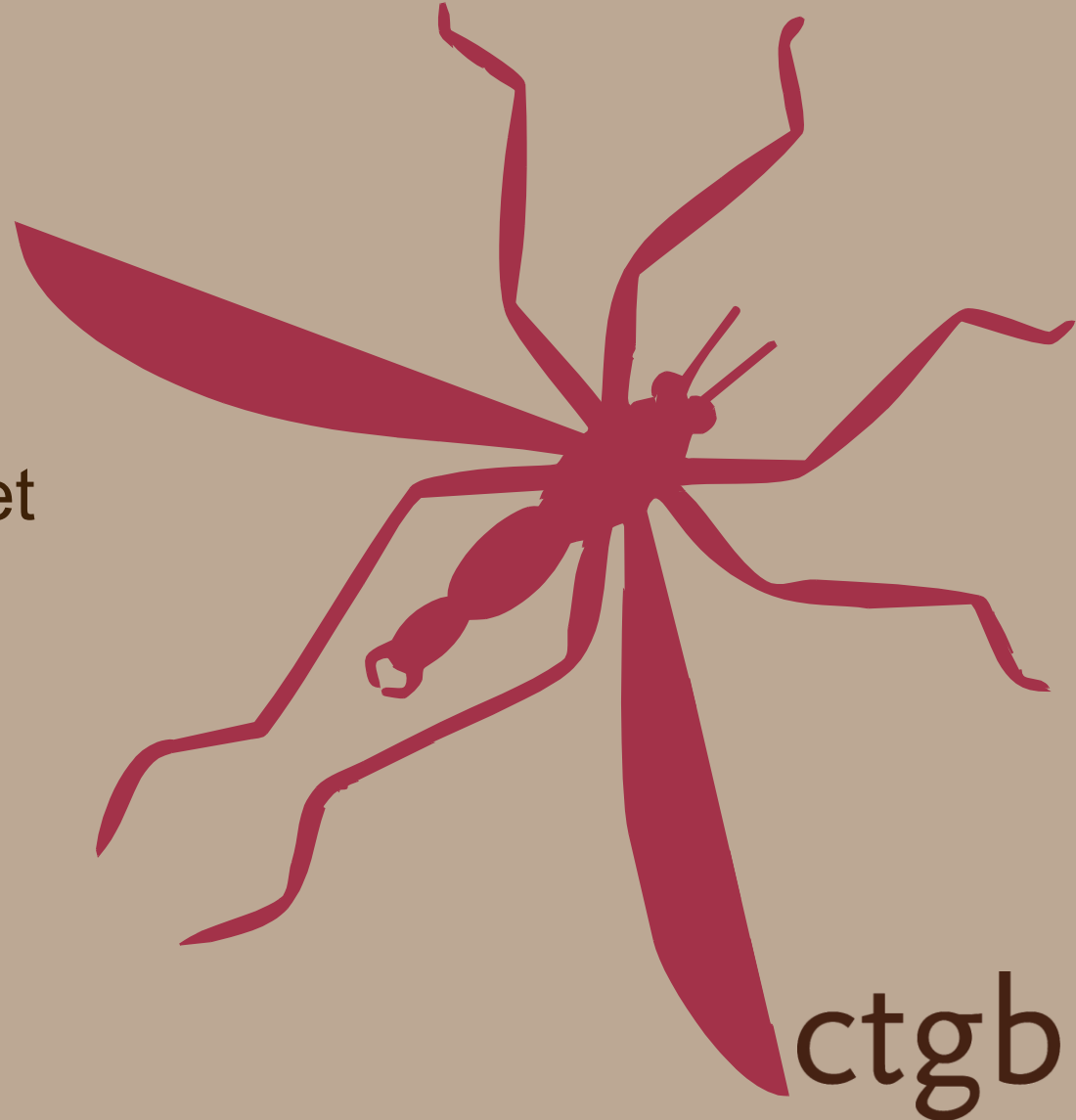




Environmental assessment

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Environmental assessment



- Hazard assessment or risk assessment or a combination of both??





Hazard or risk assessment



- In EU most environmental adverse effects are assessed using **risk assessment**
- So both toxicity data and exposure estimates are required
- Under development for chemicals are so-called:
 - “POP-criteria”: Persistent Organic Pollutant
 - “PBT-criteria”: Persistence, Bioaccumulation & Toxicity





Hazard assessment



- Environmental hazard assessment is generally considered not precise enough, and will likely be too conservative (i.e., many pesticides would not be registered).
- But risk assessment requires exposure estimates/models and is time-consuming!
- What are options for Ethiopia to screen out certain pesticides on the basis of hazard criteria, so that risk assessment is not needed?



Hazard assessment - Stockholm



- Ethiopia has ratified the Stockholm Convention
→ should not register pesticides with POPs characteristics (Articles 3.3 & 3.4 & Annex D)



Criteria for:

- Persistence: half-life in water, soil and sediment
- Bio-accumulation: BCF or BAF
- Potential for long-range transport: no specific criteria
- Adverse effects on human health and the environment: no specific criteria



In principle, **all 4** criteria should apply to a pesticide!
But criteria are not explicit!





Hazard assessment – New EU regulation on pesticides (1107/2009)

- An active substance, safener or synergist shall only be approved where it is not considered to be a persistent organic pollutant (POP)
- An active substance, safener or synergist shall only be approved if it is not considered to be a persistent, bioaccumulative and toxic (PBT) substance

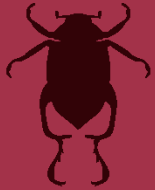


POPs: criteria



Persistence

- $T_{1/2} > 2$ months in water, or
- $T_{1/2} > 6$ months in soil, or
- $T_{1/2} > 6$ months in sediment





POPs: criteria



Bioaccumulation:

- BCF in aquatic species > 5000 , or
- $\text{Log } K_{ow} > 5$ (in the absence of data on the BCF), or
- Evidence that there are other reasons for concern, such as high bioaccumulation in other non-target species, high toxicity or ecotoxicity





POPs: criteria



Potential for long-range environmental transport:



- Measured levels in locations distant from the sources of its release are of potential concern;
- Monitoring data show that long-range environmental transport may have occurred via air, water or migratory species;





POPs: criteria



- environmental fate properties and/or model results demonstrate that there is a potential for long-range environmental transport through air, water or migratory species.
 - Half life in air > 2 days to have a potential to migrate through the air





PBT and vPvB: Introduction



- PBT substances:
 - persistent and
 - bioaccumulative and
 - toxic



- vPvB substances:
 - high persistency in combination with high tendency to bioaccumulate, but not necessarily proven toxicity





PBT and vPvB: Introduction



PBT/vPvB substances:

- potential to accumulate in parts of the environment:
 - effects are unpredictable in the long-term;
 - practically difficult to reverse as cessation of emission will not necessarily result in a reduction in chemical concentration

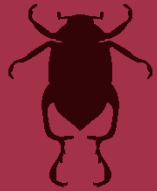




PBT/vPvB: criteria



- Criteria for PBT/vPvB in Annex XIII of the REACH-Regulation



- REACH is the European Community Regulation on chemicals and their safe use (EC 1907/2006)





PBT: criteria



Persistence:

- $T_{1/2} > 60$ days in marine water, or
- $T_{1/2} > 40$ days in fresh- or estuarine water, or
- $T_{1/2} > 180$ days in marine sediment, or
- $T_{1/2} > 120$ days in fresh- or estuarine sediment, or
- $T_{1/2} > 120$ days in soil





PBT: criteria



Bioaccumulation:

- Based on measured data on bioconcentration in aquatic species (freshwater as well as marine species)
- $BCF > 2000 \text{ L/kg}$





PBT: criteria



Toxicity:

- NOEC (long-term) < 0.01 mg/L for marine or freshwater organisms, or
- Classified as carcinogenic, mutagenic or toxic for reproduction, or
- Other evidence of chronic toxicity (T, R48, or Xn, R48 according to Directive 67/548/EEC)





vPvB: criteria



- $T_{1/2} > 60$ days in marine, fresh- or estuarine water, or



- $T_{1/2} > 180$ days in marine, fresh- or estuarine sediment, or

- $T_{1/2} > 180$ days in soil

- $BCF > 5000$ L/kg





POP, PBT and vPvB



- Methods for assessment if compound is POP, PBT or vPvB are still under development in the EU
- Hence, for the time being no further operationalisation of these criteria



Relevance for use in Ethiopia



No	Criteria	Yes/no relevant	Relevant for Ethiopia? Why?	Remarks
1	POP			
2	PBT			
3	vPvB			