Date: 3 July 2018
Doc. No: CG-30-2018-18vf

Assessment of PT21 products – new assessment tool

Background

Following discussions at CG26 and CG27, in February 2018 the UK updated a paper (Annex 1) on the assessment of environmental risk for PT21 products by two different saltwater marina models:

a) the existing model used in the PT21 active substance dossiers which is based on a single OECD marina scenario), and

b) the new model based on the 90th percentile values from 148 leisure craft marina scenarios in four European regions

Summary of MS comments

In February 2018 five MSs provided comments on the draft paper (see Annex 2 for a summary table).

On the issue of comparing the impact of the two models, MSs agreed that this was valuable; three MSs considered that this should be done at a regional level while two MSs considered that its scope should be decided at the CA meeting. No MS was able to coordinate the impact comparison study but two offered to contribute actively.

On the issue of setting different protection goals for different regions MSs considered that this was either not required at all, or not required in the first instance. Four MSs considered that additional national specific tools could in principle be used to make decisions on product authorisation.

There was some support for a proposal to restrict the authorisation of overly effective PT21 products although there were concerns over the legal basis for this action, whether it would have the desired effect for ocean-going vessels and whether it was practicable to make such a decision on the basis of the efficacy data submitted at product authorisation, since product efficacy depends on antifouling pressure and other external conditions as well as the intrinsic chemistry of the product).

In June 2018 three MSs provided comments on the expected date when draft outputs from the two marina models would be available for their products for collation. In addition to the UK, one MS considered that draft outputs would be available in autumn 2018, while for two other MSs draft outputs would not be available until mid or late 2019.

Information from other discussions and sources

1. It is recognised that PT21 products currently supplied in the EU are generally specialised for vessels having particular properties (saltwater/freshwater, hull type and speed) or may be specialised for use on propellers only, although this is not always clear from the information submitted to evaluating MSs.

At the CA meeting in January 2018 it was agreed that each PT21 product SPC should include one or more vessel categories in the use description. Each of these vessel categories can be correlated to a core environmental emission scenario in from the PT21 product authorisation manual from 2017 (see Annex 3). On this basis the proposed impact

assessment would apply to products falling into category 1 (Paint for leisure crafts with a hull length of maximum 24 meter and a berth in marine environment).

2. Regarding region-specific aspects to product assessment and authorisation decisions for leisure craft products, section 3.3 of the latest PT21 Product Authorisation guidance states: *"The 90th percentile concentration is calculated automatically by the separate calculation tools. Assessments based on all core scenarios should be included in EU level submissions and should be evaluated by the rMS and presented in the PAR. This will aid Mutual Recognition by concerned MS. Since not all scenarios or regions are relevant to all MS, the table below* [see Annex 4] *identifies the scenarios of relevance to each MS. To support authorisation in each MS without the need for additional information, all relevant scenarios for that MS must result in an acceptable risk assessment.*

3. Regarding the use of national environmental exposure tools for leisure craft products the PT21 guidance also states:
"Where unacceptable risks are identified in one or more of these relevant core scenarios, Applicants will need to provide further information to support a refined exposure and risk characterisation assessment. It may also be possible to support a submission for National Authorisation only based on additional MS specific scenario requirements or decision making criteria. Applicants are advised to discuss refinement options with the relevant MS.
Where the outcome of the risk assessment requires a product to be restricted to marine use only, individual MS will have to ensure that appropriate labelling and/or other control measures are in place to ensure that products are used in line with the conditions of authorisation
These 'other control measures' could include a variety of specific actions implemented by Applicants through appropriate product stewardship schemes e.g. poster campaigns, working closely with product suppliers or stakeholder user groups, providing additional product information sheets or via application of labelling requirements for treated articles under Article 58 of the BPR etc."

Proposed way forward
Taking into account the support among MSs for an impact assessment of the new model as well as:

-the resource limitations of individual MSs
-the need to meet deadlines on product authorisation decisions
-the appropriate forum for voting being the CA meeting
-the fact that the ECHA website software calculates the exposure and risk from both the existing OECD marina model and the new marina model

it is proposed that:

1. CAs evaluating PT21 products use the software on the ECHA website to generate outputs for both seawater marina models and then populate a spreadsheet template. To assist the

Assessment of PT21 products – new assessment tool

UK has prepared a draft spreadsheet template (attached) which could be made available to evaluating MSs on the CG section of S-CIRCA BC. The template uses existing summary information that can be simply copied from the existing ECHA spreadsheets for each active substance (and relevant substances of concern) and the overall mixture in each individual product. Collecting the standard summary information for each product in this way would allow the most comprehensive analysis to be undertaken as part of an impact assessment. If individual evaluating MSs were willing to contribute to collecting this information for products that they are evaluating and populating the template, the UK would be willing to contribute resource to collating the available results to inform a subsequent impact assessment. It is proposed that a Newsgroup is set up on the S-CIRCA BC/CG website for evaluating CAs to provide draft product outputs from both marina models.

2. The UK will collate the draft outputs comparing the two models which have been uploaded onto this Newsgroup by the end of September 2018. . Findings from these comparisons could then be discussed at the CG.

3. The collation of product outcomes could then be used by CA meeting members at future discussions to inform on the potential impact of PT21 assessments on environmental protection, the supply chain and control of invasive species at regional and/or Community level.

UK Competent Authority
July 2018

Assessment of PT21 products – new assessment tool

Annex 1. CG-26. Agenda item 14.4. Assessment of PT21 products – new assessment tool (updated February 2018)
UK statement

Colleagues will be aware of the work that the UK has been leading, with significant input from colleagues in DK, SE, FI, DE, FR and NL, on developing a new tool/model for assessing PT21 products in saltwater scenarios. This new tool provides for a more extensive assessment than the interim approach (based on the single OECD pleasure craft marina), that had to be used during the active substance approval stage. NL is in the process of developing something similar for freshwater.

UK delivered the new model to ECHA by the end of September, as planned, and we understand that ECHA will be publishing it on their website for product applicants to use. However, due to the 2 year rule on using new guidance for product submissions, applicants may choose to use the new model if they wish but will not be obliged to; instead they can use the method as presented in the CAR.

We discussed progress with the new model at the September CA meeting. UK shared feedback from one of our applicants that, using the new model, few of their extensive range of products will show acceptable use for inside marinas, when using the 90th percentile concentration, as agreed in principle at the March CA meeting. Indeed, none of their products would pass for the Mediterranean, Baltic or Baltic Transition scenarios. NL reported that their freshwater tool is likely to result in even more restricted outcomes.

So we are in an unfortunate position of having an inadequate interim tool and a new tool that applicants cannot be obliged to use, which may give unfavourable results. Unfavourable, that is, using the currently agreed protection goals.

Our understanding is that stakeholders and CAs are well informed on this issue, but we feel it necessary to establish an agreed approach for the PT21 applications due to be submitted by the end of this year to ensure a harmonised approach.

Therefore we asked the CG for agreement on a harmonised approach and for this approach to be shared with stakeholders. Following comments from DE, DK, FI and SE the UK CA updated the approach proposed at CG-26.

The proposed approach for agreement, was as follows:
1. Applicants make their submission according to the fixed deadline.

2. Applicants use the current approach, as followed for the Active Substance approvals in the CARs.

Assessment of PT21 products – new assessment tool

3. Applicants may also use the new tool to determine safe and unsafe uses according to that method.

4. refMS will conduct their assessments according to both the current and new methods. The results of both methods should be fully reported in the draft PAR.

5. A comparison of the results from the current and new methods will form the basis of an impact assessment. The comparison should be based on assessments using agreed Tier 1 default parameters as outlined in the guidance document "PT21 Product Authorisation Manual". The '*impact assessment*' should consider both the **market** impact and the **environmental** impact (for example where robust information from environmental monitoring programs is available that allows either exposure tool to be validated).

6. Final decisions on allowed uses and restrictions will not be made in each MS until the findings of the impact assessment are shared and considered amongst CAs. This process will need to respect legal deadlines already set under the BPR. It is agreed that the relevant forum for voting on allowed uses and restrictions is the CA meeting.

7. Final decisions on authorisations may have to involve a reconsideration of the protection goals and/or consideration of Art 19(5). Any reconsideration of protection goals will need to be agreed by all concerned MS of a particular region (for example in order for the protection goal for the Baltic Region to be amended, all concerned MS in this region must agree to the change – protection goals should not be set on an individual MS basis). For mutual recognition applications, Article 37 is clearly relevant.

MS that have established national specific PT21 environmental exposure scenarios should still be able to make product authorisation decisions on the basis of these national specific exposure tools. However in order to facilitate decision making in other concerned MS, the refMS should present assessments using the current and new methods as outlined in point 4 above. National specific exposure scenarios can be considered by concerned MS during the Mutual Recognition stage of the authorisation process.

Where an Applicant or refMS has proposed higher tier approaches to refine the Tier 1 assessments considered at point 5 above, these approaches should be presented and agreed at Environment Working Group level to ensure a consistent approach is taken for all relevant product/active substances.

MS are reminded that the requirement for the efficacy of PT21 products is >75% protection against macrofouling. It is important not to encourage overly effective products that may lead to unnecessarily high release of active substances to the environment, in line with Article 17(5) ("the use of biocidal products is limited to the minimum necessary and appropriate precautionary steps are taken"). Some consideration should be given to

measures aimed at reducing levels of environmental emission whilst still maintaining an acceptable level of efficacy. The impact assessment suggested under point 6 above should consider aspects of the product efficacy alongside the environmental assessment in an integrated approach.

Discussions at CG27 and possible way forward

The above proposals were discussed at CG27. In addition the document drafted by NL at the recent CA meeting on harmonising the authorisation of PT21 products (CA-Jan18-Doc.7.4.) is also considered relevant.

It is proposed that the CG discuss a way forward on the following issues

a) **Impact assessment of new exposure tool (para 5)**

Do the CG members agree that the impact assessment (considering both market impact and environmental impact) should study the impact at a Regional level for consistency with the regional separation in the new exposure tool? Alternative scales of impact assessment could range from a national level through to Community level. The CG meeting are also invited to consider who should coordinate the assessment. It should be noted that since the original work on this project, the UK is in a much less strong position to coordinate this work since very few applications for PT21 products have actually been made to the UK. It might be easier for one of those MS evaluating the majority of PT21 products to lead on this area. However the UK would be happy to work with all other MSs to develop a template for recording the outcomes of the individual product assessments in a consistent manner in order to best inform the impact assessment.

b) Regional approach to reconsidering protection goals (para 7)

Do the CG members agree with the proposals for considering protection goals at a regional level? Members should note that this potentially sets a precedent for what constitutes a region under the BPR e.g. can the Atlantic be considered to be a single region? Do CG members also accept that MS that have established national specific environmental exposure tools should still be able to use these to make product authorisation decisions? This would potentially lead to product authorisations at a national level that are not supported at the relevant regional level.

c) Restriction of overly effective PT21 products and type of vessels.

Should this be taken forward for PT21 products used for all types of vessels? A recent CA meeting paper (CA-Jan18-Doc.7.4.) on harmonising the authorisation of PT21 products identified several classes of vessel for PT21 products. The effects of a regional or Community level restriction on overly effective products might be easy to predict for small craft spending most of their time in local waters and ports. On the other hand the effects on PT21 products used on ocean-going vessels is less easy to predict; it is possible that the operators of ocean-going vessels may decide to have their vessels treated in other regions or other

parts of the world with fewer restrictions, although the treated vessels would still visit ports and waters in the Community.

UK Competent Authority
Updated 19th February 2018

Assessment of PT21 products – new assessment tool

Annex 2. Summary table of MS comments on Assessment of PT21 products – new assessment tool paper (updated 19th February 2018 – Annex 1)

Issue	DE	DK	FI	FR	NL
a1 – Should there be an impact assessment of the new exposure tool?	Yes at regional level	Yes at regional level. Additional national approach if considered necessary buy individual MSs having national scenarios to assess whether regional core scenario achieves protection. Impact assessment shouldn't delay timescales for product authorisation	Yes, at regional level	Yes, but its scope should be decided at CA meeting.	Yes, but its scope (national/regional/Community level) should be decided at CA meeting.
a2 – If so who should coordinate the impact assessment?	DE has only a few applications as eCA but would be happy to contribute actively to impact assessment and conduct assessment for at least one region	-	FI could not lead but is willing to contribute.	FR could not coordinate this work	Although NL has most applications could not lead due to resources.
b1- Should there be a regional approach to	No, protection level should be harmonised	No regional protection goals as	No, protection level should initially be	Yes in principle but should be discussed in	Use existing/agreed protection goals

Assessment of PT21 products – new assessment tool

considering protection goals?	for all regions	contrary to political decision reflected in BPR	harmonised at Community level, although region-specific approach could be explored later if all MSs in the region agree	detail at CA meeting	
b2 –Should MSs be able to use national specific environmental exposure tools to make product authorisation decisions?	Yes, this is one reason why regional marina scenarios were developed	Yes, as a temporary solution until regional core scenario in force	Yes	Do not have strong opposition but would need to resolve: -which MSs? -would national outcomes be more or less conservative? -whether national scenarios could apply to small vessels (limited to a region) or large vessels?	Use existing/agreed scenarios
c- Should overly effective products be restricted?	No. If PEC/PNEC <1 and efficacy acceptable a product should be authorised. Unclear of legal basis for restriction.	Not for ocean-going vessels: may not have desired effect as such vessels can be treated in other parts of the world	Yes, but can it be linked to efficacy studies? Efficacy may vary with region (copper in Baltic compared with oceans?)	This issue is of importance and should be part of the impact assessment	PT21 products for pleasure craft should be safe for freshwater, sea-going and ocean going craft. There are currently no scenarios for sensitive areas in oceans (atolls)

Assessment of PT21 products – new assessment tool

Annex 3. Vessel categories for PT21 products and relevant core emission scenario

Vessel category (CA – Jan 18- Doc 7.4a-Final)*	Relevant core environmental emission scenario (ECHA PT21 Product authorisation manual (environmental risk assessment) September 2017)
1.Paint for leisure crafts with a hull length of maximum 24 meter and a berth in marine environment	OECD marina/surrounding scenario or New marine scenarios (148 marinas in 4 regions)
2.Paint for leisure crafts with a hull length of maximum 24 meter and a berth in inland water	New freshwater scenarios (46 marinas in 5 MSs)
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	OECD commercial harbour scenario
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	No assessment of emissions from commercial shipping in freshwater is required as part of the core assessment performed by the rMS. It has been recognised that relevant scenarios will need to be developed in the future to support such an assessment. For those MS that do require assessment of this emission route in the future, it has been proposed that the agreed models and scenarios be assessed by the cMS in a separate National Authorisation only application.

* In the authorisation of antifouling paints it is possible to combine categories. This should be decided upon on a national level. In addition, it is of course possible to apply for an authorisation for paints that are specifically designed for a particular marine environment (e.g. Baltic or Mediterranean Sea) or a particular inland water environment (e.g. specific lake or river systems), provided that suitable scenarios and models for the assessment are available.

Assessment of PT21 products – new assessment tool

Annex 4. Marine and freshwater pleasure craft marina scenarios and relevance for individual Member States [taken from ECHA PT21 Product authorisation manual (environmental risk assessment) September 2017]

Pleasure craft scenarios	EU level	BE	DK	IE	ES	FR	NL	PT	UK	NO	BG	EL	HR	IT	CY	MT	RO	SI	DE	SE[1]	EE	LV	LT	PL	FI	LU	AT	CZ	HU	SK	CH
Core scenarios																															
Atlantic region	X	X	X	X	X	X	X	X	X	X									X												
Mediterranean region	X				X	X					X	X	X	X	X	X	X	X													
Baltic region	X																		X	X	X	X	X	X	X						
Baltic transition region	X		X																X	X											
OECD Marina	X																														
Freshwater[2]	X						X												X					X		X	X	X	X	X	X
OECD Swiss marina	X																														X
NL National marina	X						X																								
Member State specific scenarios[3]																															

EU level: These scenarios should ALL be submitted and evaluated by the rMS

X : Scenario relevant to individual MS

[1]: Note that for product authorisation in SE, KemI has considered it appropriate in some cases to use an additional Assessment Factor when deriving the PNEC for the Baltic Sea. Applicants are advised to contact KemI for advice on specific assessment factors for the relevant Baltic Sea scenarios.

[2]: The freshwater scenario here refers to those included in the separate Excel calculation tool, comprising 46 marinas from five contrasting MS.

[3]: The section on Member State specific scenarios will be updated over time as more experience is gained on individual National approaches.