

Biocides Technical Meeting

14 - 18 March 2011

INTRODUCTION

The meeting was chaired by E. van de Plassche and for specific items on the agenda by A. Payá Pérez, J. Janossy, P. Piscoi, V. Rodriguez Unamuno, S. Pakalin, B. Raffael and L. van der Wal. E. van de Plassche welcomed the participants to TM I 2011. Representatives from the MS, NO, CH, and Industry were present at the TM. For specific items of the agenda, the interested companies were invited to attend.

1. Approval of the agenda

The agenda was adopted without any further changes.

2. Adoption of the minutes

CZ on DBDCB in the TOX Session (adequate reflection of the conclusions on dermal adsorption) and UK on dichlorvos in the TOX Session had some minor comments on the draft minutes which will be send by e-mail to COM. With these additions the draft minutes were adopted.

3. Action List TM

- 1. Development of refined marina scenario for PT21 to be used in product authorisation*
COM will contact CEPE on this action.
- 2. Comments on document PL on "Harmonisation of environmental risk assessment for PT 06".*
The item is on the agenda of the ENV Session.
- 3. Distribute list with tasks MS in EUSES training validation exercise and prepare the exercise.*
COM informed that a contract will be set out to repair some bugs in the current EUSES version. Thereafter the training validation exercise will be started.
- 4. Draft guidance document on field studies and distribute to COM and involved MS.*
COM will contact IND on the progress on this action item.
- 5. Review of current efficacy guidance for PT 21 in TNsG on Product Evaluation document.*
COM received a draft document recently. This document will be distributed to the TM for a written commenting round.
- 6. Position paper on substance identity of isomeric mixtures.*

COM will contact the relevant MS on the preparation of such a document.

7. *Open a dedicated space on CIRCA where on voluntary basis exposure assessments prepared by the RMS are uploaded, before these are sent to the Commission for the start of the 90 days commenting period.*

A dedicated space on CIRCA has been created.

8. *Inform TM on participation in e-consultation group on efficacy.*

The experts are included by COM in the list of members of the TM.

9. *Finalise Document on emission estimation for insecticides for households and professional uses: targeted applications for discussion at CA meeting.*

It was decided to await and include the outcome of the agenda item 5f of the ENV Session.

10. *Start e-consultation on tier 2 risk assessment for the sediment compartment and refinement of M&R and new build ESD scenario.*

UK started the e-consultation process.

11. *Consult with the applicants for PT 13 in the Review Program to obtain more information on the parameters used in the ESD for PT 13.*

IND will inform COM on the progress on this action item.

12. *Send reactions to DE on environmental risk assessment for PT 22.*

COM will consult with DE on how to process this document.

13. *Consultation on document of DK related to several ESDs.*

COM will consult with DK on how to process this document.

4. Members of the Technical Meeting and the e-consultation group

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5. Next Technical Meetings

2011

TM II 6 – 10 June

TM III 3 – 7 October

TM IV 12 – 16 December

CA meetings: 3 - 6 May, 5 - 8 July, 20 - 23 September and 6 - 9 December

TOXICOLOGY SESSION

1. SUBSTANCES in PT 18**1a. Bifenthrin (RMS: FR)**

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1b. Permethrin (RMS: IE)

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1c. D-phenothrin (RMS: IE)

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1d. Transfluthrin (RMS: NL)

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2. SUBSTANCES in PT21**2a. Feasibility for non-professional users of antifoulings to wear gloves**

In June 2010 the TM asked UK to carry out a survey to find out how many antifouling products submitted for review and as new active substances could be used by non-professionals without the need to wear gloves to protect against systemic effects. The **UK** thanked the Member States for their help in undertaking the survey.

UK presented the position paper on the survey results and related considerations. **UK** stressed that in the paper non-professional use of antifoulings *only* are considered; other product types are not considered.

The main finding of the survey was that only one of the products – containing tolylfluanid – could be used by non-professionals without having to wear gloves (MoE>100). Yet, because of current concerns over secondary metabolites of tolylfluanid, it might not be allowed for use in freshwater environments. UK postulated that based on this survey, there could be no antifoulings available for use by non-professionals without the wearing of gloves on structures in freshwaters (including boats navigating lakes/rivers) and only tolylfluanid for use on structures in marine environments.

Present practices

UK explained that antifoulings are currently available for use by non-professionals. The antifouling products often carry a label statement to wear gloves or to 'avoid contact with skin' when using the antifouling. To comply with the label instruction to 'avoid contact with skin', users obviously have to wear gloves; non-professional application of antifoulings is usually by brush or roller.

Possible consequences of removing antifoulings from the non-professional market

The **UK** acknowledged that this is an issue for the Competent Authority meeting but that the TM had a duty to provide advice and its views for the CA meeting. **UK** explained some of the possible adverse consequences:

Fears over the economic consequences (see Section 6 of the paper)

- If cargo boat, fishermen, leisure boat owners were not allowed to use antifouling then, they would need to employ 'professional' operators to apply the antifouling. What would be the consequences for shipping on rivers such as the Vistula, Danube, Seine, the Rhine, the Dutch Canals and other freshwater transport systems? We are aware of the importance of rivers such as the Rhine in Europe's economy. What would happen to small-scale fishermen in European maritime nations? Removal of antifouling from the non-professional market could affect the economies of all Member States and the overall competitiveness of the EU.

The feasibility of non-professionals wearing gloves when using antifouling

UK explained that Section 7 of the paper attempted to set out a case for the continued use of antifouling by non-professionals. In short, non-professionals could be divided into 4 groups: fishermen could be equated to farmers of the seas and consequently could be considered to be a special case as are farmers for application of plant protection products; (iii) and (iii) cargo boat owners and commercial leisure boat owners, these are people, as are fishermen, who are familiar with boat maintenance and application of antifouling; and (iv) small boat owners who use their boats for their own leisure.

The following information has recently become available and so could not be incorporated in the TM paper. Marinas and boatyards are covered by the EU 'Integrated Pollution Prevention and Control (IPPC) Regulations'. It is understood that under these regulations marinas/boatyards are required to have a 'national environmental permit'; the permits are not only to control release of antifouling into the environment but also to control antifouling application. In the UK most non-professional application of antifouling to small boats takes place in marinas/boatyards where such control would apply. It is the owners of marinas/boatyards themselves who have the responsibility to ensure that the permits are adhered to, which includes correct application of antifouling, the wearing of appropriate PPE and availability of brochures/literature on antifouling and their use. In summary, under the IPPC Regulations marina/boatyard owners are charged with ensuring antifouling are applied correctly on their property. These Regulations are enforced by national authorities. It is understood Germany and The Netherlands were the first to implement the IPPC Regulations and in The Netherlands, VROM (Dutch Ministry for social building, regional planning and environmental administration) is actively enforcing the Regulations.

Proposal for non-professionals wearing gloves during use of antifouling products

In conclusion, **UK** acknowledged that this is a socio/economic issue for the CA Meeting to address and to resolve. However, it is appropriate for the TM to provide advice/comment. The **UK** considered that if necessary gloves can be worn by non-professionals using antifouling; in the **UK** there have been no reported incidences from current use of antifouling by non-professionals. There are two possible recommendations:

1) if necessary, non-professional use of antifouling can be allowed with the requirement for the user to wear gloves to protect against contamination. If Member States are unhappy with this recommendation then - because individual Member States will be aware of the conditions pertaining in their own country and should be able to determine whether it is feasible for their non-professionals to wear gloves - **UK** suggested the following recommendation:

2) individual Member States can at product authorisation prescribe that gloves be worn by non-professionals to protect against skin contamination to enable safe use.

Comments on the paper and recommendations:

NO commented that according to the Norwegian Poison Information Centre last year 27 incidences were reported involving antifoulings, 18 incidents involved exposure to the eye and only 2 to the skin. **NO** agreed that boat owners may have a positive interest for boats and that they may be using gloves because paints are sticky and coloured. However, **NO** expressed concern whether suitable chemical resistant gloves will be used by non-professionals. **NO** proposed to supply suitable gloves together with antifouling paints.

UK wondered whether this could be a solution as people tend to wear gloves several times, until they become unfit for use. **UK** recommended consulting IND on the issue. **NO** may need to resolve the origins of the incidences it experienced; in the UK no incidences have been reported.

DE in general agreed that such users may be considered as a special group of users and supported taking the decision at the member state level as the points described under Section 7 could be very different for every nation.

SE also had reservations whether consumers were using suitable gloves. Even though gloves are included in the packaging of instance hair dyes and MDI containing sealants, **SE** agreed with **UK** that misuse of gloves, for instance consumers using them several times, could be an issue. **SE** raised the question that if the decision on the use of gloves will be made at the member states level what will happen if during mutual recognition a member state disagrees to use gloves as a mitigation measure.

NL was content with the arguments of the discussion paper with the reservation that the economic impact arguments of a potential ban should be left out. **NL** claimed the TM is not the appropriate forum to decide on social – economic aspects; in case an analysis is required a stakeholder consultation needs to be launched. Regarding specialist users the **NL** noted that in the Netherlands there is a distinction between professional users with a degree or certificate, non-trained professionals, and consumers. **NL** pointed out that such distinction between trained specialist and non-trained specialist does not exist at EU level. With reference to the discussion on nonanoic acid (see Agenda point 4b.) **NL** suggested broadening the scope of non-trained specialist when considering "specialist users" to all PTs besides PT21.

Conclusion: UK to include the comments of the OMS into the final version of the discussion paper for the next CA-meeting. The proposal will be discussed at the following CA meeting.

3. SUBSTANCES in PT 02

3a. Perestane (RMS: HU)

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3b. Nonanoic acid (RMS: AT)

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4. AOB

4a. Update HEEG

COM informed the TM that HEEG will have a workshop first week of May. The group is aiming at the finalisation of some of its documents and at starting the work on new topics. Also HEEG will discuss identified problems with ConsExpo and produce a roadmap to enhance its activity.

Since some members have retired from HEEG, **COM** invited the MSs to join, HEEG being considered a very important group for the TM.

4b. Evaluation Manual for Product Authorisation

Separate minutes are prepared for this agenda item.

4c. Terbutryn (RMS: SK)

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4d. Genotoxicity of carbendazim

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4e. Update DRAWG

DE introduced the DRAWG proposal to develop a scenario that covers domestic use of biocides, e.g. disinfectants on kitchen counters. The methodology encompasses a tiered consumer assessment: one person using an area (default value) to prepare food, combined with the application rate of the biocidal product. The assessment results in a consumer exposure that is compared to a toxicological reference value. If the reference value is exceeded a second tier assessment may be carried out. **AT, NO, PT, SE, NL, FR, IE** supported the approach. **FR** noted that the DRAWG and the HEEG need to harmonize parameters for the exposure scenarios. **IND** noted that it did not receive the paper under discussion and asked whether this approach would mean abandoning the MRL setting. **COM** noted that DRAWG has no mandate to set MRLs. **DE** added that MRL setting is not considered for domestic uses as there is no monitoring for such scenarios. **DE** noted that there will be an MRL setting for food, but it is not yet decided what will trigger it, depending on which authority will be responsible for setting the MRL. **IE** inquired what values will be used for determining consumer exposure and what the input will be for consumer assessment. **DE** believes the exposure will probably be compared to the ADI or ARfD, and the exposure will be using default values harmonised with HEEG where applicable. **COM** stressed that they will urge DG Sanco and DG Environment to come to an agreement regarding assigning an authority for the setting of MRLs for all non-animal husbandry uses.

Conclusion: Proposal found wide approval by TM. The mandate of DRAWG was extended to continue with the development of the domestic scenario as proposed.

GENERAL SESSION

1. Reporting on 39th and 40th CA meeting

COM reported on the outcome of both CA meetings.

2. Tracking System: Progress reports

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3. SUBSTANCES in PT 18**3a. Permethrin (RMS: IE)**

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3b. D-phenothrin (RMS: IE)

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3c. Transfluthrin (RMS: NL)

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4. SUBSTANCES in PT 02**4a. Perestane (RMS: HU)**

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4b. Nonanoic acid (RMS: AT)

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5. AOB**5a. MOTA**

COM informed that a new addendum including the decisions taken at the ENV Session is available on CIRCA. A dead-line for comments was agreed upon, being April 29.

5b. Evaluation Manual for Product Authorisation

Separate minutes are prepared for this agenda item.

5c. Submission of CARs to Commission

COM informed that the number of First Draft CARs has substantially increased since mid 2010. In order to deal with this increase COM introduced revised procedures outlined in the document for this agenda item. MS were requested to follow these procedures.

In addition COM expressed its concerns over the ability of MS to cope with this increase with respect to their capacity and ability to provide comments during the 90 days commenting period. UK stated that they share these concerns and suggested to increase the level of detail in DOC II, such that the commenting MS in principle does not have to consult DOC III. COM introduced several options: assign MS to dossiers, assign PTs to certain MS and set a limit to numbers of dossiers to be uploaded in a certain time period. MS were asked to report back to the COM on this issue. COM announced to prepare a document on this issue.

5d. Specification of copper compounds

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ENVIRONMENT SESSION

1. SUBSTANCES in PT 08**1a. Cu-HDO (RMS: AT)**

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2. SUBSTANCES in PT 18**2a. Margosa extract (RMS: DE)**

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2b. Bifenthrin (RMS: FR)

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2c. Permethrin (RMS: IE)

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2d. D-phenothrin (RMS: IE)

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2e. Transfluthrin (RMS: NL)

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3. SUBSTANCES in PT21**3a. Sediment risk assessment for antifouling products**

The approach described in the revised sediment risk assessment paper by the UK was accepted by the meeting.

NO suggests maybe not writing the decisions on the sediment risk assessment for PT 21 a.s. in stone, but to await the results of the risk assessments of all antifouling a.s. **COM:** Agrees.

3b. Feedback from the PT21 e-consultation group

The UK reported on the ongoing activities of the PT 21 e-consultation group.

4. SUBSTANCES in PT 02

4a. Perestane (RMS: HU)

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4b. Nonanoic acid (RMS: AT)

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5. AOB

5a. Revision ESD PT 02, 03 and 04 after public consultation

PT 02

COM informed that the draft ESD for PT2 was amended according to the comment received, in collaboration with the authors of the document. No open issues were identified by COM for discussion and the TM did not add any issue to be dealt with, so the revised version of the document was accepted by the TM. COM informed that once the ESD will be endorsed by the CA meeting in May, then it can be published and then available for public use.

Conclusion

The revised version of the document was accepted by the TM. Next steps will be the endorsement by the next CA meeting in May and then the publication, after which the document will be available for use.

PT 03

The following issued were discussed.

1. Egg processing rate

(Comment 56, chapter 2.5.4.2)

A discrepancy between the egg processing rate and the parameters depending on it was identified between the calculations in the document and the data coming from the survey. The topic has been addressed by the authors of the documents, which were unable to process it.

Also the TM could not process the comment, so it was decided to leave the document as it is until further data might be available.

2. Exposure of animals in treated animal houses

SE would like to see also a scenario on the exposure of animals in the treated animal houses. **COM** and **NO** replied that the present document is only related to the environmental exposure and not to animal exposure, so the additional scenario should not be added. **SE** accepted the comment.

3. Emission in water

NL would like a clarification on the emission in water dealt with in table 6a of the document. In the input values it is the fraction to waste water, which implies an emission in water. COM replied that it should be intended to go in the STP. COM will check the document.

4. Terminology inconsistency

DE identified some terminology inconsistencies in the document and will send the requested changes to COM. COM will amend the document accordingly.

Conclusion

The document will be finalized by COM. Next steps will be the endorsement by the next CA meeting in May and then the publication, after which the document will be available for use.

PT 04

The draft ESD for PT4 was amended according to the comment received. No issues were identified by COM for discussion and the TM did not add any issue to be dealt with, so the revised version of the document was accepted by the TM.

Conclusion

The revised version of the document was accepted by the TM. Next steps will be the endorsement by the next CA meeting in May and then the publication, after which the document will be available for use.

5b. Topcoating PT 08

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Second the documents from **AT**, **SE** and industry on topcoating as a risk mitigation measure were discussed. **AT** indicated that they did not have the resources to continue working on this document where in addition **AT** does not have an application for a **PT 08** product containing a topcoat. **NO** indicated that in their dossiers for product authorisation it can be concluded that a topcoat reduced the leaching to different extends for the different actives in the product(s), hence a top coat can be regarded as risk mitigation measure. **UK** said that the experience with dichlofluanid products shows the same. **DK** stated that topcoating cannot be regarded as a risk mitigation measure even if this is not the primary intention of a top coat. **SE** and **NO** agree. **IND** stated that some products are designed to be used with a topcoat and indicated that decisions on several first authorisations need to be taken relatively soon, where industry has already submitted the data. **IND** would be able to work together with experts from **MS** and does have information on leaching studies for products with and without a topcoat. **IND** stated it is crucial to include representatives from the coating industry in this discussion and has therefore contacted CEPE. **NO** welcomes exchange of experience regarding top coats; however, timing is crucial.

Then questions 5 and 6 of the document were discussed:

IND pointed out that the correct use of the product when used by industrial applications is together with topcoat. **DK**: would accept a top coat as risk mitigation measure also for amateurs. **NL** was wondering whether, regarding industrial use of topcoat, at the end of the lifetime there still would be topcoat in place? While **UK** stressed that the time limit of a topcoat is defined by the duration of the leaching study submitted. **IND** pointed out that the coating industry might help

here. They give a guarantee/insurance on how long this top coat should be functioning. **NO** agrees with **DK** regarding accepting topcoat as a risk mitigation measure also for amateur use. They see also problems with time limit of topcoat as leaching data only are available for 6-12 months. Don't know how to solve this. **COM** recognised the DK/NO issue on topcoat as RMM for amateur use. The question is whether this should be acceptable? **NO** assumed that people follow label instruction. We do not assume misuse. **NL** and **DE** doubt that you can rely on people following instructions when f.e. painting fences. **FI** has so far thought that topcoat could only be used as a risk mitigation measure for industrially treated wood. There are a lot of wooden houses in FI and although in most wooden houses the topcoat is maintained in good condition, there are also houses in which the topcoat has fallen into decay. **Cefic** is concerned about the DE / NL point of view on amateur use of topcoat. **NO** as well. **NO** stressed that it never would be possible to control these things (how should application of a topcoat be enforced?) **COM** assumes that people also might take care of their fences but **UK** does not agree with **COM**. **UK** asks **IND** how industry knows about the lifetime of a topcoat? **IND** stated that it certainly would be much longer than 6 months, and that one has to look at guarantees and see what data is behind. Have to go to coating industry; not reasonable to ask every single applicant.

It was agreed that the involved MS would inform COM if they can act as a lead for this issue.

5c. Exposure assessment for PT 06

PL presented the "Background Document for Discussion of Emission Scenarios for biocides used as in-can preservatives (PT6)

General issues: The opinion that the worst-case scenario could cover all possible uses was not accepted. However, there was no agreement what should be general approach to estimation of emission in PT6. Two different positions appeared.

1. Applicant must specify intended uses very clearly; otherwise risk assessment should be done for every single possible usage. In case of risk identification the Applicant should then present some refinement or resign from the usage area causing risk.
2. It is important to choose a pragmatic approach, trying to find out where emissions are quantitatively most relevant or most relevant due to the emission pathway and to focus on these for exposure calculations. Otherwise, there is a risk to get lost in dozens of different end-use applications; it may also result in an unrealistically high risk.

PL is in favour of the 2nd approach but ask the opinion of **TM**.

DK and **ES** request the Applicant to specify all intended uses and to find out the end use.

IRL: if going for 2nd approach how pragmatically it will be assessed the most relevant exposure?

PL in the PT 6 dossier the Applicant declared that washing liquids in paint is the general tonnage scenario for paints because the final use could be indoor and out-door paints; for washing liquids **PL** used general scenario for PT 2 based on both scenarios i) tonnage and ii) average application. This general approach is good without going in too much detail.

Cumulative Risk Assessment

According to the commenting countries cumulative risk assessment should be considered.

There are various proposals how to deal with the cumulative risk assessment

(**DK**):

1. Consider all emissions from households to STP together with STP-emission from one industry at a time (argumentation: not all the large industries are in the same catchment area)

2. Consider all emissions from households to STP together with all STP-emissions from industry scaled down to one catchment area (i.e. a certain percentage of each industry is present in a single catchment area).
3. SE If a tonnage based approach is chosen and the same emission pathway applies (e.g. for human hygiene products and for liquid detergents), there might be no need for separate calculations. As the amount of in-can preservatives in products is quite small, it may well be that a tonnage-based approach with 100% release to STP for all uses with this emission pathway will show no risk. In this case, the exposure assessment can be simplified a lot.
4. NL prefers “substance-PT” evaluation and then at the end an evaluation taking into account multiple PT-analysis. It may happen that a substance can be registered under one PT but not under another. A separate decision for each PT should be possible.

Is general tonnage approach acceptable or should we consider sub-categories? DE: The tonnage approach only considers one of the emission pathways. DK: as regards the STP as tier 1 all emissions should be added, as tier 2 to assess every industry separately and the households together.

NL suggest to get how and where the products is used to know how it will be used and where it will go if as 1) the tonnage, WCS all goes to STP 2nd Tier a refinement.

ES: NL , there is important that in-can preservatives goes up to 500 ppm and need to know where the products will end, e.g. if products will end in the sea.

COM: in the end this is a discussion for product authorisation but for annex I inclusion if we have an Applicant for in-can preservatives and a safe use for in-can preservatives in can then it will go to Annex I but we can bring this discussion to CA meeting. CEFIC supports this approach.

TM agrees that the Applicant should identify very clearly the uses, and to indicate the tonnage of uses identified. COM will bring this question to CA meeting (COM will prepare a paper to be presented at the CA meeting) that for Annex I inclusion the applicant for in-can preservatives needs to demonstrate a safe use; if the safe use is demonstrated then the active substance can go to Annex I.

Calculation of emission from waste disposal of biocidal products

It does not seem to be necessary for this specific PT in general. Any disposal issues may be addressed appropriately by other EU and/or National legislation. Waste stage should be a part of the Biocidal Product Directive. This has to be checked on a case-by-case basis, if this specific exposure pathway is relevant or not. According to NL the waste stage has already been considered so there is in no need to consider this stage. Other legislation in place will cover the waste stage adequately. For this type of actives there is no need to consider the waste stage. TM Agrees. PL: add that if the applications like paints are necessary then 100% removal is to be considered so the waste stage is not necessary.

In-can preservatives used in cosmetics

European Commission has anticipated that emission of in-can preservatives applied to prolong shelf-life of cosmetics for the risk assessment in PT6 is outside of the scope of BPD. COM: This decision should be taken by the CA meeting.

Set of default values

Default input parameters should be used in the first tier approach. Refined input parameters could be proposed in higher tier. However, some parameters are defined by industries which use products containing PT6 substances and not by the formulators of PT6 products; therefore it

would be better to apply changes of parameters for the assessment of all active substances in PT6 and not for one applicant's substance only. TM agrees.

Formulation of products (e.g. paints, washing liquids)

It was agreed that formulation of products (e.g. paints, washing liquids) should be considered as first step of biocidal product use. Formulation of a product, is industrial process that can be evaluated using EUSES applying the industrial use options. There were no comments on estimation of emission during formulation. Therefore PL concludes that it is acceptable. TM agrees.

PT 6.1. Washing and cleaning fluids, human hygienic products and detergents

MS disagreed to use the worst-case ESD as most appropriate solution. Cumulative risk assessment should be considered. It should be done by summation of all single uses. Or simplified tonnage-based approach (with 100% release to STP for all uses with this emission pathway) could be considered. If this show no risk, detailed calculation will not be necessary.

Market share for these types of products will probably be difficult to refine with data, FR prefers to start with the factor of 0.5 as stated by Van der Poel 2001 than refining the factor. TM agrees to start with the factor of 0.5 as stated by Van der Poel 2001 than refining the factor.

PT 6.2. Paints and coatings

General scenarios (e.g. tonnage approach proposed by PL) facilitate the work and allow the RMS to continue with the evaluation, however do not cover all specific emission pathways therefore risk for some environmental compartments may be underestimated (e.g. emission to soil).

Specific scenarios (e.g. for PT8, PT21) should be used. The main problem of using PT 8, PT 10 or PT 21 is that neither theoretical coverage of the paint needed for PT 21, nor daily flux or fluid application rate needed for PT 8 or 10 respectively are provided by the Applicant.

NL proposes to have some default values for paints as a general scenario. Layer 25 • m, for wet layer as the concentration of the substance in the product per m², to use the standard leaching rate and to do the calculations. To agree on the compartment where the a.s. will end up, e.g. depth 50 cm depth was used for PT 8, or 10 cm depth for PT 10, NL proposes 10 cm. but we need to agree on the thickness of the layer and to go for default values then it will be easy to do the calculations.

ES would like to agree on default values. DK agree not to require leaching test, so a simplified procedure should be possible. ES: with a leaching rate of 1 we can find risk in most of the products. PL has calculated risk in some cases, but what to do when risk is identified? No need to ask the Applicants to performing leaching test, but better to go case by case depending of the type of products. NL propose to make some calculations and Applicant will make a refinement during product authorisation. COM asks to clarify what scenario we are taking about, PL: scenario for PT 8 or PT 10. ES we are considering PT 8 and PT 10 and scenario on soil not for water. IE: Is the painting of outside houses a realistic scenario? Under the WFD it has never been exceeded an EQS coming from this pathway. PL: TM view forward is that we can go forward.

Leaching tests are not necessary. Assumption that the emission occurs during Time 1 represents the absolute worst case. From this point of view examination of the service life (Time 2) is also needed. NL: Time 1 for wood preservatives is 20 years for paints a shorter period should be applied, Time 2 = 1 year should be saved. For paints outdoor we could use time of 4 years.

Some general parameters of paint Application (mean number of coats of paint for instance) could be proposed in order to have a harmonised risk assessment between MS, as these parameters are

specific to PT8, 10 and 21 and not to PT6 and cannot be set by the Applicant. NL proposes some values concentration in paint and percentage of leachate from paint.

PL expects risk in some cases using above approach. Therefore, PL is in favour to conclude in those cases that result of calculation of emission with use of specific scenarios (e.g. PT8) is not definitive. The way to refine the estimation of emission should be agreed.

Following this discussion NL will provide PL with some general default values and input parameters.

PT 6.3 Fluids used in paper, leather and textile production

Paper production

Consideration of defaults in ESDs including OECD document confirms correct selection of values. Degree of closure of the water system is not included into calculation in OECD document. This may overestimate the emission.

Concerning the Q_{active} , the problem is the number of additive types used in a realistic worst-case paper mill: around 20 for stock preparation and 15 for the paper machine, with different concentrations in in-can preservatives. Default parameters could be proposed for the fraction of additives used in the paper industry. The concentration of PT6 substance in these additives can be deduced using efficacy data.

In ESDs additives used in paper mills are listed with quantities used per tonne of paper. Some additives, probably, do not need in-can preservatives (e.g. hydrogen peroxide used as bleaching agent), some certainly are preserved with in-can preservatives.

Textiles production

Active substances in PT6 are not intended to preserve textiles therefore fixation factor of 0 was proposed as a worst case. Additionally, if it is considered no fixation to the fabric during application, a release during use could be deemed negligible and calculation of emission in this stage of product life is not necessary.

FR has proposed a $Q_{product}$ (as product used in textile industry) at 20 kg/t of fabric. Q_{active} will be deduced from the efficacy data and the $Q_{product}$.

There was no objection to set a worst-case value Q_{fiber} of 13 t/d of a.s. NL proposes to look at the properties of the substance and to examine if there is absorption.

Two different values were proposed for fraction of fabric treated with product containing substance of interest 0.3 (default in ESD) and 1 as a worst case.

NL will support the value proposed by FR of 0.3 (default in ESD) for fraction of fabric treated with product containing substance of interest and 1 as a worst case. TM agrees.

Leather production

Active substances in PT6 are not intended to protect leather therefore fixation factor of 0 was proposed as a worst case.

The Q_{active} cannot be set by default but it would probably be useful to set a $Q_{tanning}$ products (kg/t leather) which would represent an average quantity of products used for the tanning process. The value of quantity of product used in leather processing containing active substance from PT6 was not set. TM agrees.

PT 6.4. Metal Working Fluids (MWF)

Basically it was agreed that ESD for PT13 is first choice to calculate emission of a.s. used to preserve MWF during shelf-life. Additionally DE considered the possibility of using the EU-TGD ESD for IC 8.

DE would consider the a.s. in PT13 to have a preservative efficacy also for the shelf-life of the product, thus probably no additional other a.s. as in-can preservative will be subjoined in the PT13 product. Regardless of which PT6 or PT13 was considered it was underlined again that emission calculated with ESD for PT 13 is unreliable high. TM agrees.

PT 6.5. Fuels

If both private and industrial uses were mentioned as indented use, the two applications should be assessed by RMS, not only industrial use.

EU-TGD IC 9 ESD (for Mineral oil and fuel industry (EC 2003a)) was proposed as first choice to calculate emission of in-can preservatives of fuels.

UK suggested that it would be useful to get a consensus on what information would be needed to support the conclusion that no releases from fuel additives occur in service due to complete breakdown during combustion. If zero emissions can be agreed, the absence of finalised ESD would not prevent completion of the environmental assessment of these substances. Other countries have not commented on that issue.

NL: fuels may end in the engine, so need to check because if all (100%) the substance is burnt then we do not need to consider this. NL can not see what can be the emission scenarios. UK is of the same opinion. TM agrees.

PT 6.6. Glues and adhesives

General tonnage scenario and TGD- scenarios (for glues and adhesives UC 2) were accepted for calculation of emission of a.s. used as in-can preservatives in glues and adhesives. ESD for PT7 should be also considered. NL: do you have suggestions on the fractions to STP to go for default values or is case by case? PL: there is a lack of proposal for input values so we should go case by case. NL: could we propose default values like to do calculations for 50% 10% and 1% if there is no data? PL agrees to go for this default values. ES: is relevant to have industrial glues and adhesives? PL thinks it should be considered, if there are not emissions then is acceptable.

ES: there are sub-uses of PT 6 as minor uses that have not been discussed, how are we going to proceed? NL: the list is trigger by cut flowers, NL has prepared a scenario, NL can provide this scenario that could be interesting. NL will send this information to PL. ES would like to propose an oil fluid drilling. This is a live document for ESD for PT 6 where we can collect minor uses not included in this document.

Conclusion: PL will finalise the document to be endorsed by CA as a guidance document for PT 06; for the minor uses information can be gathered when they come for TM for discussion.

5d. Evaluation Manual for Product Authorisation

Separate minutes are prepared for this agenda item.

5e. Imipothrin (UK)

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5f Exposure assessment PT 18

MS were asked to send comments in writing on this agenda item to **SE** by April 15.

5g. Consultation PT 11 rapid reacting chemicals in cooling water systems

MS were asked to send comments in writing on this agenda item to **NL** by April 15.

5h. Consultation bronopol

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