

Authorisation and environmental risk assessment of biocidal antifouling products

Frequently asked questions (FAQs) concerning the environmental risk assessment in product type 21 (PT21) in frame of a submission for product authorisation under Regulation (EU) No 528/2012 in Germany.

1 Introduction

This document provides a brief overview on key questions concerning the environmental risk assessment in product type 21 (PT21) in frame of a submission for product authorisation under Regulation (EU) No 528/2012 (Biocidal Products Regulation, BPR) in Germany. The document only addresses questions relevant for products intended to be used on commercial ships and/or pleasure boats and focuses only on environmental issues.

An extensive overview on environmental exposure and risk assessment in PT21 is provided in the relevant guidance documents, which are published on the ECHA webpage. The most relevant guidance documents are the following.

- Emission scenarios for antifouling products in OECD countries (European Commission, DG Environment, 2004)
- PT21 product authorisation manual
- Consolidated list of PT 21 technical agreements; version 1.2 (TM II 2013)
- Analysis of regional marina scenarios (WG-I-2017)
- Analysis of EU freshwater marina scenarios (WG-IV-2017)
- Report for the German scenario for inland water marinas (German Environment Agency (UBA), FG IV 1.2, 2020) (only relevant for DE)

Please note that the competent authority in Germany is the Federal Office for Chemicals (BfC), a Division of the Federal Institute for Occupational Safety and Health (BAuA). The German Environment Agency (UBA) is in charge for the environmental risk assessment in frame of the BPR. Please contact only the BfC for any questions regarding an application for product authorisation. The BfC will then involve the relevant national authorities as necessary.

2 General questions for submission of product authorisation

2.1 Which product categories can be distinguished?

Products to be used on either commercial ship or pleasure boats are divided into four categories according to **CA-Jan18-Doc.7.4.a-Final**.

Table 1: Product categories for commercial ship or pleasure boats

Category	Description
Category 1	Paint for leisure crafts with a hull length of maximum 24 meter and a berth in marine environment
Category 2	Paint for leisure crafts with a hull length of maximum 24 meter and a berth in inland water
Category 3	Paint for seagoing vessels for trade or business, naval and governmental vessels, and on leisure crafts with a hull length of 24 meters or more
Category 4	Paint for inland vessels for trade or business, naval and governmental vessels, and on leisure crafts with a hull length of 24 meters or more

2.2 Which environmental emission scenarios have to be assessed and submitted in the product authorisation dossier?

The PT21 product authorisation manual defines scenario(s) which is (are) relevant to support authorisation in each member state (MS).

In case of products for category 1 and 2, the PT21 product authorisation manual defines a set of core scenarios which should be submitted by applicants and evaluated by the RefMS. Following the evaluation of the core scenarios by the RefMS, concerned Member States (cMS) can then base individual product authorisation decisions on the results of a subset of relevant core scenarios that they consider representative of their own national conditions. A summary of the scenario(s) that is (are) relevant to support authorisation in each member state (MS) is given on page 9 in the manual.

The PT21 product authorisation manual further describes the possibility to apply for product authorisation using MS specific scenarios, mitigation or refinement options or additional specific decision-making criteria that may be accepted by that MS. Against this background, the German scenario for inland water marinas was developed. It is relevant for product authorisation in category 2.

An overview of all relevant scenarios for each product category is given in Table 2.

Table 2: Relevant emission scenario in dependence of the product category

Product category	Relevant emission scenario
Category 1 and 2	OECD Marina Scenario Regional marinas: Mediterranean, Atlantic, Baltic, Baltic transition EU Freshwater Scenario OECD Swiss marina NL National marina

Product category	Relevant emission scenario
Category 3	OECD commercial harbour scenario
Category 4	No assessment in the core data set, scenarios for commercial shipping in inland waters under development; please contact the CA for further advise
Additional national specific scenario for Germany	
Category 2	German scenario for inland water marinas

2.3 Which environmental emission scenarios are relevant for a national authorisation in Germany?

The following scenarios are considered relevant for a product authorisation in Germany.

Table 3: Relevant emission scenario in dependence of the product category – national authorisation

Product category	Relevant emission scenario
Category 1	Regional marina: Atlantic, Baltic and Baltic transition
Category 2	German scenario for inland water marinas
Category 3	OECD commercial harbour scenario
Category 4	No assessment in the core data set, scenarios for commercial shipping in inland waters under development; please contact the CA for further advise

2.4 Which document describes the individual scenarios?

Please note that general agreements on environmental exposure and risk assessment in PT21 are summarized in the *Consolidated list of PT 21 technical agreements; version 1.2 (TM II 2013)* and have to be considered in the assessment. The overall concept of environmental risk assessment in PT21 has been revised and summarized in *PT 21 Product authorisation manual* and should be considered also.

Table 4: Sources for further information on the individual environmental emission scenarios.

Emission scenario	Source
Regional marinas: Mediterranean, Atlantic, Baltic, Baltic transition	A description of the relevant scenarios is contained in the document “PT 21 Product authorisation manual” and “Analysis of regional marina scenarios (WG-I-2017)”. Excel-Sheets, by which product specific PECs for all PT21 active substances (a.s) can be calculated, are published on ECHA webpage. By using these Excel-Sheets, an application of the MAMPEC model is not necessary. Beside some product specific input fields, the Excel-Sheets do also incorporate input fields for PNECs, so that a complete quantitative risk assessment dataset (PEC/PNEC) will be provided. Please follow the use instructions in the Excel-Sheet for a proper application. The Excel-Sheets are available under: https://echa.europa.eu/de/guidance-documents/guidance-on-biocides-legislation/emission-scenario-documents

Emission scenario	Source
EU Freshwater Scenario	A description of the scenario is contained in the document “PT 21 Analysis of EU freshwater marina scenarios (WG-IV-2017)” (see above). Excel-Sheets, by which product specific PECs for all PT21 a.s. can be calculated, are published on ECHA webpage. By using these Excel-Sheets, an application of the MAMPEC model is not necessary. Beside some product specific input fields, the Excel-Sheets do also incorporate input fields for PNECs, so that a complete quantitative risk assessment dataset (PEC/PNEC) will be provided. Please follow the use instructions in the Excel-Sheet for a proper application. The Excel-Sheets are available under: https://echa.europa.eu/de/guidance-documents/guidance-on-biocides-legislation/emission-scenario-documents
German scenario for inland water marinas	A description of the relevant scenarios is contained in the report for the German scenario for inland water marinas (German Environment Agency (UBA), FG IV 1.2, 2020). Excel-Sheets, by which product specific PECs for all PT21 a.s. can be calculated, are published on UBA webpage. By using these Excel-Sheets, an application of the MAMPEC model is not necessary. Besides, some product specific input fields the Excel-Sheets do also incorporate input fields for PNECs, so that a complete quantitative risk assessment dataset (PEC/PNEC) will be provided. Please follow the use instructions in the Excel-Sheet for a proper application. The Excel-Sheets are available under: https://www.umweltbundesamt.de/dokument/german-scenario-for-inland-water-marinas-data
OECD commercial harbour scenario and OECD Swiss marina	Both scenarios are described in the document “Emission scenarios for antifouling products in OECD countries (European Commission, DG Environment, 2004)”. An individual Excel-Sheet for both scenarios is not available. The OECD Swiss marina is included in the EU freshwater Excel-Sheets.
NL freshwater marina	The scenario is included in the EU freshwater Excel-Sheets. Please contact the NL CA for further information.

2.5 Which PEC value is to be used in the risk characterisation?

Depending on the product category and the emission scenario that is applied in the environmental risk assessment, different statistical parameters are defined as PEC.

Table 5: Statistical parameters which define the PEC in the different Scenarios.

Scenario	Relevant PEC
OECD Marina	The average concentration in the relevant environmental compartment (water and suspended matter) as provide in MAMPEC is defined as the PEC for the scenario.
Regional marinas	For both relevant environmental compartments (water and suspended matter) the average concentration will be calculated by MAMPEC for every individual marina of each region. The 90th percentile concentration from the average concentration in every marina within each region is defined as the PEC for the whole respective region. The 90th percentile concentration is calculated in the relevant Excel-Sheets for both environmental compartments and each region.

Scenario	Relevant PEC
OECD commercial harbour	The average concentration in the relevant environmental compartment (water and suspended matter) as provide in MAMPEC is defined as the PEC for the scenario.
EU freshwater marina	For both relevant environmental compartments (water and suspended matter) the average concentrations will be calculated by MAMPEC for every individual marina of the EU freshwater marina selection. The 90th percentile concentration from the average concentration in every marina is defined as the PEC for the whole EU freshwater region. The 90th percentile concentration is calculated in the relevant Excel-Sheets for both environmental compartments.
German scenario for inland water marinas	For both relevant environmental compartments (water and suspended matter) the average concentration will be calculated by MAMPEC for every individual marina of the German scenario for inland water marinas. The median concentration from the average concentration in every marina is defined as the PEC for the whole German inland water marina region. The median concentration is calculated in the relevant Excel-Sheets for both environmental compartments.
OECD Swiss marina	The average concentration in the relevant environmental compartment (water and suspended matter) as provide in MAMPEC is defined as the PEC for the scenario.
NL freshwater marina	Please contact the NL CA for further information

2.6 Which application factor (AF) should be applied in the environmental exposure assessment?

The application factor (AF) defines the relative share of boats that are treated with the product under consideration.

Table 6: Relevant application factor depending on the a.s. contained in the b.p.

Active substance	Relevant application factor (AF)
Copper flakes (coated with aliphatic acid) and Dicopper oxide	0.95
All other a.s.	0.90
Multiple a.s.	In case that more than one a.s. are contained in a product, each a.s. has to be assessed with the same application factor. The worst-case application factor is to be applied.

2.7 Which scenario environment is relevant for the risk characterisation?

The following scenario compartments are considered relevant for a product authorisation in Germany. For the purposes of dossier preparing, both available scenario compartments (inside marina/harbour and wider environment) have to be presented.

Table 7: Relevant scenario compartment depending on the product category.

Product category	Scenario compartment
Category 1	Inside marina
Category 2	Inside marina
Category 3	Wider environment
Category 4	A scenario for commercial shipping in inland waters under development; please contact the CA for further advise.

2.8 Is it possible to apply an authorisation for only one product category in Germany?

Yes. A product authorisation for one category only is possible. The scenario(s) for the respective category as mentioned above have to be considered in the environmental risk assessment.

2.9 Are there any restrictions for active substances that should be considered for product authorisation?

Due to the restrictions from the active substance approval, products, which contain Tolyfluanid or Dichlofluanid cannot be authorised for category 2 and 4.

2.10 What needs to be done if the PC or degradation data from any a.s. changes?

If individual substance-specific input parameters change (e.g. due to further studies), the MAMPEC modeling of the individual marinas must be carried out again and the published Excel tools (either EU or DE specific) cannot be used. In this case, please contact the CA to coordinate the procedure.

3 Specific questions concerning the German scenario for inland water marinas

3.1 Why was the German scenario for inland water marinas developed?

Pleasure boating is predominantly conducted in inland water in Germany and is therefore of special consideration. To better reflect the conditions in German inland waters the German scenario for inland water marinas has been developed.

3.2 Why are the marinas in the German scenario for inland water marinas not the same as the German marinas contained in the EU freshwater scenario?

The data basis is similar to that in the EU freshwater scenario, with some parameters being adapted in the course of the scenario development. It may therefore be the case that some of the German marinas found in the EU freshwater scenario are also contained in the German scenario for inland water marinas, but have been parameterized slightly differently.

The marinas contained in the German scenario for inland water marinas represent a worst-case selection that was identified by defining specific criteria in the context of the scenario development. This selection procedure has not been applied to the selection of German marinas included in the EU scenario. Therefore, both selections do not completely match with each other.

3.3 Which background concentrations are to be considered in the environmental exposure assessment?

EU agreed background concentration are only available for copper. For copper-based a.s., the following background concentration have to be added to the calculated PEC. For product categories 1 and 2, the addition is included in the Excel-Sheets where relevant.

Table 8: Background concentrations to be considered in the exposure assessment

Environmental compartment	Background concentration
marine water	1.1 $\mu\text{g L}^{-1}$
marine sediment	16.1 $\text{mg kg}_{\text{dwt}}^{-1}$
freshwater	0.88 $\mu\text{g L}^{-1}$
freshwater sediment	21 $\text{mg kg}_{\text{dwt}}^{-1}$

3.4 Why was the median concentration chosen in the German scenario for inland water marinas?

As described above, the selection of marinas in the German scenario for inland water marinas represents a worst-case selection of marinas in Germany, with respect to foreseeable predicted environmental concentration inside the marina. Taking the 90th percentile concentration out of this selection into account, as it is done in the EU scenarios, would result in this case in an overconservative PEC. Due to the inhomogeneous distribution of the whole dataset, the median concentration is the most robust value to represent the dataset and was defined as PEC for the German scenario for inland water marinas.

3.5 How is a summary risk assessment of several a.s. carried out?

If multiple a.s. are present in the product, the respective PEC/PNEC values are determined for each substance and each marina within one region. Then, the sum of the individual aggregated PEC/PNEC ratios for all substances is formed per marina. The relevant statistic nominal value (depending on the scenario: mean, 90th percentile, median) of this sum of PEC/PNECs is then determined and represents the crucial risk characterisation value.

3.6 How to conduct a mixture toxicity assessment for the German scenario for inland water marinas?

The approach corresponds to the principles described in the PT21 product authorisation manual (chapter 4) and is therefore literally repeated here with amendments being made where necessary.

The individual a.s. specific calculation sheets can be used to generate the relevant single substance exposure outputs and associated PEC/PNEC ratios. To facilitate the mixture assessment for more complex situations a template mixture assessment calculation tool (DE inland water marina_multiple_substance.xlsx) has also been prepared and can be accessed via the UBA website. The individual PEC/PNEC ratios for each relevant substance in the mixture for each scenario can be copied into this separate tool that then facilitates the summation of PEC/PNEC ratios and derives the median output for the different environments for the purposes of the mixture risk characterisation assessment.

At the present time substance specific calculation tools are available for all approved a.s. and zinc, which was identified as a common SoC during the development phase of the calculation tools. As an interim measure, it is proposed that an initial mixture assessment be conducted for just the a.s. in the product (plus zinc if present in the formulation). From this initial mixture assessment, the individual marina representing the median concentration can be identified (this is done automatically by the mixture assessment tool). Where necessary, this individual marina can then be used to simulate the average PEC from the additional SoC(s) within the MAMPEC 3.1 model. A step by step guide to generating SoC specific PEC values has been provided below and can also be looked up in the PT21 product authorisation manual (Appendix I). Following this guidance, the PEC/PNEC ratio(s) for the SoC(s) can then be added to the median sum of the PEC/PNEC ratios for the a.s. derived from the initial mixture assessment in order to finalise the overall assessment.

3.7 How to conduct a SoC specific risk assessment for the German scenario for inland water marinas?

A Step by Step guide is given in the PT21 product authorisation manual (Appendix 1) and could be followed 1:1 also for the German scenario for inland water marinas. For completeness, the approach is literally repeated here with amendments being made where necessary.

1. Install MAMPEC

Install MAMPEC version 3.1. This can be installed as either the installer version (if you have full administrative rights on your PC) or using the portable version (for use on any drive/directory if you have only limited administrative rights). Make sure you download the AF version rather than the BW (ballast water) version.

Installation files can be found here: <https://download.deltares.nl/en/download/mampec/>

2. Import marina scenarios

The marinas contained in the German scenario for inland water marinas are available as MAMPEC database file (.db file) published on the UBA webpage.

<https://www.umweltbundesamt.de/dokument/german-scenario-for-inland-water-marinas-data>

This database file contains the information for the different 'Environment' and 'Emission' parameters, which MAMPEC needs to run the marina scenarios. Copy and paste the embedded file below to a folder on your PC (keep them as .db files in order that MAMPEC is able to read the data correctly).

Once the model is installed (step 1 above), run the MAMPEC model by double clicking on the MAMPEC.exe file in your chosen download/installation folder. Select the 'Import' option from the menu on the left hand side. Navigate to the location of the German inland water environment .db file saved from above. Highlight all XX 'Environments' and 'Emissions' and then select 'Import environments' and 'Import emissions'.

3. Create a marina specific emission file

MAMPEC requires an emission file in order to perform the correct simulations. You will need to create a marina specific emission file for the SoC (for the marina which has been identified to represent the median concentration by adding PEC/PNEC ratios of the a.s.). This will ensure the correct number of ships, leaching rate and application factor is used in the simulation.

The easiest way to create an emission file is to amend an existing file. Select the 'Emission' option from the left hand menu and then 'Load' the emission file from the German scenario for inland water marinas with the number of the identified marina. Amend the description to reflect the SoC you want to simulate. Overwrite the leaching rate to the value for your chosen SoC. For products which do not contain copper coated flake or dicopper oxide, the application factor may be lowered to 90. All other parameters like the number of ships at berth, the surface area or the length class should not be changed. After changing the emission file, it should be 'Saved as new'.

Information for each marina can be found in the *Report for the German scenario for inland water marinas* (German Environment Agency (UBA), FG IV 1.2, 2020).

<https://www.umweltbundesamt.de/publikationen/german-scenario-for-inland-water-marinas>

4. Create the active substance file

Create the compound file based on the properties of the SoC. Data should be entered by selecting the 'Compound' option from the left-hand menu. All relevant data should be filled in and stored using the 'Save as new' option. For transparency and Quality Control we recommend that a screenshot of the final compound parameters is included as part of the regulatory submission. This will make it easier for all MS to validate.

5. Run MAMPEC for the marina

Run the MAMPEC model for the relevant scenario and the relevant SoC (s). Select 'Run models and view results' from the left hand side menu, select the relevant environment, compound and emission file by using the drop down list accessed via the 'Change' buttons.

Select the 'Run model' option, record the results (i.e. the relevant PEC_{sw} and PEC_{susp}. inside marinas and in the surrounding area). Use the modelled PEC values to generate additional PEC/PNEC ratios. The PEC/PNEC ratio for the SoC(s) can then be added to the median summed PEC/PNEC ratio for the a.s. derived from the initial mixture assessment performed in order to finalise the mixture assessment.

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