

## **Consolidated list of PT21 technical agreements**

This document provides a list of technical agreements that have been reached during previous Technical Meeting Environment discussions on PT21 active substances. Many of these agreements have already been included in MOTA version 5.

However as suggested by NO at TMIV 2012, all issues specific to PT21 assessments could be consolidated in this document and removed from the MOTA in the future.

This list should be viewed as a living document that can be updated as new agreements are reached to ensure that all PT21 active substance evaluations are performed in a harmonised manner.

### **Note for TMIII2013**

All previous highlighted track changes to this document have now been accepted. The only minor change from the version presented at TMII2013 concerns point 5.4 highlighted in yellow. This change combined two previous points to clarify the tiered assessment for sediment dwellers. Hopefully this now represents an accurate record of the current technical agreements in this area.

UK CA 20/8/2013

**General agreements**

- 1.1 The number of boats in the ESD marina scenario should be reduced to 276 to reflect a more realistic boat density of 1.38 boats / 100 m<sup>2</sup>,  
[Source: Final minutes of TM V 2007]
- 1.2 The average PEC values from the MAMPEC output will be used for the purposes of the environmental risk assessment.  
[Source: Final minutes of TM IV 2008]
- 1.3 Regarding the question of whether total or dissolved surface water concentrations should be used, it was decided that the risk assessment should be based on dissolved concentrations.  
[Source: Final minutes of TM III 2009]
- 1.4 In order to harmonize calculations of the PEC<sub>local</sub>, dissolved for the new building and M&R exposure assessments for all substances, as first tier the standard equations from the TGD will be used (i.e. based simply on total load divided by volume of receiving compartment). MAMPEC calculations can be used as a second tier of calculation.  
[Source: Final minutes of TM III 2011]
- 1.5 Version 2.5 of MAMPEC should be used for all Annex I assessments  
[Source: Final minutes of TM III 2011]
- 1.6 Results from MAMPEC should be reported for a temperature of 9°C in line with the default marine temperature from the TGD  
[Source: Final minutes of TM I 2013]
- 1.7 For Annex I listing purposes, an acceptable risk assessment in the wider environment as defined by the areas adjacent to the ESD marina and harbour scenario is sufficient in cases where an unacceptable risk is identified within a marina/harbour. This area is referred to as “surroundings” in the MAMPEC v2.5 model.  
[Source: Final minutes of TM III 2011 and Doc 6.3c from CA September 2011]
- 1.8 There is no requirement to calculate the PEC<sub>STP</sub> for new building and maintenance and repair scenarios for commercial ships due to absence of exposure.  
[Source: Final minutes of TM IV 2011]
- 1.9 Based on information provided by industry it was agreed that in order to maintain the mass balance of 100% following the principles of the CEPE mass balance calculation method the Fa.i. old paint needs to be increased to 0.9. Explanations on this were provided by industry.  
[Source: Final minutes of TM IV 2011 and TMI 2012]
- 1.10 Risk mitigation should be taken into account in a tiered manner for assessing risks from application, maintenance and repair activities for professional users

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only. The typical case is agreed to refer to the dry dock situation where no risk mitigation measures are in place whereas the realistic worst case referred to use on exposed slipways. The level of risk mitigation measure should be quantified using the data from the CEPE and CESA surveys.

[Source: Final minutes of TM IV 2011]

- 1.11 Cumulative exposure should be assessed for simultaneous losses due to application activities and in-service losses for commercial harbours. Cumulative exposure should also be assessed for losses due to removal activities and in-service losses for pleasure craft marinas. For cumulative exposure scenario additional consideration of exposure via an STP should be included<sup>1</sup>. A refinement based on the use of annual average daily emission loads should not be included for the purposes of Annex I inclusion (however this refinement may be an acceptable approach at product authorisation stage provided that an appropriate evaluation is performed).

[Source: Final minutes of TM IV 2011 and PT21 guidance document on ,multiple simultaneous exposure routes]

- 1.12 A fish net scenario was developed as part of the copper pyrrithione CAR. However, this scenario has to be further discussed and developed. An e-consultation on this issue was started by Sweden and will be re-launched by Norway in order to make it applicable for the product authorisation stage.

[Source: Final minutes of TM III 2011]

- 1.13 A super yacht marina scenario was developed in the DCOIT CAR and could be applied to other PT21 active substances to assess this additional scenario where relevant for the representative product.

[Source: Final minutes of TM III 2011]

- 1.14 Market share data can potentially be used to refine the commercial harbour scenario. This is because commercial shipping is associated with relatively long service lives and more stable markets with wide availability of active substances across the EU.

However the market share value of 90% should generally be retained for the pleasure craft marina scenario. The refinement was not agreed for marinas since this involves mostly pleasure craft where historical or average market share is not necessarily a good indicator of future market share. Also many MS have a very small number of active substances available for amateur or pleasure craft market, therefore EU average data on market share is not really relevant at a local scale. In order to refine this value in the future it would be necessary for Applicants to have robust data to support a more realistic market share value for incorporation in refined pleasure craft risk assessments

[Source: Final minutes of TM III and IV 2011 and TMI2013]

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<sup>1</sup> Note the incorporation of the STP route into the cumulative exposure scenarios is currently being developed by the UK and proposals will be made available shortly after TMII2013 meeting. This additional route was agreed at TMIII2011.

## **2.0 Substance specific input parameters (DT50's, sorption etc)**

2.1 In general for running MAMPEC simulations it is appropriate to use the geometric mean DT50 when you have acceptable results from more than one test system. However on a case by case basis it may be considered more appropriate to use a worst case longest DT50 e.g. when the data shows that degradation is dependent on pH or substance concentration for example. Although not formally recorded in TM minutes, it can be assumed that a similar approach can be used for all other parameters where multiple values are available. For example for sorption parameters it is generally appropriate to use the arithmetic mean value. This is appropriate unless there is reason to consider the mean value invalid, in which case worst case values should be chosen to ensure a conservative assessment of risks to both pelagic and sediment dwelling organisms is performed.

[Source: Final minutes of TM III 2011]

2.2 When using a total system degradation rate from a water sediment study as input for biodegradation rate in MAMPEC, care should be taken to not double count for abiotic processes by also including a hydrolysis rate constant (hydrolysis should be set to zero because this should be accounted for in the water sediment derived value).

[Source: Final minutes of TM III 2011 and PT21 Guidance on selection of kinetic input parameters for MAMPEC]

2.3 When assessing risks in the shipping lane scenario, a correction factor of 3 (from TGD Chapter 4.2.3) to correct for biodegradation in remote areas has been agreed (as long as DT50 values were derived from studies using coastal waters and degradation was due to biotic rather than abiotic processes). To implement this in MAMPEC v2.5 the rate constant should be divided by a factor of 3.

[Source: Final minutes of TM III 2011]

2.4 Photolysis should be excluded from MAMPEC calculations at the simple first tier, but can be included in refined higher tier assessments for all scenarios provided that adequate quantum yield data, which are necessary to run the advanced photolytic degradation routines of MAMPEC, are available.

[Source: Final minutes of TM III 2011]

2.5 The following text should be added in each CA-report in Doc I, Chapter 3.4 (Requirements for further information):

*"In order to address a potentially severe underestimation of the risk to sediment dwelling organisms from exposure via suspended matter, caused by the fact that sorption data (Koc) has only been studied at concentrations which are not fully relevant in the marine environment, a new study on sorption at environmentally relevant conditions (concentrations µg/l to ng/l, pH ~8, DOC not too high, etc.) is to be performed before the antifouling active substances are evaluated for a potential renewal of the approval.*

In addition the above paragraph and the further paragraph below should be added to Doc IIA to record all details on the Koc study required.

*This new sorption study should ideally be carried out in the same laboratory for all antifouling substances which are on the market at the time. By using the same seawater and sediment, the study will provide harmonized sorption data of relevance to marine environmental conditions. The study should as a minimum follow the OECD guidelines, unless by then, established*

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*scientific progress in the field of sediment risk assessment indicates other directions (SETAC books, OECD guidelines). Since low concentrations are to be studied, technical problems with limits of quantification may need to be addressed as stated in OECD 106 §34 by selecting appropriate amounts of sample matrix (water and sediment), possibly this will mean up-scaling of the traditionally small amounts used, or new test methods. An outline test protocol will by then have to be developed and agreed by the e-consultation group (of TM 2012) in dialogue with sorption researchers”.*

However no change to the Koc values for MAMPEC in the current antifouling CA-reports is needed.

[Source: TM I and IV 2012 and PT21 e-consultation group]

### **3.0 Leaching rates**

3.1 No distinction between leaching rates from ships at birth and moving need be made for the purposes of the first tier Annex I assessment. For all vessels, in the absence of substance specific leaching data, the CEPE mass balance method should be applied.

[Source: Final minutes of TM III 2008]

3.2 The leaching rate correction factor of 2.9 can only be used as a refinement when Applicants provide acceptable supporting data (e.g. leaching rate studies for example). The leaching rate correction factor should only be applied to vessels at berth.

[Source: Final minutes of TM II 2010 and TM IV 2011]

### **4.0 Metabolites**

4.1 The initial load of parent from M&R (or service life) should be used as basis for calculation of metabolite PECs. The maximum formed percentage of metabolite from the simulation study should then be used together with molecular weight correction, and this should be entered into MAMPEC to calculate steady-state concentrations of metabolites. The molecular weight correction should not simply be performed based on parent PEC<sub>sw</sub>, since this value includes loss due to degradation of parent as it is a steady state value output from MAMPEC.

[Source: Final minutes of TM III 2011]

4.2 QSARs can be used to estimate properties of metabolites in the absence of measured data. In case no reliable QSARs are available a scenario can be performed by setting the vapour pressure to zero and using a low and high Koc value (e.g. where ‘low’ is a log k<sub>oc</sub> = 0 and ‘high’ is a log K<sub>oc</sub> = 6) and investigate the consequences for the concentration on suspended matter. In case the Koc value doesn't influence this concentration the assessment can be performed and no further data are required.

[Source: Final minutes of TM IV 2011]

4.3 In principle, aerobic degradation studies will be used for establishing the maximum per cent of metabolite(s) found in sediment. However, on a case-by-case basis a RMS may deviate from this.

[Source: Final minutes of TM IV 2011]

4.4 Regarding the sediment risk assessment of metabolites, please see point 5.3 and 5.7.

## **5.0 Sediment**

5.1 In case effect studies with sediment organisms are available, it was decided not to normalise the results to a standardised organic matter content for sediment.

[Source: Final minutes of TM III 2008]

5.2 In case the PNEC<sub>sediment</sub> is based on acute data, and PNEC<sub>sediment</sub> has also to be calculated by using the EPM approach. The lower of the two values should then be used for the sediment risk assessment.

[Source: Final minutes of TM IV 2011]

5.3 A risk assessment for sediment dwellers is always required for the active substance, irrespective of the levels of active substance found in the sediment phase of a water sediment study. This is to address risks posed by leaching from intact paint particles that may be deposited on the sediment layer. For the metabolites, a sediment risk assessment has only to be conducted for major metabolites or if they are known to be highly toxic, where the risk may not be addressed by the parent assessment alone.

[Source: Final minutes of TM I 2012]

5.4 The first tier assessment of risks to sediment should be based on the PEC<sub>suspended matter</sub>. PEC<sub>suspended matter</sub> from MAMPEC is expressed on a dry weight basis and care should be taken to ensure the PNEC<sub>sediment</sub> is also expressed on a dry weight basis. If a higher tier sediment risk assessment using the PEC<sub>sediment</sub> value can be justified, it should be based on a depth of 3cm, with concentrations expressed on a dry weight basis and not normalised for organic carbon.

[Source: Final minutes of TM III 2008, TM II 2010 and TMIV 2011]

5.5 The rate constant for bulk organic carbon degradation should be set to 0 d<sup>-1</sup>.

[Source: Final minutes of TM II 2010]

5.6 To assess situations where in a water-sediment study the metabolite is found only in the sediment and not in the water phase, the percentage found in the sediment can be used as an input in MAMPEC for the percentage formed for the daily loading of the water phase. MAMPEC will then distribute the amount formed between the water phase and suspended matter. The latter concentration can then be used for the metabolite risk assessment. Also, when a metabolite is found in both phases, the percent value should be the maximum amount found in the total system on an individual daily basis. When calculating the percentage of metabolite formed, correction needs to be done for molecular weight when peak occurrence is derived from a radiolabelled study.

[Source: Final minutes of TM IV 2011]

## **6.0 Effects assessment**

6.1 A formal BCF test will be performed for all PT21 active substances as it is a PT specific core data requirement

[Source: Final minutes of TM II 2010]

6.2 PECsuspended matter from MAMPEC is expressed on a dry weight basis and care should be taken to ensure the PNECsediment is also expressed on a dry weight basis.

[Source: Final minutes of TM IV 2011]

## **7.0 Bug fixes**

7.1 For the “OECD-EU shipping lane” emission scenario in MAMPEC the Application factor for Class 6 needs to be manually updated from the incorrect default of 0 to 90%.

7.2 For the “Default open sea” and “Default shipping lane” scenarios in MAMPEC the default values for silt concentration and POC concentration have been incorrectly transposed. These should correctly be set to 5 mg/l for silt and 0.3mg/l for POC concentration.