Rijksinstituut voor Volksgezondheid
en Milieu
*Ministerie van Volksgezondheid,
Welzijn en Sport*

PBT Assessment Persistence

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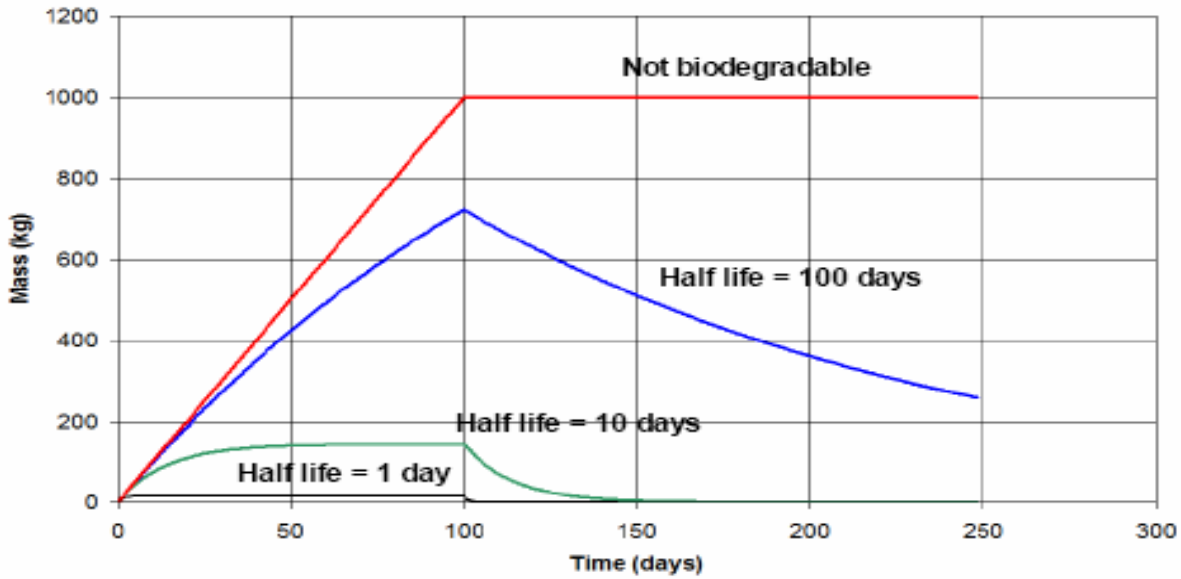
PBT criteria (Annex XIII)

PERSISTENCE

Definition of persistence

A chemical that resists degradation processes and is present in the environment for a long time

Importance of degradation



- Assumes release of 10 kg per day for 100 days
- Emission ceases after 100 days

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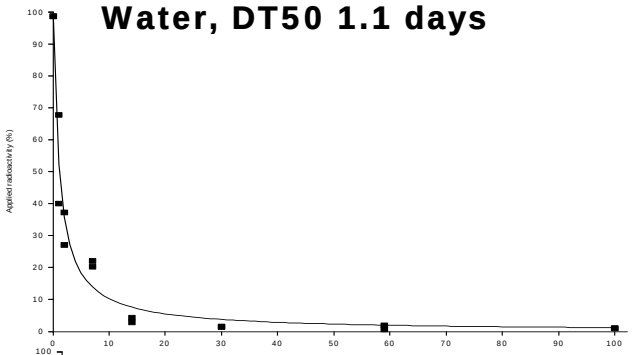
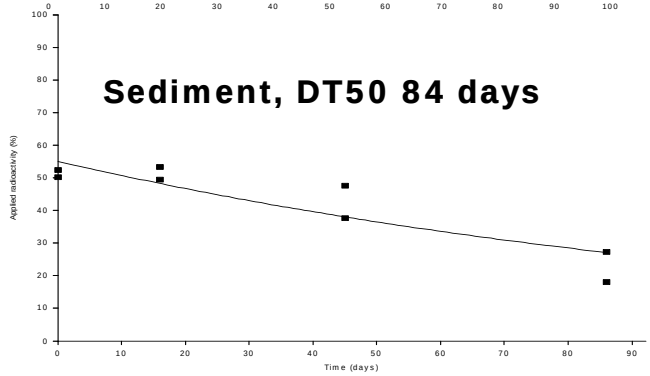
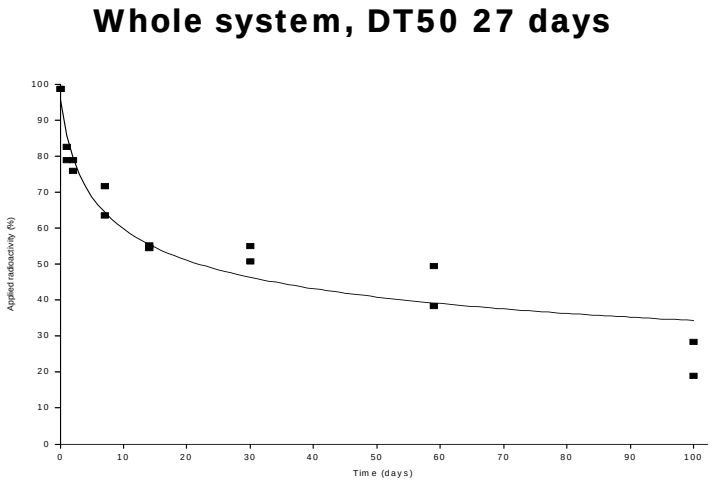
Issue: overall persistence ←→ persistence in environmental compartments







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Criterion is 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)]

Vergelijking kaders

Framework	Legislation	Indicators P
Former EU new and existing substances legislations	EU Directive 93/67/EEC and EU Regulation793/93/EEC and EC 1488/94; both now replaced by REACH	P: Marine water $t_{1/2}$ > 60 d or Freshwater $t_{1/2}$ > 40 d[a] or Marine sediment $t_{1/2}$ > 180 d or Freshwater sediment $t_{1/2}$ > 120 d[a] vP: marine or freshwater $t_{1/2}$ > 60 d marine or freshwater sediment $t_{1/2}$ >180 d
REACH	EU Regulation EC/1907/2006 (EC, 2006)	See Table 2
UNEP	Stockholm Convention (UNEP, 2001)	• Water: t½ > 2 months • Sediment: t½ > 6 months • Soil: t½ > 6 months • Other evidence
LRTAP (UN-ECE)	UNECE POP Protocol under the Convention on Long-range Transboundary air Pollution(UNECE, 1998a)	• Water: t½ > 2 months • Sediment: t½ > 6 months • Soil: t½ > 6 months • Other evidence
IMO Ballast Water Convention	International Convention for the Control and Management of Ships' Ballast Water and Sediments (IMO, 2004)	• Fresh water: t½ > 40 days • Marine water: t½ > 2 months • Freshwater sediment: t½ > 4 months • Marine sediment: t½ > 6 months

Vergelijking kaders

Framework	Legislation	Indicators P
Biocides	EU Directive 98/8/EG (EC, 1998)	
Plant protection products	EU Regulation 1107/2009 (EC, 2009)	POP: • Water: t½ > 2 months • Sediment: t½ > 6 months • Soil: t½ > 6 months PBT; P: • Marine water: t½ > 60 d; • Fresh water t½ > 40 d • Marine sediment: t½ > 180 d • Freshwater sediment: t½ > 120 d • Soil: t½ > 120 d PBT; vP: • Water: t½ > 60 d • Sediment: t½ > 180 d; • Soil: t½ > 180 d
Human pharmaceuticals	EU Directive 2004 /27/EC (EC, 2004b)	
Veterinary pharmaceuticals	EU Directive 2004/28/EC (EC, 2004c)	
OSPAR	OSPAR Convention for the protection of the marine environment of the North-East Atlantic (OSPAR, 2003)	Half-life (T½) of 50 days

Screening tests

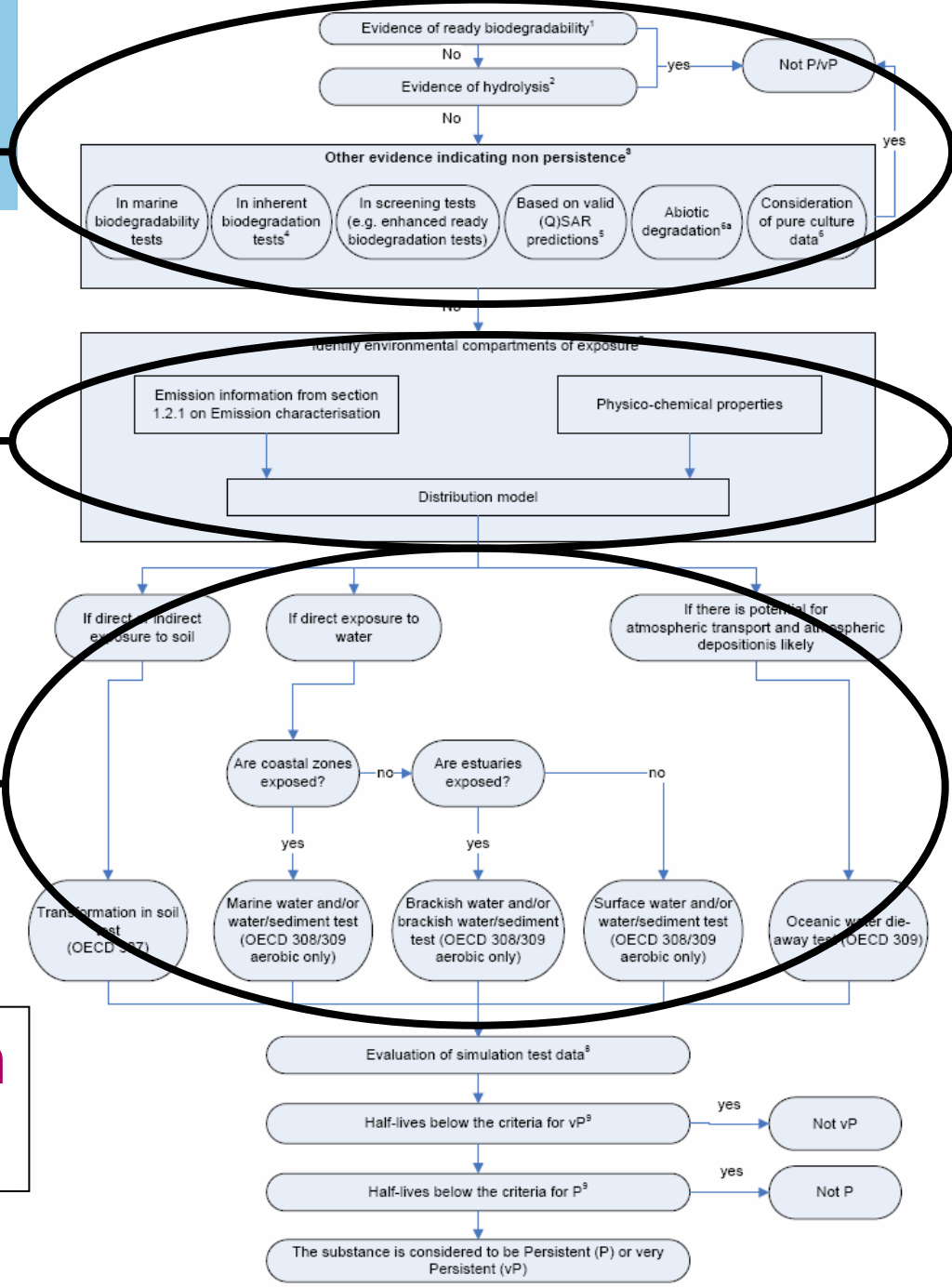
(RB ⇨ enhanced

↓

Distribution modelling

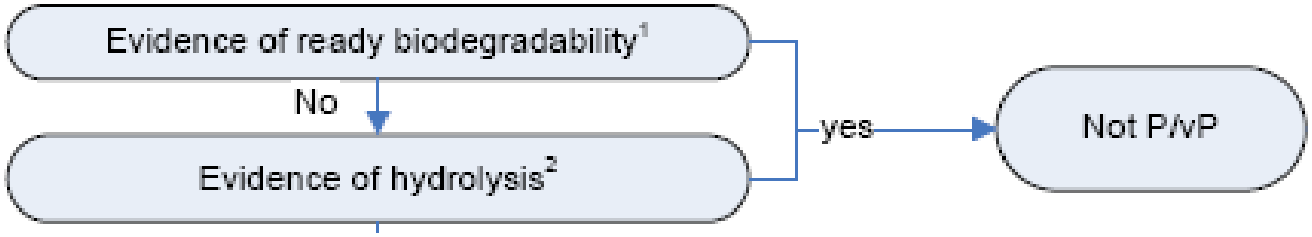
↓

Selection of simulation studies

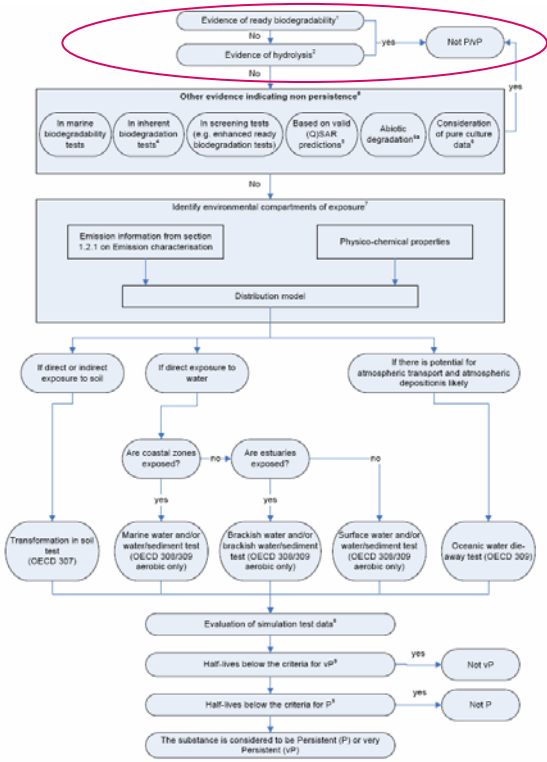


REACH guidance on testing strategy

Persistence testing



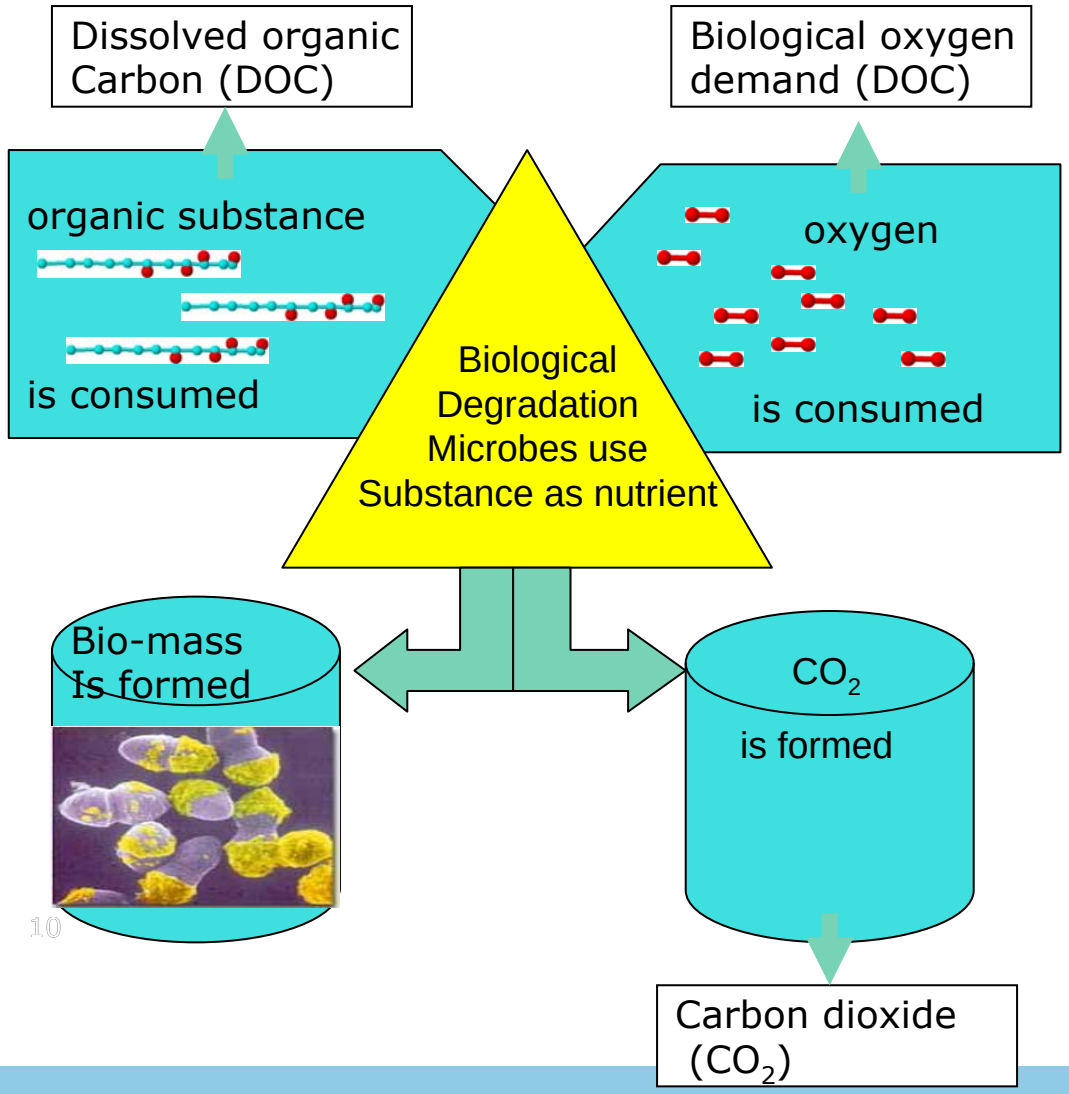
- Ready test (with exception of 10-day window)
  - Modified ready tests can be considered
- Hydrolysis ½ life less than 40 (60) days
  - Degradation products >10% considered

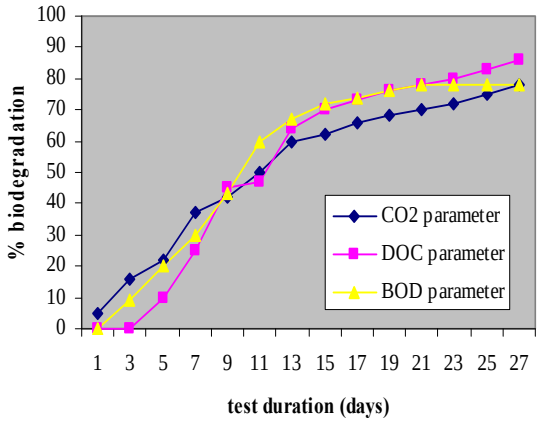


Ready Biodegradability tests

- simple, cheap and quick to perform screening test (required for all substances > 10 tonnes)
- artificial, but very stringent test conditions
- Identify substances that are fast and readily degradable in the environment

Tests ultimate degradation (OECD 301)





OECD 301 C | OECD 301 B

OECD 301 D | OECD 301 A

OECD 301 F | OECD 301 E

Reason for not reaching the pass levels:

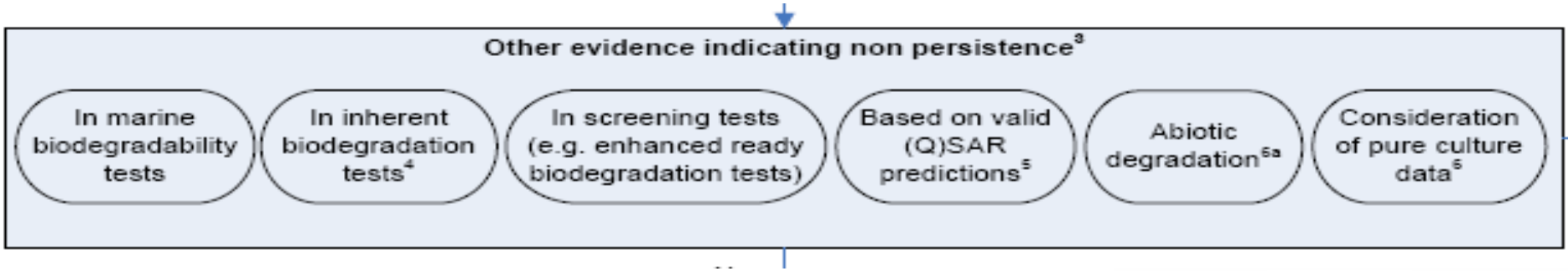
- The chemical is persistent / non degradable
- The chemical is only partially degraded
- Initial concentration is toxic to the inoculum (option: minimise concentration within allowed limits)
- The low level of microbial biomass results in the absence of competent microbial degraders
- Reduced bioavailability (Poorly water soluble, strongly sorbing substances)

Inherent biodegradability tests(OECD 302)

Test used for checking of the potential for any biological degradation

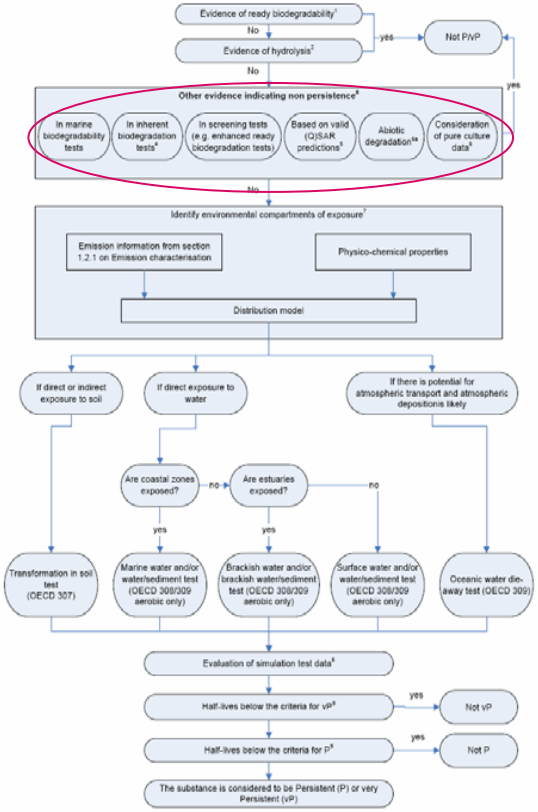
- enhanced inoculum and increased ratio between microbial biomass and test substance conc.
- but also very high conc. of test substance
- measurement of primary or ultimate degradation
- +/- pre-exposure of inoculum (pre-adaptation)

Persistence testing

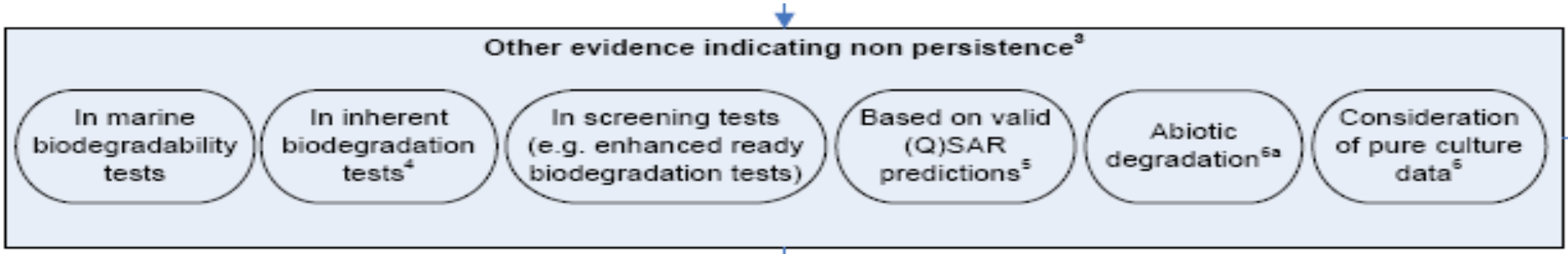


- Use Negative inherent degradation test as sufficient evidence for P
- Enhanced studies:

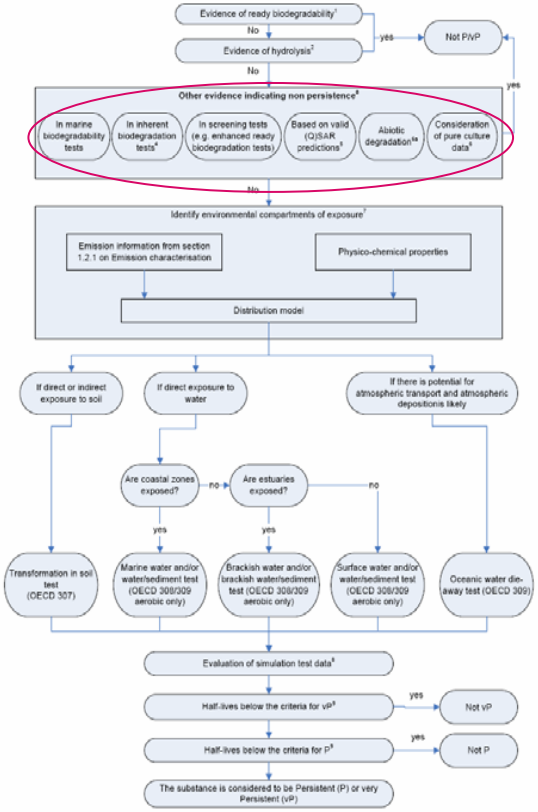
1. up to 60 d as in TG 306
2. increase number/types of microorganisms
3. "some" pre-acclimation



Persistence testing



- Use Negative inherent degradation test as sufficient evidence for P
- Enhanced studies
- QSBRs can be used as evidence for not P / P



QSARs EPIWIN Predictions

Criteria for considering substance to be persistent

BIOWIN 2 or BIOWIN 6 < 0.5

(great likelihood of not ready biodegradability)

BIOWIN 3 < 2.2

(great likelihood of degradation timeframe of

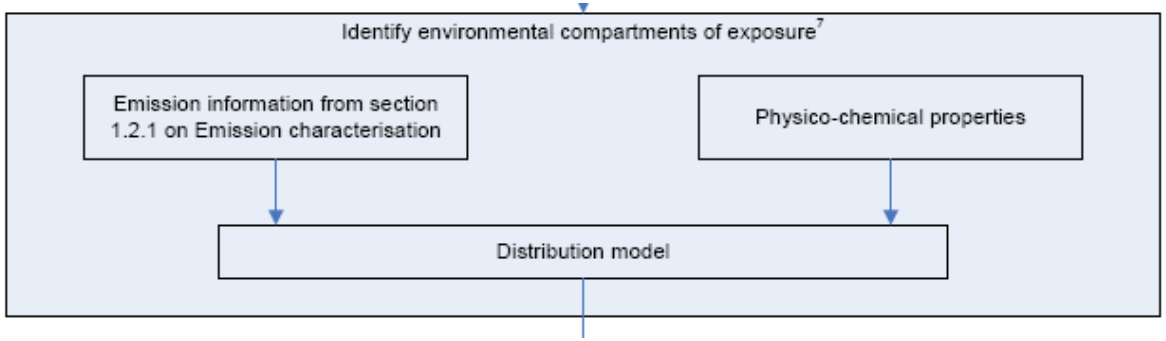
weeks -months and very high likelihood of not ready biodegradability)

Note: When the QSAR predictions are reliable and the estimation results clearly indicate that the substance is not persistent, further information will normally not be required for the PBT and vPvB assessment, and it may be considered as not fulfilling the criteria for P

Screening criteria - summary

Type of data	Criterion	
Readily biodegradable	Ready biodegradable	Not P
Enhanced ready biodegradation	Ready biodegradable	Not P
Hydrolysis	Substance hydrolyse and no metabolites > 10% are persistent	Not P
Marine biodegradability	60% (ThOD, CO_2 evolution) or ultimate70% ultimate biodegradability (DOC removal)	Not P
inherent biodegradability Zahn-Wellens (OECD 302B) MITI II test (OECD 302C)	≥ 70 % mineralisation (DOC removal) within 7/14 d; log phase longer than 3d;	Not P Not P
QSAR Biowin 2 , 3, 6	Does not biodegrade fast (probability < 0.5) and ultimate biodgradation time ≥ months (value < 2.2)	P P

Which type of simulation test should be selected?



- Consider results of Multi Media Modelling (Mackay III)

  If e.g. MMM indicates significant mass fraction of substance with realistic emission pattern goes to sea water
  => investigated in both TG 308 & 309
  => not P in estuarine sediment but P in estuarine water

-

  => overall conclusion P

Which type of simulation test?

- consider simulation testing in that or those compartment(s) to which the largest/ a large mass fraction(s) of the chemical is distributed
- degradation in mobile media like air and water is however significantly low for long range transport, i.e $DT50_{air}$ > 2 days (and thus for exposure in remote areas, which in the PBT assessment is also considered by using available monitoring data)
- consider Kp value:

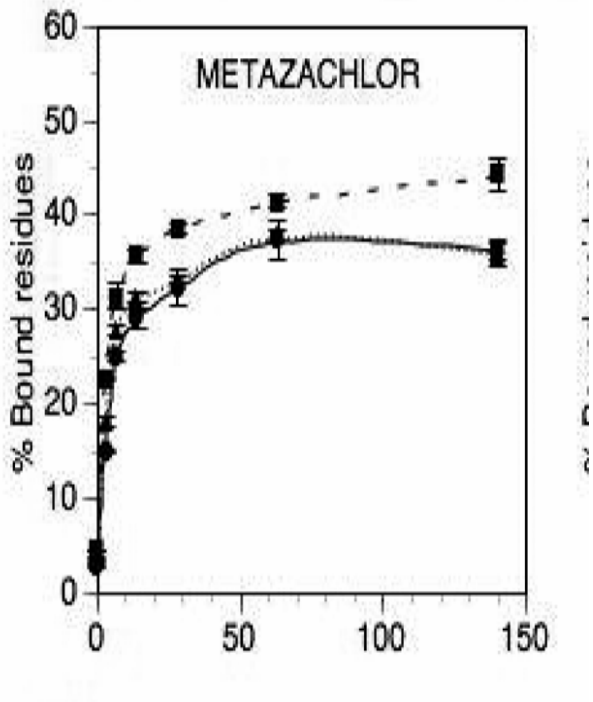
  - Kp < 2000 pelagic test (OECD TG 309)
  - Kp> 2000 pelagic (if practically possible) and sediment test (OECD TG 308 & 309) (cf. TGD)

Interpretation of simulation studies

Water - Sediment tests (OECD 308)

- don t use *removal* rate from *water* phase as general indication of half-life in the pelagic compartment, because removal may well be *dominated by adsorption* rate to sediment in the shallow water column of the test system
- consider PBT properties of *degradation products*, when substance degrade via *primary degradation*
- In the REACH guidance (R 7b and 16) a *temperature correction* of biodegradation half-lives is prescribed, although this is not mentioned in the REACH guidance on PBT assessment (R 11)

Complete
Proof that degradation does not lead to the formation of stable organic degradation metabolites (e.g. metabolite test)



Metabolite formation - bound residues

Examples non-extractable residues (NER):

- Triticonazole: <10%
- Endosulfan: <12%
- Atrazine: 20-25%
- Chlorothalonil: 5-40%
- Paraquat: >90%

Q:

1. Methodological issues: degree of denaturation of soil in use of extractants
2. Lack of criteria on when "total" extraction is reached – extraction efficiency
3. Ageing – factor time
4. NER = metabolite

Points for consideration Persistency

- Be aware that half-life in simulation studies refers to degradation and not volatilisation and adsorption
- Bound residue formation should be considered provided that exhaustive extraction procedures are followed
- Be aware that degradation products can be formed having PBT/vPvB properties
- If there is an indication that the substances will reach ocean water, an ocean die-away test (instead of a water/sediment study) should be preferred as this is considered most stringent

Aandachtspunten

- Field data
- Extrapolation of test results to half-lives
- Metabolite formation - bound residues
- T effect: Plant protection products: 12 degrees C
  - Other regulations: under consideration
- Dissipation (volatilisation) during (field) testing