

Guidance note on leaching rate estimations for substances used in biocidal products in Product Types 07, 09 and 10

This document was endorsed at the 36th meeting of representatives of Member States Competent Authorities for the implementation of Directive 98/8/EC concerning the placing of biocidal products on the market (10-12 March 2010).

THE ISSUE

Member States (MS) have been approached by Applicants regarding a number of active substances they intend to support for list 4 in PTs 07, 09 and 10. The Applicants are concerned that, unlike PT08 and PT21, there appears to be no harmonised methods for estimating the leaching from materials such as paint films, plastics, sealants, mastics, gaskets, paper, textiles, leather, mineral substrates, etc., which are commonly treated with PT07, PT09 and PT10 biocidal products. The Applicants have requested guidance on what methods should be used and also how any values generated should be used in the environmental risk assessment of representative biocidal products.

The Biocides Technical Meeting (TM) has considered what is available in the ESD guidance (see Appendix I, prepared by the UK CA, for further information) and concluded that there are 2 different approaches presented to address the environmental risk assessments, depending on the PT being supported;

1. Estimations with EUSES assessment: Both PT 07 and 09 (applying EUSES) have a number of different use patterns and so an (cumulative) exposure assessment is proposed based on the predicted environmental losses resulting from the use of biocides in the manufacture and end-use of the target preparation/article. However, from screening of the Emission Scenario Document (ESD) guidance, no data on emissions or fixation of biocides in rubber preparations/articles are given. The ESDs suggest that Applicants need to provide evidence of emissions/fixation but no methodology is recommended. Currently there is a lack of harmonized data concerning the service life time (TIME2) for PT10 and there is a need to advance further discussions regarding the suitability of leaching tests for preservatives.
2. Assessment for PT 10: this PT has a similar approach to that for PT08 and suggests that the leach rate is to be addressed as for wood preservatives but no guideline or methodology is recommended.

The UK CA sought advice from Member States at TM level to ensure a consistent response is given so that any advice given to industry can be harmonised across all Member States. The below agreed positions are presented as a final working approach agreed upon by MS during and following TM III 08.

PROPOSED GUIDANCE

The proposals below have been arrived at post application of dossiers. As such a flexible and open approach for the suggestions that the applicant has submitted should be considered.

1. PT 07: it was agreed that, depending on the use, either the tonnage approach or an approach in which leaching rates to soil are calculated similar to PT 08 using TIME 1 and 2 for a local assessment. Deviation from default emission factors is permissible, where likely information from for example applicant efficacy tests can be used to justify the change. In EUSES a local scale

assessment is included where the regional tonnage is scaled to the local level applying for example the factor "fraction of main source". Concerns still remain from several Member States as to the application of the tonnage approach as there are no legal instruments to obtain adequate information, and guidance on exactly how this information is to be used is severely lacking.

2. PT 09: it was agreed that in general the tonnage approach will be used. There may be specific uses where a leaching rate has to be used, for example the impregnation of tents. For polymerised material (e.g. plastic) an OECD guidance document suggests a default value.

For the tonnage approach, the EU total tonnage is used as the input value. This value should be provided by the applicant. In accordance with the TGD (e.g. see TGD, Part II, p.32), this tonnage is scaled down to a regional tonnage by applying a 10% rule, where it is assumed that 10% of the amount that is produced and used in the EU is produced/used within a region. Subsequently, the local tonnage can be obtained by multiplying this amount with the "fraction of main source". The latter can be obtained from the B-tables from the TGD or from specific Emission Scenario Documents (ESDs) for a certain Product Type (PT). In principle, values for the "fraction of the main source" should be included in the ESDs for a specific PT. If this is the case then these values should be used (unless more specific and reliable information is available in the dossier). If a certain ESD does not provide any value, then the TGD might contain some valuable information.

For example, in the TGD it is stated that for IC=6 (public domain) the fraction of the main source is 0.002 (TGD, Part II, p. 253). This is based on a standard city of 10,000 inhabitants and an STP with an effluent of $2000 \text{ m}^3 \cdot \text{d}^{-1}$ and is (often) used for wide dispersive uses. This value is for instance also mentioned in the ESD for PT02 (private and public health area disinfectants, Van der Poel, 2001) for disinfectants used for sanitary purposes (see ESD PT02, Table 2.1, p.9).

3. PT 10: The appropriateness of the short (TIME1) and long-term (TIME2) assessments will depend on the purpose of the product being used and the porosity of the treated surface and/or the fixation of the active substance in the masonry. Two main examples of this are:
 - i. Products applied as a remedial treatment of non-porous surfaces with no residual efficacy will be washed off quickly by rainfall. For these products a TIME1 assessment would be more appropriate.
 - ii. Products applied as a preventative treatment with residual activity will be designed to penetrate or adhere to the treated surface for a period of time (in-service life). For these products a TIME2 assessment would be more appropriate.

Therefore, for PT10 it is proposed that the short and long-term leach rates are determined from calculations relating to the amount of active substance applied to a surface in the following way:

- i. for short-term or TIME1 [$\text{kg m}^{-2} \text{d}^{-1}$] emissions, an absolute worst-case approach should be applied: application rate [kg m^{-2}]/30 days, or
- ii. for long-term or TIME2 [$\text{kg m}^{-2} \text{d}^{-1}$] emissions, a realistic worst-case approach should be applied: application rate [kg m^{-2}]/ product in-service lifetime [days]. It is noted that at the moment no harmonised methods are available for determining the long-term leach rate.

However, where refinement of the long-term risk is required (after additional fate and effects have been addressed), development of an appropriate field based protocol would be necessary, e.g. combined short-term/long-term assessment for the urban scenario (averaged emission factors). Also the fraction of households using masonry preservatives at the same time might be another option for refinement.

Regarding release during service life, the PT 10 ESD only takes into account leaching to soil from a treated house located in the countryside. The ESD does not consider run off from service life use to STPs and/or storm drains resulting from urban applications. As this might not be sufficiently protective (cf. the noise barrier scenario in the PT 8 ESD or the PT 18 ESD), it is recommended to carry out a worst case risk assessment for urban applications, based on 100 % run off going directly to STP and surface waters, respectively.

Appendix: Background to available ESDs – UK CA screen of information

For PT 07: Film preservatives – there are 2 ESDs available with reasonable guidance as to what the emission rates are for the products in which such preservatives are applied:

1. Environmental emission scenario document: PT 7 – film preservatives

This considers decorative paints and there are estimations of emissions given for the application and in-service stages for decorative paints resulting from private and professional use. These calculations can be used to consider the regional scale and then the local scale can be modelled starting from the STP. According to the ESD, the regional emission from private use to wastewater can be converted to the local scale using the emission factors in the B-tables of the TGD.

The document concludes that the available ESD; describes the emission of preservatives during the application, service life on the coated product and at the end-of-life to air, water, soil and disposal. However, no specifications are given of the receiving environment. This implies that the resulting emission is to be imported into EUSES and enables calculation of the regional concentrations in various air, water and soil.

This document suggests that a local scale scenario in the same sense as that carried out for PT08 and PT10 cannot be carried out for PT07 without first agreeing as to what a worst-case treated surface in a local scenario would be i.e. house (window frames, brick work etc.), fence, wall etc,. Secondly, we would need data on the leach rate from a treated surface, which could be experimentally determined or predicted from a calculation approach (application rate [mg m^{-2}]/in-service lifetime [days]). However, where the same active ingredients used in PT07 is also used in PT10 [but present at a much higher concentration] the risk assessment for the latter PT can be considered more worst-case in terms of the availability for environmental contamination and so a regional assessment for PT07 may be considered sufficient, providing sufficient tonnage data is available.

2. Emission scenario document for biocides used in paper coating and finishing (Product type 6, 7 & 9)

This document considers the use of biocides in the paper production industries and states that as film preservatives are used to protect the fibres that fixation is necessary for effectiveness and that 80 % fixation can be assumed. The ESD contains information about the level of production of paper and the amounts of water used. The release estimations are provided for a series of production routes to give as for the decorative paints a regional environmental release scenario.

Conclusion for PT 7 – The current guidance and TGD allows for the preliminary risk assessments to be carried out with no leach rate data.

For PT 09: Preservatives for fibres, leather, rubber and polymerised material - There are 4 ESDs available.

All of the guidance considers the use of biocides within each of the industrial uses and gives estimates of total use and releases. However, it is often a requirement of the Applicant to give an indication of the fraction of biocide that can be released from the treated material i.e. fixation value or leach rate.

It is also apparent from these documents that the 'use' of biocides in the manufacture of paper, leather, textiles, rubber and plastic items covers a wider area than previously considered. This is that the manufacturing stage of the treated material needs to be considered as well as post-manufacture use of treated items i.e. leaching from tyres in use.

1. *Emission scenario document for biocides used in paper coating and finishing (Product type 6, 7 & 9)* – this gives an estimated fixation value of 80 %.
2. *Emission scenario document for biocides used in the leather industry (Product type 9)* – this gives an estimated fixation value of 95 %.
3. *Emission scenario document for biocides used as preservatives in the textile processing industry (Product type 9 & 18)* – this gives an estimated fixation value of 70 %.
4. *Emission scenario document for biocides used as preservatives in rubber and polymerised materials (Product type 9) Jan 2004* – this does not give a fixation rate for rubber but does provide fractions released from plastic materials. There is also an OECD document '*OECD SERIES ON EMISSION SCENARIO DOCUMENTS Number 6 EMISSION SCENARIO DOCUMENT ON ADDITIVES IN RUBBER INDUSTRY (June 2004)*'. Whilst, this does not contain any data on preservatives used in rubber it does highlight that losses to the environment from car tyres will occur as much through abrasion as leaching from unfixed material. Therefore, no harmonised estimation approach is available for estimating losses from rubber items treated with a biocide.

Conclusion for PT 9 – The available scenarios will result in regional estimations as for PT07. However, there are methods within the TGD of estimating local PECs from these data and so if refinement is needed this can be carried out. The UK CA assumes that all use patterns should be investigated (using all available ESDs) and a summation of exposures for each environmental compartment carried out.

For PT 10: Masonry preservatives – there is 1 ESD available.

Emission scenario document for biocides used as masonry preservatives (Product type 10) – this document refers to leaching being treated similarly to a wood preservative but no guidance is given.

Conclusion for PT 10 – The scenarios result in a local scale exposure assessment and refer to the PT08 approach, which can be addressed through calculation¹.

¹ Settings for the default parameters used in this scenario are momentarily established by the Biocides Technical Meeting. Once agreed, these values will be incorporated in the present document.