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Mutual recognition: critical points for environment

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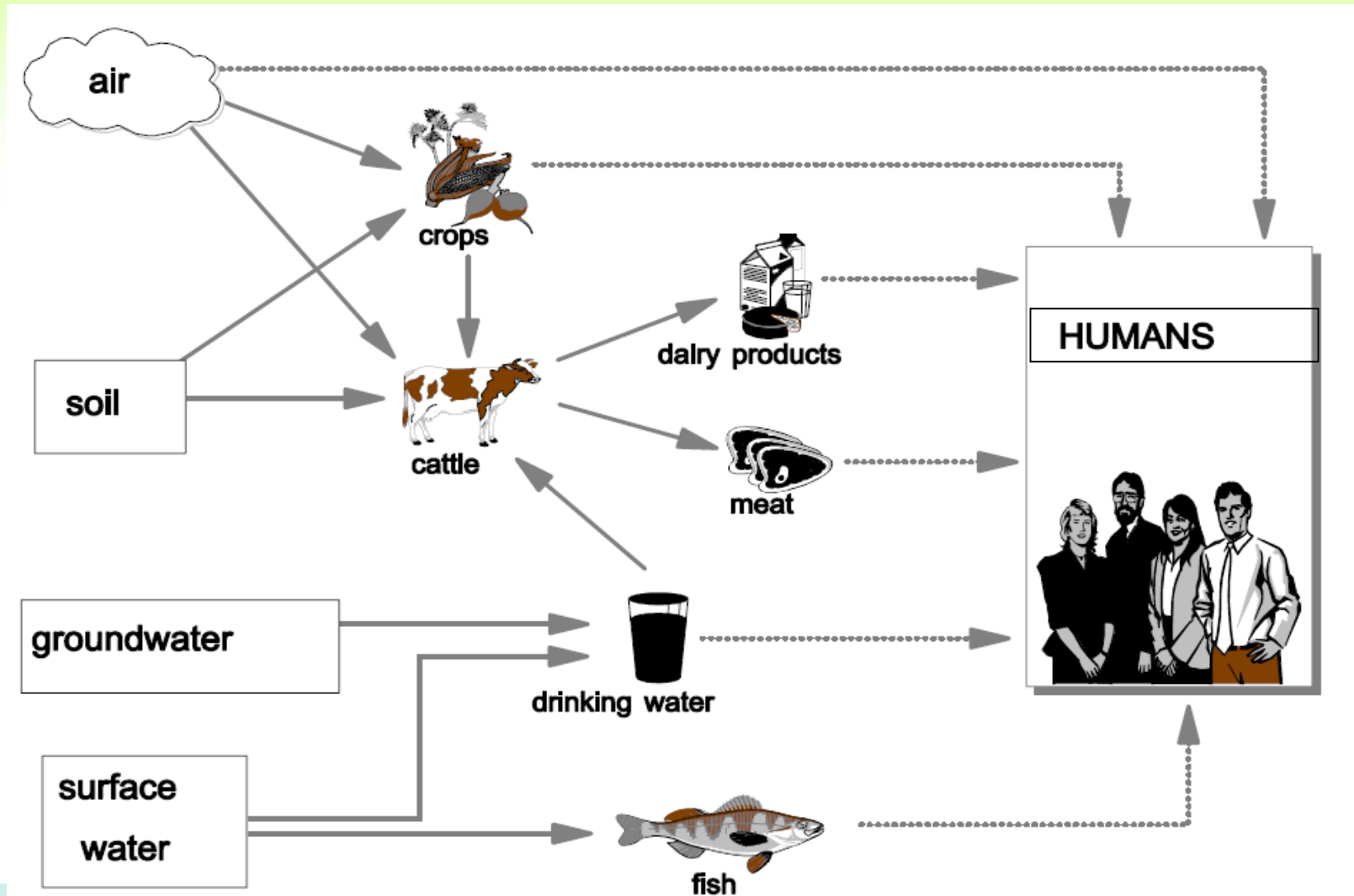
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International Centre for Pesticides and Health Risk Prevention (ICPS)



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Why environmental fate of pesticides?



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

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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

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CRITICAL POINT FOR GW

- x 2 FOCUS
 - x Evaluation
 - x MS gen
- for th
natic



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

relevant
own
water



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CRITICAL POINT FOR GW

✘ Active ingredient : trigger value is 0.1 µg/L

IF PEC_{gw} > 0.1 µg/L

✘ refined assessment with prejudice is required, or monitoring programme of 5 y at least

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CRITICAL POINT FOR GW

Metabolites

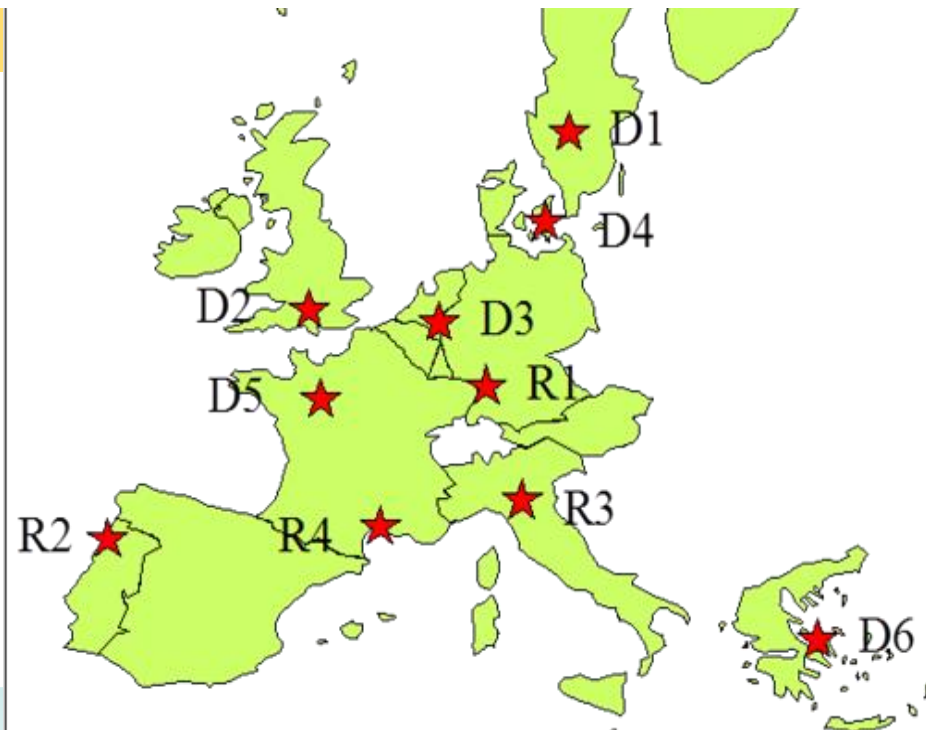
- ✗ Toxicologically relevant: $< 0.1 \mu\text{g/L}$
 - ✗ Not relevant metabolites: trigger of $0.75 \mu\text{g/L}$
 - $\text{PEC}_{\text{gw}} < 0.75 \mu\text{g/L}$: OK
 - $\text{PEC}_{\text{gw}} > 0.75 \mu\text{g/L}$ to $10 \mu\text{g/L}$, refinement
 - if NON-relevant metabolite is $> 10 \mu\text{g/L}$ → no authorisation shall be granted
 - ✗ 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
- | What about BiH? Which trigger would you use? To be decided before starting with the evaluation**

PEC surface water calculation

ST
mo
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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. **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?

