Integrated testing strategy for persistency

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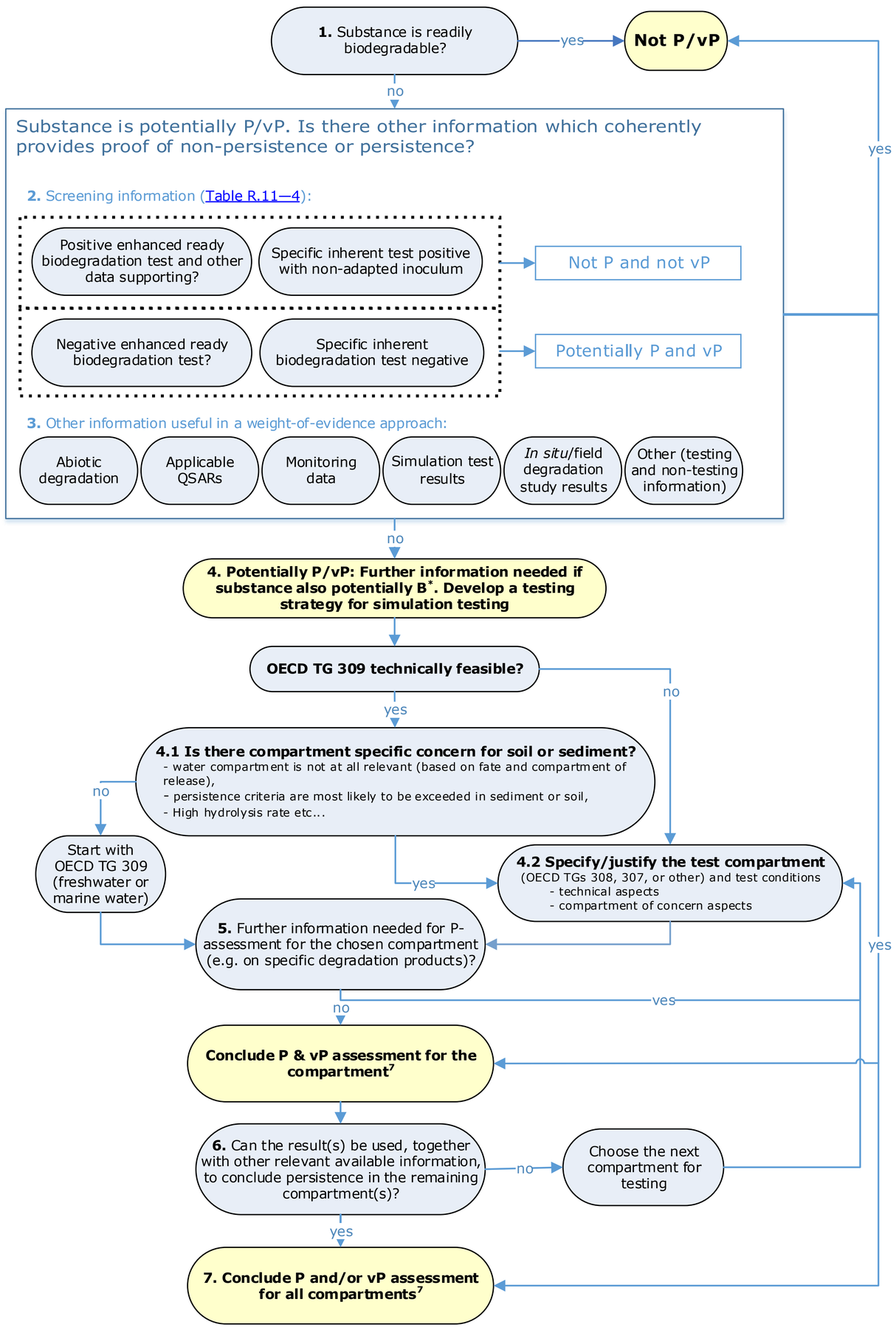
Introduction

The updated ECHA Guidance[1] R.11 for PBT/vPvB assessment was published in 2017. This update includes a revised integrated assessment and testing strategy (ITS) for persistence assessment. This tiered approach is necessary until a definitive conclusion on persistence can be drawn. In the presented approach, available data consisting solely of screening information can be employed to derive a conclusion mainly for "not P and not vP" or "may fulfil the P or vP criteria". For potentially P/vP substances higher tier information generally needs to be made available. Appropriate data need to be available to conclude the P/vP-assessment on all three compartments (or five, if including marine compartments): water (marine water), sediment (marine sediment) and soil. In case the substance is concluded as "P" or "vP" for one compartment, no further testing or assessment of persistence for other environmental compartments is normally necessary. The updated Guidance also includes advice on how to conduct PBT assessment for substances containing multiple constituents, impurities and/or additives. The steps and elements of the ITS are presented below.



* In the context of the Biocidal Product Regulation (BPR), it is worth noting that the P-criteria has to be assessed also when the T-criterion is (potentially) fulfilled.

Figure R.11—3: Integrated Assessment and Testing Strategy for persistence assessment – maximising data use and targeting testing.

Integrated assessment and testing of Persistence – Explanatory Notes to Figure R.11—3	
1	The substance is readily biodegradable, or the criteria for ready biodegradability are fulfilled with the exception of the 10-day window. If the substance is concluded as not P or vP, no further testing is needed.
2	When based on (1) the substance is potentially P/vP, evaluate other screening level information. Enhanced screening tests: • Not P/vP or potentially P/vP • Expert judgement and Weight-of-Evidence (WoE) Specified tests on inherent biodegradability for not P/vP: Zahn-Wellens (OECD TG 302B) • ≥70 % mineralisation (DOC removal) within 7 d; log phase no longer than 3d; removal before degradation occurs below 15%; no pre-adapted inoculum MITI II test (OECD TG 302C) • ≥70% mineralisation (O2 uptake) within 14 days; log phase no longer than 3d; no pre-adapted inoculum
3	When based on (1 and 2) the substance is potentially P/vP, consider other useful information for WoE approach. • All available information on (bio)degradation, including testing, non-testing and monitoring data, should be considered. • Consider if the information available on WoE coherently provides proof of (non-)persistence and is sufficient to allow concluding the P/vP assessment, or if it indicate that further testing is needed.
4	Develop a testing strategy. • Aim to conclude on P/vP with the least possible efforts in testing and at the same time cover the assessment of persistence in all environmental compartments. • Justify the selected approach, test environment(s) and the relevance of the test material.
5	Compare the results with the Annex XIII criteria. • If the substance or its degradation products are P or vP, there is no need for further testing. • If the substance and its degradation products are not-P in the test environment, consider if there is concern in remaining compartments (see step 6).
6	Consider if the available information is adequate to conclude on P/vP e.g. is extrapolation to other compartments possible and are all relevant constituents considered. NO - continue testing YES - go to STEP 7
7	Evaluate the half-life(lives) obtained against the criteria of Annex XIII and determine if P or vP criteria are met. Consider all three (five) environmental compartments. • Before finally concluding on persistency examine if there are conflicting evidence from any monitoring data e.g. findings of significant concentrations in remote and pristine environments, or in food chain in unpolluted areas.

References

1 Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.11 (June 2017)

Steps needed to incorporate scientific developments into regulatory practice

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Introduction

The PBT/vPvB assessment methodology is compiled in the ECHA Guidance R.11 (version 3.0, 2017)[1]. This methodology has been developed since 2002 based on the European PBT/vPvB assessment experiences. The Guidance focuses on specifying the registrant's duties with regard to the Annex XIII to REACH[2]. From past guidance revision processes, as well as from day-to-day work both at ECHA and in the PBT Expert Group (PBT-EG)[3], several scientific development topics with relevance for the PBT/vPvB assessment have been identified. Integration of scientific development topics into regulatory practice requires a stepwise approach and consideration of various elements. These steps and elements, as well as a set of identified scientific development topics, are presented below.

Development process

Scoping of the identified development issue

Discussion in the PBT-EG*

Drafting of a discussion paper

Discussion & agreement in the PBT-EG*

Transformation/integration into appropriate ECHA support instruments

Formal update process[4]* (if relevant)

Publication of guidance and advice on ECHA website**

Application in practice:
- Assessment work of the Member States/COM
- Work of informal discussion bodies (e.g., PBT-EG)
- Work of ECHA and its Committees
- Chemical Safety Assessments of registrants

*Includes stakeholder participation
** E.g., ECHA Guidance, Practical guides, factsheets, discussion papers

Elements to consider in the development process

The Scientific Information
- Does the scientific evidence provide enough ground to change the regulatory practice or is further research needed?
- Do the rules of regulatory practice need to be changed?
- What is the scientific applicability domain of the new/revised approach?
- Are there any constraints (e.g., reliability issues, technical feasibility)?

The Regulatory Context
- What is the relevance and applicability of the new/revised approach in terms of regulatory practice?
- What are the legal interpretation(s)?

The ECHA Guidance
- Which parts of the Guidance need to be addressed?
- What kind of changes are needed (e.g., changes to guidance structure, thresholds or terminology)?

Precedent cases from regulatory decision processes
- Are there relevant learnings and/or rules already applied in decision making process?
- Can benchmarking be applied?

Pilot cases
- Are there pilot cases that can be used for the application of the new approach?

Existing related approaches
- Are there inter-linkages with the new- and existing approaches?

Focus	Selected PBT/vPvB assessment guidance development issues
General	**Weight-of-Evidence (WoE)** What is meant by WoE by expert judgement? Improve the systematic reporting, pragmatic tools and guidance for WoE in the PBT assessment. Addressing and documenting uncertainty in systemic way.
General	**Difficult to test substances** • Environmental risk assessment of poorly soluble substances: biodegradation, (de)sorption, and modelling. • Appropriate guidance and method development are necessary for assessment of ionizing substances and surfactants. • Test material selection and identification of UVCB substances
General	**Possibilities of analytical tools in environmental fate testing** • Investigation of the practical expectations and limitations of chemical analysis in environmental fate testing for REACH: focus on degradation simulation and bioaccumulation studies.
General	**Role and use of QSARs** • What is the role and acceptance level of QSARs in PBT assessment?
P	**Non extractable residues (NER)** Reflect the latest developments in the guidance (R.7 & R.11). The topic is relevant for all simulation tests.
B	**Relevance and interpretation of the information on bioaccumulation** • Interpreting results using toxicokinetic data in B-assessment. Benchmarking by using elimination half-lives of PBT/POP substances to identify potential elimination thresholds for B and vB. • Alternative mechanisms of bioaccumulation (non lipid based); special substance groups (e.g. surfactants or ionizing substances), different uptake mechanisms (e.g. active) and different binding (e.g. protein binding). • Interpretation of the dietary bioaccumulation test results: e.g. BMFs < 1 and criteria for selecting the exposure route (OECD 305). • Bioaccumulation in soil and difference between field and experimental biomagnification factors (BMFs) including comparison of field BMFs with the B/vB criteria.
T	What kind of information is covered by the term **"Other information.."** referred to in Section 3.2.3 (f) of Annex XIII to REACH, that is not directly (numerically) comparable with the T-criteria in Section 1.1.3 of Annex XIII?

References

1 Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.11 (June 2017)
2 Commission Regulation (EU) No 253/2011 of 15 March 2011
3 See: https://echa.europa.eu/pbt-expert-group
4 See: http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation/consultation-procedure