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Development of a real-time information and monitoring system to support the risk assessment of engineered nanomaterials (ENMs) under REACH

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Deliverable

DA2a. Report on the information and quality criteria to use measured data under REACH and relevant monitoring programs

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Summary

The main goal of the present deliverable DA2a "Report on the information and quality criteria to use measured data under REACH and relevant monitoring programs" is the definition of the minimum data and data quality needed for using existing monitored data for exposure estimation in the exposure assessment of the Risk characterization process according REACH Regulation.

In the scope of the REACH regulation, Risk assessors shall undertake an exposure assessment. That step consists on the definition of the exposure scenarios (ES) and the estimation of the exposure concentrations (at the workplace and in the environment), in order to compare that exposure estimations with the values of toxicity of the chemical substance under study and thus determine the risk characterization ratio (RCR). The aim of this risk characterization task is to determine if the risk that can pose the use of a chemical substance is controlled or, if not, to manage it introducing necessary Risk management measures until risk is under control in such exposure scenario, for human health and for environment.

Exposure concentration can be directly measured at place and such determination are normally preferred because of higher confidentiality. But also other existing data can be used when they contain the minimum required information and quality. REACH contemplate that **existing adequately measured, representative exposure data** are taken into account in the exposure assessment, either on their own or in combination with modelled exposure estimates. Moreover, when dealing with nanomaterials, the use of simulation studies replicating the task or activity of concern should be taken into account when considering the use of measured data, especially taken into account the limitations of modelled estimates for nanomaterials

Existing data can proceed from different sources. Thus, apart that from measuring campaigns, some useful sources of information that might provide data on exposure levels/releases include:

- measured data taken under the actual exposure settings for the exposure scenario to be developed (company data). For example, data generated to comply with other legislation or to evaluate the effectiveness of the RMMs in place. Measured data required for site licences and permits (with documented number/frequency of sampling, analytical methods, basic statistics) can be a good source of information for REACH.
- exposure information from monitoring databases with regulatory purposes, when information requirements enabling a robust assessment are fulfilled.
- Exposure information from peer reviewed publications, when information requirements enabling a robust assessment are fulfilled.
- biomonitoring data.
- Simulated process data

The aim of the NanoMonitor project is thus to generate much information as possible regarding concentration of main nanomaterials present at the urban, industrial and workplace environments in order to facilitate the Exposure Assessment and Risk Assessment according REACH.

With that aim, generated data will be collected according requisites of information and data quality required by REACH Regulation (for measured exposure concentrations use) and main monitoring programs (for generated measured data incorporation in the databases).

Regarding the use of monitored data according REACH Regulation, needed information **to** satisfactorily **support the suitability and representativeness** of the data, as **indicators of good quality**, are:

- reference to: quality schemes, standard sampling, and measurement methodologies;
- context: enough description to support the intended scope;
- clear description of monitored tasks;
- clear information on risk management measures in operation during sampling;
- details of duration and frequency of tasks and an assessment if the sampling duration is representative of full-shift exposure or only for the task duration;
- whether data are current rather than historical (i.e. sampling period to be reported);
- collection from a wide range of the sites and processes covered by the use description;
- statistical descriptors available.

On the other hand, in order to introduce monitored data in the main environmental databases, the methodology (within and between participating laboratories), performance characteristics (e.g. precision, accuracy, sensitivity); monitoring and sampling strategy; and units and reporting format of environmental monitoring programs was analysed in order to have consistency with measuring and reporting protocols used when introducing data in these databases. It was established that fundamental required metadata are, schematically:

- Objective of the programme
- What has been analysed
- Analytical method
- Units
- Limit of quantification (LOQ)
- Blank concentration
- Recovery
- Accuracy
- Reproducibility
- Sampling protocol details
- Discrete or continuous measurements
- Location
- Date of sampling (dd/mm/yy)
- Time
- Matrix characteristics
- Proximity and influence of sources
- Discharge emission pattern and volume
- Flow and dilution or application rate of water body sampled
- Explanation of value assigned to non-detect values if used in a mean
- Description of statistical evaluation of results

Finally, a reporting format was developed according required requisites of the different main monitoring programs.

List of acronyms

- BAT: Best Available Techniques
- CDR: Chemical Data Reporting
- CEIP: the EMEP Centre on Emission Inventories and Projections
- CLRTAP: Convention on Long-range Transboundary Air Pollution.
- DPSIR: stands for: Driving forces - Pressures - State - Impact – Responses. It is a causal framework for describing the interactions between society and the environment the, adopted by the EEA.
- ECETOC: European Centre for Ecotoxicology and Toxicology of Chemicals
- EEA: European Environment Agency
- EiONET: European Environment Information and Observation Network.
- EMEP: European Monitoring and Evaluation Programme
- E-PRTR: European Pollutant Release and Transfer Register
- ESBN: The European Soil Bureau Network
- ESDAC: European soil data centre
- ETC/ACM: European Topic Centre on Air Pollution and Climate Change Mitigation.
- EU – NEC: EU - National Emission Ceilings (NEC) Inventory
- GC: gas chromatography
- GC-MS: gas chromatography mass spectrometry
- GIS: geographic information system
- GRAS: generally recognised as safe
- HAP: hazardous air pollutant
- ICP inductively coupled plasma
- ICP-AES inductively coupled plasma–atomic emission spectrometry
- ICP-MS inductively coupled plasma–mass spectrometry
- ICP-OES inductively coupled plasma–optical emission spectroscopy
- IED: The Industrial Emissions Directive (IPPC: Integrated Pollution Prevention and Control)
- IMPEL: European Union Network for the Implementation and Enforcement of Environmental Law
- ISO/DIN International Standards Organization / Deutsches Institut für Normung
- IUCLID International Uniform Chemical Information Database
- IUR Inventory Update Reporting
- LC liquid chromatography
- LOD limit of detection
- LOQ limit of quantification
- LPS: large point sources
- MEC measured environmental concentration
- MS mass spectrometry
- MS/MS tandem mass spectrometry
- ND non-detect
- NUTS: Nomenclature of Units for Territorial Statistics
- OECD Organisation for Economic Co-operation and Development
- PEC predicted environmental concentration
- PEC: Predicted Environmental Concentration
- PNEC predicted no-effect concentration
- PRTR Pollutant Release and Transfer Register
- QA/QC: quality assurance/quality control
- SNAP: Selected Nomenclature for sources of Air Pollution.
- UNECE: *United Nations Economic Commission for Europe*.

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1. Scope and goal of the deliverable

Present deliverable DA2a “Report on the information and quality criteria to use measured data under REACH and relevant monitoring programs”, focusses on the definition of the minimum data and data quality needed for using existing monitored data for exposure estimation in the exposure assessment of the Risk characterization process according REACH Regulation.

It is part of the preparatory action A2 “Definition of monitoring data information and quality requirements according REACH” of the NanoMonitor project.

With that aim, after a brief introduction of the REACH Regulation and existing monitoring programs, the Risk Assessment process according REACH Regulation is explained in detail, mainly the Exposure Assessment step where the data on exposure estimation is needed. After that, the **minimum information and quality criteria to use measured data under REACH** is described.

Exposure estimations can be measured or modelled data. Different monitoring programs generating a data base of exposure estimations, including monitoring data for air pollution, water, wastes and soil exist. In the scope of the present deliverable, minimum meta data accompanying measurements and the minimum quality control and assurance criteria for being useful, for exposure assessment under REACH and for the feeding of existing data bases, are also described.

On the other hand, in the deliverable A2b, a compendium of protocols with the minimum information and quality of data was done.

2. Introduction: monitoring programs and REACH

2.1. The use of monitoring data on the Risk Assessment

On the **risk assessment** of chemicals, including those at the nanoscale, nanomaterials, one of the main steps is estimating the concentrations that are occurring or likely to occur in the exposure media (workplace and environment). It is known as exposure assessment. For exposure assessment, "**Predicted Environmental Concentration**" (PECs) can be derived using either measured data from environmental **monitoring** studies, or predictions of exposure from **exposure models**[1] [2]. In the same way, worker exposure can be determined from monitoring data or predicted from exposure models.

Both approaches have their advantages and disadvantages. Quality monitoring data could directly reflect real concentrations in the environment/workplace, but can be very expensive to obtain or many times even not possible to measure or distinguish from background. An important point for exposure assessment purposes is how to derive the media concentration or PEC using monitoring data. The use of models to predict PECs is much less expensive than monitoring programmes, but the accuracy of their predictions is more uncertain.

For such two approaches used to derive exposure concentrations, different improvements can be made. Two main strategies are faced in the NanoMonitor project, dealing on one hand with the design of new improved monitoring initiatives that provide more appropriate data for using in the exposure assessment of chemicals in the nanoscale and, on the other hand, providing criteria to help exposure assessors decide whether existing monitoring data are suitable for using in their risk assessment process. Therefore, improved use could be made of available monitoring data to calibrate and validate exposure models.

These strategies followed in the NanoMonitor project are in line with some of key needed knowledge areas stablished during the OECD's Risk Assessment Programme´s Workshop on Improving the Use of Monitoring Data in the Exposure Assessment of Industrial Chemicals[3]:

- **Criteria for quality and representativeness of monitoring data**: the main goal of that approach is to develop a series of *criteria for quality (sampling and analysis), representativeness and coverage (in relation to exposure assessment scenarios)* of monitoring data that exposure assessors can use when deciding whether the data can be used in exposure assessment.
- **Improvements to the design of monitoring programmes**: The goal is to develop a list of recommendations to the monitoring community such as government, industry and international bodies, describing the *minimum requirements for monitoring programmes*, including a strategy of how to proceed in order to ensure that chemical monitoring programmes provide the exposure endpoints required for exposure assessment in the context of risk assessment.

[1] Note1: In the context of NanoMonitor project, RMC = PEC (modelled or monitored)
[2] OECD (2013). Guidance document for exposure assessment based on environmental Monitoring. Series on Testing and Assessment. No. 185ENV/JM/MONO (2013)7.
[3] OCDE (2000). Report of the OECD Workshop on Improving the Use of Monitoring Data in the Exposure Assessment of Industrial Chemicals. OECD SERIES ON TESTING AND ASSESSMENT Number 18. ENV/JM/MONO (2000)2.

2.2. Fundamental properties of monitoring data

Monitoring data is composed of numerical data and associated information, often referred to as meta-data[2].

As it will be described in detail in the present document, **fundamental metadata** required to support the monitoring data includes: *the target chemical, analytical method and performance information for the analysis; sampling protocol; sampling location and time; information on the nature of the sample; and other relevant information*.

Although some monitoring data are available, being collected for regulatory purposes, there exist several shortcomings for using them in exposure assessment and modelling purposes (application, calibration, validation). The most **common critical deficiencies** related to the available current data are:

- Lack of information on the ***context* in which the data were generated** and clear objectives of the monitoring programme: representativeness (location, duration, frequency), address temporal variability of sources and system dynamics;
- The ***quality of data*** is not indicated and cannot be traced;
- Data presented are aggregated and ***raw data*** cannot be obtained;
- It is not clear whether the monitoring *data represent* hot spots or are representative of background conditions;

The identification of **the target chemical limit of detection and limit of quantification (defined by analytical method); sampling location and sampling time and frequency, are key elements** for using the data for exposure assessment confidently[3]. Thus, it is highly recommended that these meta-data elements are collected when comparing data compiled from different sources.

Quality assurance and quality control are important for high quality monitoring data. **Key elements in assuring the quality of monitoring** data are: utilising reference materials; conducting inter-laboratory studies; and reporting the quality assurance procedures used in collecting the data[4][5].

When dealing with nanomaterials, it is important to mention that, at present, different problems makes difficult the determination and overall quantification of nanomaterials in the different environmental compartments, and also at the workplace, when monitoring exposure levels. These problems are related with:

- the lack of well stablished reference materials
- Background of natural nanomaterials
- No existing standardized protocols for calculation of stream concentration
- No existing established standardized measurement units for all nanomaterials: at least mass concentration (units mg m^{-3}), but where possible also particle number (units m^{-3}) and/or surface area (units m^2 m^{-3}). The metric used to assess exposure to nanomaterials should be that which most closely links to any potential health effect.

[4] UNEP (2004). Guidance for a Global Monitoring Program on Persistent Organic Pollutants, 1st Ed., UNEP.
[5] UNEP (2007). Guidance on the Global Monitoring Plan for Persistent Organic Pollutants, Preliminary version, amended in May 2007.

- No existing sensible and specific analytical methods neither techniques which can probe nanomaterials speciation

Another good practice for ensuring the collection of high quality monitoring data, apart from using a properly accredited laboratory when possible, is to use a **format for collecting data** that can be **easily harmonised** with other systems. For example, IUCLID, the International Uniform ChemicaL Information Database developed by the European Commission and recommended for REACH implementation, entirely implements the **OECD Harmonised Templates**. Therefore, information compiled in IUCLID can be exchanged with other databases that use the same templates or XML schemas.

2.2. Monitoring programs in the European Union

Data centres of the **European Environment Agency** compile various environmental data, including monitoring data for **air pollution, water and wastes**.

Through Eionet, the EEA coordinates the delivery of timely, nationally validated, high-quality environmental data from individual countries. This forms the basis of integrated environmental assessments and knowledge that is disseminated and made accessible through the EEA website. This information serves to support environmental management processes, environmental policy making and assessment, and public participation at national, European and global levels.

Reporting Obligations Database (ROD) (http://rod.eionet.europa.eu/index.html) is the EEA's reporting database which contains records describing environmental reporting obligations that countries have towards international organisations. ROD is part of Reportnet, a group of web applications and processes developed by the EEA to support international environmental reporting. ROD includes all environmental reporting obligations that EEA member countries have towards DG environment, European marine conventions, Eurostat, OECD, UN, UNECE, as well as the EEA itself.

Eionet recompiles the European Reporting obligations in its Eionet core data flows (see *Figure 1*).

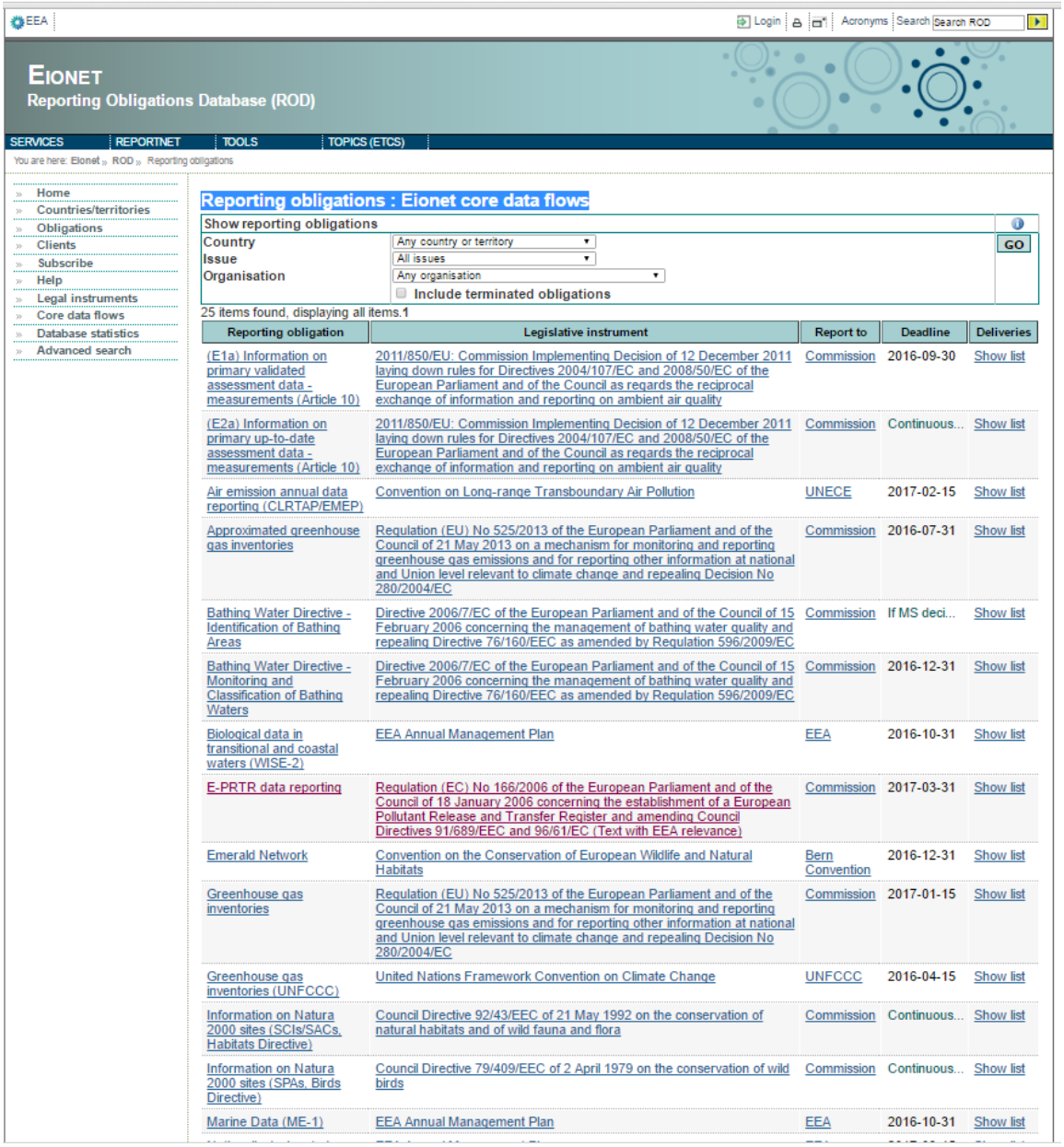

Figure 1. Reporting obligations database of the EIONET: Eionet core data flows. http://rod.eionet.europa.eu/obligations?anmode=P

On the other hand, the data portal site of the **Institute of Environment and Sustainability of the European Commission's Joint Research Centre** has compiled other environmental data sources covering a variety of monitoring data, including pollutants (https://ec.europa.eu/jrc/en/scientific-tools/?f%5b0%5d=im_field_institutes%3A108).

From those portals, monitoring data in the European Union can be accessed.

One of the main tasks of the present deliverable is to establish the minimum and most appropriate meta data, and information template for providing occupational and environmental exposure monitoring data to the main existing data bases is worked on A3 task and associated deliverable.

2.3. REACH and exposure measured data

The REACH Regulation is the European Union's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC) No 1907/2006 [6] and its amendments until 1st of June 2015. It represents a fundamental shift in the regulation of manufactured and imported chemicals in the European Union. Its main objective is to ensure a high level of protection of human health and the environment. REACH moves responsibility from authorities to industry to gather information on chemical substances and assess their safety. The provisions of REACH refer to substances (in whatever size or forms) and therefore also apply to nanomaterials, that are considered either as distinct substances or forms of a substance.

REACH includes the requirement for registration of substances (including its forms and states) manufactured or imported by a company in quantities of 1 or more tonnes per year to supply a technical dossier and, especially at volumes of 10 or more tonnes per year, a chemical safety assessment to be performed and reported by the registrant[7]. Manufacturers and importers of nanomaterials at quantities of 1 tonne or more per year must register the substance and ensure its safe use throughout the supply chain. Its provisions are underpinned by the precautionary principle. REACH is under revision and one of the possible proposals of modification is the decrease of the 1 tonnes threshold when dealing with nanomaterials.

Therefore, for ensuring the safety, **REACH Regulation requires** to undertake a **risk assessment of chemicals**. Figure 1 shows an overview of the overall process of Risk Assessment, considering the collection and assessment of existing and lacking information on the intrinsic properties of a substance, and the process of chemical safety assessment additionally required for substances produced/imported in amounts of more than 10 tonnes per year or of high concern.

Therefore, Risk Assessment process is undertaken in three main steps which are:

1. Hazard assessment: identification and characterization
2. Exposure assessment: definition of ES and exposure estimation
3. Risk Characterization

When available exposure and hazard data exists, a quantitative risk assessment is feasible.

The first outcome of the exposure assessment is the generation of Exposure scenarios (ES) for the different uses. ES are sets of information describing the conditions under which the risks associated with the identified use(s) of a substance can be controlled. The conditions of use include:

[6] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006).

[7] Note: According to article 14 of the REACH Regulation, registrants of substances are obliged to carry out a safety assessment for their substance if their manufactured or imported amount exceeds 10 tons per year. If the substance meets the criteria to be classified as hazardous or is considered a PBT/vPvB, the safety assessment must include exposure assessments for all uses of the substance the registrant intends to support, and a corresponding risk characterisation.

- ✓ Operational Conditions (OC): duration and frequency of use, the substance amount used, or the process temperature
- ✓ Risk Management Measures (RMM): engineering controls, personal protective equipment, waste water treatment, exhaust gas treatment, etc.

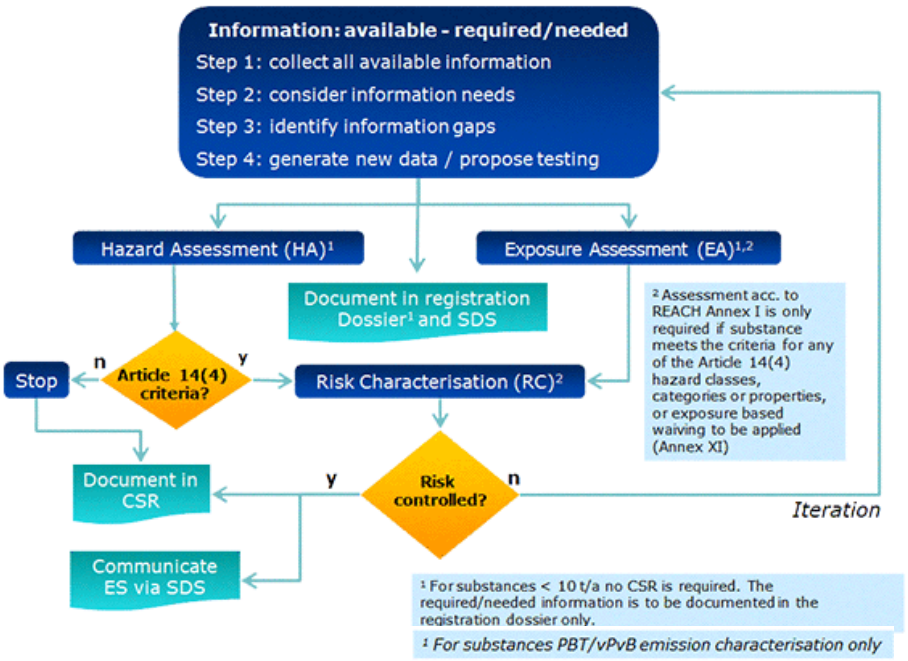

Figure 2. Overall process related to information requirements and chemical safety assessment under REACH (Source: http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment).

For each defined exposure scenario, expected exposure when the conditions of use as described in the exposure scenario are implemented is determined for risk characterization.

In detail, exposure data needed for exposure assessment and Risk Characterization and their correspondence with REACH and Chemical Safety Report articles and annexes, and parts, respectively, are recompiled in Table *1*.

Table 1. Where monitoring data are needed according REACH Regulation.

Exposure data needed for exposure estimations (for Risk Characterization in defined ES, Risk =exposure*hazard)			**CSR required by REACH Regulation**	**Article REACH** (10, information requirements)	**IUCLID**[8]
Environment (release)	Water	Freshwater	PART B. 9. Exposure assessment	See following page	CSR will be attached. Attachment in section 13 of IUCLID
		Sediment (freshwater)			
		Marine water			

[8] IUCLID: International Uniform Chemical Information Database, is a software application to capture, store, maintain and exchange data on intrinsic and hazard properties of chemical substances. It is distributed free of charge, the software is especially useful to chemical industry companies and to government authorities. It is the key tool for chemical industry to fulfil data submission obligations under REACH. The software is maintained by the European Chemicals Agency, ECHA.

		Sediment (marine water)		Article 10(b), Article 14 and Annex I set out requirements for Chemical Safety Report (b) that documents the chemical safety assessment Article 10 of REACH, in combination with annexes VI to X, defines information to be documented in the technical dossier Article 10 (x) Exposure information for substances in quantities of 1 to 10 tonnes. Anne VI section 6 Article 10 (vi) study summaries of information derived from the application of Annexes VII to XI	
		Sewage treatment plant			
	Air				
	Soil	Agricultural soil			
	Man via environment	Inhalation			
		Oral (drinking water, fish, crops, meat, milk)			
		Combined routes			
Worker	Inhalation, systemic, long-term				
	Inhalation, local, long-term				
	Inhalation, local, acute				
	Dermal, systemic, long-term				Section 3
	Dermal, local, long-term				
	Dermal, local, acute				
	Eye, local				
	Combined routes, systemic, long-term				
Biota			PART B. 4. Environmental fate properties		9.2. Degradation

In **Risk Characterisation** for human health, exposure levels are compared to suitable critical derived no-effect levels (DNEL[9]), according to the equation (1), in order to derive the risk characterisation ratios (RCRs) with the aim to assess if risks are adequately controlled for workers known to be or likely to be exposed.

Eq.1:

$$RCR = \frac{Exposure}{DNEL}$$

If Exposure < DNEL: Risk is adequately controlled

[9] Note: Worker-DNEL long-term inhalation: Repeated worker inhalation exposure for a day or more (exposure is modelled or measured as a daily air concentration in mg substance/m3)

If Exposure > DNEL: Risk is NOT controlled

Control of risk for a substance is demonstrated when the RCR for all exposures (in this case inhalation route and worker target population) are < 1, i.e. the exposure levels do not exceed the appropriate DNEL. If the Risk Characterization shows that, based on the initial exposure scenarios, risks are not controlled, iteration will be needed, refining at any point of the assessment hazard and/or exposure data by the introduction of new risk management measures or the modification of operational conditions. The iteration should continue until the Risk Characterization shows that the risks are controlled.

Again, control of risk for a substance is demonstrated when Risk Characterization Ratio are below one, i.e. the predicted environmental concentration does not exceed the predicted no effect environmental concentration. If the RCR shows that, based on the initial exposure scenarios, risks are not controlled, iteration will be needed, refining at any point of the assessment hazard and/or exposure data by the introduction of new safe by design approaches and/or risk management measures and modification of operational condition, respectively. The iteration should continue until the Risk Characterization shows that the risks are controlled (RCR<1).

Regarding Risk characterization for environment, predicted environmental concentration levels (PEC, based on environmental exposure estimation) are compared to suitable critical environmental predicted no-effect concentration (PNEC), according to the equation (2), in order to derive the risk characterisation ratios (RCRs) with the aim of deciding if risks are adequately controlled for environment.

Eq.2:

$$RCR = \frac{PEC}{PNEC}$$

For risk assessment process, **exposure level** determination is a key step. Release and exposure estimation under REACH aim to quantify the expected exposure when the conditions of use as described in the exposure scenario are implemented. Such quantification enables concluding on whether the risks can be adequately controlled. For each studied scenario, a corresponding exposure data set (for the various environmental compartments or various route of exposure to humans) is to be derived[10].

REACH requires that **existing adequately measured, representative exposure data** are taken into account in the exposure assessment, either on their own or in combination with modelled exposure estimates. Moreover, when dealing with nanomaterials, the use of simulation studies replicating the task or activity of concern should be taken into account when considering the use of measured data, especially taken into account the limitations of modelled estimates for nanomaterials. Risk assessor may then for example make use of monitoring data related to

[10] ECHA (2016). Guidance on Information Requirements and Chemical Safety Assessment. Part D: Framework for exposure assessment – Draft Version 2.0 (Public) April 2016.

worker's exposure or releases to the environment from for example their own or of well-known customer site-specific information, and also from simulation studies and modelled estimates.

Considering that, the **hierarchy for the use of exposure data when dealing with nanomaterials** would be preferentially[11] to use in as first selection measured data (having quantified key exposure determinants) and when not available, to use appropriate analogous data, including data derived from simulation studies. As the last option, to use modelled estimates.

A critical point in the process is thus to clearly confirm that the employed **measured (or modelled) data** to be used for risk assessment purposes under the context of REACH is suitable for that purpose, regarding **quality criteria and information requirements**, which include precession, accuracy, correctness, representativeness, comparability and time coverage.

When measured data sets are used, there should be sufficient contextual information available to derive exposure scenarios (describing the conditions of use leading to exposure measured including any controls that are in operation)[10].

It is for that reason that the present deliverable focuses on the definition of the minimum quality that shall be demanded to a data for being used in the Risk assessment of a chemical as is the case of nanomaterials.

[11] ECHA (2016). Guidance on information requirements and chemical safety assessment. Appendix R14-4 Recommendations for nanomaterials applicable to: Chapter R.14 Occupational exposure estimation.

3. Information requirements and quality criteria for the use of measured data under EC Regulation REACH

REACH Regulation requires information regarding chemical substances properties, exposure, use and risk management measures, and the chemical safety assessment.

Exposure assessment, in the context of **REACH Regulation, requires to build the exposure scenarios and estimate the exposure for assessing the risk**.

The REACH, Annex I Section 5.2.5., states that: *"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."*

Accordingly, there are options for risk assessors to address the exposure assessment requirement by different means, such as **models, data, or analogous data**. In some cases, a combination of such approaches may lead to the most appropriate assessment.

Apart that from measuring campaigns, some useful sources of information that might provide **data on releases** include:

- ✓ monitoring information from existing installations of a similar type or configuration
- ✓ Research reports, peer review publications, PhD reports
- ✓ data from pilot plant studies
- ✓ data from simulated processes
- ✓ calculated data, such as mass balance information, stoichiometric calculations, scaled-up laboratory data, etc.
- ✓ information from Regulatory data exchange, monitoring programs: electronic database
- ✓ information from equipment vendors or manufacturers
- ✓ Confidential company data

3.1. Sources of occupational and environmental exposure measured data

When dealing with occupational and environmental exposure assessment in the context of REACH, sources of measured data which could be used are:

- measured data taken under the actual exposure settings for the exposure scenario to be developed (company data). For example, data generated to comply with other legislation or to evaluate the effectiveness of the RMMs in place. Measured data required for site licences and permits (with documented number/frequency of sampling, analytical methods, basic statistics) can be a good source of information for REACH.
- exposure information from monitoring databases with regulatory purposes, when information requirements enabling a robust assessment are fulfilled.
- Exposure information from peer reviewed publications, when information requirements enabling a robust assessment are fulfilled.
- biomonitoring data.
- Simulated process data

In all cases, it is essential that used documentation is available and referred to in the Chemical Safety Report. In particular, a description of the methodology applied (for measurements/data collection) should be available as well as a reasoning why the data are considered relevant for the release estimation from the specific use/contributing scenario[12].

The purpose for which data were collected affects how or if the data can be used in a REACH exposure assessment. It shall be taken into account when considering the **representativeness** of the data. Relevance of the of data source must be assessed. Issues to be assessed include:

- A basic condition for acceptance of the data set is that it should be **representative o**f the **operative conditions and risk management measures** described in the exposure scenario. Similarity and potential variations needs to be considered. A key requirement for the final outcome of an assessment is to be representative of the (contributing) scenario to be assessed. For instance, the RMMs prevailing during sampling (i.e. the generation of the measured data), should be similar (provide at least the same efficiency) as the ones reflected in the exposure scenario.

- In order for the data set to be applicable to a sector, it should represent the typical conditions within the sector suitable to assure safe use. Tasks that the data set represents should be clear.

Needed information to satisfactorily **support** the **suitability and representativeness** of the data, as **indicators of good quality**, are:

- ✓ reference to: quality schemes, standard sampling, and measurement methodologies;
- ✓ context: enough description to support the intended scope;
- ✓ clear description of monitored tasks;
- ✓ clear information on risk management measures in operation during sampling;
- ✓ details of duration and frequency of tasks and an assessment if the sampling duration is representative of full-shift exposure or only for the task duration;
- ✓ whether data are current rather than historical (i.e. sampling period to be reported);
- ✓ collection from a wide range of the sites and processes covered by the use description;
- ✓ statistical descriptors available.

Even in well-defined situations, available exposure data have substantial variability, and is strongly associated with implemented OC and RMM at the moment of measure. Both, **exposure variability** and representativeness (contextual, spatial, temporal) of the data to the settings to be assessed, need to be taken into account.

Measured data variability is reflected by the **spread of the distribution** of the individual exposure data points. This variability may be introduced through a number of factors, which include: differences in application of operational conditions, level of (substance) throughput, other local conditions, variability in performance of RMM, or behavioural differences between workers.

[12] ECHA (2016). Chapter R.16: Environmental exposure assessment. Version 3.0 – February 2016.

Exposure distributions can be reasonably described by the **geometric mean** (GM) and the **geometric standard deviation** (GSD). GM estimates the central tendency of the distribution, meanwhile GSD indicates the spread of the distribution.

On the other hand, **percentiles** show the percentage of the measured exposure levels that are at or below a certain value (e.g. the 90th percentile value indicates that 90% of the measured exposure levels are at or below that value). In general, the 90th percentile value of a distribution within a generally suitable dataset (i.e. a dataset corresponding to the conditions described in a contributing scenario) should be used as the exposure value for the risk characterisation. Under particular conditions, other percentiles may be applicable as well but a justification should be provided. High values as well as values under the detection limit should remain in the distribution unless there is a sound justification from the assessor.

Finally, when appropriate representative measured data for the substance are not available, an alternative is the use of measured data for analogous substances, if analogous substances have close enough physicochemical properties, or from analogous situations, a similar enough task, with justification, providing an appropriately conservative outcome.

A higher level of suitability, representativeness and quality of data shall be assured as higher is the concerns of hazard of the substance.

In the case of environmental monitoring, apart from data on inorganic environmental compartments (mainly air, water, soil/sediment), also data from samples of living organisms (biota) may be used for. They can provide a number of advantages compared to conventional air, water and soil samples, especially with respect to sampling at large distances from a release source or on a regional scale. Furthermore, they can provide a PEC_{biota} and consequently an estimation of the body burden to be considered in the food chain. However, concentrations in biota can vary depending on species (mainly because of different feeding habits and different metabolic pathways) and on other factors such as age, size, lipid content, sex, season etc. Such information should be considered carefully before comparing or aggregating measured concentrations in biota.

3.1.1. Combining data from different databases

Diverse problems can be encountered when combining data from different databases (survey data from electronic databases, peer reviewed publications, confidential company data, PhD theses, etc.). They are can be summarized as follows[36]:

- Data quality: in many cases monitoring programmes/databases have no classification of data reliability;
- Different countries, locations, laboratories, periods of time;
- Changes of instrumentation over time (for long time trends);
- Differences in sampling methods, units, correction methods, etc.;
- Weighting often necessary, e.g. for stratified sampling;
- Need for information to understand and categorize the main emission sources (e.g. diffuse, point, wide dispersive).

Therefore, efforts should be made for accomplishing:

- Consistency of followed methodology and performance characteristics (e.g. precision, accuracy, sensitivity);

- Similarity of monitoring and sampling strategy;
- Consistency of units and reporting format

3.2. Information and data requirements on the levels of exposure in the workplace

Occupational exposure assessment, in the context of REACH Regulation, requires to build the exposure scenarios and estimate the exposure. Purpose of the exposure assessment is the description of conditions (exposure scenario) under which safe use is possible.

In the workplace, different types and routes of exposure may exist. Substances can reach the body and probably enter the body mainly by inhalation, followed by contact with the skin (dermal route), or by swallowing (ingestion/oral route).

Exposure to a particular substance is normally determined through estimating the external exposure and the routes of exposure. The nature of effect will dictate the risk management strategy that needs to be implemented.

Hence, exposure estimation shall consider these three **exposure routes** separately[13]:

- **inhalation** exposure: amount of the substance inhaled; usually represented by the average airborne concentration of the substance over a reference period of time in the breathing zone of a worker);
- **dermal** exposure: the amount of substance in contact with the skin surface,
- **oral** exposure: the amount of substance ingested.

In addition to the exposure routes, the **duration and frequency** of exposure after which the effect occurs (acute or chronic effect) needs to be taken into account. Acute effects occur rapidly after short-term exposures and chronic effects generally occur as a result of long-term exposure (months, years, etc.).

For repeated or continuous exposure, in order to compare with hazards (chronic effects), a reference period of 8 hours, a working journey, is generally used. Therefore, estimated exposures are adjusted to provide an 8-hour time-weighted average estimate so they can be compared with chronic DNELs. For the case of acute health effects, it is relevant to identify and evaluate exposure over shorter reference periods (often as a 15-minute time weighted average) and compare with a short term (15 minute) DNEL.

As previously mentioned, **inhalation** is the main exposure route of nanomaterials in the industrial setting (airborne nanomaterials). It is generally expressed as **mg/m^3** for particulates and in ppm (parts per million), but in the case of nanomaterials, more relevant metric is **cm^2/m^3**, and also **particle number/cm^3** which is especially important for high aspect ratio nanomaterials.

The exposure in the workplace is determined by many factors which should be well characterized for exposure assessment. These are related with the substance itself (**physicochemical parameters**: impurities, mixtures, physical state, dustiness, etc.), **use description**, the **operational conditions** (extent of contact area, duration and frequency of the operation, temperature, pressure, energy of the process, etc.) and the **risk management measures** in place (engineering controls (indoor/outdoor, enclosure, containment, ventilation,

[13] ECHA (2015). Guidance on Information Requirements and Chemical Safety Assessment Part R.14: Occupational exposure assessment. Draft (Public) Version 3.0 November 2015.

etc.); personal protective equipment (respiratory, dermal, eye protection); and implemented administrative controls).

An important point to be taken into account when dealing with aerosols (liquid and solid) is the **particle size** and **size distribution**, which may vary with time and place. Particle size is important as it determines the uptake and location of deposition (some particles will not be inhaled due to their size, but also, once particles are inhaled, particle properties determine the most likely location of deposition in the respiratory tract) which normally determine the possible adverse health effects. Thus, when measurements of airborne particles are undertaken, it should be indicated for which **aerosol fraction**(s) (inhalable, thoracic or respirable as defined by EN 481[14]) the measurements have been performed.

According with ECHA (2015)[13], general requirements for methods to determine the concentration of airborne chemicals in the workplace are well described in European standards (e.g. EN 482[15]) and are normally supported by published methods at a national or international level validated against the standards[16]. But when dealing with nanomaterials, up to date no standardized methods are yet available and different approaches are suggested[11].

3.2.1. Exposure estimation: data and information quality

According to REACH Regulation, there are options for registrants to address the exposure assessment requirement by different means, such as **models, data, or analogous data**. Normally, a combination of such approaches may lead to the most appropriate assessment.

The **exposure estimates** have to be adequate for the purpose of establishing safe use and lined with the real life situation described within the **exposure scenarios**. They shall cover all the described uses and take into account the variability within and between tasks, and for users and sites.

The **confidence in a modelled or measured exposure estimation** in the context of exposure assessment and risk characterisation under REACH depends on various considerations (see Figure 3). It shall always be considered for both measured and modelled data, the relationship between the actual substance and its conditions of use and the substance/conditions to which the data source refers. For establishing the similarity of **substance properties and conditions of use**, the variability/distribution of the exposure estimates need to be analysed.

Moreover, for exposure assessment, if relevant data exist for the substance used/generated in the exposure scenario describing the conditions of use at a specific site or a range of very similar sites, it should be interpreted as part of the assessment. Where no specific data exist, appropriate analogous data from similar conditions of use (measured dataset for substance and/or uses and/or use conditions analogous to the substance/use to be assessed) could be used. For establishing the similarity between sites the variability/distribution of the exposure estimates need to be analysed.

[14] UNE-EN 481:1995. Workplace atmospheres. size fraction definitions for measurement of airborne particles.
[15] UNE-EN 482:2012. Workplace exposure - General requirements for the performance of procedures for the measurement of chemical agents
[16] The GESTIS database contains validated lists of methods from various EU member states described as suitable for the analysis of chemical agents at workplaces http://www.dguv.de/ifa/Gefahrstoffdatenbanken/GESTIS-Analysenverfahren-für-chemische-Stoffe/index-2.jsp).

For exposure estimates based on **measured data**, the confidence increases when[13]:

- the exposure data has been collected and analysed according to *recognised protocols*;
- the data has been collected as *personal exposure*, or is directly related to it;
- *appropriate information* on the conditions of use and risk management measures in place are available;
- the *number of data points* is adequate (a higher number of data points is required when the RCR is close to 1)

For exposure estimates based on **modelled data**, the confidence increases when:

- Model documented and tested against independent measured datasets;
- one or more peer-reviewed scientific publication available.

Whether the source of the modelled or measured exposure estimates deviates from the general quality requirements, the data can still be used but a particular justification is needed. But in general, if the **RCR is close to 1** and/or in case of a **high potential hazard**, **higher confidence in the exposure estimate is needed**, through a higher number of data points and/or confirmation of outcome by supportive exposure estimates.

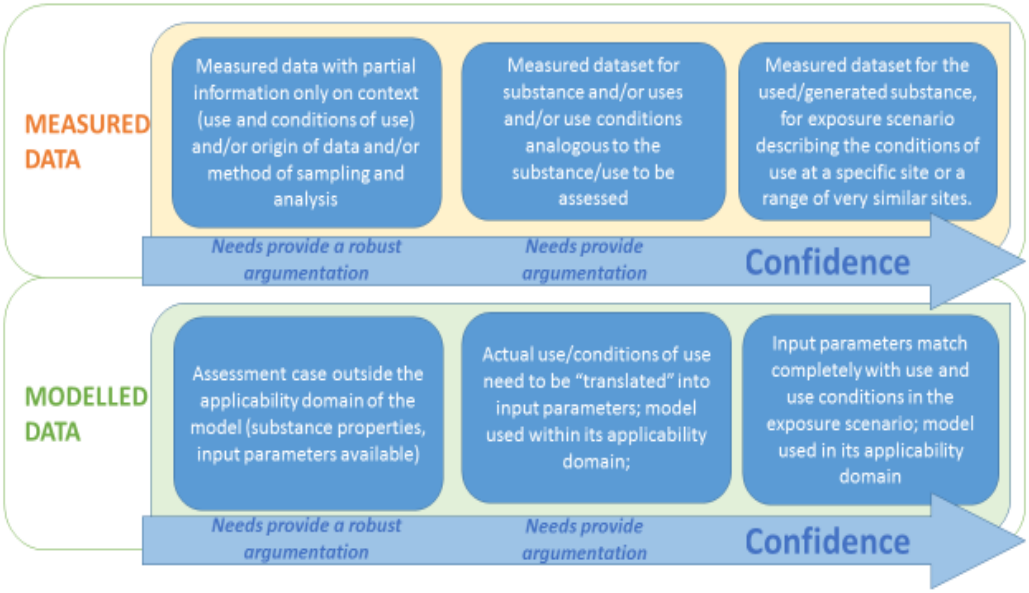

Figure 3. Implications of the employed source of exposure data (adapted from[13])

3.2.1.1. Particular considerations when dealing with exposure to nanomaterials

In the case of nanomaterials and especially considering limitations of modelled estimates for them, the inclusion of **date derived from simulations** in the hierarchy is recommended. Considering this modification, the hierarchy is adapted as follows[10]:

> 1st. **Measured** data (including the quantification of key exposure determinants);
> 2nd. Appropriate **analogous data**, including data derived from simulations (including the quantification of key exposure determinants);
> 3rd. **Modelled** estimates

3.2.2. Inhalation data

When assessing the occupational exposure under REACH, used inhalation exposure data should relate to concentration of the substance in the **breathing zone** of the operator and **before any respiratory protection is factored** into the assessment. Enough data are required to establish the key values from the distribution (inhalation exposure data tend to be log-normally distributed).

The concentration measured needs later be time-weighted averaged for a reference period (normally 8 hour or 15 minutes) before being compared with the appropriate DNEL.

The **number of data points** required will differ depending on the covered situation in the exposure scenario. For example, a top-down assessment will require more data that a single company own assessment. Moreover, *the closer the RCR is to 1, the higher number of data points is required* (taking into account that exposure estimation also has an associated uncertainty and that sources of uncertainty shall be adequately addressed and provide enough confidence in the calculated RCR); with higher variability of the data; if the representativeness or specificity of the data are suspected to be significantly uncertain for the situation to be assessed.

National and international guidelines provide advice on the number of data points and sampling strategy that may be needed to adequately perform an assessment[17],[18]. Strategy is based on the Risk Characterization Ratio and the variability of the data. For example, for the assessment of a single company, the European Standard EN 689[19] recommends that at least **6 data points** should be presented to adequately describe the exposure of **a single work activity within one company**, and requires a narrow distribution.

Finally, in order to obtain representative inhalation exposure measurements, duration and time of the monitoring should be chosen with caution (EN 689 also provides advice on **sampling time** to assure representativeness).

3.2.2.1. Particular considerations when dealing with exposure to nanomaterials

The measurement of exposure to nanomaterials provides particular challenges that include discrimination from background particles, collection and analysis of size information, effective high spatial and temporal variability, choice of metrics and measurement instruments, and measurement of high aspect ratio nanomaterials. The state of knowledge on these issues is in permanent development[10] and shall be taken into account when using exposure data.

3.2. Information and data requirements to calculate PEC values

When dealing with the environmental exposure assessment, the release of a substance and subsequent exposure to the environment are in principle assessed on two spatial scales: **locally**,

[17] EN 689. Workplace atmospheres. guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy.

[18] British and Dutch occupational hygiene societies BOHS/NVVA (2011). Testing Compliance with Occupational Exposure Limits for Airborne Substances. http://www.arbeidshygiene.nl/-uploads/files/insite/2011-12-bohs-nvva-sampling-strategy-guidance.pdf

[19] UNE-EN 689:1996. Workplace atmospheres. guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy.

in the vicinity of a representative source of the release to the environment, and **regionally**, for a larger area which includes all release sources in that area.

At the local scale, two scenarios are distinguished to assess the release to the environment: for uses taking place at industrial sites and for uses taking place in a widespread manner.

At ***industrial sites***, life-cycle stages that are assumed to take place are: manufacture; formulation and repacking; use at industrial site; and service life at industrial site (use or processing of articles). On the other hand, following life-cycle stages are assumed to be ***widespread manner***: widespread use by professional workers; use by consumers; service life by professional workers and consumers.
For each life-cycle stage, one or more uses can be identified. The release pattern and the estimated release factor are closely related to the life-cycle stages of a substance. The entire life-cycle of a substance should be taken into account for the assessment.

Environmental exposure assessment consists of three main steps:

1. recompilation of information on the main substance properties (physicochemical, fate and (eco)toxicological properties) and hazard assessment.

2. mapping of uses (identification of all uses of the substance and realistic information of conditions of use) and thus definition of the life-cycle stages of the substance giving rise to release/exposure, the construction of the Exposure Scenario. Determination of operational conditions (OCs) and risk management measures (RMMs), as they constitute the "**conditions of use**".

3. **Release estimation** consisting on the determination of the local and regional release rates for each use, starting from the appropriate release factors and the tonnage assigned to any identified use and taking into account a realistic effectiveness of the RMMs assumed to be in place;

4. Environmental distribution and fate and exposure estimation. The distribution and fate of a substance in the environment is assessed at local and regional scale. Consequently, **Predicted Environmental Concentration (PEC)** values for each environmental compartment and the daily intake of humans via the environment are derived at local and regional scales. A single overall PEC is derived for (top-) predators based on local and regional contributions. PEC values for the sewage treatment plant are calculated at the local scale.

For humans via the environment, a local and a regional exposure are estimated independently. The local scenario is a worst-case scenario.

Exposure to the environment has to be estimated in all the compartments for which a hazard has been identified for the related protection target and it is the result of the release of a substance which may partly be degraded/removed by risk management measures and the subsequent distribution and degradation within the environment.

Environmental releases may occur as a result of any process or activity during the life-cycle of a chemical substance. Release estimation is the process by which releases to the environment are

quantified, taking into account the different release pathways and the spatial scale of the releases.

The release of a substance from a certain use depends on the operational conditions and risk management practices. And is expected to occur via **different routes**:

- **Water**: the release is usually to wastewater being (potentially) treated before being ultimately released to fresh or marine water.
- **Air**: the release to air is mostly related to emission of dust or highly volatile substances or emissions of substances from hot processes. The exhaust air may be cleaned by various techniques before being released to the environment.
- **Soil**: for all uses taking place at industrial sites or urban areas (also mentioned as municipalities in this guidance) the direct releases to soil are to "non-agricultural soil". For some specific uses, direct release to agricultural soil may occur.
- **Underground**: some substances are directly released to the underground (e.g. when used in fracking).
- **Waste:** releases to waste may occur from the process itself (including the fraction left in packaging when relevant) or as a consequence of the risk management measures (applied to waste water or exhaust air)12. Also, substances incorporated into articles will be "released" to the waste at the end of service life of the article.

The following release rates are used as input to exposure estimation at local level:

- Release rates (expressed in kg/day) to wastewater, surface water, air and soil for each use at the **local scale**: a **local daily release rate** corresponding to the amount of substance released over a day (the release rate is given averaged per day (24 hours). This implies that, even when a release takes place only a few hours per day, it will be averaged over 24 hours). And a **local annual release rate** (averaged over the year).

- An **average release rate over the year** (expressed in kg/day) to wastewater, surface water, air and soil **at the regional scale**.

The release rate to a given release route for a use is then calculated using the following equation:

Eq.3:

$$E_{local,j} = Q_{daily} \cdot R_{Fj} \cdot 1000$$

Where:

$E_{local,j}$: Release rate to the release route "j" at the local scale. [kg/day]
Q_{daily}: Daily use amount at a site or annual use amount in a standard town divided by 365 days [tonnes/day]
R_{Fj}: Release factor to release route "j" [% or kg/kg]

At regional level all regional releases associated with the different identified uses, both industrial and wide disperse sources, are cumulated to estimate the total regional release (kg/day) to surface water, wastewater, air and soil.

The regional releases associated with the different identified uses are based on the tonnage at regional level for each use and the same release factors used at local scale. By default, the tonnage at the regional level for the industrial settings is set equal to 100% of the tonnage at EU

level, while for wide dispersive uses it is set equal to 10% of the registrant's supply volume at EU level. Releases at the regional scale are assessed for water, air and soil (including industrial soil). At this scale, direct releases to soil are also considered.

The default regional releases are therefore calculated, for each use, according to equation 4:

Eq. 4: $$E_{regional,IU,j} = Q_{regional\ daily,IU} \cdot RF_{IU,j} \cdot 1000$$

Where:

J = environmental compartment (air, soil, wastewater)
$E_{regional,IU,j}$ (kg/day): release rate to the compartment "j" at the regional scale for an identified use (IU);
$Q_{regional\ daily,IU}$ (tonnes/day): average daily use at the regional scale for an identified use (IU) = regional tonnage for each use/365 days;
Regional tonnage for each use (tonnes/year) = 100% × total registrant's tonnage at EU level (for industrial setting);
Regional tonnage for each use (tonnes/year) = 10% × total registrant's tonnage at EU level (for widespread uses);
$RF_{IU,}$ j: Release factor (% or kg/kg) to compartment "j" for identified use. The default value is set by ERCs.

When calculating the total regional releases, by default, 80% (representing the EU average) of the wastewater is assumed to be treated in an STP and 20% to go directly to surface water without any treatment, regardless of the assumptions made about STP connection at local scale.

Formulas to be applied for the calculation of the total regional release to air, surface water, wastewater and soil are the following:

$$E_{total,regional,air} = \Sigma\ E_{regional,IU,air}$$
$$E_{total,regional,soil} = \Sigma\ E_{regional,IU,soil}$$
$$E_{total,regional,wastewater} = \Sigma\ E_{regional,IU,wastewater} \times 80/100$$
$$E_{total,regional,surface\ water} = \Sigma\ E_{regional,IU,wastewater} \times 20/100$$

where:
$E_{total,regional,wastewater}$ passes through an STP and, subsequently, is discharged in surface water.

The final **aim of the release estimation is to calculate the release rates** (see Figure *4*, from ECHA, 2016[12]) as they are the **main input parameters to be fed into the exposure estimation**. In most cases, the release rates are not measured but calculated from a release factor (expresses the fraction (either kg/kg or %) of the used amount being released to a given release route) applied to the tonnage assumed to be present in a use process.

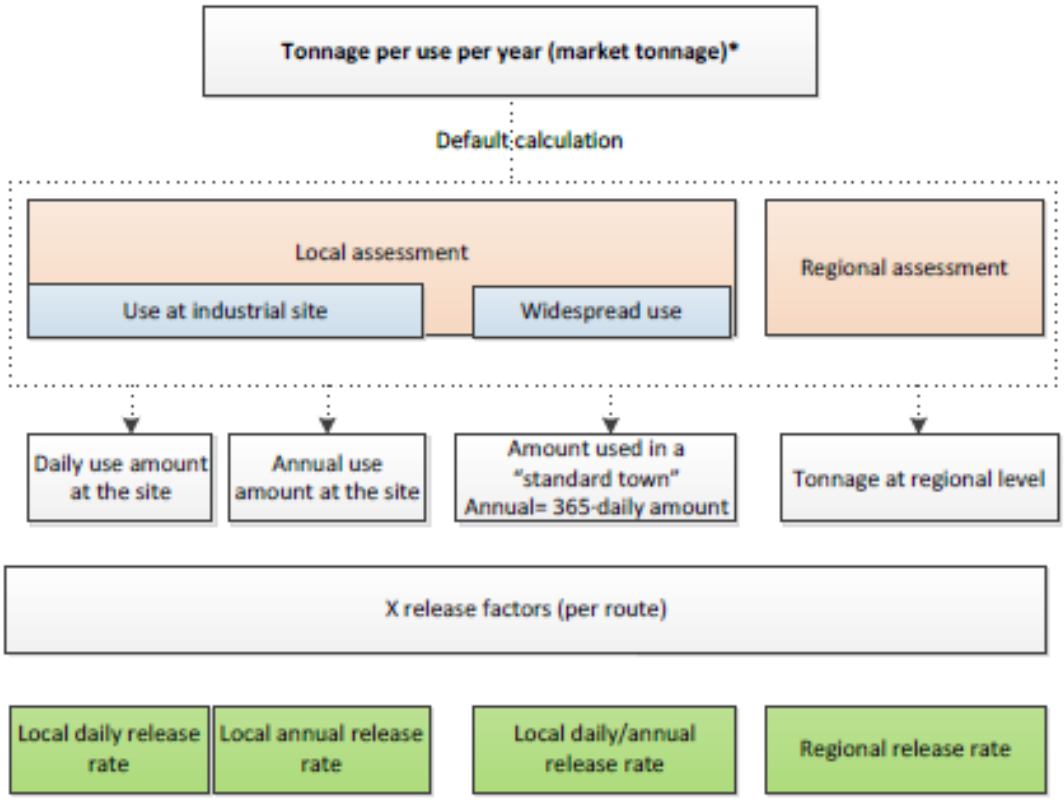

Figure 4. Estimation of the release rates (ECHA, 2016[12]).

Exposure estimates are called predicted environmental concentrations (PECs) and may be obtained by modelling or using measured exposure. Inputs for existing exposure estimation models include: release rates (see Figure *4*, from ECHA (2016)[12]), removals and distribution in biological sewage treatment plants and substance physico-chemical and fate properties.

For using measured environmental concentrations for the exposure estimate to establish PECs such data shall be:

(i) of a suitable quality,
(ii) representative of the OC/RMM that were in place when measurements were performed,
(iii) supported by sufficient contextual information, and
(iv) assigned to the appropriate spatial scale.

In the following points, processes, parameters and factors that existing models for local and regional PEC determination are described, for local (3.2.1) and regional (3.2.2.) scale.

3.2.1. Determination of local PEC

The local approach of the environmental exposure assessment aims to determine the concentrations of chemical substances released from a single point source (industrial site or standard municipal biological STP) after release to the environment. It is assumed that exposure targets are exposed at the vicinity of the release point. Therefore, concentrations are normally calculated on the basis of a realistic daily release rate.

On the other hand, predators, humans and terrestrial organisms are assumed to be exposed to levels averaged over a longer period. Thus, in such cases exposure is derived from yearly averaged release rates, because exposure is assumed not to be influenced by temporal fluctuation in release rates. In the case of predators and human beings, these fluctuations are also of a rather short-term nature compared to their life span and the time scale on which chronic effects are considered[12].

Finally, degradation in the environment and distribution processes should be taken into consideration after release to the environment in order to estimate the concentrations at the local scale. However, because of the relatively short time between release and exposure, concentrations at local scales are almost entirely controlled by initial mixing (dilution into environmental compartment) and adsorption on suspended matter. Biodegradation may take a role for the soil compartment only. No other process is considered in the calculation of local PECs.

The basis of the calculation of the predicted exposure concentration (PEC_{local}) for each compartment are explained below (see *Table 2*). For most of the compartments (except for the biological STP) a PEC regional, which is also to be estimated, is integrated in the calculation of the PEC_{local} as background concentration.

Table 2. Environmental compartments for exposure estimation (predicted exposure concentration (PEC_{local})) (adapted from [20]).

Target	Medium of exposure
Aquatic compartment	Surface water (freshwater and marine aquatic compartment)
	Sediment
	Predators (fish eating)
Terrestrial compartment	Agricultural soil
	Groundwater
	Predators (secondary poisoning) (worm eating)
Air compartment	Atmosphere
Microorganisms	STP aeration tank (STP concentration for evaluation of inhibition to microorganisms)
Humans exposed indirectly via the environment	Via inhalation and ingestion

For the biological STP, a concentration in the STP (PEC_{stp}) is estimated. For fresh and marine water, the $PEC_{localwater}$ is the sum of the local concentration during the release episode and of the regional PEC. For fresh and marine sediments, the PEC is usually estimated from the PEC in water assuming a thermodynamic partitioning equilibrium with water. For air, the $PEC_{localair}$ is the sum of the local concentration (at 100m from the point source[21]) averaged over the year and the PEC regional concentration. For soil, the $PEC_{localsoil}$ is the sum of the local concentration in agricultural soil averaged over 30 days and the PEC regional concentration.

[20] ECHA (2016). Guidance on information requirements and Chemical Safety Assessment. Chapter R.16: Environmental exposure assessment. Version 3.0 – February 2016.
[21] Note: For widespread uses, the point source is the biological STP.

Concentrations in other soil compartments and groundwater or at other scales are also calculated as they are needed for the estimation of exposure for secondary poisoning or humans via the environment. They are not used as such in the risk characterisation.

For secondary poisoning, the concentrations in the food of predators are estimated from the concentrations in the environment and the bioaccumulation. Two concentrations are estimated; one on the basis of the PEC local (in water or soil) and one on the basis of the PEC regional. It is agreed that the PEC for secondary poisoning is the mean of those two concentrations

3.2.2. Determination of Regional PEC

Concentrations of chemical substances released from all sources in a larger area are assessed for a generic regional environment. For regional assessment, the distribution and fate of the substance in a larger area from the release point are considered, and calculated in a different manner respecting local assessment.

Regional concentrations are used as background concentrations in the calculation of the local predicted environmental concentration (PEC).

For calculating the regional PEC, a multimedia fate-modelling approach can be used. Regional computations are done by means of multimedia fate models based on the fugacity concept. Models have been described by different authors. These models are box models, consisting of a number of compartments which are considered homogeneous and well mixed. A substance released into the model scenario is distributed between the compartments according to the properties of both the substance and the model environment. Several types of fate processes are distinguished in the regional assessment[12]:

- release, direct and indirect (via STP) to the compartments air, water, industrial soil, and agricultural soil;
- degradation, biotic and abiotic degradation processes in all compartments;
- diffusive mass transport (gas absorption and volatilisation).
- advective transport, by which a substance is carried from one compartment into another by a carrier that physically flows from one compartment into the other.

All releases to each environmental compartment shall be taken into account for each use and regional releases of substances are assumed to occur continuously over the year. Therefore, average exposure levels in space and time are calculated by the steady-state [22] model for the regional scale using annual release rates. Since releases and fate processes are assumed to take place over an infinite time (many years), regional exposure concentrations can be seen as worst case approximations[12].

Proposed model parameters for regional model are presented in Table *3* (from table R.16-18 of ECHA (2016)[12]).

[22] Note: Corresponding to a situation where releases and fate processes take place over infinite time. In case steady-state is only reached after several decades (e.g. in the case of metals and the soil compartment), it is recommended to calculate both the PEC after a surveyable time period of 100 years and the PEC at steady-state.

Table 3. Proposed model parameters for regional model.

PROPOSED MODEL PARAMETERS FOR REGIONAL MODEL	
Parameter	**Value in regional model**
area of the regional system	4.104 km^2
area fraction of water	0.03
area fraction of natural soil	0.27
area fraction of agricultural soil	0.60
area fraction of industrial/urban soil	0.10
mixing depth of natural soil	0.05 m
mixing depth of agricultural soil	0.2 m
mixing depth of industrial/urban soil	0.05 m
atmospheric mixing height	1000 m
depth of water	3 m
depth of sediment	0.03 m
fraction of the sediment compartment that is aerobic	0.10
average annual precipitation	700 $mm \cdot yr^{-1}$
wind speed	3 $m \cdot s^{-1}$
residence time of air	0.7 d
residence time of water	40 d
fraction of rain water infiltrating soil	0.25
fraction of rain water running off soil	0.25
EU average connection percentage to STP	80%

For regional model for the regional PEC calculation, the regional assessment takes place in a standard region corresponding to 10% of the size of the EU, represented by a typical densely populated EU-area located in Western Europe (~ 20 million inhabitants, 200 · 200 km^2). An STP connection rate of 80% (the EU average according to data available before the implementation of the Urban Waste Water Treatment Directive and currently used in EUSES) will be assumed.

In addition to the environmental characteristics of the region, selected **intermedia mass transfer coefficients** are required in the multimedia fugacity model to ensure comparability of the outcome with other models.

It should be noted an important limitation when dealing with nanomaterials as, up to date, no validated model for chemicals at the nanoscale exists and that knowledge area is still under study and development.

3.2.3. Use of environmental measured data

Measured data for different substances can be available for air, water, soil/ sediment, and/or biota. These actual measured concentrations of the substance in a particular environmental compartment can be used to facilitate the interpretation of model output and, when appropriate, can be used as predicted environmental concentrations (PECs). They will be used together with calculated environmental concentrations when deciding on the environmental concentration to be used for exposure estimation.

Sometimes, it may also be possible to estimate exposure based on measured data for another substance with similar physicochemical properties or similar properties regarding its environmental fate and has a similar use pattern.

But these data shall be carefully evaluated for their *quality and representativeness*, as many factors may impact on these measured data. If the measured values have passed a procedure of critical, statistical and geographical evaluation, a high degree of confidence can be attributed to those data and they shall overwrite the calculated values.

The evaluation should follow a stepwise procedure[20]:

- Sampling and analytical methods employed and the geographic and time scales of the measurement should be identified.
- Data should be assigned to local or regional scenarios by taking into account the sources of release and the environmental fate of the substance. If there is no spatial proximity between the sampling site and point sources of release the data represent a regional concentration. If measured concentrations reflect the releases into the environment through point sources, they are local (the regional concentration is by definition already included). Note that measured data at the local scale, representative for a specific use situation have to be clearly linked to the operational conditions and risk management measures described in the exposure scenario.
- 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 comparison of measured data and a calculated PEC.

If measured data related to environmental concentrations are available and are:

1. of a suitable quality;
2. supported by sufficient contextual information; and
3. assigned to the appropriate temporal and spatial scale, and
4. representative of the OCs/RMMs that are expected to be in place (for data at the local scale);
5. representative of a stable market (for data at the regional scale)

they can be used for the exposure estimate, as considered representative and of quality[12].

3.3. Quality and representativeness criteria for the use of existing measured data

It is advisable to obtain as much useful information on release and exposure from a data set as possible, but there is inherent danger for inappropriate use of the data for risk assessment purposes that shall be considered.

When measurements are available, in order to be used as release and exposure estimations (normally in combination with modelled estimates), they have to be assessed first. Data quality

is the most critical aspect of monitoring. Thus, quality assurance is essential for the whole data production chain and for any type of monitoring[23].

Quality of the sampling and analytical techniques; selection of data representativeness for the environmental compartment of concern and for the addressed exposure scenarios; outliers; treatment of values below the limit of quantification (LOQ); and data comparability, all are aspects that shall be considered when dealing with available measuring data.

The **risk assessor should question and evaluate the quality of the data available, and to compare data from different sources when necessary**. In many cases, there will be quantitative **measures available regarding the uncertainty** that can be attributed to the data, e.g. based on the accuracy of the analysis techniques that were employed (for example emissions monitoring results might be reported as 100 mg/m3 ± 25 %). **Where this information is available it should be recorded, so that it can be used to determine the upper and lower ranges for the sensitivity analysis, which may be necessary later in the assessment**.

According reference document on economics and cross-media effects (ECM) (Section 2.4.1 of the ECM reference document adopted in July 2006)) and Decision 2012/119/EU[24], data **quality rating systems** used for emission estimates to give a qualitative indication of the reliability of data estimates are the following. This approach has been extended to a generic data quality rating system[25]:

[23] JRC (2013). JRC Reference Report on Monitoring of emissions from IED-installations. Monitoring of emissions to air and water Industrial Emissions Directive 2010/75/EU (Integrated Pollution Prevention and Control). RB/BS/EIPPCB/ROM_Final_Draft. The aim of this document is to inform competent authorities and operators of the general aspects of the monitoring of emissions from installations under the scope of the Industrial Emissions Directive (IED, 2010/75/EU) (and, most likely, is also relevant to other agricultural/industrial installations) and to bring together background information on monitoring that may be of use to the European IPPC Bureau and Technical Working Group (TWG) members when working on sectoral BAT reference documents (BREFs) and more specifically on the BAT conclusions, the key parts of the BREFs.

This document addresses general principles and other relevant aspects concerning the monitoring of emissions and associated parameters that are the basis for deciding the approach and frequency of monitoring, as well as for the elaboration and use of monitoring data. Therefore, this document aims to promote the accuracy, reliability, representability and comparability of monitoring data from agricultural/industrial installations.

[24] Commission implementing decision of 10 February 2012 laying down rules concerning guidance on the collection of data and on the drawing up of BAT reference documents and on their quality assurance referred to in Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions 2012/119/EU.

[25] JRC (2013). JRC Reference Report on Monitoring of emissions from IED-installations. Monitoring of emissions to air and water Industrial Emissions Directive 2010/75/EU (Integrated Pollution Prevention and Control). RB/BS/EIPPCB/ROM_Final_Draft.

A. an estimate based on a large amount of information fully representative of the situation and for which all background assumptions are known;
B. an estimate based on a significant amount of information representative of most situations and for which most of the background assumptions are known;
C. an estimate based on a limited amount of information representative of some situations and for which background assumptions are limited;
D. an estimate based on an engineering calculation derived from a very limited amount of information representative of only one or two situations and for which few of the background assumptions are known;
E. an estimate based on an engineering judgement derived only from assumptions.

Data of A or B quality would be the most appropriate for exposure assessment under REACH. But it is important that data of 'inferior' quality are not suppressed nor excluded from the assessment by requiring only data of 'A' or 'B' quality. Otherwise, if less reliable data are excluded, then applying the methodology might become a barrier to innovation rather than a tool to improving environmental performance, as innovative techniques, by their very nature, will not have as much data available as established techniques. **If only data of inferior quality are available, then conclusions should be drawn cautiously**. However, conclusions can still be drawn and can form the basis for further discussion or to identify where more reliable data needs to be obtained

Based on [3, 12], two quality levels for existing data, based on the available contextual information, are given in Table *4* (these criteria will be applied in a flexible manner). **The most important factors** to be addressed are the **analytical quality** and the **availability of information necessary** to assess the representativeness of the sample.

Table 4. Quality criteria for use of existing measured data (Source[3, 12]).

Criteria	Ideal set *"Valid without restrictions"*	Minimum set for exposure assessment *"Valid with restrictions"* (difficult data interpretation)
Objective of the programme	x	Optional
What has been analysed	x	x
Analytical method	x	x
Units	x	x
Limit of detection and quantification (LOD/LOQ) *(shall be lower than the PNEC/DNEL)*	x	x
Blank concentration (background concentration)	x	Optional
Recovery	x	Optional
Accuracy	x	Optional
Reproducibility	x	Optional
Sampling protocol details	x	Optional
One shot or mean	x	x
Location	x	x
Date of sampling (dd/mm/yy)	x	Minimum required is

Criteria	Ideal set *"Valid without restrictions"*	Minimum set for exposure assessment "*Valid with restrictions*" (difficult data interpretation)
		sample year
Time	x	Optional
Matrix characteristics	x	Optional
Proximity and influence of sources	x	x
Discharge emission pattern and volume	x (required for local scale)	x (required for local scale)
Flow and dilution or application rate of water body sampled	x (required for local scale)	x (required for local scale)
Treatment of measurements below the limit of quantification	x	x
Description of statistical evaluation of results	x	Minimum required is whether one-shot or mean

x = required

Information about the purpose of the study is needed or at least provide the following evidence[26]:

- Specified sampling strategy, including what was sampled, when and where, how representative the samples were of the local or regional situation, and to what extent they allowed for an assessment of temporal and/or spatial variability;
- Clearly described analytical methodology, including the limit of detection and the quality of the analytical determinations.

In the case of using monitoring information for exposure assessment as part of risk assessment, the extent to which the data addresses **temporal and spatial** (local or regional) variability should be defined in detail. Required **degree of precision and accuracy, and other important performance characteristics such as limit of detection/quantification**, are dependent on the **objectives of the monitoring programme** and should be taken into account when using monitoring data. Reliability is associated with the laboratory undertaking the measurements and is related with the application of state-of-the-art GLP and QA/QC (ISO 17025); participation in international intercalibration and proficiency testing exercises; and analysis of CRMs (certified reference materials). The reliability of the data should be studied and determined[27].In general, exposure concentrations are close to effect levels or quality objectives, a higher degree of precision and accuracy is required than in the case where exposure is orders of magnitude below effect levels or quality objectives.

[26] ECETOC (2003). Workshop on Availability, interpretation and use of environmental monitoring data. Workshop Report No. 1

[27] Note: True data are those that are accurate and systemically uninfluenced. Accurate data are those which present a variance of measurement deviation below a given limit. Systematically uninfluenced means data are free of systemic (scale shifting) errors. Reproducible data are those for which repetition creates statistically identical results meanwhile reliable means the risk of misjudgement is smaller than a default value.

The representativeness of the monitoring data is related to the **objective of the monitoring programme** for which they were obtained. Monitoring programmes may be designed to cover a large spatial area (high number of stations over a large territory), to achieve a high spatial resolution (high number of stations per area unit), or to monitor only one-point source release.

Monitoring programmes may be designed to assess temporal trends (high sampling frequency), or to monitor the status of a site at a given time.

Precisely **what has been analysed** shall be made clear. Details of the sample preparation, including, for example, whether the analysis was of the dissolved fraction, the suspended matter or the total should be given.

In regards to the **analytical method**, it should be given in detail or an appropriate reference cited (e.g. the relevant ISO/DIN method or standard operating procedure), for both sampling and analytical techniques. Units must be clearly specified and information given as to whether it has been normalised. The limit of quantitation and details of possible known interfering substances should be quoted. Concentrations in system blanks should be given. Recovery of standard additions (spikes) should be quoted. Results of analysis of standard "reference samples", containing a known quantity of the substance should be included. Accuracy is connected to the analytical method and the matrix. The degree of confidence (e.g. 95% confidence interval) and standard deviation in the result from repeat analysis should be given. Reproducibility is also connected to the analytical method and the matrix.

Regarding **sampling**, number of samples, sampling frequency and pattern should be sufficient to adequately represent the concentration at the selected site. Samples taken at sites directly influenced by the release should be used to describe the local scenario, while samples taken at larger distances may represent the regional concentrations. Moreover, it is important to consider if data are appropriate and relevant for the scenario being investigated, thus, sufficient information on RMMs and OCs that were in place when measurements were performed should be provided.

It is also needed to know how the **data** have **been treated and reported** (as single values, means, 90-percentile, etc.).

Regarding temporal and spatial representativeness, monitoring site should be representative of the **location and scenario** chosen. If data represent temporal means, the time over which concentrations were averaged should be given too. On the other hand, the time of sampling, day, month and year may all be important depending upon the release pattern of the substance.

Detailed information on the distance to other sources in addition to quantitative information on flow and dilution are needed, for example for the local aqueous environment. It is also necessary to consider if there is a constant and continuous discharge, or if the substance under study is released as a discontinuous emission showing variations in both volume and concentration with time.

Finally, regarding outliers and measurements below the limit of quantification, where outliers have been identified, their inclusion/exclusion should be discussed and justified. The data should be critically examined with regard to possible explanations: sampling or analytical flaws, other errors (such as in data capture or treatment), random variability and an accidental, increased or new release, a recent change in release pattern or a newly discovered occurrence in a specific

environmental compartment. But shall be taken in mind that extreme values may reflect an actual sudden increase of releases, discharges or losses of the substance, and this should be considered in the assessment.

A common problem when working with monitoring data is the use of concentrations below the limit of quantification (LOQ) of the analytical method. At very low concentration levels, random fluctuations become preponderant and the uncertainty of the measurement is greater than with higher concentrations. All measurements below the LOQ constitute a special problem and should be considered on a case-by-case basis. It should be checked first that the matrix analysed is the most appropriate and that the analytical technique being used is suitable and sensitive enough. In the absence of an adequate method of analysis for the substance or if the substances are toxic in extremely low concentrations, different methods may be considered[28] [29] [30].

The most important aspect related with LOQ is that it should be lower than the PNEC or DNEL used to calculate the RCR.

Finally, the data quality is guaranteed when (control and assurance)[2]:

- Use reference materials
- Use inter-laboratory studies (chemical-matrices)
- Reporting quality assurance in collecting data
- Possess certified laboratory or accredited analysis
- If no existing reference material or inter-laboratory studies, demonstrate by regular: blank analysis, spiked samples, duplicates and confirmatory analysis

Laboratory accreditation ensures a common interpretation of standards and covers, among others, laboratories carrying out testing (measurements) and calibration in air and water. Laboratories can be run by plant operators, authorities or third parties (e.g. consultants, experts), but have to fulfil the same requirements.

The EN standard used for the accreditation of testing laboratories is EN ISO/IEC 17025:2005[31] and this requires that each laboratory applies a proven quality management system. This also covers the validation of methods, data treatment, determination of measurement uncertainty and the reporting of results. Applying the same rules given in EN ISO/IEC 17025:2005 guarantees a given level of quality assurance in accredited laboratories, and of the results provided by them.

[28] EC (2009a). Guidance on Surface Water Chemical Monitoring under the Water Framework Directive. Common Implementation Strategy for the Water Framework Directive (2000/60/EC) - Guidance Document No. 19. Technical Report – 2009-025. ISBN 978-92-79-11297-3. http://ec.europa.eu/environment/water/water-framework/facts_figures/guidance_docs_en.htm

[29] EC (2009b). COMMISSION DIRECTIVE 2009/90/EC of 31 July 2009 laying down, pursuant to Directive 2000/60/EC of the European Parliament and of the Council, technical specifications for chemical analysis and monitoring of water status.

[30] EC (1999). Study on the Prioritisation of Substances Dangerous to the Aquatic Environment: II Assessment of Options of the Statistical Treatment and Evaluation of Monitoring Data within the COMMPS Procedure. Office for Official Publications of the EC, Luxembourg.

[31] EN ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2005)

For measurement uncertainty, EN ISO/IEC 17025:2005 refers to the Guide to the Expression of Uncertainty in Measurement[32]. Based on this Guide, European Standards for measurements are available, as is the example of measurements in air (EN ISO 20988:2007)[33].

3.4. Reporting of used monitoring data in the Risk Assessment report

Used representative and reliable measured data should be compiled as tables and annexed to the risk assessment report under REACH Regulation. **The measured data should be presented with the relevant contextual information in the following manner**[12], presented in Table *5*.

Table 5. Presentation of employed **measured data** in the risk assessment report.

Location	Substance	Concentration	Period	Remark	Reference
Country Location	substance or metabolite	Units: [µg/L], [ng/L] [mg/kg]… Data mean / average range / percentile daily / weekly / monthly/annual…	month, year	limit of quantitation (LOQ) relevant information on analytical method analytical quality control Number of measured values and number of values above the LOQ.	Literature reference

[32] JCGM 100:2008 (GUM 1995 with minor corrections) Evaluation of measurement data — Guide to the expression of uncertainty in measurement

[33] EN ISO 20988:2007 Air quality - Guidelines for estimating measurement uncertainty (ISO 20988:2007)

4. Minimum set of information to measured data on the concentration of ENMs

As described in the report No. 185 of the OCDE[34], monitoring data consist of numerical data and associated information, often referred to as meta-data.

Data quality is the most critical aspect of monitoring. Thus, quality assurance is essential for the whole data production chain and for any type of monitoring[35].

Table *6* lists the **fundamental metadata required to support the monitoring data and** for being such existing information meaningful for **exposure evaluation and prediction of environmental concentrations** of chemicals. Metadata include the target chemical, analytical method and performance information for the analysis; sampling protocol; sampling location and time; information on the nature of the sample; and other relevant information. The identification of the target chemical limit of detection (LOD) and limit of quantification (LOQ), defined by analytical method; sampling location and sampling time, are key elements for using the data for exposure assessment confidently.

It is highly recommended that these meta-data elements are collected in order to be able to compare data compiled from different sources.

That monitored information will be thus useful for better and easier exposure evaluation as well as for validation of model predictions and comparison of observed and modelled data.

Table 6. Minimum meta-data needed to back up existing monitoring data and to be profitable and justify their use as Existing Data for the exposure assessment and prediction of environmental concentrations of chemicals (Source[3]).

Criteria	Ideal set	Minimum set for exposure assessment
Objective of the programme	x	
What has been analysed	x	x
Analytical method	x	x
Units	x	x
Limit of quantification (LOQ)	x	x
Blank concentration	x	
Recovery	x	
Accuracy	x	
Reproducibility	x	
Sampling protocol details	x	
One shot or mean		x
Location	x	x
Date of sampling (dd/mm/yy)	x	Minimum required is sample year

[34] OECD (2013). Guidance document for exposure assessment based on environmental Monitoring. Series on Testing and Assessment. No. 185ENV/JM/MONO (2013)7.

[35] JRC (2013). JRC Reference Report on Monitoring of emissions from IED-installations. Monitoring of emissions to air and water Industrial Emissions Directive 2010/75/EU (Integrated Pollution Prevention and Control). RB/BS/EIPPCB/ROM_Final_Draft.

Criteria	Ideal set	Minimum set for exposure assessment
Time	x	
Matrix characteristics	x	
Proximity and influence of sources	x	x
Discharge emission pattern and volume	x	
Flow and dilution or application rate of water body sampled	x	x
Explanation of value assigned to non-detect values if used in a mean	x	x
Description of statistical evaluation of results	x	Minimum required is whether one-shot or mean

Information about the purpose of the study is needed or at least provide the following information[36]:

- Specified sampling strategy, including what was sampled, when and where, how representative the samples were of the local or regional situation, and to what extent they allowed for an assessment of temporal and/or spatial variability;
- Clearly described analytical methodology, including the limit of detection and the quality of the analytical determinations.

From a biological perspective, the problems on lack of information can be grouped under limitations in content, species and trophic levels, geographical coverage, number of samples and seasonal fluctuations. In particular, the life cycle and behavioural patterns of the species under investigation need to be considered if the results are to be meaningful.

These criteria are also relevant for the design of new monitoring programmes.

In the case of using monitoring information for Exposure assessment as part of risk assessment, the extent to which the data addresses **temporal and spatial** variability should be defined in detail. Required **degree of precision and accuracy, and other important performance characteristics such as limit of detection/quantification**, are dependent on the **objectives of the monitoring programme** and should be taken into account when using monitoring data. The reliability of the data should be studied and determined.

About contextual, **spatial and temporal representativeness** (context, location, duration, frequency), these parameters are determined by the objectives of the monitoring programme; characteristics and dynamics of the system and the fact that some environmental compartments are consistently underrepresented (for example, the marine environment compared to fresh waters). Moreover, different factors need to be taken into account when selecting monitoring **locations:** local/regional locations; representative region; background/hotspots; outlets/upstream; emissions/product use/land use; inclusion of sensitive areas where effects may occur.

[36] ECETOC (2003). Workshop on Availability, interpretation and use of environmental monitoring data. Workshop Report No. 1

The sampling **frequency** must address temporal variability of sources and system, dynamics. Indoor concentrations are also highly variable and appropriate use of time integrated sampling approaches is recommended. Long-term data series have great value

Different problems can be encountered when combining data from different databases (survey data from electronic databases, peer reviewed publications, confidential company data, PhD thesis, etc.). They are can be summarized as follows[36]:

- Data quality: in many cases monitoring programmes/databases have no classification of data reliability;
- Different countries, locations, laboratories, periods of time;
- Changes of instrumentation over time (for long time trends);
- Differences in sampling methods, units, correction methods, etc.;
- Weighting often necessary, e.g. for stratified sampling;
- Need for information to understand and categorize the main emission sources (e.g. diffuse, point, wide dispersive).

Therefore, when designing new monitoring programmes, there is a need for[36]:

- Consistency of methodology (within and between participating laboratories)
- and performance characteristics (e.g. precision, accuracy, sensitivity);
- Similarity of monitoring and sampling strategy;
- Consistency of units and reporting format.

Moreover. data collection should be co-ordinated throughout Europe and data sharing structured through meta-databases via the web to ensure broad accessibility.

These monitoring programs should shortcome barriers to data availability as: open databases, standardized format of the data, detailed quality of data (information related with the nature of the samples assessed, the type of analysis performed and the quality assessment in the process must be available); include biological monitoring[36].

These considerations are taken into account in the scope of the NanoMonitor project.

5. Conclusions

When dealing with nanomateriales, exposure assessment shall be undertaken by Risk Assessors under REACH Regulation as for any other chemical substance. The aim of this Risk Assessment is to estimate the Risk Characterization ratio of the defined exposure scenario and thus corroborate the safe use of the nanomaterials or otherwise recommend necessary risk management measures for having the Risk well controlled.

REACH requires that **existing adequately measured, representative exposure data** are taken into account in the exposure assessment, either on their own or in combination with **modelled** exposure estimates. Moreover, when dealing with nanomaterials, the use of **simulation studies** replicating the task or activity of concern should be taken into account when considering the use of measured data, especially considering the limitations of modelled estimates for nanomaterials.

Risk assessor may then for example make use of monitoring data related to worker's exposure or releases to the environment from for example their own or of well-known customer site-specific information, and also from simulation studies and modelled estimates.

But should be taken into account that when dealing with nanomaterials, the inclusion of date derived from simulations in the hierarchy is recommended. Considering this modification, the hierarchy for exposure data, would be preferentially as follows:

1. measured data (including the quantification of key exposure determinants)
2. appropriate analogous data, including data derived from simulations (including the quantification of key exposure determinants)
3. modelled estimates

Regarding measured data, it should be noted that nowadays, measurement of exposure to nanomaterials provides different particular challenges. According ECHA (2016)[11], these include discrimination from background particles, collection and analysis of size information, effective high spatial and temporal variability, choice of metrics and measurement instruments, and measurement of high aspect ratio nanomaterials.

On the other hand, when considering the use of estimation tools, it should be noted that these tools have not yet been validated for use with nanomaterials. If the output of the model is used to estimate exposure for nanomaterials, this should preferably be supported by measured data. There should be a clear description in the CSR of the uncertainties associated with the estimated values and the consequences for the risk characterisation.

The state of knowledge on these issues is still under development.

The aim of the NanoMonitor project is thus to generate as much information as possible regarding concentration of main nanomaterials present at the urban, industrial and workplace environments in order to facilitate the Exposure Assessment and Risk Assessment according REACH.

With that aim, generated data will be collected according requisites of information and data quality required by REACH Regulation (for measured exposure concentrations use) and main monitoring programs (for generated measured data incorporation in the databases).

Regarding the use of monitored data according REACH Regulation, needed information **to** satisfactorily **support** the **suitability and representativeness** of the data, as **indicators of good quality**, are:

- ✓ reference to: quality schemes, standard sampling, and measurement methodologies;
- ✓ context: enough description to support the intended scope;
- ✓ clear description of monitored tasks;
- ✓ clear information on risk management measures in operation during sampling;
- ✓ details of duration and frequency of tasks and an assessment if the sampling duration is representative of full-shift exposure or only for the task duration;
- ✓ whether data are current rather than historical (i.e. sampling period to be reported);
- ✓ collection from a wide range of the sites and processes covered by the use description;
- ✓ statistical descriptors available.

On the other hand, in order to introduce monitored data in the main environmental databases, the methodology (within and between participating laboratories), performance characteristics (e.g. precision, accuracy, sensitivity); monitoring and sampling strategy; and units and reporting format of environmental monitoring programs was analysed in order to have consistency with measuring and reporting protocols used when introducing data in these databases. Was established that fundamental required meta data are:

- ✓ Objective of the programme
- ✓ What has been analysed
- ✓ Analytical method
- ✓ Units
- ✓ Limit of quantification (LOQ)
- ✓ Blank concentration
- ✓ Recovery
- ✓ Accuracy
- ✓ Reproducibility
- ✓ Sampling protocol details
- ✓ One shot or mean
- ✓ Location
- ✓ Date of sampling (dd/mm/yy)
- ✓ Time
- ✓ Matrix characteristics
- ✓ Proximity and influence of sources
- ✓ Discharge emission pattern and volume
- ✓ Flow and dilution or application rate of water body sampled
- ✓ Explanation of value assigned to non-detect values if used in a mean
- ✓ Description of statistical evaluation of results

Finally, a reporting format was developed according required requisites of the different main monitoring programs.

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