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

Workshop on environmental risk assessment for insecticides, acaricides and products to control other arthropods (Product Type 18)

Brussels, Belgium, 11th of December 2007

A workshop for technical experts evaluating PT18 active substances for the Competent Authorities implementing the Biocidal Products Directive, Directive 98/8/EC.

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This document was endorsed at the 31rd 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 (27-28 November 2008).

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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 have to be assessed and the decision on their inclusion into Annex I of the Directive shall be taken at Community level;

- Member States 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 Members States was 14 May 2000. Active substances introduced on the market after this date are new active substances 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 the Review Programme of active substances already on the market (so-called existing active substances) with the aim to assess all active substances that were already on the market before 14 May 2000. Guidance on the assessment of active substances and biocidal products is laid down in the so-called Technical Notes for Guidance (TNsG), which are published on the web page http://ecb.jrc.it/biocides/.

Active substances used as insecticides, acaricides and products to control other arthropods in product type (PT) 18 are currently being assessed by Rapporteur Member State (RMS), leading eventually to a decision on Annex I inclusion.

The assessment of environmental risks consists of exposure and effects assessments, which are then compared in the risk characterization. For insecticides, acaricides and products to control other arthropods the emission scenarios are critical in the exposure assessment. Within the Review Programme the guidance produced by the OECD entitled "Insecticides, acaricides and products to control other arthropods for household and professional uses. OECD Series on Emission Scenario Documents (4th draft 2007)" and "OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 14, Emission Scenario Document for Insecticides for Stables and Manure Storage Systems, JT00197426, Jan 2006" are used.

The progress of the Review Programme is discussed in the Biocides Technical Meeting (TM). At these TMs there appeared to be sereral outstanding issues with respect to the ESDs mentioned above, and on environmental risk assessment for this product type 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 this product type with the intention to develop a harmonised approach.

In the workshop experts from Member States participated. The workshop was chaired by Wim de Coen from JRC-IHCP. The list of participants is included in this report.

The present report contains the conclusions of the workshop and decisions taken at TM I 08 where draft workshop report was discussed. Some outstanding issues raised by the Member States were not resolved and have to be discussed at a later stage. This is indicated in the relevant section.

The present report shall be used for the evaluation of active substances used as insecticides, acaricides and products to control other arthropods in product type (PT) 18 in connection with the relevant available guidance, like the ESDs mentioned above, similar to other workshop reports for PT8 and PT21.

1. Overview and Bottlenecks on PT18 ESD on "Stables and Manure"

The ESD originated at OECD level (Biocidal Task Force) with Austrian support and funding. The ESD text was prepared by RIVM after which it was drafted by the Expert Group on ESDs for Insecticides, a sub-group under the Task Force on Biocides. The interaction of the different parties involved was highly efficient and serves as a good example of efficient collaboration creating useful ESDs. In general, this guidance is highly connected to Product Types 3, 4 and 8. The main targets in the ESD are the nuisance flies - house fly (*Musca domestica*) together with other arthropods including insects, bloodsucking flies (poultry highly susceptible), lice, mites (acarids), louse flies and fleas. The concept that is available provides a generic first tier model which can be further refined e.g. with new research that is going on.

The main compartment that is targeted in this ESD is soil, and the outcome of the ESD can be seen as the Predicted Initial Environmental Concentration for soil (PIECsoil). In addition to this compartment, substantial attention is given to leaching to groundwater. Sewage treatment plants are also important targets in the emission scenarios: i.e. the load for (private) on-farm wastewater treatment plant (WWTP) and the loading for the standard (municipal) sewage treatment plant (STP). If a problem would arise than a regional approach in the calculation could be performed. Good examples are areas in the EU where dense intensive animal husbandry is occurring (DK or NL), or where very little grassland is causing an augmentation of cattle density.

The overall scenarios are based on good agricultural practices (GAP), although some parts of the ESD are not fully in line with this concept. Some statements for example are in clear conflict with the GAP and should probably be changed. For example, “Liquid waste may be comprised of liquid manure (urine), effluents from dry manure storage, wet precipitation, cleaning water from milking systems or stable cleaning or silage effluent household waste water. The latter is normally discharged to the public sewerage”. An additional comment should be formulated indicating that this discharge should not occur under GAP.

Within the generic version of the ESD substantial differentiation was provided to take into account the climatic/husbandry differences within the EU. This will be important in the light of product authorisation. It is important to realise that it was difficult to define "defaults" for most parameters. The values presented refer mainly to the Dutch (average) situation that may not truly represent the EU average or the situation for a specific Member State (MS) or region. Default values can be changed when better (more representative) data become available. The aim of the ESD is to present realistic worst case emission scenarios that are applicable in each of the MS. The defaults presented may be overwritten by the user with more locally relevant data, as is common practice in all biocide scenarios.

The workshop agreed that the conflicts with the GAP principles should be eliminated from the earlier versions. There was furthermore agreement that a better description of the waste disposal route was needed.

2. Emission Scenario Document (ESD) for Insecticides, acaricides and products to control other arthropods (PT 18) for household and professional uses (July 2007)

The original concept of the ESD intended to cover only the household use, but along the development of the guidance applications in large buildings (restaurants for example) was added. During the last Biocidal Task Force Meeting (OECD) in 2007, the last draft version was discussed. The ESD is almost in a final version, and specific commentary statements will be added on the simultaneity factor, the characterisation of larger building (size, number) and the dimension of the environmental compartment (10-50 cm discussion).

Note to the reader: the final ESD was published on 17 July 2008 by the OECD and is available from the OECD and JRC-IHCP web-site. In the sections below reference is made in footnotes to this final version to clarify the comments and decisions made during the workshop.

During the workshop several specific aspects were highlighted.

1. Simultaneity factor: default number of private houses/buildings simultaneously treated
A default value for the simultaneity of treatment was proposed based on a French survey in which the frequency of insecticide uses was asked to the general public. The results are separate factors for indoor (5.52%) and outdoor (2.75%) simultaneous use[1].

2. Cumulative assessment: Number of private houses / larger buildings connected to STP
A proposal was made to perform cumulative assessment by summing up the releases from household and larger buildings. For this, the number of large buildings per STP was determined. It was suggested that 4 000[2] households and 1000[3] larger buildings are connected to the STP.

Considering the heterogeneity of larger building dimensions, it was judged that a default size of a larger building would be 5 times longer and larger (L= 87.5 m; l =37.5 m) than the private house (L = 17.5 m and I = 7.5 m)[4]. The proposed surface value (3 281 m^2) covers all the buildings from the UK imidacloprid risk assessment and UK average size building (ESD) except hospitals.

3. Wet and dry cleaning
In domestic applications a typical house with 5 rooms is used as model. The question was posed whether it was relevant to consider the whole surface of the house (5 rooms) for the application (e.g. treatment against specific insects). Furthermore it was questioned whether it was relevant to consider that all rooms were cleaned in the same way. As the main potential pathways for environmental exposure during the product service life are associated with cleaning of treated areas, changes in these defaults will have a major impact on the emission.
A proposal was made to modify this scenario: the potential exposure could be estimated from the fractions of the applied active substance that might be lost to waste. Rooms cleaned with water (kitchen, bathroom, etc.) would be connected to the wastewater

[1] In the final ESD this can be found in section 2.7.
[2] In the final ESD the number of 4,000 can be found in section 2.7.
[3] This value is not mentioned in the ESD and is a proposal agreed at the workshop.
[4] In the final ESD this can be found in section 2.6.

network, whereas rooms cleaned using a vacuum cleaner / broom would result in solid waste. It was proposed that for aquatic risk assessment only “wet” rooms cleaned with water would be considered relevant. As surface value for “wet” room cleaning 38.5 m^2 (private) and 971 m^2 (large building) would be relevant[5].

4. Modifications for Targeted applications

As a deviation from the generic ESD was proposed by Industry, FR suggested allowing the introduction of targeted applications. More specifically for crawling insects, the "chemical barrier scenario" was introduced (application area of 20 m^2 and 505 m^2 for household and larger building, respectively)[6].

5. Wastewater / rain water

Depending on national legislation rain or storm waters will eventually end up in a sewage treatment plant or be collected and released directly / separately to surface waters. In line with the approach retained for the assessment of wood preservatives (noise barrier scenario), mixed systems are assumed, and STP should not be by-passed.

[5] This value is not mentioned in the ESD and is a proposal agreed at the workshop.
[6] This value is not mentioned in the ESD and is a proposal agreed at the workshop.

3. Table on intended uses of active ingredients

An overview was compiled from the EU questionnaire providing information on the intended uses of PT18 active substances. The table in Annex IIa demonstrates that for most of the uses a specific exposure scenario from the ESD was selected. The table was useful to illustrate some discrepancies between MS. For example AT decided to apply "No relevant emission" if etofenprox was applied indoors. But other MS have calculated and considered emissions to STP for similar uses. In the discussion it was agreed that cleaning would highly affect the emission load to the environment. AT only used the products as spray in the air (no application in surfaces), therefore release to STP was considered negligible. But for other similar spray applications the STP route was chosen by other MS. It was considered that even if sprays are used a portion of the applied amount will be emitted to the environment (DK, BE, DE, FR). DK and UK considered that emission to STP could be waived if there would be specific reasons (e.g. half life) to neglect the final amount released. The default scenario would be to assume emission to STP, afterwards other characteristics such as degradation could be applied.

NL highlighted a substance that would only be used in waste disposal sites. As the emission reduction measures were assured by EU waste legislation no risk assessment was performed for this application. For other applications the risk was characterised. MS accepted this waiving on the condition that sufficient risk reduction measures were taken.

FR mentioned specific applications of active ingredients in overseas territories. Treatment with vehicles/airplanes would need to be foreseen in the future as these are specific applications against mosquitoes. At present there was no claim yet but this would become an issue for product authorisation.

4. Anaerobic degradation testing for biocides to be used in animal housing (PT18) - Proposal for a testing strategy

It is common agricultural practice to apply the contaminated manure as organic fertiliser to agricultural soil after a certain storage time. This entry route into the soil has to be included in the environmental risk assessment. If release to manure facilities is likely, an anaerobic degradation study is required. An overview was provided on the (dis)advantages of the existing sludge degradation guidelines (ISO 11734, 1995' (OECD 311) 'Ultimate' anaerobic biodegradability of organic compounds in digested sewage sludge'). This recommended method for digested sludge is not appropriate to reflect biodegradation in the manure matrix, making extrapolation of results from digested sludge to manure matrix difficult. DE proposed a preliminary testing strategy using a tiered approach:
Tier 1 (worst case assumption): no degradation in manure (so no correction of the fraction of the total amount of applied active substance which reaches the manure/slurry as recommended by the ESD. The outcome of tier 2 can lead to a correction of this fraction.) during storage-time. If environmental risk assessment demonstrates no risk (PEC/PNEC <1) then no further studies are required; if a risk cannot be excluded, further studies are necessary for a PEC refinement (= Go to Tier 2).
Tier 2: an anaerobic degradation simulation study in manure in the style of modified OECD Guideline 307 (Aerobic and anaerobic transformation in soil) is required. A ^{14}C-labelled radiotracer shall be used to set up a detailed mass balance. Determination of mineralisation rate, bound residues and metabolites would need to be quantified/identified if possible. The test material is manure and the test should be performed under anaerobic conditions. Presently UBA German Federal Environment Agency is involved in the development of a method for anaerobic transformation in manure for veterinary medicinal products (VMP) by a R&D project. Results of this research project will shortly be published as UBA Texte 45/07 and will be distributed through the ECB website. On 1-2 April 2008 an expert workshop will take place in Braunschweig, Germany. The research project will be finished at the end of 2008 aiming at a proposal for a new OECD guideline. A follow-up project for biocides has been started recently testing the suitability for biocides and further development of the technical protocol.

NL suggested to harmonise the approach for biocides and VMP RA (EMEA). Bound residue formation is an additional but crucial problem for assessing real degradation. Differential breakdown is to be expected depending on the type of faecal material that needs to be treated (chicken aerobic and dry, cattle & pig mainly anaerobic and wet). Research projects in NL are also ongoing. It was proposed to share experience between veterinary drugs and biocides and maximize input and knowledge with the EMEA working party.

The "Tiered approach" proposed by DE was welcomed by the meeting as the digested sludge assay is clearly not sufficiently mimicking the manure matrix. IT welcomed the DE approach but questioned whether asking additional degradation would be realistic as it might be very expensive. NL highlighted the complexity of the issue as it was already studied for VMP: Storage time for manure might vary (1 month – 6 months) also depending on season (average 3 months). If for VMP no knowledge on metabolite identity is available a "total risk" approach is followed where all metabolites are added individually and considered as toxic as the mother compound. For VMP a tiered evaluation has been proposed as well: if the exposure is expected to be low than no full RA is needed. Total mineralisation (cut off of 5%) should occur in 3 months time. If the cut-off value of 5% is met then the risk assessment (RA) is stopped. For the full RA only those metabolites present > 5% are evaluated.

DK supported the harmonisation proposed by NL, but would not like to change the degradation cut-off values as currently applied in biocidal evaluations. IE also considered total metabolisation too difficult to apply for biocides. The difference in cut-off for mineralisation was discussed for VMP and biocides: for VMP internal metabolisation by animals needs to be considered, which is not relevant for biocidal use. The biocidal cut-off should remain at 10% due to the major difference in use and exposure routes.

It was suggested that a joined workshop between the EMEA working party and the Biocidal TM would be very useful. In general, IE, UK and DK, found it important to inform Industry on the research progress, but considered it inappropriate to force industry providing such new data. DE has requested an anaerobic biodegradation test in manure according to the proposed tiered approach from the applicant for some active substances as one option of risk refinement.

5. Comments from MS related to exposure assessment: Insecticides, acaricides and products to control other arthropods for household and professional uses described in the draft OECD Emission Scenario Document

5.1 Cummulative use of insecticides in households and by professionals

By breaking down the larger house scenario an applicant provided individual PECs for each scenario (households and additional PECs for larger buildings, respectively) without calculating a cumulative exposure of all scenarios for the STP. DE proposed to derive a $PEC_{localSTP}$ and $PEC_{localsurfacewater}$ by summing up all the inputs.

DK, FR and NL agreed with this general principle as it also touched other PTs (disinfectants and in can preservatives). MS found that a strong statement was needed to stress the need for such cumulative assessment. To perform such cumulative exercise, larger houses will be taken into consideration. FR proposed to use 1000 large buildings as a standard value. This value was based on data from the French Water Agency. At present little detailed values for Europe are available. In general, MS agreed that the values available presently could be used, and if new more precise data become available, assessments might be adapted. The overall loading of the STP would remain unchanged (10.000 inhabitant equivalents per STP) but the contribution of small (4000) and large (1000) buildings would be added. To estimate the size of these large buildings, a 5 fold increase of the private dimension was accepted (3 281 m^2). DK, FR, UK suggested to use a realistic worst case depending on the claim of the product. A large hospital treatment (for example the average UK size 14 265 m^2) discharging into an STP could be considered as a realistic worst case but it should only be calculated if there is a specific claim for such specific use. The overall principle was agreed that if use without risk was identified, the actives substance can be included on Annex I. Product authorisation afterwards needs to evaluate whether other uses are envisaged.

Note for the reader: in the final ESD available from the OECD and JRC-IHCP web-site (version 17 July 2008) this cumulative use scenario is not described.

It was agreed at TM I 08 that a first tier assessment will be based on the label claim: if for example there is no claim for use in hospitals the first tier will include only emission from small and large buildings. If a risk is identified, refinement will be necessary. The workshop did not discuss refinement options.

5.2 Default number of private houses simultaneously treated

If detailed information on the application frequency of a biocidal product (b.p.) is available, the simultaneity factor can be modified accordingly. It is important that the label claim clearly describes the frequency of use of the product. It is a general principle that excessive use/misuse should not be covered.

5.3 Definition of Foundation

There was confusion regarding what exactly ‘foundations’ are. The UK believes that they should be the size of wall/building that is below ground level and which supports the property, not the first 0.5 m above it, as suggested in the diagram and text. Indeed, this

was the intention of the ESD: the text refers to the lower end of the wall. In most countries this lower end is below ground level. However, in some countries, although the lower end is the wall supporting the property (for example made of concrete), this lower end is not below but above ground level.[7]

5.4 "fraction emitted to soil due to wash-off by rainfall

It was confirmed by FR that the value of 0.5 given for default value of "fraction emitted to soil due to wash-off by rainfall" refers to the first rain event. One should consider the first rain event after 3 days of application, where in a single rain event 50% is going to the sewer. During application 30% is lost, leaving in total 20% of the applied product. A footnote needs to be added to the table[8]. The default value can be refined by specific data from wash-off studies.

5.5 Clarification on height of private house roof

A footnote will be added to p. 33, line 1042, where it is stated that 2.5 m has been agreed upon as the height of houses. The wind readings are taken at 10 m height, which should not be confused with the standard height of private house roofs[9].

5.6 Product service life

Applicants often make own assumptions on the fraction of applied residues emitted to waste water during cleaning (i.e. 0.9 instead of 1 in "wet rooms" and 0.5 in "dry rooms"). Also in the French document, a suggestion was made to refine this scenario: only hard floors could be considered for wet cleaning and the total number of rooms (5) to be treated could be changed depending on the application. E.g. for fleas applications might be restricted to carpets and these surfaces are most likely not cleaned in a wet way. The meeting agreed that diversity in this application should be allowed as long as a reasonable worst case scenario is calculated to get an idea on the overall impact (e.g. clean everything wet, 100% for STP vs. 100% to solid waste).

5.7 Selection of scenarios for outdoor spray application

An applicant claimed that only foundations of the building are treated (and not the band of soil adjacent to it). In the ESD both foundations and a band of soil should be considered. The meeting considered that the treated area should be totally covered in the assessment. This also means that the soil close to the spray-zone should be taken into account, so both foundations (first half meter of wall) and soil band should be considered.

5.8 Run-off to soil

According to the ESD the fraction of product subjected to run-off from walls is below or up to 20%. The applicant used 1% run-off in calculations and refered to the high log Koc of 5.5. The meeting did not accept this position and preferred to stay with the default value of 20% unless data prove that the run-off is lower. The default can be refined by product specific data from simulated wash-off studies.

[7] See figure 4.3-1 of section 4.3.1.4 and figure 4.3-3 of section 4.3.1.5 of the final ESD.
[8] See section 4.3.1.5 of the final ESD.
[9] See section 2.6 of the final ESD.

5.9 Size of receiving compartment - Soil depth

According to the ESD the receiving soil depth is 50 cm. However, for substances with a high Koc-value, the upper 5 cm would be more relevant. This issue was discussed previously in the e-mail consultation group, but was further discussed at this workshop.

NL suggested making distinction between horizontal versus vertical distance. Agricultural applications under the PPP use the top 5 cm, for TGD 10 cm depth is used. NL proposed to take 10 cm and 20 cm (in case of mixing) as a proposal for a local RA calculation. DK stressed the decision of the CA regarding the 50 cm under the wood preservatives, but approved the NL comments. SE, DE, IE and FR followed the NL proposal.

The proposal from NL was accepted: to use for the soil receiving compartment for the soil depth: 10 cm in case of no mixing and 20 cm in case of mixing.

Note for the reader: this proposal deviates from the final ESD available from the OECD and JRC-IHCP web-site (version 17 July 2008) where 50 cm is used.

5.10 Which ESD to use?

An applicant used ESD for masonry preservatives for soil exposure and ESD for insecticides (stables and manure storage systems) for water exposure, since no other ESDs were available at the time for submitting the dossier. However, the new draft ESD for insecticides, acaricides and products to control other arthropods (PT 18) is more appropriate. SE questioned whether the RMS or applicant should perform a new exposure assessment?

DE, DK and FR suggested not to ask the applicant to recalculate the new values according to the new ESD. In general it would be preferred if the RMS could reconduct the RA, based on new knowledge, and resend it to applicant. Consultation between the RMS and the applicant before the revised RA is distributed further is essential, especially when the conclusion impacts upon which applications or uses present acceptable or unacceptable risk.

6. Comments from MS related to exposure assessment linked to the use in animal housing and manure storage systems described in the Emission Scenario Documents

6.1 Highest N-fertilisation or amount of liquid manure maximal deposited on European fields? – Comment 14 – DE

The current ESD refers to Nitrogen emission standards which are different among EU countries. Currently the extreme values are taken (PT and BE values). However, the EU Nitrogen directive values are lower than the ESD values. DE suggested applying the high values of the ESD as a first tier and only if risk is identified to use the lower values. IE suggested to use the highest value of PT grassland as worst case and allow refinement but not below N-directive values. Mutual recognition should be based on this worst case scenario but a case by case evaluation should be possible. NL mentioned that for veterinary drugs, Eurostat information values were used (170 kg/ha is the average).

At TM I 08, 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.

6.2 Insecticides in use for poultry housing

According to default input values in the OECD ESD No.14 (PT18) the emission path of sewage to STP followed by estimation of PEC in surface water and sediment was calculated. This lead to a concern in the compartments surface water and/or sediment several times. DE questioned whether this emission path would be relevant?

NL stated that it might depend on the application: if it was sprayed on manure than it would be irrelevant. If however the substance would be used on walls than emission to STP would be more realistic (after cleaning). In principle, all waste water has to be treated so no direct emission to surface water should occur. IT stated that the WFD requires the collection/treatment of waste water from animal houses. This results from the application of Art. 10 (Combined approach) for what concerns the control of pollution caused by nitrates from agricultural sources (Council Directive 91/676/EEC of 12 December 1991). As a consequence, untreated waste water should not enter surface water. DE suggested to keep 2 routes: water to STP and waste / manure to land. It should be pointed out that one route, i.e. emission path via waste water to STP, applies to the situation where waste water from poultry housing is stored separately and discharged to the sewer system. The second route, which should be considered here, is described by common release to the waste streams, i.e. use of single intercepts for waste water and manure for subsequent simultaneous land application.

Due to concern for the environment, the applicant proposed restrictive labelling ("no use in stables with direct connection with STP"). UK questioned the usefulness of such restricted label. DK confirmed that this had been used before (e.g. vacuum pressure impregnation plants). In general the meeting found this kind of labelling acceptable, but it was stated that this should be done in close interaction with the applicant. The UK raised concerns over the wording suggested "no use in stables with direct connection with STP" as the topic of conversation included poultry houses and not just stables. Wording that was not as prescriptive as to the actual building but as to where the waste water will be

discharged was agreed to be more suitable. i.e. “Do not use where exposure to STP cannot be prevented”.

6.3 Stable insecticides – Anaerobic biodegradation stud

See Chapter 4.

6.4 Refining estimates of environmental exposure –

See Chapter 4.

7. Comments from MS related to EXPOSURE ASSESSMENT linked to other uses

7.1 Treatment of trees

This comment was skipped during the workshop.

7.2 Active substance formulated as impregnated paper

For treated paper it was difficult to calculate the fraction emitted to soil via movement of termites. For this specific compound, the fraction released to soil was based on measured residues (<LOQ) from a study with the formulated product in sand with termites. The soil volume was assumed similar as in the ESD for wood preservatives (50x50x50 cm).

The meeting suggested to follow previous decisions and select the 10 and 20 cm depths to estimate the affected volume of soil.

7.3 Reasonable irrigation scenario for household irrigation

A realistic irrigation volume for estimating the PEC_{soil} was discussed. The use of the a.i. was to treat irrigation water to avoid mosquitoes in gardens. IT pointed to official guidelines for agricultural irrigation, more specifically garden-specific or crop-specific default values. IE replied that such values could be available but these values are usually related to agricultural practices and could not be detailed enough for gardens and flowers.

8. Comments from MS related to EFFECT ASSESSMENT

8.1 Risk assessment for non target arthropods

The current risk assessment for non target arthropods for insecticides with outdoor application is rather qualitative and is largely based on PPP assessment. Effects on non target organisms are rather poorly described. Furthermore due to the natural origin of the a.i. (an "X" extract), no reliable DT50 can be measured (no labelling possible), so no degradation study can be taken into account. As a result the PECs are high.

FR mentioned the consultation round from last year and stated that in the past similar questions have remained unresolved. At present, further discussion would be needed. It was decided to postpone the discussion on this issue to a later stage.

8.2 Aquatic effects assessment

An applicant wanted to use data from a mesocosm study and simulation on recovery of organisms to increase the PNEC. RMS did not agree on this approach. There were still uncertainties and recovery may not be possible for biocides with continuous exposure. Therefore an AF needed to be applied.

From the discussion at the workshop it became clear that the RMS position was supported based on the continuous exposure of the biocides application. DK considered this to be a rather general issue, and not only specific for this PT. It was decided to postpone the discussion on this issue to a later stage.

8.3 Effects assessment for the sediment

RMS considered that a $PNEC_{sediment}$ related to a sediment concentration is needed to perform the risk assessment. Only an aquatic PNEC was available. In general, through application of equilibrium partitioning one could extrapolate to sediment. DE considered that if a risk for sediment was identified, sediment toxicity data needed to be asked. FR underlined that so far it was unclear how EP-based sediment values would need to be used if no sediment toxicity data were available. It was suggested to accept (aquatic) mesocosm data as a first tier for this case, because for most substances the water route would be the most important. According to the TGD depending on log Kow/oc one should decide whether to ask for sediment testing.

8.4 Effects on soil dwelling arthropods

During the meeting it was concluded that not enough information was available to discuss this point in-depth.

8.5 Aquatic effects assessment

The applicant had used recovery to increase effect values. The NOEC turned into a higher NOAEC or NOEAEC. SE questioned how recovery should be considered in aquatic effect assessments for biocides. In line with point 8.2 the meeting could not accept this position as it was in contrast with the concept of continuous exposure as a result of biocidal use.

8.6 Aquatic effects assessment

See section 8.2.

8.7 Soil insects

See section 8.1.

8.8 Effect assessment for STP

SE questioned how the PNEC should be calculated when there would be no observed effect on activated sludge at the highest concentration tested or at the water solubility limit of the substance in a test? IT reminded that in case of substances with low water solubility (WS), the PNEC could be derived directly from WS level. ECB confirmed that this practice had been applied in the past, only if sufficient evidence was available that no effects occurred above the WS in an activated sludge test.

9 General comments - Wider scope than PT18 only

9.1 sewage treatment plant simulation

It was discussed when sewage treatment plant simulation were considered necessary. DK stated that if there is no ready or inherent biodegradation of a compound, a simulation test should be requested. This had already been described in the TGD and could be applied for STP. NL agreed with DK. FR stated that this lack of simulation testing can be accepted only if the substance is fully biodegradable and not if the substance is not inherently biodegradable because one would have insufficient information on metabolites in such case.

9.2 Metabolites

It was briefly discussed how metabolites should be dealt with: should ecotoxicological tests with a metabolite be required if its concentration reached more than 10% of the applied amount of the active substance? This aspect is clearly missing in the TGD for the water-sediment compartment.

DK stated that is was not correct to discuss these very generic issues with some of the MS absent. ECB stated that these generic comments would only be discussed to exchange ideas and not to endorse decisions. The opinions formulated at this workshop should be taken as flexible statements. It was decided to postpone a discussion on this generic issue to a later stage.

9.3 Insecticides used on stables

The problem was that critical key studies were performed with the formulation because the product was already evaluated under the PPP. Studies with the formulation instead of the active substance were presented in the dossier. For the acute toxicity both data were available with a.i. and formulation with evidence that the formulation lowers the toxicity. Would one be willing to accept an AF to account for this difference and extrapolate this phenomenon to predict chronic values? Based on the RA so far, critical issues were identified mainly for the aquatic compartment.

It was suggested to IT to submit the dossier and evaluate the outcome later.

ANNEX I

Workshop Agenda

Agenda of the workshop

Workshop on PT18 ESDs: Bottlenecks and suggestions for improvement

Part 1. General PT 18 ESD discussion

9.30h Introduction and aim of the meeting – ECB

9.45h Overview and Bottlenecks on PT18 ESD on "Stables and Manure" – Presentation from Ireland

10.15h Overview and Bottlenecks on PT18 ESD on "Household use" –
Presentation from France

10.45h Round table discussion – ECB moderates and presents outcome of questionnaire

12.00h Lunch

Part 2. Questionnaire – round table discussion

13.30h Overview of PT18 intended uses - ECB

13.45h Proposal for a specific environmental testing strategy for biocidal active substances / biocidal products which are to be used as insecticides in stables (PT18). Germany, Astrid Wiemann

14.00h Results and discussion of outcome questionnaire

16.30h Conclusions

17.00h Closing

ANNEX II

List of participants

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