Environmental assessment

Peter van Vliet
Ctgb

Datum: 14-11-2011

Environmental assessment

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

ctgb




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

ctgb

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?

ctgb

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!

ctgb




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

ctgb




POPs: criteria

Persistence

- T1/2 > 2 months in water, or
- T1/2 > 6 months in soil, or
- T1/2 > 6 months in sediment

ctgb




POPs: criteria

Bioaccumulation:

- BCF in aquatic species > 5000, or
- Log Kow > 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

ctgb




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;

ctgb

POPs: criteria

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

ctgb




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

ctgb




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

ctgb




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)

ctgb




PBT: criteria

Persistence:

- T1/2 > 60 days in marine water, or
- T1/2 > 40 days in fresh- or estuarine water, or
- T1/2 > 180 days in marine sediment, or
- T1/2 > 120 days in fresh- or esturaine sediment, or
- T1/2 > 120 days in soil

ctgb




PBT: criteria

Bioaccumulation:

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

ctgb




PBT: criteria

Toxicity:

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

ctgb




vPvB: criteria

- T1/2 > 60 days in marine, fresh- or estuarine water, or
- T1/2 > 180 days in marine, fresh- or esturaine sediment, or
- T1/2 > 180 days in soil

- BCF > 5000 L/kg

ctgb




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

ctgb

Relevance for use in Ethiopia




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

ctgb