Environmental effects assessments for biocidal active substances that rapidly degrade in environmental compartments of concern.

This document was endorsed at the 32nd meeting of representatives of Members States Competent Authorities for the implementation of Directive 98/8/EC concerning the placing of biocidal products on the market (18-20 February 2009).

Issue: To harmonise the use of the time weighted average (TWA) and other available approaches to define effect data endpoints in aquatic and soil studies where the test concentrations cannot be maintained throughout the test.

Background: The risk within an environmental compartment posed by the use of a biocidal substance is determined by comparing the exposure [or predicted environmental concentration (PEC)] with the likelihood of no effect [or predicted no effect concentration (PNEC)] as derived from the test with the most sensitive species. Therefore, the risk assessment needs to take account of both the behaviour and effect of the substance in the environment, based on the available hazard data.

Much of the available guidance on environmental testing, exposure and risk assessment strategies concentrates on the issue of persistence and does not sufficiently tackle the issue of non-persistence. This is a particular concern for risk assessors and experimenters when testing the effects of non-persistent or rapidly degrading substances in tests where method modifications such as flow-through or static-renewal are not practical i.e. algal, sediment and soil ecotoxicological tests. Furthermore, several biocidal uses result in a continuous or semi-continuous long-term exposure for such non-persistent substances. Therefore, additional guidance on how, and when, to calculate the no effect concentration is required for a substance in aquatic and soil studies where the test concentrations cannot be maintained throughout the exposure period of the test.

Special care should be taken in the evaluation of such rapidly degrading substances that this rapid degradation is sufficiently considered for a balanced risk characterisation (PEC:PNEC). If a substance shows a rapid degradation, this is normally already considered for the exposure estimation, leading to a correspondingly lower PEC. To use nominal or initial measured concentrations on the effects side instead of (mean) measured concentrations would lead to an underestimation of the risk for the environment. This means, there is no disadvantage of degradable substances by using the approach outlined below but it ensures a balanced risk assessment.

Proposal: The following general rules are presented as guidance and are intended to encourage a consistent approach by Rapporteur Member States (RMS) when assessing ecotoxicological endpoints for active substances that disappear in the test system. It is assumed that these rules only apply to robust tests conducted to guidelines where the substances tested CANNOT be maintained through techniques such as semi-static or flow-through. These rules do not allow for endpoints to be derived from unacceptable or poor quality studies.

The proposals are based on the OECD Guidance Document No. 23 (2000) on aquatic toxicity testing of difficult substances and mixtures, with additional consideration of the potential exposure patterns for biocidal products. These approaches are to be used for the determination of the mean exposure concentration in acute or chronic tests where a substance can be shown to degrade significantly over the course of a test (< 80 % of nominal reported).

The following options are available:

(a) If measured concentrations at test start and end are available for all concentration levels tested or for the concentration levels that are close to the derived effect value, the mean (geometric) measured concentrations can be calculated. It is proposed to use the square root geometric mean formula for the calculation of the geometric mean.

(b) If analytical data indicates that the substance could not be:
   i. detected by the end of the study, the final concentration may be taken as the limit of detection (LOD) and the mean (geometric) measured concentrations can be calculated as in (a).
   ii. quantified but was detectable,by the end of the study, the final concentration may be taken as half the limit of quantification (LOQ/2) for the method and the mean (geometric) measured concentrations can be calculated as in (a).

(Options (a) and (b) are directly taken from the OECD GD on Difficult Substances) and apply mainly to aquatic studies including algae toxicity studies. Aquatic studies for instable substances performed without any analytical monitoring have to be regarded as invalid as a deviation of more than 20 % from the nominal concentration is expected.
If analytical monitoring was also performed in soil studies (not usual) the approaches (a) and (b) may also apply to these studies.

(c) If no analytical data of the (final) concentrations are available which is common for soil studies, the mean measured concentrations is calculated using the:
   TWA approach as detailed for Plant Protection Products (91/414/EEC)[1].

The calculation of a TWA mean concentration for static soil (or sediment) tests is only sensible for substances that do not degrade too fast in the test system as this would lead to unrealistically low effect values. The following cases are proposes:

1) Substances with an expected degradation half-life of < 2 d:
It is unlikely that a sensible endpoint from a static soil or sediment study (test duration normally in the range of 14 – 21 d) can be derived, as the use of TWA would result in unrealistically low effect values. For such substances any toxicity observed in the tests might predominantly be caused by one ore more degradation product(s). The use of the nominal or initial measured concentration is nevertheless justified if the PNEC derived from these tests is compared with the initial PEC without considering biodegradation, if the true exposure pattern due to the biocidal use is similar to that of the effect test method. In addition, a risk assessment for the relevant metabolites would need to be additionally performed. If the environmental exposure is due to a semi-continuous pattern, it is proposed to add for the exposure assessment the PEC for the active substance and the PEC for the metabolite(s) and to compare this PEC with the PNEC based on nominal or initial measured concentrations.

2) Substances with an expected degradation half-life of ≥ 2 d:

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[1] The following formula adapted from Guidance Document on Risk Assessment for Birds and Mammals Under Council Directive 91/414/EEC, SANCO/4145/2000 – final should be used for the TWA derivation:

$C = C_0 * f_{twa}$

C_0 Initial concentration at test start
f_{twa} Time-weighted-average factor

$f_{twa} = (1-e^{-kt})/kt$

k $\ln 2/DT_{50}$ (velocity constant)
t Test duration

Please note: This formula is not used under PPP for the derivation of mean effect concentrations, but for the estimation of mean exposure concentrations.

Endpoints from acute and chronic studies (soil/sediment) should be derived using TWA mean data. The risk assessment should also consider the relevant metabolite(s). This approach should also be considered to be applied for substances with a half-life < 2 d that have a continuous release.

The half-life to be used for the estimation of the mean concentration should be selected from the available studies based on expert judgement. It should be related to the normal test temperature (20 °C). However, the calculation of TWA is only valid for first order kinetics for the degradation rate. It has to be considered that the application of half-lives from soil degradation studies performed with real soil to ecotoxicological studies performed with artificial soil represents a worst-case situation as the degradation of the test substance in the artificial soil is likely lower than in real soils due to the lower microbial activity. However, as normally no other information on degradation in soil is available, it is recommended to use these half-lives as first approach. If a risk is identified based on the half-lives from soil degradation studies, a new effect test could be performed with chemical analysis of the test substance concentration in the test system at least at test start and test end; for long-term test or if fast degradation is expected additional measurements between test start and end (in separate analytical vessels) are advisable.

If for a special substance there is information on the mode of action from which it can be concluded that effects are only expected to be acute (e.g. oxidising substances), the initial concentrations can be used for the effects assessment and compared with the initial PEC for the risk characterisation. Examples for such substances are hydrogenperoxide or hypochlorite. However, for most biocidal active substances this information is not available. It has to be considered that the information available on the mode of action from efficacy tests cannot automatically be used to conclude on the mode of action in ecotoxicity tests, as a substance can act by different mode of actions (e.g. herbicidal and insecticidal activity) or the available information does not allow a statement on acute versus chronic effects.