PBT and Regulation

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The REACH Regulation and PBT assessment

- REACH covers all Industrial chemicals
  - Obligations placed on manufacturers/importers
  - demonstration of safe use
- For substances >10 tonnes per annum PBT assessment must be carried out
- Hazard-based, unlike usual risk approach
- Parallels with C, M, R classification for human health
- Originally came out of the marine assessment

REACH PBT/vPvB criteria: Revision

- Listed in Annex XIII of REACH
- Revised in 2011
- Numeric criteria remain unchanged
  - **"P"**: DT_{50} ≥40 days in fresh/estuarine water, ≥60 days in marine water, ≥120 days in fresh/estuarine sediment, ≥180 days in marine sediment, ≥120 days in soil
  - **"vP"**: DT_{50} ≥60 days in water, ≥180 days in sediment, soil
  - **"B"**: aquatic BCF ≥2000; **"vB"**: aquatic BCF ≥5000
  - **"T"**: (chronic) aquatic NOEC ≤0.01 mg/l **or** CMR, or STOT RE
- Various related "screening criteria" unchanged

REACH PBT/vPvB Revision (cont.)

- Additions included to capture near miss cases, by weight of evidence **and** *"…applied in particular where the criteria… cannot be applied directly to the available information."*
  - "*Assessment Information*

  The following information shall be considered for the assessment of P, vP, B, vB and T properties, using a weight-of-evidence approach..."

“P or vP:

…

(d) Other information, such as information from field studies or monitoring studies, provided that its suitability and reliability can be reasonably demonstrated.”

“B or vB:

…

(b) Other information on the bioaccumulation potential provided that its suitability and reliability can be reasonably demonstrated, such as:

— Results from a bioaccumulation study in terrestrial species;

— Data from scientific analysis of human body fluids or tissues, such as blood, milk, or fat;

— Detection of elevated levels in biota, in particular in endangered species or in vulnerable populations, compared to levels in their surrounding environment;

— Results from a chronic toxicity study on animals;

— Assessment of the toxicokinetic behaviour of the substance;

(c) Information on the ability of the substance to biomagnify in the food chain, where possible expressed by biomagnification factors or trophic magnification factors.”

REACH PBT criteria revision (cont.)

“T

…(e) Results from long-term or reproductive toxicity testing with birds as set out in Section 9.6.1 of Annex X;

(f) Other information provided that its suitability and reliability can be reasonably demonstrated.”

NB *“The identification shall also take account of the PBT/vPvB-properties of relevant constituents of a substance and relevant transformation and/or degradation products.”*

REACH Art 57(f)

"substances – such as those having endocrine disrupting properties or those having PBT properties or vPvB properties, which do not fulfil the criteria of points (d) or (e) – 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 to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with…"

(art. 57(d) & (e) = PBT/vPvB)

➔ PBT criteria and Article 57(f) of REACH text for "equivalent concern" *should be* distinct!

Bioaccumulation: a simple test?

- Fish exposed to constant concentration of dissolved substance (uptake phase) followed by depuration (clearance) phase
- "steady-state" BCF = C_{fish} / C_{water}
- "kinetic" BCF should equal steady-state BCF:

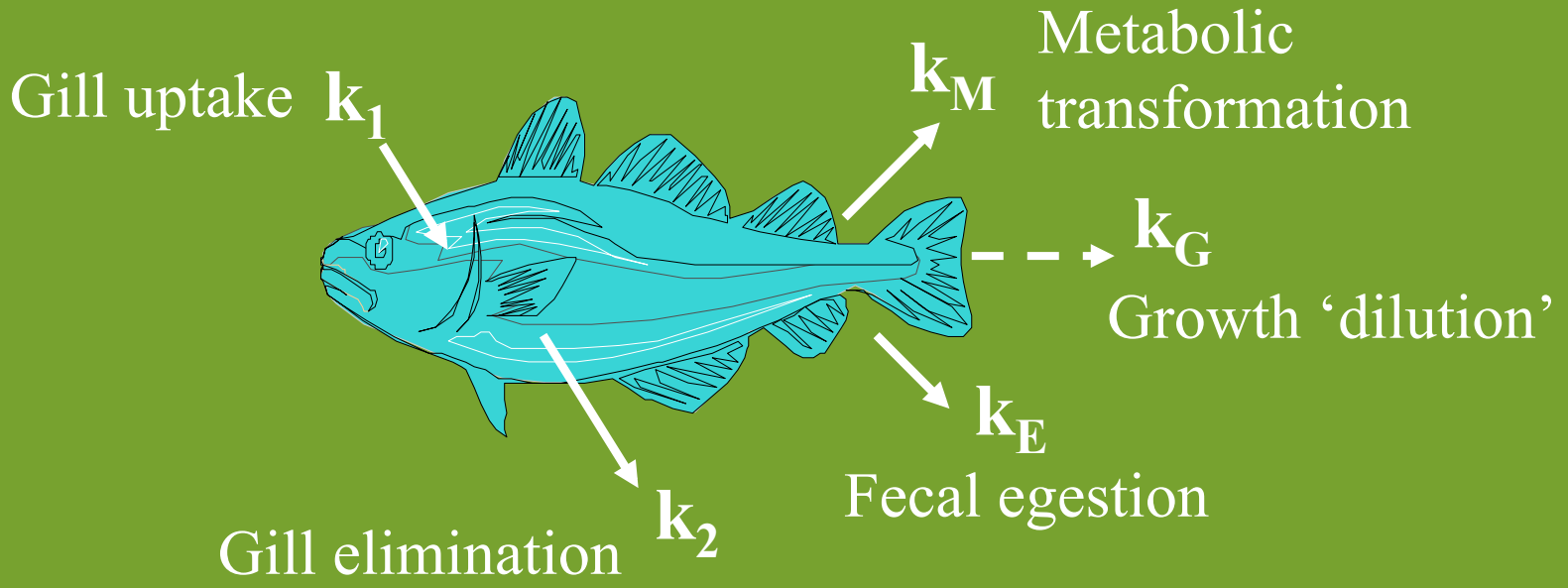
$$\text{Rate of uptake} = k_1 \times [C_{water}]$$

$$\text{Rate of depuration} = k_2 \times [C_{fish}]$$

$$BCF = \frac{[C_{fish}] \text{ at steady state (mg kg}^{-1} \text{ wet weight)}}{[C_{water}] \text{ at steady state (mg l}^{-1})} = \frac{k_1}{k_2}$$

- However as k_1 & k_2 should be constant, steady state not required for kinetic BCF

Mass-Balance Kinetic Bioconcentration Model



L_B = lipid content of organism
k_1 = gill uptake rate constant
Φ = freely dissolved fraction
k_2 = gill elimination rate constant
k_e = egestion rate
k_g = growth rate constant
k_M = rate of biotransformation

$$BCF = (1 - L_B) + (k_1 \bullet \phi / (k_2 + k_E + k_G + k_M))$$

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With thanks to Mark Bonnell for the slide

But nothing is ever simple!

- Test results and interpretation influenced by:
  - Fish growth and lipid content changes
  - rate constants may change with fish size
  - Species differences (ie metabolic capacity)
  - Potential problems with exposure concentrations
  - Potential problems with chemical analysis (limits, specificity, error…)
  - Is steady state real or apparent?
  - Model(s) used for fitting K_1 and K_2, only possible for pseudo-first order kinetics (otherwise they are not constants!)

Revision of the OECD fish bioaccumulation Test

- Bioconcentration test updated to reflect increased understanding and minimise fish numbers
- New dietary exposure method added for poorly soluble substances (important for PBT candidates) – dietary BMF
- “minimised” BCF method added as a preliminary or screening study
- A partnership effort between UK, NL and DE

How to identify PBTs in REACH?

- Screening exercises underway in MS and at ECHA to nominate candidate substances for evaluation to the Community Rolling Action Plan (CoRAP)
- Once on the CoRAP, MS will evaluate substances annually
- Called “Substance Evaluation”
  - ie the formal process to evaluate substances prioritised for assessment
- Outcome can be i) no concern; ii) further information needed or iii) concern confirmed

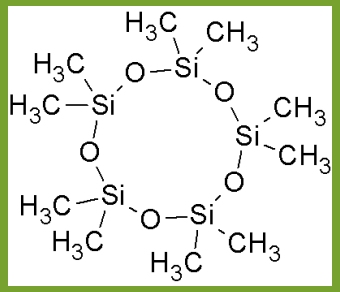
More REACH PBT identification

- PBT expert group recently reformed to informally:
  - Screen potential PBT candidates – feed into CoRAP & Substance Evaluation process
  - Give advice on PBT testing
  - Produce guidance on technical aspects relating to PBT assessment and testing
  - Work with Industry to make available all relevant information, request further testing

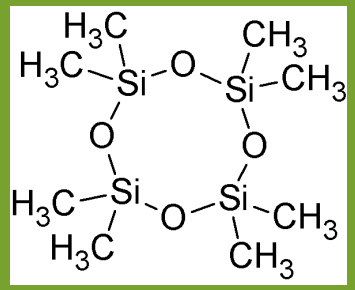
PBT confirmed, what next?

- Substance can be called a “substance of very high concern” (SVHC) and
  - placed on Annex XIV and subject to **Authorisation**
  - Or subject to a proposed **Restriction**
- Idea to minimise emissions as far as possible
- However…
  - Authorisation will permit continued use subject to socio-economic factors **but does not cover manufacture, use as intermediate or imports**
- Dossier required, subject to public consultation

Example 1: Cyclic Siloxanes



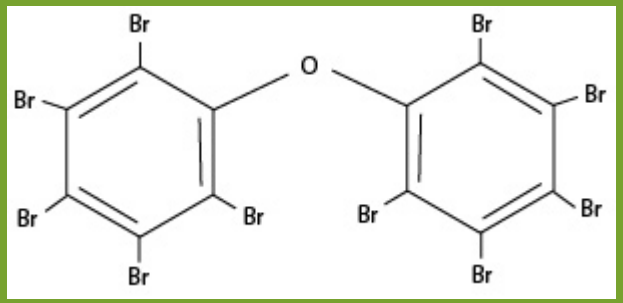
"D5"
Meets vPvB criteria



"D4"
Meets PBT criteria

- Uses:
  - chemical intermediate
  - Use in personal care products (e.g. skin- and hair-care products)
  - Use in household products (e.g. cleaning products)
  - ALSO present as impurities in silicone polymer products
- Volatile, adsorptive substances subject to hydrolysis
- However, once in aquatic environment readily adsorb to particulate matter/sediment slowing hydrolysis
  - D5 $DT_{50\ sed}$: 800-3100 d (24 °C); D4 $DT_{50\ sed}$: 242 - 365 d (24 °C)

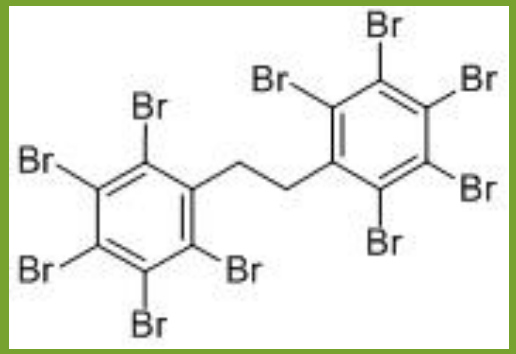
Example 2: DecaBDE



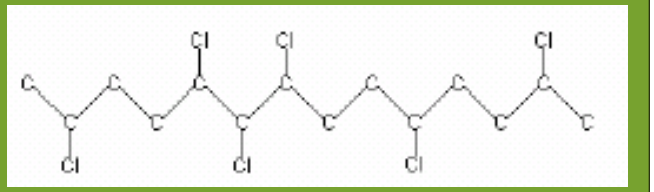
- Widely used flame retardant
- Does not meet PBT/vPvB criteria itself, but:
  - evidence for significant & widespread presence in the environment and biota
  - evidence for transformation into known PBT/POP substances in biota through debromination in soil/sediment
  - Problem = lower Br congeners were commercially produced and may be present as impurities; difficult to identify source
- Revised PBT allows identification as PBT/vPvB through transformation
- BUT: no guidance on rate or quantity of SVHC formation required to meet Annex XIII [or Art. 57(f)]

Ongoing work

- Environment Agency assessing potential SVHCs under Substance Evaluation
- Carrying out screening exercises For CoRAP and for PBT working group



1,2-Bis(pentabromophenyl) ethane (EBP)



Medium chain chlorinated paraffins

- Further UK work (e.g. river GCMS screening, monitoring for emerging pollutants innovations e.g. passive sampling, WFD (e.g. potential future priority hazardous substance)

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Further information

- ECHA website: http://www.echa.europa.eu/

(Consultations – “Addressing Chemicals of Concern” tab; CoRAP – “Information on chemicals” tab)

- Joint Research Council’s European chemical Substances Information System: http://esis.jrc.ec.europa.eu/ (“PBT” tab)
- OECD Test Guidelines: http://www.oecd.org/document/12/0,3746,en_2649_37465_48704140_1_1_1_37465,00.html

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