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Environmental assessment – introduction

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Objective of environmental assessment

- Assess whether the proposed uses of the pesticide to be registered pose an unacceptable risk to the environment.

  - pesticide -> simplified to active ingredient
  - proposed uses -> application pattern for registration
  - unacceptable risk -> criteria ?

    Political choice, not scientific choice

  - the environment -> what ? where ? how strict ?

Factors affecting the definition of registration criteria

- Legal requirements
  - other legislation setting standards (e.g. water quality, international conventions)
- Political and social support
  - importance given to environmental protection
- Agronomic conditions
  - condition of use; likelihood of Good Agricultural Practice
- Environmental conditions
  - specific national/regional situations, protected species

Environmental assessment – principles

Definitions (OECD, 2003)

- **Hazard –** Inherent property of an agent or situation having the potential to cause adverse effects when an organism, system or (sub) population is exposed to that agent.

- **Risk –** The probability of an adverse effect in an organism, system or (sub) population caused under specified circumstances by exposure to an agent.

➔ Evaluation of elements of the pesticide dossier, as well as the acceptability criteria, can be hazard-based or risk-based.

Environmental risk assessment – principles

- Hazard assessment → based on intrinsic properties of the pesticide, irrespective of exposure (dose) rate
- Risk assessment → based both on the properties of the pesticide and on exposure (dose) rate or probability

- Environmental risk assessment is preferred approach in pesticide registration, but requires locally relevant exposure estimates ("the dose makes the poison")

- Environmental hazard assessment is easier, but often overprotective

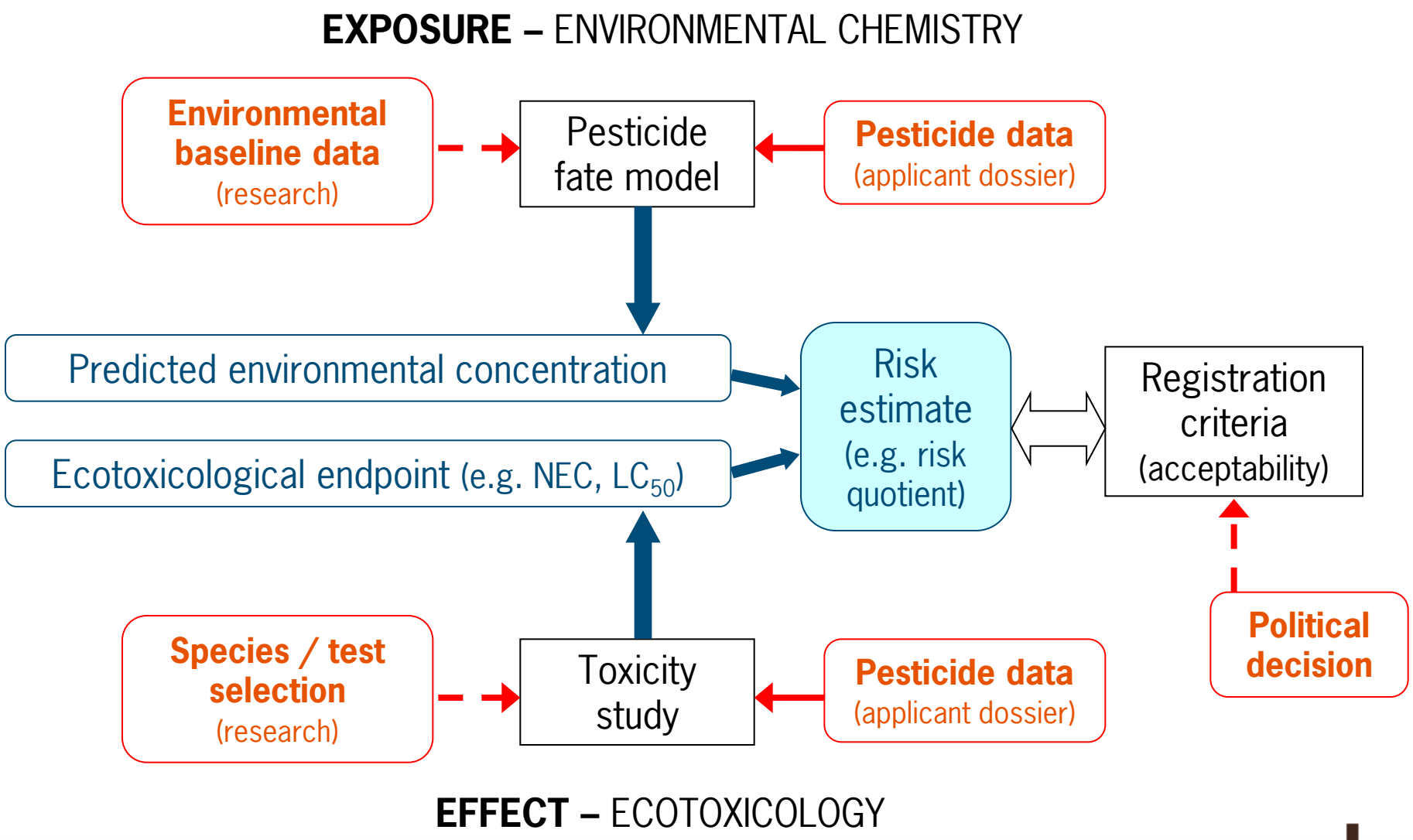
Acceptability criteria for pesticide registration

Many registration criteria are risk-based, but some are hazard-based

- Hazard-based criteria: dependent on intrinsic properties of the pesticide, irrespective of exposure (dose) rate
  - Example: the pesticide shall not persist in the soil for more than one year (i.e. DT_{90} > 1 year or DT_{50} > 3 months).

- Risk-based criteria: dependent on inherent properties of the pesticide and exposure level or probability
  - Example: no authorization will be granted if the predicted concentration in surface water is more than 10% of the No Effect Concentration for fish

Environmental risk assessment – approach in EU



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Environmental risk assessment – approach in EU

- Risk characterization: comparison between an estimate of an ecological effect and an exposure estimate:

$$Risk\ estimate = \frac{safe\ concentration\ or\ dose}{predicted\ environmental\ concentration}$$

- Predominantly, deterministic methods:
  - fixed values for exposure, toxicity and risk;
  - allow for variability and uncertainty by using worst-case assumptions and safety factors

Risk estimate

Example: Toxicity-Exposure Ratio (TER; used in the EU)

$$TER = \frac{\text{Toxicity value (LD50, LC50, NEC)}}{\text{Predicted Environmental Concentration (PEC)}}$$

In United States the ETR is used (PEC / Toxicity)

Risk estimate

TER value compared to a criterion

Registration criteria comprise a safety factor:

- Variation between individuals
- Variation between species
- Lab to field extrapolation
- Acute to long-term effects

- If the TER meets the registration criterion, the risk is acceptable
- If the TER does not meet the registration criterion, the risk is not acceptable and a higher tier risk assessment is necessary

Criteria for authorization of plant protection products

- Criteria for authorization of plant protection products in the EU:
  - General criteria for acceptability of a plant protection product
  - More specific criteria, for particular environmental compartments and organisms, in the “Uniform Principles”

- Uniform principles (chemical pesticides)

  ➔ only established in 1997

  (6 years after adoption of main legislation!)

- Now an update of the Uniform principles

EU general registration criteria

General principles relevant to the environment

- Principle of a high standard of protection
  - Protection of human health and environment takes priority over the objective of plant protection.
- Principle of prevention of pollution or unacceptable effects
  - E.g. pesticide dose as low as possible, even where higher amounts do not result in unacceptable risk.
  - E.g. expected concentration groundwater meets drinking water standard.
- Precautionary principle
  - Take into account potentially dangerous effects if there are reasonable grounds for concern, even though scientific evidence is insufficient.

EU “Uniform principles”

Specific registration criteria

- Criteria for the authorization of plant protection products (formally not for active ingredients)
  - Ensure that dossier information is evaluated in the same way throughout the EU.
  - Ensure that the same standards are used throughout the EU for accepting a plant protection product.
  - Provide transparency in decision-making.
- Criteria are defined for “normal use conditions”

EU “Uniform principles”

“Unless …” principle:

- If an acceptability criterion under the uniform principles is not complied with, no authorization shall be granted…

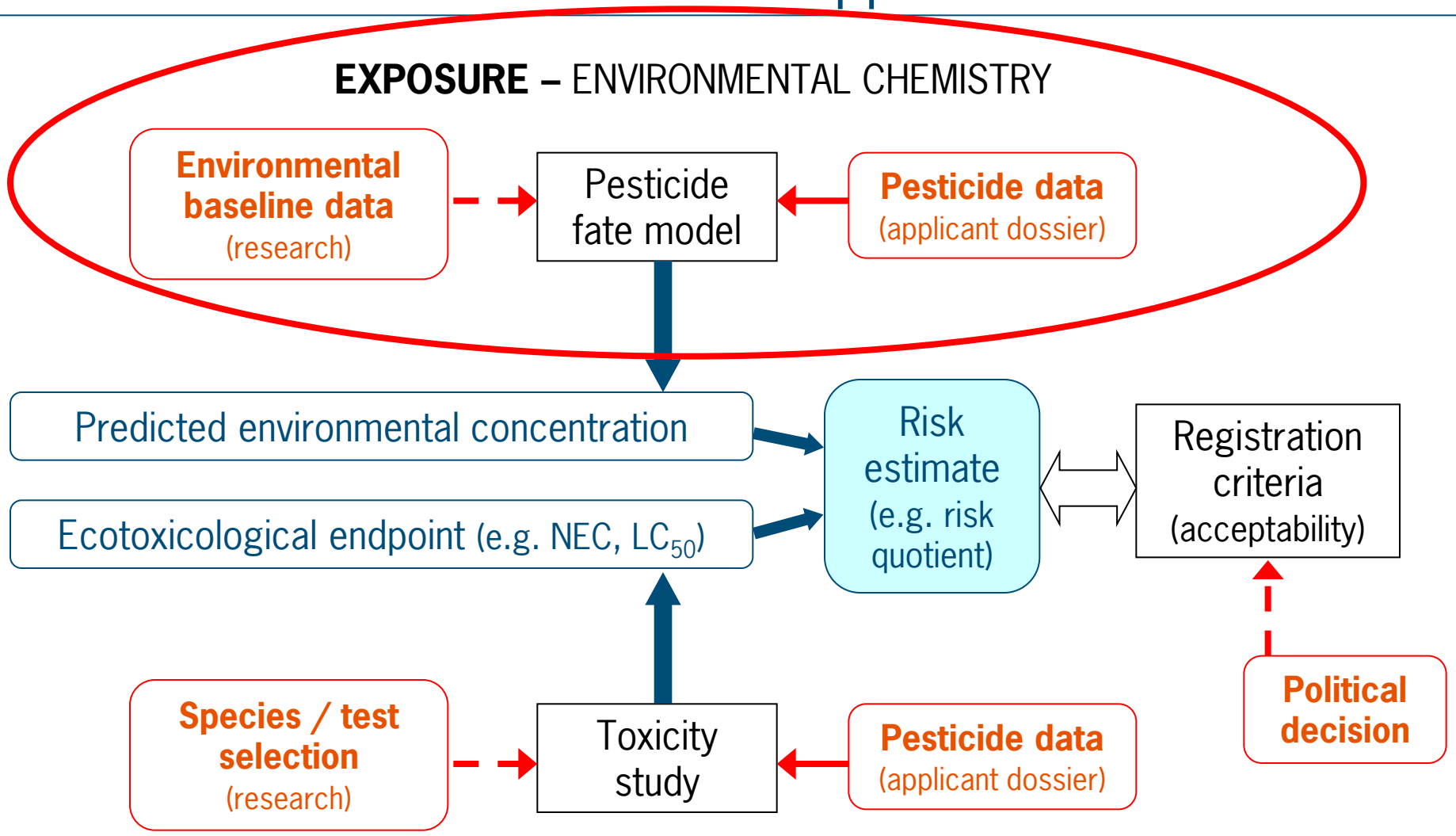
  … unless it is clearly established though an appropriate risk assessment that under field conditions no unacceptable impact occurs …

➔ Applicant must demonstrate absence of unacceptable effects.

➔ No definition of *appropriate risk assessment.*

(but guidance documents exist for most groups of organisms)

Environmental risk assessment – approach in EU



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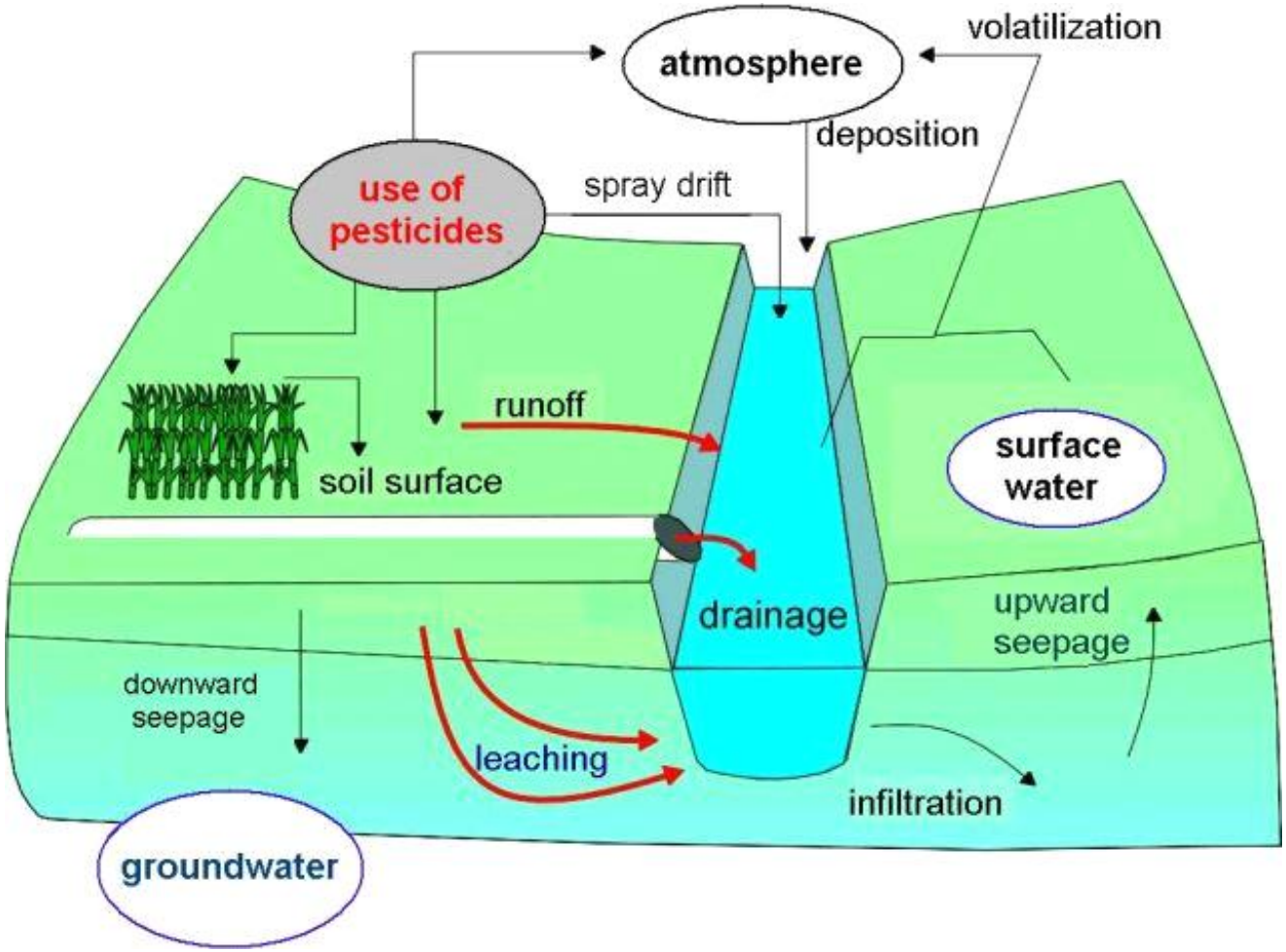
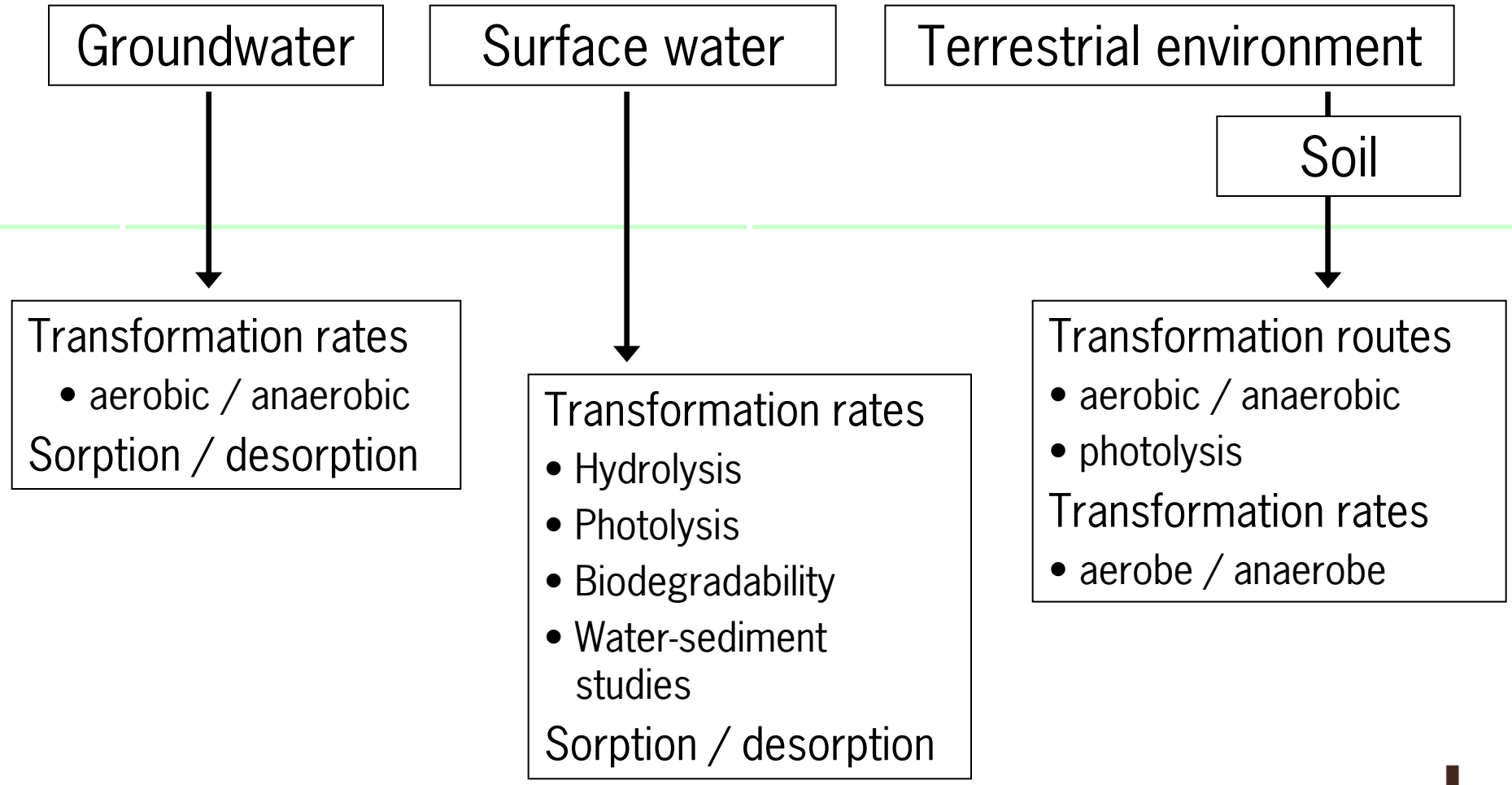
Pesticide fate modelling

Pesticide fate processes



Environmental fate studies in EU

environmental compartments



Environmental fate studies in EU

- Tier I studies laboratory-based
- Limited field studies required in higher tiers

- Test protocols highly standardised
  - Testing guidelines:
    + OECD guidelines
    + EEC methods
    + Others (e.g. SETAC)
- Internationally agreed
- Strict quality assurance required for most fate studies (Good Laboratory Practice - GLP)

Environmental fate models

- **FOCUS**: FOrum for the Co-ordination of pesticide fate models and their USe

- Harmonisation of the calculation of predicted environmental concentrations (PEC) of active substances of plant protection products

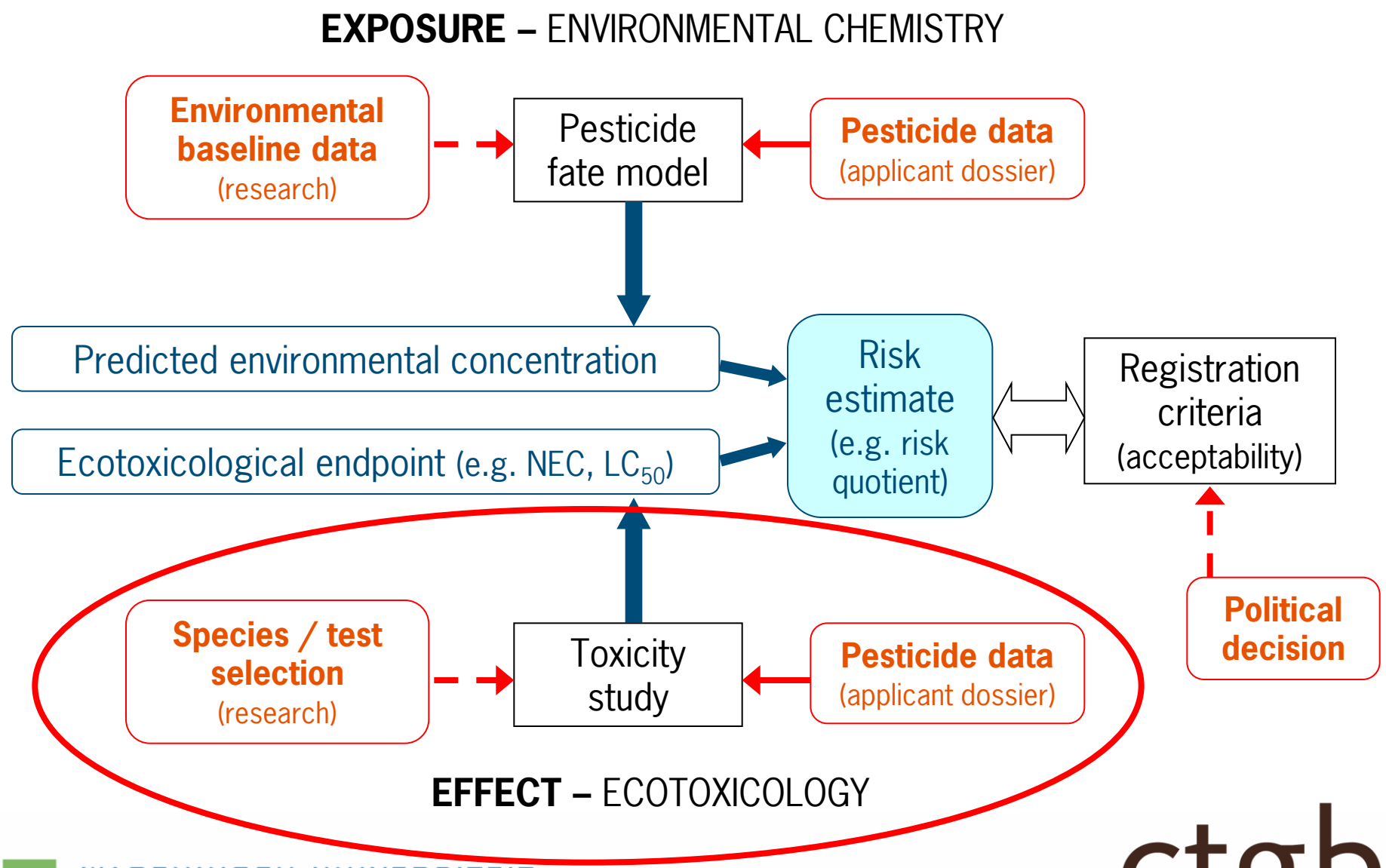
- Development of standard scenarios
  - standardised combinations of weather, soil and cropping data which collectively represent agriculture in the EU

Environmental fate models

Models to predict environmental concentrations (PECs)

- **Soil:** simple equations (no computer models)
- **Groundwater:** 4 computer simulation models
- **Surface water:**
  - Tier 1 & 2: one basic computer simulation model
  - Tier 3: three more detailed computer models
- **Bird/mammal food:** simple equations (spreadsheet model)

Environmental risk assessment – approach in EU



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Toxicity studies in EU

environmental compartments

Groundwater | Surface water | Terrestrial environment

Soil

organisms

- Fish
- Aquatic invertebrates
- Algae
- macrophytes

- Birds
- Mammals
- Honey bees
- Non-target arthropods
- Non-target plants

- Earthworms
- Soil arthropods
- Soil microbial processes

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Toxicity studies in the EU

- Tier I studies laboratory-based
- Few field studies required, even in higher tiers

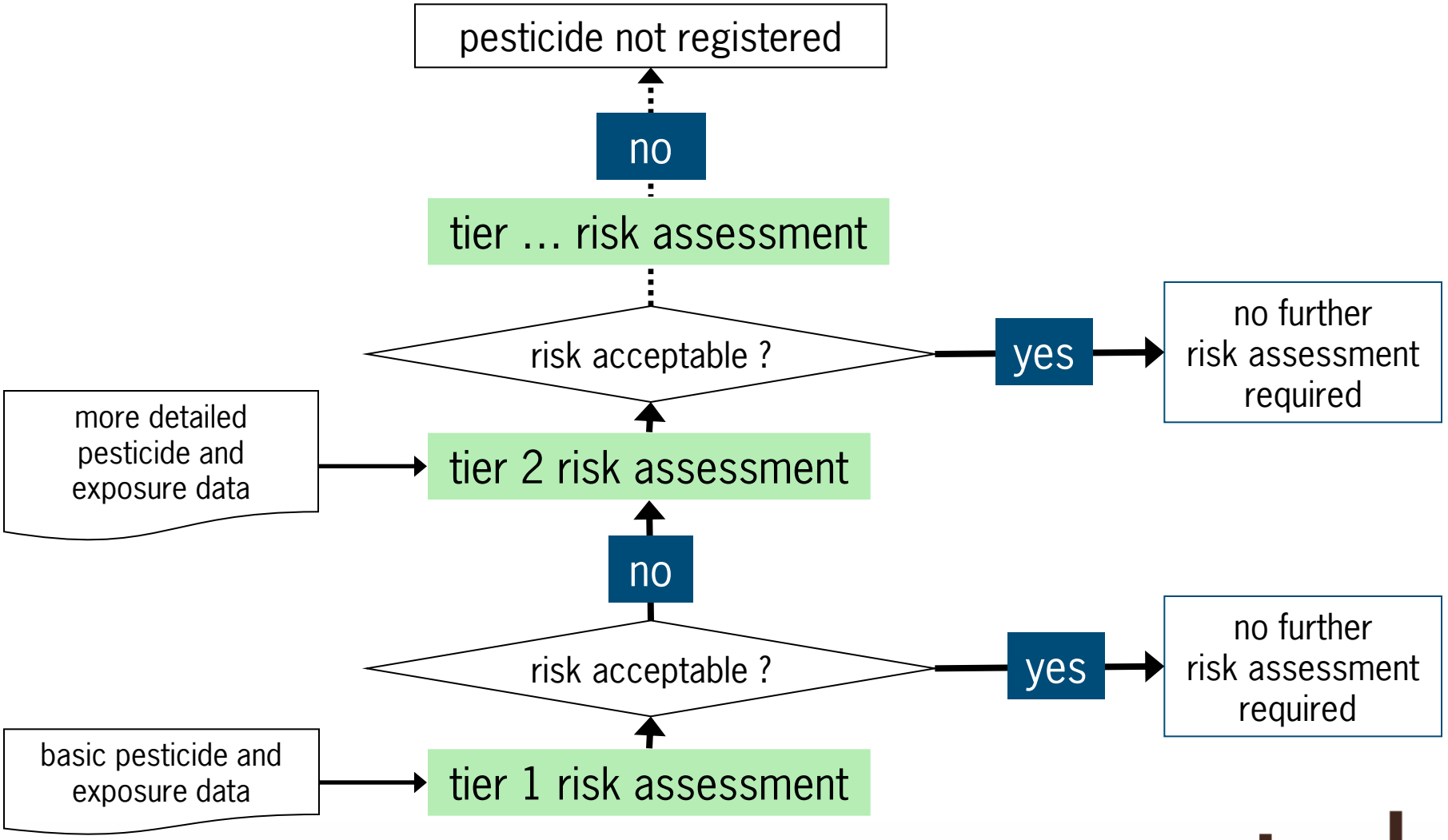
- Test protocols highly standardised
  - Testing guidelines:
    + OECD guidelines
    + EEC methods
    + Others (e.g. SETAC, EPPO)
- Internationally agreed
- Strict quality assurance required for most toxicity studies (Good Laboratory Practice - GLP)

Toxicity studies in the EU

- Type and number of toxicity studies is variable and depends on:
  - type of pesticide
  - conditions of use
  - results from lower tiers

- Example: insecticide used on a field crop:
  - minimum data set: ± 20 laboratory toxicity studies
  - often 30 – 50 studies

Tiered (=step-wise) risk assessment



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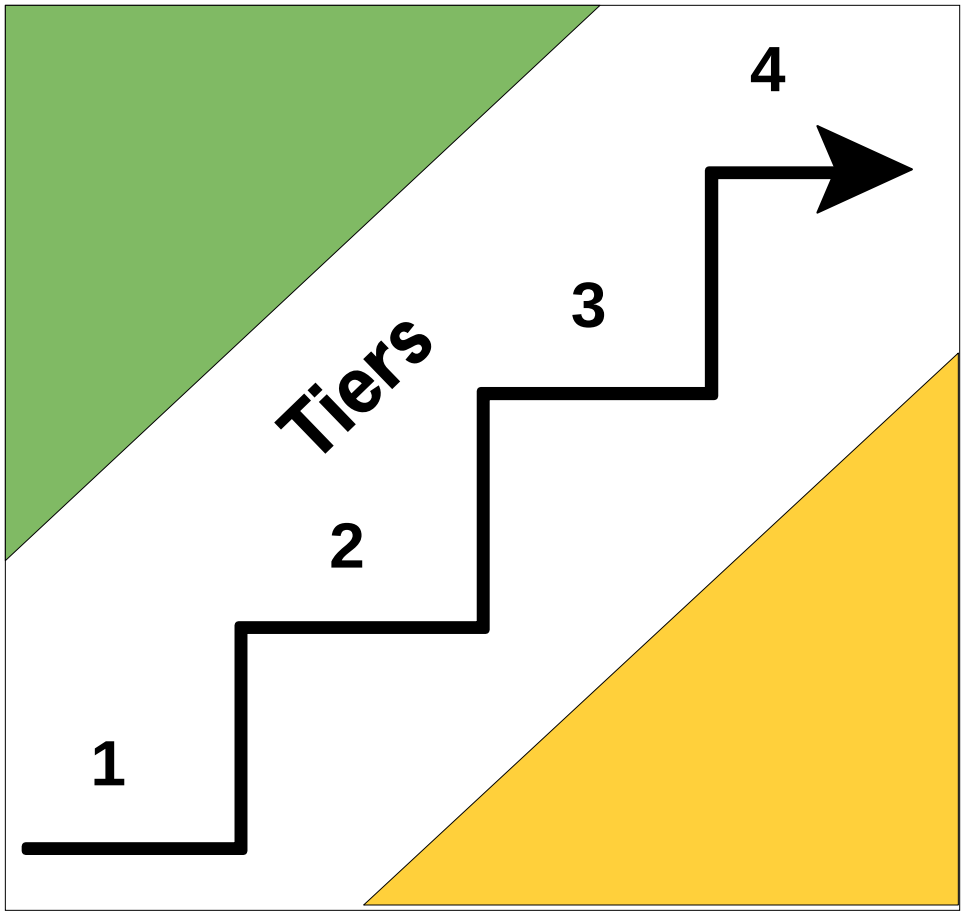
Tiered (=step-wise) risk assessment

Realistic

Conservative
(worst case)



Simple
(few data)

Complex
(more data)

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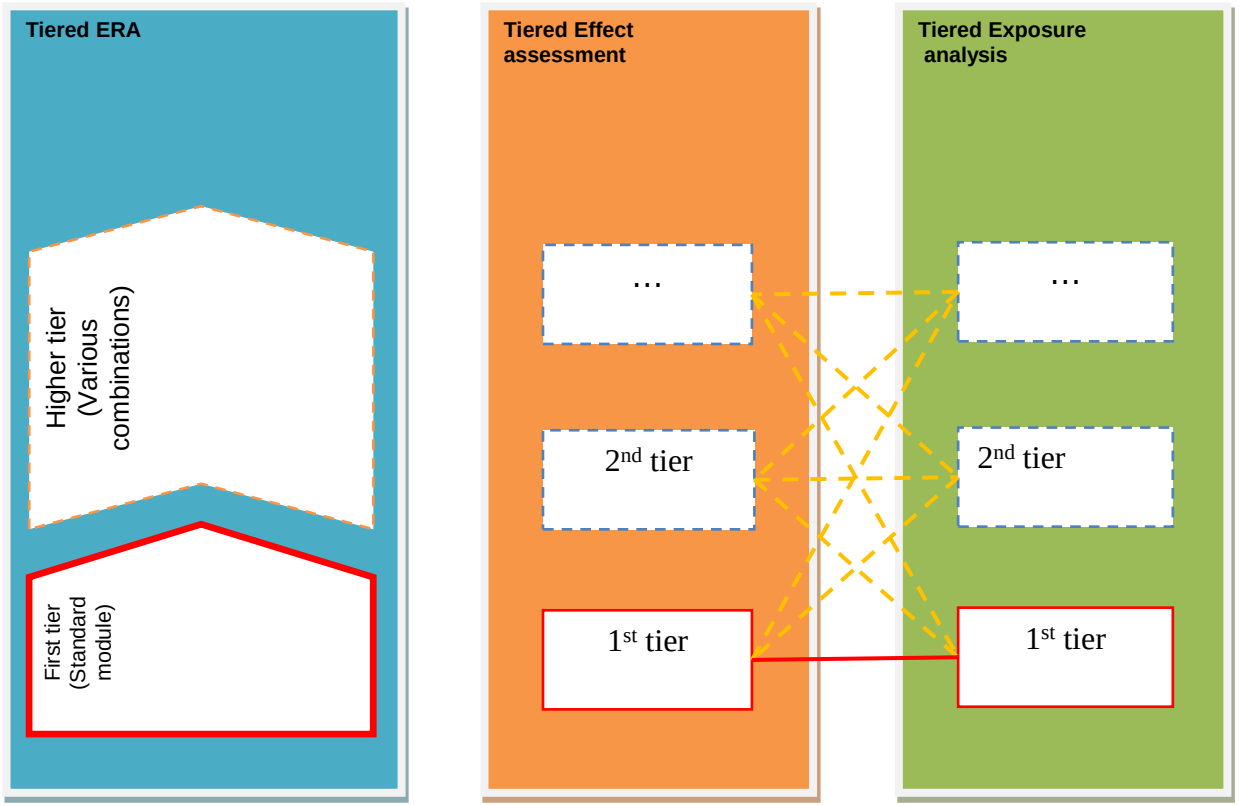
Tiered risk assessment – advantages

- Advantages of tiered risk assessment:
  - Applicants only provide data needed for the expected risk assessment tier ➔ less data required for less hazardous pesticides.
  - Registration authority does not evaluate data and carry out assessments which are not necessary to determine acceptable risk.
  - Both applicants and registration authority do not waste time, staff and money.

- Disadvantages of tiered risk assessment:
  - Need to define data requirements depending on level of risk.
  - Need for good communications between applicants and registration authorities.

Tiered risk assessment

Criss-cross model (allows flexibility in the tiered approach of the ERA)



- Thank you for your attention!!!