TEMPLATE

for third party submission of information on potential candidates for substitution

NON-CONFIDENTIAL

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SUMMARY

This submission is made in response to the public consultation regarding the active substance medetomidine (CASRN 86347-14-0), active substance under product type PT21, antifouling paint, with intended use "professional and non-professional marine antifouling product used on surfaces which are immersed (vessels and static structures)". The Rapporteur Member State has indicated in its final Competent Authority Report – as submitted to ECHA on the 12th of March 2014 that medetomidine is considered to breach the P criteria set out in the TGD based on the mere absence of compartment specific data for soil, where soil data was not a core requirement for PT21 according to the BPD, but where soil data were nonetheless unexpectedly demanded by the RMS in the latest stages of finalisation of the second draft Competent Authority report. The public consultation procedure was subsequently started on the basis that the active substance should meet two of the PBT criteria (P and T), thereby triggering the criteria for substitution as comprehended by BPR article 10(1)(d).
I-Tech continues to disagree with the RMS conclusion that medetomidine should meet the P-criterion and questions the legal rationale for and legal validity of the resulting procedure including the applicability of the public consultation at the time it was initiated.

Including medetomidine itself, there are only limited alternatives available for the prevention of hard fouling organisms such as barnacles. In addition, both the technical and economic feasibility impede the effective introduction of any new alternatives and the likelihood of companies undertaking such venture. Especially the introduction of a new active substance is highly demanding as no income can be generated and simultaneously high investments are made in the typical timeframe of at least a decade required for achieving a possible substance approval.

Furthermore, few active substances for PT21 are available today on the EU market. The first assessment reports of these substances show some unacceptable risks either for human health and/or for the environment, inherent to their hazard profiles and uses. It was commented by the EU Commission and the Competent Authorities that risks accepted today by the majority of Member States might not be accepted anymore over time. This was the reason for the EU Commission and Competent Authorities decision to approve all active substances for PT21 on the basis on the same generic conditions, to establish the same expiry date of approval for all existing active substances placed on the market for PT21, in order to evaluate the renewal of their approval at the same time.

In that context, with minor risks involved for the soil compartment from release during non-professional use, and therefore only considered for a minor use type, I-Tech are of the opinion that medetomidine should be included in the approach described above for all antifouling actives. A level playing field between PT21 substance suppliers should be maintained, particularly with the current imbalance between the feasibility of introducing existing and new actives into the new biocides regulatory arena.

The fate of medetomidine in soil may be relevant for the *risk* assessment, but soil degradation data are *not* relevant for establishing the PBT *hazard* criteria.
I-Tech sees value in generating soil degradation data for the purpose of product risk assessment, but requesting soil degradation data for the purpose of the substance PBT hazard assessment is untimely and unwarranted.

The incorrect designation of P-status to medetomidine based on the presupposed lacking of soil data has had the erroneous and ruinous result of this active substance inappropriately entering a legal procedure as a possible candidate for substitution. I-Tech is therefore seeking repair of the followed legal procedure.

A. COMMENTS ON ACTIVE SUBSTANCE STATUS AND PROCEDURE

A.1. ACTIVE SUBSTANCE P-ASSESSMENT AND CONCLUSION

I-Tech received its first draft CAR from the RMS in July 2013. In the report, the RMS had not been able to perform a conclusive P-assessment of the active substance as available lower tier data had not provided sufficient basis for a clear outcome on the P-classification. The RMS requested additional aquatic/sediment degradation data, which were later provided by I-Tech in the form of an OECD 308 water-sediment study. No mention was made about the necessity to provide soil data in addition.
The RMS submitted the first draft CAR to ECHA on September 9th, 2013, whilst the OECD 308 water-sediment study was ongoing, which was reason for ECHA not to accept the CAR into the subsequent 270-day BPR process for coming to a final BPC opinion on the active substance. Again, no mention was made about the necessity to provide soil data in addition.
I-Tech received the second draft CAR from the RMS in February 2014. This time, the RMS had come to a favourable conclusion on the aquatic-sediment data, but were now, at such a late juncture, suddenly demanding degradation data specific to the soil compartment.
I-Tech agrees that such data would be helpful for risk assessment at product authorisation stage (and is willing to generate this data), but contests that this data is a prerequisite for the PBT hazard assessment of the active substance that forms a basis for determining whether the active substance fulfils the substitution criteria, or not. The RMS concluded following in its second draft CAR, which was submitted to ECHA on the 12th of March 2014:

"Persistence
... The geomean DT50 values for medetomidine determined from the acceptable sediment / water study were 23.4 days (water phase dissipation value) and 51.3 days (whole system degradation value, range from 48.8 to 54.0 d). Based on these values the UK CA concluded that medetomidine would be unlikely to breach the persistence triggers for marine systems (i.e. >60 d in marine water and >180 d in marine sediment). By read across it is considered reasonable to conclude that medetomidine would also be unlikely to breach the triggers in fresh water either. …
…However no data was submitted on the degradation of medetomidine in soil and it is not currently possible to conclude on whether the substance would breach the persistence criteria in soil (i.e. soil DT50 > 120 d). …
…, in the absence of further specific information on the fate in soil, the UK CA concludes that the substance should, by default, be considered P in soil. This classification could be removed following submission of further data on degradation in soil. For the purposes of PBT assessment, medetomidine is considered to breach the P criteria set out in the TGD. Other MS may wish to consider whether the approach of considering substances P by default in the absence of compartment specific data is appropriate."

The criteria in the TGD (Reference 1), to which the UK refers, are as follows:

Table 30 Criteria for identification of PBT and vPvB substances

Criterion	PBT criteria	vPvB-criteria
P	Half-life > 60 d in marine water or > 40 d in freshwater* or half-life > 180 d in marine sediment or > 120 d in freshwater sediment*	Half-life > 60 d in marine- or fres marine or freshwater sediment
B	BCF > 2,000	BCF > 5,000
T	Chronic NOEC < 0.01 mg/l or CMR or endocrine disrupting effects	Not applicable

The RMS conclusion is therefore not only inappropriate, but also incorrect on the basis that:

- no characterisation of persistence can be performed on the basis of a missing value
- the degradation in soil is not a criterion for identification of PBT in accordance with the TGD.

Based on the remaining values and applicable criteria the only correct conclusion is that the active substance is not to be considered persistent.

A.2. LEGALITY OF ACTIVE SUBSTANCE PROCEDURE

A.2.1. Procedures at ECHA

Contrary to the submittal of the *first* draft CAR, where ECHA concluded that missing data on the aquatic/sediment study were grounds for not allowing medetomidine to enter the 270-day procedure, after submittal of the *second* draft CAR ECHA correctly concluded that medetomidine was eligible to enter the 270-day period, thereby confirming the fact that the availability of degradation data for the soil compartment was not a prerequisite to proceed. In contradiction, and perplexingly, ECHA *simultaneously* triggered the public consultation on the basis of the default RMS conclusion which in was based on the fact that this very information on the persistence in soil was missing.

Moreover, ECHA's own website and procedures - in place since October 10th, 2013 (Reference 2)-, as well as the Competent Authorities themselves, advocate the significance of the availability of classification assessment, specifically with regard to the PBT status in relation with the exclusion and substitution criteria:

ECHA website:

"Since harmonised classification is a key element in the exclusion criteria and therefore for the assessment of whether an active substance is a candidate for substitution, the ECHA secretariat will aim to ensure cooperation between the Biocidal Products Committee and the Risk Assessment Committee (RAC).

Similarly, the PBT properties of an active substance also need to be assessed when deciding whether an active substance is a candidate for substitution. Therefore, the ECHA secretariat will also aim to ensure cooperation among the BPC and the ECHA PBT expert group."

ECHA working procedures:

"*Accordance check*

Fulfilling the following criteria would constitute a "pass" in the accordance check performed on the CAR following the submission by the eCA. If one of the conditions is not fulfilled, the result is "fail". These criteria concern all CARs submitted after 1 January 2014 regardless of the format used:

1) …

2) …

3) The CAR includes explicit reporting of the fulfilment of exclusion criteria and the criteria for candidates for substitution. Each of the criteria needs to be discussed individually, clearly indicating whether the criteria are fulfilled or not.
4) There are no obvious inconsistencies in reporting. The conclusions need to reflect the assessment of the data. No scientific evaluation is made in the accordance check but any obvious inconsistencies would constitute a fail.
…In addition, as agreed at the Competent Authority meeting on 13 September 2013, the status on C&L, PBT, vPvB and POP of the substance needs to be considered for substances in the Review Programme. These criteria do not concern new active substances, or active substance applications under the BPR. The requirements for CARs in the Review Programme are as follows, depending on the status of the dossier and the properties of the active substance:
If at least 2 out of 3 of the PBT criteria are met, the recommendation of the PBT Expert Group needs to be available on the PBT/vPvB/POP status at the time of submitting the CAR.

CA-Sept13-Doc.8.3 – Final (Reference 3):
Establishment of the harmonised C&L, P/B/T status, when needed :
The harmonised C&L dossier, or request for the advice on the PBT/vPvB status to the PBT Expert Group (including whether 2 out of 3 of the PBT criteria are met), shall be submitted as soon as possible when the hazard evaluation of a substance has been done, and at the latest at the same time when the draft CAR is sent to ECHA. No draft CAR will be accepted anymore by ECHA if this has not been done.
In case where it is suspected that the active substance might fulfil the exclusion/substitution criteria (for the moment on CMR, P/B/T), it is highly preferable and therefore strongly recommended that Member States submit their draft CAR only when the RAC has given its opinion on the CMR status, or PBT subgroup has given its opinion, in order to take into account these opinions in their draft CAR before submitting them.

The absence of a final and conclusive PBT classification in combination with the fact that the RMS is unsure about its own conclusions - inviting other MS to consider the appropriateness of considering substances P by default in the absence of compartment specific data-, constitutes insufficient basis for the initiation of the public consultation procedure. The current consultation by ECHA is therefore both incorrect and premature in the sense that no agreed classification exists for medetomidine. The public consultation procedure on substitution started by ECHA was not legally warranted.

A.2.2.Transitional measures from BPD to BPR
The question might be raised whether the availability of soil compartment data is necessary and/or mandatory under the realms of BPR, as the active substance dossier was submitted at the time of the BPD. For the assessment of PBT criteria the BPR refers to REACH Annex XIII:

BPR Article 10.1 - An active substance shall be considered a candidate for substitution if any of the following conditions are met:
(a) …. ;
(b) …. ;
(c) …. ;
(d) it meets two of the criteria for being PBT *in accordance with Annex XIII to Regulation (EC) No 1907/2006;*
(e) …. ;
(f) …. .

REACH Annex XIII, in turn, states the following:

1. CRITERIA FOR THE IDENTIFICATION OF PBT AND vPvB SUBSTANCES

1.1.1. Persistence

A substance fulfils the persistence criterion (P) in any of the following situations:

(a) the degradation half-life in marine water is higher than 60 days;

(b) the degradation half-life in fresh or estuarine water is higher than 40 days;

(c) the degradation half-life in marine sediment is higher than 180 days;

(d) the degradation half-life in fresh or estuarine water sediment is higher than 120 days;

(e) the degradation half-life in soil is higher than 120 days.

REACH Annex XIII clearly does NOT state that a substance fulfils the P-criterion if specific soil data are missing. A default decision on the basis of missing data is therefore certainly incorrect.
Also, the list of persistence criteria might imply that a separate conclusion on the soil compartment is expected, but for medetomidine transitional measures apply, as its application was submitted for the purpose of the BPD:

BPR Article 90.2 - Applications submitted for the purposes of Directive 98/8/EC for which the Member States' evaluation in accordance with Article 11(2) of Directive 98/8/EC has not been completed by 1 September 2013 shall be evaluated by the competent authorities in accordance with the provisions of this Regulation and, where relevant, Regulation (EC) No 1451/2007.
That evaluation shall be carried out on the basis of the information provided in the dossier submitted under Directive 98/8/EC.
Where the evaluation identifies concerns arising from the application of provisions of this Regulation which were not included in Directive 98/8/EC, the applicant shall be given the opportunity to provide additional information.

This means that the active substance evaluation should be carried out on the basis of the information which was provided under the BPD. As degradation data on soil were not a core data requirement under the BPD, the RMS should perform the PBT assessment on basis of data already submitted.
Question remains whether the persistence evaluation is to be seen as arising from applications of the BPR, which were not included in the BPD. The principles on substitution may be new, but the PBT assessment is not:

CA-March14-Doc.4.1 - Final - NOTE ON THE PRINCIPLES FOR TAKING DECISIONS ON THE APPROVAL OF ACTIVE SUBSTANCES UNDER THE BPR (Reference 4) –

The conclusions of this document state:

1. Active substances shall be approved on the basis of the BPD principles and practice when the 1st draft CAR was submitted before 1 September 2013. …
2. Active substances shall be approved on the basis of the BPR principles when the 1st draft CAR was submitted after 1 September 2013.
3. In both cases, the assessment report should include conclusions regarding the new elements of the BPR on :
   - …
   - The substitution criteria
   - … .

Finally, about application of article 90.2:

This article establishes the possibility given to the applicant to provide additional information where the evaluation identifies concerns arising from the application of the provisions of the BPR which were not included in the BPD.

This provision shall only be applicable in case where there is a new specific assessment under the BPR which was not requested under the BPD in relation to specific data requested under the BPR which were not requested under the BPD. **In particular, this provision shall not be applicable in case of a substance is being targeted by substitution in relation with the P/B/T criteria, because these P/B/T properties had already to be assessed under the BPD, and are not considered as "new concerns".**

In addition, as the data requirements provided in Annex II and III are broadly equivalent to the data requirements of annex IIA, IIIA, IVA, IIB, IIIB, and IVB of the BPD, recourse to the provisions of Article 90(2) shall really be exceptional.

The Competent Authorities have therefore agreed that both in the case where the active substance evaluation takes place before *and* after September 1st, 2013 additional information to address the P-issue shall not be requested for the purpose of the PBT assessment, even though the substitution principles in the BPR are new. Again, the RMS should perform the PBT assessment on basis of data already submitted.

The RMS states that "Although soil data was not a core requirement for PT21 under the BPD, emissions to soil are predicted to occur under the OECD ESD therefore the fate of medetomidine in soil is relevant to the assessment."

The fate of medetomidine in soil may be relevant for the *risk* assessment, but soil degradation data are *not* relevant for establishing the PBT *hazard* criteria.
Through yet another route, it can be concluded that soil data shall not be requested at this stage: on page 43 of the latest Manual of Technical Agreements (Reference 5) the following is clarified (decisions at the TM take precedence and overrule comparable REACH guidance):

Q2: Can the persistence categories in soil from the PPP be used in the CAR?

A2: (TM III 05)

The PPP categories* on the categorisation of persistence in soil shall not be used neither other categories, for example on mobility, in the CAR.

* PPP 1107/2009 Annex II

3.7.2.1. Persistence
An active substance, safener or synergist fulfils the persistence criterion where:
— the half-life in marine water is higher than 60 days,
— the half-life in fresh or estuarine water is higher than 40 days,
— the half-life in marine sediment is higher than 180 days,
— the half-life in fresh or estuarine water sediment is higher than 120 days, or
— the half-life in soil is higher than 120 days.

Again, the RMS should not need soil degradation data and should perform the PBT assessment on basis of data already submitted.
I-Tech sees value in generating soil degradation data for the purpose of product risk assessment, but requesting soil degradation data for the purpose of the substance PBT hazard assessment is untimely and unwarranted.

A.3. CONCLUSIONS ON ACTIVE SUBSTANCE PROCEDURE

The RMS conclusion in the second, final draft CAR as submitted to ECHA is both inappropriate and incorrect on the basis that:

- no characterisation of persistence can be performed on the basis of a missing value
- the degradation in soil is not a criterion for identification of PBT in accordance with the TGD.

The active substance evaluation should be carried out on the basis of the information which was provided under the BPD. As degradation data on soil were not a core data requirement under the BPD, the RMS should perform the PBT assessment on basis of data already submitted. This is valid in the case where the active substance evaluation takes place before *or* after September 1st, 2013. Additional information to address the P-issue should not have been requested for the purpose of the PBT assessment, even though the substitution principles in the BPR are new. The RMS should perform the PBT assessment on basis of data already submitted.

Based on these remaining values and the applicable criteria for biocidal active substances the active substance is not to be considered persistent.

The fate of medetomidine in soil may be relevant for the *risk* assessment, but soil degradation data are *not* relevant for establishing the PBT *hazard* criteria.
I-Tech sees value in generating soil degradation data for the purpose of product risk assessment, but requesting soil degradation data for the purpose of the substance PBT hazard assessment is untimely and unwarranted.

The incorrect designation of P-status to medetomidine based on the presupposed lacking of soil data has had the erroneous and ruinous result of this active substance inappropriately entering a legal procedure as a possible candidate for substitution. The legal consequences for a possible candidate for substitution are far-reaching in the sense that there are direct penalties on both active substance approval duration and on duration of approval of connected biocidal products. Such status should only be assigned with ultimate care, as it potentially affects economic survival on the EU market. An incorrect and undeserved assignment of the P-classification and associated status as possible candidate for substitution can have devastating consequences. I-Tech is therefore seeking repair of the followed legal procedure.

B. COMMENTS ON ALTERNATIVES

Although I-Tech strongly disagrees with the designation that medetomidine should be a possible candidate for substitution, insights will be given below to confirm the lack of purpose of initiating any substitution procedure at this stage.

B.1. ALTERNATIVE IDENTITY AND PROPERTIES

The active substance medetomidine (trade name Selektope, CASRN 86347-14-0) has been unfoundedly deemed a candidate for substitution based on a combination of T(oxic) and presumed P(ersistent) properties. As a result of this incorrect conclusion, the active substance is unsuitably being considered as a candidate for substitution before the event of entering the EU market, where Selektope *itself* is to be considered as an alternative for other active substances already present on that market.

I-Tech continues to strongly disagree with the outcome of the RMS active substance PBT assessment leading to the active substance inappropriately being concluded as P and the subsequent initiation by ECHA of the public consultation process legally foreseen only for active substances for which it has indeed been proven that they fulfil the substitution criteria.

B.2. TECHNICAL FEASIBILITY

Next to developing an effective active substance, the active substance also needs to be incorporated in a final product leading to an efficacious antifouling paint. In addition to appropriate efficacy, these paints have to exhibit a host of other characteristics which make them ultimately suitable for their task, such as suitable applicability onto the vessel surface and sufficient adhesion, and maintenance of the paint layer integrity in a 'hostile' aquatic environment, where, at the same time, an active substance release mechanism is part of the way in which the antifouling paint actually works.
In terms of formulation, and in comparison with many other biocidal products, antifouling paints are to be counted amongst the most complex formulation types. Not only is this based on the required final characteristics of the paint, also in terms of the number of co-formulants antifoulings are intricate. From a technical standpoint, patience and tenacity are required for companies to succeed in introducing a viable new antifouling paint. 10 to 15 Years of research and development from the conception of a new active substance to a practical antifouling paint is not underestimated. Substitution of an active substance which is not yet on the market is further seen as premature, as the active substance has not had the opportunity to fully show its value and benefits from use in antifouling paint formulations.

B.3. ECONOMIC FEASIBILITY

A supplier of a new active substance not only has to tolerate a painfully long product development time: the current regulatory constraints and related costs, but above all the continually changing regulatory landscape and requirements, pose an ultimate challenge to the economic endurance of a company wishing to place its active substance on the market.
The regulatory circumstances are challenging for any active substance supplier, but the introduction of a *new* active substance is especially demanding with years of expenditure without *any* revenue. The process of introducing a new antifouling active substance on the market has proven to test the bounds of economic feasibility. Finally, the - incorrect and premature - status of medetomidine as possible candidate for substitution may form an undesirable disincentive for formulators to invest.

B.4. HAZARDS AND RISKS OF THE ALTERNATIVE

Based on the risk profiles connected with their intrinsic properties and uses, none of the available PT21 active substances are completely free of concern. This was recognised and a PT21 approach was endorsed in the mutual CA document between the European Commission and EU Competent Authorities (Reference 6):

"The following integrated approach is therefore suggested. It is based on risk management measures developed and refined throughout the active substances' approvals, the products authorisations, up to the renewals of the approvals and authorisations.

STRATEGY

A. **Approval stage of active substances**

Few active substances for PT21 are available today on the EU market. The first assessment reports of these substances show some unacceptable risks either for human health (ex: for the potman during a professional use), and/or for the environment (ex: in the harbour or marina during the service life, or during the application or maintenance and repair activities). **The suitability of the proposed risk mitigation measures has raised questions, with no clear conclusions in the assessment reports. There is therefore a need to re-consider them at the product authorisation stage and to gain experience on the matter.** Some risks accepted today by the majority of Member States (ex: levels of risks in the harbour or marina during the service life) might not be accepted anymore over the time.

Despite these concerns and risks arising from their use, antifouling products are nevertheless needed to prevent the growth of marine life on ships and boats allowing their safe and efficient operation. They participate to the prevention of spreading of invasive species, as well as reducing fuel consumption and related greenhouse gases emissions.

Considering this situation, without prejudice to the general principles related to the application of the exclusion and substitution criteria of the BPR, it would be proposed:

- To approve all active substances for PT21 on the basis on the same generic conditions. Additional specific conditions could be added on a case-by-case basis (for instance, if the substance is a skin sensitizer, the standard paragraph related to treated articles would be added).
- **To establish the same expiry date of approval for all existing active substances placed on the market for PT21, in order to evaluate the renewal of their approval at the same time.**
- To flag specific concerns related to each individual active substance in the assessment report."

In other words, all available alternatives will receive the same expiry date and regulatory treatment, despite any – obviously remaining – concerns for each of them. A supposed concern for the persistence in soil, since according to the RMS *"it cannot be inferred whether medetomidine is persistent in soil based on the data provided and therefore it is unclear whether it can be identified as P or not",* is given disproportionate weight in comparison to any of the remaining concerns regarding the other active substances. Moreover, data on the persistence in soil were not a core requirement under the BPD, and therefore any of the PT21 PBT assessments should have been feasible without the availability of soil data, without attributing P to all actives by default.

I-Tech not only strongly objects to the incorrectness, but also to the poor timing of the decision to enter medetomidine into the consultation for substitution. Any decision to consider an active substance for substitution should be delayed until all active substances for antifouling paint can be considered at the same time and be carried out based on the same principles. Specific concerns should, as agreed by the Competent Authorities above, be re-considered at product authorisation stage and subsequent active substance and product renewals, during which time experience on risk mitigation should be gained.

In addition, other hazards and risks such as the transmigration of invasive species through hull fouling, and the emission of greenhouse gases as a result of unnecessary usage of fuel should not be forgotten and responsible authorities should assess this in conjunction with any judgment on substitution.

A level playing field should be the point of departure, and consequently medetomidine should be approved based on the same criteria and procedure as agreed for all other PT21 active substances.

B.5. AVAILABILITY

The process as started under the European Biocidal Products Directive has ceased economic existence of 36 of the 46 notified PT21 actives for the EU market. Together with the phase-out of tributyl tin this was a severe impact for the industry to contract and to recover from. Percentually, product type 21 was hit the most in terms of the number of active substances remaining of the available actives before the process started. Only 2 new PT21 active substances have made it into the biocides review process since.

Antifouling paints are mostly formulated with more than one active substance, for covering different parts of the wide spectrum of fouling species present in the aquatic environment. For use in general antifouling paints, of the remaining active substances there are in essence only three active substances with a distinct efficacy against hard fouling, such as barnacles. Other active substances are effective against soft fouling like algae and microbial slime, but the use of such actives alone will not stop a vessel from fouling. Moreover, premature substitution cancels out any opportunities for formulators to come up with innovative solutions involving more variable combinations of active substances in antifouling paints.

Medetomidine is unique among the active substances in PT 21. Due to the specific mode of action a very low concentration can be used in an antifouling paint to deter fouling barnacles and tube worms. The low concentration needed gives the formulator flexibility to design an efficient antifouling paint with a low emission of medetomidine, a reduced overall biocide content and less volatile organic carbon. The effect of medetomidine on barnacles and tube worms, deterrent pre-fouling rather than lethal post fouling, also minimises the risk of tolerance development.

B.6. CONCLUSION ON SUITABILITY AND AVAILABILITY OF THE ALTERNATIVE

From a technical standpoint, antifouling paints are especially complex based on the required characteristics for the product as well as the product composition in terms of the number of ingredients. 10 to 15 Years of research and development from the conception of a new active substance to a practical antifouling paint is not underestimated.

The regulatory circumstances are challenging for any active substance supplier, but the introduction of a *new* active substance is especially demanding with years of expenditure without *any* revenue. The process of introducing a new antifouling active substance on the market has proven to test the bounds of economic feasibility.
The technical complexity and the demanding regulatory domain impede the effective introduction of any new alternatives and the likelihood of companies undertaking such venture.

There are only limited alternatives available for the prevention of hard fouling organisms such as barnacles. Two of the available active substances that work against hard fouling, including medetomidine, are new actives. These active substances are about to become available on the EU market next to copper. The moment is finally imminent where the industry may have access to more than one active substance with an efficacy against barnacles. In assessing the impacts on the environment, and taking decisions about substitution of active substances, authorities have an obligation to consider the effects of such decisions in the perspective of two other global environmental issues: the spread of invasive species and global warming.

Medetomidine is unique among the active substances in PT 21. Due to the specific mode of action a very low concentration can be used in an antifouling paint to deter fouling barnacles and tube worms. The low concentration needed gives the formulator flexibility to design an efficient antifouling paint with a low emission of medetomidine, a reduced overall biocide content and less volatile organic carbon. The effect of medetomidine on barnacles and tube worms, deterrent pre-fouling rather than lethal post fouling, also minimises the risk of tolerance development.

Based on the current landscape of PT21 actives and the burdensome and long-lasting introduction of any new options, the entry of medetomidine into the substitution process is neither valuable, nor responsible.

B.7. OTHER COMMENTS

I-Tech's comments have been expressed in the above.

OVERALL CONCLUSIONS

The RMS conclusion in the second, final draft CAR that medetomidine is to be classified persistent, is incorrect, as no characterisation of persistence can be performed on the basis of a missing value for soil degradation. Furthermore, the degradation in soil is not a criterion for identification of PBT in accordance with the TGD, and the BPR transitional measures prescribe that for active substances for which a dossier was submitted under the BPD, the assessment should be done based on the BPD dossier and no soil data shall be required to perform the PBT hazard assessment. Based on available data and the applicable criteria for biocidal active substances the active substance is not to be considered persistent. The active substance was therefore incorrectly entered into the public consultation process for active substances fulfilling the substitution criteria.

In addition, the benefit of substitution is questionable. As there are only limited alternatives available for the prevention of hard fouling organisms such as barnacles, substitution would be unwarranted, irrational and irresponsible in view of the environmental need for effective antifouling solutions in the fields of invasive species and global warming.

Medetomidine is unique among the active substances in PT 21. Due to the specific mode of action – deterrent pre-fouling rather than lethal post-fouling - a very low concentration can be used in an antifouling paint to deter fouling barnacles and tube worms.

Entry of medetomidine into the public consultation process for substitution is neither applicable nor valuable, and may have devastating legal and economic effects. I-Tech seeks to set the records straight on medetomidine incorrectly and undeservedly entering the public consultation process and opening the floor for unjustified scrutiny. It is I-Tech's hope and expectation that all co-operation is received in order to get the legal process rightfully repaired.

REFERENCES

1. Technical Guidance on Risk Assessment in support of Directive 98/8/EC Part II
2. ECHA document Biocidal active substance approval: working procedure for Biocidal Products Committee (BPC) (Agreed on 10 October 2013 at BPC-3) (Revised timelines agreed at BPC-5, inserted in section 5).
3. CA-Sept13-Doc.8.3 – Final – Review Programme of active substances: establishment of a work programme to meet the 2024 deadline
4. CA-March14-Doc.4.1 - Final – Note on the principles for taking decisions on the approval of active substances under the BPR
5. Manual of Technical Agreements of the Biocides Technical Meeting (MOTA), version 6, 2013
6. CA-March14-Doc.4.2-Final - Antifouling (PT21) - Way forward for the management of active substances and the authorisation of biocidal products

APPENDIXES

Not applicable.