Project title:

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

Project Acronym: **NanoMONITOR**

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Deliverable

**DC1. Definition on the starting situation**

Dissemintion Level

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| Action Leader | | ITENE | |
| Responsible Author | | Name | q |
| | | Beneficiary | Phone |

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## PROJECT CONSORTIUM INFORMATION

| Beneficiary | Contact |
|---|---|
| ITENE (Packaging, Transport & Logistics Research Centre) | Carlos Fito<br>cfito@itene.com<br>Maida Domat<br>maida.domat@itene.com |
| AXON Enviro-Group Ltd | Athena Progiou<br>ap@axonenviro.gr |
| The Mediterranean Center for Environmental Studies (CEAM) | Jose Luis Palau joseluis@ceam.es |
| The REACH Centre | Judith Friesl<br>j.friesl@thereachcentre.com<br>Stella Stoycheva<br>s.stoycheva@thereachcentre.com |

## List of acronyms

| | |
|---|---|
| ECHA: | European Chemicals Agency |
| EHS: | Environmental, health and safety |
| ENM: | Engineering nanomaterial |
| PEC: | Predicted exposure concentration |
| ES: | Exposure scenario |
| NM: | nanomaterial |
| REACH: | Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals |

## Summary

## Table of Contents

# 1. Scope and goal of the deliverable

Action C1 of the NanoMonitor project focuses on assessing the current existence and use of measured data, as well as evaluate the potential use of this data in the future. The results related from this action are presented in the present deliverable, DC1.

Present deliverable **DC1 "Definition on the starting situation"**, has as purpose the evaluation of the current use of measured data to evaluate the potential environmental, health and safety risk (EHS) posed by the use of ENMS, with special emphasis on the data concerning the measured concentrations of ENMs in both industrial settings and the environment. This deliverable will define the availability of measured data and the use of this data for regulatory purposes, including the incorporation of measured data on the concentration of both bulk forms and nanoforms into the chemical safety report reported upon REACH registration dossier. Deliverable DC1 worked in the scope of Task C1, is based on the results of the following sub-tasks:

- Task C1.1: Evaluation of the availability of environment/exposure monitoring data
- Task C1.2: Study of the potential demand of measured data under REACH regulation and relevant EU environmental regulation
- Task C1.3: Characterization of the current use of environmental/exposure monitoring data under EU environmental regulation

Task C1.4: Definition of the current lack of data Based on the above, this deliverable contains:

- Maps of Europe reflecting the availability of data for relevant regions
- A detailed list of the current demand of measured data
- A quantification of the levels of use of measured data

In addition, as a result, an inventory of these data was developed, and results presented in this deliverable, recompiled into Microsoft® Excel spreadsheets.

# 2. Availability of data

To evaluate de availability of the monitoring data **a state of the art was carried out** by searching publications, guides, databases and own data from monitoring campaigns. For each source parameters as nanoparticle, life cycle stage, activity, action, product, substance characteristics, room conditions, personal protection, exposure and measurement were registered in order to create a database to compare the data.

## 2.1 Database of collected data for worker's exposure

The first action within the task group encompassing action C1 has been to collect all available measured information and organize it into a database. In this database, the information previously prepared in action A3 has been collected and organized according to the parameters included in **Table 1**.

***Table 1 Parameters of the database created***

| | |
|---|---|
| **Scenario Type** | |
| **Nanoparticle** | |
| **Life cycle stage** | |
| **Activity** | |
| **Action** | |
| **Product** | |
| **Substance characteristics** | Physical state |
| | Primary particle size (nm) |
| | Shape |
| | Substance emission potential |
| **Room conditions** | Volume, m3 |
| | Ventilation Type |
| | Type of local ventilation, at source |
| **Personal protection, hygiene and health evaluation** | (PPE) |
| | Level of effectiveness of the PPE |
| **Exposure** | Duration |
| | Time in direct contact |
| | Exposure pattern |
| | Frequency of the activity |
| | Distance from the source to the breathing zone |
| **Measurement** | Instrument |
| | Model |
| | Type of measure |
| | Size range |
| | Period |
| | [Background] |
| | [ENMs] |

| | Units |
|---|---|
| **Release** | |

These data have been analysed and quantified. In addition, a statistical analysis of the measures has been carried out. The information corresponding to the background concentration and the measured concentration of each scenario has been collected and the increment of nanoparticles for each of the scenarios collected in the database has been calculated.

Once these increments have been calculated, two new tables have been created. They show the relationship between nanoparticles and the process. In this way it has been possible to obtain the exposure of each nanoparticle in function of the process in which it is used, and vice versa.

**Figure 1** shows some examples of the results obtained.

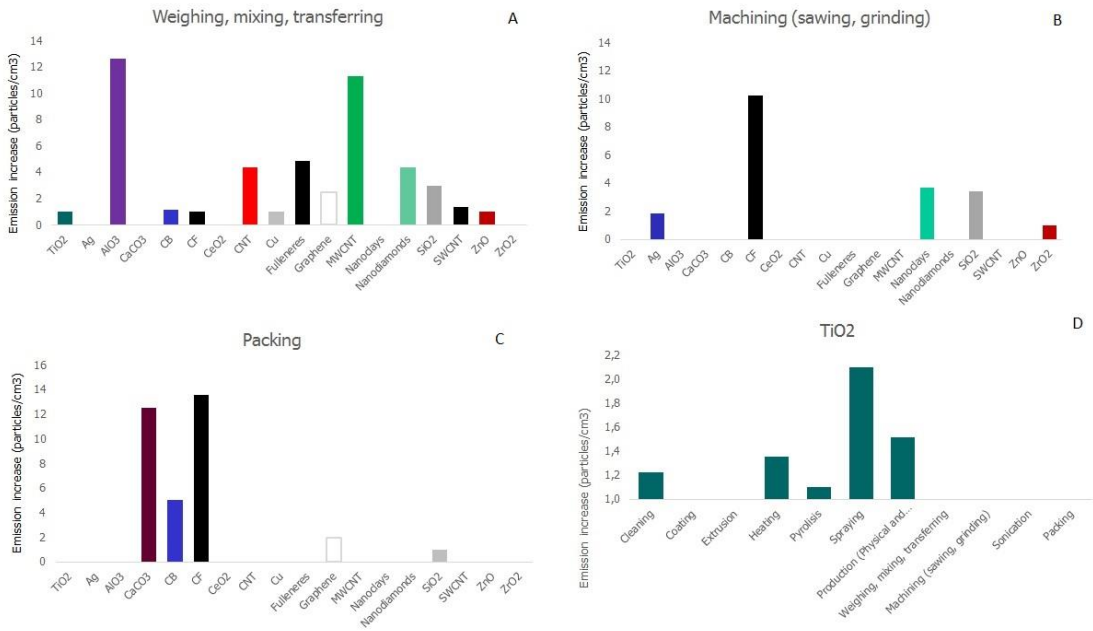



***Figure 1 Examples of the results of the analysis for the process of weighting (A), machining (B) and packing (C) and for all process in Titanium Dioxide (D)***

Apart from representing the individual graphical results for each type of process and each nanomaterial, two summary tables have been prepared, one with all information corresponding to the processes and another with all the information corresponding to the nanomaterials. The EXCEL ™ document can be consulted in the annexes.

## 2.2 Database of collected data for environmental release

The second part of the task consists of a second database of measured concentrations, on this occasion corresponding to the environmental release. In this case the data correspond exclusively to bibliographic results, obtained from an exhaustive search.

In order to quantify and classify the data obtained, they have been organized according to the following criteria:

- Nanomaterial
- Compartment
- PEC value
- Range

The data corresponding to the environmental liberation of nanomaterials are much more scarce in the bibliography than those corresponding to the previous section, worker exposure. In addition, there are no measures of their own. Therefore, the database related to environmental risk is considerably less extensive than that which has been worked with respect to exposure of workers.

The database has been divided into two sections: one has collected data on the release of nanomaterials into the environment and the other has collected the release data to the urban compartment, so that it has been possible to collect contamination data by nanomaterials in the natural environment and urban environments. In the case of urban, in addition to the criteria noted above, also took into account the Source of emission, and the measurement equipment.

## 2.3 Maps of release of nanomaterials in Europe

The databases made in the previous point were reviewed and referred to the country where the emission was made. Once this was done, data from the database were processed and the air, soil and water release statistics of each nanomaterial were obtained according to the country. An example of the results of this statistical treatment is reflected in the **Figure 2**.

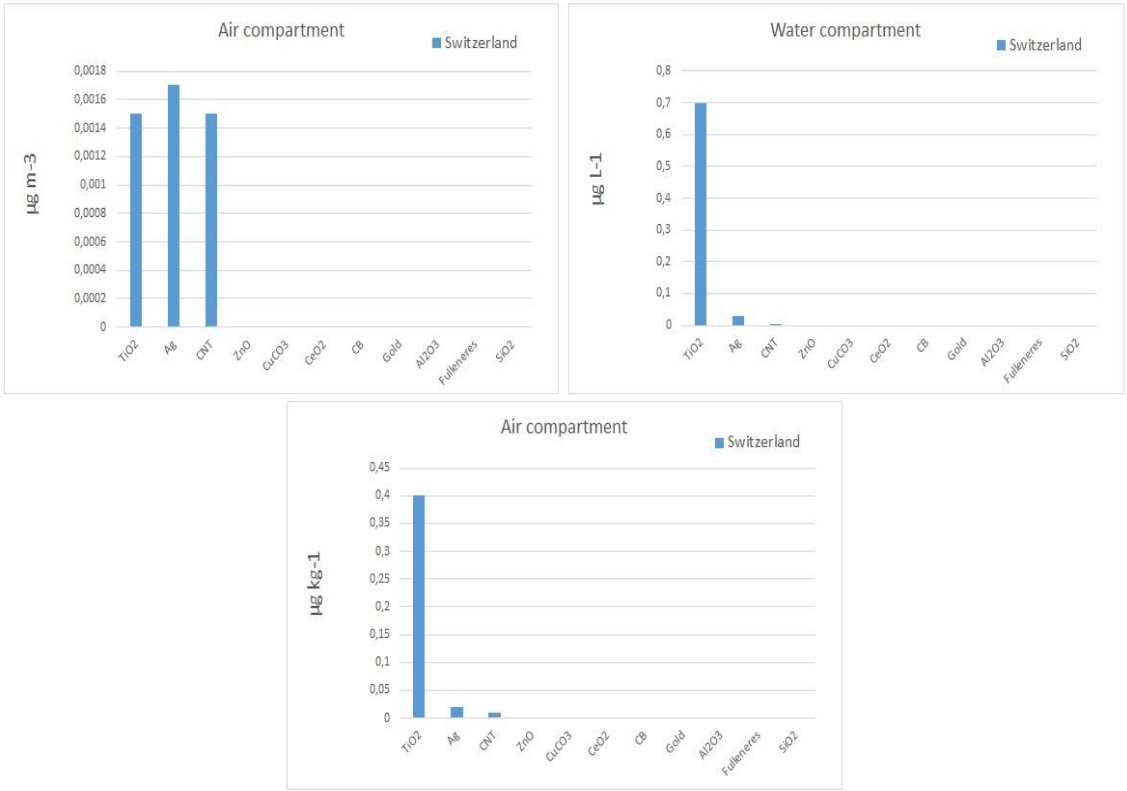
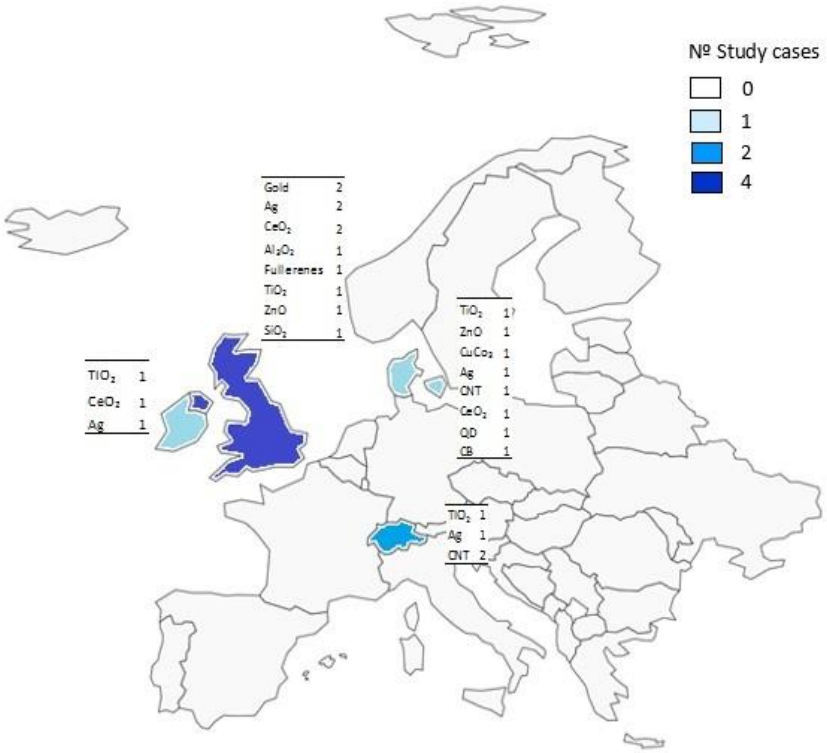



***Figure 2 Environmental release of different nanomaterials in Switzerland***

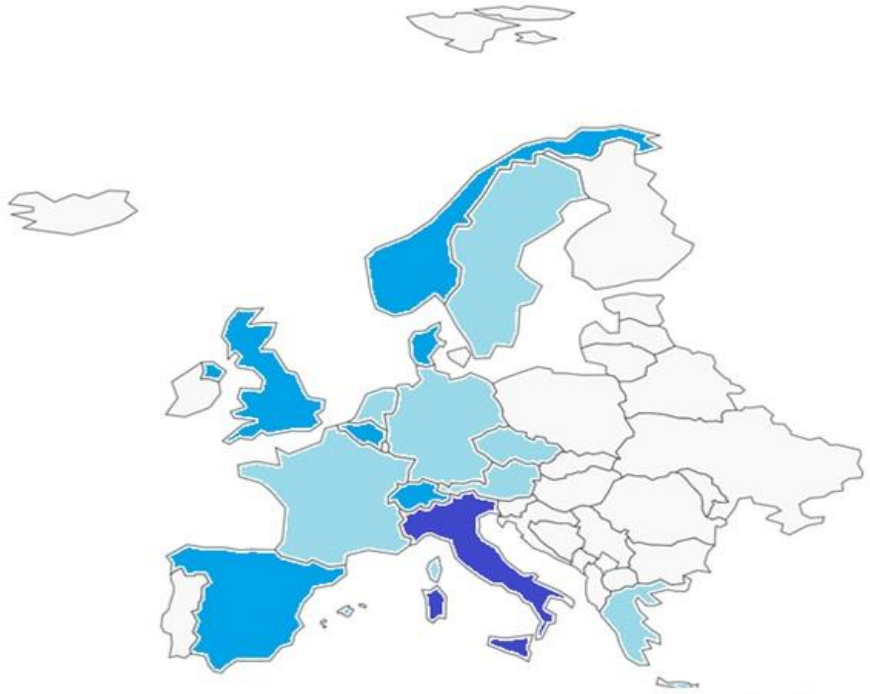
Once all the data of the two tables have been treated, two European maps have been made in which the data of release to the environment and to the urban environment of the different nanomaterials are reflected.




| | | $TiO_2$ | Ag | CNT | ZnO | $CuCO_3$ | $CeO_2$ | CB | Gold | $Al_2O_3$ | Fulleneres | $SiO_2$ |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Ireland** | Air, µg $m^{-3}$ | 0,00015 | 0,0017 | | | | 0,008 | | | | | |
| | Water, µg $L^{-1}$ | 1,45 | 0,03 | | | | 0,024 | | | | | |
| | Soil, µg $kg^{-1}$ | | | | | | | | | | | |
| **UK** | Air, µg $m^{-3}$ | | | | | | | | | | | |
| | Water, µg $L^{-1}$ | 24,5 | 0,01 | | 76 | | 0,001 | | 0,14 | 0,002 | 0,31 | 0,0007 |
| | Soil, µg $kg^{-1}$ | 1030 | 1,45 | | 3190 | | 10 | | 20,4 | 0,01 | 44,7 | |
| **Switzerland** | Air, µg $m^{-3}$ | 0,0015 | 0,0017 | 0,0015 | | | | | | | | |
| | Water, µg $L^{-1}$ | 0,7 | 0,03 | 0,0005 | | | | | | | | |
| | Soil, µg $kg^{-1}$ | 0,4 | 0,02 | 0,01 | | | | | | | | |
| **Denmark** | Air, µg $m^{-3}$ | 0,0007 | 0,000007 | 0,000042 | 0,00004 | 0,00002 | 0,0001 | 0,2 | | | | |
| | Water, µg $L^{-1}$ | 0,00027 | 0,000015 | 0,000001 | 0,00045 | 0,002 | 0,000004 | 0,5 | | | | |
| | Soil, µg $kg^{-1}$ | 1,5 | 0,024 | 0,083 | 0,12 | 60 | 0,17 | 1500 | | | | |

***Figure 3 European predicted environmental exposure at natural compartments.***

In **Figure 3** it is showed the existing PEC and environmental release data that currently exist in Europe. As can be seen, only four countries in Europe have release data, and in any case four data are exceeded. From the perspective of nanomaterials, titanium dioxide ($TiO_2$) and silver (Ag) are the most measured compounds.



| | | Urban, nº/cm³ | Roadside, nº/cm³ | Background, nº/cm³ |
|---|---|---|---|---|
| Germany | Leipzing | | 18000 | 9500 |
| | Essen | | 18000 | |
| | Erfurt | | | 26000 |
| | Augsburg | | | 12000 |
| Spain | Barcelona | 11400 | 59500 | 17400 |
| | Huelva | | | 17500 |
| | Santa Cruz de Tenerife | | | 12000 |
| | Madrid | | | 7000 |
| Greece | Athens | | 22000 | |
| Belgium | Antwerpen | 15000 | | 15000 |
| Finland | Lahti | | 39500 | 11000 |
| | Helsinki | 4000 | 15000 | |
| Italy | Roma | | 46000 | |
| | Milan | | 82900 | 26000 |
| France | Strasbourg | | 39500 | |
| Denmark | Copenhage | 8500 | 19500 | |
| Netherlands | Utrech | | 39000 | 15000 |
| | Amsterdam | | 30000 | |
| | Alkmaar | | | 26000 |
| Sweden | Stockholm | | | 11000 |
| Czech Republic | Prague | | 36000 | 7200 |
| Austria | Vieena | | 26000 | 10500 |
| | Salzburg | | 30000 | |
| | Graz | | 21000 | |
| | Linz | | 22000 | |
| Switzerland | Zurich | 10000 | 80000 | 35000 |
| | Lugano | | | 16000 |
| | Bern | | 27500 | |
| UK | London | | 21000 | 11000 |
| | Birmingham | | 170000 | 22000 |
| | Leicester | | 63000 | 31000 |
| | Cambridge | | 26000 | 9000 |
| | Manchester | | | 26000 |
| Europe | | | 38200 | 16200 |



***Figure 4 European predicted environmental exposure at human compartments.***

**Figure 4** shows the results of the urban environment data. In urban compartment there are more studies than in the environmental compartment. The data covers most of the countries of the European Union and these studies give us the quality air in the cities and the countryside. Some of this data is summarized in this table in order to show the nanoparticle concentration in urban, roadside and background for different cities of Europe. With this data, Birmingham, Milan, Zurich, Barcelona and Leicester are the cities with higher concentration of nanoparticles

# 3. Demand of measured data

This action has been carried out an exhaustive search of the information that the different existing regulations ask for the registration of substances and the emission information. The purpose of this action was to qualitatively and quantitatively detail the information requested in the different legislations and, therefore, has a greater demand.

## 3.1 REACH regulation

The European Community Regulation on chemicals and their safe use (EC 1907/2006), REACH, deals with the Registration[1], Evaluation[2], Authorisation[3] and Restriction[4] of Chemical substances. It entered into force on 1 June 2007.

The REACH regulation was adopted by the European Union in the field of chemical safety and seeks to improve the protection of human health and the environment against the risks that chemicals may present, while at the same time enhancing the competitiveness of the chemical industry.

REACH is very wide in its scope, covering all substances whether manufactured, imported, used as intermediates or placed on the market, on their own, in preparations or in articles. The Regulation exempts certain substances that are adequately regulated under other legislation, like medicinal products, or that generally present such low risks as not to require registration, like water, oxygen, certain noble gases, and cellulose pulp.

Other examples of exemptions are radioactive and subjected to customs supervision substances, or non-isolated intermediates. In other cases, substances occurring in nature such as minerals, ores and ore concentrates, cement clinker, etc. are not required to be registered as long as they are not chemically modified. Polymers are exempted as well from the requirement to register, since they usually are not very hazardous, but monomers in polymers have to be registered. Waste is specifically exempted. Other substances are exempted from parts of REACH, where other equivalent legislation applies, like food, that meets the definition of a substance, on its

[1] Registration is the submission to the Agency of a technical dossier and, if required, a chemical safety report for a substance being manufactured in or imported into the European Union

[2] There are three types of evaluation within REACH:

- Dossier evaluation performed by the Agency:
  - Compliance check: to examine whether all required information is included in the registration dossier and whether this information is adequate.
  - Checking of testing proposals: to evaluate whether the testing proposals submitted in the registration dossier by the registrant in case further testing is necessary for information specified in Annex IX and X or the Regulation are adequate.
- Substance evaluation performed by a Member State: to clarify any grounds for considering that a substance constitutes a risk to human health or the environment. Member States can also evaluate registered intermediates.

[3] The REACH Regulation sets up a system under which the use of substances with properties of very high concern and their placing on the market can be made subject to an authorisation requirement. This authorisation requirement ensures that risks from the use of such substances are either adequately controlled or outweighed by socio-economic benefits, having taken into account the available information on alternative substances or technologies. Substances requiring authorisation will be included in Annex XIV of the Regulation

[4] Means any condition for or prohibition of the manufacture, use or placing on the market

own or in a preparation, and will be subject to REACH however, such substances are largely exempted from Registration, Evaluation and Authorisation.

The two most important aims of REACH are to improve protection of human health and the environment from the risks of chemicals while enhancing the competitiveness of the EU chemicals industry, increasing transparency and promoting non-animal testing. The Regulation also calls for the progressive substitution of the most dangerous chemicals when suitable alternatives have been identified.

Manufacturers and importers that manufacture or import more than one ton of a chemical substance per year are required to gather information on the properties of their chemical substances, which will allow their safe handling, and to register the information in a central database run by the European Chemicals Agency (ECHA). ECHA manages the REACH system: it run the databases necessary to operate the system, evaluates registered information and is building up a public database in which consumers and professionals can find hazard information.

The purpose of this regulation is to fill in the existing information gaps. Information on chemicals for a long time was not regulated and this implied a great ignorance of the risks that these posed to human health and the environment. This regulation also aims to define measures to manage these risks.

For this, REACH regulation uses the following instruments:

- Pre-registration of existing substances: from 1 June 2008 to 30 November 2008. Pre-registration indicates the intention of the manufacturer's importer to register a substance within 11 years, a late registration period. A non-pre-registered substance must be registered immediately, if the production / import reaches 1 tonne or more per year.
- Registration of substances manufactured or imported for own account or prepared from articles: This stage consists of the presentation of a technical file (the contents of the technical file depends on the tonnages) and a chemical safety report (for substances over 10 Tonnes per year) to ECHA. Registration requirements depend on the amount of substance manufactured or imported.
- Assessment: At this stage ECHA reviews the technical registration dossiers together with the Competent Authority of the Member State concerned. It is separated into "file evaluation" and "substance evaluation".
- Authorization: At the stage of authorization there are two processes: on the one hand the emission by ECHA of a "List of candidate substances of very high concern (SVHC[5])" containing substances subject to authorization; On the other hand, the prioritization by ECHA of certain substances for inclusion in Annex XIV. Annex XIV includes prohibited substances unless a specific authorization of the company is issued.

[5] Substances of very high concern (SVCH) are described in Article 57 of Regulation (EC) No 1907/2006 (EC, 2006). These definitions include substances that are carcinogenic, mutagenic or toxic to reproduction (CMR). According to the new CLP Regulation, these substances will be classified as 1a (Persistent, bioaccumulative and toxic (PBT)) or 1b (very persistent and very bioaccumulative (vPvB)) according to the criteria of Annex XIII of the REACH Regulation.

Each of the stages of REACH has an impact on the different actors involved. Manufacturers and importers of substances are those that are most involved and have more obligations; They have to file the registration dossier. Downstream users do not have as much weight, but they are also involved to some extent.

### 3.1.1 Reach requirements for nanomaterials

REACH regulation, in its Article 3, defines a substance as "a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition"; a preparation as "a mixture or solution composed of two or more substances"; and an article as "an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition."

While there are no specific provisions in REACH for nanomaterials; regulation deals with chemicals in any size or shape, so they are also governed by REACH. The reason why they are not considered, is that the regulation was put in place before the ENMs were considered a risk. At present, nanomaterials are common in the market and must be considered by the exposure of workers and the means to them.

Several critical differences between the nanoforms of substances and their "bulk" (micro or macro-scale) analogues may necessitate additional considerations for REACH regulation and Regulatory requirements of ENM under REACH chemicals safety assessment guidance, including clarification of definition and identification of substance, triggers for testing requirements, validation of testing methods, and revision of criteria for authorisation.

### 3.1.2 Overview of the registration dossier

Under REACH, manufacturers and importers should collect or generate, where none exists, the data from the substances and assess how health and environmental risks should be managed. The registration dossier is the set of information submitted electronically by a registrant for a particular substance. It consists of two main components:

→ First, a technical dossier is requested, which is mandatory. This dossier is always required for all substances subject to registration obligations.
→ Second, a chemical safety report. This report is only required if the registrant manufactures or imports a quantity greater than 10tn/year. This report presents all the information concerning the chemical monitoring and the management of the same for the substance to be registered.

The technical dossier contains a set of information about:

- The identity of the manufacturer/importer
- The identity of the substance
- Information on the manufacture and use of the substance
- The classification and labelling of the substance

- A guidance on its safe use
- A study summaries of the information on the intrinsic properties of the substance;
- Robust study summaries of the information on the intrinsic properties of the substance, if required
- An indication as to whether the information on manufacture and use, the classification and labelling, the (robust) study summaries and/or, if relevant, the chemical safety report has been reviewed by an assessor;
- Proposals for further testing, if relevant
- For substances registered in quantities between 1 and 10 tones, information on exposure
- A request as to which information should be considered confidential, including a justification.

ECHA, in its registration guidelines (ECHA, 2012), specifies that the format of this dossier must be IUCLID (International Uniform Chemical Information Database). There is a software of the same name that generates these reports, whose last version in IUCLID 6. However, other computer programs (such as CHESAR) can be used, if the result is the same format. Each registrant is individually required to submit a registration dossier for each of its substances to ECHA for registration. The registration dossier must be submitted electronically through the REACH-IT portal of the ECHA website.

Article 10 (a) of REACH, as well as its annexes VI to XI, defines the information on chemicals to be provided for registration in the technical dossier. The relationship between the information to be submitted for registration, as defined in REACH, and the sections IUCLID 6 in which it is to be reported are shown in the **Table 2**.

***Table 2 Relation between the information requirements in Article10 and the corresponding sections in a IUCLID 5 file (ECHA, 2012***

| Information requires | Article | IUCLID 6 |
|---|---|---|
| (a) Technical dossier | Article 10 (a) | |
| (i) identity of the manufacturer or importer | Annex VI section 1 | Section 1 General information<br>Section 1.1 Identification |
| (ii) identity of the substance | Annex VI section 2 | Section 1 General information |
| (iii) manufacture and use(s) of the substance and if relevant use and exposure categories | Annex VI section 3 | Section 3 Manufacture, use and exposure |
| (iv) classification and labelling | Annex VI section 4 | Section 2 Classification and labelling and PBT assessment |
| (v) guidance on safe use | Annex VI section 5 | Section 11 Guidance on safe use |
| (vi) study summaries of information derived from the application of Annexes VII to XI | Annex VII to XI | Section 4 Physical and chemical properties<br>Section 5 Environmental fate and pathway<br>Section 6 Ecotoxicological information<br>Section 7 Toxicological information |
| (vii) robust study summaries of the information derived from the | Annex I, Annex | Section 4 Physical and chemical properties<br>Section 5 Environmental fate and pathway |

| | | |
|---|---|---|
| application of Annexes VII to XI if required under Annex I | VII to XI | Section 6 Ecotoxicological information<br>Section 7 Toxicological information |
| (viii) indication regarding the review by an assessor of information submitted under (iii), (iv), (vi), (vii) and (b) | | Dossier header[6] |
| (ix) proposals for testing | | Section 4 Physical and chemical properties<br>Section 5 Environmental fate and pathway<br>Section 6 Ecotoxicological information<br>Section 7 Toxicological information |
| Information requires | Article | IUCLID 6 |
| (x) exposure information for substances in quantities of 1 to 10 tonnes | Annex VI section 6 | Section 3 Manufacture, use and exposure |
| (xi) request as to which information in Article 119(2) should not be made available on the Internet | | All the relevant sub sections |
| (b) Chemical safety report | Article 10 (b) Article 14, Annex 1 | Section 13 Chemical safety report |

## 3.2 Other EU legislation and its relevance to nanomaterials

Based on the assessment of the important EU environmental legislation (IPPC Directive), it can be concluded that it is often problematic to include nanomaterials in these regulatory regimes, especially because bottlenecks occur when applied.

The IPPC does not contain specific provisions for nanomaterials. Although nanomaterials are in principle covered by almost all directives applicable to chemicals, applied standards, dose metrics or instruments often ignore specific characteristics such as particle size or surface / weight ratio.

Size units based on weight or quantity can cause nanomaterials to fall outside a regulatory regime. This could be the case with the IPPC Directive. It may also refer to standards such as the emission limit values contained in the Waste Incineration Directive and the IPPC Directive. Such requirements expressed in weight or quantity shall be unusable or usable only to a limited extent to regulate the risks of nanomaterials. After all, these are materials whose effects can be determined by non-weight-related characteristics, such as particle size or surface. Nanomaterials that, even at low concentrations, have a potentially high toxicity, often fail outside these regulatory regimes. A problem is still developing with the monitoring requirements

[6] The dossier header consists of information which is going to be used for administrative purposes and it is completed by the applicant when preparing his dossier from the substance data set

Similarly, the scope, system and instruments of various regulations limit their importance to nanomaterials. The IPPC Directive covers mainly industrial production companies and therefore does not cover research laboratories. Another obstruction occurs in reference documents of the best available techniques according to the IPPC Directive. The study shows, based on a limited exercise of fact-finding, that nanomaterials (and their potential emissions) lack a clear place in these documents.

# 4. Use of data

(ENCUESTAS POR HACER)

# 5. Lack of data

# 6. Conclusions

# 7. Annex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