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JOINT RESEARCH CENTRE
Institute for Health and Consumer Protection
Consumer Products Safety and Quality

WORKSHOP on environmental risk assessment for Product Types 1 to 6

Arona, Italy
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A workshop for technical experts evaluating PTs 1 to 6 active substances for the Competent Authorities implementing the Biocidal Products Directive 98/8/EC.

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Introduction

Directive 98/8/EC of the European Parliament and of the Council on the placing on the market of biocidal products was adopted in 1998. Two basic principles of the Directive are:

- Active substances (a.s) have to be assessed and the decision on their inclusion into Annex I of the Directive shall be taken at Community level;

- Member States (MS) shall authorise the biocidal products in accordance with the rules and procedures set in Annex VI of the Directive. They can only authorise products which contain active substances included in Annex I.

The time limit for transposition of the Directive in MS was 14 May 2000. Active substances introduced on the market, after this date, are new a. s. which can only be placed on the market after an evaluation according to the provisions of the Directive. This same date is also the starting date for a 10-year review program of a.s. already on the market (so-called existing a. s.) with the aim to assess all a. s. that were already on the market before 14 May 2000. Guidance on the assessment of a. s. and biocidal products is laid down in the so-called Technical Notes for Guidance (TNsG), which are published on the JRC-IHCP web page at http://ecb.jrc.it/biocides/.

Active substances used in product types (PT) 1, 2, 3, 4, 5 and 6 are currently being assessed by Rapporteur Member State (RMS) leading eventually to a decision on Annex I inclusion in the Competent Authorities meeting. These PTs include the Main Group I of disinfectants and general biocidal products:

PT 01: Human hygiene biocidal products

PT 02: Private area and public health area disinfectants and other biocidal products

PT 03: Veterinary hygiene biocidal products

PT 04: Food and feed area disinfectants

PT 05: Drinking water disinfectants

and one PT of the main group 2 of Preservatives:

PT 06: In-can preservatives

The assessment of environmental risks consists of an exposure and effects assessment compared in the risk characterization. In terms of the required exposure assessment, Environmental Emission Scenario Documents (ESDs) provide a tool in the assessment process providing a methodology to estimate the quantities of a. s. that may be released to the environment during the various stages of a biocidal product's life cycle. For PT 01 to PT 06, mainly diffuse sources of emission are expected and for some uses tonnage based scenario are described in the ESDs using tonnage of biocidal products as input.

The progress of the Review Programme is discussed in the Biocides Technical Meeting (TM). At these TMs there appeared to be several outstanding issues with respect to the ESDs referred to above, and on environmental risk assessment for these product types in general. In order to facilitate the evaluation process of these substances a workshop was organised related to these remaining questions of Member States for these product types with the intention to develop a harmonised approach.

According to Article 11 (2) and Annex IIA, V.5.8 of the Biocidal Products Directive (BPD), the receiving Competent Authority (CA) can ask the applicant to submit information on the likely tonnage to be placed on the market (expressed in tonnes per year), if it is necessary for further evaluation. This information will have to be treated as confidential by the CA during the evaluation and in the Competent Authority Report (CAR).

However, at earlier TMs several questions were raised by the Member States on this issue such as the variation of tonnage over time, lack of information on the market share, the information on tonnage when several companies apply for different products and the management of confidentiality in the CAR. In order to clarify those issues and to reach a common agreement on the tonnage approach versus a risk assessment based on average consumption, discussions took place in an open session of the workshop.

According to Article 10 (1) of the directive an active substance shall be included in Annex I, IA or IB if it may be expected that the biocidal products will fulfil the conditions laid down in Article 5 (1) (b), (c) and (d), taking into account, where relevant, cumulation effects from the use of biocidal products containing the same active substances.

Member States asked for clarification on how to perform the cumulative risk assessment and the legal impact with respect to Annex I inclusion for active substances in different product type combinations. In order to tackle this issue discussions took place at the open session of the workshop.

The closed session of the workshop was dedicated to the exchange of experience between Member States on the evaluation of the first substances for PT 01 to PT 06. Member States were previously invited to fill in a questionnaire to identify the exposure and effect assessment issues to be discussed.

1. Overview and bottlenecks of exposure assessment based on tonnage and average consumption

1.1. Presentation from Denmark: Tonnage versus average consumption approach- Product types 1 and 2

The main advantages and disadvantages related to tonnage based versus average consumption Risk Assessment (RA) were presented.

Tonnage approach

Pros:

- The tonnage approach allows to present the total consumption which is useful when information on the detailed use is lacking (the applicant often does not know the end-use of the active substance (a.s.) that is placed on the market).
- The emission is directly related to the volume of use
- The tonnage approach allows cumulation effects from the use of biocidal products where relevant to be assessed.
- The applicants have often information only on the total value of the amount of the a.s. placed on the market.

Cons:

- Tonnage information is confidential (e.g. total quantity, or current or planned tonnages for different use patterns). The applicant is concerned that from the information used and presented in the CARs, the underlying tonnages could be recalculated and therefore become available to his competitors.
- Precise figures on tonnages relevant for the different uses may not be available to the applicant which are in the first place producers of the active substance (a.s.) and do not hold detailed information on the downstream end-users market. The estimated figures provided in the dossier are “best guesses”.
- The fraction reaching the different relevant environmental compartments may be unknown.
- For most scenarios, a tonnage based environmental emission calculation is not defined in the current ESDs. Only for wide dispersive uses, a tonnage based calculation could be applied depending on the outcome of the break even point calculations.
- If MS should take other biocidal uses into consideration this must include other PTs and will require harmonised and agreed guidance at EU level.

Consumption approach

Pros:

- It is simple as it requires only an emission factor, the amount of product used and the concentration of substance in a product.
- Many ESDs have been agreed upon and are based on this approach.
- It is transparent as default values can be modified if this is fully justified

Cons:

- Using only the average consumption approach in specific exposure scenarios may underestimate the exposure to the environment as only one use is specified. Several uses of the same a.s. should be added when considering the emission to the same STP and finally the environment.
- Lack of reliable data leading to uncertain estimates.
- No direct relation with actual volume for the application in case of diffuse emission.

For both the tonnage and the average consumption by inhabitant approach, the exposure estimations are highly depended on the representativeness and accuracy of the data used. Furthermore, the differences between regions may be high. Therefore it is believed that both methods should be used in support of each other.

Questions on the tonnage approach

- Should MS use a tonnage-based RA or use local scenarios foreseen in the ESDs?
- If the tonnage approach is used how can MS keep the information confidential and how can their reliability be checked?
- If the tonnage approach is not used how can MS make a cumulative risk assessment, where relevant?

PT1 case example: antimicrobial liquid soap

The intended use was for hand disinfection used by professional health care personnel as rinse-off products.

The application of the tonnage approach was simple for Applicant A because the consumption figures were provided allowing calculations for private use (households) and hospital scenarios to be made according to the ESD for PT1.

A problem arose for Applicant B which is a task force comprising 5 companies and no data on the total quantity of the active substance used in the EU market was available.

DK asked whether each member of the taskforce should be requested to provide the RMS with the information on tonnage and how can this information then be kept confidential.

PT2 case example: antibacterial plastic surfaces

The intended use was as an active substance in antibacterial plastic surfaces in a hospital. These surfaces can comprise countertops, lavatory seats or door handles. The final concentration of the active substance in the finished plastic article is X% at maximum.

The questions raised related to the PT 1 and PT 2 case examples are further discussed in Chapter 3 of the workshop report.

1.2 Open discussion and conclusion

During the 27th meeting of representatives of Members States Competent Authorities for the implementation of Directive 98/8/EC concerning the placing of biocidal products on the market, it was decided to provide a note clarifying the legal basis for the inclusion of tonnage data in the risk assessment of biocidal active substances[1]. This note clearly demonstrates that tonnage data might be requested but only in specific and justified cases otherwise it could cause an immense burden for applicants.

UK proposed to perform the RA using the average consumption approach based on the worst case scenario. This was supported by the workshop participants.

The worst case values should be accurately defined and agreed upon to achieve a harmonised assessment among the MS. The tonnage approach should be followed only for relevant PTs and it will be different between PTs. For example PT01 and PT02 discharge only to STP whereas the emissions from PT06 are more complex. The applicant should provide tonnage data for each PT. The tonnage approach should be kept confidential in an annex of the CAR and should be used to check the validity of the default values used in the average consumption scenarios.

NL proposed a stepwise approach by making a recalculation (from the PNEC) back to a safe tonnage value and asking from the applicant for more data on uses for the purpose of refinement if risk is indicated.

IND reminded that tonnage data are only estimates because the applicant does not often know how the active substance is used within different PTs and the market is constantly changing. However some companies are trying to gather these data.

There was a general agreement that tonnage values will be the relevant data for performing cumulative risk assessments.

In conclusion, it was decided that both approaches have their pros and cons and that the RMS will use the tonnage approach to assess the validity of the average consumption approach and in particular the default values used in the models. The tonnage approach can be further used to perform a cumulative risk assessment where relevant. The tonnage approach should be included in the risk assessment of relevant PTs but additional guidance is needed.

[1] 27th CA Nov07 Doc 6.3

2. Overview and bottlenecks on assessing multiple uses within one Product Type and for more Product Types: cumulative risk assessment

2.1 Presentation from Denmark-Product Type 6

Case for PEC calculation for a biocidal active substance used as in-can preservative

The applicant has subdivided the different uses in PT 6 into several sub-product-types (as suggested in the ESD) and evaluated these separately:

6.1 In-can preservation of washing and cleaning fluids

6.2 In-can preservation of detergents

6.3 Paint and coatings

6.4 Fluids used in textile industries

6.7 Glues and adhesives

The RMS considered it necessary to carry out a cumulative RA as all emissions will end up in an STP. The problems identified concerning the cumulative risk assessment are:

- The applicant has not provided any data on the total quantity of the active substance used in the EU
- The sub-product types are evaluated separately by the applicant; however the emission from each of these may end to the same STP and therefore should be added.
- The RMS may want to take all emissions from the biocidal uses into consideration especially those discharged to the STP; however, what methodology should be followed?

No guidance is currently available on how to perform cumulative risk assessment. However, if the emissions from the biocidal uses are not added up, the risk assessment per sub-product type will underestimate the actual exposure to the environment. It was noted that not all scenarios are relevant for a cumulative risk assessment and the applicant may not know the downstream end-user market. The calculation of a regional background level may be important for some active substances and biocidal uses.

In the context of a decision making process, harmonised and agreed guidance needs to be prepared.

Questions on Cumulative RA

- When is it relevant to perform a cumulative risk assessment?
- No guidance is available on how a cumulative RA should be carried out. Which PTs or sub-groups of PTs or scenarios are relevant?
- Should the cumulative RA be carried out already for Annex I inclusion purposes or is only relevant at the Product Authorisation stage following Annex I inclusion of the active substance?
- How to deal with an active substance evaluated in the Review Program for more than one Product Types with different time lines for Annex I inclusion?

Only some uses, which comprise applications in a wide dispersive manner, may be relevant for cumulative risk assessment. For some PTs or sub-groups of PTs where emission to an STP occurs (local industrial point sources and/or professional uses) it would be unreasonable to assume that these point sources emit to the same local STP.

It was recommended to find and agree on a harmonised approach and methodology for each PT. A representative example is PT6 where several sub-groups can be identified:

- PT 6.1 / PT6.2 – private use

- PT 6.3 – application/during service life-private use

- PT 6.4 - fluids used in textile industry in the use phase?

Additional questions:

- Should other PTs be taken into consideration?
- Regarding PT 8 can cumulative risk assessment be performed for treated wood in service (e.g. noise barrier added to other uses)?
- With respect to PT 7, 9, 10 how should the assessment be performed taking into account that the information will be provided in the second half of 2008?
- Is a small use-area sufficient to include a substance on Annex I or IA without any restriction?
- If this will be the conclusion, is it then possible for an applicant who has submitted data for several sub-categories to withdraw all of these except one for the purpose of Annex I inclusion?
- If an applicant has submitted information on several use sub-categories how should Article 10 of the Directive be interpreted?

2.2 Presentation from Germany-Cumulative exposure of active substances used in PT 18 and PT 3

DE is the RMS for an active substance that is used as an insecticide (PT 18) and as a disinfectant (PT 3). The dossier for both product types was submitted by the same applicant. The product is applied in stables using the same technique for the same animal category; the application rate for PT 3 is threefold higher than the one for PT18.

An overlap regarding the time of the application for both uses cannot be excluded. Therefore this can lead to the same route of exposure for both PTs: slurry + manure -> soil -> groundwater -> surface water. It is concluded that a cumulative exposure assessment has to be performed.

The environmental risk assessment for PT 18 results in an approximate PEC/PNEC ratio of 30 for the soil compartment. The risk assessment can be refined by performing prolonged ecotoxicological studies for terrestrial non-target organisms. For PT 3 however, higher risk for soil is expected due to the higher application rate for this product type. The cumulative exposure approach will magnify the identified risk of the active substance stemming from the exposure to soil for both PTs.

The following options can be identified following the finalisation of the risk assessment:

without cumulative exposure approach
PT 18 RQ>1 and PT 3 RQ>1 => **no Annex I inclusion**
PT 18 RQ<1 but PT 3 RQ>1 => **Annex I inclusion only for PT 18**

with cumulative exposure approach
PT 18 RQ<1 and PT 3 RQ<1
and cumulation leads to RQ<1 => **Annex I inclusion for both PTs**
PT 18 RQ<1 and PT 3 RQ<1, but cumulation leads to RQ>1

Following the above estimations should the active substance for uses in both PTs not be included on Annex I or should label claims be used to prohibit simultaneous use of both products in the same stable? Is it possible to propose adequate risk mitigation measures? What is the necessity for a “PT 18” use when a “PT 3” dose has already been applied?

DE said that cumulative risk assessment is obligatory under the BPD. Due to the use patterns, cumulation of effects for the considered active substance needs to be considered.

In the case that the RQ from the cumulative assessment is >1, but the RQ for separate PT uses is <1, DE proposed to introduce a clear label claim prohibiting additive application of the insecticidal product after disinfection of the stable. DE added that the option of label claim is possible in this case, but may not be applicable in all cases. DE is also the RMS for several active substances for which dossiers have been submitted by different applicants, are included in several product types and have diverse use patterns. In these cases the use of label claims would not be an option. DE asked to develop harmonised guidance for performing cumulative risk assessment. The following questions were raised by DE:

- Should the $PEC_{regional}$ for each active substance be derived as a way forward? (at least for wide dispersive uses)?
- Can the $PEC_{regional}$ from the final risk assessment report under the EU Existing Substance Regulation be used?

2.3 Presentation from France - Cancelled

The presentation was cancelled because of transportation difficulties of the French representative. The scheduled presentation has been posted on CIRCA. Following the meeting, FR informed that most of the aspects that needed to be considered by FR were covered by the presentations of DE and DK, except from 2 main topics that were not fully discussed:

- The lack of guidance/methodology to assess and use the regional PEC (currently only possible if based on tonnage)
- The lack of guidance/methodology to assess human exposure via the environment (also currently only possible if based on tonnage)

FR proposes to bring back these two questions through the e-mail consultation group and/or to Technical Meeting.

2.4 Open discussion and conclusion

It was reminded that the methodology to perform cumulative risk assessment is not available yet.

The proposal for a label claim to restrict uses was questioned because it could only be made within one PT but not for different PTs as this would lead to unequal treatment of the same active substance used in several product types.

In order to avoid unequal treatment for companies who submitted dossiers indicating only one use and those who submitted information for several uses, it was questioned if cumulative risk assessment can be used for the purpose of Annex I inclusion. It was stressed that for Annex I inclusion it is only required to demonstrate one safe use. However according to Article 10 of the BPD a cumulative risk assessment has to be carried out where relevant, for the purposes of Annex I inclusion

For the time being, it was proposed to start the cumulative risk assessment for PT 01 to 06 with wide dispersive uses. The assessment should be based on the data provided by one or more applicants but not on the total amount used in the EU. It should also be clearly indicated in the CAR in case a risk was identified based on cumulative risk assessment. This might be useful to refine the risk assessment at product authorisation. It was concluded that for previous PTs already evaluated (PT 08 and PT14) there is no need at the moment to perform cumulative risk assessment which will depend on the outcome of the discussion at the next CA meeting.

There was a clear need to agree when cumulative risk assessment is considered relevant to be performed and what are the representatives uses that need to be assessed.

It was agreed that the development of an agreed methodology for cRA will be difficult but that the guidance should be available for the evaluations at the product authorisation stage. A proposal was made to refer for guidance to the cumulative risk assessment methods described in REACH Implementation Project 3.2. There was a general agreement to the AT proposal to collect all available information, also “from the outside biocidal world” and to evaluate its applicability for biocides, e.g. the OECD environmental risk indicators for PPP, US EPA approaches, methods from human exposure assessment. MS explained that there will be a need for additional resources to develop this methodology and asked the Commission to coordinate the work.

In conclusion, it was decided to start performing cumulative risk assessments for PT 01 to 06 with wide dispersive uses based on the available information. An identified risk should be flagged in the CAR.

MS asked the Commission to give a clear opinion on the fact that according to Article 10 of the BPD the cumulative risk assessment should be carried out, where relevant, for the purposes of Annex I inclusion. In addition, the Commission was asked for an opinion on the possible decisions to be taken with respect to Annex I inclusion based on the outcome of a cumulative risk assessment. It was strongly recommended to discuss this issue at the next CA meeting.

3. Comments from MSs related to the environmental risk assessment of PT 1, 2, 3, 4, 5 and 6

The main objective of the closed session of the workshop was to cover the most urgent questions related to the environmental risk assessment of PT 1-6 within the Biocidal Products Directive.

In order to prepare it, ECB invited Member States to fill a Questionnaire containing several tables to collect the issues Member States want to discuss at the workshop. A distinction was made in issues related to exposure assessment per Product Type and to effect assessment. In addition the availability of (Draft) Emission Scenario Documents (ESD) was indicated. ECB received inputs from DK, DE, FR, and NL and more than 66 questions or comments were raised.

In order to optimise the time for the discussions during the workshop, ECB offered to focus on the main important issues and to compile all the MSs questionnaires in an annex.. However the MSs were invited to provide extended texts on their comments and opinions on non discussed comments before compilation.

It should be noted that in order to harmonise this report the comments made by DK on separate documents have been put into the questionnaire format.

Within the review program several guidances have already been completed as indicated in the ESDs overview for PT 1, 2, 3, 4, 5 and 6 in Annex I of this document. Many comments from the MS are related to the ESD drafted in January 2007 by AEA Technology Environment, "Service contract for the development of environmental emission scenarios for active substances used in certain biocidal products" (AEAT/ED48587/R1, 45p.). The outcome of the discussions will be taken into account in order to update the document and a final version will be submitted to the TM for agreement before its official publication.

3.1 Comments from MS related to EXPOSURE ASSESSMENT linked to Product Type 1

Regional PEC

Question: For some substances that have also been evaluated under the EU Existing Substance Regulation regional PECs are available. Should the regional PECs published be included in the final CARs of the corresponding biocidal active substances?

Answer: DE proposed to give reference to the available information in the CAR but this should not be taken into account in the final decision on Annex I inclusion

Default value of hospital scenario: soap dose and number of applications in professional health care.

Question: The applicant used an average consumption approach using the hospital scenario as a worst case and a refinement of the ESD default values by lowering the application dose and the number of applications without providing any justification. The default values used in

the scenarios indicate that the application dose was lower than the one used in the scenario used for human exposure assessment.

Do the default values indicated in the TNsG on human exposure have to be used as a worst case instead of the ones in the ESD? More specifically, the number of applications per day proposed is 8 times/ day but additional information provided in the web (www.cdc.gov/handhygiene) indicate that hospital nurses wash their hands at least 20 times a day.

Answer: DK proposed to use the realistic worst case which is used in the human exposure scenario (3g soap per application). NL agreed in principle but reminded that the average use should be taken into consideration if documented by the applicant. DK agreed with this statement.

Default value of hospital scenario: number of nurses/bed

Question: What is the default value of number of nurses per bed?

The number of nurses (40 nurses which care for 400 patients) discharging into one standard STP is not in line with the available internet data (e.g. for Denmark: 400 nurses taking care of 400 beds). An alternative could be to use the default values indicated in the previous ESD: number of beds in hospital: 400 and average use of disinfectant per bed (Van der Poel and Bakker, 2001): 0.038 g/d; would this value be relevant for soap?

Answer: NL reminded that the scenario assumed that 1 hospital of 400 beds discharge to an STP. DK said that a standard hospital for 10000 inhabitants (connected to a STP) has 400 beds and the number of corresponding nurses was calculated. NL confirmed that the number provided by the applicant was too low and that the statistical data show higher values. Data on the number of nurses in Dutch hospitals, collected by CBS Statistics Netherlands, show an average number of approximately 2.8 nurses per bed. Other MS were asked to check the values used at National Level.

The default value of 1 nurse/bed was generally accepted.

Cumulative assessment for PT 1 and PT 2

Question: Should the emissions from a hospital for PT 1 and PT 2 (used in the same hospital and released in the same STP) be added or not?

Answer: The emissions could be added according to the decisions taken on performing cumulative risk assessment.

Use of monitoring data for risk assessment

Question: Can monitoring data be used as a higher tier assessment when the cumulative risk assessment indicate risk? If yes, which guidance on the use of monitoring data should be followed?

Answer: DK stated that monitoring data was available taking into account all uses, including non biocidal uses (e.g. cosmetics) that show lower concentrations in the environment than the ones initially predicted for cumulative risk assessment of PT 1 and PT 2. NL asked about the quality of monitoring data e.g. sampling, the correlation with the uses and the reliability of the analytical methods? ECB commented that some data are rather old and most of them come

from a few MSs. DK accepted to ask from the applicant additional data and will check their quality before using them to refine the risk.

ECB advised to use the guidance provided under the Water Framework Directive, the current TGD and in the future the RIP 3.2 under REACH (available before 1 June 2008).

$F_{penetration}$

Question: The emission rate of a disinfectant to water used for risk assessment enfolds a market share of the disinfectant (F_{penetr}). For some substances already included on Annex I and for specific notifiers it may be useful to find out whether such an application results in risk. By default, this factor is set at 0.5. However, before placing a substance on Annex I, the F_{penetr} should be set at 1, to find out whether such a substance in a reasonable worst case scenario can be put on Annex I.

Answer: ECB said that a similar discussion took place for antifoulings and it was decided that it is unrealistic to assume that for boosters one active substance will cover 100% of the market. Therefore, a lower Fpenetr was considered acceptable for boosters and the applicant can propose the use of a lower value, if this can be justified.

Diffuse emission and connection to STP

Question: Should, for wide spread uses, a direct emission scenario without a connection to an STP be used as a worst case scenario?

Answer: For wide spread use, the TGD indicates that the connection rate to an STP is only 80% whereas in the ESD for PT01 the worst case scenario does not include an STP. This could also be the case for PT02 or other wide spread uses. NO clarified that this is the case for the private house scenario. ECB highlighted that the assessment using the worst case resulting in risk might not be useful as the risk refinement will consider connection of the household to an STP.

3.2 Comments from MS related to EXPOSURE ASSESSMENT linked to Product Type 2

Non-specific scenarios

Reference to relevant section in ESD: AEAT 2.2, introductory text, p. 6 (see also PT 4, 4.2, p.33)

Question: General non-specific scenarios (Baumann) are presented as introduction without default values;

1) Should the text in the ESD be modified to indicate that the scenario is listed only for reasons of completeness and more specific scenarios follow?

2) Have Member States used these non-specific scenarios so far?

Answer: DE proposed to modify the text or delete these scenarios from the draft ESD if they are not used by MS. The workshop participants agreed to delete them as they are not used so far.

General Tonnage Based Scenario

Reference to relevant section in ESD: AEAT, 2.2 general

Question:

1) The reasons for choosing the tonnage-based scenario instead of a specific scenario are not given in the text. For better understanding, this should be further explained.

2) As the tonnage-based scenario should be preferentially used above a certain tonnage, should the $PEC_{regional}$ also be considered in this case in addition to the PEC_{local}. If not, above which tonnage level should the $PEC_{regional}$ be considered?

3) For disinfectants used for sanitary purposes (p. 9), break-even point calculation is based on EU TONNAG whereas for disinfectants used for sanitary purposes in hospitals, (p. 11), break-even point calculation is based on TONNAGEreg. Is this an editorial error?

Answer:

1) As discussed in chapter 2, the tonnage based scenario should be considered for dispersive use to confirm the results of the average consumption scenario.

2) The PEC regional will be calculated for dispersive use when tonnage data are available in order to compare the result with the PEC local.

3) This is an editorial error. Looking back to the RIVM document it is the TONNAGEreg that is used in both formulae.

Tonnage-based scenarios – Data Reliability & Confidentiality

Reference to relevant section in ESD: AEAT, 2.2 general

Question:

1) If PEC calculations are based on tonnage data how should these data be treated (when they are confidential) and how can data reliability be checked?

2) If there are changes in tonnage data on which the PEC calculations were based, should these be reported by the applicant to the Commission? How should the dependence on changeable tonnages be highlighted in the ESD as well as in the CA-report and Annex I listing?

Answer: ECB referred to the legal note of the CA meeting (CA-Nov07). The tonnage approach will only be used for comparative purposes. A realistic variation of the tonnage value and its consequences could be highlighted in the report.

$T_{emission}$

Reference to relevant section in ESD: AEAT, 2.2 a., p. 7, Table 1.

Question: Should the $T_{emission}$ for scenarios for the use of disinfectants in industrial areas be equal to 365 days (derived from private use -life cycle stage 4) or is the headline “industrial areas” not correct?

Answer: FR proposed to use one of the two values from the TGD for industrial use depending on how the product is used. It was agreed that the $T_{emission}$ should be adapted to the number of working days based on the information provided by the applicant, otherwise 5 days per week should be used instead as a worst case for industrial areas.

Chemical toilets

Reference to relevant section in ESD: AEAT, 2.2 c., p. 15

Question: How should emission to STP for disinfectants used in chemical toilets be addressed and what guidance should be followed?

Answer: This scenario should be further developed because it is an important pathway especially during the summer. There have been no applications for such uses FR explained that it was stressed during a previous workshop (June 2006) that there is no direct release to water and chemical waste has to be collected separately. MS were asked to check if the waste from this pathway has to be collected and treated separately as chemical waste or if it is released via a STP as assumed by Van De Poel (2001).

Emission scenarios for industrial areas
(disinfectants used for sanitary purposes, for hospital areas as well as for tiles and surfaces)

Reference to relevant section in ESD: AEAT, 2.2 a.

Question: For two substances no information on specific uses is given by the applicant. The main input parameter the EU tonnage is available but is not specified for different uses. Thus, for the 3 mentioned scenarios (see column 3 of the relevant tables) the emission rates to wastewater $Elocal_{water}$ was calculated using the total tonnage. For the subsequent PEC estimation the worst-case $Elocal_{water}$ was selected. Is this approach acceptable?

Answer: DE informed that it is a very conservative approach and if a risk is identified then the applicant will be asked to provide more data on the market share for the different uses. NL reminded that all uses end up in the same STP and the first assumption is correct with the worst case scenario for each use.

Confirmation of PT for an active substance in antibacterial plastic surfaces used at the hospital

Question: The intended use of the a.s. contained in a plastic polymer comprises countertops, lavatory seats or door handles. Should it be considered as PT 2 or PT 9?

Answer: DE advised to consider if the use is to protect the material (PT 9) or the person (PT 2). DK answered that it the intended use is to protect humans and therefore it was agreed to consider it within PT 2.

Active substance in antibacterial plastic surfaces: leaching rate

Question: The Average consumption approach was used and it was assumed that a percentage of the a.s. might be released during one day from wet cleaning from the plastic surface. This is based on experimental data (measured migration rate from plastic surfaces of

XX ug/a.s./cm^2 dislodged by fat) within 24 h. On the basis of these data it is assumed that 1% of the experimental value will cover the release during wet cleaning.

Is this leaching rate estimation acceptable or should a regular leaching test be requested?

Answer: DE looked at the OECD on plastic additives and found that the fraction ending into water for the complete service life is 0.01 percent per life time of the total amount leached from the plastic. Table 4.3 of the OECD ESD on Plastic Additives provides service life expectancy of plastics (e.g. furniture: 5-10 a, housewares 0-5 a). A service life time of 3 a is proposed for electronic.The assumption of 1% per day seems to be an overestimation and it was proposed to use the OECD value instead. FR asked what a regular leaching test is. DK answered that there is no standard test but it would be to add water and determine how much will be leached. However DK agreed to use the OECD value. NO didn't support the use of a leaching test because no standard test exists, and suggested to use the value of 1% proposed by the applicant instead of asking for more data. DK suggested to use 1% as a first tier and then to use the OECD value for refinement. IE noticed that the service life in the OECD is only 3 years and asked if it is realistic in that case? This was unknown and would depend on the type of product. The proposal of DK was accepted.

Active substance in antibacterial plastic surfaces: surface area

Question: A surface area of 100 m^2 (countertops, lavatory seats or door handles) has been considered and set by the author. Is 100 m^2 a realistic worst case for the ESD? The value has not been explained and it has not been possible to find comparable values. Do MS have experience or data to support this or another value?

Answer: FR explained that for PT18 data on barrier treatment were checked and if there was information that the value was higher than 100m^2 it was proposed to ask the applicant to justify the data submitted. DK agreed to ask for supporting data.

Discharge of water by private swimming-pools

Reference to relevant section in ESD: RIVM, Page 41, Table 2.2

Question: In this table, discharge of water into surface water only is reported for the acute situation. However, the applicant also considered potential concentrations in soil following disposal of pool water to garden soils. Should this emission pathway be taken into account? Or should terrestrial environment only be considered as a result of spreading contaminated sludge on land?

Answer: FR said that they propose to perform also a risk assessment for the garden soil if the workshop agreed. NL asked if a scenario exist. FR explained that the applicant provided a scenario for the release to soil. It will be evaluated and some values might be changed according to what FR considers the realistic worst case. NL explained that they have the same use and asked FR if they can provide the scenario and calculation methods. FR accepted.

Consumption per capita

Reference to relevant section in ESD, AEAT, section 2.2, Page 9, Table 2

Question: The default values of consumption general purpose and lavatory are identical to values proposed in TGD (p. 27, Tab. 4). These values are European means from 1994. These values may be outdated and be estimated.

Answer: No MS had additional recent data available. FR reminded that there is a need to update these data, and this would apply on most of the TGD default values.

3.3 Comments from MS related to EXPOSURE ASSESSMENT linked to Product Type 03

Relevance of mixing/loading and cleaning of washable coveralls of professional users

Question: For one substance, the applicant also considered exposures resulting from mixing/loading as well as cleaning of washable coveralls. Should this be done for all substances?

So far this is not considered for insecticides (PT18) applied by professionals in stables. However, in the 4th draft ESD on PT 18 Insecticides in Households both exposure pathways are considered.

Answer: FR stated that in the case of application in stables, the main emissions are direct releases to soil occurring in another place than mixing/loading, whereas for household insecticides releases to STP can be summed up. It should be first checked if it is not only a small part of the overall release because then it might be deleted from the risk assessment if negligible. DE explained that there will be a risk if the PNEC water is very low.

Nitrate

Reference to relevant section in ESD: AEAT, 3.2, p. 19, table 7 and p. 23, table 10 and p. 25, table 12 and p. 28, table 13 and p. 29, table 14

Question: According to the EC Nitrates Directive (91/676/EC) nitrogen immission limits are 210 kg N ha-1.yr -1 for grassland and 170 kg N ha -1 yr -1 for arable land. These values should be used as default values for Nitrate in tables 7, 10, 12-14.

Answer: ECB reminded that those values were already discussed at the workshop on PT18. It was decided to await the result of the discussion of the PT18 Workshop report at the Environmental Session of the TM following the workshop. At TM I 08, when the draft workshop report for PT18 was discussed, the Member States agreed to use the nitrogen immission standards from the EC Nitrates Directive (91/676/EC) of 170 kg N ha^{-1} yr^{-1} for all soils.

Default values -General

Reference to relevant section in ESD: AEAT, 3.2, p. 21, table 8

Question:

1) Explanations why certain values were chosen from the given references are lacking. Thus, the input values are partially not transparent.

2) Is it correct that the 2nd column provides days of disinfection events per year?

Answer:

1) There are several values in the RIVM report but only one value in the draft ESD, however without explanations. ECB informed that further explanations on the default values will be given in the final ESD when possible.

2) ECB will try to find this out.

Default values: Number of disinfection events - Poultry

Reference to relevant section in ESD: AEAT, Table 8, page 21

Question: In the note (A) it's indicated that 'this default value might be considered to be 6, rather than 3, since the storage period is one year, not six months'. In a worst case approach, isn't it more correct to take directly the value of 6 events to be representative of all European practices? As discussed during the workshop of June 2006, it seems that this choice was pH related. Clarification is however needed.

Answer: FR explained that in one dossier the applicant uses the value of 3 and asked why the value was changed to 6? ECB said that in the TNsG on Human Exposure the valued used is 3 and proposed to investigate and clarify the differences. NL said that the value comes from a RIVM report and proposed to contact the author of this report.

Degradation of the molecule

Reference to relevant section in ESD: Disinfection of animal housing

Question: For an application in pigsty (PT03), an applicant has considered in a Tier 2 approach that the substance applied on the wall is degraded before arriving in the slurry storage system. The applicant estimated a degradation of 90% of the molecule (the substance has been presented as readily degradable). Is this method acceptable (or partially acceptable)?

Answer: FR said that the degradation of a substance in a ready biodegradation test cannot be compared to the degradation potential of a substance applied on a wall in a stable and suggested not to accept the 90% of degradation as the default value as this results from extrapolating ready biodegradation test results to degradation in a STP. In the ESD for PT5 it is stated that rapid degradation can take place but for very specific substances. This is not the case here and FR suggested to ask experimental data but reminded that no standard test exists. NO explained that they have the same use as FR but the substance is not readily biodegradable. Their tier 2 refinement assumes that only 10% of the a.s. reaches the slurry but no justification is provided. FR concluded that no biodegradation should be taken into account prior to reaching the receiving compartment. DE reminded that for PT18 it may be asked to test the biodegradation in slurry stored tank and suggested using it as a refinement on the estimation of the final concentration in the soil compartment. DE was concerned to use the ready biodegradation test to estimate the emission to the slurry. FIN thought that it is acceptable to take into account degradation before reaching the receiving compartment for readily biodegradable substances. NL did not understand the need for the risk assessment to assume prior degradation for readily biodegradable substances because these substances will most likely anyway be degraded almost completely in the slurry. ECB said that the degradation in manure is variable and cannot be predicted without a test. DE reminded that the ESD for PT18 included that less than 100% of the applied a.s. will reach the receiving

compartment and therefore prior biodegradation is already assumed in the emission factors. NL confirmed this. NO said that for PT3 it is assumed that 100% enters the slurry system. FR said that for Tier 1 assessment prior degradation will not be taken into account. For the purpose of refinement it will be evaluated if prior biodegradation can be considered.

Discharge of slurry to the public municipal sewer

Reference to relevant section in ESD: AEAT, 3.2 Introduction p17

Question: It's indicated in this introduction that it is prohibited across Europe to discharge waste water containing slurry to the public (municipal) sewer. This sentence seems in contradiction with the PT18 ESD in which a discharge to waste water is considered for some uses. Must a discharge to STP for PT3 products be considered?

Answer: It was agreed that a discharge to STP must be considered for PT3 products as for PT18.

3.4 Comments from MS related to EXPOSURE ASSESSMENT linked to Product Type 04

Choice of plant size

Reference to relevant section in ESD: AEAT, 4.2, p. 35, Table 17

Question: Which plant size should be considered – small, medium or large plant?

Answer: A general agreement on this item should be made in order to have comparable results for all active substance evaluations. ECB recommended to use the worst case. It was agreed that the large size plant is the worst case in the absence of data which indicate the contrary.

AREA surface

Reference to relevant section in ESD: AEAT, 4.2, p. 36, Table 18

Question: No default for $AREA_{surface}$ is given. It is considered to be S, but should be D, as this will not be part of data supplied by the applicant. Are there any values that could be considered?

Answer: The default value for treated surface should be agreed upon. DE offered to derive data from the household scenario in PT18 ESD or to ask the applicant to provide data. FR asked how the data provided by the applicant will be assessed. ECB commented that at that time there were no data available for this parameter. ECB proposed to wait for the first dossier to be discussed at the TM. In addition, it was stated that if the applicant assumes a certain value for a parameter this shall be justified.

Disinfection of milking parlour systems

Reference to relevant section in ESD: AEAT, 4.2, p. 37, Table 19

Question:

1) In the text above table 19 it is stated, that the milk installation is cleaned twice a day and the tank once a day. Is this considered in the calculation of E_{local} and should these values be added up?.

2) According to the EC Nitrates Directive (91/676/EC) nitrogen immission limits are 210 kg N ha-1.yr -1 for grassland and 170 kg N ha -1 yr -1 for arable land. Should these values be used as default values for Nitrate in table 19?

Answer:

1) DE proposed to add both sources to calculate E_{local} even if it is not mentioned in the text. The workshop agreed.

2) this comment was already discussed Chapter 3.3 (Question on Nitrate)

Alternative General Scenario

Reference to relevant section in ESD: AEAT, 4.2, p. 38, Table 20

Question: In addition, a generalised scenario for liquid processing systems in the food and feed area is presented in Table 20. Which scenario is to be preferred the more specific ones described before or this generic one?

Answer: DE proposed to use first the general scenario and then the more specific scenario for the purpose of refinement. The workshop participants agreed with this approach.

3.5 Comments from MS related to EXPOSURE ASSESSMENT linked to Product Type 06

Risk evaluation of different uses for PT06

Question: The applicant has subdivided the different uses in PT 6 into 5 sub-product-types (as suggested in the ESD) and evaluated these separately. Some of them will enter the same STP. Should the sub groups be evaluated separately or should the emissions be added?

Answer: It was agreed for the time being to evaluate first the sub groups separately and then to add the emissions where relevant. This approach might be modified after the EU Commission and CA meeting consultations. DE said that they had only two sub categories for PT06 and emissions will have to be added because the releases enter the same STP. Applications were submitted for the same a.s. for PT02, 03 and 04 and emissions will be added where relevant.

In can preservative in fluid for textile industry

Question: There are available scenarios for the point source during industrial application but not for the use phase when washing will result to releases to an STP. Should this emission be taken into consideration?

Answer: ECB asked if the applicant provided information in the dossier regarding the content of the active substance in the product after the shelf life. During the discussions on the development of the EUSES 2.1 version IND claimed that in can preservatives are only active during the product shelf life and emissions after shelf life are negligible. DK did not believe

that the a.s. will not be present in the product after shelf life but that the concentrations are so low that there will be no 'preservative effect on the product' any more. FR said that the formulation stage is the main one to be considered but believed that use stages should not be neglected and in that case only tonnage based scenarios are available. DE added that in principle all life stages should be included in the assessment including release after the shelf life. When data are available they should be used, otherwise a tonnage based approach should be applied as suggested by FR. ECB explained that no fractions of residual preservatives after shelf life are available and suggested to look at the results on efficacy. DK disagreed because IND does not claim any efficacy after shelf life. NL said that for paints a differentiation should be made between indoor and outdoor uses. It was proposed to use the wood preservatives emission scenario for outdoor use with a leaching rate of 100% at 30 days and an estimation of indoor emission of 100% on a yearly basis. SI added that products containing in-can preservatives can stay on a shelf for example two years but can also be used on day one and proposed as a tier 1 approach to assume that 100% of the in can preservatives is still in the product. ECB explained that this is the approach applied in the TNsG on Human Exposure (operator exposed to paints) and a harmonised approach should be implemented. DK said that further information will be needed but it is not likely that the applicants will provide it because there are so many different products in which in-can preservatives are used. A tonnage approach can be used as it is a dispersive emission but the confidentiality of the data will be a problem. UK proposed to ask the total tonnage data from the applicant and to check if a risk exists for different tonnage bands. DK said that the total tonnage data is not sufficient and that the tonnage for sub categories have to be known because the emissions will not go to the same compartments like the STP and soil. This information is not available by the applicant. DK suggested not considering it at this stage before an agreement on sub category scenarios was reached. ECB asked for volunteers to work on this issue. BE offered to provide the work as their national experts face the same problem under their national product authorisation scheme. DK asked for an agreement on the sub categories to be used for the evaluation. FIN explained that the sub categories of their PT6 substance are not the same to the ones described by DK. ECB asked the RMS having a PT 06 dossier in the Review Program to send their data to BE that will make an overview of the existing sub categories. NL suggested also BE to have a look at the sub categories proposed in EUSES 2.1. BE agreed.

Risk Assessment - Multiple uses & Secondary Exposure

Question: How extensive should the assessment for in can preservatives be (secondary exposure)? A very broad range of intended uses is claimed, including e.g. the use in plant protection products. For the latter, it seems that no specific assessment is conducted under EC 91/414 for these preservatives. Should a PPP assessment be conducted?

Answer: SI had the same case and wondered if the use is legally covered by the PPP directive. FR said that co-formulants are not assessed under the PPPD and their PPP experts expected from their BPD experts to indicate which preservatives can be used in the PPP products. DK thought that the issue should be send to the CA to decide if it is a PPP or BPD issue. ECB agreed and will inform DG ENV.

Textile used for tents

Reference to relevant section in ESD: ESD for biocides used as In-can Preservatives (Product type January 2004)

Question: Although this issue is not addressed in the report, direct emission to soil during service time may occur. Should this emission be taken into account?

Answer: DK said that if this emission is considered then the emission to STP from washed clothes should also be taken into account. It was suggested to decide the level of detail of the risk assessment according to the importance of the use. ECB asked NL to send the scenario for tents to BE for the overview of PT6 uses.

3.6 Comments from MS related to EFFECT ASSESSMENT

No information is available on the formation of trihalomethanes/AOX degradation products of a submitted substance.

Question: The notifier indicates that these types of by-products are also formed by other oxidising actives and it would therefore be inappropriate to address this issue only for this submitted substance.

Should further data be submitted for degradation products or should it not be considered for Annex I inclusion and this issues can be addressed at product authorisation stage?

Answer: DE advised to consider it now and to have a look to the formation of trihalomethanes and formaldehyde groups. The first step for the applicant will be to look at the available literature data and to provide an estimate in the report. AT supported the comment by DE.

ANNEX I *Overview of emission scenarios and their status for PT1, 2, 3, 4, 5 and 6*

PT	Description of product type	Life cycle stage	Status	Remark(s)
1	Human hygiene biocidal products	Private use	EUBEES 2 (Royal Haskoning Report 4L1784.A0/R016)	Existing generic TGD scenario based on [1] annual tonnage or [2] average consumption adapted for use for biocides
		Professional use	EUBEES 2 (Royal Haskoning Report 4L1784.A0/R016)	Existing generic TGD scenario based on annual tonnage, adapted for biocides
2	Private area and public health area disinfectants and other biocidal products			
	- Swimming pools	Industrial use	RIVM report 601450 009	Public swimming pools; acute and chronic situations
		Professional/Private use	RIVM report 601450 009	Public and private swimming pools; acute situation
	- Sanitary sector	Formulation	RIVM report 601450 009	Existing emission scenario document 1 of TGD + generic B-tables for IC-5
		Private use	EUBEES 1 (RIVM report 601450 008)	Based on annual tonnage
		Private use	EUBEES 1 (RIVM report 601450 008)	Based on average consumption
	- Horticulture	Industrial use	RIVM report 601450 009	Existing emission scenario of USES for household products used for fogging
	- Tiles and surfaces	Formulation	RIVM report 601450 009	Existing emission scenario document 1 of TGD + generic B-tables for IC-5
		Private/Industrial use	RIVM report 601450 009	Existing generic TGD scenario based on annual tonnage
	- Medical sector			
	-- Disinfection of rooms, furniture and	Industrial use/Service life	EUBEES 1 (RIVM report 601450 008)	- Based on annual tonnage - Based on average consumptions
	-- Disinfection of instruments	Industrial use/Service life	EUBEES 1 (RIVM report 601450 008)	- Disinfection of scopes in washers - Disinfection of other instruments
	-- Laundry disinfectants	Industrial use/Service life	EUBEES 1 (RIVM report 601450 008)	- Washing streets

PT	Description of product type	Life cycle stage	Status	Remark(s)
				- Tumbler washing machines
	-- Hospital waste disinfectants	-	AEAT report ED48587/R1 (unpublished)	
	-- Disinfectants with more than one application	-		Summing of outcomes scenarios of medical sector
	- Disinfection of air conditioning systems	-	AEAT report ED48587/R1 (unpublished)	
	- Disinfection of industrial areas	-	AEAT report ED48587/R1 (unpublished)	
	- Disinfectants for sewage and wastewater	Industrial use	RIVM report 601450 009	Preliminary emission scenario
	- Soil and other disinfectants, …..	-		
	- Disinfection of chemical toilets	-	AEAT report ED48587/R1 (unpublished)	
3	Veterinary hygiene biocidal products:			
	- Disinfection of animal housing	Industrial use	RIVM report 601450 009 AEAT report ED48587/R1 (unpublished)	Adaptation of RIVM report 679102 033
	- Disinfection of footwear and animals' feet	Industrial use	RIVM report 601450 009 AEAT report ED48587/R1 (unpublished)	Adaptation of RIVM report 679102 033
	- Disinfection of milk extraction systems	Industrial use	RIVM report 601450 009	Adaptation of RIVM report 679102 033
	- Disinfection of means of transport	Industrial use	RIVM report 601450 009 AEAT report ED48587/R1 (unpublished)	Adaptation of RIVM report 679102 033
	- Disinfection of hatcheries	Industrial use	RIVM report 601450 009	Adaptation of RIVM report 679102 033
	- Disinfection of fish farms	-		
	Disinfection for veterinary hygiene: udder washes and non-medicinal teat dips	Professional use	AEAT report ED48587/R1 (unpublished)	
4	Food and feed area disinfectants	-		
	Disinfectants for small-scale applications (spraying of surfaces)/ industrial kitchens/ meat processing industry	Industrial use	AEAT report ED48587/R1 (unpublished)	
	Disinfection of entire plants (e.g.	Industrial use	AEAT report ED48587/R1 (unpublished)	

PT	Description of product type	Life cycle stage	Status	Remark(s)
	breweries, dairies, beverage processing plants)			
	Disinfection for hygiene of milking parlour systems	Professional use	AEAT report ED48587/R1 (unpublished)	
	Disinfection of liquid processing (beverages, dairy, food)			
5	Drinking water disinfectants	-	EUBEES 2 (UBA report)	
6	In-can preservatives		EUBEES 2 (Royal Haskoning Report 4L1784.A0/R018)	Overview of available ESDs
	- Washing and cleaning fluids, human hygienic products and cosmetics	Private use	RIVM report 601450 009	- New; based on annual tonnage - New; based on average consumption
	- Detergents	Private use	RIVM report 601450 009	
	- Paints and coatings	Industrial use - Product formulation - Product application)	RIVM report 601450 009	Existing emission scenario document IC-14 of TGD + generic B-tables for IC-14
		Waste treatment	RIVM report 601450 009	Based on RIVM report 601450 003
	- Fluids used in paper production	Industrial use	EUBEES 1 (INERIS report DRC-01-25582-ECOT-CTi/VMi-nº01DR0183)	- Drying sections after size-pressing - Broke
		Recycling	EUBEES 1 (INERIS report DRC-01-25582-ECOT-CTi/VMi-nº01DR0183)	
	- Fluids used in textile production	Industrial use	EUBEES 1 (INERIS report DRC-01-25582-ECOT-CTi/VMi-nº01DR0176)	
	- Fluids used in leather production	Industrial use	EUBEES 1 (INERIS report DRC-01-25582-ECOT- CTi/VMi-nº01DR0165)	
	- Lubricants	-		
	- Machine oils	-		
	- Fuels	-		

ANNEX I I

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