



**High time
to act on
nanomaterials.**

A proposal for a 'nano patch' for EU regulation.

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Imprint

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Introduction

Over 4 years ago, the Communication from the European Commission on the Regulatory Aspects of Nanomaterials¹ (“the First Communication”) concluded that “[...] current legislation covers in principle the potential health, safety and environmental risks in relation to nanomaterials. The protection of health, safety and the environment needs mostly to be enhanced by improving implementation of current legislation.” In particular, the First Communication concluded that: “Knowledge on essential questions such as characterisation of nanomaterials, their hazards, exposure, risk assessment and risk management should be improved.” A second communication² published in October 2012 (“the Second Regulatory Review”) similarly concluded that: “Important challenges relate primarily to establishing validated methods and instrumentation for detection, characterization, and analysis, completing information on hazards of nanomaterials and developing methods to assess exposure to nanomaterials.” The Second Regulatory Review further concluded that, in the Commission’s view: “REACH sets the best possible framework for the risk management of nanomaterials when they occur as substances or mixtures but more specific requirements for nanomaterials within the framework have proven necessary. The Commission envisages modifications in some of the REACH Annexes and encourages ECHA to further develop guidance for registrations after 2013.”

The First Communication found that the following regulatory instruments regulate nanomaterials:

- REACH, the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals;³
- The European Framework Directive on Safety and Health at Work;⁴
- All product-related legislation which requires the carrying out of risk assessment and the adoption of risk management measures (Plant Protection Products, Biocidal Products, Cosmetics, etc.); and
- Environmental protection legislation (the IPPC⁵, now IED Directive⁶, Seveso Directive⁷, the Water Framework Directive⁸ and Waste legislation⁹);

The First Communication pointed out that the implementation of such instruments is a necessary tool to guarantee that the risk from the marketing and use of nanomaterials is addressed.

However, years after the implementation of the above-mentioned regulatory instruments, there is no evidence that the knowledge gap around nanomaterials has been filled or that the implementation of these instruments has been adapted to address the risk from nanomaterials. In particular, REACH and products legislation provided virtually no information whatsoever to regulators, let alone the public, on hazards, uses and risk management measures relating to nanomaterials. The conclusions of the Second Regulatory Review do not propose any action, despite the fact that the related Commission Staff Working Paper pointed out the failure of REACH to provide any significant information on nanomaterials.¹⁰

Several of the regulatory instruments referred to above have been reviewed (IED, Seveso, Plant Protection Products) since the First Communication. However, only the Biocides Regulation seems to have the potential to effectively address the challenges of nanomaterials by providing that the approval of an active substance does not cover nanomaterials, unless explicitly mentioned. In particular, the REACH Regulation, as the overarching legislation which aims to fill the knowledge gap on chemicals has proved to be incapable of doing so for nanomaterials. On one hand, whilst it is true that the implementation of REACH has been poor and industry has performed poorly when submitting information on chemicals; on the other, it has been noted, in particular, that there are obstacles in the text which make it very difficult to address these information gaps for the majority of nanomaterials on the market.¹¹

It is, therefore, necessary to review all regulatory measures that allow exposure to nanomaterials for consumers, workers and the environment without requiring a thorough and appropriate risk assessment to be carried out.

The document attached is the result of several years of experience of work on the issue of nanomaterials carried out by BUND, CIEL and ClientEarth. It draws on participation in consultations, expert groups and from interaction with all stakeholders (including Member States, European Commission, and European Parliament, the NGO community, trade unions and industry associations). It presents an initial concept note in the form of an Explanatory Note typical of a Commission proposal, to present the basic idea of a horizontal piece of legislation covering nanomaterials. This concept note suggests that the best way to address the shortcomings in the regulation of nanomaterials is to have a separate horizontal instrument that foresees general principles which apply to all nanomaterials on the market in all relevant fields (chemicals, products and environmental protection legislation). In addition to setting general principles, the proposed instrument would amend REACH as the cornerstone for filling the regulatory gaps on nanomaterials and nanotechnologies as well as sectoral chemicals legislation.

Draft proposal for Regulation of the European Parliament and of the Council on the marketing and use of nanomaterials amending Regulation 1907/2006

1. Explanatory Memorandum

1.1.1 Context of the proposal

1.1 General Context

Pursuant to the implementation plan adopted on 4 September 2002 at the Johannesburg World Summit on sustainable development, the European Union is aiming to ensure that, by 2020, chemicals are produced and used in ways that lead to the minimisation of significant adverse effects on human health and the environment.¹² In this context, the safe marketing and use of all chemical substances must be achieved. With the REACH Regulation, the Plant Protection Products Regulation, the Biocides Regulation, the Cosmetics Regulation and the Food Contact Materials legislation, the EU has put considerable effort into achieving an increased level of protection of human health and the environment. However, these regulatory instruments have not been shown to be able to respond to the challenges which are arising from the development and use of nanotechnologies and materials. The specific properties resulting from the size of these substances and their widespread use give rise to concerns which are not properly addressed by existing regulations.

Estimates and forecasts of future nanotechnology markets vary tremendously. Experts predicted¹³ that their worldwide value will increase from an estimated US\$11 billion in 2009 to between US\$26 billion and US\$ 3 trillion by 2015¹⁴. The Commission's Second Regulatory Review refers to an estimate of a global market of 11 million tonnes worth Euros 20 billion.¹⁵ However, there is no reliable information available which would confirm whether these estimates are realistic. This reflects the general lack of information on products on the market containing nanomaterials or produced using nanotechnologies (generally referred to as nanoproducts). Numerous reports and databases¹⁶ have been developed to remedy this information gap.¹⁷ All of them rely on non-verifiable declarations by producers. Some products marketed as "nano" may actually not contain any nanomaterial at all. At the same time, products actually containing nanomaterials may very well escape the radar, as producers do not label their products as "nano". This may specifically be the case in sensitive

areas, such as food. While the existing databases provide a valuable overview of the wide range of nanoproducts on the market,¹⁸ they probably only scratch the surface of the real market situation.

1.1.2 Grounds for and objectives of the proposal

Nanomaterials give rise to concern as a result of their new physico-chemical properties compared to the same chemical in its conventional form. They may have different chemical reactivity, mechanical properties (such as stiffness and elasticity), catalytic properties, and material and structural surface properties (strength, weight reduction, increased stability). Further, they may have different optical, electrical or magnetic behaviours. These characteristics can lead to improved functionality in the materials used. However, there is growing concern about the potential harm that may be connected to the novel properties of nanomaterials due to a body of emerging studies on the toxicological and ecotoxicological effects of nanomaterials.¹⁹

REACH, the primary EU regulation on chemicals, is the regulatory cornerstone for addressing the health, safety and environmental risks of nanomaterials. It is aimed at ensuring that adverse effects from the use and manufacturing of chemicals are minimised. On the one hand, REACH registration is designed to be the ideal tool to fill knowledge gap on nanomaterials. On the other, REACH evaluation is also intended to validate the data submitted by companies and to ensure that all substances do not adversely affect human health and the environment.

However, a review of the information gathered on nanomaterials in registration dossiers²⁰ showed that the information provided was either inadequate or insufficient. Further, lack of appropriate testing methods result in unclear Classification and Labelling and unreliable information on the safe handling of the substances. Therefore, despite the Commission's conclusions from the First Communication on the regulatory aspects of nanomaterials which found that, in principle, current legislation covers the potential health, safety and environmental risks in relation to nanomaterials, further action is needed.

1.1.3 Problem definition

EU chemicals legislation is aimed at guaranteeing a high level of protection of human health and of the environment. Many regulatory instruments foresee prior authorisation for the marketing and use of chemicals (biocides, pesticides, food contact materials). However, REACH also provides that for all uses of chemicals that are not exempted,²¹ there is an obligation to register chemicals before placing them on the market in order to prove that they can be used safely. Indeed, chemicals bring many benefits but some have also caused serious damage to human health and to the environment. Well-known examples amongst many are asbestos or benzene. Although these substances have now been totally banned or subjected to other controls, measures were not taken until after the damage was done because certainty about the adverse impacts of these chemicals was not available before they were used in large quantities. We must avoid repeating history in the case of nanomaterials.

Experience in the implementation of REACH has shown that potential hazards and risks from the manufacturing and use of nanomaterials may not be properly considered by existing instruments and, therefore, no effective risk management measures may be applied in the absence of specific information. The same applies to other legislation: for instance, there is no evidence of workers' protection legislation being applied differently to nanomaterials in comparison to the bulk form of the substance; equally, there is no evidence of separate risk assessments being carried out for nanoforms of biocides or pesticides or food contact materials.²²

Between 1 June 2008 when registration became an obligation and September 2012, only one chemical has been registered under REACH as a nanomaterial and other three substances are registered highlighting that the dossier contains information both on the bulk substance and on the substance in the nano form. The absence of adequate, comprehensive information for nanomaterials was recently highlighted in a project carried out by the JRC.²³ This shortcoming is a major problem faced by regulators in identifying and implementing regulatory provisions relevant to nanomaterials and to making use of the full scope of REACH mechanisms. Registration under REACH²⁴ 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 measure to manage their risk. The successful

implementation of REACH registration provisions to nanomaterials is therefore at stake.

Moreover, other pieces of legislation do not regulate nanomaterials at all or cover them only partially, demonstrating the need to close regulatory gaps.

The proposed Regulation aims at setting common principles for the regulation of nanomaterials applicable to the entire spectrum of legislation that could be relevant to nanomaterials. It also aims to amend existing Regulations for the purpose of making them "nano fit", particularly through a "nano patch" for the REACH Regulation as the cornerstone for assessing and regulating chemical substances in the EU.

1.1.4 The issue or problems requiring action

Policy issue 1: Definition

There is no commonly agreed definition of nanomaterials that applies to all regulatory frameworks. Only the Biocides Regulation²⁵ contains a definition of nanomaterials that is derived from the one recommended by the Commission on 18 October 2011.²⁶ In particular, under REACH, size is not even listed as information necessary to enable each substance to be identified. Further, under other chemicals and products legislation, the assessment of the substance in the nano form is not required to be separate from the conventional form of the substance. As a result, manufacturers, users and importers of nanomaterials are free to document hazards and risk from nanomaterials using the data from the substance in the conventional form. Thus, the information is not tailored to the specific properties that the size of the substance entails in terms of toxicity and ecotoxicity. It follows that this is a barrier to defining and implementing appropriate risk management measures where they may be needed.

Policy issue 2: Status

In addition to both the lack of a definition and the existence of obstacles in substance identification, further problems have been highlighted in relation to REACH, which is designed to be the main regulatory tool for gathering information on nanomaterials on the market. REACH distinguishes 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"). It was agreed by the Commission, ECHA, and Member States' Competent Authorities that nanoforms of existing substances (i.e. those with an EINECS number)

would, by default, be treated as phase-in substances. In case the EINECS entries are shared, the substances will maintain the phase-in status. As a result, in the current form of REACH, 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 status²⁷. Therefore, the fact that the nanoform of the substance was introduced on the market at a different time is of no consequence for the definition of their status. This means that nano forms of phase-in substances benefit from the delayed registration deadlines for pre-registered substances and they will not be registered before 2018 unless they are manufactured in very high quantities.

Further, for nanoforms of phase-in substances, there would be an obligation to submit only information on physico-chemical data of the substance, unless the parent substance is likely to be a CMR or a PBT, or falls in a hazard class of the CLP for substances with dispersive and diffuse uses.²⁸ As a result, no toxicological and eco-toxicological information will be provided. Nor will the registrations include exposure information, which is currently required only for certain substances. Similar concerns apply to the availability of information down the supply chain.

Policy issue 3: Thresholds

REACH requires registration of substances manufactured or imported in quantities greater than 1 tonne per year. This volume threshold appears inadequate for nanomaterials. In fact, nanomaterials, due to their properties, are generally much more reactive than their bulk counterpart, thereby increasing the risk of harmful impact of nanomaterials compared to an equivalent mass of bulk material. This increased reactivity, together with the production price of nanomaterials account for the fact that nanomaterials are usually produced in much smaller quantities than their bulk counterparts. This conclusion is also supported by empirical data: when BAuA (the German REACH Competent Authority) analysed its failed attempt to collect data concerning exposure to nanomaterials in German companies it stated: "Furthermore, the starting criterion for the questionnaire was "activities involving nanomaterials (production, use, processing) from 10 kg/year". In retrospect, this volume turned out to be too high in the establishment of this novel and "light-weight" technology, where work at laboratory scale is still characteristic."²⁹

Notwithstanding the 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. Given these limitations, REACH, in its current form, does not equip decision-makers to evaluate the risks of nanomaterials. Indeed, manufacturers and downstream users do not perform nano-specific risk assessments. A study published in German shows that, from about 40 surveyed companies, only 7 performed tests where it can be assumed that nano-specific properties were treated as such. Also of the 130 (nano) substances subject to the study, only 10 were subjected to "nano-specific" assessments.³⁰

Policy issue 4: market surveillance and consumer transparency

The lack of requirements to register or notify the use of nanomaterials, makes it impossible to have a complete overview of which nanomaterials are on the EU market, especially as there is a rapid growth of commercial applications of nanomaterials. One of the most comprehensive databases developed by the Project on Emerging Nanotechnologies (PEN) listed 212 nanoproducts in March 2006 and 1,317 in March 2011 – an increase of almost 521%.³¹ However, as the database did not systematically gather information on all nanoproducts available at a certain point of time, no one can say whether these figures actually reflect the development of the market, illustrating the general lack of transparency on the market situation. Due to the missing market transparency, authorities responsible for market surveillance might be unable to react if a certain nanomaterial should be found to pose a health or environmental risk. This may delay urgently needed action (like a recall of affected products) in emergency situations.

Voluntary reporting systems were developed in the UK, and one-time voluntary surveys carried out in Germany³², Ireland and Denmark. All voluntary reporting schemes had very limited outcomes and did not provide adequate answers on uses, volumes and possible exposure to nanomaterials.^{33,34} For this reason, France has approved in 2011 a mandatory reporting scheme at national level.

The general lack of market transparency also affects consumers, who are unable to make informed choices about purchasing nanoproducts as they can usually not be identified, due to a lack of labelling requirements. The new

cosmetics, consumer information in food, and biocides regulations address these issues by introducing the requirement to add the suffix “nano” in the list of ingredients, if a substance is added in the nanoform. However, for all other applications no labelling requirements are foreseen yet, and none of the mentioned labelling requirements has yet entered into force.

Policy issue 5: testing protocols

There are no finalised and recognised testing guidelines fit to properly test for nanomaterials potential hazards. However, REACH includes references to OECD standards. OECD’s Working Party on Manufactured Nanomaterials (WPMN) is coordinating tests of 59 endpoints on a set of manufactured nanomaterials to assess the applicability of existing OECD test guidelines to nanomaterials and to determine whether the comparability of testing can be confirmed³⁵. All tests conducted under the review are applying the OECD test guidelines together with OECD principles such as good laboratory practice (GLP) in order to ensure the mutual recognition of results globally. The WPMN has reviewed the OECD test guidelines and concluded that “the approaches for the testing and assessment of traditional chemicals are in general appropriate for assessing the safety of nanomaterials, but may have to be adapted to the specificities of nanomaterials”. It is important to note that this statement relates to the general approaches and does not indicate the possibility of read-across from the bulk form to the nanoform of a substance. Even in the case where the testing guidelines will not need to be adapted, the test will need to be carried out on the specific nanoform to yield adequate information. A preliminary version of guidance on sample preparation and dosimetry has now been published.³⁶

The safety aspects of nanomaterials are also addressed in the work of ISO/CEN from the point of view of standardizing methods and practices applied to nanomaterials.

Policy issue 6: workers' protection

Workers’ protection legislation foresees the obligation to carry out a risk assessment and, when risks are identified, these risks must be eliminated. However, due to the lack of information on nanomaterials, workers’ protection measures may prove to be neither adequate nor sufficient. Of particular concern is the growing level of application of nanomaterials which will lead an increased number of workers to be exposed to nanomaterials. Therefore, expo-

sure to nanomaterials that are not used in closed systems should be addressed.

1.1.5 Existing provisions in this area

As the First Communication on Regulatory Aspects of Nanomaterials points out, a wide range of EU legislation is, in principle, applicable to nanomaterials. However, only the following pieces of legislation specifically address nanomaterials:

Regulation (EC) No 1223/2009 on cosmetic products:

The EU Regulation on cosmetics products defines nanomaterials as an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1-100 nm. It provides for the obligation, from 11 July 2013, to notify electronically to the Commission cosmetic products containing nanomaterials and it also includes the obligation to indicate ingredients in the nanoform followed by the word ‘nano’ in brackets. It provides for a positive list of nanomaterials when used as UV-filters, colorants or preservatives and for the obligation to notify all other nanomaterials (inter alia identification, quantity, safety data, exposure). A public catalogue of all nanomaterials in cosmetics will be established by the Commission. The Commission may take restrictive action on the basis of a potential risk to human health, including when there is insufficient data.

Regulation (EU) No 1169/2011 on food information to consumers:

The EU Regulation on food information for consumers provides for the mandatory labelling from 13 December 2014 of any product containing engineered nanomaterials with the suffix ‘nano’ in brackets in the list of ingredients. It defines engineered nanomaterial as any “intentionally produced material that has one or more dimensions of the order of 100 nm or less or 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, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale.”

Regulation (EU) No 528/2012 Concerning the making available on the market and use of biocidal products:

The Regulation on biocides adopted the definition of nanomaterials from the Commission Recommendation of Octo-

ber 2011. It provides for the separate assessment of nanomaterials in biocidal products and it does not allow the simplified approval procedure for nanomaterials. Further, it provides for the name of all nanomaterials contained in the biocidal products to be listed followed by the word 'nano' in brackets; Finally, it provides for the obligation to clarify the appropriateness of the standard test methods, or their adaptation for nanomaterials.

Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterials

1. Member States, the Union agencies and economic operators are invited to use the following definition of the term "nanomaterial" in the adoption and implementation of legislation and policy and research programmes concerning products of nanotechnologies.
2. "Nanomaterial" means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm.
In specific cases and where warranted by concerns for the environment, health, safety or competitiveness, the number size distribution threshold of 50% may be replaced by a threshold between 1 and 50%.
3. By derogation from point 2, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials.
4. For the purposes of point 2, "particle", "agglomerate" and "aggregate" are defined as follows:
 - (a) "particle" means a minute piece of matter with defined physical boundaries;
 - (b) "agglomerate" means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components;
 - (c) "aggregate" means a particle comprising of strongly bound or fused particles.
5. Where technically feasible and requested in specific legislation, compliance with the definition in point 2 may be determined on the basis of the specific surface area by volume. A material should be considered as falling under the definition in point 2 where the specific surface area by volume of the material is greater than $60 \text{ m}^2/\text{cm}^3$. However, a material which, based on its number size distribution, is a nanomaterial should be con-

sidered as complying with the definition in point 2 even if the material has a specific surface area lower than $60 \text{ m}^2/\text{cm}^3$.

6. By December 2014, the definition set out in points 1 to 5 will be reviewed in the light of experience and of scientific and technological developments. The review should particularly focus on whether the number size distribution threshold of 50% should be increased or decreased.

The French Decree on nanomaterials' reporting system³⁷

As of 2013, producers, importers and distributors of nanomaterials on their own or in a mixture, without or in an article when intended to be released under normal and foreseeable conditions must make a declaration if they import or distribute at least 100 grams per year in France. This declaration must be made before May 1st of every year products placed on the French market in the previous year.

Information regarding the identity and uses declared will be made public with the exception of confidential information.

The declaration must give information on the identity and uses of the substance, information available regarding dangers of the substance and possible exposures, and all useful information to evaluate health and environmental risks. If the producer, importer or distributor does not comply with the declaration procedure, they risk a fine of 3000€ and an additional fine of 300 € per day.

1.1.6 Consistency with other policies

The main reason for the proposed Regulation is to provide a consistent approach to the Regulation of nanomaterials across EU law. There is a need to harmonize the definition of nanomaterials in all existing EU legislation and to fill in the gaps of existing regulatory frameworks that do not properly cover nanomaterials.

1.2. Consultation of interested parties and impact assessment

1.2.1 Consultation of interested parties

Since 2004, stakeholders (including, individual companies, industry associations, NGOs, Member State competent authorities) have been consulted in a number of ways, including public consultations, consultation of competent

authorities in the Member States, meetings of the committee of competent authorities for REACH and CLP. Further, the Commission has organized annual meetings for the Nanotechnology Safety for Success Dialogue³⁸. These dialogues have all highlighted the need for more information on nanomaterials.

In addition, since 2008, the Commission has involved stakeholders in formal discussions on the regulatory aspects of nanomaterials via the creation of the Competent Authority SubGroup on Nanomaterials (CASG nano) under REACH. The chemicals industry, environmental NGOs and workers' organizations have been involved in the RIPoN projects (Reach Implementation Projects on Nanomaterials)³⁹. The work of CASG nano has consistently highlighted the need to improve information-gathering schemes while RIPoNs have either failed to come up with a consensus solution on the substance identification rules to be applied to nanomaterials registration (RIPoN-1), and suggested guidance modifications that could be useful in closing some of these gaps (RIPoN-2 and 3). However, because of the non-binding nature of REACH guidance, it is impossible to close the identified legal gaps in the text in an efficient and consistent way⁴⁰.

In 2009, the European Parliament adopted a report at an overwhelming majority to call on the Commission to close the legal gaps on nano regulation⁴¹. The report identified a number of loopholes and called, in particular, for an in-depth revisions and adaptation of REACH to the specificities of nanomaterials, and, more generally, for the Commission to revisit all relevant Community laws to ensure safety for all applications of nanomaterials over their life cycle.

Finally, further to the consultations organized by the Commission itself, and initiatives from the Parliament, Member States and other stakeholders have taken on themselves to jointly explore the regulatory nano-related gaps and needs.

In that respect, it is important to mention the conference organized by the Dutch government in March 2012, entitled "Choice for Safety", to identify and assess the available choices to ensure proper risk assessment of nanomaterials, identify necessary actions and sequence of events. The consultation brought together 14 Member States, industry players and NGOs. Its conclusions mentioned broad support for the Commission to take urgent action

on regulating the production and use of nanomaterials, and identified two complementary ways forward which were supported by many participants:

- Amending the relevant annexes and guidance documents of REACH; recognizing that this cannot solve certain issues such as the appropriateness of tonnage limit value and exposure assessment; and
- Considering stand-alone legislation for the registration of nanosubstances, parallel with and linked to REACH.

Similar recommendations were sent to the Commission in an open letter from the governments of Austria, Belgium, Czech Republic, Denmark, Finland, France, Italy, Luxembourg, Spain, Sweden, the Netherlands and Croatia after an extensive discussion during the June 2012 Council Meeting.

Several Member States have also conducted national stakeholder dialogues to take into account opinions from a wide range of non-governmental stakeholders. For instance, in Germany, the so-called "NanoKommission", including representatives from industry, civil society groups and academia, has formulated detailed policy recommendations to close the data gaps for nanomaterials, including concrete proposals for amendments in REACH.⁴²

1.2.2 Collection and use of expertise

As part of the review process, several studies were carried out by external contractors. These included a study on a proposal for an EU Reporting System for Nanomaterials which analysed how REACH deals with nanomaterials⁴³ and a study carried out by the JRC on 25 REACH registration dossiers including information on nanomaterials.⁴⁴ Further, a Group Assessing Already Registered Nanomaterials (GAARN) was established with the purpose of building a consensus in an informal setting on best practices in assessing and managing the safety of nanomaterials under the REACH regulation. Finally, a study on risk perception and risk communication with regard to nanomaterials in the workplace has been carried out for the European Agency for Safety and Health at Work.⁴⁵

1.2.3 Impact assessment

A full impact assessment is to be conducted by the European Commission.

2. Legal elements of the proposal

2.1 Summary of the proposed action

The proposed Regulation aims at implementing a regulatory framework for the placing on the market and use of nanomaterials. It aims at remedying the weaknesses of existing provisions on nanomaterials. It is in the form of a Regulation in line with the most relevant experience with chemicals related legislation. Therefore, it will ensure a more harmonised implementation of the regulatory framework in Member States.

The proposal is composed of two parts: the first part includes general provisions applicable to all nanomaterials in the EU; the second part amends existing regulatory instruments such as REACH, the Plant Protection Products Regulation, the Cosmetics Products Regulation and the Food Contacts Materials Regulation. In particular, it provides for a definition of nanomaterials that applies to all existing regulations.

The proposed regulation also provides for an obligation to register all nanomaterials placed on the market, as well as harmonised procedures for the notification of products containing nanomaterials. The technical and scientific tasks relevant to the centralised system of notification and registration will be carried out by the European Chemicals Agency (ECHA) who has gained relevant experience from the operation of REACH. ECHA will further be responsible for coordinating the evaluation of all registered nanomaterials. The registration will be exempted for nanomaterials that are already separately assessed from their bulk form under other EU legislation (food contact materials, biocides, plant protection products). The volume thresholds for nanomaterials are lowered considerably to 10 kg per year.⁴⁶ Ten kilogrammes was initially proposed in the negotiation for REACH and it was the threshold for notification of new substances in place under the previous directive on classification, packaging and labelling.⁴⁷ The negotiators decided on 1 tonne as the threshold for registration of new substances but the special situation of nanomaterials was not considered at the time.

The Annexes to the proposal include information requirements to be submitted for registration purposes in order to document the hazards and risks deriving from nanomaterials, including tailored test guidelines.

The proposal also foresees the establishment a monitoring programme for workers potentially exposed to nanomaterials.

2.2 Legal basis

The primary objective of the Regulation is the protection of the environment. This proposal is, therefore, based on Article 192, TFEU.

2.3 Subsidiarity principle

The right for the EU to regulate nanomaterials with significant impact on the internal market and the environment is established in the TFEU. Article 3, TFEU stipulates that: “The Union shall establish an internal market. It shall work for the sustainable development of Europe based on balanced economic growth and price stability, a highly competitive social market economy, aiming at full employment and social progress, and a high level of protection and improvement of the quality of the environment”. Moreover, Article 191, TFEU states that “Union policy on the environment shall contribute to [...] preserving, protecting and improving the quality of environment, protecting human health, prudent and rational utilisation of natural resources, promoting measures at international level to deal with regional or worldwide environmental problems [...]”.

Chemical substances are regulated at the EU level. It is, therefore, desirable to have a harmonized regulation of nanomaterials across the EU which guarantees the correct functioning of the internal market.

2.4 Proportionality principle

The proposal complies with the proportionality principle for the following reasons. The proposal extends to nanomaterials the existing obligations which already apply in principle to substances in the nanoform. In so doing, it also does not exceed what is necessary, given its scope and any consequent administrative burden on industry as well as the Member States Competent Authorities.

2.5 Choice of instrument

Proposed instrument: Regulation.

Other means would not be adequate for the following reason(s):

- Differences in the transposition and/or the implementation of measures would have very serious consequences for the functioning of the internal market on chemical products. Rather than a directive, a regulation will ensure the uniform application of the new instrument throughout the EU. For this reason, regulations are the prime legal instrument for regulating chemicals at the EU level; as is the case with REACH, the Pesticides Regulation, the Food Contact materials regulation, the cosmetics Regulation and the biocides regulation.
- A regulation as legal instrument will also reduce the administrative burden and ensure clarity for industry.

2.6 Budgetary implications

The proposal will not have major budgetary implications as the registration, evaluation and notification requirements for nanomaterials will be managed by the existing European Chemicals Agency (the Agency). The Agency will receive specific fees from registrants. An initial support budget may be needed, in the form of a subsidy from the EU to set up the additional tasks for the Agency; in particular, to cover the 100% dossier and substance evaluation. This support from the EU will be limited in time as the activities of the Agency should be self-funding through fee revenues after a number of years. Detailed rules on the budget of the Agency and its implementation are already laid down in REACH Regulation (EC) No. 1907/2006. These rules shall apply accordingly in the con-

text of this Regulation. No significant budgetary implication is foreseen for the other regulatory frameworks affected by this Regulation.

2.7 Detailed explanation of the proposal

Title I – General issues

The Regulation aims at regulating nanomaterials and ensuring that tailored information on hazards and risks to human health and environment are duly documented in all the relevant regulatory frameworks related to chemicals legislation. The Regulation shall apply to any use of nanomaterials. Unless otherwise stated, the other provisions from the relevant regulatory framework apply.

The definition from Recommendation 2011/696/EU is included in the proposal for all nanomaterials marketed in the EU. The Regulation, thereby, amends the existing definitions for nanomaterials in the Cosmetic Products Regulation and the regulation on food information to consumers. The definition shall also be valid in the context of all legislation identified in the Communication from the European Commission on the Regulatory Aspects of Nanomaterials⁴⁸ as being principally applicable to nanomaterials. The recommended definition allows a deviation from the definition for the number of size distribution when health and safety concerns exist.

Title II – Communication obligations

General obligations for manufacturers and importers

Registration: The Regulation introduces a requirement for all nanomaterials to be registered under REACH with a separate dossier from their bulk materials before they can be placed on, or imported into, the EU market. All nanomaterials not registered with ECHA, according to the requirements outlined in REACH by the time of entry into force of this Regulation, are considered “non phase-in substances” according to REACH.

Production volumes: The threshold that triggers registration for nanomaterials is set at 10 kilograms per year as provided under the previous Directive on classification, packaging and labelling for the notification of new substances.⁴⁹ Registration dates will be staggered over a period of three years following the entry into force of the Regulation on the basis of production volumes (10 kg –

100 kg – 1000 kg tonnage bands). The information to be submitted will depend on the production volume with the thresholds specified above and is to be set out in Annex 2 of this regulation. A Chemical Safety Assessment, as outlined in REACH Article 14, is required for all nanomaterials registrations.

Nano-substances regarded as being registered: Substances having received a specific authorisation for the substance in the nanoform under Regulation 1107/2009 (Plant Protection Products) or under Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products. Substances authorised under Regulation 1935/2004 on food-contact materials shall be registered only for their environmental hazards and risks.

Safety Data Sheet for workers.

All suppliers of a substance in the nanoform or a mixture containing nanomaterials have to provide the recipient with a Safety Data Sheet compiled in accordance with the requirements of Annex II of REACH.

Classification and labelling inventory

Any manufacturer or importer, or group of manufacturers or importers who places on the market a nanomaterial, shall notify ECHA of the information required under Article 40 of the CLP Regulation.

Register of nanomaterials

The Regulation establishes a register of nanomaterials which requires operators to report the quantities of substances and uses in the nanoform which are produced, distributed or imported into the EU. The register is designed to achieve better understanding of the uses of nanomaterials and to allow their traceability in the supply chain.

The notification has to be sent to ECHA each year. It is mandatory if a minimum of 1 kilogram of a nanomaterial is produced, imported or distributed.

It applies to each manufacturer, importer and distributor of a substance in the nanoform on its own, in a mixture, or in an article when the substance is likely to be released (whether intentionally or not) under reasonable and foreseeable conditions during its entire life cycle, including disposal and recycling.

The obligation to register does not apply to substances on their own that have been registered for that use.

Further, on request by a consumer, any supplier of an article containing nanomaterials has an obligation to provide the consumer with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of the nanomaterial.

Labelling

In addition to the existing labelling requirements for nanomaterials in food, cosmetics and biocidal products, the Regulation establishes a requirement to label nanomaterials also found in all other consumer products that legally require labels detailing ingredients (e.g. detergents, aerosols, sprays, paints). The suffix "nano" shall be added to the name of the ingredient.

Title III

Evaluation

ECHA shall perform a compliance check for all registered nanosubstances in addition to its obligation to perform a minimum 5% of compliance checks as foreseen by Article 41 of REACH. Chronologically, priority shall be given to substances that have wide dispersive use, and substances registered above 1 tonne.

All registered nanomaterials shall be included in the CoRAP within 2 years from registration.

Title IV

Member States are required to set up monitoring surveillance programmes for workers potentially exposed to nanomaterials. The worker shall be able to undergo, if appropriate, relevant health surveillance prior to exposure and at regular intervals thereafter. This obligation does not apply to nanomaterials used in closed systems when the lack of exposure can be demonstrated. A report on the results of such health surveillance shall be submitted to the Commission.

Title V

Fees Reporting and Penalties

The Regulation empowers the Commission to establish fees for meeting the registration and notification obligations. It also mandates the European Commission to issue a report on the functioning of the Regulation on the basis of information received by Member States and the European Chemicals Agency.

Member States are required to include penalties for non-compliance with the Regulation.

Title VI

Transitional and final provisions

As the question of approved testing methods remains unresolved, transitional measures are necessary to ensure adequate testing methods are used for the production of registration data for nanomaterials. Therefore:

A registration dossier for nanomaterials must contain an explanation of the scientific appropriateness of tests used for nanomaterials and the technical adaptations and adjustments that have been made in order to respond to the specific characteristics of the materials.

Resolution of the questions relating to testing methods for nanomaterials should later entail amendment to Council Regulation No 440/2008 of 30 May 2008 on test methods.

Pursuant to each registration deadline adopted for nanomaterials, ECHA is to report on the amount and quality of information gathered through the registration of nanomaterials, with a view to recommend adaptation of the information requirements where needed.

The Commission, in collaboration with ECHA and Member States Competent Authorities will conduct a full review of the Regulation after 5 years of its entry into force.

Annexes

Annex I will contain the information to be submitted for the nanoproducts register and Annex II will contain detailed information requirements to be submitted for nanomaterials under the registration procedure.

Endnotes

- 1 Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee – Regulatory Aspects of Nanomaterials, COM (2008) 366 final.
- 2 Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee – Second Regulatory Review on Nanomaterials, COM (2012) 572 final.
- 3 Regulation (EC) No 1907/2006; OJ L 396 of 30.12.2006.
- 4 Council Directive 89/391/EEC, OJ L 183, 29.6.1989.
- 5 Council Directive 2008/1/EC concerning integrated pollution prevention and control, OJ L 24/8, 29.01.2008.
- 6 Directive 2010/75/EU on industrial emissions (integrated pollution prevention and control), OJ L 334/17, 17.12.2010.
- 7 Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances, OJ L 197/1, 24.7.2012.
- 8 Directive 2000/60/EC of the European Parliament and of the Council establishing a framework for the Community Action in the field of water policy, OJ L 237/1, 22.12.2010.
- 9 Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste, OJ L 312/3, 22.11.2008.
- 10 See Commission Staff Working Paper, Types and uses of nanomaterials, including safety aspects Accompanying the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee on the Second Regulatory Review on Nanomaterials, SWD(2012) 288 final. Page 26.
- 11 See Just out of REACH, CIEL, 2012; Information from Industry on Applied Nanomaterials and their Safety: Final Report Proposal for an EU Reporting System for Nanomaterials, Milieu Ltd and RPA Ltd, European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials (2008/2208(INI)).
- 12 page 3.
- 13 Nanotechnology: A realistic Market Assessment, BCC Research 2010.
- 14 This estimate is based on calculations including the entire value of nanotechnology-impacted products, as opposed to the value of nanotechnology-based components alone. For example, if a car uses nanotechnology-enhanced paint, the entire value of the car is integrated into the estimate rather than estimating the value of the paint alone. Thus, the lower estimate is likely to provide a more accurate picture of the short- to mid-term future of nanotechnology.
- 15 COM (2012) 572 final, Communication from the Commission to European Parliament, the Council and the European Economic and Social Committee: Second Regulatory Review on Nanomaterials, p.3.
- 16 See for example Nanowerk's Nanomaterials Database (of commercially available nanomaterials), BUND's nanoproduct database (www.nanowatch.de), and The Danish Consumer Council and Technical University of Denmark database.
- 17 A list of these can be found in section 6.1 of the Staff Working paper accompanying the second regulatory review, available @ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2012:0288:FIN:EN:PDF>.
- 18 Information available so far, tend to show that most of the products available on the market belong to the category "Home furnishing & household products", with the majority of consumer products in the subcategories "Cleaning products" and "Coatings". Cosmetics, food packaging, sports equipment also feature prominently.
- 19 See for example: 'Novel material in the environment: The Case of Nanotechnology' UK Royal Commission on Environmental Pollution, November 2008 p.13, available at <http://www.rcep.org.uk/novel%20materials/Novel%20materials%20summary.pdf>.
- 20 See Nano Support Project (Ref. Ares(2012)314828 - 16/03/2012) in which a detailed analysis of 45 dossiers likely to include information on nanomaterials was performed by the JRC in cooperation with the ECHA staff.
- 21 See Article 2 of REACH.
- 22 The Biocides directive has been revised in May 2012, and includes specific provisions for nanomaterials, including a separate risk assessment for nanomaterials containing Biocides. These provisions will enter into force on Sept. 1st 2013.
- 23 NANO SUPPORT Project Scientific technical support on assessment of nanomaterials in REACH registration dossiers and adequacy of available information (Contract AA N°07.0307/2010/581080/AA/D3).
- 24 REACH, Title II, Arts 5- 24.
- 25 Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, OJ. L 167/1, 27.6.2012
- 26 Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial. OJ. L 275/38, 20.10.2011
- 27 Phase-in definition.
- 28 See Article 12 and Annex III of REACH.
- 29 See "Exposure to nanomaterials in Germany, Results of the corporate survey of the Federal Institute for Health and Safety (BAuA) and the association of the chemicals industry (VCI) using questionnaires", Federal Institute for Health and Safety (BAuA), 24.04.2008, page 1.
- 30 See Julian Schenten, Recht und Innovation bei Nanomaterialien: Zwischenergebnisse einer juristisch-empirischen Untersuchung, StoffR 2, 2012 (upcoming).
- 31 www.nanotechproject.org/inventories/consumer/updates/.
- 32 <http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/Nanotechnology/pdf/survey.pdf>
- 33 See analysis in "Information from Industry on Applied Nanomaterials and their Safety: Final Report" prepared by Milieu Ltd. and RPA Ltd, under Contract NV.D.1/SER/2008/00105f.
- 34 For example in 2006, the German Institute for Occupational Health and Safety (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin) jointly with the the Chemical Industry Association (VCI) launched a voluntary survey with the aim of having a better understanding of the activities involving nanomaterials. The questionnaire was sent to 656 companies but only 217 companies responded (33%)
- 35 <http://webdominol.oecd.org/comnet/env/wp-nano.nsf> .
- 36 OECD (2010): Preliminary Guidance Notes on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials. ENV/JM/MONO(2010)25.
- 37 Décret No 2012-232 du 17 février 2012 relatif à la déclaration annuelle des substances à l'état nanoparticulaire pris en application de l'article L. 523-4 du code de l'environnement ; JORF No 0043 du 19 février 2012 page 2863 texte No 4.
- 38 http://ec.europa.eu/health/nanotechnology/events/ev_20110329_en.htm.
- 39 The reports from the RiPoN projects are available at <http://ec.europa.eu/environment/chemicals/nanotech/index.htm#ripon>
- 40 See for example "Just out of REACH".
- 41 Report on regulatory aspects of nanomaterials (2008/2208(INI)) <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+REPORT+A6-2009-0255+0+DOC+PDF+V0//EN>
- 42 http://www.bmu.de/files/english/pdf/application/pdf/nano_abschlussbericht3_en_bf.pdf.
- 43 Milieu, "Proposal for an EU Reporting System for Nanomaterials", Information from Industry on Applied Nanomaterials and their Safety: Final Report, May 2012.
- 44 See note 23 above.
- 45 EU-OSHA, Workplace exposure to nanoparticles, Luxembourg, 2009. Available at: http://osha.europa.eu/en/publications/literature_reviews/workplace_exposure_to_nanoparticles/view.
- 46 See note 33 above, page 46.
- 47 Directive 92/32/EEC amending for the seventh time Directive 67/54/EEC on the classification, packaging and labelling of dangerous substances, Art. 13.2.
- 48 SEC(2008) 2036.
- 49 Directive 92/32/EEC amending for the seventh time Directive 67/54/EEC on the classification, packaging and labelling of dangerous substances, Art. 13.2.



“Current legislation covers in principle the potential health, safety and environmental risks in relation to nanomaterials. The protection of health, safety and the environment needs mostly to be enhanced by improving implementation of current legislation.”

1st Regulatory Review on Nanomaterials by the Commission, June 2008

The European Parliament

“does not agree, [...] with the Commission's conclusions that

a) current legislation covers in principle the relevant risks relating to nanomaterials, and

b) that the protection of health, safety and the environment needs mostly to be enhanced by improving implementation of current legislation,

when due to the lack of appropriate data and methods to assess the risks relating to nanomaterials it is effectively unable to address their risks”

European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials, adopted virtually unanimously

“The Commission is urged to take action to guarantee the health of European citizens and the protection of the environment by ensuring that European legislation takes possible risks associated with the production and use of nanomaterials into account. ”

Joint letter of ten EU Member States and Croatia, July 2012

„Current risk assessment methods are applicable, even if work on particular aspects of risk assessment is still required. [...] Overall the Commission remains convinced that REACH sets the best possible framework for the risk management of nanomaterials when they occur as substances or mixtures but more specific requirements for nanomaterials within the framework have proven necessary. The Commission envisages modifications in some of the REACH Annexes and encourages ECHA to further develop guidance for registrations after 2013.”

2nd Regulatory Review on Nanomaterials by the Commission, Oct. 2012

"Despite the glaring need to provide proper EU-level regulation of nanomaterials, the Commission has today only committed to nano-steps. [...]. It is highly misleading to suggest that the generic rules of REACH, designed for normal substances, are appropriate for nanomaterials, and contradictory to the calls for a case-by-case approach for the risk assessment of nanomaterials."

Carl Schlyter, MEP, in reaction to the 2nd Regulatory Review on Nanomaterials by the Commission, Oct. 2012

