

Environmental Research  
of the Federal Ministry for the Environment,  
Nature Conservation and Nuclear Safety

Environmental Monitoring

Project No. FKZ 3710 63 404

## **Evaluation and Coordination of Methods and Indicators for the Environmental Monitoring of Chemicals in Germany to Fulfil an Efficacy Assessment and a Success Control under REACH**

by

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ON BEHALF OF THE FEDERAL ENVIRONMENT AGENCY

February 2013



## Report Cover Sheet

|  |   |
|--|---|
| <b>Report No.</b>                                  | UBA-FB 00   |
| <b>Report Title</b>                                | Evaluation and Coordination of Methods and Indicators for the Environmental Monitoring of Chemicals in Germany to Fulfil an Efficacy Assessment and a Success Control under REACH |
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| <b>Funding Agency</b>                              | Umweltbundesamt<br>Postfach 14 06<br>06813 Dessau-Roßlau  |
| <b>Report Date</b>                                 | 28 February 2013  |
| <b>Project No. (FKZ)</b>                           | FKZ 3710 63 404   |
| <b>No. of Pages</b>                                | 111   |
| <b>Supplementary Notes</b>                         |   |
| <b>Keywords</b>                                    | Authorisation; biomonitoring; effects; emission; environmental compartments; exposure; immission; registration; restriction   |

## Berichtskennblatt

|  |  |
|--|--|
| <b>Berichtsnummer</b>                                  | UBA-FB 00  |
| <b>Titel des Berichts</b>                              | Evaluierung und Abstimmung von Methoden und Indikatoren für ein Umweltmonitoring von Chemikalien in Deutschland zur Erfüllung einer Wirksamkeitsbewertung und Erfolgskontrolle unter REACH |
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| <b>Fördernde Institution</b>                           | Umweltbundesamt<br>Postfach 14 06<br>06813 Dessau-Roßlau   |
| <b>Abschlussdatum</b>                                  | 28. Februar 2013   |
| <b>Forschungskennzahl (FKZ)</b>                        | FKZ 3710 63 404  |
| <b>Seitenzahl des Berichts</b>                         | 111  |
| <b>Zusätzliche Angaben</b>                             |  |
| <b>Schlagwörter</b>                                    | Beschränkung; Biomonitoring; Effekte; Emission; Exposition; Immission; Registrierung; Umweltkompartiment; Zulassung  |

## **Abstract**

The study analyses which of the various REACH tasks (i.e. registration, restriction, authorisation, etc.) could be supported by measured data and indicators delivered from environmental monitoring programmes (EMP). The analysis shows that depending on the REACH task, different types of environmental monitoring are required to provide adequate data: whereas some tasks require emission-related monitoring data, other tasks require concentrations of substances in environmental media (i.e. immission-related monitoring data), exposure data in biota or food or effect data. The study further describes for each task how EMP need to be designed with regard to their method-related parameters. Especially the requirements in respect of sampling location and frequency, the geographical coverage, the programme duration and the actuality of data vary for the different tasks. Existing EMP are reviewed for their method-related parameters showing that many of the established EMP can already now be used to support the different REACH tasks. A first proposal for a practical guide "How to use Environmental Monitoring Data for REACH" has been developed aiming to give practical advice to the different actors under REACH (i.e. authorities, manufacturers and downstream users) on the use of monitoring data for the assessment of chemicals and for the efficiency control of REACH.

## **Kurzbeschreibung**

Die vorliegende Studie untersucht, welche der verschiedenen REACH-Aufgaben (z.B. Registrierung, Beschränkung, Zulassung usw.) durch Messdaten und Indikatoren aus Umweltmonitoringprogrammen (Environmental Monitoring Programmes: EMP) unterstützt werden könnten. Die Analyse zeigt, dass, je nach Aufgabenstellung verschiedene Arten von Umweltmonitoring notwendig sind: während einige Aufgaben emissionsbezogene Monitoringdaten erfordern, werden für andere Aufgaben die Stoffkonzentrationen in Umweltmedien (d.h. immissionsbezogene Monitoringdaten), Expositionsdaten in Biota oder Lebensmitteln oder aber Daten zu Auswirkungen benötigt. Darüber hinaus beschreibt die Studie für jede der REACH-Aufgaben, wie EMP hinsichtlich ihrer methodischen Parameter gestaltet sein sollten, um den Regulationsanforderungen der jeweiligen Aufgabe gerecht werden zu können. Insbesondere die Anforderungen in Bezug auf den Ort und die Frequenz der Probenahme, die geografische Abdeckung, die Dauer des Programms und die Aktualität der Daten variieren entsprechend den unterschiedlichen Aufgaben. Die Überprüfung existierender Monitoringprogramme auf ihre methodischen Parameter hin zeigt, dass viele der etablierten EMP bereits jetzt zur Unterstützung der verschiedenen REACH Aufgaben herangezogen werden können. Ein erster Entwurf eines Leitfadens zur „Nutzung von Umweltmonitoringdaten für REACH“ wurde entwickelt mit dem Ziel, den verschiedenen Akteuren unter REACH (Behörden, Herstellern und nachgeschalteten Anwendern) praktische Nutzungsmöglichkeiten von Monitoringdaten bei der Chemikalienbewertung und der Erfolgskontrolle unter REACH vorzustellen.



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## List of abbreviations

|         |  |
|---------|--|
| CA      | Competent Authority  |
| CARACAL | Competent Authorities for REACH and CLP  |
| COPHES  | Consortium to Perform Human biomonitoring on a European Scale                      |
| DPSIR   | Driver-Pressure-State-Impact-Response Approach                                     |
| DU      | Downstream user  |
| EMP     | Environmental monitoring programme   |
| ESB     | Environmental Specimen Bank  |
| HBM     | Human Biomonitoring  |
| I       | Importer   |
| IE      | Industrial Emission  |
| IPPC    | Integrated Pollution Prevention & Control  |
| MS      | Member state   |
| M       | Manufacturer   |
| MSC     | Member State Committee   |
| PAH     | Polycyclic aromatic hydrocarbons   |
| PBT     | Persistent, bioaccumulative and toxic substances                                   |
| PCB     | Polychlorinated biphenyls  |
| POP     | Persistent organic pollutants  |
| RAC     | Committee for Risk Assessment  |
| REACH   | Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals |
| RMM     | Risk management measures   |
| SDS     | Safety Data Sheet  |
| SEAC    | Committee for Socio-Economic Analysis  |
| SOP     | Standard operating procedure   |
| SVHC    | Substances of very high concern  |
| vPvB    | Very persistent and very bioaccumulative substances                                |

A further list of abbreviations related to the evaluated environmental monitoring programs is presented in the annex, section 11.5.

## Summary and conclusions

In Germany as well as at EU level, there are a variety of chemical related environmental monitoring activities ongoing. These programmes have been established for various reasons and under different regulatory regimes such as the Water Framework Directive (WFD), the UNECE-Convention on Long-range Transboundary Air Pollution (CLRTAP), the Stockholm Convention for Persistent Organic Pollutants (POP) or the European Pollutant Release and Transfer Register (E-PRTR). The practical use of monitoring data in chemical exposure and risk assessment – as done under the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) – is, however, less established up to now, even though the REACH text refers to monitoring activities and explicitly mentions the use of monitoring data as source of information.

In this context, the study analyses which of the various REACH tasks (i.e. registration, evaluation, restriction, authorisation, and implementation by Competent Authorities and general enforcement) could be supported by measured data and indicators delivered from environmental monitoring programmes (EMP). It further describes for each task how EMP need to be designed with regard to their method-related parameters such as sampling location, geographical coverage, programme duration to fulfil the regulatory needs of the respective task. Existing EMP are reviewed and evaluated for their method-related parameters and indicators. On the basis of this analysis the study then identifies existing EMP fulfilling the individual requirements of the different REACH tasks.

In a first step, terms and definitions related to monitoring are specified. The term ‘environmental monitoring’ is defined as “periodic and/or continued measuring, evaluation, and determination of environmental parameters and/or pollution levels in order to prevent negative and damaging effects to the environment including the forecasting of possible changes in ecosystem and/or the biosphere as a whole. Environmental monitoring may have different functions:

- Analytical function: measuring and evaluating of environmental parameters relevant for the state of the environment (*state*).
- Early warning function: identifying and evaluation of risks (*impact*).
- Control function: addressing the results (performance and compliance) of environmental policy and legislation (*response*).

These functions can be linked to different steps of the fate of a substance, starting with the release of the substance (emission), the level of “pollution” of environmental media, the exposition of organisms, the resulting effects as well as the evaluation whether those effects are considered as an adverse impact. Consequently, different types of environmental monitoring (EM) can be distinguished.

EM-type 1 – Release of substances (Emission): monitoring the release of substances („pollutants“, in terms of concentration and loads in relation to time) at the point of “discharge” (e.g. chimney, water treatment plant).

EM-type 2 – Concentration of substances in environmental media (Immission): monitoring the concentration of substances in environmental media (resp. compartments in the terminology of REACH).

EM-type 3 – Exposure assessment: monitoring of concentrations in target oriented samples such as biota or food.

EM-type 4 – Environmental effects: monitoring of (biotic and abiotic) effects of toxic substances in biota.

EM-type 5 – Adverse impacts: analysis of the results from step 4 under the perspective whether the observed effects (“adverse impacts”) can be regarded as environmental damage

The text of the REACH Regulation and the related ECHA guidelines refer in many provisions to “monitoring activities” or the “use of monitoring data and indicators”. But they neither specify the type of monitoring proposed for different tasks nor give detailed guidance on how to use monitoring data.

Therefore, the different REACH tasks are examined in detail to identify which of them could be supported by environmental monitoring. For a better overview and understanding, the different REACH tasks are grouped into the following three clusters:

- Tasks related to specific parts of REACH (e.g. registration, authorisation and restriction): i.e. mostly related to specific substances.
- Tasks related to enforcement and success control of REACH, i.e. mostly related to specific substances.
- Tasks related to evaluate the effectiveness of REACH as a whole: i.e. related to the total impact of all chemicals on human health and the environment.

In a next step it is discussed how EMP need to be designed with regard to their method-related parameters such as sampling location, geographical coverage, programme duration to fulfil the regulatory needs of the different REACH tasks.

The results of this evaluation are condensed in two detailed overview tables (Table 8 and Table 9 in section 11.2 of the annex; for detailed explanations see Chapter 5) summarising the different REACH tasks and their respective data requirements as well as the requested design and reported values of environmental monitoring programmes to fulfil these data requirements.

The analysis shows that depending on the task, different types of environmental monitoring are required to provide adequate data: whereas some tasks require emission-related monitoring data (EM-type 1), other tasks require concentrations of substances in environmental media (i.e. immission-related monitoring data; EM-type 2), exposure data in biota or food (EM-type 3) or effect data (EM-type 4). Also, the method-related parameters of the programmes need to fit to the respective tasks. Especially the requirements in respect of sampling location and frequency, the geographical coverage, the programme duration and the actuality of data vary for the different tasks: Whereas, for example, some tasks require monitoring data from remote and pristine regions such as the Arctic sea or Alpine lakes other tasks require monitoring data from the vicinity of an emitter. And with regard to the programme duration the requirements may vary from single samplings to time trend over several years.

Following this more theoretical consideration of requirements of the different REACH tasks regarding environmental monitoring data, a comprehensive review of existing monitoring programmes has been carried out.

Although the focus of this review was set on EMP conducted at a regional, federal and national level in Germany (local EMP included on a screening basis), also EMP on a European and world-wide level have been taken into consideration on a screening basis as well as monitoring programmes carried out by companies and industry associations and human biomonitoring programmes.

The identified monitoring programmes and corresponding metadata are compiled in an excel database.

The overall excel database comprises metadata on 323 programmes and related information. Thereof, 194 programmes are classical EMP and can be allocated to one or more of the different environmental monitoring types described above (EM-type 1-5), potentially delivering valuable information in the context of REACH. The remaining programmes are human biomonitoring programmes, monitoring programmes of companies/associations and other useful information related to environmental monitoring, e.g. databases aggregating/comprising environmental monitoring data. Obstacles encountered during the review were based on the complexity of accessibility and even restricted accessibility of metadata/data as well as the absence of harmonised terms and use of different definitions in regard to environmental monitoring in the literature. Further, many programmes are related/connected to other programmes and forward their data to such programmes due to reporting obligations, i.e. leading to double information or intersections in regard to data/metadata. These currently existing obstacles do often hinder single REACH actors to identify relevant environmental monitoring data/metadata.

The EMP have been further statistically evaluated in regard to the environmental monitoring type (EM-type 1-5) as well as the method-related parameters, i.e. matrices included, the geographical coverage, programme duration, sampling locations and sampling frequency. Identified EMP cover all types of environmental monitoring, whereas the majority of programmes are immission-related programmes (EM-type 2), followed by monitoring in biota (EM-type 3) and by effect monitoring (EM-type 4), including different (bio-)indicators. Emission monitoring (EM-type 1) and analysis of adverse impacts (EM-type 5) are limited to a small number of programmes. In regard to the method-related parameters, it can be summarised that the classical environmental compartments water, air, soil and biota are investigated the most. The majority of EMP which have been identified within the framework of the current project is conducted at national level in Europe, followed by EMP carried out at a federal level in Germany. Most programmes identified have been/are being implemented for more than 10 years and therefore can be expected to deliver valuable data, e.g. in regard to time trends, if taking sampling frequency into account as well. Sampling frequency of programmes is very different, since strongly dependant on the matrix investigated. A statistical evaluation of the programme sampling locations (classified according to ecosystems) leads to the conclusion that nearly all ecosystems are equally covered by identified EMP and therefore can give valuable information, if data is required for a specific ecosystem.

After describing the monitoring-related requirements of the different REACH tasks and examining existing EMP regarding their method-related parameters and indicators these two aspects have been combined by evaluating the existing EMP according to their suitability to support the different REACH tasks. The evaluation has been done on basis of the specification of the method-related parameters. The results of this evaluation are summarised in detail in Table 8

and Table 9 in section 11.2 of the annex: Table 8 gives an overview on the different REACH subtasks and their respective data requirements including the requested type of environmental monitoring (i.e. EM-types 1-5). Table 9 specifies the method-related parameters requested to meet these data requirements and refers to existing EMP fulfilling the method-related parameters and thus, providing useful data to support the respective REACH subtasks.

The allocation of the existing programmes to the REACH tasks shows that many of the tasks can already be supported by data deriving from the established EMP. This does, however, not apply for those REACH tasks that require data of local and company specific situations. These tasks comprise release estimation and exposure assessment on local scale, supply chain information as well as success control of company specific risk management measures. Here, new EPS adapted to the company specific situation are required.

Neither the REACH regulation nor the existing ECHA guidance documents give detailed guidance on how to use environmental monitoring data under REACH. However, a guidance summarising the possibilities and requirements for the use of (environmental) monitoring data under REACH could help to improve the use of this kind of data for chemical assessments. Therefore, a first proposal for a practical guide “How to use Environmental Monitoring Data for REACH” has been developed within the framework of the current research project. Due to the diversity of tasks under REACH, this practical guide addresses not only tasks of authorities but also tasks for manufacturers and downstream users. In this proposed practical guide, a six steps approach for the use of environmental monitoring data under REACH is outlined, starting from the (1) identification of the specific task, (2) clarification of data requirements to fulfil the tasks, (3) gathering of available monitoring data or – in case there are no adequate data available – (4) generation of new data, (5) quality assessment of monitoring data, up to (6) the use of the data. This proposal for a practical guide is designed as a stand-alone document, also including the key aspects of the present report, and aims on enabling different actors under REACH to benefit from existing monitoring data.

Within the framework of the project a workshop was held in Dessau/Germany on 18 – 19 April 2012 under the patronage of the German Federal Environment Agency (UBA). The participants, mainly European experts working in the fields of chemical (risk) assessment, discussed opportunities, requirements and challenges regarding the use of substance-related environmental monitoring data under REACH. Furthermore, indicators derived from substance-related environmental monitoring and effect monitoring were discussed with respect to their adequacy for chemical assessment under REACH. The participants stressed the importance of environmental monitoring for chemical assessments and superior, for the protection of human health and environment by the reduction of hazardous chemicals in the environment. It was recognised that environmental monitoring and REACH can support each other mutually: EMP can provide data to support different REACH tasks, while REACH delivers specific substance information to adapt and optimise EMP. The participants also named existing obstacles still hindering the use of environmental monitoring data under REACH (see Chapter 7).

Taking into account both the results of the present study and the discussions of the experts on the workshop, the following conclusions and future recommendations can be formulated with regard to the use of environmental monitoring data under REACH:

- Many of the existing EMP can provide data to support different REACH tasks. A first proposal for a practical guide “How to use Environmental Monitoring Data for REACH” has been developed within the framework of the current research project. This proposal could serve as basis for the development of a harmonised guidance on EU level.
- The gathering of environmental monitoring data (e.g. by registrants) might be complicated by lacking transparency on respective web-site or even restricted accessibility to data/metadata. For some REACH tasks it may even be essential to have access not only to the metadata but also to raw data of EMP. Therefore it is necessary to clarify and harmonise the different access criteria to easily obtain results of EMP. In this context the implementation of a central European data base (“Chemical Data Centre”) to ease the access to available monitoring data is to be discussed.
- In compliance with the various objectives of monitoring programmes and with the need to ensure that no methodological changes are made in long-term trend analyses, a harmonization of environmental monitoring activities (especially of the documentation) should be aimed at on EU level.
- Existing EMP do only monitor a limited number of chemical substances. Consequently the majority of chemical substances registered under REACH is not (yet) included in any EMP. Therefore in future additional substances need to be included in EMP. It has to be noted, however, that the ongoing EMP are driven by the respective institutional framework. Some of them are located at an international level, e.g. the UNECE-Convention on Long-range Transboundary Air Pollution (CLRTAP), the Convention for the Protection of the marine Environment of the North-East Atlantic (OSPAR) and the POP-Convention, others are part of EU secondary legislation (WFD) or of national or regional programmes. The institutional background of each programme has to be taken into account when the REACH orientated adaptation of EMP is considered. In most cases the inclusion of additional substances or sampling methods are not likely to be decided upon in a short term perspective. All the more it is important to establish environmental monitoring from a specific REACH perspective, in particular in the field of SVHC and PBTs.
- The exchange between chemical (risk) assessment experts under REACH on the one hand and environmental monitoring experts on the other hand needs to be intensified, for example by establishing annual expert meetings for information exchange.
- Administrative and organisational structures need to be improved with regard to data exchange between different authorities in order to eliminate existing information barriers. With this respect the regulatory framework established in the context of the Aarhus Convention on the European, national and regional level providing, i.a., the active dissemination of environmental data, might support activities in order to simplify the availability and accessibility of monitoring results.

In the case of human monitoring data, the projects COPHES and DEMOCOPHES support the harmonisation of data from many different countries. A similar European activity for environmental monitoring data would be a big step forward to use these data for REACH.

## Zusammenfassung und Schlussfolgerungen

In Deutschland sowie auf EU-Ebene wird derzeit eine Vielzahl stoffbezogener Monitoringaktivitäten im Umweltbereich durchgeführt. Diese Programme sind unter unterschiedlichen Regelungen eingerichtet worden, wie z.B. der Wasserrahmenrichtlinie (WRRL), dem Luftreinhalteübereinkommen der UNECE<sup>1</sup> (LRTAP – Convention on Long-range Transboundary Air Pollution), dem Stockholmer Übereinkommen zu persistenten organischen Schadstoffen (POP) oder dem Europäischen Schadstofffreisetzung- und Verbringungsregister (PRTR-E). Solche Monitoringdaten werden jedoch bisher nur in geringem Maße bei der Expositionsschätzung und Risikobewertung von Chemikalien unter REACH verwendet, obwohl im Text der REACH Verordnung sowohl Monitoringaktivitäten und die Verwendung von Monitoringdaten als Informationsquelle explizit erwähnt werden. In diesem Kontext untersucht die vorliegende Studie, welche der verschiedenen REACH-Aufgaben (z.B. Registrierung, Beschränkung, Zulassung usw.) durch Messdaten und Indikatoren aus Umweltmonitoringprogrammen (Environmental Monitoring Programmes: EMP) unterstützt werden könnten. Ferner beschreibt sie für jede der Aufgaben, wie EMP hinsichtlich ihrer methodischen Parameter wie z.B. Probenahmeorte, geografischer Erfassungsbereich sowie Programmdauer usw. gestaltet sein sollten, um den Regulationsanforderungen der jeweiligen Aufgabe gerecht werden zu können. Zu diesem Zweck werden existierende EMP im Hinblick auf ihre methodischen Parameter und Indikatoren überprüft und bewertet. Auf der Grundlage dieser Analyse wird eruiert, welche der vorhandenen EMP die jeweiligen Anforderungen der verschiedenen REACH-(Unter-)Aufgaben erfüllen.

In einem ersten Schritt werden Begriffe und Definitionen in Bezug auf „Monitoring“ festgelegt. In diesem Zusammenhang wird der Begriff „Umweltmonitoring“ definiert als „periodisch und/oder kontinuierlich durchgeführte Messung, Bewertung und Bestimmung von Umweltparametern und/oder Schadstoffbelastungen, um negative und schädliche Effekte auf die Umwelt zu verhindern, einschließlich einer Prognose über mögliche Veränderungen im Ökosystem und/oder der Biosphäre insgesamt. Umweltmonitoring kann dabei unterschiedliche Funktionen erfüllen:

- Analytische Funktion: Messung und Beurteilung von Umweltparametern, die für den Zustand der Umwelt relevant sind (*Zustand*).
- Frühwarnfunktion: Identifizierung und Bewertung von Risiken (*Wirkung*).
- Kontrollfunktion: Auseinandersetzung mit den Ergebnissen (Leistung und Aufgabenwahrnehmung) von Umweltpolitik und Umweltrecht (*Reaktion*).

Diese Funktionen können mit verschiedenen Stufen des Lebenswegs eines Stoffes verknüpft werden, beginnend mit der Freisetzung des Stoffes (Emission), dem Grad der „Verschmutzung“ der Umweltmedien, der Exposition von Organismen sowie den daraus resultierenden Auswirkungen und der Beurteilung, ob diese Wirkungen als nachteilig betrachtet werden müssen. Somit können folgende unterschiedliche Arten des Umweltmonitorings (Environmental Monitoring: EM) unterschieden werden:

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<sup>1</sup> United Nations Economic Commission for Europe

EM-Typ 1: Freisetzung von Stoffen (Emission): Monitoring der Freisetzung von Stoffen („Schadstoffen“, in Bezug auf ihre Konzentration und ihre Frachten im Verhältnis zur Zeit) am Ort des „Austritts“ (z.B. Kamin, Kläranlage).

EM-Typ 2: Konzentration von Stoffen in Umweltmedien (Immission): Monitoring der Konzentration von Substanzen in Umweltmedien (bzw. Kompartimenten im Vokabular von REACH).

EM-Typ 3: Expositionsschätzung: Monitoring der Konzentrationen in zielorientierten Proben wie Biota oder Lebensmittel.

EM-Typ 4: Umweltauswirkungen: Monitoring der (biotischen und abiotischen) Auswirkungen von toxischen Stoffen in Biota.

EM-Typ 5: Nachteilige Auswirkungen: Analyse der Ergebnisse aus Typ 4 unter dem Gesichtspunkt, ob die beobachteten Effekte („nachteilige Auswirkungen“) als Umweltschäden betrachtet werden müssen.

Der Text der REACH-Verordnung und die ECHA-Leitfäden beziehen sich in vielen Absätzen auf „Monitoringaktivitäten“ bzw. die „Nutzung von Monitoringdaten“. Sie spezifizieren jedoch weder den Monitoringtyp, der für die unterschiedlichen Aufgaben geeignet ist, noch geben sie detaillierte Anleitung zur Nutzung von Monitoringdaten.

Aus diesem Grund werden die verschiedenen REACH-Aufgaben im Bericht dahingehend analysiert, welche von ihnen durch Umweltmonitoring unterstützt werden könnten. Zur besseren Übersicht und zum besseren Verständnis werden die verschiedenen REACH-Aufgaben in die folgenden drei Bereiche eingeteilt:

- Aufgaben, die sich auf bestimmte Teile von REACH (Registrierung, Zulassung und Beschränkung) beziehen: d. h. vor allem in Bezug auf bestimmte Stoffe.
- Aufgaben im Zusammenhang mit der Erfolgskontrolle von REACH, d. h. vor allem in Bezug auf bestimmte Stoffe.
- Aufgaben im Zusammenhang mit der Bewertung der Wirksamkeit von REACH insgesamt: d.h. in Bezug auf die Gesamtauswirkungen aller Chemikalien auf die menschliche Gesundheit und die Umwelt.

In einer nächsten Arbeitsstufe wird diskutiert, wie EMP hinsichtlich ihrer methodischen Parameter, wie z.B. Probenahmeort, geografischer Erfassungsbereich sowie Programmdauer usw., gestaltet sein sollten, um den Regulationsanforderungen der verschiedenen Aufgaben gerecht werden zu können.

Die Ergebnisse dieser Bewertung werden in zwei detaillierten Übersichtstabellen (Table 8 und Table 9 in Kapitel 11.2 des Anhangs; bezüglich der detaillierten Erklärungen siehe Kapitel 5) zusammengefasst. Hierin werden die verschiedenen REACH-Aufgaben und ihre spezifischen Datenanforderungen sowie die im Hinblick auf die Erfüllung dieser Anforderungen notwendige Ausgestaltung und die Art der im Rahmen der Umweltmonitoringprogramme zu übermittelnden Werte zusammenfassend dargestellt.

Die Analyse zeigt, dass, je nach Aufgabenstellung, verschiedene Arten von Umweltmonitoring notwendig sind: während einige Aufgaben emissionsbezogene Monitoringdaten (EM-Typ 1) erfordern, werden für andere Aufgaben die Stoffkonzentrationen in Umweltmedien (d.h.

immissionsbezogene Monitoringdaten; EM-Typ 2), Expositionsdaten in Biota oder Lebensmitteln (EM-Typ 3) oder aber Daten zu Auswirkungen (EM-Stufe 4) benötigt. Darüber hinaus müssen die methodischen Parameter der einzelnen Programme zur jeweiligen Aufgabe passen. Insbesondere die Anforderungen in Bezug auf den Ort und die Frequenz der Probenahme, die geografische Abdeckung, die Dauer des Programms und die Aktualität der Daten variieren entsprechend den unterschiedlichen Aufgaben: während z.B. zur Erfüllung einiger Aufgaben Monitoringdaten aus entlegenen und unberührten Regionen wie der Arktis oder Bergseen benötigt werden, erfordern andere Aufgaben Monitoringdaten aus der Umgebung eines Emitters. Im Hinblick auf die Programmdauer können sich die Anforderungen von einzelnen Stichproben über mehrjährige Zeitreihen erstrecken.

Nach dieser eher theoretischen Betrachtung der Anforderungen der verschiedenen REACH-Aufgaben im Hinblick auf Umweltmonitoringdaten, wird eine umfassende Überprüfung existierender Monitoringprogramme durchgeführt. Obgleich der Fokus dabei hauptsächlich auf EMP ausgerichtet ist, die auf lokaler, regionaler, föderaler und nationaler Ebene in Deutschland durchgeführt werden, erfolgt auch ein Screening europäischer und weltweiter Programme. Darüber hinaus werden auch von Unternehmen und Industrieverbänden durchgeführte Monitoringprogramme sowie Humanbiomonitoringprogramme miteinbezogen.

Die ermittelten Monitoringprogramme sind in einer Excel-Datenbank zusammengestellt.

Die gesamte Excel-Datenbank umfasst Metadaten und relevante Informationen von 323 Programmen. 194 dieser Programme sind klassische EMP, die einer oder mehreren der unterschiedlichen Arten von Umweltmonitoring zugeordnet werden können (EM-Typ 1-5). Die restlichen Programme sind Humanbiomonitoringprogramme, von Unternehmen/Verbänden durchgeführte Monitoringprogramme und andere im Zusammenhang mit Umweltmonitoring nützliche Informationen (z.B. Umweltmonitoringdaten) umfassende bzw. zusammenfassende Datenbanken. Bei der Erstellung der Programmübersicht mussten verschiedene Hürden überwunden werden, die derzeit auch einzelnen REACH-Akteuren die Identifizierung relevanter Umweltmonitoringdaten/-metadaten erschweren. Das sind zum einen die teils unübersichtlichen Daten-/Metadatenaufbereitungen (bis hin zu Zugangsbeschränkungen), zum anderen nicht-harmonisierte Begrifflichkeiten und Verwendung unterschiedlicher, das Umweltmonitoring betreffenden Definitionen in der Literatur. Darüber hinaus sind viele Programme mit anderen Programmen vernetzt/verlinkt und übermitteln ihre Daten infolge ihrer Meldepflichten auch an diese Programme. Dies führt zu einer doppelten Informationserfassung bzw. Überschneidungen bei den Daten/Metadaten.

Die EMP wurden im Hinblick auf die Art des Umweltmonitorings (EM-Typ 1-5) sowie die methodischen Parameter wie Umweltmedium, geografische Abdeckung, Programmdauer, Probenahmeort und Probenahmehäufigkeit weiter statistisch ausgewertet. Die untersuchten EMP decken alle Arten von Umweltmonitoring ab, wobei die meisten Programme Immissionsprogramme (EM-Typ 2) sind, gefolgt von Monitoring in Biota (EM-Typ 3) und Effektmonitoring (EM-Typ 4) mit verschiedenen (Bio-)Indikatoren. Emissionsmonitoring (EM-Typ 1) und Analyse der negativen Auswirkungen (EM-Typ 5) erfolgten nur in sehr wenigen Programmen. In Bezug auf die methodischen Parameter kann man zusammenfassend feststellen, dass die Umweltkompartimente Wasser, Luft, Boden und Biota am häufigsten untersucht werden. Die Mehrheit der im Projekt identifizierten EMP wird auf nationaler Ebene (Deutschland und Europa) durchgeführt. Danach folgen die Programme auf Ebene von Bundesländern in Deutschland. Die meisten Programme haben Laufzeiten von mehr als 10 Jahren. Man kann daher erwarten, dass

sie wertvolle Daten liefern werden, z.B. in Bezug auf Zeitverläufe und Trends, sofern die Probenahmehäufigkeit ebenfalls berücksichtigt wird. Die Probenahmehäufigkeit der Programme ist sehr unterschiedlich, da sie sehr stark von der untersuchten Matrix abhängt. Eine statistische Auswertung der Programme hinsichtlich der Probenahmeorte (eingestuft nach Ökosystemen) lässt den Schluss zu, dass fast alle Ökosysteme gleichermaßen von den identifizierten EMP abgedeckt werden. Diese Programme können somit wertvolle Informationen liefern, wenn Daten für ein bestimmtes Ökosystem benötigt werden.

Nach Beschreibung der monitoringbezogenen Anforderungen der verschiedenen REACH-Aufgaben einerseits und Untersuchung der vorhandenen EMP auf ihre methodischen Parameter und Indikatoren andererseits wurden diese beiden Aspekte zusammengeführt, indem die existierenden EMP hinsichtlich ihrer Eignung zur Unterstützung der verschiedenen REACH-Aufgaben bewertet wurden. Die Bewertung erfolgte auf Grundlage der methodischen Parameter. Die Ergebnisse dieser Auswertung werden in den Tabellen in Kapitel 11.2 des Anhangs detailliert zusammengefasst: Table 8 liefert einen Überblick über die verschiedenen Teilaufgaben unter REACH und ihre jeweiligen Datenanforderungen einschließlich des jeweils erforderlichen Typs von Umweltmonitoring (EM-Typ 1-5). Table 9 spezifiziert die methodischen Parameter, die zur Erfüllung der Datenanforderungen erforderlich sind und nennt zu diesen Parametern passende EMP, die nützliche Daten zur Unterstützung der jeweiligen REACH-Unteraufgaben liefern können. Die Zuordnung der existierenden Programme zu den REACH-Aufgaben zeigt, dass viele der Aufgaben bereits durch Daten aus etablierten Programmen unterstützt werden können. Dies gilt jedoch nicht für diejenigen REACH-Aufgaben, zu deren Erfüllung Daten für lokale und vor allem unternehmensspezifische Situationen benötigt werden. Letztere umfassen die Abschätzung der Freisetzung und der Exposition auf lokaler Ebene, Informationen innerhalb der Lieferkette sowie die Erfolgskontrolle von unternehmensspezifischen Risikomanagementmaßnahmen. Hier sind neue, an die Unternehmenssituation angepasste EMP erforderlich.

Weder die REACH-Verordnung noch die bestehenden ECHA-Leitlinien enthalten genaue Erläuterungen dazu, wie Umweltmonitoringdaten im Rahmen von REACH eingesetzt werden sollten. Mithilfe eines Leitfadens, der die Möglichkeiten und Voraussetzungen für die Nutzung von (Umwelt-)Monitoringdaten im Rahmen von REACH zusammenfasst, könnte jedoch die Nutzung dieser Art von Daten für Stoffsicherheitsbeurteilungen verbessert werden. Im Rahmen des aktuellen Forschungsprojektes wurde daher ein erster Entwurf eines Leitfadens zur „Nutzung von Umweltmonitoringdaten für REACH“<sup>2</sup> entwickelt. Wegen der Vielfalt der Aufgaben unter REACH beschäftigt sich dieser praktische Leitfaden nicht nur mit den Kernaufgaben der Behörden, sondern auch mit den Pflichten von Herstellern und nachgeschalteten Anwendern. Er skizziert einen sechsstufigen Ansatz für die Nutzung von Umweltmonitoringdaten im Rahmen von REACH, ausgehend von (1) der Ermittlung der spezifischen Aufgabe, (2) der Klärung der Anforderungen im Hinblick auf die Erfüllung der Aufgaben, (3) der Erfassung der verfügbaren Monitoringdaten, bzw., sofern keine ausreichenden Daten vorliegen, (4) der Erhebung neuer Daten, (5) der Qualitätsbewertung von Monitoringdaten, bis hin zur (6) Nutzung der Daten. Der Leitfadentwurf ist als eigenständiges Dokument konzipiert, das zugleich die wichtigsten

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<sup>2</sup> „How to use Environmental Monitoring Data for REACH – Proposal for a practical guide on the use of environmental monitoring data for chemical assessment, effectiveness assessment and success control under REACH“

Aspekte des vorliegenden Berichts enthält. Ziel dabei ist, den verschiedenen Akteuren unter REACH die Nutzungsmöglichkeiten von aktuell verfügbaren Monitoringdaten vorzustellen.

Im Rahmen des Projekts wurde am 18.–19. April 2012 in Dessau ein Workshop unter der Schirmherrschaft des Umweltbundesamtes (UBA) durchgeführt. Die Teilnehmer, bei denen es sich vor allem um europäische Experten auf dem Gebiet der (Risiko-)Bewertung von Chemikalien handelte, erörterten Möglichkeiten, Anforderungen und Herausforderungen im Zusammenhang mit der Verwendung von stoffbezogenen Umweltmonitoringdaten im Rahmen von REACH. Darüber hinaus wurde die Eignung von Indikatoren – abgeleitet stoffbezogenem Umwelt- und Effektmonitoring – für die Chemikalienbewertung im Rahmen von REACH diskutiert. Die Teilnehmer betonten die Bedeutung des Umweltmonitorings für die Chemikalienbewertung und vor allem für den Schutz der menschlichen Gesundheit und der Umwelt im Sinne einer Reduzierung von gefährlichen Chemikalien in der Umwelt. Dabei wurde hervorgehoben, dass Umweltmonitoring und REACH sich gegenseitig unterstützen können: EMP liefern Daten, die der Erfüllung der verschiedenen REACH-Aufgaben dienen, während REACH stoffspezifische Informationen hervorbringt, die zur Anpassung und Optimierung von EMP geeignet sind. Die Teilnehmer benannten jedoch auch derzeit noch bestehende Hindernisse in Bezug auf die Verwendung von Umweltmonitoringdaten im Rahmen von REACH (siehe Kapitel 7).

Unter Berücksichtigung sowohl der Ergebnisse der vorliegenden Studie als auch der im Workshop geführten Expertendiskussionen können die folgenden Schlussfolgerungen und künftige Empfehlungen in Bezug auf die weitere Nutzung der Umweltmonitoringdaten im Rahmen von REACH formuliert werden:

- Viele der aktuell laufenden EMP können Daten zur Unterstützung der verschiedenen REACH-Aufgaben liefern.  
Im Rahmen des aktuellen Forschungsprojektes wurde ein erster Entwurf eines Leitfadens zur "Nutzung von Umweltmonitoringdaten für REACH" entwickelt. Dieser Entwurf kann als Grundlage für die Entwicklung einer harmonisierten Handlungsanleitung auf EU Ebene dienen.
- Das Zusammentragen von Umweltmonitoringdaten (z.B. durch den Registranten) kann durch fehlende Transparenz auf der jeweiligen Website oder sogar eine Zugangsbeschränkung zu den Daten/Metadaten erschwert werden. Bei einigen REACH-Aufgaben ist unter Umständen nicht nur der Zugriff auf die Metadaten, sondern auch auf die Rohdaten der EMP erforderlich. Um problemlos an die Ergebnisse von EMP zu gelangen, ist folglich eine Klärung und Harmonisierung der verschiedenen Zugangskriterien unerlässlich. In diesem Zusammenhang sollte die Implementierung einer zentralen europäischen Datenbank („Chemical Data Centre“) diskutiert werden, durch die der Zugriff auf die verfügbaren Monitoringdaten erleichtert würde.
- Unter Beachtung der verschiedenen Zielsetzungen von Monitoringprogrammen und der Notwendigkeit bei langfristigen Trenduntersuchungen keine methodischen Veränderungen vorzunehmen, sollte eine Harmonisierung der Umweltmonitoring-Aktivitäten (insbesondere der Dokumentation) auf EU Ebene angestrebt werden.
- Aktuell laufende EMP überwachen nur eine begrenzte Anzahl von chemischen Stoffen. Folglich sind die meisten unter REACH registrierten Chemikalien (bislang) noch in

keinem EMP enthalten. In Zukunft müssen daher zusätzliche Stoffe in die EMP aufgenommen werden. Dabei ist jedoch zu beachten, dass die laufenden EMP von ihrem jeweiligen institutionellen Rahmen geprägt sind. Einige davon sind auf internationaler Ebene angesiedelt, wie z.B. das UN/ECE-Übereinkommen über weiträumige grenzüberschreitende Luftverschmutzung (CLRTAP), das Übereinkommen zum Schutz der Meeresumwelt des Nordostatlantiks (OSPAR) und die POP-Konvention. Andere sind Bestandteil des abgeleiteten Gemeinschaftsrechts (WRRL) oder nationaler sowie regionaler Programme. Der institutionelle Hintergrund der einzelnen Programme muss bei der Prüfung von Anpassungen der EMP hinsichtlich ihrer REACH-spezifischen Ausrichtung berücksichtigt werden. In den meisten Fällen ist es unwahrscheinlich, dass eine Aufnahme weiterer Stoffe oder Probenahmemethoden kurzfristig beschlossen werden kann. Umso wichtiger ist es, ein Umweltmonitoring zu etablieren, das sich, vor allem im Bereich der SVHC und der PBTs, konkret an den REACH-Erfordernissen ausrichtet.

- Der Austausch zwischen Experten für die (Risiko-)Bewertung von Chemikalien unter REACH einerseits und Experten für Umweltmonitoring andererseits muss intensiviert werden. Dieser Informationsaustausch kann z.B. durch die Organisation jährlicher Expertentreffen unterstützt werden.

Im Fall von Humanbiomonitoring fördern die Projekte COPHES und die DEMOCOPHES die Harmonisierung von Daten aus vielen verschiedenen Ländern. Ähnliche Aktivitäten zu Umweltmonitoringdaten auf europäischer Ebene wären ein großer Schritt vorwärts im Hinblick auf die Nutzung dieser Daten im Rahmen von REACH.

## 1 Introduction and objectives

One of the aims of the REACH Regulation is the comprehensive protection of the environment. To achieve this aim REACH defines a complex set of tasks for authorities, for manufacturers and/or importers as well as for downstream users. The different REACH tasks range from registration, restriction and authorisation of individual substances, the success control of risk management measures up to the effectiveness evaluation of REACH as a whole. In this regard the text of the REACH Regulation refers in many provisions to “monitoring activities” or the “use of monitoring data and indicators”.<sup>3</sup> However, the implementation of monitoring programmes and the use of monitoring data in chemical assessment are not well established under REACH up to now.

Accordingly, the majority of existing monitoring programmes have not been implemented under REACH, but under different other regulatory regimes: So far, environmental monitoring data are mainly collected and evaluated to support media-related protection targets as for example the Water Framework Directive (WFD), Air quality legislation, Emissions Ceilings Directive, Clean Air for Europe/CAFÉ) and/or to control the implementation of substance bans as for example under the Stockholm Convention for Persistent Organic Pollutants (POP). Each monitoring programme follows the intrinsic logic of the respective legislative framework. Consequently, elements of the monitoring programmes such as the method-related parameters (matrix/media, sampling location and frequency, geographical coverage), the reported values and indicators as well as the way of data publication differ to a large extent. Thus a multilateral use of the data may be confronted with a wide range of technical, organisational and institutional impediments.

Against this background it was the overall aim of this project to elaborate a general recommendation for the use of environmental monitoring data under REACH, considering both the different REACH tasks and the different actors. In this context relevant methods (i.e. method-related parameters) and indicators of environmental monitoring programmes (EMP) should be analysed with respect to their usefulness for the different REACH tasks. On basis of a compilation of German and European EMP, the possibilities and restrictions of the use of existing EMP under REACH should finally be evaluated.

The report starts with terms and definitions related to (environmental) monitoring in chapter 2. Chapter 3 describes the different REACH tasks in view of their data requirements. It is furthermore discussed whether and in which form environmental monitoring data could support the respective REACH task and how EMP need to be designed with regard to their method-related parameters such as sampling location, geographical coverage, programme duration to fulfil the regulatory needs of the different REACH-tasks.

Following this more theoretical consideration of REACH requirements, a comprehensive review of existing monitoring programmes has been carried out. The programmes have been analysed to identify those which can contribute substance-related data to the different REACH tasks. The methodology applied for the review of monitoring programmes is described in chapter 4. The

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<sup>3</sup> The meaning of the term “monitoring” in the REACH regulation is more general than its meaning within the present study (see Chapter 2). In REACH the term “monitoring” includes also the observation of developments, etc.

monitoring programmes themselves have been compiled in an Excel Database provided on an accompanying CD-ROM and will be published under [www.reach-info.de](http://www.reach-info.de).

After describing the monitoring-related requirements of the different REACH tasks and analysing existing EMP with respect to their method-related parameters and indicators, Chapter 5 brings these two aspects together by evaluating the existing EMP according to their suitability to support the different REACH tasks. For this purpose it was assessed whether the identified programmes fulfil any of the specified data requirements in regard to a specific REACH sub-task. If applicable, a programme was allocated to a REACH task / subtask.

Up to now there is no detailed guidance available on the use of (environmental) monitoring data for chemical assessments and success control under REACH. To overcome this hurdle of lacking guidance, a proposal for a practical guide “How to use Environmental Monitoring Data for REACH” has been developed as part of the project. This practical guide intends to give instructions for the use of environmental monitoring data for chemical assessment, effectiveness assessment and success control under REACH. Chapter 6 summarises the main parts of this proposed guidance. The full proposal is available as separate document: “How to use Environmental Monitoring Data for REACH – Practical guide on the use of environmental monitoring data – for chemical assessment, effectiveness assessment and success control under REACH”.

Within the framework of the project an expert workshop was held in Dessau/Germany on 18 – 19 April 2012 under the patronage of the German Federal Environment Agency (UBA). During this workshop the (preliminary) research results were presented, including the proposal for the practical guide and opportunities, requirements and challenges regarding the use of substance-related environmental monitoring data under REACH were discussed. Furthermore, indicators derived from substance-related EM and effect monitoring were discussed with respect to their adequacy for chemical assessment under REACH and lessons learnt from other regulatory areas (e.g. monitoring under the Pesticide Directive and human biomonitoring) were presented. The key messages, conclusions and future recommendations elaborated by the experts during the workshop are summarised in chapter 7. The detailed workshop programme is included in the annex, section 11.3.

## 2 Terms and definitions related to “Environmental Monitoring”

This project is dealing with questions in the context of “Environmental Monitoring of Chemicals in Germany”. Terms and definitions used in this context are summarised in the following.

### 2.1 Monitoring as a general term

The first distinction has to be made to the broad meaning of the term “monitoring”. This general term used for all kinds of observation of the intersubjectively detectable states of conditions of a system over the course of time:<sup>4</sup>

The etymology of the term 'monitoring' derives from the Latin *monere*:<sup>5</sup> to warn (that is, “something or someone that warns, an overseer”). Originally, in English, the definition of the term monitoring was limited to characterizing “someone who gives a warning so that a mistake can be avoided”. Now, it also connotes the act of observing something (and sometimes keeping a record of that observation; or to: keep watch; keep track of; keep under surveillance; or check, usually for a special purpose). With ever-increasing technological capability, the term can be used to describe a device (usually electronic) used to record, regulate, or control a process or system. Its meaning extends to keeping track of systematically (that is, on a regular or ongoing basis) with a view to collecting information. For example, to monitor the plant or animal populations of an ecological system or drinking water for impurities, to measure the condition of a nation's economy, or to monitor a peoples' social, political or cultural views or habits.

For the purpose of this project the notion of “keeping track of systematically (that is, on a regular or ongoing basis) with a view to collecting information” seems to be most relevant.

The Environmental Terminology and Discovery Service (ETDS), provided by the European Environment Agency (EEA), refers to monitoring as<sup>6</sup>

“a combination of observation and measurement for the performance of a plan, programme or measure, and its compliance with environmental policy and legislation”.

This adds a normative orientation to the term by addressing the “performance” and “compliance”. Both elements have to be considered in the context of the project.

Thus the general term “monitoring” describes a systematic approach to collect information against a normative background allowing to classify the results as “performance” and/or “compliance”.

Not part of the definition is the actor conducting the monitoring. This can be done by authorities but also by industry actors (“self-surveillance”, “self-control” or “self-monitoring”).

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<sup>4</sup> Rüdél 2009, p. 488 referring to Draggan (2006/2011)

<sup>5</sup> Also: advise, remind (German: erinnern, ermahnen, warnen, mahnen, avisieren)

<sup>6</sup> <http://glossary.eea.europa.eu/EEAGlossary/M/monitoring> with a reference to *European Commission 1999*. Integrating environment concerns into development and economic cooperation. Draft version 1.0. Brussels.

## 2.2 Environmental monitoring (EM)

For the term “environmental monitoring” the Environmental Terminology and Discovery Service (ETDS) offers the following definition:<sup>7</sup>

“Periodic and/or continued measuring, evaluating, and determining environmental parameters and/or pollution levels in order to prevent negative and damaging effects to the environment. Also include the forecasting of possible changes in ecosystem and/or the biosphere as a whole.” This definition would also be valid for the term “environmental observation”. In (partial) contrast to “environmental monitoring” the link to the “performance of a plan, programme or measure, and its compliance with environmental policy and legislation” is relatively weak. “Environmental observation” is serving a more general purpose by identifying developments of the above mentioned parameters (which might lead to the formulation to a policy or legislation).

Taking into account the “DPSIR framework” (Driving forces – Pressures – State – Impact – Responses), an approach which “can encourage and support decision-making, by pointing to clear steps in the causal chain where the chain can be broken by policy action”, specific function of environmental monitoring are relevant:<sup>8</sup>

- Analytical function: measuring and evaluating of environmental parameters relevant for the state of the environment (*state*),
- Early warning function: identifying and evaluation of risks (*impact*),
- Control function: addressing the results (performance and compliance) of environmental policy and legislation (*response*).

In the context of this project only chemicals and their impact are at stake. The above cited definition thus has to be read with this modification.

The above mentioned functions can be linked to different steps of the fate of a substance, starting with the release of the substance (emission), the level of “pollution” of environmental media, the exposition of organisms, the resulting effects as well as the evaluation whether those effects are considered as an adverse impact. Different types of monitoring programmes address these steps.

### Type 1: Release of substances (emission)

Type 1 aims at monitoring the release of substances („pollutants“, in terms of concentration and loads in relation to time) at the point of “discharge” (e.g. chimney, water treatment plant). The term “emission” (latin *emittere*, i.a. for: send forth, discharge, emit) is used mainly for

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<sup>7</sup> [http://glossary.eea.europa.eu/terminology/concept\\_html?term=environmental%20monitoring](http://glossary.eea.europa.eu/terminology/concept_html?term=environmental%20monitoring) and refers to the source: UNUN with a link to <http://www.eionet.europa.eu>.

<sup>8</sup> Rosenkranz and Knetsch 2003; see also [http://ia2dec.ew.eea.europa.eu/knowledge\\_base/Frameworks/doc101182/](http://ia2dec.ew.eea.europa.eu/knowledge_base/Frameworks/doc101182/).

point sources from industrial installations.<sup>9</sup> *Releases* from diffuse sources, such as the use of products, are not covered by *emission* monitoring.<sup>10</sup>

### **Type 2: Concentration of substances in environmental media (immission)**

Type 2 addresses the concentration of substances in environmental media (resp. compartments in the terminology of REACH). It covers the „immission“ (latin *immittere*, i.a. for: send in[to], insert), i.e. the input of substance in an environmental media resp. the level of pollution of water, soil, air.

In the context REACH environmental concentrations are relevant inter alia in the PEC/PNEC-ratio (Annex I, No. 6.4). The term PEC stands for “predicted environmental concentration”. Immission-related monitoring programs offer data and factual (not predicted) “environmental concentrations”. From a terminological perspective it has to be noted that REACH when speaking of “exposure” in the context of environmental compartments is referring to “environmental concentrations” in the sense of concentration of substances in environmental media, here defined as “immission”. This distinction is relevant in the context of type 3 (see below).

### **Type 3: Exposure assessment**

Expert analysis (inter alia based on modelling) of information deriving from type 2 or target oriented samples (food or biota).

In most cases the concentration of substances in environmental media defines the exposure of the organisms living in the respective media.<sup>11</sup> In some cases, however, other exposure-related factors have to be taken into account, i.a. the different routes of incorporation, the bioavailability and/or the bioaccumulation in food chains.

### **Type 4: Environmental effects**

Effect monitoring refers to the detection of biotic and abiotic effects of toxic substances. The range of effects might vary from the molecular to biological systems. Different sorts of indicators are covered, including those for stress, indicator species or indicators for biodiversity.<sup>12</sup>

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<sup>9</sup> See Art. 3(4) IE-Directive (2010/75): ‘emission’ means the direct or indirect release of substances, vibrations, heat or noise from individual or diffuse sources in the installation into air, water or land.

<sup>10</sup> The Regulation No 166/2006 concerning the establishment of a European Pollutant Release and Transfer Register (PRTR-Regulation) addresses also emissions from “installations”; the releases from diffuse sources are included only in a supplementary manner (Art. 8 PRTR-Regulation) insofar as “such information exists and has already been reported by the Member States”.

<sup>11</sup> Rüdél et al. (2009, 489) mention only „exposure monitoring“: In their perspective the terms “refers to the chemical- analytical monitoring for the purpose of quantifying the content of substances in environmental or biological samples in order to determine the exposure of an organism to a chemical.”

<sup>12</sup> For details, including biodiversity monitoring and biodiagnostics (samples from type 2 are applied to test-organisms), see Rüdél et al. 2009, 489.

### **Type 5: Adverse impacts**

In the final step, experts analyse the results from type 4 under the perspective whether the observed effects ("adverse impacts") can be regarded as environmental damage.

For each of the five types, different method-related parameters (such as sampled media, sampling location, programme duration, geographical coverage, etc.) and different reported values or indicators are relevant. Consequently the monitoring methods show a great variety; ranging from permanent emission monitoring for point sources (type 1) to samples taken from environmental media in specific intervals (type 2) or samples from organisms (type 3). Environmental effects are monitored by specific indicators (type 4, see above), while type 5 assesses the results of the previous steps.

#### **2.2.1 Specific terms used in the context of EM within this study**

##### **Method-related parameters:**

Method-related parameters characterise the design and method of EMP including substances monitored, sampling material/media/compartiment, sampling location, geographical coverage, programme duration, etc.

##### **Reported values / indicators**

Depending on the type of EMP (i.e. emission monitoring, exposure monitoring, effect monitoring, etc.) the reported values may be measured loads or concentrations in environmental media or biota, observed effects, up to (highly aggregated) indicators.

In this context indicators are qualitative or quantitative parameters used as a measure of an environmental condition, e.g. pollution level of water quality.

##### **Metadata**

Generally, metadata describes other data. It provides information about a certain item's content. In the case of EMP, metadata can contain information about the geographical area the EMP covers, the time duration an EMP is implemented or the sampling frequency of an EMP.

### **2.3 Human biomonitoring (HBM)**

Human biomonitoring is the 'assessment of human exposure to environmental chemicals using body fluids (for example blood or urine), body tissues or hair of men. This information provides a picture of the amount of a chemical actually absorbed into the body. Exposure to such chemicals does not necessarily result in ill health but it is important to understand how people are exposed and to what extent.<sup>13</sup>

Human biomonitoring is an important tool to support environment and health policy making. It allows superior quantification of exposure of the general European population to existing and emerging environmental substances. Human biomonitoring also enables evaluation of

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<sup>13</sup> <http://www.eu-hbm.info/cophes/frequently-asked-questions/frequently-asked-questions#What%20is%20human%20biomonitoring?>

policy actions aimed at reducing exposure, more comprehensive health impact assessments of policy options, control of chemical regulations (e.g. REACH), etc. People are living in an (outdoor/indoor) environment which includes immissions of chemicals every day. Human biomonitoring thus is the logical next step to environmental monitoring.

## 2.4 Monitoring under REACH

The text of the REACH Regulation addresses the different aspects of “monitoring”. The meaning of the term “monitoring” in the REACH regulation is, however, more general than its meaning within the present study (see section 2.2). In REACH the term “monitoring” includes also the observation of developments, etc.

Some provisions in REACH explicitly mention “monitoring”, e.g. in the context of Chemical Safety Assessment (CSA), such as

- Assessment of substance properties (toxicity, PBT, see section 3.1.1);
- Release estimations and related parameters (section 3.1.2), and
- Exposure scenarios (section 3.1.3),

as well as Authorization (section 3.4), Restriction (section 3.5) and tasks of the competent authorities and Member States related to implementation and enforcement of the Regulation (Art. 124, 127; sections 3.6 and 3.7).

Other obligations under REACH are linked implicitly to monitoring results.<sup>14</sup>

In other cases an administrative decision might lead to a monitoring programme: In the context of substance evaluation the competent authorities might come to the conclusion “that further information is required, including, if appropriate, information not required in Annexes VII to X”, it can require the registrant(s) to submit the further information and setting a deadline for its submission. From the legal text it is possible to ask for monitoring data as part of the additional information.

A detailed overview on the mentioning of the term „monitor“/„monitoring“ in the text of the REACH Regulation are given in section 11.1 in the annex.

As an interim conclusion it should be noted, that (environmental) monitoring is linked to the tasks and mechanisms which are located in the very heart of the new regulation: Industry actors as well authorities are obliged to take monitoring results into account or even to establish a specific monitoring programme. So far, however, no specific guidance is given in the REACH context as how to address the different monitoring tasks, taking into account, inter alia, the five types of environmental monitoring.

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<sup>14</sup> See the detailed analysis in chapter 4 with the list of REACH tasks related to environmental monitoring in Table 1, page 22. All types of REACH tasks with links to substance related environmental monitoring are listed in Table 8 in the annex, section 11.2. In this table, the different types of environmental monitoring, as described above, are assigned to the REACH tasks.

### 3 Use of environmental monitoring data under REACH

REACH defines a complex set of tasks linked to the registration, evaluation, authorisation and restriction of substances. In doing so, the REACH legislation lays down specific duties and obligations on manufacturers, importers and downstream users of substances as well as on authorities. In the following section, the different REACH tasks are described in detail. Subsequently it is analysed which of the different REACH tasks could be supported by data from environmental monitoring. Finally it is discussed how environmental monitoring programmes need to be designed with regard to their method-related parameters such as sampling location, geographical coverage, programme duration etc. to fulfil the regulatory needs of the different REACH-tasks.

For a better overview and understanding, the different REACH tasks are grouped into three clusters:

- Tasks related to specific parts of REACH (e.g. registration, authorisation, restriction): i.e. mostly related to specific substances;
- Tasks related to the success control of REACH, i.e. mostly related to specific substances;
- Tasks related to the effectiveness evaluation of REACH as a whole: i.e. related to the total impact of all chemicals on human health and the environment.

An overview on the tasks is given in the following table. It specifies for each task the relevant actor and gives a first indication on the relation of the specific task to environmental monitoring. For a more detailed overview on REACH tasks, subtasks, environmental monitoring types and their data requirements see also Table 8 in the annex, section 11.2).

Table 1: Overview on different REACH tasks and their relation to environmental monitoring

| REACH task  | Actor    | Action   |
|---|----------|--|
| <b>I. Specific REACH mechanisms (mostly related to specific substances)</b> |          |  |
| <i>Registration</i>   | M, I     | Preparation of registration dossiers   |
|   |          | Monitoring data may support the evaluation of substance properties e.g. persistence, bioaccumulation, biomagnification, (eco)toxicity, PBT assessment. (Standard information requirements according to Annexes I, VI – XI) |
|   |          | Monitoring data may support exposure estimations e.g. by delivering measured environmental concentrations (local and regional)   |
| <i>Supply Chain Information</i>   | DU       | Communication on Risk Management Measures and new hazardous properties   |
|   |          | Use of monitoring data to show adequateness of risk management measures  |
|   |          | Use of monitoring data to prove local accumulation / effects of substances   |
| <i>Evaluation</i>   | MS, ECHA | Dossier and substance evaluation   |
|   |          | Dossier evaluation:<br>Monitoring data for priority setting in dossier evaluation.<br>Check of information on persistency and bioaccumulation potential  |
|   |          | Substance evaluation:<br>Information on emerging new pollutants from monitoring for priority setting. Art. 46(1). Request to the registrant to deliver further information (e.g. monitoring data).                         |

| REACH task   | Actor   | Action  |
|--|---|---|
| <i>Authorisation</i>   | MS, ECHA  | Preparation of Annex XV dossiers: Identification of SVHC  |
|  | Information on persistency, bioaccumulation, background concentrations and timelines as criteria for inclusion into Annex XIV.  |   |
|  | Interested parties  | Comments on Annex XV dossiers for authorisation   |
|  | Information on persistency and bioaccumulation. Support of PBT / vPvB assessment.   |   |
|  | M, I, DU  | Voluntary monitoring programmes as argument for non-prioritisation of substances for inclusion in Annex XIV<br>Application for an authorisation (based on registration dossier of substance (incl. PBT assessment)) |
| Proposal for in-house monitoring, local and regional monitoring  |   |   |
| <i>Restrictions</i>  | MS, ECHA  | Preparation Annex XV dossiers for restrictions proposal   |
|  | Interested parties  | Comments on Annex XV dossiers for restriction   |
|  | Information on persistency and bioaccumulation. Support of PBT / vPvB assessment<br>Information on critical exposure situations (PEC/PNEC >1)   |   |
| <b>II. Success control (mostly related to specific substances)</b>   |   |   |
| <i>RMMs, SDSs</i>  | M, I, DU, CA  | Self-monitoring/success control authorities (enforcement)   |
| <i>Authorisation and restrictions</i>  | M, I, DU  | Self-monitoring of emission control measures  |
|  | CA  | Control by authorities (enforcement (single companies), success control (regional/national/EU scale))   |
| <b>III. REACH Regulation as a whole (related to the total impact of all chemicals on human health and the environment)</b> |   |   |
| <i>Information/ Art. 117, 121</i>  | MS, Commission  | Evaluation of efficiency of the REACH Regulation  |
|  | Monitoring data may provide information on the following key questions:<br>- Sufficient protection of environment and human health?<br>- Trends of concentrations of hazardous substances?<br>- (Local) Accumulation of hazardous substances?<br>Art. 117 does not explicitly mention environmental monitoring activities. However, they are not excluded and can be important to answer the key questions given above. |   |

List of abbreviations: MS: Member State; M: manufacturer; I: Importer; DU: Downstream user; CA: Competent Authority; RMM: Risk management measures; SDS: Safety Data Sheet

In the following sections, the tasks which have been mentioned in the overview above are described in detail. The description is structured as follows:

- Chemical safety assessment as part of registration of substances (section 3.1)
- Supply chain Information (3.2)
- Evaluation (section 3.3)
- Authorisation (section 3.4)
- Restriction (section 3.5)
- Self-control and enforcement (section 3.6)
- Efficiency assessment of REACH as a whole (section 3.7).

The sections are structured in such a manner that first the specific REACH tasks are described in detail followed by the consideration whether and in which form environmental monitoring data could support the respective REACH task. Requirements and recommendations related to the use of measured data given in the ECHA Guidance Documents are explicitly mentioned.

Finally, it is discussed how the method-related parameters of monitoring programmes (such as the sampling location, geographical coverage of sampling sites, programme duration and

sampling frequency) need to be designed and which data or values or indicators need to be reported, so that the programme could provide adequate data for the respective REACH task. Quality aspects (such as quality of the sampling and analytical techniques) are not further discussed here as sufficient data quality is considered as a prerequisite for all environmental monitoring data to be used under REACH. Here, reference is made to respective monitoring guidelines as well as to data quality criteria for the use of existing measured data given in different ECHA Guidance documents and OECD reports (e.g. ECHA 2010, R.16, p. 23; OECD 2000).

Table 8 and Table 9 in chapter 11.2 of the annex give an overview on

- different REACH tasks and their respective data requirements,
- the requested design and reported values of environmental monitoring programmes to fulfil these data requirements.

### **3.1 Chemical safety assessment (as part of registration)**

A chemical safety assessment is performed for all substances produced or imported in quantities of 10 tonnes or more per year per registrant.

The chemical safety assessment of a substance includes the following steps (Art. 14(3) and Annex I):

- (a) human health hazard assessment
- (b) physico-chemical hazard assessment
- (c) environmental hazard assessment;
- (d) persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) assessment.

If, as a result of carrying out steps (a) to (d), the registrant concludes that the substance meets the criteria for classification as dangerous or is assessed to be a PBT or vPvB, the chemical safety assessment shall include the following additional steps:

- (e) exposure assessment including release estimation;
- (f) risk characterisation (including risk quotients PEC/PNEC)

Environmental monitoring data may give valuable input for the following steps of the chemical safety assessment:

- Evaluation of substance properties within the environmental hazard and PBT/vPvB assessment (see section 3.1.1), particularly the assessment of persistence, bioaccumulation/biomagnification and toxicity of a substance;
- Release estimations (see section 3.1.2);
- Local and regional exposure estimation and predicted environmental concentrations (PECs) (3.1.3).

The ECHA Guidance Document on endpoint specific guidance (ECHA 2008, R7b, p. 168) gives some general recommendations regarding the use of data obtained from existing monitoring programmes which have not specifically been designed to fulfil regulatory needs (in the context of REACH). For the use of existing and the generation of new field data attention should be given to following aspects (ECHA 2008, R7b, p. 168):

- Reliable and representative data should be selected by evaluation of the sampling and analytical methods employed and the geographic and time scales of the monitoring campaigns. As sampling and measurements are usually performed at a local geographical a justification is required to demonstrate that measured chemical concentrations are representative for the risk assessment, particularly if the data are to be used in regional exposure models.
- The data should be assigned to local or regional scenarios by taking into account the sources of exposure and the environmental fate of the substance.
- The measured data should be compared to the corresponding calculated PEC. For naturally occurring substances background concentrations have to be taken into account. For risk characterisation a representative PEC should be decided upon based on measured data and a calculated PEC.

### **3.1.1 Assessment of substance properties**

#### **Assessment of degradation and persistency**

Most important data sources for the assessment of degradation and persistency are results from (ready) biodegradation tests and abiotic degradation tests such as hydrolysis and phototransformation.

In this context, the ECHA Guidance Document R.7b (2008) states that representative immission-related monitoring data may demonstrate the removal of contaminants from the environment, e.g. monitoring of organic substances in surface water in the vicinity of emitters (which could show that there are no substances found above the detection limits). The following aspects should be considered before use of EM data for this REACH task:

- Is the removal a result of degradation, or is it a result of other processes as e.g. dilution or distribution between compartments (transfer to ground water, sorption, volatilisation)?
- Is formation of non-degradable intermediates excluded?

Only when it can be demonstrated that removal as a result of ultimate degradation fulfils the criteria for rapid degradability, such data might be used directly for classifying a substance as degradable or persistent. In general, monitoring data can only be used as supporting evidence for demonstration of either persistence in the aquatic environment or a rapid degradation (ECHA 2008, R.7b, p. 192).

However, data from immission-related monitoring play an important role before a final conclusion is taken that a substance is “not P” or “not vP”. In the ECHA Guidance, it is stated that monitoring data from national monitoring programmes of Member States or internationally acknowledged organisations such as e.g. OSPAR or the Danube Convention could give evidence for persistence even if the earlier steps in the persistence assessment – mainly

based on testing – give no indications. Findings of significant concentrations of a substance in remote and pristine compartments, such as the Arctic sea or Alpine lakes, are examples for such evidence, provided that there is no natural source known.

In addition, significant concentrations of the substance in higher levels of the food chain in unpolluted areas may indicate high persistency (besides a potential to bioaccumulate). Such evidence indicates that the substance may be persistent and require further investigations to decide whether the P or the vP criterion is fulfilled (ECHA 2008, R.11, p. 24).

In order to provide data for the persistence assessment of a substance environmental monitoring programmes should fulfil the following method-related parameters:

Sample should be taken in remote and pristine regions such as the Arctic sea or Alpine lakes. Thereby, the compartment of concern depends on the substance properties. Also, findings in samples taken from higher levels of the food chain in unpolluted areas support the persistency assessment. These data may come from short-term measurements. However, data from programmes that last several years can give additional support in form of time trends. The reported concentration values should be up-to date data: even if for the persistence assessment itself the actuality of data might not be of big relevance, current data are of higher significance in the PBT assessment.

#### **Assessment of bioconcentration<sup>15</sup>/bioaccumulation<sup>16</sup> and biomagnification<sup>17</sup>**

The information on (aquatic) bioaccumulation is used for the hazard classification and PBT assessment as well as wildlife and human food chain exposure modelling for the chemical safety assessment. It is also a factor in deciding whether long-term ecotoxicity testing might be necessary. This is because chemical accumulation may result in internal concentrations of a substance in an organism that cause toxic effects over long-term exposures even when external concentrations are very small. Highly bioaccumulative chemicals may also transfer through the food web, which in some cases may lead to biomagnification (ECHA 2008 R.7c, p. 9).

Traditionally, the bioaccumulation has been assessed using laboratory experiments that expose fish to a substance dissolved in water. The ratio of the concentration of a substance in an organism (e.g. fish) to the concentration in water is reported as bioconcentration factor (BCF).

The results of field measurements and environmental monitoring (i.e. concentrations in environmental media and exposure assessments according to EM-types 2 and 3; described in section 2.2) can be used to support the assessment of risks due to secondary poisoning and the

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<sup>15</sup> Bioconcentration refers to the accumulation of a substance dissolved in water by an aquatic organism. The bioconcentration factor (BCF) is the ratio of the concentration of a substance in an organism to the concentration in water.

<sup>16</sup> Bioaccumulation refers to uptake from all environmental sources including water, food and sediment. The bioaccumulation factor (BAF) can be expressed as ratio of the substance concentration in an organism to the concentration in the surrounding medium (e.g. water in natural ecosystems or sediment for sediment dwelling organisms).

<sup>17</sup> Biomagnification refers to accumulation via the food chain. It may be defined as an increase in the (fat-adjusted) internal concentration of a substance in organisms at succeeding trophic levels in a food chain.

PBT assessment, however it has to be kept in mind that interpretation of the results is often difficult. The following study types can provide information on bioaccumulation properties of substances (ECHA 2008, R.7c, p. 9):

**Exposure-related monitoring data:** Detection of a substance in the tissue of an organism provides a clear indication that it has been taken up by that organism, but does not by itself indicate that significant bioconcentration or bioaccumulation has occurred. For that, the sources and contemporary exposure levels (for example through water as well as food) must be known or reasonably estimated.

**Field measurements** of specific food chains/webs: Measurement of concentrations in organisms at various trophic levels in defined food chains or food webs can be used to evaluate biomagnification. The biomagnification potential can be expressed as either:

- a *trophic magnification factor* (TMF), which is the concentration increase in organisms with an increase of one trophic level; or
- a *biomagnification factor* (BMF), which is the ratio of the concentration in the predator and the concentration in the prey.

Such exposure-related field data are strong indications that the substance is taken up from food in an efficient way and not easily eliminated. Relevant BMF or TMF values higher than 1 can as well be considered as an indication of bioaccumulation.

Further details on the evaluation of field and monitoring data on aquatic bioaccumulation are given in the ECHA guidance Part R.7.10.4.2 (ECHA 2008, R.7c, p. 35): Bioaccumulation data obtained from field studies can differ from those measured in laboratory tests with fish or aquatic invertebrates. This is because the latter are designed to provide data under steady-state conditions, and generally involve water-only exposures, little or no growth of the test species, consistent lipid content in the organism and its food, constant chemical concentrations, and constant temperature. These conditions are not achievable in field settings, where there are also additional influences such as differences in food diversity and availability, competition, migration, etc. Nevertheless, field biomonitoring data are the ultimate indicator of whether a substance's bioaccumulation potential is expressed in nature.

The precision or uncertainty of a field bioaccumulation factor (BAF) determination is defined largely by the total number of samples collected and analysed. Data from a field study that will be used to quantify bioaccumulation should ideally report the following (ECHA 2008 R.7.10.4.2, p. 36):

- Sampling design (site selection, spatial resolution, frequency of determination, etc.) and details of the sampling methodology, sample handling, sample storage and delivery conditions and stability, steps taken to reduce contamination, and of all equipment being used.
- Description of analytical methods (including use of field blanks, procedural and instrumental blanks in analysis, laboratory pre-treatment, standard reference materials, etc.), as well as evidence of quality control procedures.
- Spatial and temporal gradients in substance concentrations – in particular, care should be taken that the samples used to derive bioaccumulation factors are collected at the same time from the same location, and sufficient details provided to relocate the sampled site. Samples grabbed randomly without consideration of the organism's home

range will, in high likelihood, have poor predictive ability for substance residues in the organisms because the water (and/or sediment) data will not be representative of the organism's actual exposure.

- Physical details of the site, including temperature, salinity, direction and velocity of water flow, water/sediment depth and physico-chemical properties (e.g. particulate organic carbon and dissolved organic carbon levels).
- Details of the organisms being analysed, including species, sex, size, weight, lipid content and life history pattern (e.g. migration, diet, and food web structure and composition). For resident species, the sample collection should be fairly straightforward. Migratory species may present special challenges in determining which food, sediment, or water sample should be used to calculate the BAF.
- information enabling an assessment of the magnitude of sorption coefficients to particulate matter, e.g. whether sorption is controlled by organic carbon or black carbon;
- Details of data handling, statistical analysis and presentation.
- Any other detailed information that is important for understanding or interpreting the field data.

The results of field measurements (i.e. concentrations in environmental media and exposure assessments according to EM-types 2 and 3; described in section 2.2) may also be used to support the assessment of persistency, in particular for possible long range transport if significant concentrations are found in biota in remote areas.

### **Assessment of toxicity**

The assessment of the toxicity of a substance (including acute toxicity, carcinogenicity, mutagenicity, reproductive toxicity) is based on animal testing and non-testing approaches such as QSAR, in vitro testing, read across and category approach. Data from environmental monitoring programmes are usually not applicable to support the classification of a substance as “toxic”.

However, effect monitoring of a substance on selected species (i.e. the detection of effects of toxic substances on organisms according to EM-type 4, described in section 2.2) or biological monitoring of the species composition upstream and downstream of a discharger in the receiving surface water can give evidence of toxic impacts and can, thus, provide supporting data for the environmental risk assessment of the substance. If species upstream and downstream of a discharger show the same effect level or if the species composition upstream and downstream of a discharger is comparable, then it can be concluded that the emissions of the discharger do not have (additional) effects at the local scale.

In order to provide data for such an “effect assessment” environmental monitoring programmes should fulfil the following method-related parameters in addition to the above given aspects:

Sample should be taken parallel at an uncontaminated and a related contaminated location as for example up- and downstream of a discharger in order to be able to compare the uncontaminated with the contaminated site. The programme duration is a less important

parameter than the sampling time: the latter needs to consider possible seasonal variations with regard to the species (composition) investigated and the emission pattern of the discharger. The reported values could be substance-related effects on biota (e.g. SPEAR index) or species composition/number. In addition, concentration values in biota and the surrounding media provide information on the concentration-effect relationship.

### **PBT / vPvB assessment**

PBT substances are substances that are persistent, bioaccumulative and toxic; vPvB substances are characterised by a particular high persistency in combination with a high tendency to bioaccumulate, but not necessarily proven toxicity. Substances have to fulfil all three – respectively two - inherent properties to be considered as PBT or vPvB. These properties are defined by the criteria laid down in REACH Annex XIII.

Chapter R.11 of the Guidance on information requirements and chemical safety assessments describes in detail the PBT and vPvB assessment. The assessment comprises three steps:

- (1) comparison of substance specific information with the criteria of REACH Annex XIII,
- (2) emission characterisation, and (3) risk characterisation aiming to minimise emissions.

In the first step, the registrant has to compare the available information on intrinsic properties with the criteria for persistence, bioaccumulation and long-term toxicity given in Annex XIII. The registrant needs to consider all the information that is available in his technical dossier. In cases where the information in the technical dossier does not allow a *direct* comparison with the criteria in Annex XIII, Annex I (4.1) requires the registrant to consider, on a case-by-case basis, other available evidence like monitoring data giving rise to an equivalent level of concern (ECHA 2008, R.11, p. 8).

In this context, monitoring data can play an important role for the assessment of persistence (P)/(vP) and bioaccumulation (B)/(vB) (see section on persistence and bioconcentration above).

### **3.1.2 Release estimations and related parameters**

Release estimations aim at quantifying emissions to the different environmental compartments during the various life cycle stages and uses of a substance taking into account the operational conditions (OC) and implemented risk management measures (RMMs). First tier release estimations as part of the registration are based on modelling, using exposure estimation tools such as Chesar, EUSES or ECETOC TRA.

Registrants (i.e. manufacturer/importer) can use data from emission-related environmental monitoring (EM-type 1; described in section 2.2) to validate or refine the assumptions made in the first tier release estimation.

Downstream users (DU) can use this kind of monitoring data to assess whether the calculated release estimations give a realistic picture of the real release situation on a local scale. By doing this, DU can evaluate the effectiveness of the recommended risk management measures for the given operational conditions and can determine the integrity and validity of the exposure control advice received from further up the supply chain (ECHA 2012 D.5.2, p. 39).

In order to provide representative release rates the monitoring programmes should fulfil the following method-related parameters:

The immission-related monitoring/sampling site needs to be representative of the location and exposure scenario chosen for the environmental risk assessment. Depending on the substance properties either effluent or exhaust air samples should be sampled to cover the relevant release path. The frequency as well as the time point(s) of sampling need to relate to the discharge/emission pattern and should be sufficient to adequately represent the concentration at the selected site. Single samplings can provide data of peak loads (if the sampling is correlated to the emission pattern) whereas short- or long-term monitoring can provide data of temporal mean or average loads. The monitoring data need to be up-to-date in order to be representative of risk management measures and operating conditions.

Besides the support of release estimations, emission-related environmental monitoring data may also be used to validate the removal of a substance in sewage treatment plants (STPs). Thereby, the percentage removal should preferably be based upon measured influent and effluent concentrations (ECHA 2010, R.16, p. 50). As described above, the measured data from STPs should be assessed with respect to their representativeness for the location and exposure scenario. Consideration must be given to the fact that the effectiveness of elimination in treatment plants is quite variable and depends on operational conditions, such as retention time in the aeration tank, aeration intensity, influent concentration, age and adaptation of sludge, extent of utilisation, rainwater retention capacity, etc. The data may be used provided that certain minimum criteria have been met, e.g. the measurements have been carried out over a longer period of time to cover different climatic conditions (e.g. summer/winter).

Data from dedicated (i.e. highly adapted) STPs should be used with caution. For example, when measured data are available for highly adapted STPs on sites producing high volume site-limited intermediates, these data should only be used for the assessment of this specific use category of the substance.

### **3.1.3 Local and regional exposure estimation and predicted environmental concentrations (PECs)**

Exposure concentrations in environmental compartments – expressed in terms of Predicted Environmental Concentrations (PECs) are needed to calculate the risk quotients PEC/PNEC.

Exposure estimation is performed on two spatial scales: locally in the vicinity of point sources and regionally for a larger area which includes all point sources and wide dispersive sources in that area. Chapter R.16 of the ECHA Guidance on information requirements and chemical safety assessments gives a comprehensive description of environmental exposure estimation (ECHA 2010, R.16). Specific guidance in selecting measured data for exposure assessment of metals is given in Annex R.7.13-2 (ECHA 2010, R.7).

For registration under REACH, default exposure assessments are performed and PEC are calculated by means of modelling. Actual measured concentrations in environmental media (i.e. immission-related monitoring according to EM-type 2; described in section 2.2) can be used to facilitate the interpretation of model output and, eventually can be used as PEC for the development of exposure scenarios (ECHA 2010, R.16, p.21).

In this context, manufacturers and importers can use these measured concentration data as part of their registration. Beyond that, measured data can become part of the communication between downstream users (DU) and their suppliers: immission-related monitoring constitutes a

valuable tool for helping DUs determining the integrity and validity of the recommended risk management measures received from further up the supply chain (ECHA 2012, D.5.2, p. 39).

For the local exposure estimation ( $PEC_{local}$ ) environmental concentrations in the vicinity of emitters (i.e. point sources) are required. In contrast, if there is no spatial proximity between the sampling site and point sources of release (e.g. from rural regions), the data represent a regional background concentration ( $PEC_{regional}$ ).

The compartment(s) of concern (i.e. air, surface water, sediment, soil, marine water) depend(s) on the substance properties.

Immission-related environmental monitoring programmes intended to provide data for the local or regional exposure estimation need to fulfil the following method-related parameters.

- The monitoring/sampling site needs to be representative of the location and exposure scenario chosen for the environmental risk assessment. Furthermore, the sampling site(s) should represent either a local or regional scenario: samples taken at sites directly influenced by the release should be used to describe the local scenario, while samples taken at larger distances to emitters (e.g. rural areas) may represent the regional concentrations (see above). Measured data at the local scale have to be clearly linked with the operational conditions and risk management measures described in the exposure scenario (ECHA 2010 R.16, p.21; ECHA 2012 D.5.2, p. 39).
- Whereas for the local scenario, sampling can focus on one site, namely the respective discharger, there are several sampling sites distributed in the region under consideration necessary to obtain a regional coverage.
- For the local scenario, the frequency as well as the time point(s) of sampling need to relate to the discharge/emission pattern to sufficiently and adequately represent the concentration at the selected site. In contrast, for the regional scenario the sampling frequency/time depends more on the media to be sampled: for the soil compartment one sampling per year could be sufficient whereas water samples should be taken more frequently like monthly or at least quarterly.
- For the local scenario, single samplings can provide data of peak loads (if the sampling is correlated to the emission pattern) whereas long-term monitoring (> 1 year) can provide data of temporal mean or average loads. To obtain a representative regional concentration long-term sampling of at least one year is necessary.
- For the derivation of  $PEC_{local}$  and  $PEC_{regional}$ , the monitoring data need to be up-to-date in order to be representative of risk management measures and operating conditions.

The measured environmental concentrations should be compared to the corresponding calculated PEC. If they differ in the order of magnitude, analysis and a critical discussion of divergences are required in order to decide which of the data are used for exposure estimation (ECHA 2008, R.11, chapter R.16.6.6.9, p. 85ff):

- If calculated PECs are higher than measured environmental concentrations, this might indicate that relevant elimination processes were not considered in the PEC calculation or that the applied model was not suitable to simulate the real environmental conditions for the regarded substance. Care has to be taken because measured data may

not be reliable or present only the background concentration or PEC regional in the regarded environmental compartment. If the PEC based on measured data has been derived from a sufficient number of representative samples, then they should override the model predictions. However if it cannot be demonstrated for the calculated PEC that the scenario is not unrealistically worst case, the calculated PEC should be preferred.

- If calculated PECs are lower than ECs based on measures concentrations, it might indicate that relevant sources of release are not taken into account or the models used were not suitable. Further explanations may be overestimation of degradation, spillage, recent change in use pattern, or release reducing measures not covered by the modelling. Therefore a further analysis of the exposure situation is indicated if it has been confirmed that the measured concentrations are representative.
- Immission-related monitoring data can indicate that there are local additional factors not covered by a conventional tier 1 exposure modelling. This can be a transboundary flux between different environmental compartments or a natural source. Furthermore the substance could represent a metabolite of another substance; a retarded mobilisation may result from a pool present in other environmental compartments.

### 3.2 Supply chain information

Under Title IV, Supply Chain Communication, REACH Art. 34 requires that any actor in the supply chain of a substance or a mixture shall communicate specific information “upstream”. The following two types of information have to be communicated to the next actor or distributor up the supply chain:

- a) New information on hazardous properties, regardless of the uses concerned.
- b) Any other information that might call into question the appropriateness of the risk management measures identified in a safety data sheet supplied to him, which shall be communicated only for identified uses.

Distributors shall pass on that information to the next actor or distributor up the supply chain.

Monitoring data can be used in two ways to support this requirement:

- They can show new hazardous properties of substances, if data prove new effects of substances or local accumulation of substances;
- they can prove the appropriateness of risk management measures which have been proposed in the exposure scenario of the supplier.

**New hazardous properties** of substances can refer to specific (eco)toxicity endpoints (e.g. chronic effects in the aquatic environment) or to persistency, bioaccumulation of biomagnification of substances. Monitoring of environmental effects from downstream users could indicate additional hazardous properties which so far have not been identified by the registrant. Data on substance concentrations in environmental media and effect data on organisms can be used (i.e. immission-related monitoring according to EM-type 2 and effect data according to EM-type 4; described in section 2.2). In this regard, data from whole effluent testing upstream and downstream of the company (i.e. emitter) would be helpful to show effects (see section on ‘*Assessment of toxicity*’, p. 25). They should refer to environmental concentrations in the vicinity of the downstream user. The environmental compartments of

concern as well as the choice of media depend on the substance properties; in reality, data on the aquatic compartment will be available, if at all. Sampling should take place close to the downstream user, if possible, up- and downstream – therefore on a local scale. The programme duration depends on the use pattern of the substance and possible seasonal (e.g. variations in species compositions).

Such monitoring data from downstream users can show the appropriateness of risk management, if they give information on emissions, concentrations or effects of substances in the effluent of the company. This possibility is described in detail in section 3.6, success control and enforcement.

### 3.3 Substance evaluation

Substances which are assumed to cause a risk to human health or the environment are subject of substance evaluation coordinated by ECHA. The substances on the Community rolling action plan are evaluated by the competent authorities. As a result of the evaluation (Art. 48), it is decided whether the substance should be subjected to authorisation (Art. 59(3)), restriction (Art. 69(4)) or to a harmonised classification and labelling (Art. 36 of CLP Regulation (EC) No 1272/2008).

There can be cases in which further information is required for substance evaluation. In these situations, competent authorities can request further information from the registrant, according to REACH Art. 46.1. If appropriate, this request could include environmental monitoring data which have to be submitted by the registrant. Art. 46.1 refers to all substances under registration; it is not restricted to substances of very high concern.

Prioritisation of substances for evaluation takes place on a risk-based approach. The criteria for prioritisation which are set in REACH Art.44, consider hazard information (i.e. properties of concern such as persistence or bioaccumulation), exposure information and tonnage. Environmental monitoring data can be useful to support the hazard assessment (particularly persistence and bioaccumulation assessment; see section 3.1.1 on persistence and bioconcentration) and to provide exposure information in form of immission data (substance concentrations in environmental compartments, see section 3.1.3).

Immission-related environmental monitoring can also be useful to identify new emerging substances<sup>18</sup>. Emerging environmental substances are substances that have often long been present in the environment but whose presence and significance are only now being elucidated (NORMAN Network<sup>19</sup>). Data for emerging substances are often scarce and measurement methods are often at the research and development stage or have not yet been harmonised at

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<sup>18</sup> "Emerging substances" can be defined as substances that have been detected in the environment, but which are currently not included in routine monitoring programmes at EU level and whose fate, behaviour and (eco)toxicological effects are not well understood (NORMAN network).

<sup>19</sup> NORMAN Network: [http://www.norman-network.net/index\\_php.php?interface=1024](http://www.norman-network.net/index_php.php?interface=1024)

the European level. The NORMAN Network has identified a list of the currently most frequently discussed emerging substances and emerging pollutants<sup>20</sup>.

Substances identified as such “emerging substances” should receive special attention under REACH in such a form that these substances could be subject to substance evaluation as soon as they have been registered.

### 3.4 Authorisation of chemicals

Authorisation under REACH aims to assure that the risks from substances of very high concern (SVHC) are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable (Art. 55). The authorisation procedure for inclusion of substances in Annex XIV involves different stages: identification of SVHC; prioritisation of substances for Annex XIV inclusion; application for authorisation.

#### Identification of SVHC

First step in the authorisation procedure is the identification of a substance as SVHC– according to the criteria given in REACH Art. 57 and the related Annex XIII.

##### PBT and vPvB properties:

Substances with PBT / vPvB properties fulfil the criteria in REACH Art. 57 (d) or (e). The revised version of Annex XIII allows the use of monitoring data to show that a substance is a SVHC according to REACH Art. 57 (d) and (e). Thus, environmental monitoring data can be of high importance to show that the persistence and bioaccumulation criteria are fulfilled or not fulfilled. For further details on this type of environmental monitoring data please refer to section 3.1.1.

##### Substances of equivalent concern:

REACH Art. 57 (f) defines an “equivalent level of concern” for substances not fulfilling the criteria of Art 57 (d) or (e), but for which there is scientific evidence of probable serious effects to human health or the environment giving rise to an equivalent level of concern to those of other substances listed in Art. 57 (a) – (e). Such substances have to be identified on a case-by-case basis.

The ECHA Guidance on identification of SVHC describes the approach to show an equivalent level of concern. These additional concerns arise particularly for substances that persist for long periods, bioaccumulate in biota and can give rise to toxic effects after a greater time and over a wider geographical distribution than substances without these properties. As described in section 3.1.1 environmental monitoring studies can provide data to prove that a substance has such properties (ECHA 2007, Guidance SVHC, p. 23ff) – even if it does not fulfil the PBT / vPvB criteria of REACH Annex XIII. Note: as mentioned above, the revised version of Annex XIII allows the use of monitoring data to show that for a substance REACH Art. 57 (d) or (e) applies (PBT or vPvB substances). Alignment between REACH Annex XIII criteria and the description in

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<sup>20</sup> [http://www.norman-network.net/index\\_php.php?module=public/about\\_us/emerging&menu2=public/about\\_us/about\\_us#substances](http://www.norman-network.net/index_php.php?module=public/about_us/emerging&menu2=public/about_us/about_us#substances)

the related ECHA Guidance SVHC is a task of the ECHA PBT Expert Group. This task is expected to be finished in 2013.

### **Prioritisation of substances for Annex XIV inclusion**

After identification of a substance as SVHC, inclusion of the substance in Annex XIV can be proposed. Annex XIV lists substances which require an authorisation for further use. Prior to a decision to include substances in Annex XIV, the Agency recommends priority substances for inclusion. Priority shall normally be given to substances with PBT or vPvB properties, or wide dispersive use, or high volumes.

Immission-related monitoring data can be used to prove wide dispersive use by showing ubiquitous environmental exposure of a substance, i.e. the measurement of concentrations in environmental media according to EM-types 2; described in section 2.2). Thus, environmental monitoring can become an important argument for prioritisation of substances for inclusion in Annex XIV.

These immission-related data should fulfil the following method-related parameters: Samples should be taken in rural, remote and pristine areas all over the EU to cover a broad geographical region to show the omnipresent distribution of the substance. The compartment of concern depends on the substance properties. The programmes should last at least some to provide time trends: Gradually increasing concentrations coupled with ubiquitous distribution stress the need for action. Sampling frequency/time depends on the media to be sampled: for the soil compartment one sampling per year could be sufficient whereas water samples should be taken more frequently like monthly or at least quarterly.

### **Application for authorisation**

For substances included in Annex XIV, companies who wish to continue the use of the substance or its placing on the market have to apply for an authorisation. Such an application can include a company-specific monitoring programme to show reduction of emission and thus prove the success of implemented risk management measures for a substance requiring authorisation (see section 3.6).

## **3.5 Restriction of chemicals**

Restriction under REACH aims at avoiding unacceptable risks to human health or the environment arising from the manufacture, use or placing on the market of a substance, which needs to be addressed on a community-wide basis (Art. 68(1)1).

For substances causing such a risk, the Commission shall ask the Agency to prepare an Annex XV dossier for restrictions proposals (REACH Art. 69.1). In addition, such a dossier can be prepared by a Member State (Art. 69.4). Inter alia, the Annex XV dossier should include all available relevant information on the hazards and risks of the substance (ECHA 2007, Guidance restrictions). It shall provide evidence that implemented risk management measures are not sufficient.

Similar as described for the authorisation process (see section 3.4), immission-related environmental monitoring (according to EM-type 2; described in section 2.2) data can provide EU-wide concentration time trends to show problematic exposure situations and risks as a result of insufficient risk management measures. Sample should be taken in rural, remote and pristine

areas all over the EU to cover a broad geographical region to show the omnipresent distribution of the substance. The compartment of concern depends on the substance properties. The programmes should last at least some years to provide time trends: Gradually increasing concentrations coupled with ubiquitous distribution stress the need for action. Sampling frequency/time depends on the media to be sampled: for the soil compartment one sampling per year could be sufficient whereas water samples should be taken more frequently like monthly or at least quarterly.

In addition, it has to be justified that restriction is the most appropriate Community wide measure. One of the criteria used for this justification is monitorability (see REACH Annex XV, 3). It must be possible to monitor the results of the implementation of the proposed restriction. Monitoring is here understood widely and may cover any means to follow up the effect of the proposed restriction in reducing the exposure. According to the ECHA Guidance for the preparation of an Annex XV dossier for restrictions (2007), such monitoring may include the measuring of the relevant emission and/or immission levels, thus data provided by environmental monitoring programmes.

### 3.6 Success-control and enforcement

Monitoring programs can be elements of licenses and permits set by authorities. Often they focus on monitoring of emissions to environmental compartments. Emissions can originate from production, formulation or industrial use of substances. Other releases might occur outside the scope of environmental permits by smaller downstream users as well as by consumers.

Under REACH, monitoring by companies can be an element of voluntary emission reduction programmes set up by specific sectors of industry. They aim to prove safe use of substances and efficient reduction of emissions to the environment. Examples for such voluntary programmes are the VECAP Initiative and the US EPA PFOA Stewardship Program.

In the context of granting an authorisation for Annex XIV substances, company-specific monitoring programmes can be used by companies to document their emission reduction.

National authorities can use monitoring data on a local scale to control enforcement of risk management measures and operational conditions by individual companies.

On a regional scale, such data can be used to evaluate the effectiveness of measures taken for the authorisation or restriction of individual substances or classes of substances. At present, this is not yet part of the enforcement activities.

All above mentioned initiatives can be allocated to emission- and immission-related environmental monitoring (i.e. EM-types 1 and 2; described in section 2.2).

**Control of company-specific risk management measures** can take place as self-control of the company or by national authorities as part of the enforcement. In both cases, company-specific data are required on emissions or loads to the environment, on concentrations of substances in the receiving environmental compartments or on effects caused by the emissions (i.e. EM-types 1, 2 and 3, respectively; described in section 2.2). A comparison between data from upstream and downstream from the company would help to assess whether the effluents of the company lead to any additional impacts. The sampling frequency should take into account specific emission patterns of the substances as well as seasonal variations e.g. in species composition (if

biological effects are included in the analysis). Data need to be up-to-date in order to be representative of risk management measures and operating conditions.

In order to control the **effectiveness of authorisation/restriction**, substance-specific immission-related monitoring-data can be used. It requires regional data on concentrations of the substances in the environmental compartments. In order to contain a regional coverage, several sampling sites should be used. In order to see trends, duration of the programs should be longer than 1 year. The sampling frequency is compartment-specific. The sampling frequency should take into account specific emission patterns of the substances as well as seasonal variations e.g. in species composition (if biological effects are included in the analysis). Recent data required to see trends compared to reference points before REACH.

### 3.7 Efficiency assessment of REACH as a whole

REACH Article 125 obliges Member States to maintain a system of official controls and other activities as appropriate to the circumstances. Every five years Member States shall submit to the Commission a report on the operation of the REACH Regulation (REACH Art. 117,1). This includes sections on evaluation and enforcement as described in REACH Article 127. Article 127 mentions official inspections and “monitoring carried out” as base for the reporting. Here the “general monitoring” addressing the “performance” of the overall REACH mechanisms, including the various aspects of “compliance” (see section 2.1) is at stake. This includes to some extent also “environmental monitoring” (see section 2.2), but only as part of the comprehensive assessment of the implementation of REACH in all aspects.

Regarding human health and the environment, the European Commission formulated three key questions for the reporting obligations mentioned above (CARACAL 2009; Heiss 2011, p. 339):

- Does REACH protect environment and human health sufficiently?
- Do timelines for hazardous substances in humans and in environmental compartments decrease?
- Are there specific regions with accumulation of hazardous substances (spatial distribution)?

Releases of hazardous chemicals have the potential to damage not only individual species, but ecosystems as a whole. Evaluation of REACH as a whole should try to assess the total impact of all chemicals or at least a larger group of chemicals on human health and the environment – rather than assessing individual chemicals and local sources.

In this context indicators for biodiversity could play an important role as instruments to assess the protection level of the environment – before and within REACH implementation. However, these indicators are influenced by many factors – chemicals are only one of them. Only a limited number of existing biodiversity indicators refer directly to chemicals. At present, no biodiversity indicators are available which can be used directly to evaluate the effectiveness of REACH as a whole. Additional efforts are needed to develop appropriate indicators for this task.

Data from environmental monitoring programs can be helpful to find answers for the three key questions mentioned above.

Question 1: Does REACH protect environment and human health sufficiently?

Data on effects of representative species, on environmental quality standards (EQS) and on the total emission of chemicals into the environmental compartments can be used to answer this question. It requires monitoring data from sampling sites which reflect the regional situation – in urban, rural and pristine areas. Reference areas are required which are representative for the EU. Programs should be of long duration in order to see time trends. The sampling frequency has to be endpoint- and species-specific. Recent data are required, which can be compared to reference points before REACH. It will need additional efforts to decide which parameters are used as indicators: they should address the total load of chemicals to the environment as well as the protection level for all trophic levels.

As an additional challenge, it needs to be shown in which way exposure to chemicals lead to specific adverse effects on organisms. At present, such a causal link could only be shown for a restricted number of specific effects, especially for chemicals affecting the endocrine system.

Question 2: Do timelines for hazardous substances in humans and in environmental compartments decrease?

This key question addresses hazardous substances. Immission-related monitoring data can provide timelines for specific substances or groups of substances. Also in this case, sampling sites should reflect the regional situation – in urban, rural and pristine areas. Reference areas are required which are representative for the EU. Programs should be of long duration in order to see time trends. The sampling frequency has to be substance-specific. In addition, indicators need to be developed which address the total concentration of hazardous chemicals in the different environmental compartments. Recent data have to be compared to reference points before REACH.

One major challenge is to define substances or groups of substances which are representative for the large number of different hazardous substances. At present, only a few indicators are available for groups of structurally related substances (e.g. dioxins, furanes, PAHs) and for heavy metals (heavy metal index). In future, at least one sum indicator should address the concentration of all substances of very high concern in a specific environmental compartment and in biota. Fortunately, environmental species banks offer the possibility to determine these indicators also for earlier points in time.

Question 3: Are there specific regions with accumulation of hazardous substances (spatial distribution)?

This question sets an additional focus on the important group of persistent substances, which might lead to geo- or bioaccumulation.

**Note:** Authorisation of pesticides require a prediction of (geo)accumulation which is at present not foreseen in REACH. Such a prediction would be important also for industrial chemicals in order to assess whether a chemical has the potential to build up environmental loads in the long run.

Substance- specific time trends from immission-related environmental monitoring can be used to answer this key question. The compartment of concern depends on the substance properties, however, usually soil and sediment serve as sinks for substances as well as biota. Also in this

case, EU- representative data are required from long-term programs. Time trends should allow a comparison of recent data with the situation before REACH.

Indicators should be developed for the total burden of biota or soil/sediments with accumulating substances, integrating data for single substances.

### **3.8 Summary**

Chapter 3 gives an overview on the different REACH tasks and describes for each task how environmental monitoring programmes need to be designed with regard to their method-related parameters to fulfil the regulatory needs of the respective task. The analysis makes clear that depending on the task, different types of environmental monitoring (see section 2.2) are required to provide adequate data: whereas some tasks require emission-related monitoring data (EM-type 1), other tasks require concentrations of substances in environmental media (i.e. immission-related monitoring data; EM-type 2), exposure data in biota or food (EM-type 3) or effect data (EM-type 4). Also, the method-related parameters of the programmes need to fit to the respective tasks. Especially the requirements in respect of sampling location and frequency, the geographical coverage, the programme duration and the actuality of data vary for the different tasks: Whereas, for example, some tasks require monitoring data from remote and pristine regions such as the Arctic sea or Alpine lakes other tasks require monitoring data from the vicinity of an emitter. And with regard to the programme duration the requirements may vary from single samplings to time trend over several years.

Following this theoretical consideration of requirements of the different REACH tasks with regard to the use of environmental monitoring data, the following chapter 4 gives an overview on existing environmental monitoring programmes (EMP) and evaluates the programmes with respect to their method-related parameters and reported values or indicators.

## 4 Review and evaluation of existing monitoring programmes (EMP)

The aim of the review was to compile a comprehensive overview on existing EMP on a regional, federal and national level in Germany. EMP performed at a local level were included on a screening basis.<sup>21</sup> Although the focus of the review was set on Germany, also EMP on a European and worldwide level have been taken into consideration on a screening basis.

Apart from EMP established and conducted by authorities or other organisations, the review also included monitoring programmes carried out by companies and industry associations as examples for self-surveillance efforts of the industry. These monitoring programmes are typically implemented to demonstrate that certain products or production processes do not have negative impacts on the environment or to demonstrate the success of activities related to voluntary agreements of the industry.

Furthermore, information on existing human biomonitoring programmes – on German, EU or international level - were collected within the scope of this project. HBM and its programmes are of particular interest since at present an EU wide harmonisation of HBM is under development and first results have already been achieved in this direction within the project “COPHES” (Consortium to Perform Human biomonitoring on a European Scale) and its pilot study “DEMOCOPHES” (Demonstration of a study to Coordinate and Perform Human Biomonitoring on a European Scale)<sup>22</sup>.

In the frame of this review, only metadata (c.f. 2.2.1) of environmental monitoring programmes has been collected. The review of the programmes was carried out in the following way:

1. Development of a metadata collection sheet (definition of the required metadata);
2. Collection metadata based on various sources;
3. Compilation of metadata into an overall excel-file (“metadata collection sheet”) and quality check (e.g. identification of gaps, avoidance of double entries).

The “metadata collection sheet” gives a comprehensive overview on identified monitoring programmes and corresponding metadata and is available as a separate excel-file.

An evaluation of the monitoring programmes was carried out. They were i.a. allocated to the different types of environmental monitoring according to the fate of a substance (“five types”), which are described in detail in section 2.2. Further, the environmental monitoring programmes were statistically investigated in regard to the method-related parameters identified in section 3.8.

The resulting list of existing EMP and their subsequent evaluation served as working basis for the allocation of existing EMP to the different tasks under REACH (see chapter 5).

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<sup>21</sup> It has to be noted that the terms ‘local’, ‘regional’, ‘federal’ and ‘national’ are not consistent with the terms ‘local’ and ‘regional’ used in the context of REACH. The terms ‘local’, ‘federal’ and ‘national’ in regard to EMP refer to the administrative level; the term ‘regional’ refers to EMP conducted in a specific geographical area, e.g. the Baltic Sea.

<sup>22</sup> [www.eu-hbm.info](http://www.eu-hbm.info)

#### **4.1 Development of a metadata collection sheet (definition of the required metadata)**

In a first step, a metadata collection sheet was developed (c.f. separate excel file). With this metadata sheet a structured approach of the metadata collection was possible and it was assured that all information relevant for a later evaluation of the programmes is available.

The following general parameters have been identified as relevant for the characterisation and evaluation of environmental monitoring as well as human biomonitoring programmes:

- information source (e.g. web link)
- short name and detailed name of the programme
- general description (context) of the programme
- substance(s) and/or parameter(s) monitored, sampling material, matrix/compartment
- geographical coverage
- total number of samples/data sets, sampling method, sampling frequency
- duration of the programme
- analysis methods and quality assurance
- objective and legal background of the programme
- data storage and availability of the data

For every identified EMP, metadata has been collected for the above listed general parameters.

#### **4.2 Metadata collection – scope, literature sources and experiences**

##### **Scope**

The focus of the review was the identification and metadata collection of EMP in Germany, which have been or are currently being conducted on a regional, federal and national level. Also local programmes in Germany were included in the review on a screening basis. Besides German programmes, EMP carried out in Europe, such as EMP of other countries conducted at national level, EMP carried out by two or more European countries (pan-European EMP) as well as EMP conducted by all European Member States (European EMP), were comprised within the review. Further, EMP conducted on a worldwide scale were included within the review on a screening basis. Within this review no time restrictions were defined regarding the implementation of programmes. For a statistical description of the results on the geographical coverage of the identified programmes please refer to section 4.4.

##### **Literature sources**

The metadata collection was based on literature provided and recommended by the German Federal Environment Agency (UBA), personal communication with contacted authorities<sup>23</sup> and on an intensive internet research taking into account information available from

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<sup>23</sup> Federal Environment Agency Austria

- national and federal authorities in Germany (UBA (DE), LfU Bavaria, LUBW Baden-Württemberg, MLUR Schleswig-Holstein, LAVES Lower Saxony, etc.) or other countries (e.g. Defra (UK), FDA (USA)),
- national, European and international organisations and Commissions (e.g. HELCOM, OSPAR, ICES, EEA, ICPR (IKSR) etc.),
- web pages from existing (monitoring) projects and programmes (AMAP, MONARPOP, EMEP, ICP Forests, TMAP, Modelkey-project, etc.),
- scientific journals, e.g. Environmental Science and Pollution Research, Science of the total environment, Environmental Pollution),
- databases (PortalU, Environmental Specimen Bank, Dioxin Database, MUDAB, STARS, EEA Air Pollution Data Centre and Water Data Centre, etc.),
- information from working groups (e.g. LAWA, GDCh) and networks (e.g. NORMAN, NEFO),
- companies and industry associations (VECAP, Henkel, Wacker, E-ON, etc.).

Literature which was not taken into account includes e.g. short-term studies from universities.

For an overview on abbreviations please refer to the annex, chapter 11.5. For a comprehensive list on references see chapter 9. The main sources of information are also included in the excel-file.

Numerous documents with useful information provided by the German Federal Environment Agency (UBA) and project partners have been thoroughly investigated. In order to fill in remaining information gaps on programmes identified from provided documents, a parallel or subsequent conducted internet based research was carried out.

Furthermore, homepages of monitoring programmes carried out at national and international level (e.g. Trilateral Monitoring and Assessment Programme of the Waddensea (TMAP), Monitoring Network in the Alpine Region for Persistent and other Organic Pollutants (MONARPOP) as well as international organisations and institutions (AMAP, HELCOM, OSPAR, etc.)) have been investigated in detail.

Another approach to obtain information on EMP was conducted by means of an internet and database based keyword search using generally available search tools (e.g. Google) as well as open databases as PortalU (available via the German Federal Environment Agency (UBA)). Various combinations of key words as 'environment', 'monitoring', 'program(me)s' and related wordings as well as matrix/compartments specifications as 'biota', 'water', 'air', etc. were used. Received hits were thoroughly investigated and relevant programmes and related metadata included in the collection sheet described in section 4.1.

The metadata collection was conducted separately for each relevant environmental matrix/compartment, i.e. air, water, biota, soil, sediment, sludge, products, waste, human tissue. With this procedure it was assured that all relevant monitoring programmes for the different compartments are identified.

## Experiences

The main focus during the metadata collection process was to cover as many programmes and information on programmes as possible. Therefore, during this process not only classical EMP have been screened, but also databases, strategies, networks or laboratories related to or connected with EMP.

Many programmes conducted at national or federal level contribute to European and/or worldwide programmes, e.g. the German moss monitoring programme which contributes to the ICP-Forest/Level II-programme as well as to the international control instrument under the Convention on Long-range Transboundary Air Pollution (CLRTAP) called EMEP (European Monitoring and Evaluation Programme) by reporting of aggregated data. In many cases data resulting from monitoring programmes are used in different aggregated form for various international programmes, for which Germany has specific reporting obligations. For example, data collected via the UBA Air Monitoring Network contributes to various international programmes e.g. to EMEP. In this programme, more than one hundred stations in 25 countries measure transboundary air pollution.

On the other hand data collected at a national level under the framework of specific programmes like HELCOM-, OSPAR-, EIONET- and AMAP-programmes contribute also to further international programmes like the International Council for the Exploration of the Sea (ICES) on contaminants as heavy metals, pesticides, organochlorines and polycyclic aromatic hydrocarbons (PAHs).

These important international programmes were also included in the review.

In case relations between programmes and/or strategies were identified during the review and metadata collection, a reference to related programmes/strategies was made in the excel-file for each programme. A reference in the excel-file was made by a notion within the metadata field on short or long title, description, legal background of a programme, and/or any other field of a programme listed in the excel-file, where reasonable.

The majority of monitoring programmes are conducted by authorities (e.g. UBA) or international organisations / institutions (e.g. HELCOM). But to a certain extent companies or industry associations also carry out environmental self-monitoring programmes.

Information on company level is only available to a very limited extent. Although some big companies might have monitoring programmes, the metadata/data is typically not publically available due to confidentiality reasons.

Legally required emission control (e.g. according to the German "TA Luft") have not been taken into account in this review.

A comprehensive compilation of human biomonitoring (HBM) programmes taking place at national and international level was carried out. The intention of the compilation of these HBM programmes was to derive or use certain aspects for the future monitoring of the effectiveness of REACH. Furthermore, HBM might also be an integrated part of the evaluation process of REACH. Based on human biomonitoring data long-term effects, e.g. of the phase out of certain monitored substances can be observed.

The most important source for human biomonitoring programmes is the currently ongoing EU-project COPHES by providing information on relevant HBM data such as contact points,

brochures and comprehensive lists on currently ongoing as well as completed HBM programmes conducted at national and international level.

The currently ongoing pilot project DEMOCOPHES includes i.a. certain phthalates, which already have been included in Annex XIV or in the candidate list of substances of very high concern.

A major problem during the metadata collection was the identification of relevant metadata. In many cases different terms or definitions are used or the web pages follow different structural and logical approaches. Furthermore, especially specific metadata as e.g. exact number of (available) datasets, number of samples per measurement/measuring period, analytical and validation procedures were sometimes difficult to identify, resulting in time intensive investigation. Also metadata on availability of and access to programme results, e.g. time trends, concentrations, etc., differed significantly between identified programmes. In reports fixed tables and time trends are reported, whereas in contrast databases offer a much higher flexibility due to the possibility of selection of specific criteria, e.g. substances monitored and monitoring period.

### **4.3 Compilation of metadata into an overall excel file and quality check**

The collected metadata was compiled in the metadata collection sheet (c.f. separate excel file).

By entering the metadata in the excel file, a first quality check of the programmes and corresponding metadata took place and remaining metadata gaps were filled as far as possible by additional research.

In the course of the metadata compilation not only classical EMP have been identified, but also databases comprising monitoring data/metadata as well as further supplementary information such as networks, tools, laboratories and superior strategies connected to EMP.

Although this information is not of particular relevance for the derivation of REACH relevant data, it was decided to include this information in the excel file as complementary information. For a clear distinction between the different types of programmes and information, the following categorisation of the collected information was introduced and each data set in the excel file has been allocated to one of the following categories:

- EMP: environmental monitoring programme
- MP: monitoring programme
- D: database
- T: tool
- L: laboratory (e.g. national laboratories with specific importance with respect to environmental monitoring)
- S: strategy
- N: network

Entries marked as “EMP” are classical environmental monitoring programmes and can be allocated to the different types of environmental monitoring as described in chapter 2.2. In

these programmes, permanent emission monitoring of substances from point sources (type 1), sampling of environmental media (type 2) or organisms/biota (type 3) in specific intervals, monitoring of environmental effects by means of specific indicators (type 4) and/or assessment of the results of type 1 to type 4 (type 5) take place. Generally, specific substances are measured in certain matrices/compartments and/or observations in regard to their (negative) effects on the environmental status are carried out.

A distinction was made for programmes, which monitor substances in other matrices than environmental compartments, e.g. food / foodstuff. Such programmes have been allocated to the category “MP”.

Databases in which data/metadata from monitoring programmes are stored enabling access to relevant results have been indicated with a “D” (e.g. UBA dioxin database).

Programmes/projects marked with a “T” include valuable information on tools, which correlate and/or are connected with EMP. Example for such a tool is the polar organic chemical integrative sampler (POCIS), which is a passive sampler developed to improve sampling and monitoring of chemicals in the environment, e.g. in river systems.

Further, laboratories (“L”) and networks (“N”) with valuable information on environmental monitoring were included in the excel file, e.g. the CEMAGREF institute laboratories in France and the NORMAN network (Network of Reference Laboratories for the Monitoring of Emerging Environmental Substances), respectively.

As example for the category strategy (“S”) the UK Marine Monitoring and Assessment Strategy (UKMMAS) can be referred to. Such overall strategies trigger the implementation of EMP and therefore have been included in the excel file.

Though the metadata collection was carried out for each compartment separately, programmes covering more than one matrix / compartment have been included in the list of programmes only once.

For many programmes carried out at federal state or regional level, the data is submitted to superior authorities (e.g. German Environment Federal Agency (UBA)), who collect, subsequently aggregate and evaluate the received data. This applies for example to programmes monitoring air pollutants carried out by federal state authorities, who submit their data to the German Federal Environment Agency (UBA) in the framework of the UBA Air Monitoring Network. Another example is the “Bundesweites Lebensmittel-Monitoring” (national food monitoring programme). For the majority of such cases, the superior programmes were always included in the excel file. In most cases, not all, but exemplary sub-programmes were included in the excel-file, since they comprise the same metadata, e.g. in regard to sampling procedures. Subordinate programmes at federal/regional level which were included in the excel file were listed beneath the corresponding superior programme.

For most of the programmes implemented on national or international level, detailed metadata e.g. on sampling procedures or defined analytical methods are available. Also the accessibility to metadata is given for most of the programmes. However, in particular for regional programmes or studies including monitoring activities, often only limited information and data is given.

#### 4.4 Results of the review

A total of 262 programmes including EMP, other monitoring programmes (MPs), databases (D), tools (T), networks (N), strategies (S) and laboratories (L) were identified. Additionally, 13 monitoring programmes, which are conducted by companies or industrial association (C), and 48 programmes related to human biomonitoring activities (HBM), were included in the excel file in separate excel sheets. The overall excel database including all 323 programmes is available as a separate excel file (“metadata collection sheet”).

An overview on the number of different types of programmes classified according to categories is given in Table 2. In regard to the classification of programmes according to the categories, only one allocation per programme was made.

Table 2: Overview on the number of different types of programmes classified according to categories

| Category                            | No.        |
|-------------------------------------|------------|
| Environmental monitoring programmes | 194        |
| Monitoring programmes               | 12         |
| Human biomonitoring programmes      | 48         |
| Company programmes                  | 13         |
| Databases                           | 24         |
| Tools                               | 17         |
| Networks                            | 7          |
| Strategies                          | 5          |
| Laboratories                        | 3          |
| <b>Total</b>                        | <b>323</b> |

The majority of programmes (194) collected during the review are classical EMP and can be further allocated to the five different types of environmental monitoring (see below).

Programmes monitoring substance concentrations in non-environmental matrices (MP), such as drinking water, food and foodstuff, have been indicated separately for complementary reasons.

Information on 48 human biomonitoring programmes has been collected. They have been taken into account due to the potential added-value human biomonitoring can contribute in the framework of this project (see section 4.4).

A number of 24 databases comprising environmental monitoring data have been identified, which contain information on individual substance concentrations in various matrices collected and reported over decades by agencies.

EMP conducted by companies or associations were difficult to identify due to confidentiality reasons and restricted information access. Only 13 programmes have been included in the database.

The remaining information identified is related to environmental monitoring and are tools (17), networks (7), strategies (5) and laboratories (3), which were included for complementary information reasons.

### Allocation to the “five types” of environmental monitoring

The 194 EMP were further assessed and allocated to one or more of the different environmental monitoring types described in chapter 2.2, i.e. emission-related monitoring (EM-type 1), immission-related monitoring (EM-type 2), exposure data in biota (EM-type 3), effect data (EM-type 4) and adverse impact data (EM-type 5). Many programmes were assigned to more than one type, e.g. EMP which conduct emission as well as immission-related monitoring.

An overview on the number of programmes assigned to a respective type is summarised in Table 3.

Table 3: Overview on number of EMP allocated to the environmental monitoring types 1-5

| Environmental monitoring type                  | No. of EMP |
|--|------------|
| EM-type 1: emission-related monitoring         | 12         |
| EM-type 2: immission-related monitoring        | 146        |
| EM-type 3: exposure data in biota or organisms | 89         |
| EM-type 4: effect data                         | 40         |
| EM-type 5: adverse impact data                 | 15         |

EM-types 2 and 3 are the ones most often conducted within the identified environmental monitoring programmes, frequently in combination. The number of programmes, which carry out immission-related monitoring (EM-type 2), i.e. monitoring of substances in the matrices air, soil, water, sludge and/or sediment, amounts to 146 programmes from 194 identified EMP. A number of 89 EMP were assigned to EM-type 3 and carry out monitoring of substances in biota, e.g. fish, moss, pine needles. In regard to effect monitoring, 40 programmes were allocated to EM-type 4, detecting biotic or abiotic effects of substances by using different indicators in order to quantify the effects, e.g. indicator species such as moss.

EM-type 5, the final step in the causal chain in which a subsequent analysis of the results of EM-type 4 is performed, is only conducted in a small number of programmes (15). Also in regard to the first step in the causal chain, EM-type 1 on emission-related monitoring, only a small number of 12 programmes were assigned to this step.

### Method-related parameters

The 194 EMP were also investigated in regard to the method-related parameters, i.e. matrices included, the geographical coverage, programme duration, sampling locations and sampling frequency. These aspects were identified to be most relevant with regard to a possible usefulness of the programmes to provide data for the different REACH tasks (see chapter 3). Other data sets/information obtained during the review, such as programmes/data sets allocated to e.g. the categories network (“N”) or strategy (“S”), were not considered as relevant in regard to contribution of valuable information required under the different REACH subtasks, and therefore were not taken into account here. Also programmes carried out by the industry and HBM programmes were not regarded due to information access restrictions (confidential data) or classified as inappropriate, respectively, in the frame of this project.

Table 4 gives an overview on the number of programmes delivering environmental data for a specific compartment.

Table 4: Overview on the number of environmental monitoring programmes (EMP) delivering environmental metadata for a specific (environmental) compartment

| Compartment   | No. of EMP |
|---|------------|
| Biota   | 89         |
| Soil  | 63         |
| Air   | 51         |
| Marine water  | 26         |
| Groundwater   | 16         |
| Surface water   | 33         |
| Waste water   | 8          |
| Sludge  | 12         |
| Sediment  | 30         |
| Waste (manure)  | 2          |
| Human tissue  | 4          |
| Others: drinking water, food and foodstuff                | 4          |
| no data available (i.e. not identified in the literature) | 3          |

Almost 50% of the 194 EMP identified deliver data on biota (89) followed by the matrices soil (63) and air (51). The compartment water has been investigated in detail and therefore split into the sub-categories marine water, groundwater, surface water and waste water (effluents), with 26, 16, 33 and 8 EMP delivering data for these matrices, respectively. Further, data for the compartments sediment and sludge is available within the EMP. In regard to sediment 30 EMP deliver data. A specification between marine and freshwater sediment could not be made since it was not always indicated in the literature. Information for sludge, mostly sewage sludge, is available in 12 programmes. Other non-environmental matrices, such as waste (manure), human tissue and drinking water, food and foodstuff, were included for complementary reasons in case of programmes measuring these matrices additionally besides environmental matrices. For 3 programmes no information on investigated compartment(s) was available since not identified in the literature.

Table 5 gives a statistical overview on the geographical coverage of the identified EMP.

Table 5: Overview on geographical coverage of identified environmental monitoring programmes with specification of local, regional, national level as well as cross-border cooperation between Member States (pan-EU), EU-wide and worldwide level

| Geographical coverage of EMP | No. of EMP |
|------------------------------|------------|
| Local level                  | 9          |
| Federal level                | 52         |
| Regional level               | 17         |
| National level               | 94         |
| pan EU                       | 5          |
| EU level (all Member States) | 5          |
| Worldwide level              | 12         |

The majority of EMP included in the excel database have been / are being conducted at a national level (94 programmes). This includes programmes conducted at national level in Germany as well as programmes carried out at national level in other EU Member States. Further 52 programmes are conducted at federal level, i.e. programmes which are implemen-

ted at a federal state level in Germany, e.g. in the German federal state Bavaria. A number of 17 programmes performed at regional level have been identified. This includes programmes which cover specific regions, such as marine regions as the Waddensea, the Mediterranean Sea, the Baltic Sea, or riverine systems, e.g. the Rhine. Programmes conducted on a local level in Germany have been included on a screening basis only. Only 9 local programmes were identified. These are small programmes, which deliver data for a specific city or for a defined and small area (e.g. the programm “Systemare Boden-Grundwasser-Forschungen im Fuhrberger Feld”). Some programmes (5) are implemented on the basis of a cross border cooperation of two or more Member States (pan-EU), e.g. the programme MONARPOP. Another 5 programmes are conducted on a EU wide level by all EU Member States due to obligatory reasons, e.g. the E-PRTR. Further 12 programmes have been identified, which deliver environmental data on a worldwide level, mostly also due to obligatory reasons on the basis of international cooperations (e.g. the ICP programmes).

The 194 EMP have also been statistically investigated in regard to their duration. For 19 programmes no information could be identified. A statistical overview on the time duration of EMP is available in Table 6.

Table 6: Overview on time duration of identified environmental monitoring programmes

| Time duration of EMP           | No. of EMP |
|--------------------------------|------------|
| < 1 year or single measurement | 10         |
| 1 year                         | 4          |
| 2 years                        | 11         |
| 3 years                        | 9          |
| 4 years                        | 10         |
| 5 years                        | 2          |
| 6 years                        | 3          |
| 7 years                        | 2          |
| 8 years                        | 1          |
| 9 years                        | 7          |
| 10 years                       | 4          |
| > 10 years                     | 111        |
| no data available              | 19         |

In summary, more than 50% of the EMP included in the excel database are/have been conducted for a time period longer than 10 years (111 programmes) and therefore could deliver valuable environmental data, e.g. on time trends. Time trends on concentrations of substances in a specific environmental compartment in a specific vicinity can give valuable information on whether e.g. the substance concentration stays constant, decreases or increases over time. For the latter case (increase over time), this may be an indicator that the substance is (bio-)accumulating and/or that an entry, e.g. from a plant near the sampling vicinity, takes place. However, further information such as sampling frequency has to be taken into account as well (sampling frequency has been investigated separately – see Table 7). For 19 programmes no information on the time duration was available. A number of 10 programmes comprised single measurements or had an implementation duration smaller than 1 year. The remaining programmes are almost equally distributed in regard to their implementation phase between 1 and 10 years (number of programmes, respectively: 4, 11, 9, 10, 2, 3, 2, 1, 7, 4).

Figure 1 gives an statistical overview on the different sampling locations of the EMP. For this evaluation, the systematic specification of sampling areas of the German Environmental Specimen Bank (ESB) has been used as basis, i.e. specification of sampling areas according to ecosystems.<sup>24</sup> Besides the categories agrarian, riverine, forestry, marine and (nearly) natural ecosystem used by the ESB, the categories “urban areas” for sampling sites in cities and sites close to cities, “industrial areas” for sampling sites at or near (industrial) emitters and “other systems” for programmes, which measure substance concentrations in drinking water, food and foodstuff, have additionally been introduced.

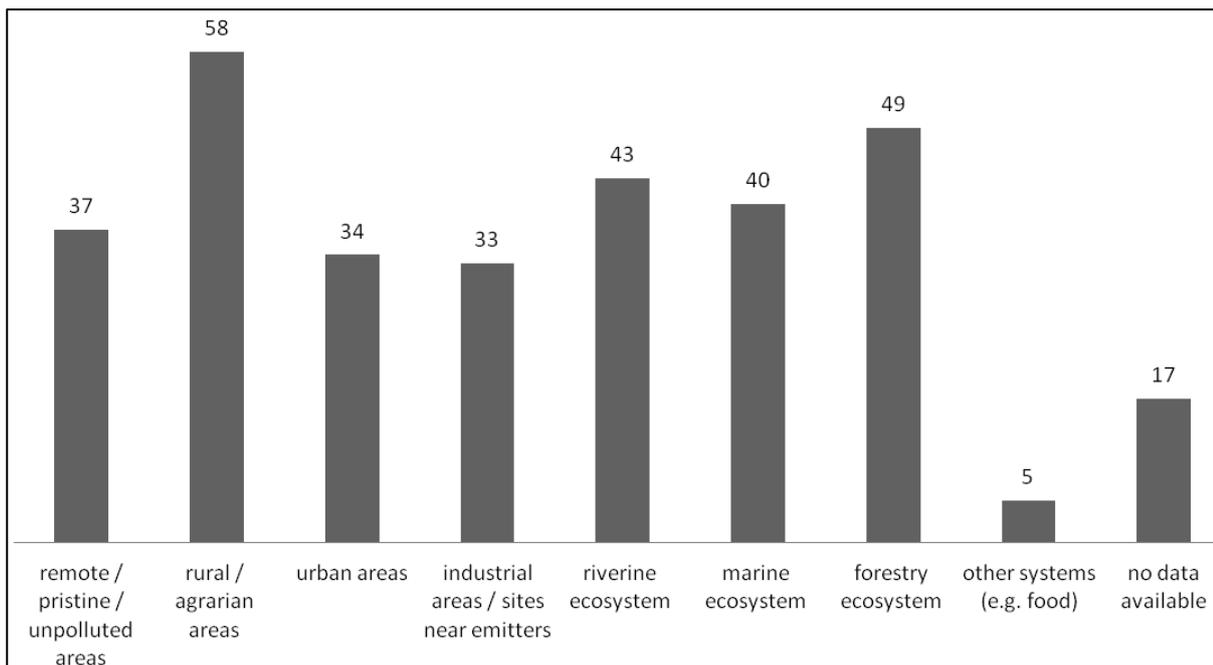


Figure 1: Statistical overview on sampling locations of identified environmental monitoring programmes specified according to the different (eco)systems; numbers indicated in the illustration represent the number of programmes, which perform monitoring in the respective (eco)system.

It should further be noticed that for this evaluation programmes with sampling locations in more than one of the described systems, all sampling locations have been taken into account, e.g. a programme in which sampling is performed in forests, rivers and in urban areas, all mentioned systems were counted once. For the other descriptive statistics one allocation was applicable. In summary, the 194 environmental programmes cover nearly equally all ecosystems. 37 programmes deliver environmental data for remote, pristine and unpolluted areas as the Alpine region or the Arctic (e.g. all AMAP programmes in the Arctic region or the programmes MONAPOP and MONAR+ in the Alpine region). 58 programmes perform sampling in agrarian ecosystems, i.e. rural and agricultural areas, whereas mostly the compartment soil is investigated. 34 programmes take samples e.g. on air, soil and other matrices, in urban areas, whereas 33 programmes conduct sampling in industrial areas and near emitters, e.g. on waste water, sewage sludge and air. Another 43 programmes deliver environmental information due to sampling at riverine systems, e.g. the Rhine, and other surface water systems e.g. lakes. Sampling in the marine ecosystem, i.e. seawater, marine fish and sediment, is conducted

<sup>24</sup> <http://www.umweltprobenbank.de/en/documents/details/11263>

in 40 programmes. In regard to sampling at riverine and marine systems, most frequently measured matrices are water and biota samples. Further, 49 programmes deliver data for the forest ecosystem by sampling of e.g. soil, biota and air. As already mentioned, 5 programmes deliver data for non-environmental systems, i.e. food, foodstuff and drinking water. For 17 programmes no information on the sampling location was identified and consequently no allocation could be made to the described systems.

The last statistical analysis has been made in regard to the sampling frequency of EMP. The number of programmes and their sampling frequencies are described in Table 7.

Table 7: Overview on sampling frequency of identified environmental monitoring programmes

| Sampling frequency of EMP          | No. of EMP |
|------------------------------------|------------|
| single or random sampling          | 29         |
| daily sampling or even more often  | 18         |
| weekly                             | 3          |
| monthly                            | 7          |
| 1x/year                            | 36         |
| 2x/year                            | 3          |
| 3x/year                            | 2          |
| 4x/year                            | 3          |
| >4x/year                           | 1          |
| every 3 years                      | 6          |
| every 4 years                      | 3          |
| every 5 years                      | 13         |
| every 6-10 years                   | 8          |
| every >10 years                    | 1          |
| various (e.g. dependent on matrix) | 32         |
| no data available                  | 36         |

Since many of the EMP identified include more than one matrix and sampling frequency often varies among the different matrices due to organisational efforts, 32 of the programmes could not be allocated to one of the sampling frequency categories (see category 'various'). Single measurements and random measurements, respectively, were the case for 29 programmes. In 36 programmes, samples are taken on an annual basis. More frequent sampling as twice, thrice, 4 times or more per year, was identified for only a small number of programmes. For 18 programmes it was indicated that sampling takes place daily or even more often, e.g. on an hourly basis. This was most often the case for automatic passive sampling of air. In 3 programmes, a weekly sampling frequency was indicated, in 7 programmes a monthly sampling frequency. For 6, 3, 13, 8 and 1 programmes, samples are taken in a 3, 4, 5, 6-10 year interval or even on a >10 year basis, respectively. No data was available for 36 programmes, since no information on sample frequencies were indicated in the literature.

In summary, the matrices which are being monitored the most are the classical environmental compartments water, air, soil and biota. The majority of identified EMP is conducted at national level in Europe, followed by EMP carried out at a federal level in Germany. Most programmes identified have been/are being implemented for more than 10 years and therefore can be expected to deliver valuable data, e.g. in regard to time trends, if taking sampling

frequency into account as well. Sampling frequency of programmes is very different, since strongly dependant on the matrix investigated. For example automated passive sampling can be done without significant effort, as it is the case for e.g. the compartment air, while sampling of biota can be connected with enormous effort, resulting in yearly sampling frequencies. A statistical evaluation of the programme sampling locations classified according to ecosystems leads to the conclusion that nearly all ecosystems are equally covered by identified EMP and therefore can give valuable information, if data is required for a specific ecosystem.

#### **4.5 HBM added value**

Information on human biomonitoring programmes – on German, EU and international level – has been collected within the scope of this project. A total of 48 HBM programmes and corresponding metadata have been included in the metadata collection sheet. Following the project requirements, these programmes were excluded from the evaluation process. However, included HBM programmes might provide interesting approaches as indicators for the success of REACH and other chemicals legislation what justifies their mentioning.

HBM and its programmes are of particular interest since they can link exposure to pollutants with biomarkers and health effects. Over the last years and in particular in Germany a wide range of experiences has been collected. One example of an added value resulting from human biomonitoring programmes in the context of human health and chemical legislation was the examination and monitoring of lead concentrations in human blood. Identification of elevated lead concentrations due to the use of i.a. lead containing fuel for vehicles led to policy measures prohibiting lead in fuel. With help of human biomonitoring programmes a drastic decrease of lead concentrations could be observed as a consequence of legal action. This example demonstrates that HBM does not solely represent a tool for identification of human health hazards, but also can be used as powerful tool to monitor results of policy measures implemented.

At present an EU wide harmonisation of HBM is being conducted and first results have already been achieved within the project “COPHES” (Consortium to Perform Human biomonitoring on a European Scale) and a Europe wide pilot project DEMOCOPHES<sup>25</sup>. COPHES establishes a new state of the art in regard to human biomonitoring activities with the overall aim to achieve comparable results all over Europe. This is realised by a structured working plan developed and conducted by a consortium consisting of interdisciplinary experts coming from 35 institutions from 24 EU member states as well as Norway, Switzerland and Croatia. The working plan includes a harmonised approach for sampling, recruitment and sample collection, sample handling, analysis and biobanking, data analysis and integrated interpretation of results, communication and dissemination, training and capacity building. Also horizon scanning and linking to other research projects and policy support of HBM is addressed. The developed procedures are tested in an especially developed feasibility study “DEMOCOPHES”, which was launched at the end of 2010. Within this feasibility study, the focus is set on examination of the substances cadmium, mercury, cotinine and the chemical group of phthalates in human urine and hair of 120 mother-child couples for each of the 16 participating countries.

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<sup>25</sup> [www.eu-hbm.info](http://www.eu-hbm.info)

HBM has come a long way so far and is now accepted as powerful tool for scientists, policy makers and other interest groups. HBM also attracts public attention and is anchored in public mind.

Environmental monitoring programmes have already been conducted for decades, similar to HBM programmes; however, it seems that programmes are being carried out in various and different ways by means of sampling aspects as e.g. procedures (SOPs, guidelines, manuals) and frequency, as well as analytics and validation of results and/or other aspects due to geographical and/or matrix specific conditions (e.g. environmental monitoring only being conducted in the Baltic Sea region, Alpine region, etc.). This fact complicates or even makes it impossible to compare results of different environmental monitoring programmes with each other in a proper and reliable way.

EU wide harmonisation of environmental monitoring programmes being useful as tool for assessment and evaluation of environmental health status and enabling the delivery of comparable results is not yet as far developed as it is for HBM.

It is therefore recommended to investigate the added value a better harmonised conduction of environmental monitoring programmes can have on a European scale in regard to harmonised sampling procedures and analytics for specific matrices as well as a better harmonisation related to organisational and administrative aspects. It is expected that at least similar advantages will result as it was experienced for the EU wide harmonisation in regard to HBM.

Based on the experiences of COPHES and the European HBM approach, a call for a EU wide harmonisation of environmental monitoring programmes might be advisable, e.g. for specific substances in selected natural matrices such as water, air, biota, soil, sludge and sediment, generally covering sampling in specific matrices, recruitment of sampling personnel, sample collection and transport, handling, storage, analysis, and preservation (development of EU wide SOPs on the basis of already existing, best practice methods), data analysis connected with integrated interpretation of results. Also proper and overall communication and dissemination of results connected with policy aspects, training and capacity building, identification and linking with other research project might be recommended.

It is obvious that the working structure of the COPHES project is not completely transferable in order to establish an EU harmonised environmental monitoring programme prototype, but it demonstrates a possibility and might be a starting point and/or driving force for future activities in the field of environmental monitoring.

#### **4.6 Summary of the review and evaluation of existing EMP**

A number of 194 EMP were identified during the review and corresponding metadata on specific general parameters collected.

Firstly, programmes were allocated to one or more steps, if applicable, in regard to the different types of environmental monitoring (“five types”: EM-types 1-5, see chapter 2.2). Identified EMP cover steps ranging from emission monitoring (EM-type 1), immission monitoring (EM-type 2), monitoring of substances in biota and other organisms (EM-type 3), effect monitoring (EM-type 4) to hazard effect analysis in type 5 (EM-type 5). The majority of programmes can be allocated to EM-type 2, EM-type 3 and EM-type 4. In regard to effect monitoring (EM-type 4) different (bio)indicators were identified, ranging from bioindicators

such as plant species (e.g. moss, grass cultures), specific fish or daphnia species (e.g. bream as an accumulation indicator for hexabromocyclododecan (HBCD)) to indicators for biodiversity, e.g. counting of species inventories. EM-type 1 on emission monitoring and EM-type 5 on analysis of adverse impacts are limited to a small number of programmes.

In a second step, a descriptive statistical analysis was carried out for all EMP on the basis of the identified method-related key parameters, i.e. matrices sampled, geographical coverage, time duration, sampling sites and sampling frequency for all programmes identified during the review (company programmes and HBM programmes excluded). The descriptive statistics are given in (see section 4.3). Water, air, soil and biota are the environmental compartments investigated the most. The majority of identified EMP is conducted at national level in Europe, followed by EMP carried out at a federal level in Germany. Most programmes identified have been/are being implemented for more than 10 years and therefore can be expected to deliver valuable data, e.g. in regard to time trends, if taking sampling frequency into account as well. Sampling frequency of programmes is very different, since strongly dependant on the matrix investigated. For example automated passive sampling can be done without significant effort, as it is the case for e.g. the compartment air, while sampling of biota can be connected with enormous effort, resulting in yearly sampling frequencies. A statistical evaluation of the programme sampling locations classified according to ecosystems leads to the conclusion that nearly all ecosystems are equally covered by identified EMP and therefore can give valuable information, if data is required for a specific ecosystem. However, during the metadata collection different obstacles were encountered.

A major problem was the identification of specific data, e.g. for some EMP sampling frequencies could not be identified. Reasons for this were given due to the complexity of accessibility or even restricted accessibility to data/metadata. Another problem arose from the absence of harmonised terms and use of different definitions in the literature, bearing a confusion potential. Further, many programmes are related/connected to other programmes (“hierarchy”) and forward their data to such programmes due to reporting obligations, i.e. leading to double information or intersections in regard to data/metadata.

To conclude, environmental monitoring programmes however offer a broad spectrum of different data/metadata and therefore bear the potential to be used as universal toolbox in regard to specific REACH tasks and according to individual data requirements.

The following figure illustrates schematically how data from EMP could contribute to the different REACH tasks / subtasks, if appropriate and significant method-related key parameters are applied.

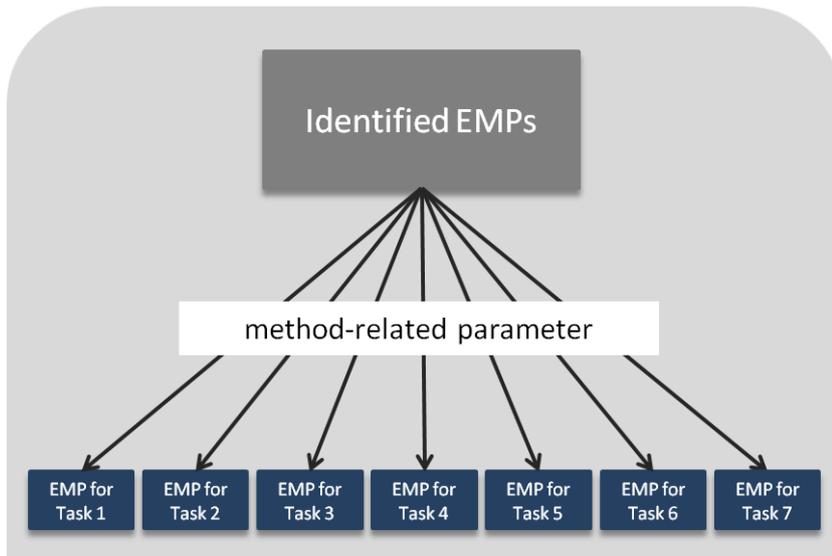


Figure 2: Schematic overview on possible contribution of identified environmental monitoring programmes (EMP) based on specific method-related parameters to support authorities under different REACH tasks and subtasks

## 5 Allocation of existing EMP to REACH tasks

After describing the monitoring-related requirements of the different REACH tasks in chapter 3 and examining existing EMP regarding their method-related parameters and indicators in chapter 4, the present chapter 5 brings these two aspects together by evaluating the existing EMP according to their suitability to support the different REACH tasks. For this purpose it was assessed whether the identified programmes fulfil any of the specified data requirements in regard to a specific REACH subtask. If applicable, a programme was allocated to a REACH task / subtask.

For the allocation of existing EMP to REACH tasks only classical environmental monitoring programmes (category “EMP”) were taken into account. Other information obtained during the review summarised in chapter 4, such as programmes/data sets allocated to e.g. the categories network (“N”) or strategy (“S”) was not considered as relevant in regard to contribution of valuable information required under the different REACH subtasks, and therefore was not taken into account in this allocation procedure. Also programmes carried out by the industry and HBM programmes were not regarded due to information access restrictions (confidential data) or classified as inappropriate, respectively, in the frame of this project.

The restriction to EMP only resulted in a number of 194 classical environmental monitoring programmes, which were taken into consideration for screening and analysis with respect to the individual REACH tasks. Not all of these programmes were allocated to the REACH subtasks since several programmes did not meet the data requirements formulated for the individual subtasks or basic requirements such as data quality.

The results of this evaluation are summarised in detail in Table 8 and Table 9 in chapter 11.2 of the annex: Table 8 gives an overview on the different REACH subtasks and their respective data requirements including the requested type of environmental monitoring (i.e. EM-types 1-5). Table 9 specifies the method-related parameters requested to meet these data requirements and refers to existing EMP fulfilling the method-related parameters and thus, providing useful data to support the respective REACH subtasks.

General aspects on the availability of suitable EMP for the different REACH tasks are given in the following – broken down on the single method-related parameters:

Sampling location: from pristine to industrial

Some REACH tasks (e.g. T.1.1: assessment of persistency)<sup>26</sup> require data from unpolluted sites such as remote or pristine regions. In contrast, other tasks demand data taken directly in the vicinity of emitters or even taken directly from the effluent of a certain emitter. As can be seen from the descriptive statistics on sampling locations (see Figure 1) and from the allocation in Table 9 in chapter 11.2, there are several EMP taking samples in natural ecosystems (i.e. delivering data from remote and pristine regions) or agrarian and forestry ecosystems (i.e. delivering data from rural areas) whereas other EMP take place in urban or industrial areas. Thus, existing EMP cover a broad range of different sampling locations. Publicly less available are, however, EMP which can be used for company specific release estimations or to control the

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<sup>26</sup> The numbers T.1.1, etc. refer to the REACH Subtasks as described in Table 8 and Table 9 in chapter 11.2 of the annex

efficiency of (company specific) risk management measures (see REACH task T.1.6 and T.6.2 in Table 9). Here, emission-related EMP – primarily conducted by companies themselves – would be required.

Geographical coverage: from local to regional

For some REACH tasks such as the prioritisation of SVHC for inclusion into Annex XIV it is necessary to show a wide dispersive occurrence of a substance or to have regional background concentrations. This is best achieved by EMP having a broad geographical coverage such as regional, national or European EMP. To fulfil other tasks local emission data or local concentration values may be sufficient. The overview on geographical coverage of identified EMP (see Table 5) and the allocation in Table 9 show that many of the existing EMP are conducted at regional or national level, thus covering larger geographical areas. On a local level, only a limited number of EMP have been identified. These are small programmes which deliver data for a specific city or for a defined area. Consequently, for those REACH tasks requiring a broad geographical coverage, several EMP – even on European level – are available. Less EMP are available to support REACH tasks requiring measured/observed data on a local level.

Programme duration: from single sampling to time trends

Whilst for some tasks it is sufficient to get data from single sampling (e.g. for the assessment of bioaccumulation), for other tasks it is necessary to get long-term data series to deduce time trends or to show that levels in environmental media are rising or falling (e.g. persistency assessment). As can be seen from the descriptive statistics on programme duration (see Table 6) most of the EMP run for periods longer than 10 years and thus cannot only provide single sampling results, but also long-term data series (see allocation of EMP in Table 9).

Sampling frequency / sampling time:

The sampling frequency depends mainly on the media or matrix to be sampled. For example, air and water need to be sampled more frequently than soil. However, for selected REACH tasks the sampling frequency and the sampling time are also important method-related parameters. For example, for local release estimations and local exposure assessments the sampling time needs to relate to the discharge/emission pattern and the sampling frequency should be sufficient to adequately represent the concentration at the selected site. Consequently, EMP intended to provide data for local release estimations (T.1.5), local exposure estimations (T1.6), supply chain information (T.2) and success control of company-specific risk management measures (T6.1) need to be closely adapted to the respective discharge patterns and local situations in general. Therefore, these REACH tasks cannot be supported by existing EMP, but need the implementation of new EMP (usually conducted by companies).

In summary, the large variety of existing EMP can already support many of the different REACH tasks. This does however not apply to those REACH tasks that require data for local and mostly company specific situations. The latter comprise local release estimations (T.1.5), local exposure estimations (T1.6), supply chain information (T.2) and success control of company-specific risk management measures.

Furthermore, it needs to be stressed that existing EMP do only monitor a limited number of substances. Consequently the majority of substances registered under REACH is not (yet) included in any EMP. In future additional substances need to be included in EMP.

It has to be noted, however, that the ongoing EMP are driven by the respective institutional framework. Some of them are located at an international level, e.g. the UNECE-Convention on Long-range Transboundary Air Pollution (CLRTAP), the Convention for the Protection of the marine Environment of the North-East Atlantic (OSPAR) and the POP-Convention, others are part of EU secondary legislation (WFD) or of national or regional programmes. The institutional background of each programme has to be taken into account when the REACH orientated adaptation of EMP is considered. In most cases the inclusion of additional substances or sampling methods are not likely to be decided upon in a short-term perspective. All the more it is important to establish environmental monitoring from a specific REACH perspective, in particular in the field of SVHC and PBTs.

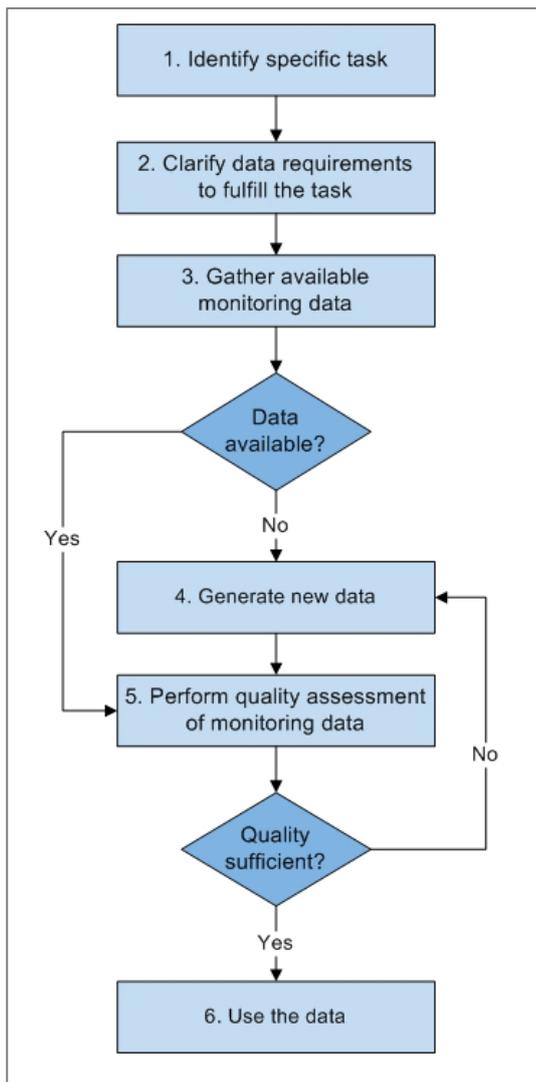
## **6 Proposal for a practical guide on the use of environmental monitoring under REACH**

Despite the fact that environmental monitoring takes place in Europe and globally since decades and consequently numerous monitoring data are available, the use of such measured data seems to be no important issue under REACH so far. One probable reason may be that there is no guidance document available summarising the possibilities and requirements for the use of (environmental) monitoring data under REACH. Therefore, a proposal for a practical guide “How to use Environmental Monitoring Data for REACH” has been developed within the framework of the current research project. This guide aims to support the use of environmental monitoring data for different REACH tasks, namely for chemical assessment, effectiveness assessment and success control under REACH. Due to the diversity of tasks under REACH, this practical guide addresses not only tasks of authorities, but also tasks for manufacturers and downstream users.

The proposed “Practical Guide – How to use Environmental Monitoring Data for REACH” is provided as a stand-alone document including also the key aspects of the present report.

The practical guide gives an introduction into substance-related environmental monitoring and illustrates the use of such data for the assessment of chemicals and for the efficiency control of REACH. Several examples make it easier to see the benefits of environmental monitoring data as an additional source of information. In addition, possibilities are described to find existing data or to build up a specific environmental monitoring programme if data do not yet exist.

In the practical guide, six steps are proposed to use environmental monitoring data for REACH, starting from the identification of the specific task up to the use of the data. These six steps are arranged in the following order:



**Note:** this flow diagram focus on the use of environmental monitoring data. In step 3, also other data should be gathered. If no data are available, in step 4 new data are generated. This can be done by monitoring – or by other activities, such as testing.

Figure 3: Working steps to use data from environmental monitoring programmes (EMP) for tasks under REACH.

In principle, the structure of the practical guide follows the proposed six steps:

Chapter 1 clarifies terms and definitions related to (environmental) monitoring. Chapter 2 and 3 of the practical guide address steps 1 and 2, i.e. the identification of the specific REACH task and the clarification of data requirements to fulfil this task, respectively. Thereby, chapter 2 aims to give a general overview on the type of data, on benefits and challenges which are related with their use, whereas chapter 3 describes the different REACH tasks in detail and clarifies the data requirements to fulfil each task.

Chapter 4 gives an overview on sources for environmental data in order support step 3 – the gathering of data.

Chapter 5 treats the generation of new data if no adequate data are available (step 4) and gives a rough description how to build an environmental monitoring program. It should be noted, however, that only in rare cases a new environmental monitoring programme can be imple-

mented. If no data from environmental monitoring are available, in most cases other data have to be used.

Chapter 6 describes quality requirements for environmental monitoring data (step 5). In most cases, environmental monitoring data will support other type of data. Therefore, they are assessed in a weight of evidence approach<sup>27</sup>.

Chapter 7 of the practical guide deals with some practical aspects with regard to the reporting of such data as part of the registration dossier.

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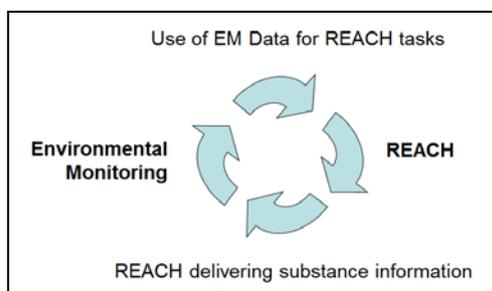
<sup>27</sup> The weight of evidence approach is described in detail in the ECHA Practical Guide No 2 ([http://echa.europa.eu/documents/10162/13655/pg\\_report\\_weight\\_of\\_evidence\\_en.pdf](http://echa.europa.eu/documents/10162/13655/pg_report_weight_of_evidence_en.pdf)).

## 7 Workshop “REACH Chemical Assessment meets Environmental Monitoring: Opportunities and Challenges”

Within the framework of the project an expert workshop was held on 18 – 19 April 2012 under the patronage of the German Federal Environment Agency (UBA). The workshop programme can be found in the annex, section 11.3. During the workshop the (preliminary) research results, including the practical guide, were presented to European experts working in the fields of chemical (risk) assessment and environmental monitoring. The participants discussed opportunities, requirements and challenges regarding the use of substance-related environmental monitoring data under REACH. Furthermore, indicators derived from substance-related EM and effect monitoring were discussed with respect to their adequacy for chemical assessment under REACH and lessons learnt from other regulatory areas (e.g. monitoring under the Pesticide Directive and human biomonitoring) were presented.

The key messages and conclusions elaborated by the experts during the workshop can be summarised as follows:

- One main aim of REACH is the protection of human health and environment by the reduction of hazardous chemicals in the environment. Environmental monitoring (EM) could be used as an important tool to support those actions required to reach this aim.
- EM and REACH can support each other mutually: EM Programmes (EMP) can provide data to support different REACH tasks, while REACH delivers specific substance information to adapt and optimise EMP.



- EMP have been established for various reasons and under different regulatory regimes, e.g. to support media-related protection targets as defined in the Water Framework Directive (WFD). Experiences show that substance identities in EMP and under REACH often do not match: Registration of a substance under REACH takes place in its commercial substance form, while in contrast EMP often monitor substances in their e.g. acidic, basic, ionic form, having different CAS numbers. Consequently, it may be difficult to match the substance lists of EMP with REACH substances. Under REACH it is unclear, to what extent metabolites are covered in the dossier, while EMP will often measure metabolites.
- As proved by the review of existing monitoring programmes in the frame of the research project there is a large variety of EM activities in Germany / EU (see chapter 2 of the present report). However, it is quite difficult to obtain the raw data (i.e. measured values) of the existing EMP. Difficulties are, inter alia, that

- often, only meta-data are published, not the original data,
  - concepts of EMP as well as presentation/publication of data are not harmonised,
  - property rights complicate the use of data,
  - administrative and organisational barriers/obstacles in data exchange between different authorities exist.
- The above listed difficulties may at least partly explain why EM data are rarely used for REACH tasks at present. The workshop participants recommend a coordinated European approach for the use of EM data under REACH as well as a central data base and/or a central data access of EM data.
  - The research project team presented an overview on the different REACH tasks that could be supported by EM data (see chapter 3 of the present report). Field reports on the practical experiences of the participants confirmed the usefulness of EM data to proof wide dispersive uses/distributions of possible substances of very high concern (SVHC) and to prove a bioaccumulation potential. However, up to now EM data are rarely used under REACH and experiences in this field are very limited. Reasons for the limited use of EM data may inter alia arise due to the fact that up to now no adequate guidance, e.g. in form of “fact sheets” or “practical guides”, exists on how to use EM data under REACH.
  - The participants expressed the wish that such a practical guide should also consider a proposal for a data format to include monitoring data into the IUCLID database in a structured manner. So far, the “Monitoring” section in IUCLID consists of a non-structured full text field. It was proposed that the requested template should provide a detailed structure for monitoring data instead.
  - In this context, the participants discussed briefly the duties of registrants and authorities, if EM data are available: It was stressed that both the registrant and the authorities have to consider all available relevant data – including EM data – within the registration and substance evaluation process.
  - The majority of EMP report concentration values of single substances in different media (e.g. µg/L). Some programmes in addition report aggregated values, such as concentrations of groups of substances /congeners (e.g.  $\Sigma$ HCH/kg), sum parameters as AOX (adsorbable organic halogens) and multi metal index (over 12 heavy metals). Besides concentration monitoring, effect monitoring can provide valuable information on contamination levels. For example, by means of SPEAR-<sup>28</sup> and NemaSPEAR-index<sup>29</sup> the effects of groups of chemicals (e.g. organic substances, metals, pesticides) on the environmental compartments surface water and sediment, can be quantified. Based on the effect monitoring, the identification of individual stressors / pollutants could subsequently be conducted. Effect data from monitoring can also be used to indicate which substances or groups of substances are of high priority for further actions such as

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<sup>28</sup> SPEAR: SPEcies At Risk

<sup>29</sup> NemaSPEAR: Nematode SPEcies At Risk

restrictions or authorisations. Furthermore, this effect monitoring could support the effectiveness evaluation of REACH as a whole.

- The workshop participants stressed the importance of a close co-operation with industry.

The workshop concluded with the formulation of four necessary steps to support the further use of environmental monitoring data under REACH.

1. **Bridge the gap between REACH and EM!**

The two pillars REACH and EM need to be connected by encouraging exchange between experts of both fields and by bringing the organisational structures (e.g. ECHA responsible for REACH and EEA responsible for EM) closer together.

The exchange of information and experiences between REACH and EM experts should be continued in annual meetings.

2. **Single access point to EMP data** is needed (e.g. in form of a central database) to make the most effective use of existing EM data.
3. The preparation of a **practical guide** “How to use monitoring data under REACH” is a good starting point both to raise awareness (on EU level and in the Member States) to this topic and to provide guidance on the practical approach.
4. A clear **political commitment** is required for the use of environmental monitoring data in chemical evaluations – and for a harmonisation of the existing monitoring activities and data bases – as it has been made for human biomonitoring. This kind of policy support is necessary to achieve more success within the scientific community with regard to an intensive exchange between REACH and EM experts.

## 8 Conclusions

With regard to the overall aim of the study to elaborate a general recommendation for the use of environmental monitoring data under REACH and to evaluate the possibilities and restrictions of the use of existing EMP, the following conclusions and future recommendations can be drawn:

- Many of the existing EMP can provide data to support different REACH tasks. A first proposal for a practical guide “How to use Environmental Monitoring Data for REACH” has been developed within the framework of the current research project. This proposal could serve as basis for the development of a harmonised guidance on EU level.
- The gathering of environmental monitoring data (e.g. by registrants) might be complicated by lacking transparency on respective web-site or even restricted accessibility to data/metadata. For some REACH tasks it may even be essential to have access not only to the metadata but also to raw data of EMP. Therefore it is necessary to clarify and harmonise the different access criteria to easily obtain results of EMP. In this context the implementation of a central European data base (“Chemical Data Centre”) to ease the access to available monitoring data is to be discussed.
- In compliance with the various objectives of monitoring programmes and with the need to ensure that no methodological changes are made in long-term trend analyses, a harmonization of environmental monitoring activities (especially of the documentation) should be aimed at on EU level.
- Existing EMP do only monitor a limited number of chemical substances. Consequently the majority of chemical substances registered under REACH is not (yet) included in any EMP. Therefore in future additional substances need to be included in EMP. It has to be noted, however, that the ongoing EMP are driven by the respective institutional framework. Some of them are located at an international level, e.g. the UNECE-Convention on Long-range Transboundary Air Pollution (CLRTAP), the Convention for the Protection of the marine Environment of the North-East Atlantic (OSPAR) and the POP-Convention, others are part of EU secondary legislation (WFD) or of national or regional programmes. The institutional background of each programme has to be taken into account when the REACH orientated adaption of EMP is considered. In most cases the inclusion of additional substances or sampling methods are not likely to be decided upon in a short term perspective. All the more it is important to establish environmental monitoring from a specific REACH perspective, in particular in the field of SVHC and PBTs.
- The exchange between chemical (risk) assessment experts under REACH on the one hand and environmental monitoring experts on the other hand needs to be intensified, for example by establishing annual expert meetings for information exchange.
- Administrative and organisational structures need to be improved with regard to data exchange between different authorities in order to eliminate existing information barriers. With this respect the regulatory framework established in the context of the Aarhus Convention on the European, national and regional level providing, i.a., the active dissemination of environmental data, might support activities in order to simplify the availability and accessibility of monitoring results.

In the case of human monitoring data, the projects COPHES and DEMOCOPHES support the harmonisation of data from many different countries. A similar European activity for environmental monitoring data would be a big step forward to use these data for REACH.

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## 11 Annex

### 11.1 Excerpts: Use of the term „monitor“/„monitoring“ in the REACH Regulation

The term „monitor“/„monitoring“ occurs in the text of the REACH Regulation (EC) No 1907/2006 in different contexts. In order to allow a condensed overview the relevant provisions are collected in the following excerpts- The different tasks deriving from these provisions are discussed in chapter 3.

#### ***Recitals***

- (72) To support the aim of eventual replacement of substances of very high concern by suitable alternative substances or technologies, all applicants for authorisation should provide an analysis of alternatives considering their risks and the technical and economic feasibility of substitution, including information on any research and development the applicant is undertaking or intends to undertake. Furthermore, authorisations should be subject to time-limited review whose periods would be determined on a case-by-case basis and normally be subject to conditions, including **monitoring**.
- (82) To allow effective **monitoring** and enforcement of the authorisation requirement, downstream users benefiting from an authorisation granted to their supplier should inform the Agency of their use of the substance.
- (116) Regular reports by the Member States and the Agency on the operation of this Regulation will be an indispensable means of **monitoring** the implementation of this Regulation as well as trends in this field. Conclusions drawn from findings in the reports will be useful and practical tools for reviewing this Regulation and, where necessary, for formulating proposals for amendments.
- (121) In order to ensure compliance with this Regulation, Member States should put in place effective **monitoring** and control measures. The necessary inspections should be planned, carried out and their results should be reported.

#### **Art. 60 Granting of authorisations**

8. Authorisations shall be subject to a time-limited review without prejudice to any decision on a future review period and shall normally be subject to conditions, including **monitoring**. The duration of the time-limited review for any authorisation shall be determined on a case-by-case basis taking into account all relevant information including the elements listed in paragraph 4(a) to (d), as appropriate.

9. ....

(f) any **monitoring** arrangement.

#### **Article 124 Other responsibilities**

Competent authorities shall submit electronically to the Agency any available information that they hold on substances registered in accordance with Article 12(1) whose dossiers do not contain the full information referred to in Annex VII, in particular whether enforcement or

**monitoring** activities have identified suspicions of risk. The competent authority shall update this information as appropriate.

### **Article 127 Report**

The report referred to in Article 117(1) shall, in relation to enforcement, include the results of the official inspections, the **monitoring** carried out, the penalties provided for and the other measures taken pursuant to Articles 125 and 126 during the previous reporting period. The common issues to be covered in the reports shall be agreed by the Forum. The Commission shall make these reports available to the Agency and the Forum.

## **Annex I**

### **4. PBT AND VPVB ASSESSMENT**

#### 4.1. Step 1: Comparison with the Criteria

This part of the PBT and vPvB assessment shall entail the comparison of the available information, which is submitted as part of the technical dossier, with the criteria given in Annex XIII and a statement of whether the substance fulfils or does not fulfil the criteria.

If the available information is not sufficient to decide whether the substance fulfils the criteria in Annex XIII, then other evidence like **monitoring** data available for the registrant and giving rise to an equivalent level of concern shall be considered on a case-by-case basis.

### **5. EXPOSURE ASSESSMENT**

#### 5.2. Step 2: Exposure Estimation

5.2.5. Where adequately measured representative exposure data are available, special consideration shall be given to them when conducting the exposure assessment. Appropriate models can be used for the estimation of exposure levels. Relevant **monitoring** data from substances with analogous use and exposure patterns or analogous properties can also be considered.

## **ANNEX II (SDS) – Reg. 2010/453**

#### 4.3. Indication of any immediate medical attention and special treatment needed

Where appropriate, information shall be provided on clinical testing and medical **monitoring** for delayed effects, specific details on antidotes (where they are known) and contraindications.

#### 8.1. Control parameters

8.1.2. Information on currently recommended **monitoring** procedures shall be provided at least for the most relevant substances.

## **ANNEX XIII – PBT/VP/VB-CRITERIA**

### Introduction para 4

A weight-of-evidence determination means that all available information bearing on the identification of a PBT or a vPvB substance is considered together, such as the results of **monitoring** and modelling, suitable in vitro tests, relevant animal data, information from the application of the category approach (grouping, read-across), (Q)SAR results, human experience

such as occupational data and data from accident databases, epidemiological and clinical studies and well documented case reports and observations. The quality and consistency of the data shall be given appropriate weight. The available results regardless of their individual conclusions shall be assembled together in a single weight-of-evidence determination.

### 3.2.1. Assessment of P or vP properties

(d) Other information, such as information from field studies or **monitoring** studies, provided that its suitability and reliability can be reasonably demonstrated.

## **Annex XV**

### **3. Dossiers for restrictions proposal**

#### Justification for Restrictions at Community Level

Justification shall be provided that:

- action is required on a Community-wide basis,
- a restriction is the most appropriate Community wide measure which shall be assessed using the following criteria:
  - (i) effectiveness: the restriction must be targeted to the effects or exposures that cause the risks identified, capable of reducing these risks to an acceptable level within a reasonable period of time and proportional to the risk;
  - (ii) practicality: the restriction must be implementable, enforceable and manageable;
  - (iii) **monitorability**: it must be possible to monitor the result of the implementation of the proposed restriction.

## **ANNEX XVI – SOCIO-ECONOMIC ANALYSIS**

### ***An SEA may include the following elements:***

- impact of a granted or refused authorisation on the applicant(s), or, in the case of a proposed restriction, the impact on industry (e.g. manufacturers and importers). The impact on all other actors in the supply chain, downstream users and associated businesses in terms of commercial consequences such as impact on investment, research and development, innovation, one-off and operating costs (e.g. compliance, transitional arrangements, changes to existing processes, reporting and monitoring systems, installation of new technology, etc.) taking into account general trends in the market and technology

## 11.2 REACH tasks, data requirements and allocated EMP

Table 8: Overview on REACH tasks, subtask, allocated environmental monitoring types and their data requirements

| REACH tasks  | Subtasks   | Type of environmental monitoring (see section 2.2)   | Required data   |
|--|--|--|---|
| T1: Registration<br>1. Assessment of substance properties (including hazard assessment);<br>2. Exposure assessment | T1.1: Assessment of persistency (e.g. PBT assessment)                            | EM-type 2  | Persistency data such as concentrations in remote and pristine regions e.g. Arctic sea or Alpine lakes or in higher levels of the food chain; time trends showing that levels in environmental media/biota are rising |
|  | T1.2: Assessment of bioaccumulation (e.g. PBT assessment)                        | EM-type 3  | Bioconcentration data; for PBT assessment: widespread occurrence in biota unrelated to local sources, particularly top predators and biota in remote areas  |
|  | T1.3: Assessment of biomagnification (e.g. PBT assessment)                       | EM-type 3  | Bioconcentration data in different trophic levels   |
|  | T1.4: Assessment of (eco)toxicity (e.g. PBT assessment)                          | EM-types 4 and 5   | Monitoring data are not applicable to support the classification of a substance as "toxic". However, effect monitoring or biological monitoring can give evidence of toxic impacts.                                   |
|  | T1.5: Release estimations  | EM-type 1  | a) Release rates; Loads to environm. compartments; Effluent concentration   |
|  |  | EM-type 1  | b) Removal in sewage treatment plants (STP)   |
|  | T1.6: Local exposure estimation / Validation of exposure modelling               | EM-type 2  | Environmental concentrations in the vicinity of emitters (point sources): air, water, sediment, soil  |
| T1.7: Regional exposure estimation / Validation of exposure modelling  | EM-type 2  | Environmental concentrations in rural areas (i.e. sites with larger distances to emitters) |   |
| T2: Supply Chain Information   | T2.1: New hazardous properties: local accumulation/ local effects                | EM-types 4 and 5   | Concentration in environmental compartments close to the emittent / Data from whole effluent testing or effect monitoring or biological monitoring could give evidence of toxic impacts.                              |
|  | T2.2: Appropriateness of RMM   | EM-type 1  |   |
| T3: Substance evaluation   | T3.1: Prioritisation of substances for evaluation (criteria given in Art. 44(1)) | EM-type 3  | a) Hazard information: Properties of concern (SVHC), Persistency data, Bioaccumulation data; Concentration in environmental compartments / biota  |
|  |  |  | b) Exposure information: Concentration in environmental compartments / biota  |
|  | T3.2: Identification of new emerging   | EM-type 2  | Concentrations in environmental compartments / biota  |

| REACH tasks                                   | Subtasks  | Type of environmental monitoring (see section 2.2) | Required data   |
|---|---|--|---|
|   | pollutants  |  |   |
| T4: Authorisation of substances               | T4.1. Identif. of substances as SVHC (PBT, vPvB) i.e. for candidate list/Annex XIV;<br>Preparation of Annex XV dossiers | EM-type 3<br>EM-type 2                             | a) Data showing bioaccumulation and/or persistence of substances<br>b) Data showing ubiquitous exposure of the environment  |
|   | T4.2: Success control of risk management measures for substances requiring an authorisation                             | EM-type 1  | Concentrations in waste water and in receiving environmental compartments   |
| T5: Restriction of substances                 | T5.1: Decision making support for proposals on substance restriction  | EM-type 2  | Concentration time trends (EU wide)   |
| T6: Self-control of industry and enforcement  | T6.1: Control of company-specific risk management measures for substances   | EM-types 1 and 2                                   | Local emissions to or concentrations in waste water (effluents) and in receiving environmental compartments;<br>Local effect data from whole effluent testing;<br>Local impact indicators such as SPEAR and nemaSPEAR |
|   | T6.2: Success control of risk management measures for substances requiring an authorisation/ restriction                | EM-types 1 and 2                                   | Regional data on concentrations in waste water (effluents) and in receiving environmental compartments  |
| T7: Efficiency assessment of REACH as a whole | T7.1: Sufficient protection of environ. + human health  | EM-type 2  | Data on effects on biota, EQS + total emissions of chemicals into the compartments  |
|   | T7.2: Trends of concentrations of hazardous substances  | EM-type 2  | Trends in EM data for all environmental compartments  |
|   | T7.3: Geo- and bioaccumulation of persistent substances   | EM-type 2  | EM data for all environmental compartments  |

Table 9: Requested method-related parameters and reported values/indicators of single REACH Subtasks (see Table 8) and allocation of existing EMP fulfilling these requirements to single REACH Subtasks

| Sub task | Method-related parameters   |   |  |                               |                     |  |   | Reported value / Indicator  |                                 | Existing programmes <sup>30</sup>  |
|----------|---|---|--|-------------------------------|---------------------|--|---|-----------------------------|---------------------------------|--|
|          | Compart-ment  | Media/ Sample Material                  | Sampling location <sup>31</sup>  | Geogr. coverage <sup>32</sup> | Pro-gramme duration | Sampling frequency/ time   | Actuality of data   | Type of value <sup>33</sup> | Details on values <sup>34</sup> |  |
| T1.1     | Compart-ment of concern depend- ing on sub- stance proper- ties <sup>35</sup> | Depen- ding on compart- ment of concern | Remote and pristine regions e.g. Arctic sea or Alpine lakes; Higher levels of the food chain in unpolluted areas | n.r. ("not relevant")         | Long-term           | Depending on media: soil: once per year; water: monthly or quarterly | For persistency assessment itself not relevant, however, for PBT assess- ment current data are of higher significance | Concen- trations            | time trends                     | UPB / ESB (#1), EMEP (#8), MONARPOP (#78), MONAR+ (#253), UBA Luftmess- netz (#11), most of the AMAP program- mes (#79-#96; #98), Environmental Specimen Bank Sweden (#102), National Monitoring and Assessment Programme for the Aquatic and Terrestrial Environments (NOVANA) (#103), Environmental Soil Survey (ESS) (#116), Soil Monitoring Austria (#118), Global Atmosphere Watch (GAW) (#126), National Swedish Environmen- |

<sup>30</sup> (# no.) refers to Excel-overview-Sheet on Monitoring Programmes

<sup>31</sup> e.g. remote area; up-/downstream of discharger

<sup>32</sup> local / regional / national / EU-wide

<sup>33</sup> e.g. concentration / load / sum / parameters / indices

<sup>34</sup> e.g. single values / mean/average values / percentiles / time trends

<sup>35</sup> Environmental monitoring is done in different environmental compartments, i.e. air, surface water, groundwater, sediment, soil, etc. The compartment of concern for a certain substance depends on the intrinsic physico-chemical substance properties. Section 11.4 in the Annex describes exemplarily for some selected substances how the compartment of concern can be determined on basis of the intrinsic substance properties. Although this is less relevant for the use of existing monitoring data under REACH, this is a major aspect for the design of new EMP.

| Sub task | Method-related parameters                                     |  |   |  |   |  |  | Reported value / Indicator  |                                 | Existing programmes <sup>30</sup>   |
|----------|---|--|---|--|---|--|--|-----------------------------|---------------------------------|---|
|          | Com-part-ment   | Media/ Sample Material   | Sampling location <sup>31</sup>   | Geogr. coverage <sup>32</sup>  | Pro-gramme duration                                 | Sampling frequency/ time   | Actuality of data  | Type of value <sup>33</sup> | Details on values <sup>34</sup> |   |
|          |   |  |   |  |   |  |  |                             |                                 | tal Monitoring Programme - Integrated Monitoring (#133), MONAIRNET (#252)   |
| T1.2     | Biota; Biota & surrounding compartment (e.g. water, sediment) | Biota (fish, earth-worm, mammals, birds, predators) and surrounding media (e.g. for fish: surface water) | Sampling at organisms home range; for PBT assessment: bioaccumulation in remote, unpolluted areas is of higher significance | n.r. for PBT: widespread occurrence (unrelated to local sources) is of higher significance | n.r. (from single sampling to long-term programmes) | Biota & surrounding compartment (e.g. water, sediment) need to be sampled at the same time | For bio-accumulation assessment itself not relevant, however, for PBT assessment current data are of higher significance | Concentrations              | Single values                   | UPB / ESB (#1), AMAP programmes (e.g. temporal trends and spatial variations in persistent organic pollutants and metals in sea-run char from the Canadian arctic, temporal trends of contaminants in arctic seabird eggs: inter-year variability; temporal trends of heavy metals and halogenated organic compounds in arctic marine mammals; temporal trends of persistent organic pollutants and metals in ringed seals from the Canadian arctic; temporal and spatial trends of organic and metal contaminants in Canadian polar bears; (#79-#96; 9#8)), Trilaterales Monitoring and assessment programme (TMAP) (#47), ICP Vegetation / ICP Crops (#35), MONARPOP (#78), MONAR+ (#253), National Swedish Monitoring Programme (#99), PREStige (#141) |
| T1.3     | Biota   | Biota from different trophic levels;   | n.r. for PBT assessment: bioaccumulation in remote, unpolluted areas is of  | n.r. for PBT: widespread occurrence (unrelated to local sources) is of higher              | n.r. (from single sampling to long-term programmes) | depending on media: time of year could be relevant   | for biomagnification assessment itself not relevant, however, for PBT assessment current                                 | Concentrations              | Single values                   | UPB / ESB (#1), PREStige (#141), AMAP programmes (e.g. Temporal and spatial trends of organic and metal contaminants in Canadian polar bears; (#79-#96; #98))   |

| Sub task | Method-related parameters  |   |   |                               |   |  |   | Reported value / Indicator   |   | Existing programmes <sup>30</sup>            |
|----------|--|---|---|-------------------------------|---|--|---|--|---|--|
|          | Com-partment   | Media/ Sample Material  | Sampling location <sup>31</sup>   | Geogr. coverage <sup>32</sup> | Pro-gramme duration   | Sampling frequency/ time   | Actuality of data   | Type of value <sup>33</sup>  | Details on values <sup>34</sup>                       |  |
|          |  |   | higher significance   | significance                  |   |  | data are of higher significance   |  |   |  |
| T1.4     | Com-partment of concern depending on substance properties, but most probable surface water | Sub-stance-related effects on biota; Composition/ number of species | Comparison of uncontaminated and contaminated locations, e.g. up-/down-stream of discharger | n.r.                          | n.r. (from single sampling to long-term programmes)   | Sampling frequency/ time needs to consider possible seasonal variations (e.g. with regard to species composition) and emission pattern of discharger                 | n.r.  | Possible effects induced by substance; Indices (e.g. SPEAR); in addition: concentration values in biota and surrounding media for concentration-effect relationships |   | UPB (1)                                      |
| T1.5 a)  | -  | Effluent or exhaust air, depending on substance properties          | Effluent of a discharger  | Local at the discharger       | Single sampling: e.g. measurement of peak loads; short-/long-term: e.g. determination of temporal mean/ average loads | Sampling frequency/ time needs to relate to the discharge/ emission pattern and should be sufficient to adequately represent the concentration at the selected site. | Data need to be up-to-date in order to be representative of risk management measures and operating conditions | Concentrations   | Single values<br>Mean/ average values;<br>percentiles | Monitoring programmes conducted by companies |

| Sub task   | Method-related parameters |                        |                                 |                               |   |                                   |  | Reported value / Indicator  |                                    | Existing programmes <sup>30</sup>            |
|------------|---------------------------|------------------------|---------------------------------|-------------------------------|---|-----------------------------------|--|-----------------------------|------------------------------------|--|
|            | Com-part-ment             | Media/ Sample Material | Sampling location <sup>31</sup> | Geogr. coverage <sup>32</sup> | Pro-gramme duration   | Sampling frequency/ time          | Actuality of data  | Type of value <sup>33</sup> | Details on values <sup>34</sup>    |  |
| T1.5<br>b) | STP                       | Water                  | Influent and effluent of STP    | n.r.                          | Longer period of time to cover different climatic conditions (summer/ winter) | Daily over the programme duration | Data need to be up-to-date in order to be representative of operating conditions | Concentra-tions             | Mean/ average values (over a year) | Monitoring programmes conducted by companies |

| Sub task | Method-related parameters                                 |                                       |  |   |   |  |  | Reported value / Indicator  |                                 | Existing programmes <sup>30</sup>   |
|----------|---|---------------------------------------|--|---|---|--|--|-----------------------------|---------------------------------|---|
|          | Com-partment  | Media/ Sample Material                | Sampling location <sup>31</sup>  | Geogr. coverage <sup>32</sup>   | Pro-gramme duration   | Sampling frequency/ time   | Actuality of data  | Type of value <sup>33</sup> | Details on values <sup>34</sup> |   |
| T1.6     | Com-partment of concern depending on substance properties | Depen-ding on compart-ment of concern | Sampling sites in the vicinity of emitters, i.e. samples taken at sites directly influenced by the release | Local coverage, single site sufficient  | Single sampling: e.g. measure-ment of peak loads; short-/long-term: e.g. determi-nation of temporal mean loads/ average loads | Sampling frequency/ time needs to relate to the emission pattern     | Data need to be up-to-date in order to be representa-tive of risk management measures and operating conditions | Concentra-tions             |                                 | Monitoring programmes conducted by companies  |
| T1.7     | Com-partment of concern depending on substance properties | Depen-ding on compart-ment of concern | Sampling sites should represent regional scenario: i.e. sites with larger distances to emitters            | Several sampling sites distributed in the region under consideratio n to obtain a regional coverage | Long-term   | Depending on media: soil: once per year; water: monthly or quarterly | Data need to be up-to-date in order to be representativ e of risk management measures and operating conditions | Concentra-tions             |                                 | UBA Luftmessnetz (#11); Bioindikationsmonitoring der Länder (#67); European Monitoring and Evaluation Programme EMEP (#8); ICP Integrated Monitoring (#37); OSPAR Comprehensive Atmospheric Monitoring Programme (CAMP) (#39), Int. Kommission Schutz Rhein (IKSR) (#53), LAWA Messnetz (#52), Boden-Dauerbeobachtung (#73-#76), UPB / ESB (#1) |

| Sub task | Method-related parameters                                  |                                       |  |  |  |  |                   | Reported value / Indicator  |                                 | Existing programmes <sup>30</sup>   |
|----------|--|---------------------------------------|--|--|--|--|-------------------|---|---------------------------------|---|
|          | Com-partment   | Media/ Sample Material                | Sampling location <sup>31</sup>  | Geogr. coverage <sup>32</sup>                | Pro-gramme duration                                  | Sampling frequency/ time   | Actuality of data | Type of value <sup>33</sup>   | Details on values <sup>34</sup> |   |
| T2.1     | Com-partment of concern depending on sub-stance properties | Depen-ding on compart-ment of concern | Sampling sites in the vicinity of emitters/ compare up- and down-stream data | Local coverage, for specific downstream user | n.r. (from single sampling to long-term pro-grammes) | Sampling frequency/ time needs to consider possible seasonal variations (e.g. with regard to species composition) and emission pattern of discharger | n.r.              | Possible effects induced by the sub-stance; Indices (e.g. SPEAR); in addition: concentration values in biota and surrounding media for concentration-effect relationships |                                 | Monitoring programmes conducted by companies  |
| T2.2     | see T6.1   |                                       |  |  |  |  |                   |   |                                 | Monitoring programmes conducted by companies  |
| T3.1     | see T1.1.-T1.4   |                                       |  |  |  |  |                   |   |                                 |   |
|          | see T1.5.-T1.7   |                                       |  |  |  |  |                   |   |                                 |   |
| T3.2     | see T1.1.-T1.7   |                                       |  |  |  |  |                   |   |                                 | UPB / ESB (#1), NORMAN (#231), Ökologische Flächenstichprobe (#129) (retrospective analysis of new emerging pollutants) |
| T4.1 a)  | see T1.1.-T1.4   |                                       |  |  |  |  |                   |   |                                 | Monitoring network Alpine Region (MONARPOP) (#78), Arctic monitoring and assessment programme (AMAP) (#79-#96; #98),    |

| Sub task   | Method-related parameters                                 |                                       |                                    |   |                     |   |  | Reported value / Indicator  |  | Existing programmes <sup>30</sup>  |
|------------|---|---------------------------------------|------------------------------------|---|---------------------|---|--|-----------------------------|--|--|
|            | Com-partment  | Media/ Sample Material                | Sampling location <sup>31</sup>    | Geogr. coverage <sup>32</sup>   | Pro-gramme duration | Sampling frequency/ time  | Actuality of data                                | Type of value <sup>33</sup> | Details on values <sup>34</sup>  |  |
| T4.1<br>b) | Com-partment of concern depending on substance properties | Depen-ding on compart-ment of concern | Rural, remote and pristine regions | Broad geographical coverage over EU to demon-strate ubiquitous distribution | Long-term           | Depending on media: e.g. soil: once per year; water: monthly or quarterly | Recent data required to reflect actual situation | Concentra-tions             | Time trends (increasing concentra-tions coupled with ubiquitous distribution stress the need for action) | Moss monitoring (#65); Bioindikationsmonitoring der Länder (#66); European Monitoring and Evaluation Programme EMEP (#8); ICP Integrated Monitoring (#36), OSPAR Comprehensive Atmospheric Monitoring Programme (CAMP) (#38), OSPAR CEMP (#40), Int. Kommission Schutz Rhein (IKSR) (#52), LAWA Messnetz (#51), OSPAR Riverine inputs and direct discharges (RID) (#39), Boden-Dauerbeobachtung (#73-#76), Trilaterales Monitoring and assessment programme (TMAP) (#47), International Council for the exploration of the sea (#37), UPB / ESB (#1), Monitoring network Alpine Region (MONARPOP) (#78), Arctic monitoring and assessment programme (AMAP) (#79-#96; #98), Coop. monitoring Baltic Marine Environment (HELCOM COMBINE) (#41) |
| T4.2       | see T6.1 and T6.2   |                                       |                                    |   |                     |   |  |                             |  |  |

| Sub task | Method-related parameters |                        |                                 |                               |                     |                          |                   | Reported value / Indicator  |                                 | Existing programmes <sup>30</sup>  |
|----------|---------------------------|------------------------|---------------------------------|-------------------------------|---------------------|--------------------------|-------------------|-----------------------------|---------------------------------|--|
|          | Com-part-ment             | Media/ Sample Material | Sampling location <sup>31</sup> | Geogr. coverage <sup>32</sup> | Pro-gramme duration | Sampling frequency/ time | Actuality of data | Type of value <sup>33</sup> | Details on values <sup>34</sup> |  |
| T5.1     | see T4.1                  |                        |                                 |                               |                     |                          |                   |                             |                                 | Moss monitoring (#65);<br>Bioindikationsmonitoring der Länder (#66);<br>European Monitoring and Evaluation Programme EMEP (#8); ICP Integrated Monitoring (#36), Int. Kommission Schutz Rhein (IKSR) (#52), LAWA Messnetz (#51), OSPAR Riverine inputs and direct discharges (RID) (#39), OSPAR CEMP (#40), Boden-Dauerbeobachtungen (#73-#76), Trilaterales Monitoring and assessment programme (TMAP) (#47), International Council for the exploration of the sea (#37), UPB / ESB (#1), Monitoring network Alpine Region (MONARPOP) (#78), Arctic monitoring and assessment programme (AMAP) (#79-#96; #98) |

| Sub task | Method-related parameters  |   |   |  |   |  |   | Reported value / Indicator  |                                 | Existing programmes <sup>30</sup>                             |
|----------|--|---|---|--|---|--|---|---|---------------------------------|---|
|          | Compart-ment   | Media/ Sample Material                  | Sampling location <sup>31</sup>   | Geogr. coverage <sup>32</sup>  | Pro-gramme duration                                   | Sampling frequency/ time   | Actuality of data   | Type of value <sup>33</sup>   | Details on values <sup>34</sup> |   |
| T6.1     | Compart-ment of concern depend- ing on sub- stance proper- ties  | Depen- ding on compart- ment of concern | Sampling sites in the vicinity of emitters/ compare up- /downstream                             | Local coverage, addressing the specific company  | n.r. (from single sampling to long-term pro- grammes) | Sampling frequency/ time needs to consider possible seasonal variations (e.g. with regard to species com- position) and emission pattern of discharger | Data need to be up-to-date in order to be representa- tive of risk management measures and operating conditions | Possible effects induced by the sub- stance; Indices (e.g. SPEAR); in addition: concentration values in biota and surrounding media for concentration -effect relationships | Single values                   | Monitoring programmes conducted by companies e.g. EON/Datteln |
| T6.2     | Compart- ment of concern dependin- g on sub- stance proper- ties | Depen- ding on compart- ment of concern | Sampling sites should represent regional scenario: i.e. sites with larger distances to emitters | Several sampling sites distri- buted in the region un- der consi- deration to obtain a regional coverage | Long-term   | Depending on media: soil: once per year; water: monthly or quarterly   | recent data required to see trends compared to reference points before REACH                                    | Concentra- tions  | Time trends                     | Monitoring programmes conducted by companies e.g. EON/Datteln |

| Sub task | Method-related parameters  |   |   |                                      |                         |  |  | Reported value / Indicator  |                                 | Existing programmes <sup>30</sup>  |
|----------|--|---|---|--------------------------------------|-------------------------|--|--|---|---------------------------------|--|
|          | Compart-ment   | Media/ Sample Material  | Sampling location <sup>31</sup>   | Geogr. coverage <sup>32</sup>        | Pro-gramme duration     | Sampling frequency/ time   | Actuality of data  | Type of value <sup>33</sup>   | Details on values <sup>34</sup> |  |
| T7.1     | Environ. Comp. + Biota   | Biota from different trophic levels; Substance-related effects on biota; Composition/ number of species | Sampling sites should represent regional scenarios; including rural, urban and pristine areas | EU wide and selected reference areas | Long-term to see trends | Endpoint / effect specific (e.g. with regard to species composition); for time trends sampling has to take place every year at the same time | Recent data required to see trends compared to reference points before REACH | Biodiversity indices and effect data/ Total load of chemicals emitted to the compartments   | Time trends                     | Ökologische Flächenstichprobe (#129), Moss monitoring (#65)<br>LAWA Messnetz (#51): water quality classes on basis of e.g. AOX Indicator;<br><br>(all effect programs; biodiversity programs)  |
| T7.2     | Compartment depending on properties of selected indicator substances/ groups of substances | Media depending on properties of selected indicator substances/ groups of substances                    | Sampling sites should represent regional scenarios; including rural, urban and pristine areas | EU wide and selected reference areas | Long-term to see trends | For time trends sampling has to take place every year at the same time   | Recent data required to see trends compared to reference points before REACH | Concentrations of indicator substances or indicator groups (which have to be specified)/ Sum parameters for total exposure of the environment | Time trends                     | LAWA Messnetz (#51): water quality classes on basis of e.g. AOX Indicator; UPB / ESB (#1)<br>Programmes determining sum parameters such as heavy metal index; Environmental Specimen Bank (ESB) and comparable approaches have the potential to determine these parameters retrospectively |

| Sub task | Method-related parameters  |  |   |                                      |                         |  |  | Reported value / Indicator  |                                 | Existing programmes <sup>30</sup> |
|----------|--|--|---|--------------------------------------|-------------------------|--|--|---|---------------------------------|-----------------------------------|
|          | Com-part-ment  | Media/ Sample Material   | Sampling location <sup>31</sup>   | Geogr. coverage <sup>32</sup>        | Pro-gramme duration     | Sampling frequency/ time   | Actuality of data  | Type of value <sup>33</sup>   | Details on values <sup>34</sup> |                                   |
| T7.3     | Com-part-ment depending on properties of selected indicator sub-stances/ groups of sub-stances | Media depending on properties of selected indicator sub-stances/ groups of sub-stances | Sampling sites should represent regional scenarios; including rural, urban and pristine areas | EU wide and selected reference areas | Long-term to see trends | For time trends sampling has to take place every year at the same time | Recent data required to see trends compared to reference points before REACH | Concentra-tions for indicator substances (which have to be specified)/ Indicator for the total bio-burden/geo-burden with accumulating substances | Time trends                     | -                                 |

### 11.3 Background and programme of the UBA-workshop



UBA Workshop, 18 – 19 April 2012

#### **REACH Chemical Assessment meets Environmental Monitoring: Opportunities and Challenges**

Umweltbundesamt (UBA), Wörlitzer Platz 1, D-06844 Dessau-Roßlau, Germany

Authors: Rita Groß, Dirk Bunke, Yvonne Floredo, Martin Führ

#### Background

The chemicals legislation REACH defines a complex set of tasks for authorities, for manufacturers and/or importers as well as for downstream users. These different REACH tasks range from registration, restriction and authorisation of individual substances up to the effectiveness evaluation of REACH as a whole. Many of these tasks could be supported by environmental monitoring (EM) data.

In the frame of a currently conducted research project (FKZ 371 063 404) funded by the German Federal Environment Agency (UBA) environmental monitoring programmes (EMP) have been reviewed and analysed for their methods and indicators in order to identify how existing and future EMP need to be designed so that they can be used for the different REACH tasks. A guidance document developed within the project framework intends to give instructions for the use of environmental monitoring data under specific REACH tasks.

This UBA Workshop presented preliminary research results, including the guidance document and discussed opportunities, requirements and challenges regarding the use of substance-related environmental monitoring data under REACH. In a further session indicators derived from substance-related EM and effect monitoring were discussed with respect to their adequacy for chemical assessment under REACH. In addition, lessons learnt from other regulatory areas (e.g. monitoring under the Pesticide Directive and human biomonitoring) were presented. Finally, necessary steps to support the further use of environmental monitoring data under REACH were formulated.

## Programme of the Workshop

### **Welcome & Opening** (K. G. Steinhäuser, UBA)

### **Session 1: Regulatory tasks under REACH and environmental monitoring**

#### Key notes

- Overview on the project “Environmental Monitoring of Chemicals under REACH”(R. Groß, ÖI)
- Existing monitoring programmes in Germany & Europe (Y. Floredo, BiPRO)
- Support of environmental monitoring data for specific REACH tasks (R. Groß, ÖI)
- Effectiveness of REACH: Options at Union level and for MS authorities (M. Führ, sofia)

### **Session 2: Practical experiences in utilising environmental monitoring under REACH**

#### Key notes

- French examples of environment monitoring actions for the identification of chemicals of concern (S. Andres, INERIS)
- Project RISK-IDENT and feed-back to chemicals legislation (F. Geldsetzer, LfU Bayern)
- Prioritizing emerging substances based on environmental concern (P. van Beelen, RIVM)
- Hot spot monitoring (I. Offenthaler, UBA Austria)
- Peregrine Falcon Egg Pollutants: Mirror Stockholm POPs-List (T. v.d. Trenck, LUBW)
- Guidance document “How to use monitoring data under REACH” (D. Bunke, ÖI)

### **Session 3: Indicators derived from substance-related environmental monitoring**

#### Key notes

- Existing indicators in environmental monitoring programmes (R. Groß, ÖI)
- SPEAR (M. Liess, UfZ)
- NemaSPEAR – A chemical impact indicator for sediment pollution (M. Brinke, BfG)

### **Session 4: Next steps to support the use of environmental monitoring data under REACH**

#### Lessons learnt from other areas / Requirements for harmonisation

#### Key notes

- Plant Protection Products – Environmental Monitoring (P. Klaas, UBA)
- Lessons learnt from: Human Biomonitoring, Europe and the use of monitoring data for policy making (M. Kolossa-Gehring, UBA)

Next steps to support the use of environmental monitoring data under REACH (Y. Floredo, BiPRO)

## 11.4 Exemplary selection of relevant environmental compartments for monitoring

Environmental monitoring is done in different environmental compartments, i.e. air, surface water, groundwater, sediment, soil, etc. The compartment of concern for a certain substance depends i.a. on the intrinsic physico-chemical substance properties and the effects to organisms and ecosystems. The following chapter is the report's 'icing on the cake' where we describe exemplarily for some selected substances how the compartment of concern can be determined on basis of the intrinsic substance properties. Although this is less relevant for the use of existing monitoring data under REACH, this is a major aspect for the design of new EMP.

The elaboration of a monitoring concept includes the selection of the environmental media (compartments) that are most appropriate as samples for the aim of the study. Substances in the environment partition between the different media or compartments such as water, suspended particulate matter, sediment, soil, air and/or biota. Predicting the distribution of the chemical substances requires knowledge of their physico-chemical properties including octanol-water partitioning coefficient (log Kow), water solubility, vapour pressure, etc.

The octanol-water partitioning coefficient (log Kow) is one key parameter for the prediction of the distribution and behaviour of a chemical substance in the environment.<sup>36</sup> The log Kow enables the prediction whether a substance is to be expected (dissolved) in the water phase or (adsorbed) in the suspended particulate matter or sediment phase or bioaccumulated in organisms (Moltmann et al. 2007). The (ad)sorption and bioaccumulation potential usually increase with increasing Kow-values.

The adsorption potential can be roughly divided in the following three ranges:

log Kow < 2.5 low adsorption potential (hydrophilic substance)

log Kow > 2.5 und < 4.0 average adsorption potential

log Kow > 4.0 high adsorption potential (lipophilic substance)

Moltmann et al. (2007) give the following general recommendations for the selection of the appropriate media/phase for environmental monitoring:

- Highly soluble substances should be analysed in the water phase.
- Substances with a high adsorption potential should be analysed in the suspended particulate matter phase, in sediment and/or in soil.
- Volatile substances with high vapour pressures should be analysed in the air.

The expected distribution of a substance between the different environmental compartments can be assessed with the support of relevant software instruments.

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<sup>36</sup> The definition of Kow is the ratio of the concentration of a chemical in octanol relative to the concentration of the chemical in water, when the octanol and water phases are at equilibrium.

The procedure to assess the environmental distribution is subsequently illustrated for five exemplary substances. Using the two software instruments EUSES 2.0 and EPIWIN 4.0 the expected mass fractions of these substances in the different environmental compartments are calculated. On basis of the physico-chemical properties and the calculated mass fractions the most relevant compartments for environmental monitoring are given.

#### Selection of exemplary substances

The selected exemplary substances fulfil the criteria for substances of very high concern (SVHC) according to REACH Art. 57. They have been identified by van der Veen & Knacker (2011) as priority substances within the categories PBT or vPvB.

#### Information sources

Data on physico-chemical properties of the 5 potential SVHC substances were taken from van der Veen & Knacker (2011). Additional information such as molecular weight, melting and boiling point that are requested by the model EUSES was gathered from publicly available sources.

#### EUSES 2.0

The European Union System for the Evaluation of Substances (EUSES) is a decision-support instrument which enables government authorities, research institutes and chemical companies to carry out rapid and efficient assessments of the general risks posed by chemical substances. Depending on their physico-chemical properties EUSES calculates emission fractions of substances by sewage treatment plants (STP) directed to the different receiving compartments such as air, water and sludge.

These emission fractions reflect the expected distribution of a substance in the different environmental compartments air, water and soil.

The EUSES software together with the respective documentation can be downloaded for free from the official EC JRC IHCP website:

[http://ihcp.jrc.ec.europa.eu/our\\_activities/public-health/risk\\_assessment\\_of\\_Biocides/euses](http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/euses)

#### EPI Suite v4.10

EPI Suite is a software package from the US EPA which contains several modules for the estimation of physico-chemical properties, of data on environmental fate and ecotoxicity. EPI Suite is a screening-level tool which is intended for use in screening level applications such as to quickly screen chemicals for their release potential. The tool should not be used if acceptable measured values are available. EPI Suite also contains an integrated database of measured physico-chemical values, which are included in the output if available.

EPI Suite is publicly available and can be obtained – together with a User's Guide – from the following site: <http://www.epa.gov/opptintr/exposure/pubs/episuite.htm>.

The module LEV3EPI™ contains a level III multimedia fugacity model (i.e. Level III fugacity model) and predicts partitioning of chemicals among air, soil, sediment, and water under steady state conditions for a default model "environment".

EPI Suite™ requires only a single input, a representation of the chemical structure in SMILES notation<sup>37</sup>. Entry of SMILES via a linked file of CAS numbers is also possible.

Expected distribution in the environment

Emission fractions respectively steady state mass fractions have been calculated with EUSES and EPI Suite v4.10. The physico-chemical properties used as input data for the EUSES calculation are listed in Table 10. A closer view on the physico-chemical properties already allows a first assessment of the expected distribution in the environment.

Table 11 summarises the results of the EUSES 2.0 and EPI Suite v4.10 calculation and reflects the expected distribution of the substances between the different environmental compartments.

### ***Substance #1:***

Based on the vapour pressure of  $6.3 \times 10^{-5}$  Pa (at 20°C) Substance #1 is very slightly volatile; thus Substance #1 is not expected to be detected in the compartment air.

The low water solubility (0.8 mg/L) and the high log Kow (5.94) indicate a high adsorption potential; thus, Substance #1 is expected to adsorb to suspended matter and sediment rather than be diluted in water.

The high log Kow (5.94) and experimental BCF (18,100) indicate that bioconcentration in (aquatic) organisms may occur.

The distribution modelling in a sewage treatment plant (STP) with EUSES 2.0 indicates that nearly 85% of Substance #1 is adsorbed to sludge. A minor 15.5% is emitted to the waste water.

EPI Suite predicts the partitioning of Substance #1 to soil (76%), sediment (15%) and water (8%).

Relevant compartments for environmental monitoring are thus suspended matter, sediment, soil and biota.

### ***Substance #2:***

Based on the vapour pressure of 0.26 Pa (at 20°C) Substance #2 is slightly volatile; thus Substance #2 is not expected to be detected in significant amounts in the compartment air.

The low water solubility (0.06 mg/L) and the very high log Kow (9.37) indicate a high adsorption potential; thus, Substance #2 is expected to adsorb to suspended matter and sediment rather than be diluted in water.

Although the high log Kow (9.37) indicates a high potential for bioaccumulation<sup>38</sup>, the experimental BCF of 310 (OECD 305 test results with *Cyprinus carpio*) seems not to confirm

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<sup>37</sup> SMILES means "Simplified Molecular Information and Line Entry System."

this assumption. However, a quality check of the test data by EU PBT WORKING GROUP (PBT LIST NO. 88)<sup>39</sup> revealed that the reliability of the BCF test results cannot be confirmed. According to their assessment, Substance #2 is considered to fulfil the REACH screening B criterion. Consequently, bioconcentration in (aquatic) organisms may occur.

The distribution modelling in a sewage treatment plant (STP) with EUSES 2.0 indicates that > 90% of Substance #2 is adsorbed to sludge. Only 8% is emitted to the waste water. The fraction emitted to air is negligible (0.005%).

EPI Suite predicts the partitioning of Substance #2 to water (73%), soil (22.2%), air (3.7%) and sediment (0.9). Due to the high adsorption potential and low water solubility the high percentage in water may be attributed to fraction adsorbed to suspended matter rather than the diluted fraction.

Relevant compartments for environmental monitoring are thus suspended matter, sediment, soil and potentially biota.

### ***Substance #3:***

Based on the vapour pressure of  $1.35 \times 10^{-4}$  Pa (at 25°C) Substance #3 is very slightly volatile; thus Substance #3 is not expected to be detected in the compartment air.

With regard to the water solubility two different values have been found in the literature with the two of them ranging from not readily soluble (0.026 mg/L) to highly soluble (1000 mg/L). The high log Kow (5.82) indicates a high adsorption potential; thus, Substance #3 is expected to adsorb to suspended matter and sediment, however, dissolution in water cannot be excluded on basis of the available water solubility.

With regard to the bioconcentration factor a wide range of measured and estimated values can be found in the literature (0.26 to 62,000). Consequently, bioconcentration in (aquatic) organisms may occur.

The distribution modelling in a sewage treatment plant (STP) with EUSES 2.0 indicates that nearly 50.4% of Substance #3 is adsorbed to sludge, whereas 28.2% and 21.3% are emitted to waste water and air, respectively.

EPI Suite predicts the partitioning of Substance #3 to soil (49.2%), sediment (41.7%), water (8.6%) and air (0.5%).

CICAD 73 reports monitoring data of Substance #3 in Swedish wastewater treatment plant water and sludge: relevant findings were detected in sludge, but not in water.

The most relevant compartments for environmental monitoring are thus suspended matter, sediment, soil and potentially biota.

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<sup>38</sup> According to the ECHA Guidance Document on SVHC identification a log Kow value of around 4.57 or greater is generally accepted as indicating a high potential for bioaccumulation.

<sup>39</sup> [http://esis.jrc.ec.europa.eu/doc/PBT-evaluation/PBT\\_sum088\\_CAS\\_1461-25-2.pdf](http://esis.jrc.ec.europa.eu/doc/PBT-evaluation/PBT_sum088_CAS_1461-25-2.pdf)

***Substance #4:***

The high vapour pressure (520 Pa) indicates that Substance #4 is volatile. Therefore, if released into air, the substance is expected to remain within this compartment with little tendency to move into other environmental compartments.

The moderate to high predicted Kow value of 4.8 together with the low water solubility (0.034 mg/L) suggest that Substance #4 – if released into water - will tend to adsorb onto suspended matter in the water column, with possible subsequent settling to sediments.

If released to soil, the high vapour pressure (and very high Henry's Law constant) suggests there will be significant tendency for Substance #4 to volatilize from the soil surface into air. However, most of the substance is predicted to remain within the soil compartment likely adsorbed to soil particulates due to the moderate to high log Kow. This adsorptivity, along with low water solubility (0.034 mg/L), suggests that Substance #4 will be relatively immobile in soil.

Experimental and modelled log Kow values of 4.80 to 6.6 suggest that this substance has high potential to bioaccumulate.

The distribution modelling in a sewage treatment plant (STP) with EUSES 2.0 indicates that 57.4% of Substance #4 is emitted to air and nearly 39% adsorbed to sludge. A minor 3.7% is emitted to the waste water.

EPI Suite predicts the partitioning of Substance #4 to water (49.7%), air (41.4%), sediment (7.5) and soil (1.4%).

Relevant compartments for environmental monitoring are thus air, suspended matter, sediment, soil and biota.

***Substance #5:***

The vapour pressure of 0.72 Pa indicates that Substance #5 is slightly volatile.

The low water solubility (0.6 mg/L) and the moderate to high log Kow (4.64) indicate a high adsorption potential; thus, Substance #5 is expected to adsorb to suspended matter and sediment.

The moderate to high log Kow and the high BCF (12,589) indicate that bioconcentration in (aquatic) organisms may occur.

The distribution modelling in a sewage treatment plant (STP) with EUSES 2.0 indicates that Substance #5 is mainly emitted to air (42.4%), adsorbed to sludge (36.5%) and to some degree emitted to the waste water (21.1%).

EPI Suite predicts the partitioning of Substance #5 to soil (86%), water (8%), air (5%) and sediment (1.26%).

The most relevant compartments for environmental monitoring are thus air, suspended matter, sediment, soil and biota.

Table 10: Physicochemical properties of example substances for calculation of emission fractions with EUSES 2.0

| # | CAS No.   | Name   | MW    | Melting point | Biodegradability   | logKow    | Adsorption-potential | Vapour pressure (Pa) | Water solubility (mg/L)              | BCF               |
|---|-----------|--|-------|---------------|--------------------|-----------|----------------------|----------------------|--------------------------------------|-------------------|
| 1 | 3194-55-6 | Cyclododecane, 1,2,5,6,9,10-hexabromo- (HBCDD) | 641.7 | 190           | Not bio-degradable | 5.94      | high                 | 6.3E-05 (20°C)       | 0.8                                  | 18,100            |
| 2 | 1461-25-2 | Stannane, tetrabutyl- ; Tetrabutyltin (TTBT)   | 347.2 | -97           | Not bio-degradable | 9.37      | Very high            | 0.26                 | 0.06396                              | 310               |
| 3 | 3542-36-7 | Stannane, dichlorodioctyl- (DOTC)              | 416   | 47            | Not bio-degradable | 5.82      | high                 | 6.68E-03             | 0.0260 (estimated) 1000 (literature) | 0.26 to 62,000    |
| 4 | 107-51-7  | Trisiloxane, octamethyl- (MDM)                 | 236.5 | -82           | Not bio-degradable | 4,8 – 6.6 | medium to high       | 445 - 520            | 0.034                                | No data available |
| 6 | 95-94-3   | 1,2,4,5-Tetrachlorbenzene                      | 215.9 |               | Not bio-degradable | 4.64      | medium to high       | 0.72                 | 0.595                                | 12,589            |

Table 11: Emission and mass fractions calculated with EUSES 2.0 and EPI Suite v4.10

| # | CAS No.   | Name   | EUSES Emission fractions by STP | EPI Suite 4.10 Level III fugacity model       | EPI Suite 4.10 Distribution in Wastewater Treatment | BCF            | Reviews   | Relevant compartments for environmental monitoring |
|---|-----------|--|---------------------------------|---|---|----------------|---|--|
| 1 | 3194-55-6 | Cyclododecane, 1,2,5,6,9,10-hexabromo- (HBCDD) | A: 0.005<br>W: 15.5<br>SI: 84.5 | A: 0.3%<br>W: 8%<br>S: 76%<br>Se: 15          | A: 0%<br>BD: 0.78%<br>W: 6%<br>SI: 93.22%           | 18,100         | Annex XV dossier <sup>40</sup>  | Suspended matter, Sediment, Soil, Biota.           |
| 2 | 1461-25-2 | Stannane, tetrabutyl- (TTBT)                   | A: 0.2<br>W: 8<br>SI: 91.9      | A: 3.68%<br>W: 73.2%<br>S: 22.2%<br>Se: 0.897 | A: 1.82%<br>BD: 0.75%<br>W: 5.69%<br>SI: 91.73%     | 310            | PBT WORKING GROUP – PBT LIST NO. 88 <sup>41</sup>   | Suspended matter, Sediment, Soil, (Biota)          |
| 3 | 3542-36-7 | Stannane, dichlorodioctyl- (DOTC)              | A: 21.3<br>W: 28.2<br>SI: 50.4  | A: 0.511%<br>W: 8.55%<br>S: 49.2%<br>Se: 41.7 | A: 1.25%<br>BD: 0.75%<br>W: 8.53%<br>SI: 89.47%     | 0.26 to 62,000 | Concise International Chemical Assessment Document 73 <sup>42</sup>   | Suspended matter, Sediment, Soil, (Biota)          |
| 4 | 107-51-7  | Trisiloxane, octamethyl- (MDM)                 | A: 57.4<br>W: 3.7<br>SI: 38.9   | A: 41.4%<br>W: 49.7%<br>S: 1.44%<br>Se: 7.47  | A: 56.94%<br>BD: 0.13%<br>W: 0.5%<br>SI: 42.87%     | -              | Draft Screening Assessment for the Challenge: Trisiloxane, octamethyl - (Octamethyltrisiloxane) <sup>43</sup> | Air, Suspended matter, Sediment, Soil, Biota.      |
| 5 | 95-94-3   | 1,2,4,5-Tetrachlorbenzene                      | A: 42.4<br>W: 21.1<br>SI: 36.5  | A: 4,87%<br>W: 8.14%<br>S: 85.7%<br>Se: 1.26  | A: 11.17%<br>BD: 0.49%<br>W: 30.27%<br>SI: 58.06%   | 12589          |   | Air, Suspended matter, Sediment, Soil, Biota       |

<sup>40</sup> <http://echa.europa.eu/documents/10162/d12ef98c-3fb9-484b-b354-4a2c74931cdd>

<sup>41</sup> [http://esis.jrc.ec.europa.eu/doc/PBT-evaluation/PBT\\_sum088\\_CAS\\_1461-25-2.pdf](http://esis.jrc.ec.europa.eu/doc/PBT-evaluation/PBT_sum088_CAS_1461-25-2.pdf)

<sup>42</sup> <http://www.inchem.org/documents/cicads/cicads/cicad73.pdf>

<sup>43</sup> [http://www.ec.gc.ca/ese-ees/19584F14-D972-46A1-B71C-FA9A36FFB0FE/batch12\\_107-51-7\\_en.pdf](http://www.ec.gc.ca/ese-ees/19584F14-D972-46A1-B71C-FA9A36FFB0FE/batch12_107-51-7_en.pdf)

## 11.5 List of abbreviations used in the excel database and in the report

| Abbreviation         | Full denomination  |
|----------------------|--|
| AEPS                 | Arctic Environmental Protection Strategy   |
| AFBI                 | Agrifood and Biosciences Institute   |
| AMAP                 | Arctic Monitoring and Assessment Programme   |
| AOX                  | Adsorbable organic halogen compounds (AOX)   |
| BAFU                 | Bundesamt für Umwelt, Schweiz  |
| BaP                  | Benzo[a]pyren  |
| BBA                  | Biologische Bundesanstalt für Land- und Forstwirtschaft                                    |
| BBIS                 | Bundesweites Bodeninformationssystem   |
| BBodSch<br>Gesetz/VO | Bundes-Bodenschutzgesetz/-Verordnung   |
| BDF                  | Boden-Dauerbeobachtungsflächen   |
| BfG                  | Bundesanstalt für Gewässerkunde  |
| BfH                  | Institut für Weltforstwirtschaft   |
| BfLR                 | Bundesforschungsanstalt für Landeskunde und Raumordnung                                    |
| BfN                  | Bundesamt für Naturschutz  |
| BfR                  | Bundesinstitut für Risikobewertung   |
| BFRs                 | Brominated Flame Retardants (bromierte Flammschutzmittel)                                  |
| BfS                  | Bundesamt für Strahlenschutz   |
| BGR                  | Bundesanstalt für Geowissenschaften und Rohstoffe  |
| BgVV                 | Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedizin                 |
| BLMP                 | Bund-Länder Messprogramm Nord- und Ostsee  |
| BlmschVO             | Bundes-Immissionsschutzverordnung  |
| BMVEL                | Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz                      |
| BOD                  | Biochemical oxygen demand (mg O <sub>2</sub> /l); dt: biochemischer Sauerstoffbedarf       |
| BODC                 | British Oceanographic Data Centre  |
| BSH                  | Bundesamt für Seeschifffahrt und Hydrographie  |
| BVL                  | Bundesamt für Verbraucherschutz und Lebensmittelsicherheit                                 |
| CAMP                 | Comprehensive Atmospheric Monitoring Programme   |
| CEFAS                | Centre for Environment, Fisheries and Aquaculture Science                                  |
| Cefic                | European Chemical Industry Council   |
| CEMAGREF             | National Research Institute of Science and Technology for Environment and Agriculture      |
| CEMP                 | Co-ordinated Environmental Monitoring Programme  |
| CLRTAP               | Convention on Long-Range Transboundary Air Pollution                                       |
| COD / CSB            | Chemical oxygen demand (COD); chemischer Sauerstoff Bedarf (CSB)                           |
| COMBINE              | Cooperative Monitoring in the Baltic Marine Environment                                    |
| COPHES               | Consortium to Perform Human biomonitoring on a European Scale                              |
| CSEMP                | Clean Seas Environmental Monitoring Programme  |
| CWSS                 | Common Wadden Sea Secretariat  |
| DBT                  | Dibutylzinn  |
| DDE                  | Dichlordiphenyldichlorethan (Metabolit von DDT)  |
| DDT                  | Dichlordiphenyltrichloroethan  |
| DEFRA                | Department for Environment, Food and Rural Affairs   |
| DEMOCOPHES           | Demonstration of a study to Coordinate and Perform Human Biomonitoring on a European Scale |
| DK-Rhein             | Deutsche Kommission zur Reinhaltung des Rheins   |
| DOC                  | Dissolved organic carbon (DOC)   |
| DOD                  | Deutsches Ozeanographisches Datenzentrum   |
| EBFRIP               | European Brominated Flame Retardant Industry Panel   |
| EEA                  | European Environment Agency  |
| EHS                  | Environment and Heritage Service   |

| Abbreviation | Full denomination   |
|--------------|---|
| EIONET       | European Environment Information and Observation Network                                  |
| EMEP         | European Monitoring and Evaluation Programme  |
| EMP          | Environmental Monitoring Programme  |
| EPER         | Europäisches Schadstoffemissionsregister (now E-PRTR)                                     |
| E-PRTR       | European Pollutant Release and Transfer Register  |
| FCKW         | Fluorochlorinated hydrocarbons (Fluorchlorkohlenwasserstoff)                              |
| FDA          | U.S. Food and Drug Administration, USA  |
| FFRC         | Federal Forest Research Centre, Austria   |
| FGG Weser    | Flussgebietsgemeinschaft Weser  |
| FRS          | Fisheries Research Services   |
| GAW          | Global Atmosphere Watch   |
| GDCh         | Gesellschaft Deutscher Chemiker   |
| HCB          | Hexachlorbenzol   |
| HCBD         | Hexachlorbutadien   |
| HCH          | Hexachlorcyclohexan   |
| HELCOM       | Helsinki Commission, Baltic Marine Environment Protection Commission                      |
| HYDABA       | Hydrologische Datenbank des BfG   |
| ICES         | International Council for the Exploration of the Sea                                      |
| ICP          | International Cooperative Programme   |
| IGKB         | Internationale Gewässerschutzkommission für den Bodensee                                  |
| IKSE         | Internationale Kommission zum Schutz der Elbe   |
| IKSMS        | Internationale Kommissionen zum Schutze der Mosel und der Saar                            |
| IKSR (ICPR)  | Internationale Kommission zum Schutz des Rheins   |
| INERIS       | Institut National de l'Environnement Industriel et des Risques                            |
| JAMP         | Joint Assessment and Monitoring Programme   |
| JRC          | Joint Research Centre, Ispra, Italy   |
| LABO         | Bund/Länder-Arbeitsgemeinschaft Bodenschutz   |
| LAVES        | Landesamt für Verbraucherschutz und Lebensmittelsicherheit                                |
| LAWA         | Bund/Länder-Arbeitsgemeinschaft Wasser  |
| LfU Bayern   | Bayerisches Landesamt für Umwelt  |
| LOD          | Limit of detection  |
| LOQ          | Limit of quantification   |
| LUBW         | Landesanstalt für Umwelt, Messungen und Naturschutz, Baden-Württemberg                    |
| MAB          | Man and Biosphere Program der UNESCO  |
| MBT          | Monobutylzinn   |
| MED POL      | Marine pollution assessment and control component of MAP                                  |
| Meros        | Monitoring of European Raptors and Owls   |
| MLUR         | Ministerium für Landwirtschaft, Umwelt und ländliche Räume                                |
| MONARPOP     | Monitoring Network in the Alpine Region for Persistent and other Organic Pollutants       |
| MSD          | Marine Strategy Directive   |
| MUDAB        | Meeresumwelt-Datenbank (Marine Environmental Data Base)                                   |
| NABO         | Nationale Bodenbeobachtung Schweiz  |
| NABU         | Naturschutzbund Deutschland e.V.  |
| NEFO         | Netzwerk-Forum zur Biodiversitätsforschung Deutschland                                    |
| NERI         | National Environmental Research Institute   |
| NIVA         | Norwegian Institute for Water Research  |
| NLfB         | Niedersächsisches Landesamt für Bodenforschung  |
| NMMP         | National Marine Monitoring Programme, UK  |
| NMP          | National Monitoring Plan, UK  |
| NORMAN       | Network of Reference Laboratories for the Monitoring of Emerging Environmental Substances |
| NVOC         | Non-volatile organic compound   |
| OECD         | Organisation for Economic Co-operation and Development                                    |
| OSPAR        | Oslo-Paris Commission   |

| Abbreviation | Full denomination  |
|--------------|--|
| PAHs/PAKs    | Polycyclic aromatic hydrocarbons / Polyzyklische aromatische Kohlenwasserstoffe  |
| PBDE         | Polybrominated diphenyl ethers   |
| PCBs         | Polychlorinated biphenyls  |
| PCDD/Fs      | Polychlorinated dibenzodioxins and furans  |
| PCP          | Pentachlorophenol  |
| PFC          | Perfluorinated compounds   |
| PFOA         | Perfluorooctanoic acid   |
| PFOS         | Perfluorooctane sulfonate  |
| PM           | Particulate matter (PM; PM 10: particulate matter <10 →g radius; dt: Feinstaub)  |
| POCIS        | Polar Organic Chemical Integrative Sampler   |
| POPs         | Persistent Organic Pollutants  |
| RID          | Comprehensive Study on Riverine Inputs and Direct Discharges   |
| RIVM         | National Institute for Public Health and the Environment   |
| SECURE       | Self Enforced Control of Use to Reduce Emissions   |
| SEPA         | Scottish Environment Protection Agency   |
| SOP          | Standard operating procedures  |
| STARS        | Stoffdatenbank für Altlasten/umweltrelevante Stoffe  |
| TBBPA        | Tetrabrombisphenol-A   |
| TBT          | Tributyltin  |
| TDS          | Total Diet Study, USA  |
| TMAP         | Trilateral Monitoring and Assessment Program of the Wadden-Sea/ Trilaterales Monitoring und Assessment Programm des Wattenmeeres |
| TOC          | Total organic carbon   |
| UBA          | Umweltbundesamt  |
| UFZ          | Helmholtz Zentrum für Umweltforschung  |
| UKMMAS       | UK Marine Monitoring and Assessment Strategy   |
| UNECE        | United Nations Economic Commission for Europe  |
| UNESCO       | United Nations Educational, Scientific and Cultural Organization   |
| UPB          | Umweltprobenbank des Bundes  |
| VECAP        | Voluntary Emissions Control Action Programme   |
| VOC          | Volatile organic compound  |
| WFD          | Water Framework Directive  |
| WISE         | Water Information System for Europe  |
| WZE          | Waldzustandserhebung   |
| ZEBS         | Zentrale Erfassungs- und Bewertungsstelle für Umweltchemikalien des Bundesinstituts für Risikobewertung (BfR)                    |
| ZSE          | Zentrales System Emissionen  |