Identification of potential PBT/vPvB substances under the European REACH Regulation (EC) No. 1907/2006

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Talk outline

- Setting the scene
- The process
- Some examples
- Summary & what you can do for us

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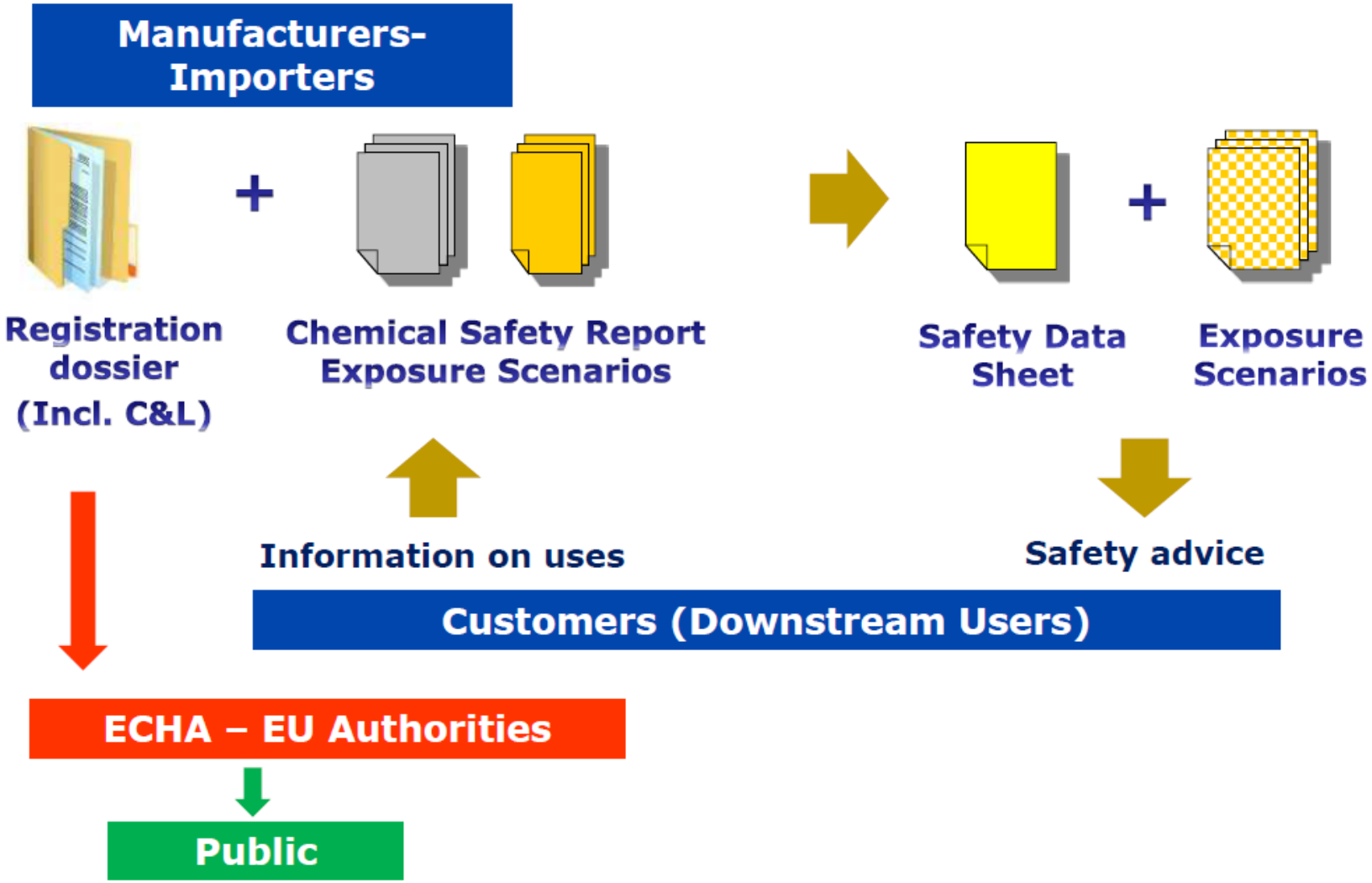
Registration, Evaluation, Authorisation (and restriction) of Chemicals



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REACH risk management options

- Authorisation
  - Chemicals with specific group of hazards can be added to a “Candidate List”
  - Placed on Annex XIV if exposure potential is high
  - Continued use beyond sunset date requires an authorisation to be granted by COM
- Restriction (Annex XVII)
  - Any condition on manufacture/supply/use
  - Regulatory authorities prepare the case
  - Need to demonstrate a risk
  - Consider socio-economic factors

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REACH is not fully comprehensive

- Reduced registration requirements for:
  - substances subject to equivalent legislation, e.g. pesticides, human/veterinary medicines, food additives [cosmetic ingredients for health end points]
  - isolated chemical intermediates used under strictly controlled conditions
  - R&D purposes
- Applies to chemicals intentionally placed on the market (not dioxins or waste)
- Does not directly deal with POPs
  - Annex XVII restrictions are deleted following addition of a substance to the EU POPs Regulation (e.g. PBDEs)

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PBT & vPvB substances

- Persistent, Bioaccumulative & Toxic (PBT) and very persistent very bioaccumulative (vPvB)
  - criteria are specified in Annex XIII of REACH
  - half-life, bioconcentration factor, aquatic toxicity
- High priority for risk management
  - “No safe threshold”
  - Either authorisation or restriction may be appropriate
  - COM Roadmap (February 2013) aims to identify all ‘relevant’ PBT/vPvB substances by 2020
  - Some may go on to become POPs

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Relevant data

- Registration data (tonnage dependent)
  - Usually standard test guideline studies to GLP
- Monitoring data from governments/academia indicating:
  - Food chain biomagnification
  - Presence in wildlife, especially from remote regions
  - Temporal trends from sediment cores, etc.
- Non-EU regulatory reviews or action (e.g. by Canada, USA, Japan)
- Non-test methods

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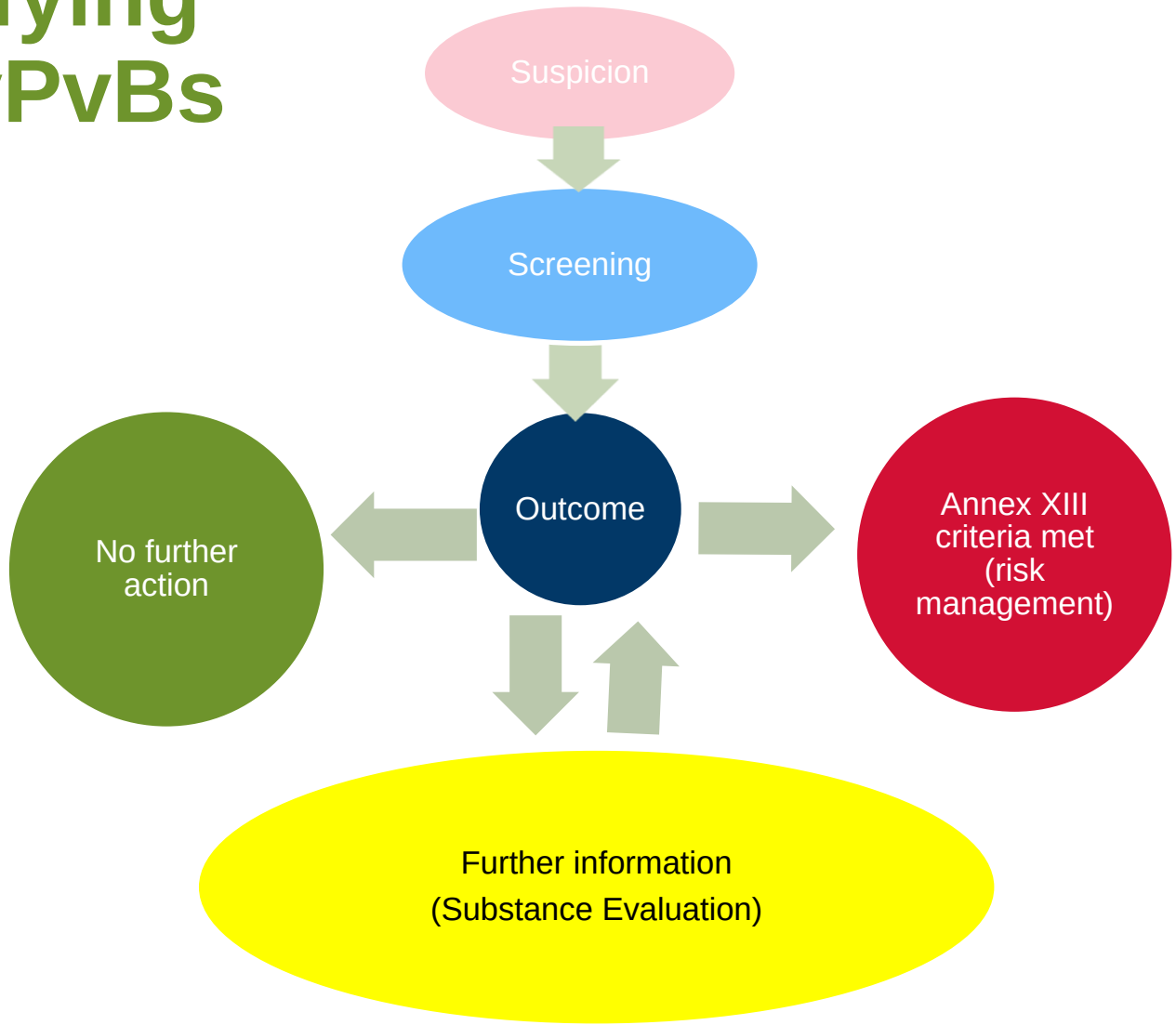
Identifying PBT/vPvBs



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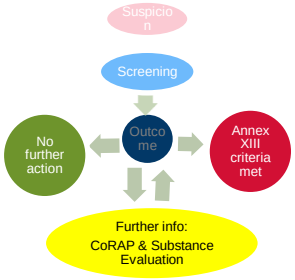
Screening work



- Output is a PBT “fact sheet”
  - Summarises key environmental fate and hazard data, with a comparison against the PBT criteria
  - Purpose is to decide if a chemical meets the criteria, needs more data or can be deselected
- Discussion at ECHA’s PBT Expert Group

  http://echa.europa.eu/en/addressing-chemicals-of-concern/substances-of-potential-concern/substance-specific-groups/pbt-expert-group
  - Closed or open session depending if substance is subject to a formal REACH evaluation process
  - Agreed fact sheets are published
  - Can progress to formal dossier for Candidate Listing or restriction (involves public consultation)

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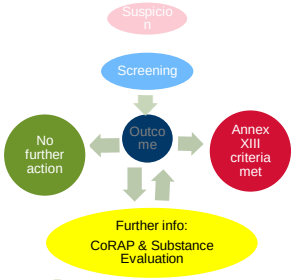
“Further information required”



- Community Rolling Action Plan (CoRAP) for Substance Evaluation
  - In-depth review of registrations by a Member State Competent Authority over 12 months
  - Outcome is (usually) a legally binding information request, with deadlines for delivery
    - E.g. New tests, monitoring, details of exposure assessment and/or risk management measures

Substance Name	EC Number	CAS Number	Year	Member State	Initial Grounds for Concern	Status	
1,1'-(ethane-1,2-diyl)bis [pentabromobenzene]	284-366-9	84852-53-9	2012	United Kingdom	Environment/Suspected PBT; Exposure/Wide dispersive use, high aggregated tonnage	Ongoing	Details

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PBT/vPvBs on the Candidate List

- DecaBDE
- Hexabromocyclododecane
- Short chain chlorinated paraffins
- PFOA and long chain perfluoro-carboxylic acids
- Bis(tributyltin)oxide (TBTO)
- Musk xylene
- Anthracene

http://echa.europa.eu/web/guest/candidate-list-table

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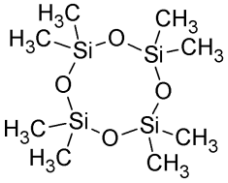
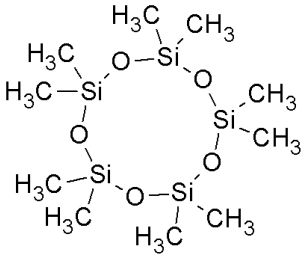
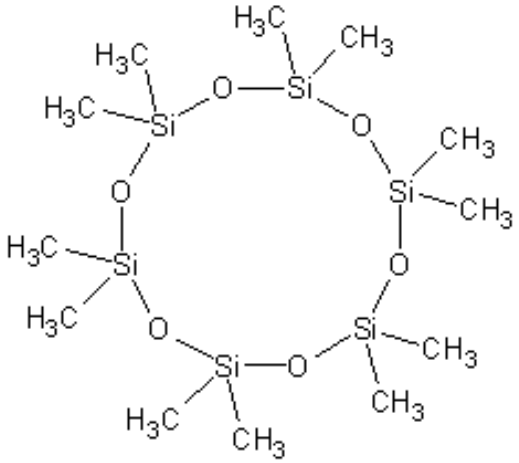
Siloxanes

- D4 and D5 meet the PBT and/or vPvB criteria and will be subject to a targeted restriction in due course
- We are still waiting for information on D6 and a series of linear siloxanes before making a final decision on their categorisation







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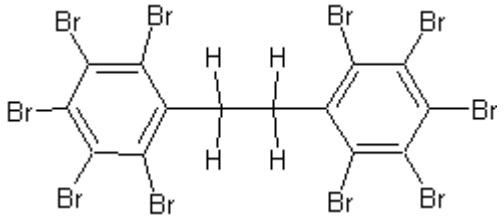
Decabromodiphenyl ethane (EBP)



- Drop-in replacement for decaBDE
- Meets screening criteria for vPvB
- UK Substance Evaluation in 2012
- Further data requested from industry:
  - Sediment and soil simulation tests (focus is on transformation, as already meets vP criterion)
  - Fish dietary bioaccumulation test
  - Exposure assessment (not classified as hazardous)

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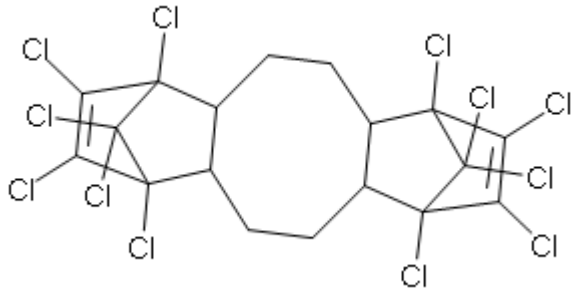
Dechlorane Plus



- Flame retardant supplied at relatively low tonnage – UK screening fact sheet recently prepared
- Poor data set in registration dossier (1970s studies)
- Likely to be persistent, but no confirmatory half-life data
- Low measured fish BCF
- Fish feeding bioaccumulation study in literature suggests biomagnification
- UK needs to prepare a risk management options analysis to decide on next steps

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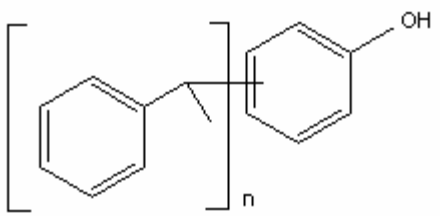
Styrenated phenol

- Anti-oxidant in rubber, nonylphenol replacement in surfactants
- 2014 UK Substance Evaluation
  - No final decision yet (work started in March)
- Three main components
  - Different profiles – tristyryl phenol screens as a vPvB substance
- Substance is difficult to test
- No monitoring data



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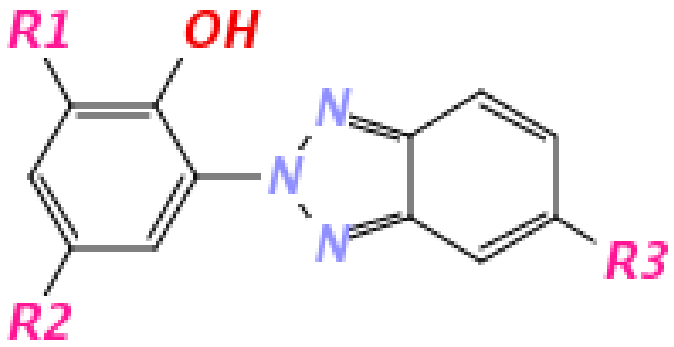
Other Member States' work - I



- Phenolic benzotriazoles
  - Meet B or vB criteria (some also T)
  - US monitoring data suggest persistence, but no measured half-lives available
  - No agreement yet about whether are P or vP

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Other Member States' work - II

octocrilene

dichloro(dimethyl)silane

trixylyl phosphate

2,2',6,6'-tetra-tert-butyl-4,4'-methylenediphenol

N,N'-dithiodi-o-phenylenedibenzamide

bis(4-chlorophenyl) sulphone

tetrapropylenebenzene

triclosan

http://echa.europa.eu/en/information-on-chemicals/evaluation/community-rolling-action-plan/corap-list-of-substances

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Summary

- SVHC Roadmap governs EU regulatory approaches to 2020
- We can only review registered substances
- Chemicals are in different stages of evaluation
  - screening, in-depth review, further data gathering, with only a handful subject to risk management action
- Potential PBT/vPvB chemicals are used in many applications, and have a variety of structures – more than just halogenated organics

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What can you do?

- Should all PBT/vPvB substances be treated as being equally dangerous?
  - What factors might indicate actual real world impacts?
- Screening relies on experimental data – are we missing substances because current test methods are inadequate?
- Please tell us about research that:
  - identifies substances in sediment cores and wildlife
  - provides more realistic degradation information over long time scales (e.g. micro/mesocosm studies)

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Any questions?

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