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**Follow-up to the 6th Meeting of the REACH Competent
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(REACH)**

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**Centre A. Borschette,
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- Concerns:** **Nanomaterials in REACH**
- Agenda Point:** **8.2**
- Action Requested:** **This document has been endorsed by the Competent Authorities with a view to its publication on the Commission's website.**

This document reflects the current state of ongoing discussions within the REACH Competent Authorities (REACH CA) and its subgroup on nanomaterials on how REACH applies to nanomaterials. Further updates of this document can be expected following continued discussions. Stakeholders are invited to take note of the content of this document and follow its further development.

The Commission services do not accept any liability with regards to the contents of this document.

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NANOMATERIALS IN REACH

1. INTRODUCTION

1.1. Background

Manufactured nanomaterials may bring significant innovation and advances to society and benefits for human health and the environment. They are also expected to provide a new competitive edge to European industry and to the European economy as a whole, and to contribute to job creation. At the same time, it will be necessary to ensure their safety for humans and the environment and to avoid negative impacts on society. Nanomaterials are manufactured for their specific properties providing possibilities for new uses and products. These specific properties may lead to different interactions with the physiology in humans and the environment and to effects that significantly differ from those known of materials without such properties. Within the context of REACH, the main issue pertaining to the development of nanotechnologies and nanomaterials is to ensure their safety to the human health and the environment covering the whole life-cycle. This is a prerequisite for the sustainable use of nanotechnologies and for the success of nanotechnologies in terms of market uptake and societal acceptance.

The purpose of REACH is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on internal market while enhancing competitiveness and innovation. REACH is an EU Regulation laying down provisions on substances. These provisions apply to the manufacture, placing on the market and use of substances on their own, in preparations or in articles. REACH is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.

There are no provisions in REACH referring specifically to nanomaterials. However, REACH deals with substances, in whatever size, shape or physical state. Substances at the nanoscale are therefore covered by REACH and its provisions apply. It thus follows that under REACH manufacturers, importers and downstream users have to ensure that their nanomaterials do not adversely affect human health or the environment.

This document describes the current state of discussion on how REACH applies to nanomaterials and identifies a number of challenges in the REACH implementation in relation to nanomaterials. The description in this document of how REACH applies to nanomaterials is without prejudice to any future amendment to the legislation that may be deemed appropriate in order to improve and clarify the effective application of REACH to nanomaterials.

1.2. Definition of nanomaterials in the context of REACH

The prefix ‘nano-’ comes from the Greek word *νάνος* which means dwarf. In science, nano means a measure of 10^{-9} units. Both the small size and engineered structure of

nanomaterials may create specific properties¹ (e.g. due to increased surface area) which distinguish them from other materials with a different particle size or structure and thus characterise nanomaterials, substances at the nanoscale and nanoforms of substances in the meaning described below.

In the absence of legal definitions within REACH, the term “**nanomaterial**” is used in this paper as a general term to cover manufactured (or engineered) nano-sized and nanostructured materials, without further specifying whether these materials are substances, forms of substances etc. under REACH.

In addition, as REACH is based on the substance concept, it will be necessary to define terms relating to substances which are nanomaterials. In the Commission Staff Working Paper² on Regulatory aspects of Nanomaterials both the terms 'substances at the nanoscale' and 'substances in nanoform' were used (the term substance at the nanoscale was used in the context of REACH).

REACH addresses substances, on their own, in preparations or in articles. It deals with all substances, in whatever size, shape or physical state. The term “**substance at nanoscale**” is used in this paper to describe substances with properties specific for nanomaterials. Unless further specified in the context, the term does not distinguish between substances which only exist at the nanoscale and nanoforms of substances which also exist in bulk form. The term “**nanoscale**” mainly refers to the size of the particles, with at least one dimension at a nanoscale.

The term “**nanof orm**” will be useful in cases where reference is made to particular forms of a substance with nanomaterial properties, as opposed to the “**bulk form**” of the same substance, i.e. (the) form(s) of the substance without nanomaterial properties.

It is important to underline that most substances have internal structures at the nanoscale, for example atoms, molecules, crystal layers etc., that individually could be considered as being at the nanoscale. As long as these are embedded in the matrix of larger sized structures they will not exert the specific characteristics of the nanoscale units. As defined by ISO (TS 27687), aggregates and agglomerates are “nanostructured materials”. “Nanostructured materials” are a subcategory of the term “nanomaterial”. Aggregates and agglomerates, often existing at a micro size, may have some of the behaviour and effects of their smaller sub units, e.g. due to an increased surface area. Thus, the terms nanomaterials, substances at nanoscale and nanoforms in the context of REACH are meant to cover both 'nano-objects' and 'nano-structured materials' as defined by ISO (TS 27687).

The terms used in this document are working definitions and may be revisited as appropriate for their application in the context of REACH. . In particular, the terminology used should take into account the ongoing work at the level of OECD, which will be considered as soon as it becomes publicly available. For reference, definitions suggested by the EU Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) are included in Annex I of this document.

¹ For further reference on the nature of these properties, please consult scientific literature.

2. REGISTRATION AND ASSESSMENT

Substances, including substances at the nanoscale, manufactured or imported in volumes of 1 tonne or more per year have to be registered under REACH. At volumes of 10 or more tonnes per year a chemical safety report (CSR) based on a chemical safety assessment (CSA) has to be included in the registration. REACH Articles 10 and 14 respectively contain detailed requirements as regards the composition of the technical dossier and the CSR.

All available information on the substance has to be gathered and considered for the registration but as a minimum the information required in the registration is set out in Annexes VI-X of REACH and increases with the tonnage manufactured or imported. It may also depend on what additional information the registrant considers needed to make an appropriate chemical safety assessment for the substance. The technical dossier and the CSR must be submitted to the European Chemicals Agency.

The tonnage triggers for registration apply to the **total** volume of a substance manufactured or imported by a registrant. Thus, for substances which exist both in a bulk form and in a nanoform, the total volume determines the need and the timing for registration and the information requirements.

REACH is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment (Article 1(3) of REACH). **This principle is applicable to substances in whatever size or form and for all their identified uses.** Thus, a registration of a nanomaterial has to include all relevant information on the nanomaterial as manufactured or imported, covering the properties, uses, effects and exposure related information as well as the relevant classification and labelling, safety assessment and any relevant exposure scenarios. This principle is elaborated in more detail below.

As the relevant information on the nanoform has to be included in the registration, it also has to be shared with other manufacturers and importers of the same substance and all other provisions related to the registration apply. Substances in articles have to be registered if they are intended to be released from the article under normal or foreseeable conditions of use. Substances of very high concern are subject to a notification if they are present in the produced or imported article above a concentration of 0.1% (w/w). Again, these provisions apply for substances at the nanoscale as for any other substance.

Registrants have an obligation to update and register new information in relation to issues such as changes in quantities manufactured or imported, new uses or new knowledge of risks to human health or the environment of which they may be reasonably be expected to have become aware. This may lead to changes in the safety data sheet or the chemical safety report, or changes in the classification and labelling. Furthermore (e.g. with higher quantities of production or import) more information may have to be submitted to the Agency to fulfil the REACH requirements. These provisions on updates are relevant in cases where for instance a substance was already registered in its 'bulk' form and the substance is subsequently intended to be manufactured or imported also in a nanoform.

With regard to the information requirements, REACH currently does not contain requirements that are specifically targeted at substances at nanoscale, yet all information requirements provided for in REACH apply also to substances at nanoscale.

2.1. Phase-in and non-phase-in substances

The Commission Services and Member State Competent Authorities decided in the context of the legislation on new (Directive 67/548/EEC, NONS) and existing substances (Regulation (EC) 793/93, ESR) that the decisive criterion whether a nanomaterial is a **new or existing substance** is the same as for other substances, that is whether or not the substance is included in the European INventory of Existing Commercial chemical Substances, EINECS (Manual of Decisions (MoD) to Directive 67/548/EEC, 2006, see Annex 2). The working group discussing the issues concluded in this context:

“No further criteria or decision steps are proposed at this stage. The working group concluded that the issue of whether nanomaterials are new or existing substances is not related to the definition of substance (broad enough to encompass all substances in all sizes and forms) but of substance identification: what determines that one substance is the same as another. So far substance identification is done on the basis of the information on chemical structure, purity, the chemical name (IUPAC and CAS) and the supporting spectral and analytical data. More information is needed on the type of parameters that may be relevant (e.g. particle size, geometry) for characterisation of nanomaterials. The working group found that the fact that a substance has different properties can in itself not be used to decide if it is a new substance.”

REACH distinguishes between **non-phase-in and phase-in substances**. A phase-in substance is defined by a substance meeting the criteria of Article 3(20) of REACH. Unless the substance is a no-longer polymer or has not been placed on the market in line with Article 3(20)(b), this means that the substance must have been listed in the European Inventory of Existing Commercial Chemical Substances (EINECS). The intention behind this provision is to give phase-in status to substances which have been listed in EINECS in the past and which therefore were considered as existing substances before the entry into force of REACH. In interpreting whether a concrete material is covered by a particular EINECS entry, therefore historical criteria need to be applied. In other words, whenever the material was considered to be covered by a particular EINECS entry in the past, it should be considered to have phase-in status under REACH. Whenever the substance was considered to be subject to notification as a new substance in the past, it should be considered as a non-phase-in substance under REACH. This also applies to nanomaterials.

Substances at nanoscale which were considered as **new substances** (e.g. when they have a new structural formula) had to be notified in accordance with NONS if they were placed on the market in the past in quantities of 10 kg or more. Notified substances are considered as registered under REACH.

Since 1 June 2008, substances at the nanoscale which are considered as non-phase-in substances and which are manufactured or imported in quantities of 1 tonne/year or more need to be registered before manufacturing or importing.

Substances at the nanoscale, which are phase-in substances, can benefit from the extended registration deadlines, provided they have been pre-registered. These extended deadlines are:

- 1 December 2010 for:
 - substances that are CMRs cat. 1 or 2 in a volume ≥ 1 tonne/yr, substances
 - classified as very toxic to aquatic organisms which may cause long-term adverse effects in the aquatic environment (R50/53) and in a volume ≥ 100 tonnes/yr;
 - substances manufactured or imported in volumes ≥ 1000 tonnes/yr
- 1 June 2013 for substances manufactured or imported in volumes ≥ 100 tonnes/yr;
- 1 June 2018 for substances manufactured or imported in volumes ≥ 1 tonne/yr.

For substances at nanoscale that are **phase-in substances**, the registration can be more complex, especially when the same substance exists in the nanoform as well as in the bulk form. In such a case not only the information of the substance in the bulk form should be included in the registration dossier, but also any information regarding intrinsic properties where the properties of a substance in the nanoform differs from the bulk form, any different classification and labelling, any different chemicals safety assessment as well as all identified uses (see also Annex VI.3 of REACH) and relevant exposure scenarios for the nanoform of the substance.

2.2. Classification and labelling

The Commission Services and Member State Competent Authorities under ESR and NONS also decided with regard to classification and labelling of nanomaterials that

Nanomaterials having specific properties may require a different classification and labelling compared to the bulk material, also when the nanoform is derived from a bulk substance.

It is current practice that a substance with different sizes or forms can have different classifications, as is the case for nickel and nickel powder (particle diameter < 1 mm). This concept should be applied in the same way in the context of REACH and substances at nanoscale. SCENIHR has advised that, due to still unpredictable characteristics of nanomaterials, their hazard assessment should be done on a case-by-case basis. The proposed Regulation on Classification, Labelling and Packaging (CLP) contains the following requirements that are relevant when dealing with substances with different forms and properties:

- Identification and examination of available information on substances

"The information shall relate to the forms or physical states in which the substance is placed on the market and can reasonably be expected to be used."

- Evaluation of hazard information for substances and mixtures

"When evaluating the available information for the purposes of classification, the manufacturers, importers and downstream users shall consider the forms or physical states in which the substance or mixture is placed on the market and in which it can reasonably be expected to be used."

- *Generating new information for substances and mixtures*

"Tests that are carried out for the purposes of this Regulation, shall be carried out on the substance or on the mixture in the form(s) or physical state(s) in which the substance or mixture is placed on the market and can reasonably be expected to be used"

2.3. Substance identification and sameness

A substance is defined in REACH (Article 3(1)):

"substance: means 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;"

The definition goes beyond a pure chemical compound defined by a single molecular structure. The definition of the substance includes different constituents like impurities and additives necessary to preserve its stability.

Under the REACH legislation, when a registration is required, it shall include information on the identification of the substance as specified in item 2 of Annex VI (see Annex 2). This information shall be adequate to enable each substance to be identified sufficiently.

In most cases, a substance is completely identified by its chemical composition as in the case of a mono-constituent substance or a well defined multi-constituent substance. Although such straightforward identification may be possible for most substances, for certain substances it is not feasible or not adequate within the scope of REACH.

In the REACH guidance on substance identification, it is recognised that some substances which can be identified by their chemical composition need to be further specified by additional identifiers to get their own substance identification. This is laid down in more detail for UVCB substances. However, such additional identifiers might also be needed for well-defined substances if the properties of the substance differ significantly for reasons other than their chemical composition. This may be the case for some substances at nanoscale, where for instance information on characterisation of the substances may be needed for their proper identification. However, the Technical Guidance Document (TGD) on substance identification (June 2007) considered that "the current developments in nano-technology and insights in related hazard effects may cause the need for additional information on size of the substances in the future. The current state of development is not mature enough to include guidance on the identification of substances in the nanoform in this TGD"³.

³ Guidance for identification and naming of substances, p. 28.

For this reason, further work is needed to provide guidance for substances at nanoscale. In particular, the question needs to be clarified in which cases a nanomaterial is to be considered as a separate substance and in which cases it should be considered as a particular form of a bulk substance. As part of the preparations for such guidance, the Commission services are currently preparing a separate document in co-operation with the REACH Competent Authorities and its subgroup on nanomaterials.

Under REACH, this “sameness” analysis has to be done by potential registrants. Nevertheless, the outcome of this analysis is not at the discretion of potential registrants but must be in line with the substance definition, information related to molecular and structural formula, composition and other relevant provisions of REACH. Any decisions taken by SIEFs may therefore also be challenged, e.g. by ECHA during the compliance check.

As it is not straightforward how the substance definition and other relevant REACH provisions need to be interpreted, further guidance on how to determine the “sameness” for the purpose of data sharing and registration has been provided in the guidance on data sharing.

In particular, the guidance provides that *“for substances with a well-defined composition (i.e. mono-constituent and multi-constituents substances) the sameness of the naming is in principle sufficient to be able to share data even though certain impurities might lead to a different classification/hazard profile. Only in cases where all data is clearly not suitable for the other substance these substances can be regarded as different (e.g. in case of very different physical properties which have essential impact on the hazard properties, like water solubility).”*⁴

“In certain cases, the exact nature of a substance covered by one EINECS entry will have to be scrutinised in order to ascertain whether it can be covered by the same joint submission of data and that the relevant hazard data can be purposefully exchanged. Typically, this may happen in the following situations:

- the description in EINECS given for a substance is very broad to the extent that the physical-chemical and (eco)toxicological properties of the different substances covered by this one entry are not sufficiently similar to use the same data to describe it. [...]”⁵

In the case of substances at nanoscale, it is possible that some substances which in the past have been identified by the same EINECS number may have to be considered as different substances for the purpose of REACH. In this case, all substances which were covered by the original EINECS number retain phase-in status.

For this situation, the guidance on data sharing provides the following considerations: *“In this case, it is for Potential Registrants to decide among themselves what SIEF(s) shall be formed to represent each of the substances so identified. In this context, the main criteria for deciding on the sameness of a substance should be those laid down in the Guidance on substance identification and **whether or not data sharing would give a***

^{4,5} Guidance on data sharing, p. 35.

meaningful result that can be used throughout the SIEF. It is important to underline that the formation of several SIEFs is only possible when the substances are indeed different. The formation of several SIEFs for the same substance violates data sharing obligations.”⁶

2.4. Chemical safety assessment of substances at nanoscale and information requirements

In section 2.1 the main principles for registration of substances at the nanoscale have been presented, including aspects related to information requirements and chemical safety assessment (CSA). The information requirements for substances are specified in Annexes VI – XI of REACH. The principles for the CSA are provided by Annex I of REACH.

The behaviour and effects of substances at nanoscale are dependent on several characteristics, including size, number concentration, surface area, charge and overall surface reactivity, and the risk assessment related to both human health and the environment have to take into account these characteristics. In order to address the specific hazards associated with substances at nanoscale, additional testing or information may be required. To determine specific hazards associated with substances at nanoscale, current test guidelines may need to be modified. Until revised and specific test guidelines for substances at nanoscale exist, toxicity testing will have to be carried out according to already existing guidelines unless they have been shown to be inadequate and/or by corresponding test methods complying with the conditions laid down in Annex XI section 1.1.2 in REACH.

Extensive guidance on information requirements and chemicals safety assessment (IR-CSA TGD) is available from ECHA⁷. The principles and approaches to risk assessment of substances as elaborated in the IR-CSA TGD are considered to be applicable to the risk assessment of substances at nanoscale. However, the guidance does not yet address specific properties of substances at nanoscale and it will need further adjustments to be able to fully assess the information related to substances at the nanoscale/nanoform, to assess their behaviour and effects on humans and the environment, and to develop relevant exposure scenarios and risk management measures.

The EU Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) has produced two opinions in relation to risk assessment of nanomaterials, respectively in March 2006⁸, and in June 2007⁹. In its first opinion, SCENHIR concluded

⁶ Guidance on data sharing, p. 35 f;

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http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm?time=1231925038

⁸ Scientific Committee on Emerging and newly identified risks; modified Opinion (after public consultation) on The appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies; 10 March 2006 http://ec.europa.eu/health/ph_risk/committees/04_scenihir/docs/scenihir_o_003b.pdf

⁹ SCENHIR, Opinion, approved for public consultation, on the appropriateness of the risk assessment methodology in accordance with the technical guidance documents for new and existing substances

that the existing toxicological and ecotoxicological methods are appropriate to assess many of the hazards associated with the products and processes involving nanoparticles, but that they may not be sufficient to address all the hazards. The assays may need to be supplemented by additional tests, or replaced by modified tests, as it cannot be assumed that current scientific knowledge has elucidated all the potential adverse effects of nanoparticles. Specifically, attention needs to be given to the mode of delivery of the nanoparticle to the test system to ensure that it reflects the relevant exposure scenarios.

For exposure, SCENIHR also expressed the view that the use of mass concentration data alone to express dose is insufficient, and that the number concentration and/or surface area would need to be used as well. Equipment that enables routine measurements for exposure to free nanoparticles is not yet available. In particular, existing methods used for environmental exposure assessment may not necessarily be appropriate for determining the environmental fate of nanomaterials.

Consequently, current risk assessment procedures may require modification for nanomaterials both regarding test methods for hazard identification and exposure assessment.

SCENIHR suggested that there is insufficient knowledge and data concerning characterisation of nanoparticles, their detection and measurement, the fate (and especially the persistence) of nanoparticles in humans and in the environment, and all aspects of toxicology and environmental toxicology related to nanoparticles, to allow for satisfactory risk assessments for humans and ecosystems to be performed. This will not allow the identification of any systematic rules that govern the toxicological characteristics of all products of nanotechnology. Therefore the risk assessment will need to be made on a case by case basis.

In its second opinion, dealing particularly with the **appropriateness of the risk assessment methodology in accordance with the Technical Guidance Documents (“TGD”) for new and existing (chemical) substances for assessing the risks of nanomaterials**, the SCENIHR concluded that current methodologies described in the TGDs are likely to identify certain hazards, but that modifications are required for the assessment of risks to human health and the environment. The opinion also emphasized that not all nanoparticle formulations have been found to induce a more pronounced toxicity than the bulk formulations of the same substance. The evaluation of nanoparticle formulations should be carried out on a case by case basis and it is important that it is determined whether test procedures will be predictive for human health hazards for all types of nanoparticles. In the absence of sufficient data on the fate and effect of nanoparticles on the environment, the applicability of existing methods for risk assessment of nanoparticles should be evaluated.

Furthermore, the opinion highlighted needs to further develop dosimetrics and determine appropriateness of current test procedures for the prediction of human health hazards and estimation of risks for all types of nanoparticles¹⁰. In particular, the SCENIHR focussed on the potential of nanomaterials to reach new target organs in the body, when

for assessing the risks of nanomaterials.

http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_004c.pdf

¹⁰ http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_004c.pdf

administered in similar ways as bulk chemicals (translocation). This observation would lead to additional requirements of test methods to demonstrate potential new hazards.

Based on the opinions of the SCENIHR and their forthcoming update, on work undertaken by the EU Joint Research Centre and on the international organisations on test methods and test guidelines, the CASG Nano may provide further advice to ECHA for improvement of the REACH IR-CSA guidance with regard to its applicability to substances at nanoscale.

2.5. Concerns raised by CASG members and observers

Several stakeholders have raised the concern that the 1 tonne threshold for registration may exclude registration of many substances at nanoscale, as they believe these are manufactured or imported in volumes below 1 tonne per entity. Chemical industry foresees that most substances at nanoscale currently on the market in their field of activity will be registered since the majority is produced in high volumes. These differences in assessment of the actual situation and the appropriateness of the registration thresholds in REACH illustrate the need to get a more complete picture of the actual situation before final conclusions can be made.

As several nanomaterials are only produced at low tonnage level another key concern was lack of information on nanomaterials due to the present tonnage triggers for data requirement under REACH. Furthermore the information on those nanomaterials that are phase-in substances would become available at a very late stage, due to the staggered registration deadlines. This may lead to a lack of information to inform risk management.

In order to address these concerns, it has also been suggested that all substances at nanoscale should be registered, regardless of the volume in which they are manufactured or imported. Below the current registration volume of 1 tonne, reduced information requirements should then apply, e.g. similar to those for PPORDs. However, registration in REACH is a vehicle for data gathering and the act of registering a substance should not be seen as an indication that the substance is harmful.

With respect to substance identification it was also discussed at which point nanomaterials with different kind of surface modifications should be seen as belonging to the same substance or whether they should be considered as separate substances, and also in which respect a nanomaterial consisting of layers of different chemicals should be considered as a substance or a preparation.

2.6. Reactions by the Commission services and action points

Overall, the Commission services recognise that those issues require further consideration with a view to getting a solid understanding of the current regulatory coverage of REACH and identifying any needs for further review at a subsequent stage. It is important to note that the individual obligations of REACH should not be seen in isolation. The obligations for registration, mandatory data sharing and joint data submission as well as provisions on classification and labelling, information in the supply chain and evaluation complement each other and may lead to significant generation and flow of information to ECHA, already in the early stages of REACH implementation. Further dissemination of information will take place on the basis of the REACH provisions. Building on this assessment, further needs to adapt REACH can be considered in the context of the 2012 review of REACH.

Moreover, companies and industry associations are encouraged to continue and intensify their own actions and assist authorities in elaborating the relevant information. This should also help to gain confidence in the pro-active role of industry to ensure the safe use of substances at nanoscale. In particular, companies can decide to register their substances before the relevant deadline. REACH also does not prevent companies from registering on a voluntary basis their substances if they are below the 1 tonne threshold. A registrant may decide that he needs to generate further information beyond what is required in Annexes VII-X of REACH to demonstrate and document that the risks of the substance (in all its forms) are controlled. This also applies to substances at nanoscale which have specific properties that may not in all cases be covered by the endpoints in the REACH Annexes. ECHA may request additional information, beyond the information requirements in Annexes VII to X.

3. COMMUNICATION ON SUBSTANCES AT NANOSCALE DOWN THE SUPPLY CHAIN

REACH contains a number of provisions dealing with the **supply of information**. Particularly relevant are the following provisions:

- Regardless of quantities produced, suppliers of a dangerous substance or preparation must provide a safety data sheet (SDS), containing the data required by REACH (Article 31). REACH introduces a 'safety net' in Article 32 for cases where a SDS would not be obligatory, but where the substance is subject to authorisation, to restrictions or where information is required to enable appropriate risk management measures to be identified and applied.
- Throughout the supply chain, suppliers of articles containing substances on the candidate list in a concentration above 0.1% weight by weight must provide the recipient with sufficient information available to the supplier to allow safe use of the article including, as a minimum the name of the substance. On request, such information must be given also to consumers (Article 33). According to Article 34, new information on hazardous properties, regardless of the uses concerned and any other information that might call into question the appropriateness of the risk management measures identified in the safety data sheet must be passed on from any actor in the supply chain to the next actor or distributor up the supply chain.
- Article 35 creates a right for workers to have access to such information in relation to substances or preparations that they use or may be exposed to.

Downstream users (e.g. producers of paints, tyres) are required to consider the safety of the use of substances, based on information from their suppliers, and to apply appropriate risk management measures. They must therefore communicate with the manufacturer of the substance, obtain the information needed through the SDS, possibly communicate their "intended" use to the manufacturer in order to have this qualified as an intended use and to widen the relevant exposure scenarios developed for SDSs, or develop his own safety assessment. Downstream users are responsible for assessing the risks from substances if such use is not covered by the SDS provided.

The submission of SDSs is obligatory for substances/preparations that meet the criteria for classification as dangerous that are PBTs or vPvBs or that otherwise have been identified as substances of very high concern. It is common practice in the chemical and nanotechnology industry to provide SDSs also for other substances and as a consequence

SDSs have become a standard means of providing information on substances down the supply chain.

The above provisions apply also to substances and preparations at the nanoscale. In practice, the provision of SDSs and safety information in line with Article 32 allows provision of relatively specific information and recommendation of risk management measures which address the risks of nanomaterials in a more specific way than classification and labelling. It is recommended to use this flexibility. In case the nanomaterial exists also in the bulk form and no separate SDS is provided, the information about the nanoform of the substance has to be included in SDS for the substance or preparation, including information on the safe handling of substances at nanoscale. The relevant information to be provided includes 'Composition and information on ingredients', 'Handling and storage', 'Exposure controls/personal protection', 'Physical and chemical properties', 'Toxicological information' and 'Ecotoxicological information'. The information on the nanomaterials should be clearly recognisable in the SDS, e.g. by using specific (sub)headings.

4. EVALUATION

Substances that have been registered may be subject to evaluation. Evaluation provides a means for the authorities to require registrants, and in very limited cases downstream users, to provide further information. There are two types of evaluation under REACH: dossier evaluation and substance evaluation.

- Dossier evaluation is conducted by the Agency to (1) examine proposals for testing to ensure that unnecessary animal tests and costs are avoided, and (2) to check the compliance of the registration dossier with the registration requirements.
- Substance evaluation is performed by a Member States Competent Authority when there is a reason to suspect that a substance presents a risk to human health or the environment. On the basis of the evaluation, the European Chemicals Agency can require further information, which may include information not required in Annexes VII to X of REACH.

Substances at nanoscale can pose specific issues relating to evaluation due to their specific properties and due to the fact that certain standard tests may not be sufficient or appropriate. It could be useful to prioritise a small number of nanomaterials, both for dossier and substance evaluation in ECHA, as this would allow the issues that are likely to occur to be raised, discussed and resolved as far as currently practical. This in turn could provide useful guidance to other registrants, Member State authorities and the Commission on what to do.

4.1. Dossier evaluation

a) The objectives of the **examination of testing proposals** are to investigate whether the information requirements according to REACH are fulfilled and whether the proposed studies are appropriate and will increase the knowledge of the dangerous properties of chemicals in order to protect human health and the environment, while at the same time preventing unnecessary animal testing and costs. According to Article 40 all proposals for tests specified in Annexes IX and X submitted as part of registrations or in downstream user reports **have to** be examined and a decision drafted by the Agency.

Testing should only be required when information on the dangerous properties is needed for compliance under REACH, i.e. when the registrant considers and the Agency agrees that it is necessary to obtain additional information to allow to assess and document that risks are adequately controlled. Consequently Annex XI, as well as specific adaptation rules in Annexes VII to X, have been developed with a view to keeping animal testing to a minimum. Two main aspects in relation to examination of testing proposals can be identified that are also relevant for substances at nanoscale:

- Whether the proposal complies with the standard –testing requirements.
- Whether reasons for proposing additional testing for endpoints beyond the standard testing requirements are appropriate.

b) The main purpose of a **compliance check** is to evaluate whether a registrant has met his obligations. It is a means by which the Agency may request further information from registrants in case the information submitted does not comply with the requirements of REACH. In relation to substances at nanoscale and the registration requirements as explained in section 2.1 above, the Agency may verify amongst others that:

- the required information is included in the technical dossier(s) and any adaptations of the standard information requirements and the related justifications submitted in the technical dossier(s) comply with the obligations;
- any required chemical safety assessment and chemical safety report comply with the requirements of Annex I and the proposed risk management measures are adequate to the substance in the sizes and forms in which it is manufactured and/or for which the registrant and DUs have identified uses.

4.2. Substance evaluation

Substance evaluation aims at the clarification of a concern for human health or the environment. The substance evaluation process provides a mechanism for MS-CA, where necessary, to require (the) registrant(s) to obtain and submit additional information to address the initial concern. The outcome of a substance evaluation shall be to decide whether sufficient information is available to clarify the concern and, where further information is required, it results in a formal decision that is drafted by the MS-CA and finally taken by the Agency.

Substance evaluation may be particularly relevant for substances at nanoscale for which there are grounds to consider that they may constitute a risk for humans and/or the environment and in order to ensure that reliable data are provided by (the) registrant(s) and made available to the relevant bodies. Under substance evaluation *any* information can be requested by ECHA, which can go beyond the standard information requirements of REACH and thus provides the possibility to request specific non-standard information that may be considered relevant to clarify the risks of a nanomaterial.

Following substance evaluation, the MS-CA may come to the conclusion that action should be taken under the authorisation, restriction or classification and labelling procedures in REACH, that information should be passed to other authorities responsible for relevant legislation, or that no further action is needed. Last but not least, the registrant(s) should update their registrations, including the technical dossier(s) and chemical safety reports, with any additional information obtained.

5. AUTHORISATION

The aim of authorisations is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern (SVHC) are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable.

Authorisation applies to SVHC regardless of their volumes, i.e. there is no tonnage trigger. Authorisation is also independent of registration in the sense that substances do not need to be registered in order to be subject to authorisation.

For substances of very high concern included in Annex XIV of REACH an authorisation at Community level is required for their use and their placing on the market. Substances that may be included in Annex XIV are:

- CMRs (carcinogenic, mutagenic or toxic for reproduction) category 1 and 2
- PBTs (persistent, bioaccumulating and toxic) and vPvBs (very persistent and very bioaccumulating)
- Those for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern as CMRs and PBTs/vPvBs and which are identified on a case-by-case basis. This is for instance the case for substances with endocrine disrupting properties.

The identification of a SVHC is done on the basis of a clearly defined process. Once a substance is included in Annex XIV, a “sunset date” is set, from which date onwards a substance can only be placed on the market or used if it is covered by an authorisation or an exemption from authorisation. If an authorisation application concerns a substance at the nanoscale, this should also be clarified in the application (Art.62 (4)).

REACH specifies in detail the conditions in which a substance may be authorised, in accordance with the regulatory comitology procedure, based on criteria relating to the control of risks, (taking into account all discharges, emissions and losses, including risks from diffuse or dispersive uses), risk management measures, socio-economic benefits, availability of alternatives and available knowledge on risks in relation to alternatives. The European Chemicals Agency through its Committee for Risk Assessment and Committee for Socio-Economic Analysis is required to provide an opinion. Authorisations can be subject to conditions, such as monitoring arrangements.

Specific provisions are foreseen dealing with the review of authorisations, for instance when the circumstances of the original authorisation have changed so as to affect the risk to human health or the environment, or the update of information.

In case a nanomaterial fulfils the criteria mentioned above, an Annex XV dossier identifying the nanomaterial as a SVHC should be provided for ECHA. If it is in the nanoform that the substance meets the SVHC criteria, this should be clarified in the proposal and the dossier (Art. 59). Moreover, if an authorisation application concerns a substance at the nanoscale/nanoform, this should also be clarified in the application (Art. 62 (4)).

The guidance on identification of SVHC recognised the possibility that *‘as yet unidentified substance properties can be captured under the consideration of equivalent concern, where there is scientific evidence (relating to probable serious effects) that these properties give rise to an equivalent level of concern to those of CMR cat 1 and 2, PBT and vPvB substances. It might be that other as yet unidentified aspects of a chemicals behaviour in the environment or its impacts on organisms will lead to a change in the current paradigm for chemical hazard and risk assessment. Authorities are encouraged to employ the underlying principles behind the preceding sections in considering such aspects and properties in the future.’* This should be taken into account when considering the identification of relevant substances at nanoscale that do not meet the criteria for CMRs or PBTs per se.

6. RESTRICTIONS

REACH also contains provisions regarding **restrictions on the manufacturing, placing on the market and use of certain dangerous substances, preparations and articles**. When there is an unacceptable risk to human health or the environment arising from the manufacture, use or placing on the market of a substance, which needs to be addressed at Community-wide basis, restrictive measures shall be laid down by the Commission, taking into account opinions of the European Chemicals Agency (through its Committee for Risk Assessment and Committee for Socio-Economic Analysis) and in agreement with Member States. This procedure can be initiated by the Commission or a Member State.

As there are no tonnage triggers for the application and there is no need for prior registration, restrictions can apply to any substance for which it is considered that the manufacture, placing on the market or use poses a risk to human health or the environment that is not adequately controlled (Art. 69).

7. CONCLUSIONS AND PLANNED FURTHER STEPS

This document reflects the current state of ongoing discussions within the REACH Competent Authorities (REACH CA) and its subgroup on nanomaterials on how REACH applies to nanomaterials. The document has been endorsed by the REACH Competent Authorities on 16 December 2008. Further updates of this document can be expected following continued discussions. Stakeholders are invited to take note of the content of this document and follow its further development.

Further work of CASG(Nano) is planned on other aspects of the application of REACH to nanomaterials, including substance identification, further details on how to prepare registration dossiers for nanomaterials and on information requirements and testing. Documents to be developed on these issues are envisaged to be published on the same websites after their endorsement. At a later stage, they might also be handed over to ECHA to assist in the preparation of specific guidance documents.

ANNEX 1

Working definitions

SCENIHR

The EU Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) has, based on an analysis of existing definitions, provided the following suggestions for definitions¹¹:

Nanoscale: a feature characterised by dimensions of the order of 100 nm or less.

Nanostructure: Any structure that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less.

Nanomaterial: Any form of a material that is composed of discrete functional parts, many of which have one or more dimensions of the order of 100 nm or less.

¹¹ Scientific Committee on Emerging and Newly Identified Health Risks. Opinion on the scientific aspects of the existing and proposed definitions relating to products of nanoscience and nanotechnologies. http://ec.europa.eu/health/ph_risk/committees/04_scenihhr/docs/scenihhr_o_012.pdf

ANNEX 2

**Excerpt from the
MANUAL OF DECISIONS FOR IMPLEMENTATION OF THE SIXTH AND
SEVENTH
AMENDMENTS TO DIRECTIVE 67/548/EEC ON
DANGEROUS SUBSTANCES
(DIRECTIVES 79/831/EEC AND 92/32/EEC)**

5.1.3 Substances in Nanoform

The question was raised whether substances in the nanoscale form should be regarded as new or existing substances. It was agreed¹² that the decisive criterion whether a nanomaterial is a new or existing substances is the same as for other substances, i.e. whether or not the substance is on EINECS.

Thus, substances in nanoform which are in EINECS (e.g. titaniumdioxide) shall be regarded as existing substances.

Substances in nanoform which are not in EINECS (e.g. carbon allotropes other than those listed in EINECS) shall be regarded as new substances.

New information on existing substances, including those with nanoforms, shall be submitted in accordance with Art.7 of Regulation (EEC) No 793/93.

New information on new substances already notified, including those with nanoforms, shall be submitted in accordance with Art.14 of Directive 67/548/EEC.

¹² 13th Joint Competent Authorities Meeting (May 2006)

Substance identification parameters in REACH Annex VI item 2

- 2. IDENTIFICATION OF THE SUBSTANCE** For each substance the information given shall be sufficient to enable each substance to be identified. If it is not technically possible or if it does not appear scientifically necessary to give information on one or more items below, the reason shall be clearly stated.
- 2.1 Name or other identifier of each substance**
- 2.1.1 *Name(s) in the IUPAC nomenclature or other international chemical name(s)*
- 2.1.2 *Other names (usual name, trade name, abbreviation)*
- 2.1.3 *EINECS or ELINCS number (if available and appropriate)*
- 2.1.4 *CAS name and CAS number (if available)*
- 2.1.5 *Other identity code (if available)*
- 2.2 Information related to molecular and structural formula of each substance**
- 2.2.1 *Molecular and structural formula (including SMILES notation, if available)*
- 2.2.2 *Information on optical activity and typical ratio of (stereo) isomer (if applicable and appropriate)*
- 2.2.3 *Molecular weight or molecular weight range*
- 2.3. Composition of each substance**
- 2.3.1 *Degree of purity (%)*
- 2.3.2 *Nature of impurities, including isomers and by-products*
- 2.3.3 *Percentage of (significant) main impurities*
- 2.3.4 *Nature and order of magnitude (.....ppm,%) of any additives (e.g. stabilising agents or inhibitors)*
- 2.3.5 *Spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum)*
- 2.3.6 *High performance liquid chromatogram, gas chromatogram*
- 2.3.7 *Description of the analytical methods or the appropriate bibliographical references for the identification of the substance and, where appropriate, for the identification of impurities and additives. This information shall be sufficient to allow the methods to be reproduced.*