Topical Scientific Workshop on Risk Assessment for the Sediment Compartment
7-8 May 2013, Helsinki, Finland

CASE STUDY – SUMMARY FORM

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(Number to be filled by the organisers)

INTRO TEXT

The case studies covering concrete examples of sediment risk assessments for particular chemicals and/or conditions are intended to support the breakout group discussions. All submitted case studies will be distributed to the participants as supporting material for the workshop and will included in the workshop proceedings. The Scientific Committee will select some case studies or selected areas of the case studies and will invite the authors to present these cases during the workshop, either at the plenary or during the break-out groups.

NOTE: By submitting this form the authors confirm that they have the ownership of the information presented in the case study and that they authorise ECHA to distribute the submitted information to the workshop participants and to publish it in paper and/or electronic forms as part of the workshop proceedings.

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Case study details

Case study is particularly relevant for the subthemes:
Note: the case study should cover all three areas, but please indicate if it is particularly relevant/informative for one or more subthemes

[X] Problem definition and conceptual model for sediment risk assessment
[X] Exposure assessment
[X] Effect assessment

Authors: Anne-Mari Karjalainen
Title: Comparison of Risk Assessment for an Industrial Chemical Between Two Regulatory Schemes
Keywords: EU RAR, REACH, CSR
Summary: A comparison of the risk assessment for the sediment compartment reported in an EU Risk Assessment Report (EU RAR) and in the Chemical safety report (CSR) of a registration dossier submitted for the same industrial chemical under the REACH Regulation was carried out. In the EU RAR measured concentrations in EU sewage treatment plants (STPs) and site specific volumes were used to arrive at PECs. In the CSR similar approach was taken for some scenarios whereas for most maximum allowable concentrations were used. The key parts of the effect assessments did not differ. A quantitative assessment of risks was carried out in both reports where environmental concentrations (PECs) were compared with (PNECs) to arrive at RCRs. The conclusion of no risk to the sediment compartment and environment as a whole was made in both reports.

Poster exhibition

The case study will be presented also as a poster

[ ] Yes [x] No

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SUGGESTED CONTENT FOR THE CASE STUDY: please try to limit the case study to 5 pages (or a maximum of 10 pages for complex case studies) focussing on the elements relevant for a broad general discussion on concepts, methods and approaches applicable to all chemicals or to specific chemical groups.

1. BACKGROUND AND PROBLEM DEFINITION

The purpose of this case study was to compare the risk assessment for the sediment compartment reported in an EU Risk Assessment Report (EU RAR) and in the Chemical safety report (CSR) of a registration dossier submitted under the REACH Regulation for that same substance. For the purposes of confidentiality substance specific details are not included. The EU RAR has been finalised a few years before the substance was registered under REACH. The Registrant has legal obligations under REACH Annex I to take the findings of the EU RAR into account in their substance safety assessment and registration submission. Throughout the CSR reference is indeed made to the EU RAR and typically chemical companies work closely together with the rapporteur member state in the EU RAR process.

Summary of substance uses and classification: The substance is an organic multi constituent substance with a harmonised environmental classification as Aquatic Chronic 1 H410: Very toxic to aquatic life with long lasting effects. In addition the hazard statement of P273: Avoid release to the environment is included. In Europe the substance has a production volume of 1000 to 10000 tonnes per annum. The substance is produced in Europe and may be imported; product compounding and end product formulation occurs at several sites. There are also consumer uses.

Summary of relevant physico-chemical properties: The substance has a relatively low vapour pressure. Its solubility in water is within the range of 1-10 mg/L. The substance has a water-octanol partitioning coefficient of around 5 whereas the LogKoc in sediment has been found to be approximately 4. The partition coefficients reported in the CSR have been taken from the EU RAR.

Summary of fate and behaviour in the environment: For the purposes of environmental risk assessment the substance is regarded as inherently biodegradable. In the environment this substance will partition to organic material and lipid tissues leading to elevated concentrations in sludge, sediment and soil organic matter in comparison to the surrounding water. The Predicted Environmental Concentrations (PECs) for surface water, sediment and soil have been calculated using conservative biodegradation rate constants expressed as half-life times that are less than 100 days in surface water and less than 200 days in the soil and sediment compartments . Same terminology is used in both the CSR and EU RAR and in the CSR reference is specifically made to the EU RAR.

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2. MAIN CASE STUDY DESCRIPTORS

- Comparative risks assessment for an industrial chemical (manufacturing and use) between two regulatory frames: REACH and the previous EU legislation on existing substances:
- Generic and site specific local scenarios
- Generic regional and continental assessment (EU)

3. CONCEPTUAL MODEL

The EU Risk Assessment was carried out in accordance with the Council Regulation (EEC) 793/931 on the evaluation and control of the risks of "existing" substances. The methods for carrying out an in-depth Risk Assessment at Community level are laid down in Commission Regulation (EC) 1488/942, which is supported by a technical guidance document 3. In the regulation there are four stages for reducing risks: data collection, priority setting, risk assessment and risk reduction. Tiered approach has thus been used for risk estimation.

Under REACH the legal basis for chemical safety and subsequent risk assessments is laid down in Article 14, whereas the general provisions for preparing CSRs are given in Annex I. ECHA guidance documents give more specific assistance. In REACH the chemical safety assessment (CSA) is the instrument to ensure that risks are identified and controlled. In the CSA process there are three major steps: the hazard assessment, the exposure assessment (EA) and risk characterisation (RC).

The conceptual model for both assessments is similar in both cases. The environmental risk assessment entails a quantitative assessment of risks whereby predicted environmental concentrations (PECs) are compared with predicted no effect concentrations (PNECs) as risk characterisation ratios (RCRs). The main difference is that the EU-RAR was done by the authorities (a Member State) and discussed at the EU level while the CSR is done by the company as part of the REACH registration dossier.

4. EXPOSURE ASSESSMENT

The exposure assessment (EA) in the CSR covers the life cycle stages from production to consumer use. Quantitative exposure assessment based on hazard assessment and using EUSES 2.1 was carried out by the registrant. Site specific exposure scenarios are given for the production site and some compounding sites. In addition, generic exposure scenarios have been developed for large/medium and small compounding sites and for small and large formulators separately. These generic exposure scenarios are based on industry specific SpERCs. A specific SpERCs is always identified, but no details are given. Rather, the reader is referred to the SpERC creator for justification.

According to the Registrant for the production site and specific formulation sites actual volumes of substance handled at these sites were used in exposure

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assessment, for some specific compounding sites site specific information is likewise given. For the generic large/medium compounding sites initial release factors have been based on measured data from 5 sites. For the generic formulation sites and small compounding sites the maximum amount of substance that can safely be released to an STP with a default capacity and default flow rate was calculated and used in estimating exposure. The SpERC initial release factors for the generic small compounding sites are reported to be based on the EU RAR.

At the end, for the production site the release rate to water is also calculated as the maximum tonnage that can be released from the site. There are no further explanations as to how the sediment predicted environmental concentration ($PEC_{sediment}$) has been arrived at. The freshwater $PEC_{sediment}$ is the same for all of the generic sites, for the sites were site specific information has been used the $PEC_{sediment}$ is considerably lower. The marine $PEC_{sediment}$ has been given for the generic sites and is 10 orders of magnitude smaller.

Under the overview of exposure scenarios in the CSR six exposure scenarios are identified for consumers. These scenarios are said to cover also a number of other consumer use/product scenarios. These are not further specified as according to the Registrant the releases will not exceed releases from a specified scenario and are thus covered. For the environmental assessment all uses by workers, professionals and consumers have been regarded as wide dispersive with a worst-case release of 100 % and finally all have been addressed in one generic wide-dispersive use scenario. The initial release factor to water is set at 100 %. However, substance concentrations have been measured in various STPs in EU. These are reported in detail in the EU RAR. In the CSR in the assessment of this wide dispersive-use the 90th-percentile concentrations were used to replace the results calculated from use volumes and release factors.

EU RAR: In the EU RAR releases have likewise been discussed for each life stage and site specific information has been used for calculating releases from the production site and some compounding sites. Generic scenarios are also given for large/medium and small compounding sites and for small and large formulators. EUSES has been used in the exposure estimation. The reported PECs are based on the 90^{th} percentile of the measured values in EU STPs or site specific volumes and are in general somewhat lower than in the CSR.

Even when in the CSR it is stated that the actual volumes were used for estimating releases from the production site, only the maximum tonnage that may safely be released from the production site is given. This is below the amount lost from the site daily reported in the EU RAR based on site specific data.

Whereas in the CSR several consumer use scenarios are identified even if at the end they are grouped together under the wide-dispersive use scenario, no specific scenarios for consumer use are defined in the EU RAR although different uses are listed. Total volume of substance used in the EU has been used as basis for

estimating a PEC. It has been assumed that all consumer uses will result in substance being released to waste water and STP.

As according to the EU RAR the quantification of the material being released from compounding sites is rather difficult, the 90th percentile of the available monitoring data rather than modelling based on volumes used in compounding has thus been used in estimating exposure. In the CSR this approach has been used for the wide-dispersive use scenario only. The reported 90th percentile values are the same in the CSR and the EU RAR and there is a close match between the local $PEC_{sediment}$ values reported for the wide-dispersive use.

In the CSR, one regional PEC per environmental compartment is given whereas in the EU RAR different PECs are given for different areas of EU. There is no explanation as to why this approach has not been used in the CSR. Likewise the actual measured concentrations in the EU RAR have been divided according to regions and it is stated that for the risk assessment the Southern Scenario is used. From the numbers submitted it is clear that the Southern European scenario has been used also in the wide-dispersive use scenario in the CSR although this has not been stated.

5. EFFECT ASSESSMENT

The following sediment toxicity studies were submitted by the Registrant:

- *Hyalella azteca* 28-day sediment-water toxicity test using spiked sediment (OECD 218). 28-d NOEC based on growth (nominal and measured). Most sensitive of the species tested.

- *Lumbriculus variegatus* 28-day sediment-water toxicity test using spiked sediment (OECD 218). 28-d NOEC based on reproduction (nominal). NOEC twice that of *H. azteca.*

- *Chironomus riparius* 28-day sediment-water toxicity test using spiked sediment (OECD 218). 28-d NOEC based on emergency rate (nominal). Least sensitive. NOEC circa 20 times higher than for the most sensitive species.

The lowest NOEC from the *H. Azteca* study was standardised to 5 % organic carbon content, to match the PEC sediment OC content.The PNECsediment has been derived using an assessment factor of 10 (three long-term studies available).For comparison $PNEC_{sediment}$ was also derived using the equilibrium partitioning method (EPM). $PNEC_{sediment}$ derived using the EPM is 5 times higher than the $PNEC_{sediment}$ based on AF.

In addition, in the CSR reference is made to bioaccumulation studies in *C. riparius* and *L. variegatus*. For *C. riparius* the results show biotransformation and not bioaccumulation whereas *L. variagetus* was bioaccumulating this substance to a high degree.

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Same 3 sediment toxicity studies are included in the EU RAR and the lowest NOEC has been used for PNEC derivation. The same $PNEC_{sediment}$ and $PNEC_{sediment,eqb}$ are reported. However, the bioaccumulation studies are not included although they have been available when the RAR was compiled. On the other hand LC50 data from two other poorly reported studies on sediment organisms *Chironomus riparius* and *Lumbriculus variegatus* tested in water is included in the EU RAR and omitted from the registration dossier.

6. RISK CHARACTERISATION & CONCLUSIONS

In the CSR quantitative risk characterisation has been conducted. With regards to sediment, for the production site and the formulation sites with specific exposure scenarios risk characterisation ratios (RCRs) are given for freshwater sediment alone. For the generic exposure scenarios also marine sediment is included.

For the exposure scenarios where maximum allowable concentrations of emissions were used in exposure assessment the RCRs are 1. Registrant has concluded that risks are controlled. For marine water sediment the RCRs are around 0.5. The sediment RCRs are the same for all generic ESs for industrial uses. For worker, professional and consumer uses the environmental risk characterisation has been grouped under one entry alone, the wide-dispersive use exposure scenario. The RCRs here are below 1 and conclusion of risk is controlled is made. Under overall exposure (combined for all relevant emission/release sources) the combined marine sediment RCR from all wide dispersive uses is below 0.5. The RCR for freshwater sediment has for some reason been omitted. There is no explanation/justification for this omission.

In the EU RAR all sediment RCRs are below 1. The RCRs differ from those reported in the CSR since different approach has been used. In the EU RAR the actual measured concentrations were used whereas in several scenarios in the CSR maximum allowable emissions were defined or SpERCs were used. Thus it is not possible to directly compare the RCRs. The same monitoring values were used in the wide-dispersive use scenario and the private use scenario in the EU RAR. The freshwater sediment RCRs given for this scenario in the CSR and the EU RAR are a very close match. In the CSR the very generic conclusion of risks are controlled is made with regards to the environmental risk assessment including sediment, there are no other details given in any sections. In the EU RAR the conclusion of the risk assessment for the aquatic compartment is that there is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already. The conclusion applies to all uses.

7. ATTACHMENTS, REFERENCES AND BACKGROUND MATERIAL

Both guidance documents are available from the list prepared for the workshop.