PBT substances within REACH

Dan Merckel
Environment Agency, UK

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What is REACH?

- Regulation (EC) No. 1907/2006 – eif 1/6/2007
  Registration, **E**valuation, **A**uthorisation and Restriction of **Ch**emicals

- Producers/suppliers have to:
  - assess hazards of their substances
  - communicate risk management options to their customers

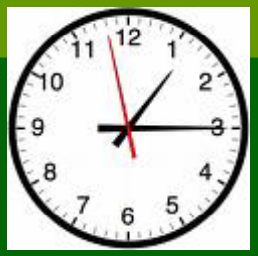
- PBT assessment for all substances supplied by a company above 10 tonnes/year

Why PBT?

- Persistent chemicals can reach remote regions
- Bioaccumulative substances can contaminate animals at the top of food chains - long-term effects are difficult to predict
- Exposure is difficult to stop due to long half-life

⇨ Current risk assessment methods considered inadequate

PBT criteria 1



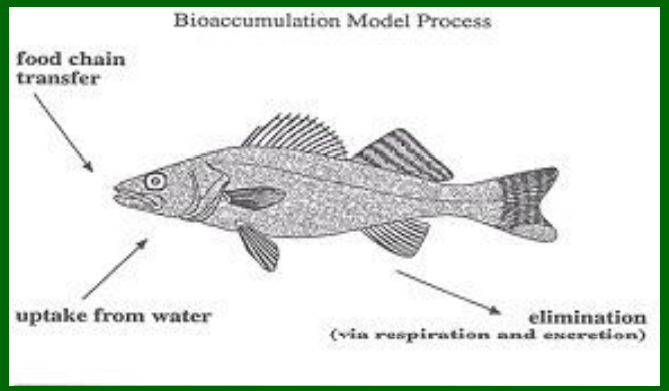
- PERSISTENCE
  - Need data on degradation half-life collected under “adequate conditions”
  - Criterion met if
    - Water: t½ > 60 d (marine) or 40 d
    - Sediment: t½ > 180 d (marine) or 120 d
    - Soil: t½ > 120 d

  [‘Very P’ if t½ > 60 d (water) or > 180 d (others)]

PBT criteria 2

- BIOACCUMULATION
  - Need measured data on bioconcentration in aquatic species
  - Criterion met if
    - bioconcentration factor (BCF) > 2000

['Very B' if BCF > 5000]



PBT criteria 3

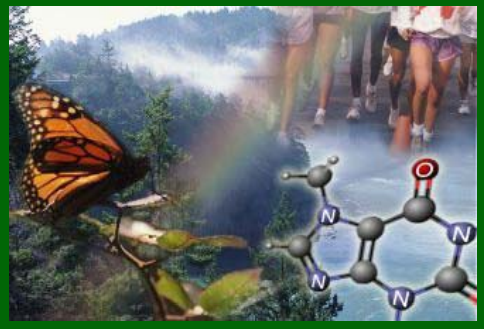
- TOXICITY
  - Criterion met if
  - long-term no-observed effect concentration (NOEC) for aquatic organisms < 0.01 mg/l; or
  - classified as C (cat. 1 or 2), M (cat. 1 or 2), or R (cat. 1, 2, or 3); or
  - there is other evidence of chronic toxicity, as identified by the classifications: T, R48, or Xn, R48

Test strategies

- Laid out in technical guidance for each end point
  - Begin with screening level data (e.g. ready biodegradation test, or K_{ow})
  - Move to more detailed (expensive!) tests if required by CSA
  - May need to consider degradation products

- Technical guidance also available on how to carry out the PBT assessment

http://guidance.echa.europa.eu/guidance_en.htm



Equivalent concern

- Article 57 (f):
- Substances - such as those having endocrine disrupting properties or those having PBT/vPvB properties, which do not fulfil the Annex XIII criteria - for which

  "there is **scientific evidence of probable serious effects** to human health or the environment which give rise to an equivalent level of concern"
- Identified on a case-by-case basis

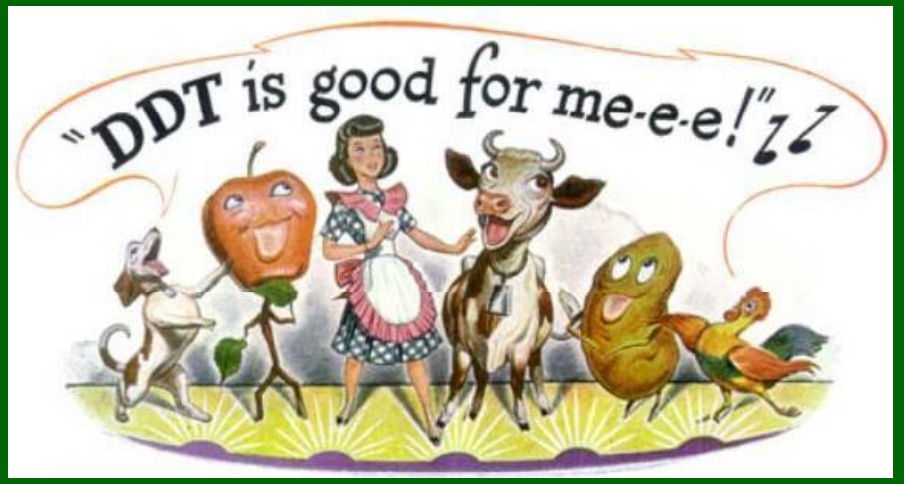
My substance is a PBT – so what?

- Registrant must minimise exposure by rigorous containment for the whole life cycle – specifying risk management options for own use and customers

- Member State CA or ECHA can identify it as a 'substance of very high concern'
  - Triggers prioritisation procedure for inclusion on Annex XIV (wide dispersive use/high volume)
  - If included on Annex XIV, sunset date for authorisation – no legal use without prior approval
  - N.B. does not apply to manufacture, use as chemical intermediate or import of treated articles

Which substances are PBTs?

- Do these sound familiar?
  - short-chain chlorinated paraffins
  - Pentabromodiphenyl ether
  - tributyl tin oxide
  - DDT



- But what about…?
  - decamethylcyclopentasiloxane
  - tristyryl phenol (possibly!)

Environment Agency work

- High production volume chemical screening exercise
  - Used by the UK Chemicals Stakeholder Forum to produce their list of substances of concern
  - Fed into EU prioritisation process – see fact sheets at **http://ecb.jrc.ec.europa.eu/home.php?CONTENU=/DOCUMENTS/PBT_EVALUATION/**
  - Many substances now undergoing testing to legally enforceable deadlines

- Initial screen of substances supplied between 10 and 1,000 tonnes – work in progress
  - Only *potential* PBTs – need test data
  - Also need exposure information to set priorities – opportunities to build on work by OSPAR and Environment Canada

Environment Agency work (cont.)

- "PBT" used as a screening criterion for prioritisation reports for specific chemical sectors:
  - alkylphenols
  - UV-filters used in cosmetics
  - flame retardants
  - fragrances (later in 2009)

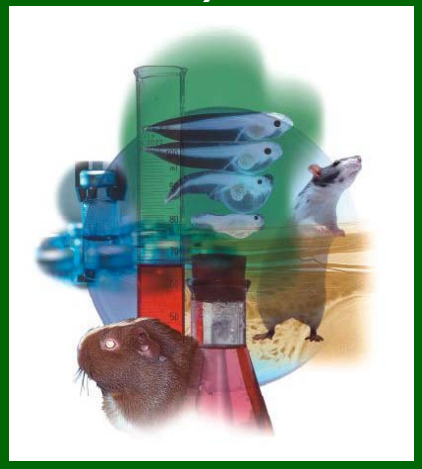
  See http://publications.environment-agency.gov.uk

- Early warning for industry so they can plan ahead, and other interested groups (e.g. POPs network!)

- Support for Green Chemistry – finding the substitutes

Developments and Future Challenges

- Driven by animal welfare and cost
  - Existing test revisions (e.g. OECD 305)
  - New tests (e.g. fish dietary bioaccumulation)
  - Ongoing refinement and development of QSAR/ grouping approaches (e.g. prediction of metabolism)
  - New approaches to risk assessment – is there a safe level for PBTs?



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Any questions?

daniel.merckel@environment-agency.gov.uk