Assessment of PBTs in the EU: A critical review and proposed evaluation scheme with reference to plant protection products

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Introduction

A number of international and national programs classify substances that are persistent (P or very P), bioaccumulative (B or very B), toxic (T), or have the potential for long-range transport. The oldest of these programs is the Stockholm Convention on Persistent Organic Pollutants. More recent programs address persistent, bioaccumulative, and toxic (PBT) properties for chemicals in general (Registration, Evaluation, Authorisation and Restriction of Chemicals, REACH; EC 253/2011) and plant protection products (PPPs) (EC 1107/2009). However, these programs used different criteria for categorization. We critically assessed the criteria and process used in the categorization of PPPs and noted that EC1107/2009, in contrast to the Stockholm Convention or REACH, offers no process for carrying out a further, more refined assessment of those pesticides that are identified as having PBT properties. Thus, in contrast to REACH, few basic screening criteria are used for final-step management decisions. In the following, we suggest guidance on how to use the defined criteria to avoid missing potentially critical compounds (false negatives) or to classify non-PBT compounds as critical (false positives).

Assessment of P, B and T under EC 1107/2009

The persistence criterion is triggered where half-life exceeds specific values, however:

- No guidance is given as to how the half-lives in soil, water, and sediment should be derived.
- The term “half-life” is not clearly defined (e.g., dissipation or degradation).
- Underlying numerical trigger values are based on the half-lives of legacy POPs (“dirty dozen”) and based on standard degradation studies for these compounds created at that time.

The use of a simple trigger value implies that persistence is an inherent property of a chemical, however, persistence also is strongly dependent on environmental conditions. Thus, some chemicals, which are persistent in the environment will not be identified as persistent and vice versa.

Important considerations when developing data for bioaccumulation of PPPs:

- Extremely low solubility in water is a potential source of errors when testing for B in aquatic systems.
- Laboratory tests usually measure bioconcentration; testing biomagnification (BMF) through food may be more relevant, particularly for compounds with low water solubility. However, trigger values for BMF are not available.
- Bioaccumulation patterns in terrestrial food-webs may be substantially different from those in aquatic food webs but, at present, there are no trigger values for B in terrestrial systems.
- Trophic magnification factors are the “gold standard” but usually would be derived from field-data and thus not easily available for prospective assessment of B.
Important considerations when developing data for toxicity of PPPs:

- PPPs are designed to be toxic to at least one group of organisms, however, use-rates are proportional to potency and this normalizes toxicity under field conditions.
- The T criterion for PBT classification provides a toxicity threshold but does not indicate a specific organism or provide guidance where data from more than one species are always available.
- Guidance for the use of information from species sensitivity distributions (SSDs) is not provided but would be very useful.

General recommendations

- A formal, quantitative, and transparent process of weight of evidence should be included in the guidance for the selection of appropriate data and how these are compared to the criteria.
- The quality of data produced under GLP with QA/QC is high and should be recognized in the guidance for selecting the data for classification of PPPs.
- Data for P, B and T of acceptable quality from multiple studies should be combined depending on the distribution of the data (normal or log-normal). For data on toxicity from multiple species, the use of centiles, such as the HC5 from SSDs, is recommended but with appropriate attention to the protection goals.
- The evaluation of PBT should consider the overall environment, integrating all of the information available from all compartments.
- Guidance for classification of PPPs under Regulation 1107/2009 should include a decision-tree for selection and application of the criteria.

Recommendations for P

- Studies carried out under appropriate use conditions should be preferred. Normalized degradation half-lives - corrected for other loss processes can be compared to the P criterion. Furthermore, other degradation processes such as photolysis should be included in the evaluation and appropriate conditions and triggers need to be defined.
- Non-extractable bound residues are generally not bioavailable and should not be considered for the estimation of the half-lives.
- DT50 (i.e., DisT50) in fresh water < 40 d does not negate concerns for P. The DT50 trigger for water derived from water-sediment studies may only be considered as passed if degradation in water can be demonstrated (e.g., via hydrolysis, photolysis, biodegradation) or if dissipation from water to the sediment is associated with sufficiently rapid degradation in sediment. The DT50 for the whole water/sediment system may be used as a conservative value for the half-life in sediment.

Recommendations for B

- For compounds with low water solubility and low relevance in the aquatic phase, BMF < 1 should be considered a sufficiently conservative criterion.
- Where persistence is clearly not relevant in aquatic but is in terrestrial systems, criteria for bioconcentration or BSAF from soils need to be developed.
- An alternative approach to characterizing TMF prospectively would be to make use of ecological magnification (EM) values from food-web model ecosystems. This would provide a physical model of trophic transfer and an estimate of magnification in the food-chain.

Recommendation for T

- To be relevant to compounds that are P, B, and T, the toxicity trigger should primarily be based on endpoints in organisms higher up in the food chain such as vertebrates (and relevant invertebrates).

References