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Safety of the Food chain
Chemicals, contaminants, pesticides

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DG SANCO Working Document
on
"Evidence Needed to Identify POP, PBT and vPvB Properties for Pesticides"

The present document summarises the conclusions of:

1. An Expert Meeting on "Evidence Needed to Identify POP, PBT and vPvB Properties for Pesticides" held on 25 April 2012;
2. A written commenting round on the Discussion Document circulated by DG SANCO after the Expert Meeting;
3. A follow-up teleconference held on 14 September 2012, to discuss and draw the conclusions on the main issues identified during the Expert Meeting and in the commenting phase.

These conclusions will be used for:

- a) the initial establishment of a list of Candidates for Substitution (CFS), to which the Commission is legally obliged by 14 December 2013 according to Art. 80(7) of Reg. 1107/2009;
- b) the assessment of new/existing active substances against the PBT (and POP/vPvB) criteria when these substances are evaluated for approval/renewal under Reg. 1107/2009. Such assessment includes the regular update of the list of CFS.

As regards the initial establishment of a list of CFS, the expert group concluded that a modified approach to the assessment of some parameters is necessary in view of the scope of the exercise to be conducted and the limited timeframe.

For some issues, a need for further guidance was identified. This should preferably be developed in co-operation with ECHA to enable a harmonised approach for industrial chemicals, and active substances in biocides and plant protection products, to the extent possible. Any difference in guidance and procedures under different legislation may need to be identified and discussed.

The conclusions are summarized below:

1) Issue: POP persistence assessment - Water bodies

For assessment of the POP persistence criterion, data on both fresh and marine water is acceptable and can be used, whichever is available in the dossier. Ideally, data on both fresh and marine water is available and should be used.

2) Issue: POP persistence assessment - DT50

For assessment of the POP persistence criterion, DT50 should refer to degradation, as specified in Annex II to Reg. 1107/2009, point 3.7.1.1.

Field dissipation studies should be included in the assessment if it is possible to derive degradation half-lives from them, i.e. if it can be excluded that dissipation is due to volatilisation from soil, leaching, surface run-off or uptake into plants.

As regards the initial establishment of a list of CFS, field dissipation studies should only be included in the assessment if Vapour pressure $\leq 1 \times 10^{-4}$ Pa at 20°C (FOCUS air Sanco/10553/2006 rev 2 June 2008) and Henry's Law constant ≤ 0.1 Pa m³ mol⁻¹.

Data on biodegradation and hydrolysis should be taken into account. Data on photolysis should also be considered when relevant (e.g. soil photolysis may not be relevant for substances only used for seed treatments).

Further Guidance is needed on when photolysis data are required and how they should be interpreted.

As regards the initial establishment of a list of CFS, photolysis studies should not be considered.

3) Issue: Persistence assessment - Water/sediment studies

First, the compartment(s) relevant for degradation needs to be established (water, sediment or both). A compartment is relevant for degradation if there is evidence of accumulation in that compartment/partitioning of the substance into that compartment. Then, the cut-off value for that compartment is compared to the whole-system DT50.

4) Issue: Persistence assessment - Unextractable residues

Unextractable residues should be excluded from further assessment. They can be considered degradation loss, not bioavailable and therefore unable to exert toxicity.

This approach is consistent with the SCHER opinion on aclonifen EQS (30 March 2011).

Future Guidance might foresee taking into account "adsorbed unextractable residues", which could be mobilised in the long term and become relevant for further assessment.

5) Issue: PBT /vPvB persistence assessment - Target half-life assessment

For assessment of the PBT/vPvB persistence criterion, half-life should refer to degradation.

Field dissipation studies should be included in the assessment if it is possible to derive degradation half-lives from them, i.e. if it can be excluded that dissipation is due to volatilisation from soil, leaching, surface run-off or uptake into plants.

As regards the initial establishment of a list of CFS, field dissipation studies should only be included in the assessment if Vapour pressure $\leq 1 \times 10^{-4}$ Pa at 20°C (FOCUS air Sanco/10553/2006 rev 2 June 2008) and Henry's Law constant ≤ 0.1 Pa m³ mol⁻¹.

Data on biodegradation and hydrolysis should be taken into account. Data on photolysis should also be considered, when relevant (e.g. soil photolysis may not be relevant for substances only used for seed treatments).

Further Guidance is needed on when photolysis data are required and how they should be interpreted.

As regards the initial establishment of a list of CFS, photolysis studies should be not considered.

6) Issue: PBT /vPvB persistence assessment - Half-lives DT50

The kinetic model that gives the best description of the chemical's behaviour should be selected. Guidance provided in FOCUS Degradation Kinetics Guidance (Sanco/10058/2005, ver 2.0, June 2006) on how to derive best fit DT50 should be applied.

As regards the initial establishment of a list of CFS, if a DT50 value based on single first order kinetics is available in the list of endpoints, the cut-off value should be compared to it directly. Otherwise, the cut-off value should be compared to the DT90 value in the list of endpoints divided by 3.32, provided the DT90 value is calculated and not estimated.

7) Issue: PBT /vPvB persistence assessment - Appropriate conditions to generate half-lives data

Anaerobic data should be used, but only as additional information.

As regards the initial establishment of a list of CFS, anaerobic data should not be considered.

8) Issue: Persistence assessment in general - Metabolites

Data on metabolites should not be included in the assessment against the criteria laid down in point 3.7 of Annex II to Regulation (EC) No 1107/2009. Data on metabolites that are considered relevant according to Art. 3(32) of Regulation 1107/2009 (both from laboratory studies, field studies and alternative testing strategies such as in silico methods) should be taken into account in the context of the overall approval decision or of the definition of risk mitigation measures.

As regards CFS, the second hyphen of point 4 of Annex II to Regulation (EC) No 1107/2009 (meeting two of the criteria to be considered as a PBT substance) applies to the active substance but not its metabolites.

9) Issue: Persistence assessment in general - Temperature for normalization of DT50/half lives

Laboratory studies: DT50 values should be normalised to a temperature of 20°C, as this is the current practice in recent assessments of soil degradation rates of active substances. Guidance on temperature normalisation is available in ECHA GD 7.b.

Field studies: DT50 values should not be normalised. A Weight of Evidence approach should be used for the evaluation of field studies. Significant variations among studies should be described and explained to inform decision making by risk managers.

Further guidance and harmonisation with biocides legislation and REACH is needed.

As regards the initial establishment of a list with CFS, all DT50 values should be normalised to a temperature of 20°C.

10) Issue: Persistence assessment in general - Geomean or worst case

DT50 values from different studies should not be aggregated. A Weight of Evidence approach should be used for the evaluation of laboratory and/or field studies. Significant variations among studies should be described and explained to inform decision making by risk managers.

Further guidance and better harmonisation with biocides legislation and REACH is needed.

As regards the initial establishment of a list of CFS, values from different studies should be aggregated by calculation of the geometric mean. Only DT50 values based on single first order kinetics should be used for data aggregation. When values do not follow first order kinetics, instead the DT90 value in the list of endpoints should be divided by 3.32 and then included in the calculation of the geometric mean, provided the DT90 value is calculated and not estimated.

11) Issue: Persistence assessment in general - Stakeholders view on "one compartment approach"

The three PBT criteria referred to in Annex II to Reg 1107/2009 do not necessarily have to be met in the same compartment.

12) Issue: Toxicity assessment in general – Higher tier studies (e.g. mesocosm studies)

Higher tier data (e.g. mesocosm data) should be included in the assessment when possible, using a Weight of Evidence approach. In the absence of a relevant NOEC value, EC50 values (with an assessment factor of 10) or EC10 values (without assessment factor) can be used instead. When assessing the standard endpoints from algal and aquatic macrophyte studies, the NOEC or ECx value should be based on the effect on growth rate.

As regards the initial establishment of a list of CFS, higher tier data should not be included in the assessment (*exposure might be difficult to standardise*).

13) Issue: Bioaccumulation assessment in general – Data on different classes of organisms

Values for the bioconcentration factor (or for the bioaccumulation factor for assessment of the POP bioaccumulation criterion) derived from different studies should not be aggregated but considered in a Weight of Evidence approach.

As regards the initial establishment of a list of CFS, studies in plants should not be included in the assessment. If several studies in animals are available, they should be aggregated:

a) in case the studies were performed with the same taxonomic group of organisms (e.g. fish), BCF values should be aggregated by calculation of the geometric mean (*as sufficiently similar in design and route of exposure*);

b) in case the studies were performed with different taxonomic groups of organisms, BCF values should be aggregated using the worst case.