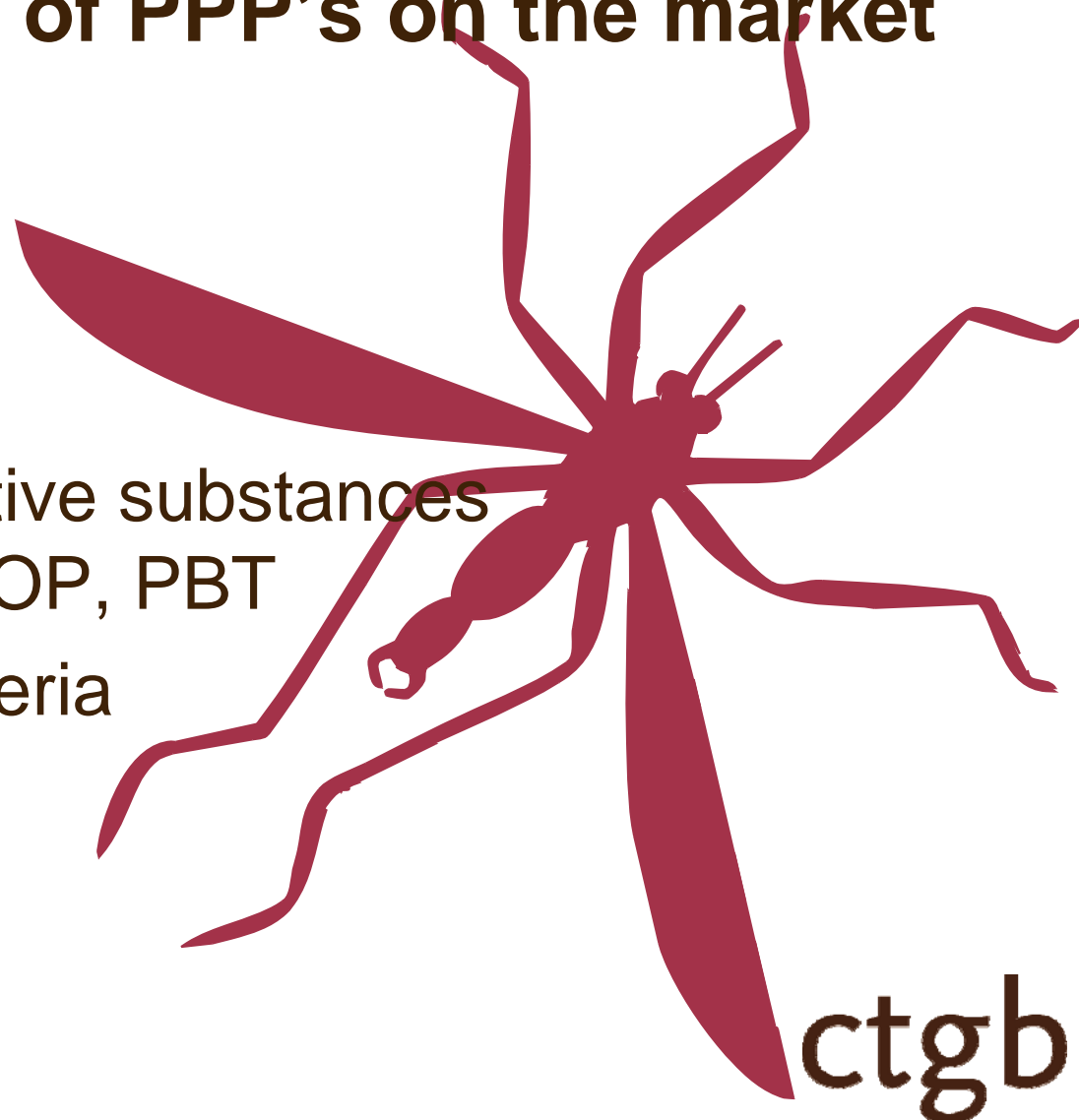


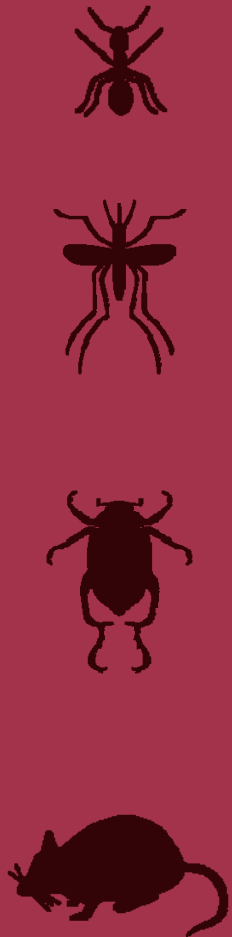
EU Regulation 1107/2009. the placing of PPP's on the market

assessing active substances
against the POP, PBT
and vPvB criteria



12/12/2011

ctgb



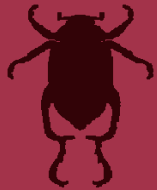


Criteria regulation 1107/2009



An active substance... shall only be approved when it is not considered to be:

- a Persistent Organic Pollutant (POP)
- Persistent Bioaccumulative and Toxic (PBT)
- Very Persistent and Very Bioaccumulative (vPvB)







An active substance shall be approved as a candidate for substitution when:

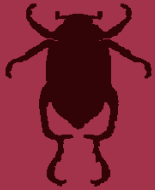
- It meets two of the criteria to be a PBT substance



Based on intrinsic properties

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- 
- 
- 
- in order to be considered a **POP**, a substance must fulfil all three criteria with regard to
 - (a) persistence in water, sediment or soil
DT50 in water > 2 months, or DT50 in soil > 6 months, or DT50 in sediment > 6 months.
 - (b) bioaccumulation/toxicity in fish or other organisms
measured bio-concentration factor or bioaccumulation factor in aquatic species > 5 000 or, in the absence of such data, $\log K_{o/w} > 5$ or, other reasons for concern
 - c) the potential for long-range environmental transport
by valid monitoring data or by modelling, DT50 in air > 2 days

Similar criteria for PBT and vPvB



Criteria PBT

- DT50 marine water >60d
- DT50 fresh/estuarine water >40d
- DT50 marine sed >180d
- DT50 soil, fresh/estuarine sed >120d
- Measured BCF >2000
- Chronic NOEC aquatic <0.01 mg/L
- Substance classified

vPvB

- DT50 marine, fresh/estuarine water >60d
- DT50 soil, marine, fresh/estuarine sed >120d
- BCF >5000

Some key questions regarding POP/PBT/vPvB assessment

- Marine water, freshwater or both (text for POP assessment only says water)?
- How to obtain DT50 for water and sediment separately from the potentially available studies (OECD 308, OECD 309)?
- Is mass that forms unextractable residues considered to be a degradation loss?
- Potential for long-range environmental transport, Annex II of Reg. (EC) 1107/2009 and FOCUS air guidance clear enough?

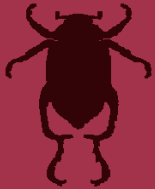


- half life is single first order DT50 as defined by FOCUS kinetics, or are other best fit kinetics acceptable?



- Laboratory data vs field data.

DT50 values from field studies are more appropriate than laboratory data. As non-normalised field values are influenced by the boundary conditions of the experiment (e.g. dry and cold conditions -> longer halflives), normalized field DT50-values under defined reference conditions (20°C, moisture at pF2?) should be derived.



- Is a dissipation half life from soil, water or sediment matrices the target for assessment or is it transformation half life?

photolysis/hydrolysis, a biotic degradation to be taken into account

- What are the 'appropriate conditions' to generate the half life data?

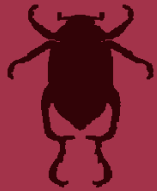


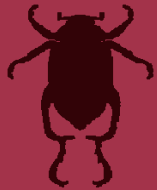


- Data requirements result in a range of DT50 values for each matrix. The variability of this range will be strongly influenced by the conditions of the tests and not just the inherent persistence of a substance.



- An agreed procedure for manipulation of results (eg. use of geometric mean value at a specified environmentally relevant temperature) before comparison to cut of values may therefore be considered appropriate.





- **Bioaccumulation**

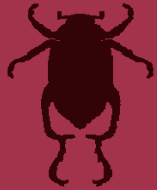
- Measured data, PPP regulation says study with fish

- **Toxicity**

- Relevance of typical NOEC from study on aquatic organisms
- For toxicity (T) Annex II of Reg. (EC) 1107/2009, ECHA guidance and pertinent classification rules appear clear

Harmonisation required

- Assessment
- Endpoint derivation



Stelling:

The assessment can only be valid if the respective properties co-occur, which is the case if the combination of triggers relates to the same environmental compartment.

For example, if bioaccumulation is only shown towards aquatic organisms (and is not observed in terrestrial organisms) and persistence is only indicated in soils (and does not occur in the aquatic environment), then a concern does not result.