FKZ 3710 63 403

CONSOLIDATION OF INFORMATION FOR MIXTURES UNDER REACH

ANALYSIS OF THE DPD+ METHOD

EXECUTIVE SUMMARY

November, 2012

Ökopol GmbH
Institut für Ökologie und Politik
Nernstweg 32-34
D-22765 Hamburg

Authors: Antonia Reihlen, Dirk Jepsen, Olaf Wirth

Imprint

ÖKOPOL GmbH
Institut für Ökologie und Politik

Nernstweg 32–34
D – 22765 Hamburg
@0049-40-39 100 2 0
fax:0049-40-39 100 2 33

www.oekopol.de
info@oekopol.de

Content

Figures

Tables

1 CONTEXT

The identification and communication of safe conditions of use (CoU) including risk management measures (RMM) for substances is one central mechanism of REACH to improve the level of protection of human health and the environment.

Formulators play a crucial role in the communication along the chemicals supply chains: they ensure a proper link between substance registrants and end-users of substances as such, in mixtures or in articles. Formulators frequently have a good understanding of the chemistry of substances and mixtures as well as the conditions under which they are applied by their end-users. They are required to forward received information to their customers in an "adequate form"; i.e. a form that is understandable and helpful and takes account of all the substances eventually present in a mixture.

The core questions analysed in this project were how two tasks of formulators can be efficiently performed. These are:

- Task 1– Identification of operational conditions (OCs) and RMMs ensuring safe use of all substances and mixtures contained in a produced mixture, based on the information received from substance and mixtures suppliers[1] or generated by himself[2]- and
- Task 2 – Processing and forwarding that information in an understandable language and manageable form to the customers.

These two tasks are commonly called "consolidation of information". The term "consolidation" does not exist in the REACH text but evolved in the discussion on the downstream user (DU) obligations during REACH implementation..

The consolidation process is not entirely new to formulators: The compilation of safety data sheets (SDSs) required the use of substance information, also on RMMs, already before REACH came into force. However, under REACH the OCs and RMMs may be described more precisely and quantitative information on efficiencies of emission and exposure reduction may have to be processed by the formulator.

The ECHA DU guidance should provide respective support to formulators. Chapter 14 "Information on preparations to be delivered by formulators" describes the legal obligations and outlines a workflow to structure and support the collection, processing and use of information on CoU to develop SDSs and other information for mixtures. In this workflow a critical component approach (CCA) is mentioned but it has never been further described in the ECHA guidance documents.

[1] I.e. safety data sheet (SDS), exposure scenario(s) (ESs) and/or information according to Article 32

[2] E.g. results of DU chemical safety reports (DU CSRs) for substances, testing of mixtures

The method "DPD+" was developed by CEFIC[3] based on a first proposal by two of its sector associations (ESIG and FEICA) and industry, the EU Commission and ECHA discussed it at a workshop in May 2008. CEFIC states that DPD+ is one way of implementing the workflow on preparing information for mixtures outlined in ECHA's downstream user guidance.

2 AIM OF PROJECT

The first aim of the German UFOPLAN project "Consolidation of Information for Mixtures under REACH" was to evaluate whether the consolidation of information for mixtures using DPD+

- ensures that all potential environmental risks are correctly covered,
- supports the formulator in efficiently identifying the operational conditions (OCs) and risk management measures (RMMs) that ensure safe use of all substances in the mixture,
- leads to the derivation of adequate (understandable, meaningful and practically implementable) information to the end-users of the mixture.

The second aim of the project was to propose how an appropriate method for the consolidation of information for mixtures could be developed involving either

- the (potentially necessary) improvement of DPD+ or
- the outline of an alternative approach.

The project was performed by Ökopol between 11/2010 and 10/2011 as desk research. It only concerned environmental risks and information; occupational and consumer aspects were not considered.

This executive summary presents the main project results in the following sections:

- 3.1: Core elements of DPD+ and similar prioritisation approaches
- 3.2: Limitations of DPD+ in identifying risk determining substances for the environment
- 3.3: Limitations of DPD+ in consolidating OCs and RMMs
- 3.4: Non prioritisation approach as alternative to DPD+
- 3.5: Exemplification of DPD+ and the alternative approach
- 4: Recommendations

The final report contains, besides the details of the assessment information on legal obligations, information availability, mixture toxicity assessment and some more detailed conclusions and recommendations[4].

[3] CEFIC: "REACH: Exposure scenarios for preparations - Methodology for the identification of substances that represent the dominant risks to human health and/or the environment and the drivers for risk management measures", June 2009; http://www.cefic.org/Documents/IndustrySupport/ES_for-preparations-DPD+methodology.pdf

[4] Several specific references are included here in the executive summary to enable easy identification of the related parts in the final report.

3 MAIN PROJECT RESULTS

3.1 Core elements of DPD$^+$ and similar prioritization approaches

DPD$^+$ aims to support formulators in consolidating information received with their input materials (safety data sheets (SDSs), exposure scenarios (ESs) and information according to Article 32) in order to develop information to be forwarded with their mixtures. The workflow and core elements of DPD$^+$ are described in the CEFIC guidance[3]. The approach is based on Chapter 14 of the ECHA guidance document for downstream users[5].

The workflow of DPD$^+$ and the ECHA approach are divided into two steps:

- Step 1: Selection of the risk determining substance(s), called “lead substances” (LS) by CEFIC and “critical components” (CC) by ECHA
- Step 2: Use of the OCs and RMMs in the risk determining substances’ ESs as basis for safe CoU which, after a consistency check, should be communicated with the mixture (this step is neither well elaborated by CEFIC nor the ECHA guidance)

Figure 1 gives an overview of the process which is applicable to any prioritising approach. DPD$^+$ as the most elaborated prioritising approach for consolidation was analysed in detail regarding whether it results in coverage of all environmental risks and if the information on OCs and RMMs selected for communication to the downstream users is adequate. DPD$^+$ is therefore specifically addressed in the following sections[6].

[5] •http://echa.europa.eu/documents/10162/13634/du_en.pdf

[6] For a more detailed description of the method and how it was interpreted by Ökopol see Section 6 of the final report.

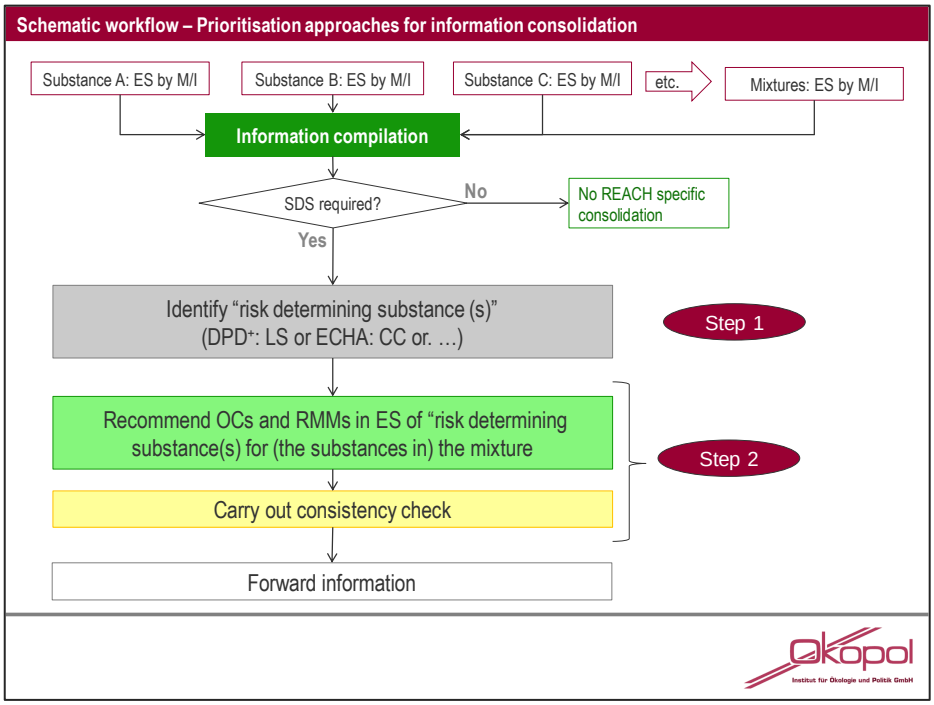

Figure 1: Generic workflow for prioritising approaches to consolidation of information on substances for mixtures

DPD$^+$ sets out detailed rules for the selection of lead substances[7] based on the classification principles of the dangerous preparations directive (Step 1). All information on OCs and RMMs from the lead substance(s) ES(s) should be compiled and reviewed in order to derive the information for the mixtures (Step 2). With regard to the review of information (consistency check) in Step 19.7 of the CEFIC guidance it is specified that it should serve to

"[…] remove any replication and ensure there are no inconsistencies in the information from the individual substance ESs. In the event that there are differences, the highest or most demanding OC and/or RMM must be selected."

The in-depth assessment of DPD$^+$ aimed to answer two questions:

1. (How) Is the identification of environmental risks limited, incomplete or wrong if lead substances are selected based on the classification?
2. Which challenges for the communication of appropriate OCs and RMMs are connected with a prioritisation method like DPD$^+$?

3.2 Limitations of DPD$^+$ in identifying the risk determining substance for the environment

In this section only the main limitations are presented, the details of the assessment and further minor limitations are presented in Chapter 7 of the final report.

[7] Normally only one lead substance is selected for the environment. Only if the lead substance indicator value (LSI) varies within 10% for two or more substances all these selected as LS.

DPD$^+$ defines the substances with the highest lead substance indicator (LSI) as environmental lead substance. The LSI is calculated as follows:

$$LSI = Conc_{mix} / Conc_{lim}$$

$Conc_{mix}$: concentration of the substance in the mixture

$Conc_{lim}$: limit concentration triggering classification for the classification of the substance

The following Table 1 shows which limit concentrations to use for which R-phrase.

Table 1: Limit concentrations for the identification of LSIs

R-phrase	Limit concentration ($Conc_{lim}$)
R53	25 %
R 52/53	25 %
R 51/53	2.5%
R 50/53	0.25%
R 50	0.25 %
R 50; R50/53	Specific concentration limits may have been introduced

Because the classification system is used to identify the lead substance, **hazards** other than those covered by the aquatic classification **are systematically overlooked** by DPD$^+$. These hazards are normally addressed in the registrants' chemical safety assessments. The respective OCs and potentially necessary RMMs in the ES may be lost in the consolidation process, if these hazards are not covered by the selection of lead substances. Amongst others, the following environmental hazards may not be (adequately) represented by the lead substance[8]:

- hazards to microorganisms in the STP, to sediments and/or to soils[9]; (final report, Chapters 7.3 and 8),
- hazards via air to terrestrial organisms and plants or to the ozone layer are completely missing[10] (final report, Chapters 7.1., 7.3 and 8),

Secondly, the **environmental classification does not always indicate** the substance with **the highest risk** expressed as risk characterization ratio (RCR). This is due to two reasons:

- the step-wise increase of classification categories and connected concentration limits: For substances with an aquatic toxicity and/or an actual concentration in the mixture which is very close to the respective limit values the lead substance indicators may not represent the actual risk (c.f. example in the final report Table 7.12)
- the lack of consideration of the mobility of a substance, in particular the volatility and water solubility, which may lead to a wrong weighting of hazards/risks (final report Chapter 7.3).

[8] Only if the substance bearing this risk is at the same time the lead substance for the environment, i.e. has an aquatic classification, the formulator will consider respective risks and information via the use of the related ES.

[9] These risks don't always coincide with the aquatic classification of a substance.

[10] The classification system according to Directive 67/548/EEC and the CLP-Regulation include the classification of ozone depleting substances but this has not been taken over to DPD$^+$.

Consequently, the identified options to improve DPD$^+$ are for example to select two environmental lead substances – one for the aquatic environment and one via air – and to include respective indicators, such as the classification as ozone depleting substance or toxicity indicators from studies with plants or testing of terrestrial organisms. In addition it could be considered to use the LC_{50} values instead of the limit concentrations in deriving the LSI and to include mobility as a parameter in to improve the quality of the LSI.

In conclusion, the lead substances selected according to DPD$^+$ may not always determine the overall risk of the mixture and is not necessarily the substance which factually poses the highest risks. There are several options to improve the selection of environmental LS. The relevance of these shortcomings derived by desk research for actual mixtures could not be evaluated during the project[11].

3.3 Limitations of DPD$^+$ in consolidating OCs and RMMs

According to DPD$^+$ the operational conditions (OCs) and risk management measures (RMMs) of the lead substance's (LS) exposure scenario (ES) are copied to the ES for the mixture[12]. In a second step the consistency of information should be ensured (c.f. Section 3.1). Since normally only one environmental LS is selected the consistency check is not likely to change the RMMs but may lead to changes in OCs, because of the consolidation for occupational health[13]. Consequently, the OCs may differ but the RMMs in the ES of a mixture are in most cases the same as described in the ES of the LS. Due to this, formulators consolidating according to DPD$^+$ may be formally incompliant and risks to the environment may not be adequately controlled.

Apart from this, there are some other reasons why adequate control of risks may not be achieved by consolidation based on DPD$^+$, which concern the dependency of emission pathways and RMMs on substance properties (c.f. Chapter 9, final report). It is important to note that the formulator is not legally required to check if the CoUs he receives for the substances ensure that risk are adequately controlled. However, in order to ensure that he forwards useful information "in an adequate form" to his clients he may consider taking more responsibility than required.

3.3.1 Formal incompliance and factual risks

The conditions of use are defined for each substance separately and they are separately binding for any downstream user[14]. Adequate control of risks is

[11] Because at that time no REACH compliant SDS (including ES) where available to assess substances in marketed formulations to the necessary extend and level of detail, a "laboratory test" using modeled mixtures showed that if DPD+ were improved, different substances would be selected as lead substance if DPD+ was modified with these changes (see also Section 3.5).

[12] REACH does not require the preparation of an ES for the mixture. Apart from providing a consolidated mixture ES it is also possible to forward the individual substance ESs received or include information in the main body of the SDS.

[13] 3 lead substances are identified for human health and hence, 3 sets of operational conditions are compiled together with those, which are selected for the environmental LS.

[14] The term safe use of "a substance as such, in mixtures or in articles" is used. The duties to identify, implement and recommend the safe CoU apply to the individual substances.

achieved if the risk characterization ratio (RCR), which is the quotient of a substance's predicted environmental concentration (PEC) and predicted no effect concentration (PNEC) remains under the value of 1. Only if the conditions of use for the mixture cover all conditions of use (CoU) received with the input materials, the formulator can rely on that the RCR remains under 1 for all substances in the mixture.

DPD^{+} disregards the conditions of use which are defined and recommended for any substance other than the lead substance. Although these substances may not determine the overall risk, it is still formally required to ensure that also their conditions of use are implemented and communicated.

Consequently, without checking that all conditions of use received are covered by the conditions of the lead substance, the formulator risks being formally incompliant with REACH using DPD^{+}. A refined scope and aim of the consistency check including a cross check with all received information and potential revisions of conditions, if necessary, could solve this problem.

3.3.2 Appropriateness of RMMs

RMMs are appropriate when they achieve the intended emission or exposure reduction (efficiency) and when it is feasible to implement them in a given process. The following core aspects are relevant for determining a RMM's appropriateness[15]:

1) The efficiency of most environmental RMMs depends on the properties of the substances to be treated. For example, there is no biodegradation of metals or inorganic compounds and volatile substances are not easy to contain in landfills etc. Hence, for different substances in a mixture the same RMM has a different efficiency.
2) The type of the process and the mobility properties of substances determine how a substance is emitted from the process.
    a. The efficiency of RMMs needs to take into account which fraction of the emitted substance is actually captured and treated by the device. This is frequently not considered.
    b. Risks may occur in different compartments than the emission pathway. Therefore, for example substances that deposit from air may cause risks in surface waters but RMMs are needed for the air pathway.
3) RMMs may be incompatible with certain emission types (e.g. ultrafiltration should not be used for water emissions with a high share of solid particles) and is hence inappropriate for certain processes
4) The efficiency of RMMs may be reduced by certain substances, e.g. some substances may be catalyst poisons or increase another substances solubility thereby preventing sedimentation in water treatment.

[15] Approaches for the selection of appropriate RMMs are explored in an ongoing project by the German UBA "Efficiency of risk management measures for emission reduction" (FKZ 3711 63 419)

5) In practice, some RMMs are state of the art, others are only applied in specific cases; combinations of measures may preferred over highly efficient single RMMs and vice versa.

Formulators using DPD$^+$ who only check the consistency between selected lead substances may risk not being in conformity with the requirements to forward information along the supply chain.

If DPD$^+$ were implemented with a completeness check that considers all substances' information, the formulator would select the strictest OCs from all received ESs and may either

- select the RMM with the highest efficiency or
- formally "add up" all different RMMs.

If the RMM with the highest efficiency was selected, all aspects listed above may apply and, apart from a potential legal incompliance, lead to both lack of factual control of risk for some of the substances and the selection of a RMM which is not appropriate for the process. The latter is however only likely to occur in cases, where the operational conditions are defined so widely that fairly different processes could be covered[16].

If all RMMs were added up, legal compliance would be definitely achieved but appropriateness is not ensured as the approach is overly conservative and not likely to be implemented by any DU.

3.3.3 Conclusions on the selection of CoUs

The current description of DPD$^+$ does not ensure legal compliance in all cases, because it is not explicitly prescribed to check that the conditions of use of any substance for which respective information is received is covered by the information forwarded with the mixture. The problem of legal compliance could be solved by including all substances in the consistency check and recommending to list all RMMs for the mixture.

As described above this "solution" would result in RMMs which often are not implementable in practice. Consequences would be communication up the supply chains in order to have the chemical safety assessment refined, formulators conducting DU CSRs, the cease of uses or incompliance of DUs.

This analysis not only shows that a prioritization approach like DPD$^+$ is partly insufficient to ensure compliance and control of risk but also highlights the challenges in defining appropriate risk management measures and poses the question of which actor in the supply chain is able (and can take the responsibility) for the identification of such adequate RMMs (c.f. recommendations in Section 4).

[16] E.g. the PROC 7 – industrial spraying may be used to define the process; different types of the process could be understood, such as electrostatic powder coating or lacquering with high pressure guns. The former would require quite different RMMs than the second.

3.4 Non prioritisation approach as alternative to DPD+

An alternative to consolidation methods prioritizing risk determining substances is seen in considering all information on environmentally relevant substances from the very beginning of the consolidation process. In addition, sector knowledge of the formulator on OCs and RMMs should be integrated at an early stage to ensure that the CoUs are implementable in practice.

Both approaches, DPD+ as an example of a prioritizing approach and a non-prioritizing method for consolidating information for mixtures are illustrated in the following workflows.

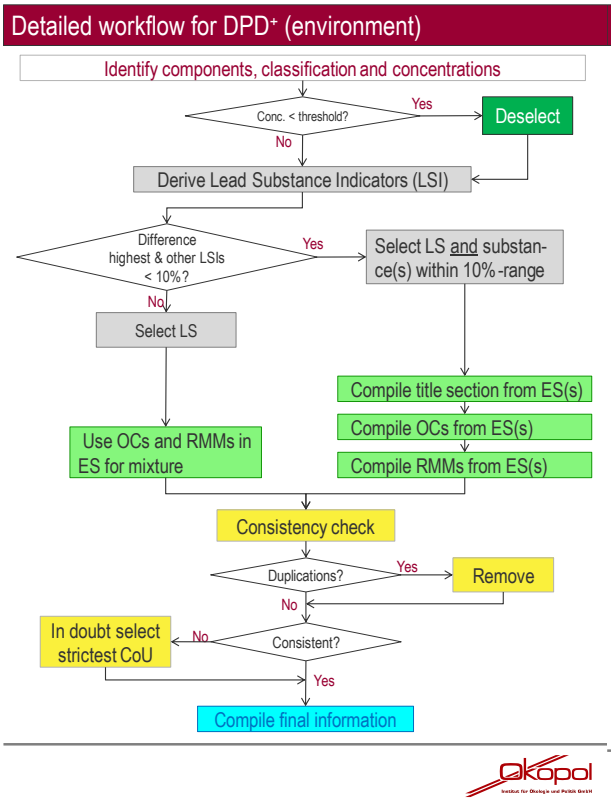

Figure 2: Workflow of DPD+

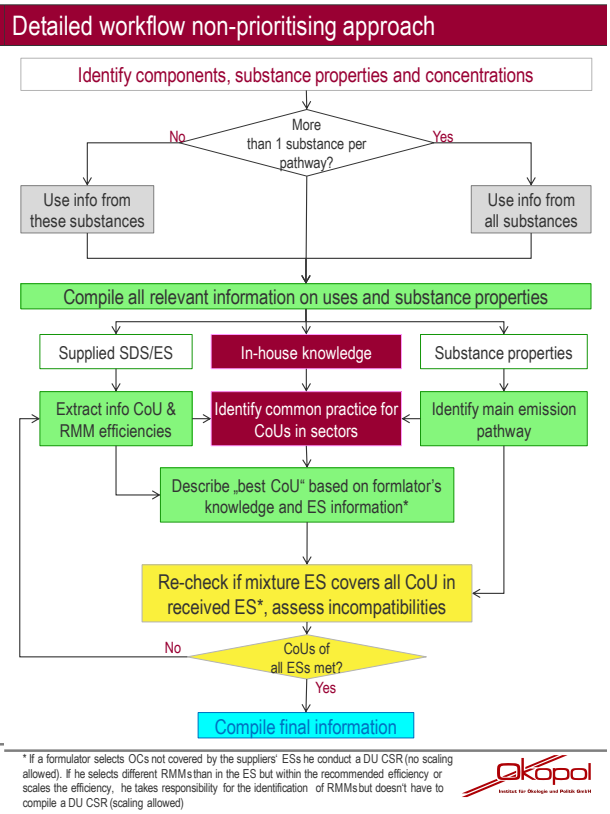

Figure 3: Workflow of non-prioritizing approach

The core differences between the two approaches are that

- DPD+ starts with information from only one substance which is taken from the ES and the non-prioritizing approach starts using all available information from the relevant substances,
- the non-prioritizing approach explicitly foresees the use of practical knowledge of the formulator, which may lead to the identification of RMMs which are appropriate but not explicitly named in the input materials' ESs.

Regardless of the method, a consistency check is needed at the end of each process; however the factual outcome may be different as well as the resource needs to perform it.

3.5 Exemplification of DPD$^+$ compared to a non-prioritizing approach

The different approaches to consolidate information were exemplified on a modelled basis (c.f. Chapter 10, final report): mixtures were defined for two different uses (metal cutting fluids and textile finishing agents) based on generic information on their normal composition. Each of the modelled mixture contained 6 substances posing different environmental hazards[17]. For each substance an ES was compiled and the consolidation process played through using both methods[18]. It was assumed that the substance ESs contained similar information on OCs, e.g. because the same use descriptions were used by the registrants. Due to the theoretical basis of the exemplification, it cannot be predicted to which extend the identified issues occur in "real-life"-situations.

3.5.1 Illustration of approaches

The core factual results of the exemplification confirm the conclusions on the limitations of DPD$^+$ from the generic assessment (c.f. Section 3.3) regarding the selection of CoUs. The following two tables illustrate these findings for the textile finishing agent. The first table illustrates DPD+, the second the non – prioritizing approach. The tables should be read from the left to the right.

In the first two columns of both tables, the RMMs for water emissions and air emissions are quoted from the suppliers' ES. In the orang shaded columns, for DPD$^+$ the initial RMMs selection from the lead substances ES is presented and for the non-prioritizing approach the RMMs according to sector and process knowledge are given. In the grey shaded columns, the RMMs are presented which would be selected after a consistency check aimed at legal compliance. For DPD$^+$ in addition the selection is presented that would result if only the RMM with the highest efficiency was chosen.

[17] The modeled exemplification was done because practical examples were missing by that time. Furthermore the use of modeled mixtures allowed checking the consequences of using either method in a targeted way.

[18] The exemplification also included an approach called "revised DPD$^+$" where the proposed improvement options were included. This is not included in the executive summary in order to focus on the most relevant aspects.

Table 2: Illustration of RMM selection according to DPD⁺ in a modeled textile finishing mixture

Substance	RMM in ES of supplier for air	RMM in ES of supplier for water	RMM in mixture ES from lead substance (air)	RMM in mixture ES from lead substance (water)	Consistency check (formal compliance) (air)	Consistency check (formal compliance) (water)	Consistency check selecting only strictest measure by efficiency	Consistency check selecting only strictest measure by efficiency
A (organic)	Thermal oxidiser efficiency > 90%	Biological treatment acc. to degradability (87%)	Not needed	Precipitation efficiency > 95% and filtration efficiency > 95%	Thermal oxidiser efficiency > 90% B not considered as not classified Carbon filter efficiency > 95% ~~Not needed~~	Biological treatment acc. to degradability and Filtration efficiency > 99% and Precipitation efficiency > 95% and ~~filtration efficiency > 95%~~ Ozone oxidation efficiency > 90%	Substance B is not considered because it is not classified Carbon filter > 95% efficiency	Substance B is not considered because it is not classified Precipitation efficiency > 95% and filtration efficiency > 95% *RMM may not be sufficient for the removal of the organic substance F*
B (volatile organic); hazardous but not classified	Thermal oxidiser efficiency > 99.99%	Biological treatment acc. to degradability (67%) and filtration efficiency > 99%						
C (organic)	Not needed	Ultrafiltration efficiency > 80%						
D (volatile organic)	Carbon filter efficiency > 95%	Filtration efficiency > 85%						
E (metal) **Lead substance acc. to DPD⁺**	Not needed	Precipitation efficiency > 95% and filtration efficiency > 95%						
F (organic)	Not needed	Filtration efficiency > 92% and ozone oxidation efficiency > 90%						

Table 3: Illustration of RMM selection according to a non-prioritizing and sector knowledge based approach in a modeled textile finishing mixture

Substance	RMM in ES of supplier for air	RMM in ES of supplier for water	Selection by sector knowledge air	Selection by sector knowledge water	Check of ES coverage (air)	Check of ES coverage (water)
A (organic)	Thermal oxidiser efficiency > 90%	Biological treatment 87% acc. to degradability	Thermal oxidiser eff. 99.8% with exhaust filter for particles / metals eff. 80 – 95% depending on substance	Precipitation eff. metals & organics 95%; filtration and biological treatment (eff. acc. to degradability)	OK	OK
B (VOC); hazardous but not classified	Thermal oxidiser efficiency > 99.99%	Biological treatment acc. to degradability (67%) and filtration efficiency > 99%			OK	OK; filtration efficiency ensured due to additional precipitation step (responsibility of selection of RMM shifts to formulator)
C (organic)	Not needed	Ultrafiltration efficiency > 80%			OK	OK
D (VOC)	Carbon filter efficiency > 95%	Filtration efficiency > 85%			May be critical, detailed substance specific check needed	OK
E (metal)	Not needed	Precipitation efficiency > 95% and filtration efficiency > 95%			OK	OK; filtration efficiency may have to be verified
F (organic)	Not needed	Filtration efficiency > 92% and ozone oxidation efficiency > 90%			OK	OK; oxidation covered by biology and precipitation

The exemplification shows differences in the selection of RMMs and illustrates the compliance and practical issues discussed before. It is notable that the substance B, which requires strict RMMs for air would, due to a missing aquatic classification, not be considered by DPD^{+}. It can be seen that the lead substance not necessarily has the ES with the strictest RMMs and the differences in applicability of RMMs are particularly apparent when comparing the measures for metals and for organic substances.

Furthermore, the examples once more illustrate that the communication of specific RMMs rather than only required efficiencies by the registrant may even cause more problems that it supports the formulators. Related to that it is apparent, that the core question of obtaining the efficiency of RMMs in relation to specific substances (substance properties) is an issue which cannot be resolved by consolidation but needs separate attention.

3.5.2 General conclusions from exemplification

The more general learning from the exemplification is the following:

The selection of OCs and RMMs cannot be fully automated. Ensuring consistency and adequacy of conditions of use requires expertise and individual assessment of information in ESs.

So the final selection of RMMs using DPD^{+} mainly depends on the quality of the consistency check. If the consistency check:

- is not done at all the CoUs for the mixture may not cover all ESs and hence be incompliant,
- is done only with view to compliance (adding up all RMMs) the CoUs are likely to be overly strict and not implementable in practice,
- is done to high quality the CoUs are likely to be compliant and appropriate. In this case there is no difference to the non-prioritizing approach.

Whether the evaluation of all information is performed at the beginning (non-prioritizing approach) or the end ("DPD^{+} with high quality consistency check") of the process doesn't make a big difference with regard to compliance.

Both approaches are manageable if the CoUs received in the suppliers' ESs are comparable in structure and content. Whereas the RMMs only concern the emission from the process, the OCs determine how a substance is to be applied. The OCs should not be subject to scaling[19]. If the CoUs of the input materials' ESs differ the formulator needs to take action to bring the ES into a comparable format[20].

[19] Scaling is the modification of conditions of use in an exposure scenario by a downstream user in cases, where the actual use differs from the conditions in the ES but is believed to remain within the scope. Regarding the environment scaling is understood as applicable to the efficiency of RMMs and the environmental conditions, e.g. lower or larger dilution volumes in rivers etc. For more information see for example http://www.umweltdaten.de/publikationen/fpdf-l/4224.pdf

[20] This situation is similar to a "use not covered by the ES"; the formulator may scale the conditions which can be scaled or conduct a DU CSR or communicate with his supplier or stop the use of the substance.

The non-prioritizing approach is likely to derive more realistic CoUs if combined with in-house knowledge from the formulator at an early stage of the process. This could be further supported if the registrant communicated needed RMM efficiencies rather than detailed technical types of measures because the process of selecting appropriate RMMs by the formulator may be simpler if he first identifies the most frequently applied measures and then checks, if the required (substance-specific) efficiencies of emission reduction can be achieved for any of the relevant components.

The (legal) consequences regarding a possible shift of responsibility for the identification of RMMs from the registrant to the DU if the registrant only recommends required efficiencies and the formulator identifies the specific technical measure were not subject to the study, but should be further explored to inform the discussion on this possible future option.

The need to consider all information is obvious for the non-prioritizing approach. It is not so obvious but rather "hidden in the consistency check" for DPD$^+$. In particular an IT-implementation of DPD$^+$ may bear the risk that the results are not quality checked in such a way by the users.

4 RECOMMONDATIONS

Based on the conclusions from the project the consultants developed the following set of recommendations.

Open discussion with the chemical industry

The results of the analysis of DPD$^+$ should be discussed openly with the responsible persons/working groups at CEFIC. The aim of a discussion should be to raise awareness and a common understanding of the identified shortcomings of the method.

It should be communicated that an improvement of the identified weaknesses of DPD$^+$ may not resolve the core challenge of the identification and selection of appropriate environmental RMMs. The substance-specific efficiencies of RMMs and the influence of the mobility of substances on their emission pathways from processes and in the environment require that the identification of conditions of safe use consider all information on substances potentially causing an environmental risk. This contradicts an approach to prioritise information for further use.

It should be pointed out that the use of DPD$^+$ may result in the communication of CoU which are not covered by the received ESs, and that formulators would run the risk of non-conformity with REACH.

Avoid integration of DPD$^+$ in IT-tools if thorough quality checks cannot be ensured

The problem of non-conformity with REACH may be particularly relevant, if DPD$^+$ or other prioritising approaches are integrated in IT-tools, because the users normally do not actually reconstruct the logics of automated consolidation, and are not likely to carefully review the outcome of such computer-generated information.

With view to the fact that an effective consistency check is necessary for the initial consolidation results of DPD$^+$ and that the consolidation of conditions of use is in general difficult to standardize, an IT-implementation at the current time may not be helpful at all.

Involve the downstream user industry

The result of the generic analysis and the modelled exemplification of DPD$^+$ should be communicated to the downstream user industries, in particular to the formulators of mixtures. They should be made aware of the limitations of DPD$^+$ and the need to conduct a thorough consistency check if the method is applied, in order to ensure formal conformity with the ESs.

Secondly and even more important is the discussion on the standardized descriptions of use by formulators and end-users of mixtures up the supply chain, in order to harmonize ESs received from suppliers. This approach of "making a use known to the supplier" has proven to be effective[21]. This could generate the following benefits:

- Registrants would be supported in their registration process. This may be particularly important for the second registration deadline, as more small and medium sized enterprises are expected to register.
- OCs would be communicated in a harmonized way, facilitating the checking of coverage of ESs by formulators' and end-users.
- Described OCs and release factors may be less conservative than ERCs or spERCs reducing the need for additional RMMs
- Formulators would receive appropriate RMM recommendations instead of theoretical technically described measures which cause difficulties in consolidation.
- Appropriate and already implemented RMMs would be recommended rather than measures which are not practical or overly strict.

Downstream users may once more consider how a sector-wide process of compiling information on uses could be organized and in which form information could be provided up stream to registrants. One difficulty currently faced in this discussion is that there is little confidence among DUs in the readiness and the

[21] In the exemplification, the conditions of use were described in a similar way for each of the two examples which can be regarded as all suppliers having used the same format for providing their exposure scenarios. The information was compiled at a higher level of detail than e.g. the spERCs and could represent an example of how DUs would make their use known to a supplier. This facilitated the consolidation of information significantly.

available resources of suppliers to work with information provided from downstream. Hence, one precondition for the DUs' motivation would be a clear commitment of registrants to work with the DUs, e.g. in specific information exchange fora.

Discuss responsibility for the identification of RMMs

The project showed that consolidation of information is more difficult if specific RMMs are recommended by the registrant and may even result in wrong, inapplicable or incompatible measures. Therefore a discussion is needed about which actors should actually identify the appropriate technical measures.

Under REACH formulators are neither to make exposure assessments nor to calculate risk characterization ratios or to identify the conditions that ensure adequate control of risk for single substances. This is clearly the task of the registrant. However, this project showed that an approach where the formulator defines the technical specification of RMMs that achieve an efficiency of emission / exposure reduction which is calculated and communicated by the registrant may be useful to develop practical and meaningful information on risk management. This would also better ensure that the measures suits to the process, all substances in the mixture and the mixture as a whole and achieves the necessary emission and exposure reduction[22].

Another approach would be to have an informal and iterative information exchange between registrants and formulators based on exposure scenarios before registration or formal communication via the SDSs.[23]

Further activities

The further development or support of DPD^{+} is not recommended based on the results of this project. However, the generation of knowledge and experience in the consolidation process using real-life substances and mixtures is of high priority to identify where (standardized) support tools could be developed and how they could look like. An analysis of challenges faced by the formulators applying non-prioritizing approaches and "manually" consolidating ESs of registered substances is yet missing. Respective activities in example sectors should be launched soon, in order to be able to provide results before the second registration deadline.

The most important step to follow-up on this work, which does not necessarily requires real-life eSDSs would be to develop guidance and tools for formulators to assess the appropriateness and efficiency of risk management measures. This could be in the form of an excel table listing different types of (end-of-pipe)

[22] Such an approach may be interpreted as a partial shift of responsibility from the registrant to the downstream user with respective legal consequences. Further elaboration on such legal issues was not part of the project

[23] . However, this may be more complex for the formulator (many input materials) and difficult, as some substances may already be registered and have ESs.

risk management measures with a specification of which efficiency could be reached for which (group) of substance[24].

Mixture toxicity

In the context of the project also a small research on methods to assess the mixture toxicity was conducted and the results evaluated with regard to their usefulness in the consolidation of information on mixtures.

DPD$^+$ is not intended for the assessment of mixture toxicity and it therefore also not suitable. Furthermore, the joint action of substances is not covered by any of the current provisions under REACH except for some very vague formulations in the context of the chemical safety assessment.

The debate on mixture toxicity is of high priority EU level but should be discussed separately from the REACH process of consolidation[25].

[24] A respective project has recently been launched by the Umweltbundesamt "Efficiency of risk management measures for emission reduction" (FKZ 3711 63 419) and is currently performed by Ökopol

[25] A project that assesses the feasibility of integrating mixture toxicity aspects in the REACH processes has recently been launched by the Umweltbundesamt to further work on this aspect. "Mixtures in the environment – development of assessment strategies for the European chemicals regulation REACH" (FKZ 3711 63 429)