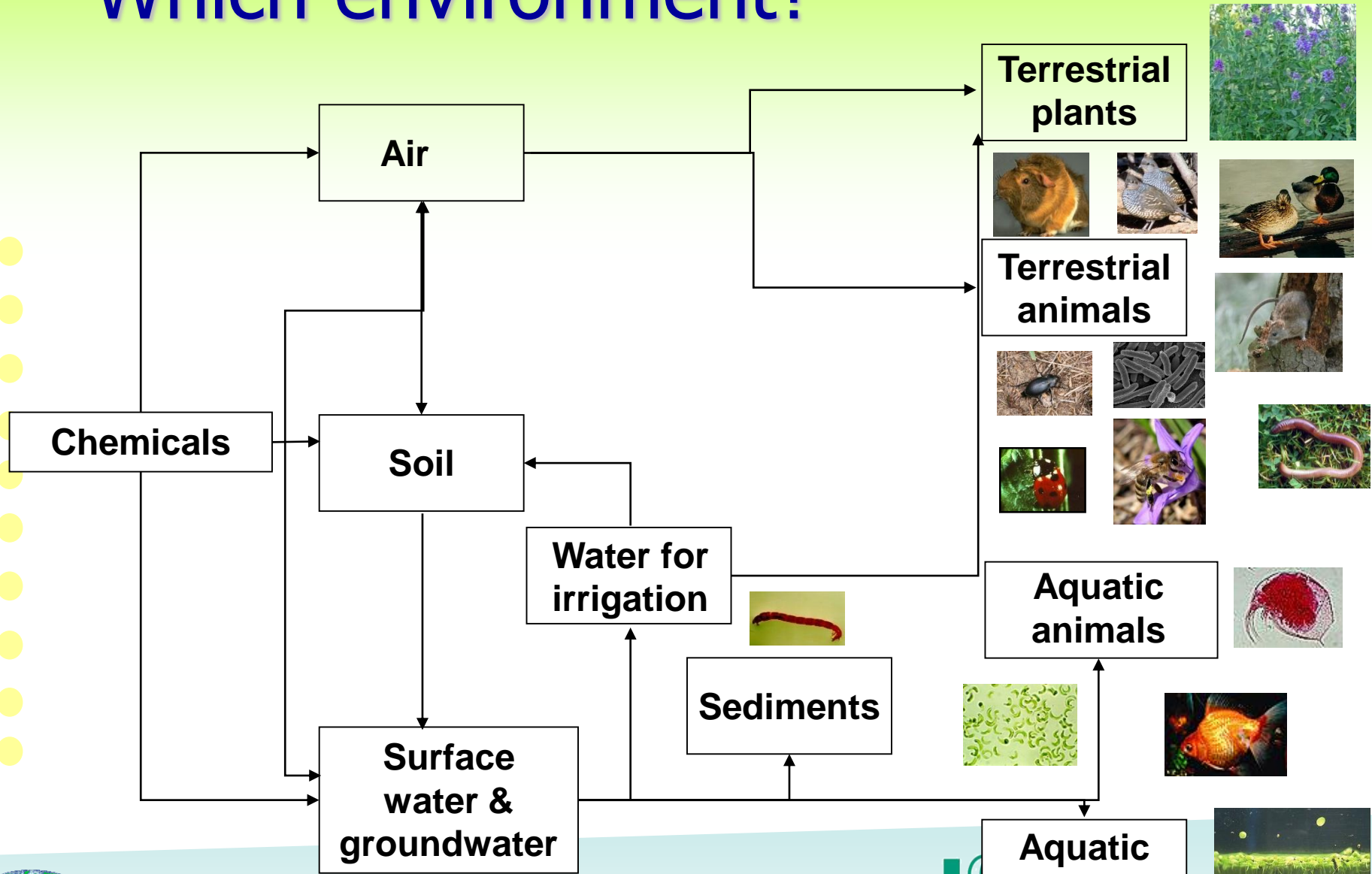
Ospedale Luigi Sacco
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Sistema sanitario Regione Lombardia

Why environmental fate of pesticides?



Which environment?



Mutual recognition and environment

- When a dossier is presented for mutual recognition
- ✘ Generally the major end-points of e-fate have already been evaluated at EU level (same as a.i.).
- ✘ New for e-fate: PEC in soil, groundwater and surface water. Evaluated by zRMS for the zone.
- ✘ New for ecotox: aquatic organisms (acute toxicity on fish, algae and daphnia), studies on bees and NTA. aquatic and terrestrial plants just for herbicides. Evaluated by zRMS

4



CRITICAL POINT FOR PEC

- ✗ Models to be used are the FOCUS ones, agreed at EU level
- ✗ Models are complex, therefore standard scenarios to represent agriculture in EU were defined
- ✗ Scenario: combination of data on crop, soil, climatic conditions representative of reasonable worst case conditions of agriculture in Europe.
- ✗ Generally applicants provides evaluations on all scenarios, but may be referred to a specific zone

5



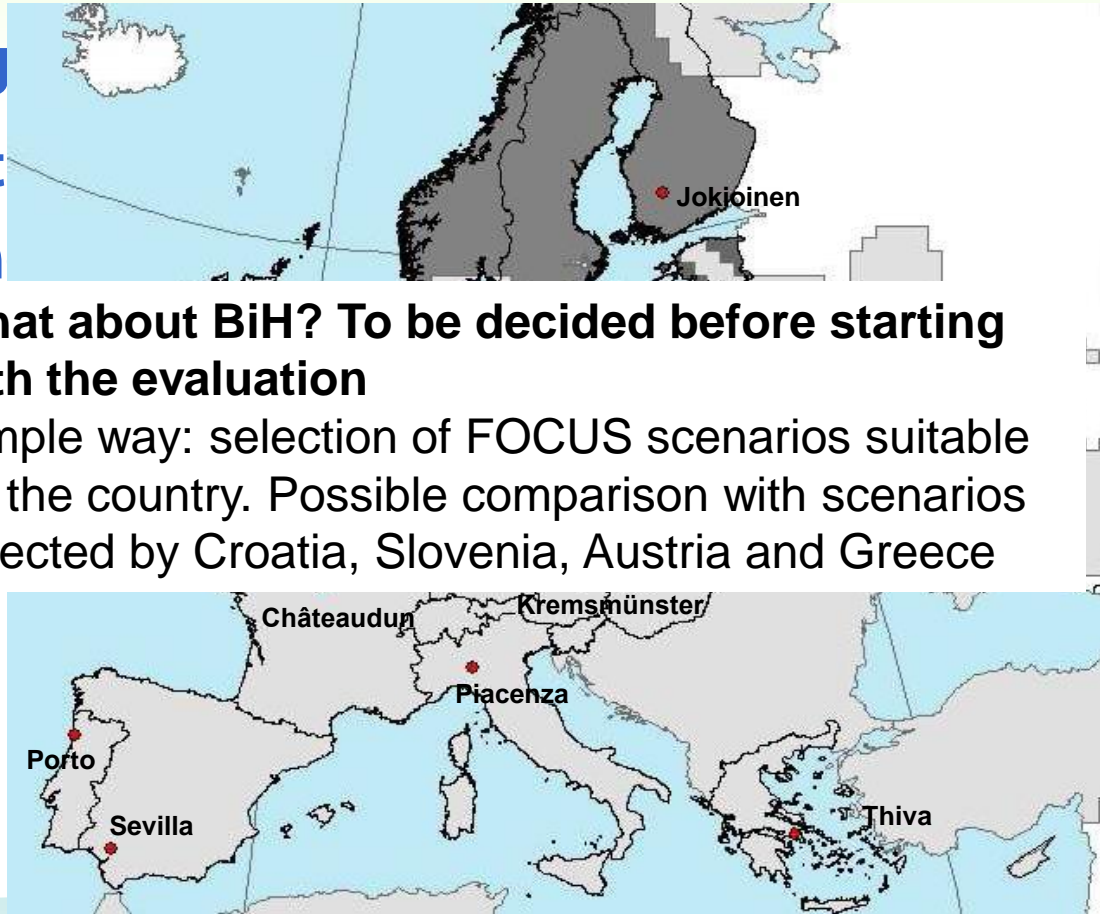
CRITICAL POINT FOR GW

- x 2 FOCUS
 - x Evaluat
 - x MS gen
- for th
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What about BiH? To be decided before starting with the evaluation

Simple way: selection of FOCUS scenarios suitable for the country. Possible comparison with scenarios selected by Croatia, Slovenia, Austria and Greece

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CRITICAL POINT FOR GW

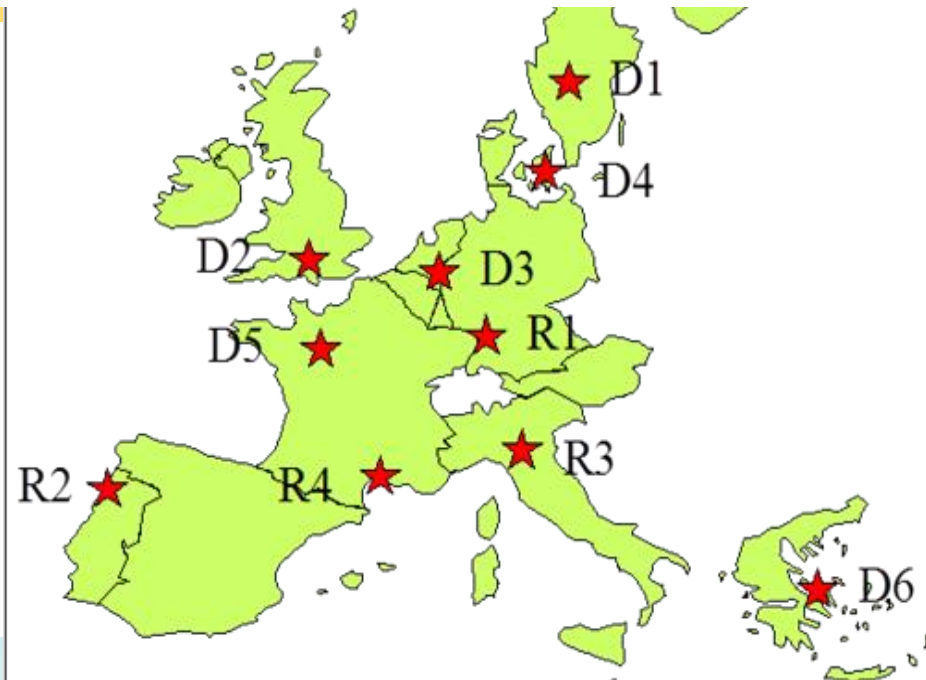
Metabolites

- ✗ Toxicologically relevant: $< 0.1 \mu\text{g/L}$
- ✗ Not relevant metabolites: trigger of $0.75 \mu\text{g/L}$
 - $\text{PEC}_{\text{gw}} < 0.75 \mu\text{g/L}$: OK
 - $\text{PEC}_{\text{gw}} > 0.75 \mu\text{g/L}$ to $10 \mu\text{g/L}$, refinement
- ✗ some MS consider $0.1 \mu\text{g/L}$ for all metabolites (relevant or not). Other consider $0.75 \mu\text{g/L}$, other $10 \mu\text{g/L}$.

What about BiH? Which trigger would you use? To be decided before starting with the evaluation

PEC surface water calculation

- ST** What about BiH? To be decided before starting with the evaluation
- MO** Simple way: selection of FOCUS scenarios suitable for the country.
- 10** Possible comparison with scenarios selected by Croatia, Slovenia, Austria and Greece. **To clear identify which contamination route have to be considered other than drift: runoff? Drainage? Both?**



PEC surface water mitigation

STEP 4: generally used to introduce mitigations to be reported in the label according Commission Regulation (EU) No 547/2011 of 8 June 2011.

**Which water bodies are to be protected?
To be defined before starting with the evaluation.**

All surface waters, whether natural or artificial, are to be considered relevant EXCEPT:

- ✗ **Overflow ditches: ditches running alongside cultivated fields for the collection of excess water.**
- ✗ **Irrigation reservoirs/outlets: Water sources intended only or the irrigation.**
- ✗ **•Perched aquifers: Water sources whose water level is at least one meter above the level of the crop treated.**



WHICH MITIGATION?

✗ Anti-drift nozzles? No spray zones?



✗ Vegetated buffer?



✗ Hedgerows?



✗ High technology?

