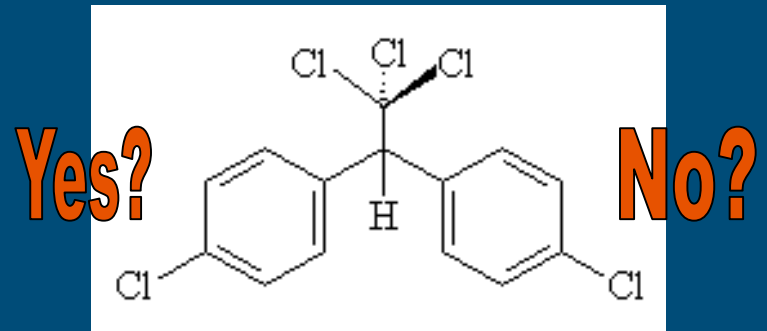


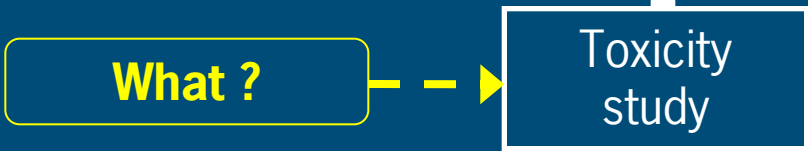
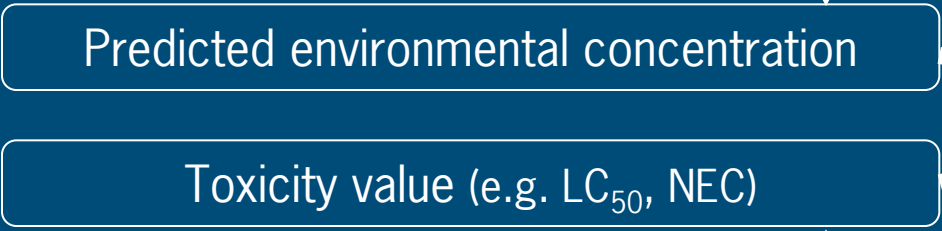
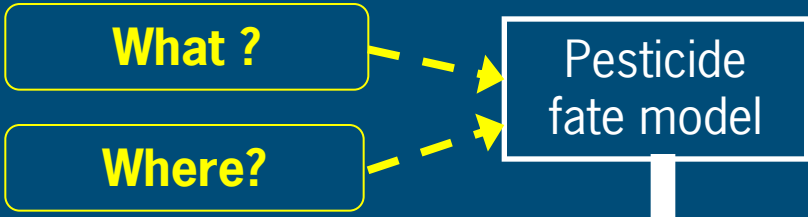
# Setting environmental criteria for pesticide registration

## Introduction

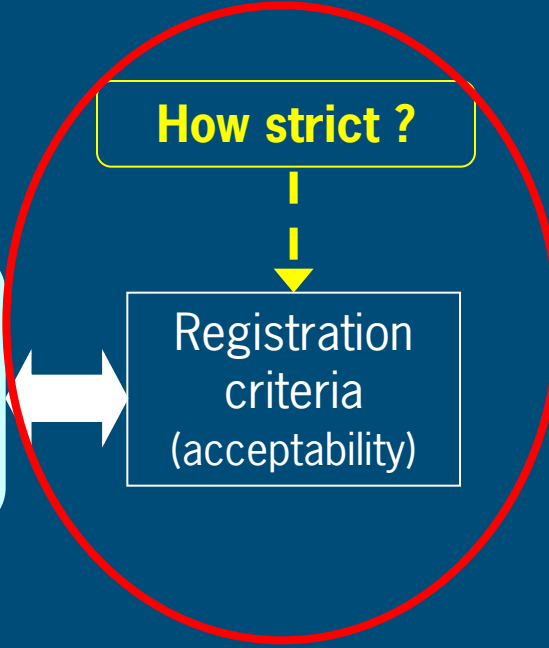


# Environmental risk assessment – Questions to answer

## EXPOSURE – ENVIRONMENTAL CHEMISTRY



## EFFECT – ECOTOXICOLOGY



# Registration criteria – different definitions

## Risk-based criteria

- What level of environmental effect is acceptable in Ethiopia?
  - *example:* no acute fish mortality in lakes and rivers when pesticide is used according to the label

## Hazard-based criteria

- What level of a pesticide characteristic is acceptable in Ethiopia?
  - *example:* maximum  $DT_{50}$  in soil

## Environmental quality standards

- What level of pesticide residue is acceptable in Ethiopia?
  - *example:* maximum pesticide concentration in groundwater

# Registration criteria – different definitions

## **Risk-based criteria**

- Good option (uses both data on toxicity and exposure)

## **Hazard-based criteria**

- Simple option (only uses intrinsic properties of pesticides (e.g. toxicity,  $DT_{50}$ ), but does not estimate actual risk)

## **Environmental quality standards**

- Can be based on risk assessment (e.g. WHO guidance values for drinking water)
- Can be based on political choice (e.g. EU general drinking water criterion)

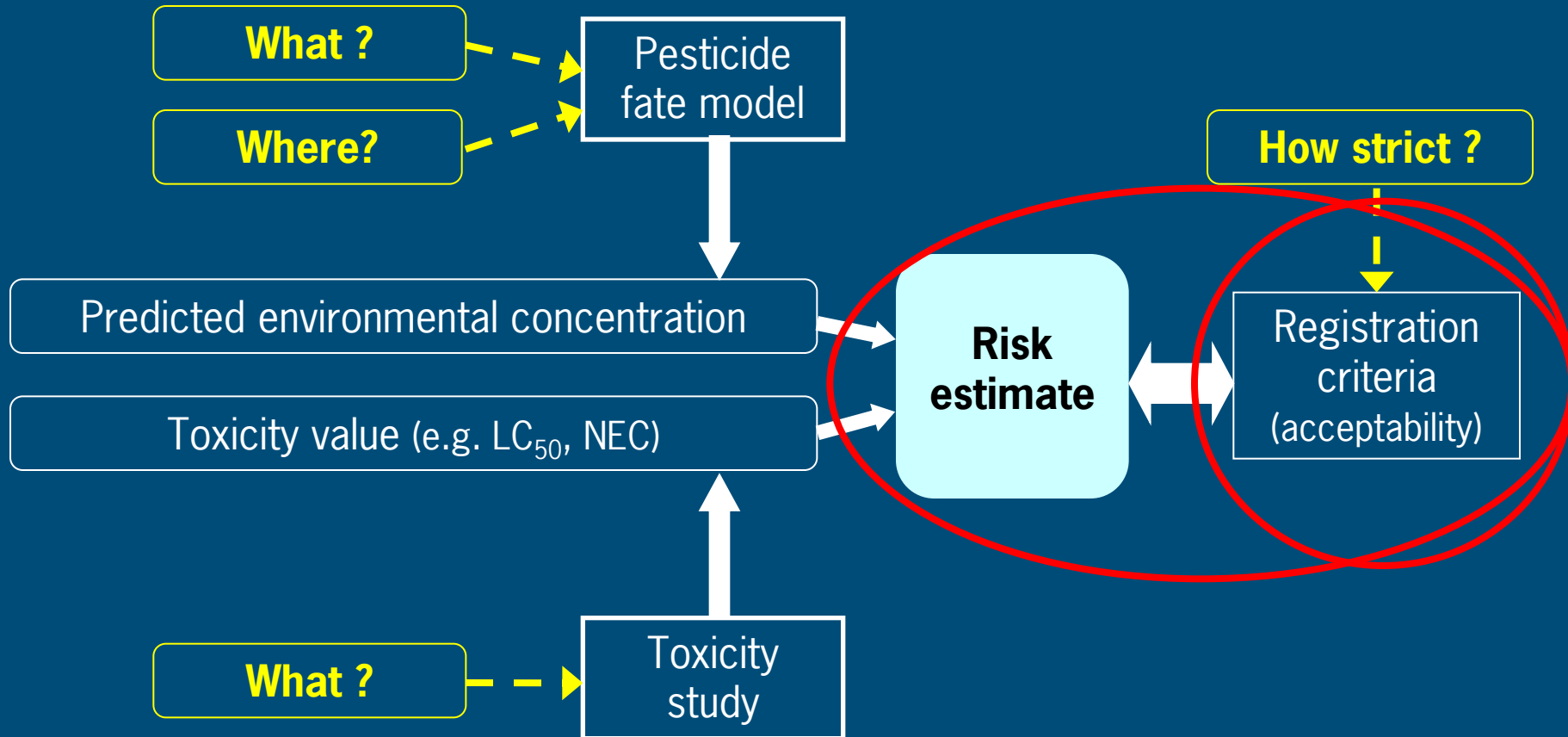
# General issues relevant for setting risk criteria

1. Quantification of risk
2. Tiered assessment of risk



# Environmental risk assessment – setting criteria

## EXPOSURE – ENVIRONMENTAL CHEMISTRY



## Toxicity Exposure Ratio (TER)

= comparison between an estimate of an ecological effect and of exposure

$$\text{TER} = \frac{\text{toxicity value (LD}_{50}, \text{LC}_{50}, \text{NOEC})}{\text{predicted environmental concentration(PEC)}}$$

# Risk estimate: different terms – same principle

## Toxicity Exposure Ratio (TER)

[EU-plant protection products]

$$\text{TER} = \frac{\text{toxicity value (LD}_{50}, \text{LC}_{50}, \text{NOEC})}{\text{predicted environmental concentration (PEC)}}$$

## Risk Quotient (RQ) or Exposure Toxicity Ratio (ETR)

[e.g. USA, Australia, EPPO, EU-biocides]

$$\text{ETR} = \frac{\text{predicted environmental concentration (PEC)}}{\text{toxicity value (LD}_{50}, \text{LC}_{50}, \text{NOEC})}}$$



# Risk estimate: different terms – same principle

Examples:

$$\text{TER} = 0.1 \Leftrightarrow \text{RQ or ETR} = 10$$

*or*

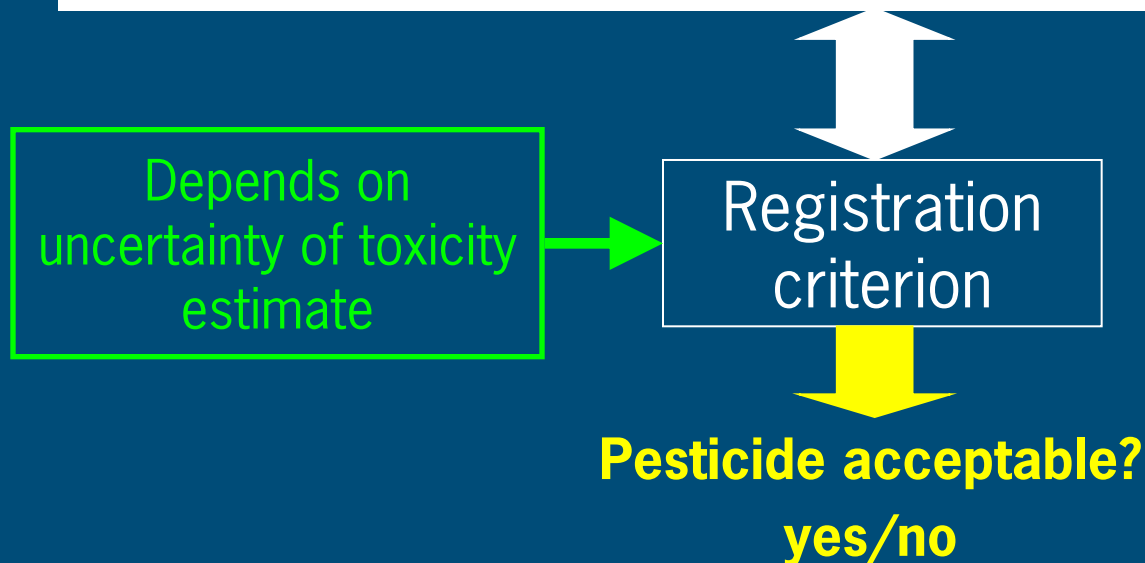
$$\text{TER} < 100 \Leftrightarrow \text{RQ or ETR} > 0.01$$

# Risk estimate: different terms – same principle

- Project proposes to use ETR approach
- Advantages:
  - more widely used
  - more logical
    - + higher ETR means higher risk
    - + lower ETR means lower risk
- But: be careful how trigger values are used in background documents from different sources!!

# Risk estimate compared to registration criterion

$$\text{ETR} = \frac{\text{predicted environmental concentration(PEC)}}{\text{toxicity value (LD}_{50}, \text{LC}_{50}, \text{NOEC})}$$



# Uncertainty in risk estimate – toxicity

Registration criteria often comprise a **safety factor** (also: **assessment factor, uncertainty factor, extrapolation factor**)

- Variation between individuals
  - because tests are done in different laboratories
- Variation between species
  - if protection goal is more than tested species
- Acute to long-term effects
  - if only acute tests are available
- Laboratory to field extrapolation
  - if toxicity data only come from the laboratory

# Uncertainty in risk estimate

- Ideal situation

acceptable

$$ETR = \frac{\text{exact environmental concentration}}{\text{no effect concentration of ecosystem to protect}}$$

<1

- Real situation for Tier 1

$$ETR = \frac{\text{predicted environmental concentration(PEC)}}{\text{acute LC}_{50} \text{ for 3 aquatic species}}$$

<0.0

1

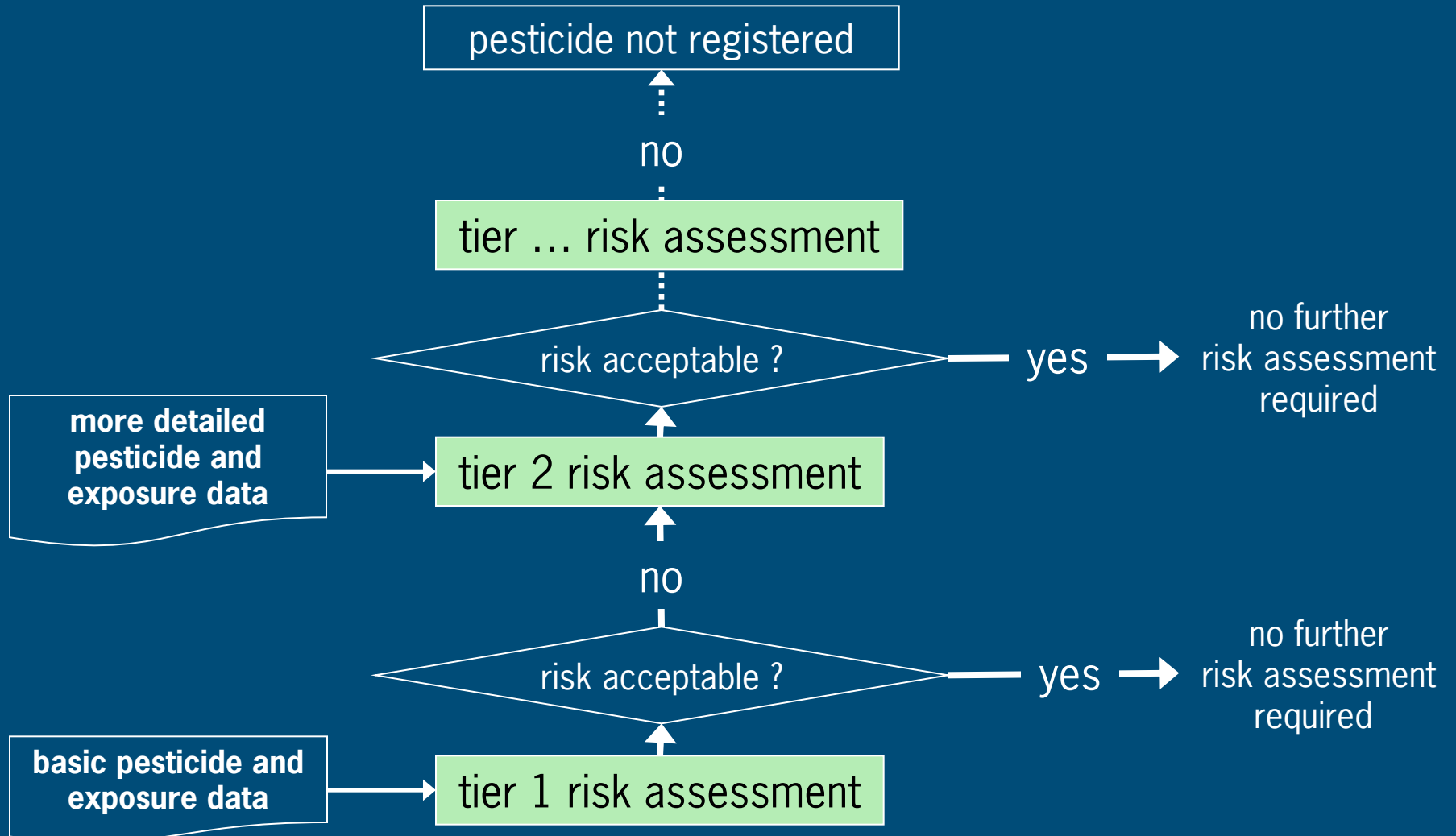
- Need to extrapolate:
  - acute → chronic
  - 3 species → community/ecosystem
  - laboratory test → field situation

# Registration criteria for environmental risk

- Registration criteria (safety factors) depend on the organism being assessed
  - example: different for bees than for aquatic organisms
- Criteria will (often) depend on the quantity and quality of the available data used for the ETR
  - Better and/or more data → often lower safety factor is acceptable

Normally step-wise risk assessment is done

# Tiered (=step-wise) risk assessment



# What if ETR of 1<sup>st</sup> tier does not meet criteria?

## Options

- Refine exposure estimate
- Refine effects assessment (higher tiers)
- Re-evaluate risk in more detail (magnitude, probability and ecological significance of effects)
  
- Consider risk reduction measures
- Do not authorize certain uses of particular concern
- Do not authorize pesticide for all uses



# What if ETR of 1<sup>st</sup> tier does not meet criteria?

## Options for Ethiopia

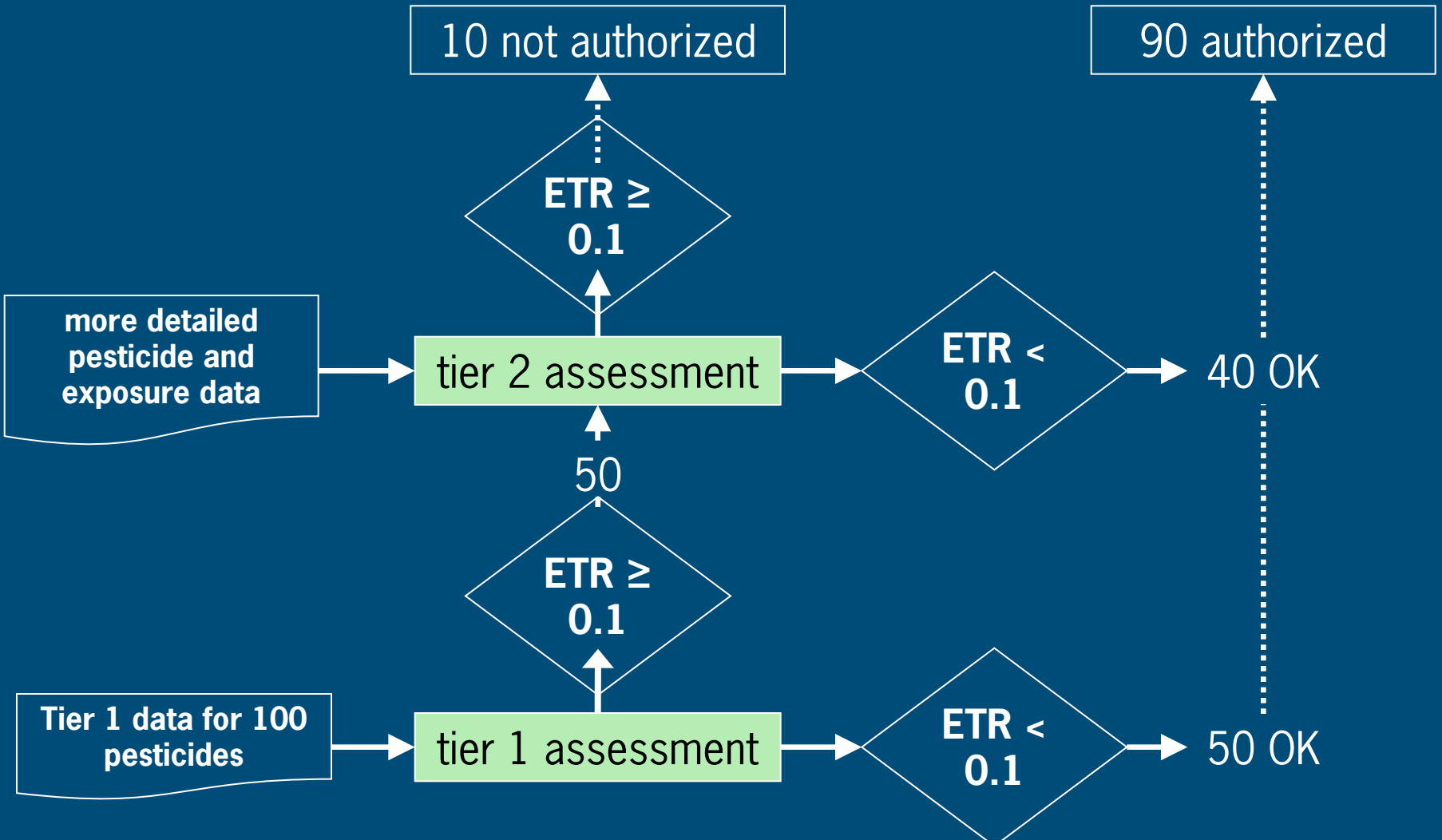
- Refinement options are for the time being no option
  - too complex
  - more capacity of people needed
  - Tier 1 assessment is the highest step for the time being
- Other options can be applied (risk reduction measures; non-authorisation of certain uses; no authorisation at all)

# Decision criteria

- But:
- Limited data often means higher levels of uncertainty – higher safety factor needed
- 1<sup>st</sup> tier criteria are therefore relatively conservative
  
- Criteria debated:
  - too strict: high economic consequences?
  - too weak: high ecological consequences?

# Example 1: two-tier system

**ETR < 0.1 is acceptable risk**



# Example 2: one-tier system & same criteria

**ETR < 0.1 is acceptable risk**

protective of environment  
*but*  
economic problem?

50 not authorized

50 authorized

~~tier 2 assessment~~



Tier 1 data for 100 pesticides

tier 1 assessment

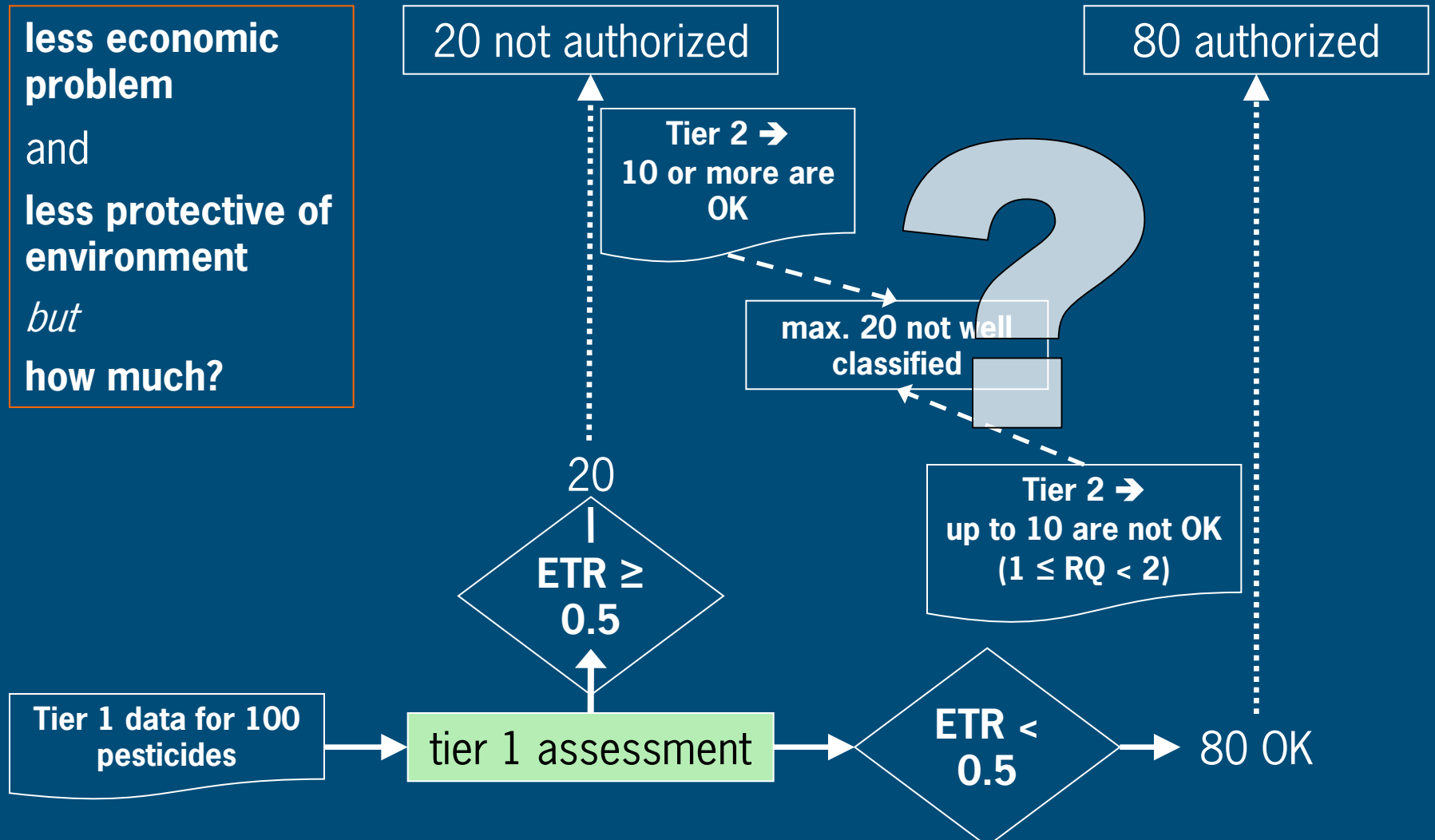


50 OK

# Example 3: one-tier system

**ETR < 0.5 is acceptable risk**

less economic problem and less protective of environment *but* how much?



# Examples summary

System	Acceptable ETR	Number of pesticides		
		Authorized	Not authorized	
2 tiers	< 0.1	90	10	“Ideal”
1 tier	< 0.1	50	50	Economic constraint
1 tier	< 0.5	80	20	Environmental constraint

- 30 pesticides have maybe a risk for the environment
- If only Tier 1 data/assessments possible → find best balance between economic and environmental interests

# Proposal for Ethiopia

- Determination of risk classification criteria
  - low risk
  - possible risk
  - high risk
- Low risk: if  $ETR < 1/\text{safety factor of the EU}$  → risk acceptable
- Possible risk: if  $ETR \geq 1/\text{safety factor of the EU}$  but  $\leq$  a certain exceedance factor (different for different protection goals) → risk acceptable for the time being, but if risk reduction measures are possible they should be applied
- High risk: if  $ETR >$  certain exceedance factor → risk unacceptable; authorisation not possible, unless sufficient risk reduction measures can be applied to reduce the risk to an acceptable level

# Proposal for Ethiopia

Advantages of this approach:

- the focus can be directed on the real high risk pesticides
- No high economic consequences due to loss of too many pesticides

In future refinement steps can be introduced → the risk of pesticides with a possible risk can be estimated in a better way



Thank you for your attention!!

Questions??????

