

# Just Out of REACH

How REACH Is Failing to  
Regulate Nanomaterials  
and How it Can Be Fixed

A hand is shown from the bottom, reaching upwards towards a key that hangs from the top of the frame. The background is a solid blue color. The key is a simple, dark metal key with a circular ring at the top and a rectangular bit at the bottom. The hand is positioned in the lower right quadrant of the image, with fingers spread and palm facing slightly towards the viewer.  
The logo for COIEL, featuring a stylized globe icon within the letter 'O' and a registered trademark symbol (®) to the right of the word 'COIEL'.  
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# Just Out of Reach

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David Azoulay,

Managing Attorney, Geneva Office, Switzerland

The Center for International Environmental Law (CIEL)

+41 22 321 4774

dazoulay@ciel.org

[www.ciel.org](http://www.ciel.org)

## **About CIEL**

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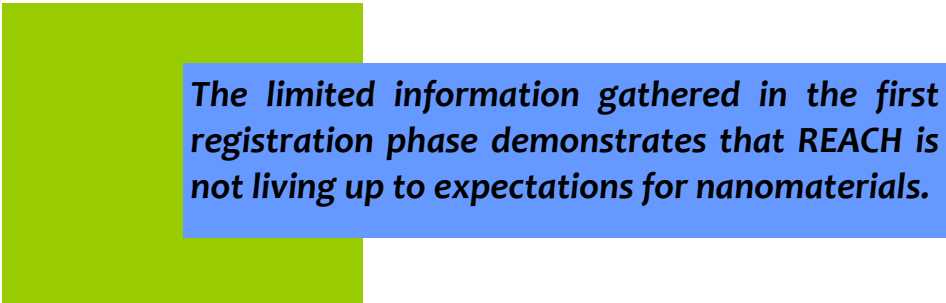


## Executive Summary

More than three years after the European Commission's communication on the regulatory aspects of nanomaterials, numerous questions remain regarding the practical effectiveness of existing European Union law to manage nanomaterials. REACH, the primary EU regulation on chemicals, is assumed to be the regulatory cornerstone for addressing the health, safety and environmental risks of nanomaterials. In particular, REACH registration is described as the ideal tool to fill the problematic knowledge gap on nanomaterials. However, the limited information gathered in the first registration phase demonstrates that REACH is not living up to expectations for nanomaterials.

The study identifies four areas in which REACH's registration provisions fail to account for the specificities of nanomaterials:

1. Identifying nanomaterials: REACH currently does not define nanomaterials and leaves to the registrant the final decision of determining whether a substance is a nanomaterial. As a result, the final decision to identify substances as nanomaterials is made by the registrants according to their own criteria. In addition to creating confusion in the implementation of REACH, this situation is likely to severely impair efforts to use REACH as the main regulatory tool for gathering information on nanomaterials on the market and defining and implementing appropriate risk management measures if needed.



***The limited information gathered in the first registration phase demonstrates that REACH is not living up to expectations for nanomaterials.***

2. Phase-in status of nanomaterials: REACH distinguishes new and existing substances, between substances that were already on the market before its entry into force (so called “phase-in substances”) and new substances (so called non phase-in substances). As REACH is currently implemented, if a material is considered a phase-in substance in its bulk form, then a nanomaterial sharing the same chemical composition will automatically benefit from the bulk version’s phase-in status, regardless of its newness. As a consequence, nanomaterials derived from a bulk phase-in substance, or sharing the same chemical composition, will not be registered before the 2013 deadline if they are manufactured or imported in quantities above 100 tonnes per year per registrant. Such materials manufactured or imported in quantities of 1-100 tonnes per year per registrant will not be registered until 2018, further extending the knowledge gap surrounding nanomaterials. Because most nanomaterials currently on the market are derived from ‘parent substances’ that benefit from a phase-in status, the vast majority of nanomaterials currently marketed benefit from delayed registration deadlines in direct contradiction with the “no data, no market” principle underlying REACH.

3. Tonnage thresholds and nanomaterials: Production volumes play a significant role in determining whether and how substances are accounted for under REACH. The overall rule of thumb is that the higher the volume, the more data is required, and the sooner the registration. REACH registration requirements apply only for production volumes of one tonne or more per year per manufacturer or importer. This volume threshold is grossly inadequate for nanomaterials, usually produced in much smaller quantities. Furthermore, in the few cases in which nanomaterials are produced in volumes above the one tonne/year per registrant threshold, most of those nanomaterials will benefit from a phase-in status. As a result, the information required by the registration dossier will be limited to the physicochemical properties of the substance, excluding any toxicological and eco-toxicological information, which may otherwise be required. Nor does the dossier include exposure information, which is currently required only for substances of “very high concern”. Similar concerns apply to the availability of information down the supply chain.

4. Risk assessment provisions: According to the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and independent researchers, and notwithstanding other limitations discussed above, any risk assessment information made available on a nanomaterial in the context of REACH would be based on testing guidelines that fail to consider the special hazards and exposure pathways of nanomaterials. Furthermore, if a bulk substance is characterized as non-hazardous, as is the case for the vast majority of substances from which nanomaterials are derived, this classification will be extended to the nano-form of the substance, with no additional requirements to generate data on specific nano-form effects. Therefore, a nanomaterial could move through its entire life-cycle without further requirements to assess its properties. Given these limitations, REACH in its current form does not equip decision-makers to manage the risks of nanomaterials.

Several REACH Implementation Projects on Nanomaterials (RIPoN 1, 2 and 3) were designed to address these concerns without modifying the text of the regulation. RIPoN 1, in particular, aimed at adapting the substance identification rules (defined in a Technical Guidance Document (TGD)) to clarify the implementation of REACH to nanomaterials. This expert group proposed two options: addressing nanomaterials as 1) “well defined substances” or as 2) “Substances of defined chemical composition and additional identifiers”.

Although these options might improve the situation to a limited extent, most of the issues identified above would remain. In particular, the problems related to the tonnage band rules and the inadequacy of the traditional hazard and exposure testing guidelines persist. Furthermore, substance identification rules are not binding, so attempts to address the gaps for nanomaterials by modifying these rules could create confusion in implementation and thwart efforts to use REACH as the main regulatory tool for nanomaterials. If REACH is to serve as the regulatory cornerstone for nanomaterials, it will require more profound changes of the regulatory framework.

This study presents two options for altering REACH to accommodate nanomaterials:

Option 1: Modifying the REACH text, its annexes and technical guidance documents

Addressing the regulatory gaps for nanomaterials identified in the registration process of REACH would require, at a minimum:

- Including a definition of nanomaterial in the REACH text, presumably in Article 3, next to the general "substance" definition;
- Specifying that nanomaterials are not considered phase-in substances in Article 3 (20);
- Introducing specific (and significantly lower) tonnage triggers for substances within the scope of the definition of "nanomaterial" as Article 7(4)bis. This modification would require a corresponding modification of Article 6;
- Modifying Article 14(1) to require that registration dossiers for nanomaterials categorically include a Chemical Safety Assessment, in order to reach the "high level of protection of human health and the environment;" and
- Finally, updating testing and risk assessment provisions and guidelines to include specific nanomaterials provisions, through modifications of Annexes VI to X as well as technical guidance documents.

These proposals would go a long way to ensure that the registration process under REACH generates necessary information on nanomaterials. Additional modifications of other REACH provisions, annexes, and guidance would be required to address shortcomings of other core elements of REACH, including evaluation, authorisation, and restriction.

**Instead of modifying REACH itself, a possible alternative for addressing nanomaterials would be to develop a stand-alone regulation specifying how REACH tools and provisions are to be applied to nanomaterials.**

## Option 2: Developing a stand-alone regulation

Instead of modifying REACH itself, a possible alternative for addressing nanomaterials would be to develop a stand-alone regulation specifying how REACH tools and provisions are to be applied to nanomaterials. This regulation could list general principles for the management of nanomaterials, indicate that all terms would be consistent with their definition in REACH and define nanomaterials using the Commission proposal. Other provisions would, among other things, establish a production/import threshold of 10 kilograms for registration, together with registration deadlines. This stand-alone regulation could serve as a “nano patch,” providing a simpler and more elegant solution to adapting REACH to the special properties of nanomaterials. By creating a flexible instrument with simplified revision procedures, it would be possible to adapt to changing experience with nanomaterials, without adding further layers of complexity to REACH.



## Acronyms and Abbreviations

CA	Competent Authority
CAS	Chemical Abstracts Service
CLP	Classification, Labeling, and Packaging Regulation
CSA	Chemical Safety Assessment
DG	Directorate General
ECHA	European Chemicals Agency
EEB	European Environmental Bureau
EINECS	European Inventory of Existing Commercial Chemical Substances
ERS	Existing Substances Regulation
EU	European Union
IUPAC	International Union of Pure and Applied Chemistry
JRC	Joint Research Centre (European Commission)
NONS	Notification of New Substances Regulation
PBT	Persistent, Bioaccumulative, and Toxic substance
RCEP	UK Royal Commission on Environmental Pollution
REACH	Registration, Evaluation, Authorization, and Restriction of Chemicals
RIP-oN	REACH Implementation Projects on Nanomaterials
RIVM	Dutch National Institute for Public Health and the Environment
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SRU	Sachverständigenrat für Umweltfragen (German Advisory Council on the Environment)
TGD	Technical Guidance Document
vPvB	very Persistent and very Bioaccumulative substances

## SECTION 1/ Introduction

More than three years after the European Commission's communication<sup>1</sup> on the regulatory aspects of nanomaterials, questions relating to the regulatory provisions applicable to nanomaterials in the European Union are still numerous. From improved products and services, to better-targeted medicines and enhanced physical characteristics of natural resources, nanomaterials are anticipated to pave the way towards new interactions, reshaping and shifting societal dynamics.<sup>2</sup> The rapid growth of nano-applications, however, coupled with the potential of nanomaterials to adversely impact human health and the environment, has placed the issue of safety at the forefront of current regulatory concerns.<sup>3</sup>

"[C]hemicals regulation, and in particular REACH,<sup>4</sup> constitutes a cornerstone for addressing health, safety and environmental risks in relation with nanomaterials . . ."<sup>5</sup> However, many interested parties—including member States,<sup>6</sup> the European Parliament,<sup>7</sup> consumers organiza-

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<sup>1</sup>European Commission, *Communication from the Commission to the European Parliament, the Council and the European Economic and Social Council Committee on the Regulatory Aspects of Nanomaterials*. Sec (2008) 2036, 17 June 2008, available at [http://ec.europa.eu/nanotechnology/pdf/comm\\_2008\\_0366\\_en.pdf](http://ec.europa.eu/nanotechnology/pdf/comm_2008_0366_en.pdf) (hereinafter "Commission Nanomaterials Regulation Review 2008").

<sup>2</sup>European Environmental Bureau, *EEB position paper on nanotechnologies and nanomaterials, Small scale, big promises, divisive messages*, February 2009, at 1.

<sup>3</sup>Scientific Committee for Emerging and Newly-Identified Health Risks, *Opinion on the appropriateness of the risk assessment methodology in accordance with the Technical Guidance Documents for new and existing substances for assessing the risks of nanomaterials*, Brussels: European Commission Health & Consumer Protection Directorate-General, 28 (June 2007), available at [http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihr/docs/scenihr\\_o\\_010.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_010.pdf) (hereinafter "SCENIHR 2007")

<sup>4</sup>Regulation of the European Parliament & Council No. 1907/2006, Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation, 2007 O.J. (L 136) 3, 18 (hereinafter "REACH").

<sup>5</sup>Commission staff working document accompanying document to the Communication from the Commission to the European Parliament, the Council and the European Economic and social Council Committee on the regulatory aspects of nanomaterials. Com (2008) 366 final, 17 June 2008, available at [http://ec.europa.eu/nanotechnology/pdf/com\\_regulatory\\_aspect\\_nanomaterials\\_2008\\_en.pdf](http://ec.europa.eu/nanotechnology/pdf/com_regulatory_aspect_nanomaterials_2008_en.pdf).

<sup>6</sup>See e.g., the NL CA reaction on document Caracal/58/2011, Brussels, 20 July 2011 on Rip-oN1; the FR CA comments on document Caracal/58/2011 and question from the Commission on the way forward concerning the JRC final report on RIP-oN1, 1 September 2011;

<sup>7</sup>European Parliament, *Resolution of 24 April 2009 on Regulatory Aspects of Nanomaterials*, (2008/2208(INI)), P6\_TA (2009)0328 (hereinafter "EU Parliament 2009 Resolution").

tions,<sup>8</sup> trade unions<sup>9</sup> and environmental organizations<sup>10</sup> —have underscored the need to adapt REACH provisions and implementation processes to ensure that nanomaterials are subject to the same information requirements and protections as other chemicals. The objective of this study is to explore in detail how nanomaterials are treated under the Registration provisions of REACH that support the principle of ‘no data, no market’, and suggest changes where needed. Registration is critical to the functioning of REACH because it generates the fundamental information on which the safety of chemicals is judged. If nanomaterials evade Registration, or if their adverse effects are underestimated, the remaining provisions of REACH, including Evaluation, Authorisation and Restrictions, could be undermined. How nanomaterials are treated under these other provisions is beyond the scope of this analysis.

REACH is based on the primary understanding that adequate information regarding each substance provides the basis for identifying and implementing risk management measures when needed.

***If nanomaterials evade Registration, or if their adverse effects are underestimated, the remaining provisions of REACH, including Evaluation, Authorisation and Restrictions, could be undermined.***

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<sup>8</sup>See The European Consumers' Organization (BEUC), The European Association for the Co-ordination of Consumer Representation in Standardization (ANEC), *Nanotechnology: Small is beautiful but is it safe?*, ANEC & BEUC leaflet on nanotechnology and nanomaterials, November 2009, available at <http://docshare.beuc.org/docs/1/NKOLJLCBMGLDJPKAOEPCGOOGPDBG9DBW769DW3571KM/BEUC/docs/DLS/2009-00893-01-E.pdf>, at 6.

<sup>9</sup>See the European Trade Union Confederation (ETUC), ETUC 2<sup>nd</sup> Resolution on nanotechnologies and nanomaterials, Adopted at the Executive Committee on 1-2 December 2010, available at [http://www.etuc.org/IMG/pdf/13-GB\\_final\\_nanotechnologies\\_and\\_nanomaterial.pdf](http://www.etuc.org/IMG/pdf/13-GB_final_nanotechnologies_and_nanomaterial.pdf), at 4, 5.

<sup>10</sup>See the European Environmental Bureau, *EEB position paper on nanotechnologies and nanomaterials, small scale, big promises, divisive messages*, February 2009, available at <http://www.eeb.org/EEB/?LinkServID=5403FF15-9988-45A3-0E327CBA2AFD88BA>, at 7, 9-10.

The absence of adequate, comprehensive information for nanomaterials is a major problem faced by regulators in identifying and implementing regulatory provisions relevant to nanomaterials, and to make use of the full scope of REACH mechanisms. Registration under REACH<sup>11</sup> is designed to remedy exactly this kind of knowledge gap, requiring the submission of essential data on all substances marketed in the EU to enable the application of the most appropriate regulatory provisions. The successful implementation of REACH registration provisions to nanomaterials is therefore critical.

However, experience from the first registration round strongly suggests that registration of nanomaterials has been very limited and has not yet helped significantly in bridging the existing knowledge gap.

This study will therefore focus on the adaptations to REACH needed to ensure that nanomaterials are properly registered and that the registration phase provides the information necessary to further implement the risk management tools integrated in the REACH framework. After a brief summary of REACH provisions relevant to the registration of nanomaterials, the study will identify obstacles and legal shortcomings that impede the successful registration of nanomaterials, review the possible role of substance identification rules in addressing these shortcomings and propose policy options to remedy the remaining gaps.

## **SECTION 2 / Key registration provisions for nanomaterials**

The registration provisions of REACH are founded on the “no data, no market” principle. These provisions require manufacturers and importers to submit a minimum set of information on a substance in order to market that substance within the EU.<sup>12</sup> This general obligation to register nanomaterials applies solely for those manufactured or imported in quantities of 1 tonne

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<sup>11</sup>REACH, Title II, Arts 5- 24.

<sup>12</sup>REACH, Art 5, Art 6.



or more per year.<sup>13</sup> The registration dossier must be submitted to the European Chemicals Agency (ECHA) for substances manufactured or imported in the EU above the 1 tonne threshold (or, for substances in articles, that are intended for release during normal usage of the article), unless stated otherwise.<sup>14</sup>

Under this regulation, registrants are responsible for complying with data production and testing requirements under the Regulation. The registration deadline and information requirements vary depending on the hazard profile and the quantity manufactured or imported. Four tonnage bands act as regulatory thresholds (1 - 10 tonnes, 10-100 tonnes, 100-1,000 tonnes, and 1,000+ tonnes). Information requirements become progressively more extensive as the tonnage band increases. The rationale behind this approach was the assumption that a higher tonnage means a higher exposure, which implies higher risks posed by the substance. The emergence of nanomaterials might challenge this assumption.

Furthermore, REACH distinguishes the tens of thousands of chemicals already on the market from new chemicals seeking pre-market approval. Registration of the existing chemical inventory is staggered in three phases, with specific deadlines in 2010, 2013, and 2018. These “phase-in substances” include chemicals listed in the European Inventory of Existing Commercial Chemical Substances (“EINECS”) prior to the entry into force of REACH. Irrespective of their production volume, phase-in substances benefit from delayed registration deadlines provided that they were successfully pre-registered by December 1, 2008.<sup>15</sup> Pre-registration required manufacturers and importers of chemicals determined to qualify for “phase-in” status to sub-

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<sup>13</sup>REACH, Art 6, with the exception of Substances of Very High Concern.

<sup>14</sup>REACH, Art 7. Although for substances in articles meeting the criteria in Art 57 and identified in accordance with Art 59(1), a producer or importer must notify the Agency in accordance with Art 7(4) if the substance is present in those articles in quantities totaling over 1 tonne per producer/importer per year, and the substance is present in those articles above a concentration of 0,1% w/w.

<sup>15</sup>REACH, Art 3(20).

mit information on the identity of the substance to ECHA, including its EINECS number (if relevant), tonnage band, and any applicable identifier such as CAS number or IUPAC name.<sup>16</sup>

Full registration requirements found under Art 10 of REACH include the necessity for manufacturers and importers to submit a technical dossier. These requirements are meant to gather a minimum set of information on each substance.<sup>17</sup> For substances in the 10 tonnes tonnage band and higher, registration further requires a detailed chemical safety assessment (CSA),<sup>18</sup> based on more comprehensive and detailed data on the intrinsic properties, uses and exposures of each substance.<sup>19</sup> Significantly, the CSA requires the assessment of basic hazard characteristics (e.g., physicochemical, environmental, persistence, bioaccumulation, and toxicity), and, if indicated, an exposure assessment and risk characterization.<sup>20</sup>

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<sup>16</sup>An EINECS number was assigned to each chemical substance under the European Inventory of Existing Commercial Substances, which was subsumed by REACH. Substances with EINECS numbers were available in the EU between January 1, 1971 and September 18, 1981. EuroChem, Registry Numbers Description, <http://www.eurochem.cz/index.php?MN=Registry+Numbers&ProdID=00026D060C0537860002ED39> (last visited Aug. 4, 2010). CAS (Chemical Abstract Services) numbers, on the other hand, are unique numerical identifiers without scientific significance. CAS is a division of the American Chemical Society. CAS, CAS Registry & CAS Registry Numbers, <http://www.cas.org/expertise/cascontent/registry/regsys.html> (last visited Aug. 4, 2010).

<sup>17</sup>REACH, Art 14(1); Art 10 respectively.

<sup>18</sup>REACH Art. 10, 14; With the exception of substances in articles that are present in low concentrations.

<sup>19</sup>R.G. Lee & S. Vaughan, *REACHing Down: Nanomaterials and Chemical Safety in the European Union* (Regulatory Governance Standing Group, Regulation in the Age of Crisis, Conference Paper, 2010), available at <http://regulation.upf.edu/dublin-10-papers/5B3.pdf>, at 18.

<sup>20</sup>REACH Art. 14 (3) & (4); The last two steps are necessary where a substance is classified as dangerous or found to be either a PBT or vPvB substance, *as per* E. Spencer Williams et al., *The European Union's REACH Regulation: A Review of Its History and Requirements*, 30 *Critical Rev. in Toxicology* 553, 556 (2009), at 561.



## SECTION 3 / Applying REACH provisions to nanomaterials

REACH contains strong provisions to gradually collect minimum data for all substances available in the EU market in quantities of more than one tonne. REACH provisions are further complemented by extensive Technical Guidance Documents (TGDs) that specify how to implement the various provisions. However, because both REACH and the TGD were drafted before nanotechnology was widely used, neither the regulation nor the guidance are fully adapted to answer the questions raised by the special properties of nanomaterials. There are four major gaps for nanomaterials under Registration: (1) the identification of nanomaterials; (2) 'phase-in' status; (3), tonnage thresholds; and (4) risk assessment methods.

### 3.1 Identifying nanomaterials

There is a general consensus that nanomaterials are not excluded by the substance definition in REACH. But REACH provides only limited opportunities to identify them as such<sup>21</sup> and to take into account their special characteristics. The limitations in identifying nanomaterials are particularly severe when a bulk substance with a similar chemical composition exists.

Although they may be variants of bulk substances, sharing the molecular structure or the same chemical composition, nanomaterials possess unique properties, which are exhibited solely at the nano-scale.<sup>22</sup> Typical bulk substance parameters like aqueous solubility, rate of dis-

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<sup>21</sup>REACH, Art. 3(1).

<sup>22</sup>European Commission, Environment Directorate-General & Enterprise & Industry Directorate-General, *Follow-up to the 6th Meeting of the REACH Competent Authorities for the Implementation of Regulation (EC) 1907/2006 (REACH)*, CA/59/2008 rev. 1 (Dec. 16, 2008), available at [http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/nanomaterials\\_en.pdf](http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/nanomaterials_en.pdf), (hereinafter "Commission Follow-up to the 6<sup>th</sup> REACH CA Meeting"), at 4; Swedish expert, in the JRC European Commission, Institute for Health and Consumer Protection, *Advisory Report, REACH Implementation Project Substance Identification of Nanomaterials (RIP-oN 1)*, AA N°070307/2009/D1/534733 between DG Environment and JRC, March 2011. (hereinafter "Advisory Report for the RIP-oN 1 process"), available at [http://ec.europa.eu/environment/chemicals/nanotech/pdf/report\\_ripon1.pdf](http://ec.europa.eu/environment/chemicals/nanotech/pdf/report_ripon1.pdf), Appendix 1, at 1.

solution, dynamics of dispersion, melting point, conductivity, physical adsorption, or magnetic qualities can greatly differ for nanomaterials.<sup>23</sup>

The second REACH Implementation Project on Nanomaterials (RIP-oN2), focused on information required for characterising and evaluating nanomaterials, proposed a set of modifications of a TGD that was considered poorly suited to nanomaterials (i.e., with regards to preparation, exposure quantifications, measurement, dose metrics, etc.). Recommendations from RIPoN2 address a number of domains (including physiochemical properties, toxicological, ecotoxicological endpoints, and more), which would require a modification of the REACH annexes. However, for such modifications, once adopted, to be implemented, nanomaterials must first be systematically identified. The fifth version of the International Uniform Chemical Information Database (IUCLID5) system allows registrants to identify nanomaterials in registration dossiers. REACH, however, does not explicitly define nanomaterials. Therefore, the final decision in determining whether a substance is a nanomaterial rests with the registrant.<sup>24</sup>

As a result, it is the discretion of registrants to identify substances as nanomaterials according to their own criteria. In addition to creating confusion in the implementation of REACH, this situation is likely to thwart efforts to use REACH as the main regulatory tool to gather information on nanomaterials on the market and to define and implement appropriate risk management measures if needed.

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<sup>23</sup>Scientific Committee for Emerging and Newly-Identified Health Risks, *Opinion on the appropriateness of the risk assessment methodology in accordance with the Technical Guidance Documents for new and existing substances for assessing the risks of nanomaterials*, Brussels: European Commission Health & Consumer Protection Directorate-General, 28 (June 2007), available at [http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihr/docs/scenihr\\_o\\_010.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_010.pdf) (hereinafter "SCENIHR 2007"), at 13, 28.

<sup>24</sup>See REACH, Annex VI, Step 2, stating "The registrant shall identify what information is required for the registration"

### 3.2 The “phase-in” status of nanomaterials

Under REACH, substances are currently identified by their chemical composition alone. When two substances share the same chemical composition, they are considered to be the same substance. As a consequence, if a substance exists both in the bulk and nano form, and if the bulk substance is a phase-in substance, a nanomaterial sharing the same chemical composition will automatically benefit from the bulk version’s phase-in status, regardless of its newness.<sup>25</sup> This can be inferred from the EINECS reporting rules and the Manual of Decisions,<sup>26</sup> which states that, “[S]ubstances in nano-form which are EINECS shall be regarded as existing substances”.<sup>27</sup> The Commission EACH Review further stresses this point by stating that even though potential registrants may decide that the bulk and nano-form should be registered separately during the SIEF formation process due to such intrinsic differences, the nano-form would still be allowed retain phase-in status.<sup>28</sup> This failure to include additional identifiers, such as the material’s size, represents one of the fundamental gaps in REACH’s ability to effectively regulate nanomaterials.

As a consequence, nanomaterials sharing the same chemical composition with a bulk phase-in substance will not be registered before the 2013 deadline if they are manufactured or imported in quantities above 100 tonnes per year per registrant. Nanomaterials manufactured or imported in quantities of 1-100 tonnes per year per registrant will not be registered until 2018,<sup>29</sup> with the consequence that the current, longstanding knowledge gap on nanomaterials will be prolonged still further.

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<sup>25</sup>Commission, Follow-up to the 6<sup>th</sup> REACH CA Meeting, *supra* note 22, at 7-8, 10.

<sup>26</sup>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 Non confidential version, available at [http://ecb.jrc.ec.europa.eu/esis/doc/Manual\\_of\\_decisions.pdf](http://ecb.jrc.ec.europa.eu/esis/doc/Manual_of_decisions.pdf), (hereinafter “MOD”).

<sup>27</sup>MOD, *supra* note 26, Section 5.1.3, at 64, *as per* The Advisory Report for the Rip-oN 1 process, *supra* note 22, at 20.

<sup>28</sup>Commission 2008 REACH Review, *supra* note 1, at 10 (stating that where two substances formerly fell under the same EINECS number, but were considered too dissimilar to register together, both substances would nevertheless retain phase-in status under REACH).

<sup>29</sup>REACH Arts 23(2), (3).

The rationale for granting a delayed registration deadline for phase-in substances lies in the practical challenges of registering and evaluating the tens of thousands of substances already present in the EU market before the adoption of REACH. Based on the assumption that basic information on such substances already exists, phase-in substances are not prioritized under REACH unless warranted by specific hazardous characteristics (see Article 57). However, this reasoning may not be relevant to nanomaterials as, even though their chemical composition was not unknown at the time of adoption, their physiochemical, toxicological and ecotoxicological properties, as well as uses and exposure patterns may differ greatly from their bulk counterparts. Toxicological and ecotoxicological information on bulk substances are therefore not automatically transposable to the corresponding nanomaterials. A simple ‘read across’ from the bulk form, as proposed by the European chemical industry federation is not always possible.<sup>30</sup> As a result, the availability of toxicological and ecotoxicological information on the bulk form does not justify the phase-in status granted to nanomaterials.

***This results in nanomaterials entering and remaining on the market with little or no information available regarding their potential risks, in direct contradiction with the “no data, no market” principle underlying REACH.***

Furthermore, although reliable information regarding which nanomaterials are currently on the market is very limited, available studies show that the ‘parent substances’ of many nanomaterials (i.e., those with which they share their core chemical composition) are relatively common<sup>31</sup> and pre-existing in bulk form. In fact, a 2008 study<sup>32</sup> found that for a database of consumer products containing nanomaterials currently on the market, only six parent substances<sup>33</sup> were used, all with phase-in status. It follows that under the current rules, the vast majority of

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<sup>30</sup>European Chemical Industry Council (Cefic), *Risk Assessment of nanomaterials from an industry perspective*, available at [http://ec.europa.eu/health/nanotechnology/docs/ev\\_20110329\\_co12\\_en.pdf](http://ec.europa.eu/health/nanotechnology/docs/ev_20110329_co12_en.pdf)

<sup>31</sup>Millieu, Risk & Policy Analysts (RPA), *Information from Industry on applied nanomaterials and their safety: Deliverable 1*, prepared for European Commission DG Environment, September 2009, available @ <http://www.nanomaterialsconf.eu/documents/Nanos-Task1.pdf>.

<sup>32</sup>Hansen et al., *Categorization Framework to aid Exposure Assessment of Nanomaterials in Consumer Products*, *Ecotoxicology*, Vol. 17 No 5, July 2008, 438–447

<sup>33</sup>Silver, Carbon (all allotropes), Zinc Oxide, Silica, Titanium dioxide and gold.

nanomaterials currently marketed benefit from phase-in status, delaying registration deadlines. This results in nanomaterials entering and remaining on the market with little or no information available regarding their potential risks, in direct contradiction with the “no data, no market” principle underlying REACH. This undermines the effectiveness and credibility of REACH as the primary regulatory tool to bridge the knowledge gap on nanomaterials.

### **3.3 Tonnage thresholds**

Production volumes play a significant role in determining whether and how substances are accounted for under REACH. The general rule of thumb is that the higher the volume, the more data is required, and the sooner the registration.<sup>34</sup> Regulatory thresholds are based on four tonnage bands (1 - 10 tonnes, 10-100 tonnes, 100-1,000 tonnes, and 1,000+ tonnes).

Registration of nanomaterials is key to their regulation since it allows for the collection of the necessary information fundamental to the application of other REACH mechanisms, such as restriction and authorisation. Moreover, the information provided on nanomaterials under REACH has significance beyond REACH itself. According to the Commission, this information “will serve as input to other regulation, such as worker protection, cosmetics and environmental protection [and] complements product legislation (e.g., general product safety) to the extent that this does not cover environmental aspects.”<sup>35</sup>

Ever since REACH was adopted, the relevance of REACH tonnage thresholds to nanomaterials has been questioned.<sup>36</sup> In effect, the requirement for registration laid down in Article 6 (1)

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<sup>34</sup>There are exceptions to this principles relating to the registration of substances meeting certain toxicity criteria (i.e.: Carcinogen, Mutagen, Reprotoxic, Persistent or bio-accumulative). This exception is however not deemed relevant in the context of the present study, as enduring data gap preclude that any nanomaterials be the object of such toxicity classification in the near future.

<sup>35</sup>Commission Nanomaterials Regulation Review 2008, *supra* note 1, at 5.

<sup>36</sup>See for example: M. Führ, A. Hermann, S. Merenyi, K. Moch, M. Moller, *Legal appraisal of nanotechnologies, Existing legal framework, the need for regulation and regulative options at a European and national level. Final Report*, UBA, 2006, at section 5.3.1 available at <http://www.umweltdaten.de/publikationen/fpdf-l/3198.pdf>; Commission Nanomaterials Regulation Review 2008, *supra* note 1, at 3: “current legislation may have to be modi-

of REACH applies only for production volumes of one tonne or more per year per manufacturer or importer. Reliable information on the production volumes of nanomaterials is very scarce, and “hampered by the lack of definitive inventory on the types and uses of nanosubstances”.<sup>37</sup> Based on the very small quantities in which nanomaterials are marketed,<sup>38</sup> however, it seems likely that the production and import of most nanomaterials would fall below the one tonne threshold required for even basic regulation under REACH. It therefore must be assumed that the standard principle in Article 5 of REACH—“No data, no market”—is ineffective with respect to many nanomaterials.<sup>39</sup> The German Advisory Council on the Environment (SRU) suggests that “a core data set should still have to be submitted if a nanomaterial is produced in quantities of less than 1 tonne per year.”<sup>40</sup>

Even in the few cases in which nanomaterials are produced in volumes above the one tonne/year per registrant threshold, most nanomaterials will still benefit from phase-in status derived from their bulk counterparts.<sup>41</sup> Consequently, the information set required by the registration dossier will be limited to the physicochemical properties of the substance, excluding any toxicological and eco-toxicological information,<sup>42</sup> which may otherwise be required. Nor will it include exposure information, which is only required for “substances of very high concern.”<sup>43</sup> Similar concerns apply to the availability of information down the supply chain.<sup>44</sup>

A detailed CSA, which mandates human health, physicochemical, and environmental hazard assessment, is only mandated for substances manufactured or imported above the ten

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<sup>37</sup>R.G. Lee & S. Vaughan, *supra* note 199, at 15.

<sup>38</sup>See, for example, the substance of manufacturer Sigma-Aldrich, catalogue no. 519308 Carbon nano-tube, single-walled Carbo-Lex AP-grade 50-70 % purity as determined by Raman spectroscopy, tubes in bundle of length about 20 µm, which is sold in quantities of 0.25 g or 1 g v (price for 1 g: 250.70 euros), in M. Führ et al., *supra* note 366, at section 5.3.2.4, 6.1.2.1.

<sup>39</sup>M. Führ et al., *supra* note 36, at 43, §6.1.2.1.

<sup>40</sup>German Advisory Council on the Environment (hereinafter “SRU”), *Precautionary Strategies for Managing Nanomaterials, Summary for Policy Makers*, Sep 2011, at 6.

<sup>41</sup>See *supra*, Section 2.2

<sup>42</sup>REACH, Annex VII.

<sup>43</sup>REACH, Art 14(3).



tonne threshold/year by a single registrant.<sup>45</sup> Because most nanomaterials are likely to be produced in low volumes (under the 10 tonne threshold), CSA will be unavailable for the great majority of nanomaterials.

### **3.4 Risk assessment provisions**

REACH rules for the provision of physicochemical, toxicological and ecotoxicological data, as well as CSA performance criteria reflect methodologies developed for traditional substances. Several commentators have highlighted the need to modify both the rules and the implementation guidelines in order to effectively address the special risks posed by nanomaterials.<sup>46</sup>

The Scientific Committee on Emerging and Newly Identified Health Risk (SCENIHR), in particular, mentions that there are a number of areas where the risk assessments as outlined in REACH, and explained in greater detail in the ECHA 2011 Guidance,<sup>47</sup> may need modification to give a complete picture of the risks presented by substances in the nano-form.<sup>48</sup> SCENIHR observes, for example, that the uptake, distribution, clearance and elimination of nanoparticles may differ from those of the chemical substances for which the TGDs were initially developed. It is uncertain whether the base set of standard tests and recommended procedures are adequate to assess effects of nanoparticles.<sup>49</sup> Specifically, the traditional methods of measuring

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<sup>45</sup>See article 10 of REACH, as well as annexes VI and VII, 7.

<sup>46</sup>See The Netherlands National Institute for Public Health and the Environment (RIVM), *Exposure to nanomaterials in consumer products*, RIVM Letter Report 340370001/20998, 2009, at 12, which points out that the submission of kinetic information, which is necessary to properly assess nano-form substances, is not required under REACH. RIVM also calls for REACH exposure models to be adapted to nano-form substances and for its "standard default assessment factors... to be examined for their applicability to nanomaterials..." Other important work on the topic has been done by the Scientific Committee for Emerging and Newly-Identified Health Risks, *Opinion on the appropriateness of the risk assessment methodology in accordance with the Technical Guidance Documents for new and existing substances for assessing the risks of nanomaterials*, Brussels: European Commission Health & Consumer Protection Directorate-General, 28 (June 2007), available at [http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihr/docs/scenihr\\_o\\_010.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_010.pdf) (hereinafter "SCENIHR 2007")

<sup>47</sup>European Chemicals Agency (ECHA), *Guidance for identification and naming of substances under REACH and CLP*, November 2011, Version 1.1 (hereinafter "ECHA 2011 Guidance"), available at [http://guidance.echa.europa.eu/docs/guidance\\_document/substance\\_id\\_en.pdf?time=1323858278](http://guidance.echa.europa.eu/docs/guidance_document/substance_id_en.pdf?time=1323858278).

<sup>48</sup>SCENIHR 2007, *supra* note 46, at 11.

<sup>49</sup>SCENIHR 2007, *supra* note 46, at 48.

and evaluating the dose-response relationship, relying on mass as an indicator of exposure and toxicity, was found to be inappropriate by the scientific committee.<sup>50</sup> Exposure assessments were also found to require modifications to reflect the physicochemical characteristics of nanomaterials and their potential to change throughout the substance's life cycle.<sup>51</sup> Indeed, since these nanomaterials may, for example, accumulate in areas with increased permeability and cross barriers such as the olfactory mucosa or the blood brain barrier,<sup>52</sup> more complex risk assessment procedures are necessary for nanomaterials.<sup>53</sup>

This problem remains even under the most stringent requirements for the 1000 tonne threshold. SCENIHR opines that, "[o]n the basis of current knowledge, the risk characterization of bulk materials as described in the TGD<sup>54</sup> cannot be directly extrapolated to nanomaterials."<sup>55</sup> The required testing and information submission may not identify its true risks due to the limitations of conventional methods.<sup>56</sup> As it stands, REACH's failure to distinguish between the bulk and nano-variants of a substance when assessing their risks "implicit[ly] (and inaccurate[ly]) [assumes] that the risk of a substance is the same at whatever scale."<sup>57</sup>

Industry has often argued that the absence of data on the fate and effect of nanoparticles on the environment and human health renders it infeasible to propose firm rules on how substances should be evaluated. By this argument, existing rules and assessment methods for

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<sup>50</sup>SCENIHR 2007, *supra* note 46, at 11.

<sup>51</sup>*ibid.*

<sup>52</sup>M. Semmler, et al. 2004, WG. Kreyling et al. 2006, Oberdorster 2004, Elder 2006, *as per* SCENIHR 2007, *supra* note 46, at 17.

<sup>53</sup>SCENIHR 2007, *supra* note 46, at 34. "... the safety evaluation of nanoparticles and nanostructures cannot rely on the toxicological and ecotoxicological profile of the bulk material that has been historically determined."

<sup>54</sup>Available at [http://ihcp.jrc.ec.europa.eu/our\\_activities/health-env/risk\\_assessment\\_of\\_Biocides/doc/tgd](http://ihcp.jrc.ec.europa.eu/our_activities/health-env/risk_assessment_of_Biocides/doc/tgd).

<sup>55</sup>SCENIHR, *supra* note 46 at 26.

<sup>56</sup>A. Franco, S.F. Hansen, S.I. Olsen, L. Butti, *Limits and Prospects of the "Incremental Approach" and the European Legislation on the Management of Risks related to Nanomaterials*, *Regul Toxicol Pharm* 48: 171-183 (2008), at 171; Crane et al. 2008, Powell et al. 2008, Shatkin 2008, *as per* K.D. Grieger, A. Baun, R. Owen, *Redefining risk research priorities for nanomaterials*, 2 *Journal of Nanoparticle Research* 12: 383-392, at 384.

<sup>57</sup>R.G. Lee & S. Vaughan, *supra* note 199, at 14.

chemicals in the bulk form should remain equally applicable to nanomaterials.<sup>58</sup> The lack of data should not, however, justify the use of conventional rules and assessment methods. Indeed, the REACH framework is not capable of estimating the health and environmental risks of nanomaterials.<sup>59</sup> This is due not only to the time, but also to the cost, of research to generate meaningful results.<sup>60</sup>

Given these limitations, REACH in its current form does not equip decision-makers for effective nano-regulation because it would lead to decisions based on hazard and exposure assessment methods ill-suited to properly assess the risks of nanomaterials.

Indeed, the United Kingdom's Royal Commission on Environmental Protection (RCEP) has highlighted that REACH may actually have an indirect but adverse effect on risk data generation for nanomaterials.<sup>61</sup> Under the current regime, if a bulk substance is characterized as hazardous, the supplier will be required to provide further information on the nature of the hazard and the possible risks involved. But if the material is non-hazardous, as is the case for the vast majority of substances from which nanomaterials are derived, this classification will be extended to the nano-form of the substance, with no additional requirements to generate data on specific nano-form effects. From there on, the substance could move through its entire life-cycle without further assessment, "despite the possibility that, although it is not considered harmful to human health or the environment in its approved use, it might have the capacity for adverse impacts at some other stage, for example, as a result of release of the products of abrasion or combustion."<sup>62</sup>

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<sup>58</sup>European Chemical Industry Council (Cefic), *Risk Assessment of nanomaterials from an industry perspective*, available at [http://ec.europa.eu/health/nanotechnology/docs/ev\\_20110329\\_co12\\_en.pdf](http://ec.europa.eu/health/nanotechnology/docs/ev_20110329_co12_en.pdf)

<sup>59</sup>K.D. Grieger, A. Baun, R. Owen, *supra* note 56, at 389.

<sup>60</sup>*ibid.*

<sup>61</sup>UK Royal Commission on Environmental Pollution, *Novel Materials in the Environment: The case of nanotechnology*, 27<sup>th</sup> Report, November 2008 (hereinafter "RCEP").

<sup>62</sup>RCEP, *supra* note 61, at 63, § 4.39.

### **3.5 Summary: Four gaps regarding nano within REACH**

REACH in its current form demonstrates four distinct and significant gaps with regard to the effective regulation of nanomaterials:

**Given these limitations, REACH in its current form does not equip decision-makers for effective nano-regulation.**

1. As REACH currently stands, it is impossible to formally identify a nanomaterial with consistency across the board. This creates confusion and serious doubts as to the capacity of REACH to generate comprehensive data on nanomaterials currently being marketed.
2. Since substance identification within REACH is exclusively based on a substance's chemical composition, a nanomaterial sharing the same chemical composition as an existing ('phase-in') bulk substance will automatically benefit from the bulk form's phase-in status, resulting in a delayed registration deadline.
3. Existing tonnage thresholds far exceed the quantities in which most nanomaterials enter the EU market, thus greatly limiting the information required for registration of nanomaterials.
4. Finally, and in addition to the foregoing limitations, any risk assessment information made available in the context of REACH would rest on inadequate testing guidelines, very seriously limiting its potential utility.

If regulators intend to use REACH as the "cornerstone for addressing health, safety and environmental risks" of nanomaterials,<sup>63</sup> it is imperative that these shortcomings be remedied.

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<sup>63</sup>See *supra* note 5.

## SECTION 4 / Addressing the nano gaps: the limits of substance identification

In an effort to address these concerns and evaluate the applicability of existing TGD (and ultimately of REACH) to nanomaterials, the Commission set up three REACH Implementation Projects on Nanomaterials (RIP-oN). The first of these RIP-oNs, addresses the specific issues revolving around substance identification. Having sought to develop scientific and technical advice on how to establish the substance identity of nanomaterials, the RIP-oN 1 advisory report highlights the existing divergence of opinions on the adequacy of current identification parameters, and presents two options for adapting substance identification rules to nanomaterials: (1) treating nanomaterials as “well defined substances” or (2) as “substances of defined chemical composition and additional identifiers.” Yet the report leaves unaddressed the underlying questions of how to adapt substance identity rules under REACH to nanomaterials. Nor does it address the material consequences that selecting one or another of the options can have on potential registration dossiers of nanomaterials. This section explores the impact of these choices in addressing the inherent gaps identified in the previous section. As a preliminary remark, it is important to consider that guidance documents (including those on substance identification) are not binding. Thus, if a definition of “nanomaterial” were to be included in such documents, registrants would still retain flexibility in deciding whether to use this definition in their registration process. Modification of the guidance document alone would therefore be insufficient to adapt REACH to effectively regulate nanomaterials.

## **4.1 Nanomaterials as “Well-Defined Substances”**

### 4.1.1 Nanomaterials derived from a bulk chemical

In its current form, REACH substance identification rules are based on chemical composition alone.<sup>64</sup> Considering nanomaterials as well defined substances<sup>65</sup> means that a nanomaterial sharing the same molecular composition as a chemical in the bulk form will be automatically assimilated to its bulk counterpart. As a consequence, other characteristics of the substance, such as its size, will not be considered identifiers for purposes of substance identification under REACH, but rather as a “characteriser.”<sup>66</sup> Consequently, traditional substance identity rules will apply; requiring not only that the nano and bulk versions be registered as one substance, but also that the substance’s tonnage threshold be calculated based on the total volume of substance (both bulk and nano combined) manufactured or imported by each party.<sup>67</sup> This has two main implications.

First, the assimilation of the nanomaterial and the bulk as one substance for registration purposes enables, in theory, the inclusion of the former under REACH regulation because of the combined tonnage. In practice, however, this may not be enough to remedy the problem identified in section 3.3. It would only bring nanomaterials into the REACH regime insofar as both the bulk and nanomaterial are manufactured or imported by the same legal entity. In effect, REACH tonnage thresholds are defined by the volumes applicable to each potential registrant.<sup>68</sup> In cases where the nanomaterial is manufactured or imported by a different legal entity than the one who manufactures or imports the bulk (regardless of whether they are regarded as one substance) tonnage thresholds will be considered independently from one another.

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<sup>64</sup>ECHA 2011 Guidance, *supra* note 477, at 14, §4.1

<sup>65</sup>ECHA 2011 Guidance, *supra* note 477 at 14 §4.1; at 18, §4.2.

<sup>66</sup>Advisory Report for the RIP-oN 1 process, *supra* note 22, at 20, § 4.1.1.1

<sup>67</sup>Commission Follow-up to the 6<sup>th</sup> REACH CA Meeting, *supra* note 22 , at 6.

<sup>68</sup>REACH, Art 6, 12.



Second, if nanomaterials are considered effectively inseparable from the bulk substance, the registration requirements under REACH provide registrants with the flexibility to decide whether or not to include information relevant to the nano-form: There is no binding obligation. The Commission opines that “all relevant information” on nanomaterials, “covering the properties, uses” and “any relevant classification and labelling” should be included in the dossiers.<sup>69</sup> However, REACH does not currently contain sufficiently binding requirements to require systematic and extensive examination of nanomaterials in the registration dossier. The lack of guidance as to what may constitute such “relevant information” allows registrants broad discretion. In fact, when determining what information may be relevant for purposes of registration of a substance, Annex VI states that simple “consideration” (as opposed to an obligation to take into account) of any information on exposure, use and risk management measures is sufficient, suggesting a lenient approach in including nanomaterials.

Similar limitations apply to the obligation to classify and label substances in the technical dossier.<sup>70</sup> The Commission Services and Member State Competent Authorities have decided in the context of the legislation on new<sup>71</sup> and existing substances,<sup>72</sup> that the specific properties of nanomaterials may warrant a “different classification and labelling compared to the bulk chemical”, including “when the nano-form is derived from a bulk substance.”<sup>73</sup> Despite this determination, the Classification, Labelling and Packaging Regulation<sup>74</sup> referred to by section 4 Annex VI of REACH contains no provisions which impose such duties. Under the CLP, registrants must “identify the relevant information” relating to the “forms and physical states in which the substance is placed on the market and in which it can be reasonably used” for purposes of haz-

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<sup>69</sup>Commission Follow-up to the 6<sup>th</sup> REACH CA Meeting, *supra* note 22, at 6.

<sup>70</sup>REACH, Art 10(a)(iv).

<sup>71</sup>Directive 67/548/EEC, NONS)

<sup>72</sup>Regulation (EC) 793/93, ESR

<sup>73</sup>Commission Follow-up to the 6<sup>th</sup> REACH CA Meeting, *supra* note 22 at 8.

<sup>74</sup>Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (hereinafter “CLP Regulation”).

ard classification. However, according to the text,<sup>75</sup> identifiable data must be readily “available”, meaning that there is no obligation to generate new data on a given substance. Considering present knowledge gaps on nanomaterials and the newness of the technologies, it can only be assumed that the “available” information to which registrants will refer to in the dossiers will relate solely or at least overwhelmingly to the bulk form of the chemical.

In addition, when actually evaluating the collected hazard information, the CLP only requires that registrants “consider”, rather than mandatorily take into account, the “forms, or physical states” of the substance in the final classification decision.<sup>76</sup> It follows that, contrary to the views of industry experts as presented in the Rip-oN 1 advisory report, there is no binding obligation to include nano-specific properties such as size, in the classification of substances under the CLP Regulation, and by consequence in the registration dossier.<sup>77</sup>

Even the registration dossier update requirement may not adequately compensate for information-deficient provisions. The requirement to update the registration dossier is triggered when registrants are aware or reasonably expected to have become aware of “[changes in] quantities manufactured or imported, new uses or new knowledge of risks to human health or the environment.”<sup>78</sup> With only the ability to rely on the (available) toxicological profile of the bulk material, and without nano-adequate test guidelines to produce meaningful results, it is unclear how companies can effectively fulfil this obligation and resolve the tension between intent of REACH and its text.<sup>79</sup>

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<sup>75</sup>CLP Regulation, Art 5.

<sup>76</sup>CLP Regulation, Art 9.

<sup>77</sup>“... the industry experts argue that substance identity is based on molecular identity, not on physical properties (...) Therefore, size as characterizer shall be used to determine appropriate classification under the CLP Regulation” *as per* the Advisory Report for the RIP-oN 1 process *supra* note 22, at 20

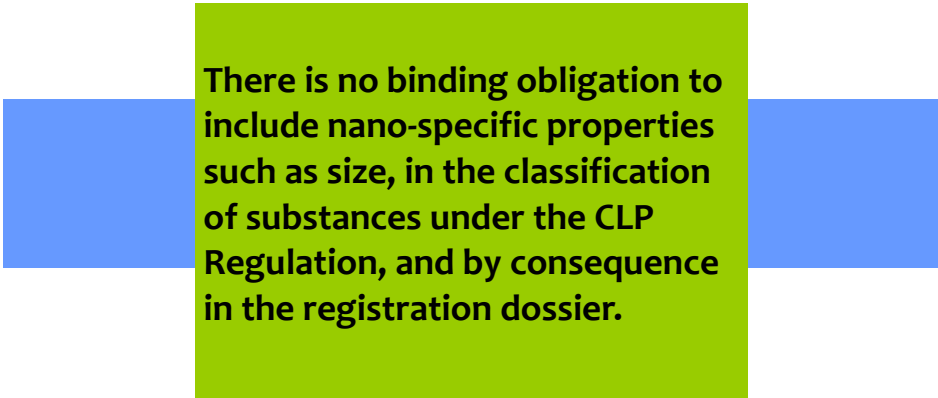
<sup>78</sup>REACH, Art 22.

<sup>79</sup>S. F. Hansen, *Regulation and Risk Assessment of Nanomaterials: Too Little, Too Late?* 20 (Feb 2009) (PhD Thesis, Technical University of Denmark), available at <http://www.nanolawreport.com/Steffen%20Foss%20Hansen%20PhD%20Thesis%20web-version.pdf>, at 20.

As a consequence, this approach towards substance identification, which maintains that substances of similar chemical composition should be regarded as identical for regulatory purposes, is inappropriate. This is especially true in view of the precedents outside the nanomaterials context in which other conventional substances with similar chemical compositions have been found to be “different” and therefore have been identified as such.<sup>80</sup>

#### 4.1.2 Nanomaterials with no corresponding bulk substance

In this case, nanomaterials would be registered in their “own right.” A number of issues would however remain. In particular, issues exist relating to the binding nature of the guidance document,<sup>81</sup> issues arising from the phase-in status of most nanomaterials currently on the market,<sup>82</sup> tonnage thresholds,<sup>83</sup> and the adequacy of test guidelines and risk assessment provisions.<sup>84</sup>



**There is no binding obligation to include nano-specific properties such as size, in the classification of substances under the CLP Regulation, and by consequence in the registration dossier.**

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<sup>80</sup>Swedish expert, the Advisory Report for the RIP-oN 1 process, *supra* note 22, Appendix 1.

<sup>81</sup>See *supra* introduction to Part III.

<sup>82</sup>See *supra* section 2.2

<sup>83</sup>See *supra* section 2.3

<sup>84</sup>See *supra* section 2.4

## **4.2 Nanomaterials as “Substances of Defined Chemical Composition and Additional Identifiers”**

As demonstrated above, while generally well-defined substances can be “completely identified by [their] chemical composition,”<sup>85</sup> there are other circumstances in which they “need to be further specified by additional identifiers.”<sup>86</sup> This may be true, for example, when substances’ “properties . . . differ significantly for reasons other than chemical composition.” Through the TGD, REACH thus distinguishes between “well- defined substances” and “substances of defined chemical composition and additional identifiers”. Like well-defined substances, substances of defined chemical composition can be either mono- or multi-constituent,<sup>87</sup> but require other parameters for proper identification.

Designating the nanomaterial as a “substance of defined chemical composition” with “additional identifiers” means that the substance cannot be adequately defined at the nano-scale by chemical composition parameters alone. Although a manufactured or imported bulk-substance with the same chemical composition may exist, the nano-form is recognized as requiring “additional identifiers” to be precisely identified. This clearly sets it apart from the bulk form, even though the bulk form itself may also possess additional identifiers. In concrete terms, this would permit the recognition of the nano-substance in its own right, independent from pre-existing bulk forms, making distinct registrations possible.

By design, engineered nanomaterials are typically manufactured for their unique properties precisely because such properties differ from those of bulk substances. This amply justifies discrimination on the basis of size.<sup>88</sup> This analysis is supported by SCENIHR’s opinion that

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<sup>85</sup>ECHA 2011 Guidance, *supra* note 47 at 14.

<sup>86</sup>ECHA 2011 Guidance, *supra* note 47 at 24, §4.2.3.

<sup>87</sup>See ECHA 2011 Guidance, *supra* note 47 at 21, table 4.1 for a clarification of the concept of the multi-constituent substance.

<sup>88</sup>Swedish expert, RIP-oN1, *supra* note 22 Appendix 1, at 67.

“the mechanisms of toxic effects of engineered nanoparticles may be dominated by those characteristics specifically introduced in order to meet the intended function of the product of interest (...), therefore, any unpredicted interactions between nanoparticles and biological systems may depend on their unique physical and chemical properties and their multiple functionalities.”<sup>89</sup> By using size as an “identifier” rather than a “characterizer”, a nanomaterial with the same chemical composition as a bulk material would be recognized as a unique substance that would need to be registered on its own. This policy decision could lead to a different implementation of the phase-in provisions, by not automatically extending the bulk form’s phase-in status to the nanoform. It would thus provide a solution to the gap identified in section 2.2.

However, such a policy decision would fall short of addressing the shortcomings of the Regulation identified in section 3.1, 3.3 and 3.4. Furthermore, as substance identification rules are defined in TGDs,<sup>90</sup> which are non-binding in nature, implementation of such a decision would still be within the discretion of each registrant.

**Making REACH the “cornerstone for addressing health, safety and environmental risks in relation with nanomaterials” will therefore require a more substantial modification of the current regulatory framework.**

In summary, although the decision to consider size as an “identifier” in the context of REACH substance identification would potentially lead to an earlier registration, such an option would not fully close the existing gaps in the Regulation in relation to nanomaterials. In particular the problems related to the existing tonnage band rules and the inadequacy of the traditional risk assessment methods persist. A further issue relates to the non-binding nature of the TGDs. Making REACH the “cornerstone for addressing health, safety and environmental risks in relation with nanomaterials” will therefore require a more substantial modification of the current regulatory framework.

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<sup>89</sup>SCENIHR, *supra* note 23, at 26.

<sup>90</sup>ECHA 2011 Guidance, *Supra* note 47 at 14, §4.

## SECTION 5 / Policy recommendations

Although REACH provides a good foundation for regulating conventional chemicals within the EU, a closer look at its mechanisms reveals significant deficiencies with respect to nano-regulation.<sup>91</sup> REACH tools, which are *de facto* applicable to nanomaterials, cannot bridge the existing information gap until they are adapted to the specific characteristics of nanomaterials. As noted by the European Parliament, lack of appropriate data on the safety and use of marketed nanomaterials jeopardizes the concept of a “safe, responsible, and integrated approach”<sup>92</sup> to nanotechnologies advocated by the European Union, preventing rather than promoting the protection of health, safety, and the environment.

The previous sections demonstrate that addressing the shortcomings identified in this study will require more than just updating the REACH TGD. This section discusses two policy options for filling the gap and explores the advantages and disadvantages of each option.

### Option 1: Modifying the REACH text, its annexes and TGDs

The first option for addressing the regulatory shortfalls described herein would be to modify the REACH regulation by inserting specific provisions applicable to nanomaterials:

- In order to effectively solve the identification issue related to substances in nano-form, a definition of ‘nanomaterial’ should be included in the REACH text. The Commission has, after years of debate, now put forward a recommendation for a nanomaterial definition. The definition is intended to provide “clear and unambiguous criteria” to identify nanomaterials for which it might be necessary to apply specific provisions, such as those relating to risk assessment.<sup>93</sup> Such a definition

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<sup>91</sup>View that is also supported by the European Parliament, see Resolution of 24 April 2009 on Regulatory Aspects of Nanomaterials (2008/2208(INI)), P6\_TA (2009)0328 (hereinafter “EU Parliament 2009 Resolution”).

<sup>92</sup>EU Parliament 2009 Resolution, *supra* note 89.

<sup>93</sup>See DG Environment, *Definition of nanomaterial*, available at: <http://ec.europa.eu/environment/chemicals/nanotech/index.htm>



should be included in Article 3 of REACH, next to the general ‘substance’ definition.

- In order to specifically address the delays arising from “phase-in” status outlined in Section 3.2 of this study, Article 3(20) should further specify that nanomaterials are not considered phase-in substances.
- In order to account for the low production volume of most nanomaterials on the market and ensure that a core data set is submitted even for nanomaterials produced in quantities of less than 1 tonne per year, the implementation of tonnage triggers should be adapted to nanomaterials. To this end, an Article 7(4)bis should be introduced with specific tonnage triggers for substances within the scope of the definition of ‘nanomaterials’. This modification would, in turn, require a corresponding modification of Article 6.
- Furthermore, it is necessary to modify Article 14(1) to require that registration dossiers for nanomaterials categorically include a CSA, in order to respond to existing concerns relating to the toxicity of some nanomaterials and the existing knowledge gap, and in order to reach the “high level of protection of human health and the environment.”
- Finally, to adapt the testing requirements and risk assessment procedures applicable to nanomaterials, thus addressing the gap outlined in Section 3.4 while also complying with the recommendations from SCENIHR,<sup>94</sup> it is necessary to update testing and risk assessment provisions and implementation guidelines to include specific nanomaterials provisions. This last change would require modifications of Annexes VI to X as well as TGDs.

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<sup>94</sup>See SCENIHR, *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, available at [http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihr/docs/scenihr\\_o\\_003b.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_003b.pdf) (hereinafter “SCENIHR 2006”), at 4, stating “SCENIHR concludes that current risk assessment methodologies require some modification in order to deal with the hazards associated with nanotechnology and in particular existing toxicological and ecotoxicological methods may not be sufficient to address all of the issues arising with nanoparticles”; SCENIHR, *Risk Assessment of Products of Nanotechnologies*, 19 January 2009, available at [http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihr/docs/scenihr\\_o\\_023.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_023.pdf), at 7, stating, “the knowledge and methodology for both exposure estimations and hazard identification needs to be further developed, validated,

These considerations focus on the registration process. Further modifications of other REACH provisions or its annexes and TGDs (e.g., adaptation of the concept of multi-constituent substances to account for coated nanomaterials) might be necessary to adapt other elements of the regulation and would require further analysis.

Considering the complexity of REACH revision processes, in particular for the revision of the core of the text, a number of stakeholders, including the Commission, have questioned the advisability and/or feasibility of renegotiating REACH itself. In this context, they recommend addressing the identified shortcomings of REACH, in particular in relation to nanomaterials, through alternative methods.

#### Option 2: Developing a stand-alone regulation

In order to avoid modifying REACH itself, while ensuring its effectiveness in addressing the unique characteristics of nanomaterials, it is possible to add a “nano patch” to the regulation in the form of a stand-alone regulation. Such a regulation would specify how REACH tools and provisions should be applied with respect to nanomaterials. To be effective, the regulation should include the following basic elements:

- A *preamble* that sets forth general principles for the management and governance of nanomaterials and indicate that all terms are used in accordance with their definition in REACH except as otherwise expressly provided;
- A definition of “nanomaterials” (or “nano-substance” to adhere to REACH terminology) in accordance with the definition proposed by the Commission;
- A specification for how the REACH concept of multi-constituent substance will be applied to nano-substances, to address the issue of coated nanomaterials;<sup>95</sup>


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<sup>95</sup>See for example ETUC: “*ETUC concept of a regulatory definition of a substance in the nanoform*” available at: [http://www.etuc.org/IMG/pdf/REACH\\_nanosubstance\\_definition\\_ETUC\\_concept.pdf](http://www.etuc.org/IMG/pdf/REACH_nanosubstance_definition_ETUC_concept.pdf)

- A requirement that all manufacturers and importers of nanomaterials in quantities over an appropriate tonnage shall submit a registration to ECHA (10kg is considered an appropriate precautionary thresholds to account for nanomaterials specificities while limiting unnecessary burden), together with subsequent tonnage thresholds to implement the REACH incremental approach.

The specifics of the registration would be cross-referenced to the relevant section in REACH and adapted where necessary. As an example, such adaptation would relate to specific tonnage triggers, registration deadlines and other aspects such as the requirement for a CSA. Similarly, the regulation annexes would specify, via a cross-reference mechanism to REACH annexes, where the relevant sections would differ for nanomaterials. Specific information requirements and deviation from the original REACH annexes provisions would require further refinement, which could be the object of a similar subsequent study.

A stand alone “nano patch” would provide a simple and elegant solution for adapting REACH to the specificities of nanomaterials. It could furthermore be conceived as flexible instrument with simplified revision procedures. It would thus be possible to adapt nano-regulation regularly without adding further layers of complexity to REACH.



**A stand alone “nano patch” would provide a simple and elegant solution for adapting REACH to the specificities of nanomaterials.**

## SECTION 6/ Conclusion

There is no doubt that REACH provides an incremental approach that could be very useful in collecting much needed information regarding nanomaterials and implementing further management measures. As the regulation currently stands, however, it contains gaps that render it completely ineffective for the regulation of nanomaterials. These gaps allow nanomaterials to enter the EU market with little or no information available regarding their potential risks, in direct contradiction with the “no data, no market” principle.

Efforts to address these issues have been undertaken, but proposals fall short of providing adequate solutions. To date, all of these proposals have focused on using the non-legally binding guidance documents to address these gaps. Our analysis demonstrates that revisions to these guidance documents alone will be inadequate to address gaps and shortcomings present in the regulation itself. While renegotiating REACH to include specific provisions on nanotechnology would be theoretically feasible, it appears practically impossible, as well as inadvisable in the current political context.

An alternative solution—better adapted to the specific context of nanomaterials—is available in the form a stand alone “nano-patch” to REACH that would tailor the REACH mechanisms to nanomaterials. Such a stand alone regulation would establish clear and legally binding provisions applicable to nanomaterials, thus providing a transparent and certain legal environment for the safe production and use of nanomaterials in the EU without adding complexity to the already complex instrument that is REACH. This solution would have the further advantage of being more flexible, and would make it possible to adapt the legal framework for nanomaterials more easily as our understanding grows. CIEL is looking forward to working with all interested parties and stakeholders to develop a blue print for such a “nano-patch” and fully realize REACH’s potential as the regulatory cornerstone for addressing the health, safety and environmental risks of nanomaterials.



15 Rue des Savoises  
1205 Geneva, Switzerland  
Tel: +41.22.789.0500  
Fax: +41.22.789.0739  
Email: [geneva@ciel.org](mailto:geneva@ciel.org)

1350 Connecticut Ave., NW, Ste. 1100  
Washington, DC 20036-1739 USA  
Tel: +1 202.785.8700  
Fax: +1 202.785.8701  
Email: [info@ciel.org](mailto:info@ciel.org)

Visit us online at [www.ciel.org](http://www.ciel.org).