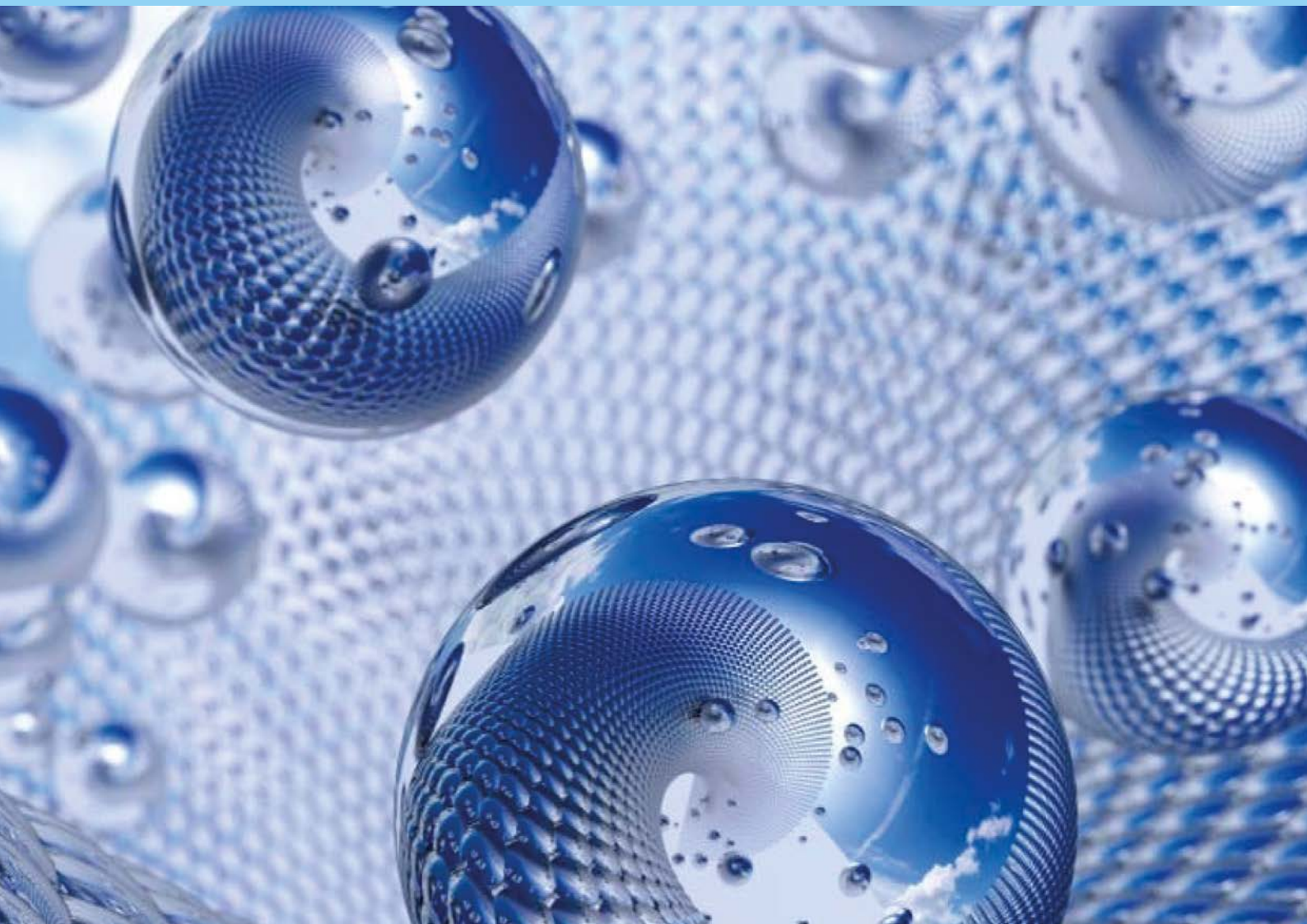




National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

The European Union Observatory for Nanomaterials

A step forward?



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Summary

In March 2016, the European Commission (EC) announced that an observatory would be the most cost-effective solution to address the need for better accessible information on nanomaterials. As a result, the online European Observatory for Nanomaterials (EUON) has been launched (euon.echa.europa.eu) in order to provide objective and reliable information about the use and safety of nanomaterials to interested audiences, including the general public. The EUON will be implemented in a step-by-step approach starting with providing basic information about nanomaterials in phase one, which will be complemented with available information (from regulatory contexts, scientific literature/projects, national registries, etc.) in the following phases (2018-2020) and a separate portal for consumers.

In this KIR-nano opinion document we discuss what can be expected from the EUON with regard to the Dutch policy aims, in particular the aim to gain better knowledge of what is on the market (which nanomaterials, products and uses). This knowledge can raise awareness among consumers and workers (transparency), and can help to follow nanomaterials along the value chain (traceability), and thereby enable priority setting in e.g. risk research, assessment, management and policy (monitoring). The need for such knowledge on the European market has also been expressed by other governments, policy makers and also by non-governmental organisations (NGOs).

The EUON intends to facilitate finding, inspecting and analysing the available information on nanomaterials and nanoproducts on the European market. A major benefit of the EUON will be that all available information on nanomaterials and nanoproducts will be collected in one place and presented in an easily understandable way which will facilitate availability and sharing of (scientific) data. Nevertheless, the EUON will not generate new data nor will it provide a complete overview of the nanomaterials and the nanoproducts on the European market in sufficient detail to be useful for consumers. In addition, it has vulnerabilities in its dependence on the data management and control in the underlying sources, the voluntary nature of contributions, and the limited resources provided by the EC to collect data and maintain the EUON.

For the aims of the Dutch government (i.e. improving traceability as well as risk assessment and management) the usefulness of the EUON depends heavily on the underlying sources. In general, the type of information needed to enable a translation from the EU situation to a national level will be limited, in particular when the national (Dutch) situation differs strongly from that of the EU.

In order to ensure that the EUON will fulfil its aims and purpose, it is key to continue urging the EC to provide necessary preconditions such as an update of REACH Annexes, a harmonised and unequivocal EU definition on nanomaterials, and (financial) future commitment of the EC.

1. Introduction

On June 14, 2017, the European Observatory for Nanomaterials (EUON) has been launched (euon.echa.europa.eu). The European Chemicals Agency (ECHA) has been entrusted by the European Commission (EC) to develop, maintain and update the EUON, in order to provide objective and reliable information about the use and safety of nanomaterials [1]. Such an instrument has been long called for, since manufactured nanomaterials increasingly find their way into industrial processes as well as consumer products, while a number of questions about their safety has not been resolved yet. However, whether an observatory is the appropriate instrument has been severely contested by non-governmental organisations, consumer groups and research organisations [2]. These discussions may well start over again now that the EUON has been publicly launched.

On request of the Interdepartmental Working group on Risks of nanomaterials of the Dutch government (IWR) KIR-nano¹ discusses in this opinion document what can be expected from the EUON with regard to the Dutch policy aims. The Dutch policy on nanomaterials aims to manage the potential risks of nanomaterials in order to ensure safety of human health and environment [3]. In order to do so, one of the goals is to gain better knowledge of what is on the market (which nanomaterials, products and uses). This knowledge can raise awareness among consumers and workers (transparency), and can help to follow nanomaterials along the value chain (traceability), and thereby a fast and adequate response if needed (risk assessment and risk management) [4]. The Dutch government has stated that in relation to nanomaterials the Dutch legislation and

regulation are – to an important extent – based on European legislation [5]. In 2009 the Dutch parliament adopted a resolution on a mandatory notification system for nanomaterials and an independent body providing information about products incorporating nanomaterials (further referred to as ‘nanoproducts’) at the market [6]. In response, the Dutch government argued that such a system would have to be established at European level.

In its second regulatory review on nanomaterials [7], the EC stated the need for better accessible information, which has been followed up by an impact assessment of potential transparency measures [8]. In March 2016, the EC announced that an observatory would be the most cost-effective solution to address this need and subsequently has initiated the EUON.

In this opinion document we discuss the political context in which the EUON has been launched (section 2), the design and organisation of the EUON (section 3) and to what extent various objectives can be achieved by the EUON (section 4). In addition, we also sketch the (diverging) expectations with respect to the EUON as voiced in interviews with stakeholders (section 5). Section 6 closes with reflections on the opportunities and limitations of the EUON as highlighted by the preceding sections. Our discussion of the EUON, as it now stands, builds on desk-research and interviews commissioned by KIR-nano as well as participation of RIVM in various committees². Furthermore, we build on earlier RIVM reports on the topic [4, 9, 10].

¹ KIR-nano is the Dutch Knowledge and Information centre for Risks of Nanotechnology established at RIVM (http://www.rivm.nl/en/Topics/N/Nanotechnology/Risks_of_Nanotechnology_Knowledge_and_Information_Centre_KIR_nano).

² These include, but are not restricted to, ECHA nanomaterials expert group (NMEG), Competent Authorities for REACH and CLP (CARACAL) subgroup on nanomaterials (CASG-nano), European Food Safety Authority (EFSA), and Scientific Committee on Consumer Safety (SCCS).

2. The political context of the EUON

There is a need for an overview of the nanomaterials and nanoproducts on the European market to address part of the uncertainty about the safety of nanomaterials. The main issues of such an overview are its function (transparency, traceability, and monitoring), the relation to other regulatory measures, and interactions between national and European measures.

The EUON is one of the instruments for addressing uncertainty about the safety of nanomaterials. From about 2004 onwards, emerging concerns about ‘nanosafety’ became widely acknowledged and a range of activities has been initiated across the world. Much effort has gone into research on health and environmental effects of nanomaterials, underlying mechanisms and methods for risk assessment. Ultimately, these efforts have to inform if and how current regulatory frameworks (e.g. for chemicals, food, cosmetics or working conditions) have to be adjusted to account for ‘nanosafety’. However, since this is a long term effort, an important question is how nanomaterials have to be treated in the meantime. In this respect, a set of basic questions is about which nanomaterials are actually on (or close to) the market, in what volumes, at which work floors and in which products. Addressing these questions is part of regulatory management, for which an observatory like the EUON is one of the possible instruments.

Though the need for creating an overview of nanomaterials on the market seems obvious, the discussion about how this has to be achieved is rather complex. Here, we discuss three main issues: 1) demands to be served by the EUON, 2) the relation of the EUON with other regulatory mechanisms, and 3) differences between monitoring at European level or at national level.

Multiple demands

Typically, the main functions of a market overview are:

- **Transparency:** from surveillance and accountability (e.g. openness about the availability of safety information) of industry to consumers’ right-to-know and freedom of choice
- **Traceability:** enabling safety information flows along value chains, regulatory enforcement and adequate responses in case of calamities

- **Monitoring:** enabling priority setting in e.g. risk research, assessment, management and policy

The importance of each of these functions is valued differently over time and across stakeholder groups. For example, in 2009 the European Parliament (EP) called for an inventory of nanomaterials at the market, including safety information and making this information publicly available before 2011 [11]. In the same year the Dutch parliament demanded a mandatory notification system on short notice to inform both consumers and workers [6], while workshops with Dutch stakeholders in 2012 yielded consumer choice and traceability as the most important functions [4]. In general, for any information collection, the purposes of collecting that information have to be clear, including their requirements in terms of what, when and how to register [10]. In general, when multiple demands are to be met concurrently, this will have significant implications for resources.

The EUON in relation to other regulatory mechanisms

A second issue concerns the question whether information gathering has to be achieved by voluntary or mandatory approaches. Where mandatory requirements under conditions of uncertainty may come along with time-consuming judicial procedures, voluntary approaches can have the benefit of being more flexible. However, since a number of voluntary initiatives for nanomaterials have failed in the past (i.e. low response rate, no reliable reflection of actual use, and only basic information becomes available [12]) and the introduction of an European initiative for product registration was severely delayed, some member states (France, Belgium, Norway and Denmark) have already established mandatory product registries at national level or are preparing to do so (Sweden). Against this background, the EC has opted for an observatory instead of a product registration. This observatory, the EUON, partly relies on voluntary cooperation of stakeholders, but also collects information already gathered in regulatory contexts. These include those administered by ECHA (REACH for chemicals [13], CLP for hazard classification [14], BPR for biocidal products [15]),

but also others, like those for food [16-21] and cosmetics [22] (including the recently published inventory of nanomaterials in cosmetics [23]), and also information from the national registries will be collected.

According to the EC the EUON is the most cost-effective solution, if only to avoid duplication of legal requirements posed by the frameworks mentioned above. However, by the same token, it makes the EUON dependent on how nanomaterials are being covered in these frameworks specifically. For example, in REACH – which will be an important source for the EUON – the current guidance documents on information requirements for nanomaterials [24-28] have little legal power as long as necessary changes to the REACH Annexes have not been adopted. Moreover, the discussions on REACH also depend on the ongoing discussion about the update of the recommendation on the definition of nanomaterials. In 2011, the EU adopted a rather broad recommendation for a definition of nanomaterials for regulatory purposes [29]. This definition has been used, but could not be adopted integrally, resulting in (slightly) different definitions in the different specific EU legislations that cover nanomaterials.

National versus European level

Finally, as has already been touched upon, there is the question whether, or what kind of, measures have to be arranged at national or at EU level. For nanomaterials nobody would favour a patchwork of national registries, but as long as the preceding issues are not agreed on, calls for national initiatives continue (e.g. Sweden only recently decided to set-up a registry). In the Netherlands, the government facilitated pilot projects with industry associations on information sharing between 2009 and 2011 (e.g. [30, 31]). Together with a pilot substance evaluation on nanosilver in 2009 [32] and formal substance evaluations under REACH on silicon dioxide³ and silver⁴, these projects were fed into the different regulatory discussions at European level (e.g. on REACH, definition, and registry). Regarding a registry both government and industry associations have urged the EC to arrange a registry at European level to avoid a patchwork of national registries [4, 9].

³ See <https://echa.europa.eu/nl/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/obo236e1807e44e8>.

⁴ See <https://echa.europa.eu/nl/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/obo236e180697558>

3. How is the EUON designed and organised?

The EUON, hosted by ECHA, is an online observatory which mainly aims to contribute to transparency of nanomaterials. It presents available information on all nanomaterials and nanoproducts from a broad range of sources to a wide audience. The EUON will be implemented in a step-by-step approach starting with providing basic information in phase one (launched at June 14, 2017) complemented with available information in the following two phases. There will be a website for professionals and a separate portal for consumers. The agreement between EC and ECHA covers an initial five years (2016-2020).

The Delegation agreement between the EC and ECHA on establishing the EUON explains that the online observatory mainly aims to contribute to transparency about the use and safety of nanomaterials, in conjunction with a foreseen update of the REACH Annexes to accommodate nanomaterials [1]. ECHA has stated that the EUON aims to be a one-stop shop for information on nanomaterials, particularly focused on presenting available information in a clear, objective and understandable way to interested audiences, including consumers, workers, industry and competent authorities of the EU member states [33]. To this end the EUON will aim to cover information on all nanomaterials, consumer products, biocides, cosmetics, food, pesticides, medicine, etc., as well as occupational health and safety information. For consumers a separate portal will be developed (currently only a link to information on the general ECHA website is available).

Being an observatory, the EUON will not generate new information. Instead, it will compile available data about the use of nanomaterials and nanoproducts on the European market from a broad range of sources. Also, without horizontal definitions for nanomaterials and nanoproducts, heterogeneous data will be collected. As will be discussed below, some of the sources can be immediately accessed by ECHA, whereas for other sources agreements with other parties have to be made. Therefore, the EUON will be developed in three phases. The first phase, providing basic information has been launched June 14, 2017 (euon.echa.europa.eu). For the next phases ECHA will have to explore which sources can be added and in which order. For all activities which include launch, maintenance, further development and translation to all EU languages, ECHA receives a budget of €800.000 for the first year (2016 - 2017) and an indicative annual budget of €600.000 until 2020.

Sources of information

Currently the EUON provides general, non-specific information on nanomaterials (what they are, how they are used, and safety information). In the first year, ECHA will provide further details based on public data generated by REACH [13], CLP [14] and the Biocidal Products Regulation (BPR) [15]. Data for these regulatory frameworks are already managed and evaluated by ECHA. Whereas under the BPR separate assessment of nanomaterials is required, the REACH registrations pose several challenges in extracting nanospecific information. REACH registration requirements only apply to substances that are manufactured or imported on the European market in volumes over 1 tonne/year and for substances already on the market when REACH entered into force (so called “phase-in” substances). Transitional registration registration deadlines were introduced depending on their tonnage and/or hazardous properties (the last deadline will be 31 May 2018 for substances manufactured or imported in quantities of 1-100 tonnes per year). In addition, there is no obligation under REACH to indicate whether or not a substance is registered in nanoform. Nanomaterials sharing the same chemical composition as a non-nanomaterial with phase-in status will be included in the same dossier and will automatically benefit from the phase-in status of the non-nanomaterial, regardless of whether the nanomaterial is being newly introduced or not. If the total quantity of non-nanomaterials and nanomaterials remains below 1-100 tonnes per year, they may not have been registered (yet), and below 1 tonne per year they will not be registered at all. Moreover, REACH does not provide detailed information on substances (including their nanoforms) as present in products, because substances (including their nanoforms) are registered as they are manufactured, i.e. before they are processed or applied in a product. Finally, REACH works with rather broad product and article categories (e.g. ‘adhesive or sealant’, ‘coatings’ or ‘softeners’) and therefore will not provide specific information about products containing nanomaterials.

In the following phases, the EUON shall be complemented with available information from other sources. Currently, ECHA is exploring collaborations with national registries, i.e. France [34], Belgium [35], Denmark [36], and Sweden

(upcoming) [37]. In Norway, the existing Product Register for hazardous chemicals has been extended to indicate the presence of nanomaterials in the product [38]. Submission of data to these registries is mandatory, but the national registries have varying scopes, exemptions and technical characteristics. The French, Belgian, Norwegian and Swedish registries cover nanomaterials, where the Danish registry covers products releasing nanomaterials. In general, products that are already covered by various regulations (e.g. biocides [15], food and food contact materials [16-19]) are exempted. Pigments are generally also exempted (not in France and Norway), but also other exemptions may exist (e.g. wood conservation agents and glues in Denmark). The nanomaterials are typically characterised by the same 11 physico-chemical parameters⁵, and minimum amounts for registration may also differ (100 g per substance in France and Belgium, 100 kg in Norway, and expected to be 100 kg in Sweden). Data on the produced nanomaterials cover the use, annual amount, and

the identity of downstream users (confidential) in the French and Belgian registries. Data on articles and products include the category of application, product volume, and amount of nanomaterial in the Belgian and Danish registries. The France registry also includes trade names (confidential).

In addition, ECHA will have to discuss and agree with the owners of other information sources (e.g. from EU-funded research projects) on co-operation and exploit synergies between various existing information tools (e.g. databases that collect scientific information from EU-funded research projects like e-Nanomapper, NanoDATA), including data on use of nanomaterials in authorised regulated products (e.g. foods, food contact materials, pesticides, medicines) made available in scientific opinions (e.g. from EFSA), and voluntary contributions from stakeholders (e.g. industry, workers and consumer associations).

⁵ At least in France and Belgium, i.e. chemical name and formula (including CAS and EC numbers), particle size, particle shape, number size distribution, aggregation and agglomeration state, state of the mixture, specific surface area, surface charge, crystalline state, coating, impurities.

4. To what extent can the EUON enable transparency and consumer choice?

The limitations mentioned in the political context (section 2), but also issues arising from the use of different sources (section 3) raise the question what to expect from the EUON. In this section, we focus on the main objective as set by the EC – transparency about use and safety – as well as the two main objectives raised by Dutch stakeholders [4] – traceability (discussed under ‘safety’) and consumer choice (discussed separately in section 4.3).

4.1 Will the EUON provide insight in the use of nanomaterials and nanoproducts on the European market?

The EUON should make it easier to find, inspect and analyse the available information on nanomaterials and nanoproducts on the European market. Nevertheless, it will not provide new information nor will it provide a complete overview of the nanomaterials and the nanoproducts on the European market in sufficient detail.

The main aim of the EUON is to improve transparency of nanomaterials in products on the EU market [33]. With that intent available data about the use of nanomaterials and nanoproducts on the European market will be compiled from a broad range of sources and primarily no new data will be generated. The question, therefore, remains whether the collected information will be sufficient to fulfil its purpose, since several limitations can be indicated.

Firstly, as indicated above, a lot of nanomaterials may remain under the radar, e.g. because they remain under the REACH tonnage levels, or are exempted from national registries. Also, confidentiality issues may prove a major barrier that limits the usefulness of the EUON (e.g. can confidential data be supplied by the EUON, e.g. with pass-word protection, or will it be needed to consult the original sources for such information).

Secondly, the level of detail provided by some of the sources may hamper an adequate analysis of the nanomaterials and nanoproducts on the European market, e.g. the product and article categories in REACH (e.g. ‘adhesive or sealant’, ‘coatings’ or ‘softeners’) may appear too broad for sufficient transparency of nanomaterials. Also differences in geographical areas covered by the different sources (national, Europe, worldwide) may hamper comparisons and integrations of data. In such cases ECHA may be able to complement the information retrieved from these official sources by voluntary contributions, but these have their own limitations as well.

Finally, the budget for the EUON generates limitations to what is feasible.

Despite these limitations, the EUON can provide a more complete overview of all available information, which makes it easier to find, inspect and analyse the data and thereby saving time compared to consulting the different sources separately. Also, compiling data as facilitated by the EUON could improve an evaluation of the nanomaterials and nanoproducts on the market by ensuring that the limitations of one type of data are balanced by the strengths of another. Every data format is designed for a reason and represents information in a unique way with unique elements, metadata, and structure. Integrating data from different sources could add various levels to the dataset. The possibility to perform (cross-database) queries is important to benefit from the centralisation of information from various sources (easy way to find, inspect and analyse the information). The other way around, when the EUON can provide easily accessible data, this may stimulate data sharing and maintenance, which is key for sustainable information sharing. However, carrying through such functionality quickly requires a much larger budget than currently available.

4.2 Will the EUON provide insight into the (most important) risks of using nanomaterials and nanoproducts?

Integration of relevant and good quality data and easily accessible information should provide more insight into the risks of using nanomaterials and nanoproducts, but the EUON will not provide new scientific opinions on the safety of particular nanomaterials or applications. It will link to the outcome of existing scientific opinions and to results from EU-funded research projects for available information on human health and environmental risks of nanomaterials which will facilitate availability and sharing of scientific data.

The Delegation agreement states that with respect to risks of nanomaterials, the main purpose shall be to present available information on human health and environmental risks of nanomaterials in a clear, understandable and objective view [1]. Whether the EUON provides (additional) insight into the risks of using nanomaterials and nanoproducts depends on various factors, i.e. integration, presentation and availability of data.

The way the information of the various sources is integrated

The information on substances required under REACH is (currently) not sufficient. Identification of nanoforms, determination of the specific properties of nanomaterials, or to assess how these properties affect their behaviour and effects in humans and the environment is not required. In the national registries, the nanomaterials are typically characterised by the same eleven physico-chemical parameters (at least in France and Belgium), but information on most of these are lacking in European regulatory required information. As stated in section 4.1, by compiling the data, the limitations of one type of data could be balanced by the strengths of another.

Whether the EUON provides insight into the risks of using nanomaterials and nanoproducts depends to a large extent on how the information of the various sources (exposure and hazard information) is integrated and can complement each other. Initially, the EUON will (only) provide links to the available information.

The way the compiled information is presented and made accessible, i.e. the user interface

The user interface will differ for the various stakeholder groups, i.e. consumers, workers, industry and regulators, related to the different needs. For regulators the information needs to help in tracing nanomaterials along the value chain, and thereby enable an adequate response in case of calamities. In contrast, for consumers and workers their primary need is to know whether the nanomaterials and nanoproducts they use are safe.

The availability of relevant, complete, and good quality data

In order to assess the risks of using a particular nanomaterial or nanoproduct, it is important that the information available and used for the risk assessment is relevant, complete and of good quality. REACH only registers nanomaterials before they are processed or applied in a product and does not provide detailed information on the nanomaterials as present in products. Since the structure, size and behaviour of nanomaterials can change during the production process, also the risks of nanomaterials in a product could differ from nanomaterials before being processed into a product (primary nanomaterials).

Risk assessment information made available in the context of REACH (or other legal frameworks) will be based on test guidelines (e.g. from OECD, ISO) that often need adaptations in order to apply for nanomaterials. In case a substance in non-nanoform is characterised as non-hazardous, this classification may generally be extended to the nanoform(s) of the substance without an additional requirement to generate data on the nanoform(s). ECHA will not give scientific opinions on the safety of particular nanomaterials or applications but will link to the outcome of existing scientific opinions (e.g. from SCCS, EFSA) and results from EU-funded research projects. For easy access to scientific information, links with eNanoMapper and NanoDATA are being explored to facilitate availability and sharing of scientific data. ECHA will not be responsible for data curation but instead the responsibility for data control and management will be up to the ones providing the data.

4.3 Will the EUON improve consumer choice for products containing nanomaterials?

Based on the information provided by the EUON it is expected that it will remain difficult for the consumer to assess whether he uses a nanoproduct and what the potential health impact of such use is. Despite information being made available on a separate website for consumers, the EUON appears to be most relevant to stakeholder experts in competent authorities and industry, and at the workplace.

The EC emphasises that the EUON plays a role in communicating validated information on nanomaterials to different user groups, including consumers. Although an assumption, it is likely that the consumer is primarily interested in whether the product used contains nanomaterials (or not) and whether the use of the nanoproduct could lead to an environmental or human health risk. As the EUON currently directs consumers to the very general information on nanomaterials at the ECHA website, it is difficult to predict how the EUON will provide specific information for consumers in the future.

The observations below should therefore be seen as preliminary.

It will remain difficult for consumers to find out whether a specific product used contains nanomaterials.

As already addressed before (sections 3.1 and 4.1), a lot of nanomaterials and nanoproducts remain under the radar within REACH and the various national registries. In addition, the lack of detail provided by the various sources (i.e. broad product/article categories and no trade names) hampers an overview of the nanoproducts on the European market in sufficient detail for the consumer to find out whether the specific product used contains nanomaterials without making assumptions. The European legislations on cosmetics, biocides and food [15, 22, 39] require producers of nanoproducts to clearly indicate the presence of nanomaterials in the list of ingredients on the label (name of the ingredient, followed by 'nano' in brackets). However, these frameworks only cover a small fraction of the large variety of consumer products containing nanomaterials. Comparable labelling requirements for other types of consumer products could provide more transparency and inform consumer choice.

The EUON does not provide the consumer with ready to use information on potential health impacts of nanoproducts.

In general, also for conventional chemicals, it is difficult to gain information on what chemicals are used in consumer products. Once identified, however, potential health impacts of these chemicals are relatively easily traceable. An additional complicating factor for nanomaterials is the

fact that they (may) change from pristinely produced to applied in the product, which may have impact on their potential health effects.

As stated above (section 3.1), REACH only registers nanomaterials before they are processed or applied in a product and does not provide detailed information on the nanomaterials as present in products. Also in other legislation detailed information is often lacking. In Biocides, apart from a safety assessment of the active ingredient (e.g. a nanomaterial), such a safety assessment is also required for the biocidal product that incorporates the active ingredient. In addition, current risk assessment information (e.g. in REACH, in Biocides) is mainly based on (extrapolations from) non-nanomaterials. Labelling products with 'nano' will only give information about the presence of nanomaterials without the (potential) risk for consumers. Consequently, consumers do not necessarily understand the implications of the presence of nanomaterials.

The EUON may have the advantage of giving compiled information about the presence of nanomaterials in products and also about the implications for the consumer in order to improve consumer choice. To what extent the consumer benefits from the EUON depends on the user-friendliness of the system. The EC and ECHA aim to make the EUON as useful for consumers as possible, but state that it is up to those that provide the data to take this opportunity and help improve the availability of information on nanomaterials and make this information as relevant as possible [33].

5. How did stakeholders receive the EC course of action for the EUON?

Interviews with stakeholders show that the aims of transparency and to some extent monitoring are expected to be fulfilled by the EUON. The majority of the stakeholders, including the Dutch government, have reservations about the plans for the EUON. Other measures for risk governance of nanomaterials are proposed, e.g. adaption of regulation (e.g. REACH Annexes), harmonisation of the definition of nanomaterials, and labelling of products containing nanomaterials.

The EC course of action for the EUON is part of an ongoing discussion about regulation and risk governance of nanomaterials. Various stakeholders have publicly commented on the EC course of action and on wider issues in risk governance of nanomaterials. Commissioned by RIVM/KIR-nano, circa five representatives of each stakeholder group, i.e. regulators (including competent authorities of the EU member states and members of the EC), industry and representatives of Civil Society Organisations (CSOs)⁶, have been interviewed to gain insight in the current discussion about the EUON, including the functions transparency, traceability and monitoring (see section 2.1). As the EUON has only recently been launched, opinions reflected in these interviews were based on expectations and some (limited) information provided by the EC and ECHA.

Aim of the EUON

The EUON aims to contribute mainly to transparency of nanomaterials [1]. In the public reactions, it becomes apparent that the stakeholders do not agree on what would be feasible aims for the EUON. While Member States and CSOs tend to emphasise all three functions (i.e. transparency, traceability and monitoring), the EC and industry put more emphasis on transparency and to some extent monitoring.

The stakeholder interviews show that the aims of transparency and to some extent monitoring are expected to be fulfilled by the EUON. Traceability and further monitoring require other instruments such as a registry, regulation (e.g. REACH), and/or a harmonised definition of nanomaterials.

Scope of the EUON

The scope of the EUON as proposed by the EC was seen as too limited by several interviewed persons. The limitations seen include the use of information in the public domain, and confidentiality issues hampering exchange of information with national registries. Budget restrictions were also mentioned.

Issues of the EUON

Proponents of the EUON emphasise its potential benefits, including cost-effectiveness compared to a registry, expected contributions to transparency of nanomaterials on the market for several audiences, and contributions to monitoring. Opponents tend to criticise its voluntary nature, question its usefulness as an instrument for traceability and risk assessment, and challenge the EC's estimation of the costs and benefits of different options.

Valuation of the EUON

Most regulators and representatives from industry and CSOs see limited use for the EC plans for the EUON. However, the majority of the regulators appeared sympathetic, and offered their cooperation in making information available to the EUON.

⁶ Civil Society Organisations encompass both Non-Governmental Organisations and Trade Unions. In many cases, both subgroups have the same positions.

Other measures for risk governance of nanomaterials

Despite the fact that the EC has opted for an observatory, an EU-registry for nanomaterials would be preferred by some regulators and most CSOs (primarily because of the voluntary nature of the observatory). Most industry and some regulators do not see the need for a registry, i.e. in some industrial sectors (such as cosmetics and food) data provision is already mandatory so a registry would not provide additional information. The majority of the stakeholders stress the need for updating the REACH Annexes as an instrument for collecting hazard data. This would have to be complemented by an observatory or a registry for collecting exposure data. Other measures mentioned include adapting other regulations, harmonising the definition of nanomaterial, developing adequate test methods, labelling and inclusion of nanomaterials in safety data sheets.

Initial views of the Dutch government towards the EUON

Interviews with various Dutch regulators conducted before the launch of the EUON show that the Dutch government prefers a mandatory registration system of nanoproducts to be implemented at European level above the EC plans for

a voluntary observatory, but will cooperate loyally. Interviewed Dutch regulators share the view that the EUON will have limited use as an instrument to solve current problems in regulation and risk governance of nanomaterials. The main criticisms are referring to the quantity and quality of the information received, i.e. its voluntary nature, confidentiality issues that hamper exchange of information with national registries, varying aims, scopes and technical characteristics of the underlying sources, and budget restrictions that can hamper quality control. Interviewed Dutch regulators state that the EUON could play a role, depending on the type of information provided, in improving transparency by summarising and communicating validated information that consumers and workers can use. However, the EUON is not expected to contribute to increasing traceability or monitoring of nanomaterials. Alternatives mentioned are labelling of products (to improve transparency), emphasising the responsibility of companies to ensure traceability in the value chain and take precautions (e.g. to prepare for potential calamities), oblige employers to make a proper risk inventory and assessment (including the specific nanomaterials to avoid exposure to), application of Safe-by-Design of nanomaterials, emphasising those nanomaterials the government is concerned about and collaborate with companies in communication (using existing channels), and a mandatory EU-registry.

6. KIR-nano reflections

The EUON will collect in one place all available information on nanomaterials and nanoproducts and present it in an easily understandable way. This will help different audiences to understand what information is available and where (highest) uncertainty is. By collecting all available scientific (hazard-, exposure-, and risk-) information in one place, the EUON can increase transparency and limit uncertainties on use and safety of nanomaterials. Although it will not generate new data, an overview of existing information can to some extent help improve traceability and monitoring, and as such help the priority setting in risk research and policy.

In the management of potential risks of nanomaterials, the Dutch government aims to gain better insight in nanomaterials on the Dutch market to improve transparency, traceability, and risk assessment and management (see section 1). In principle the EUON could be a useful instrument to improve transparency, but translating information provided by the EUON on a European scale to the Dutch situation is likely to be a challenge. The usefulness depends on the availability of specific information within the underlying sources (e.g. who produces the nanomaterials/nanoproducts, in which country is the nanomaterial/nanoproduct produced or used). When the Dutch market strongly differs from the overall European picture, it is expected that the type of information needed to enable a translation from the EU situation to a national level will be limited or only available for competent authorities, hampering transparency for other stakeholders. Also for the other aims (i.e. improving traceability as well as risk assessment and management) the usefulness depends heavily on the underlying sources.

Since, the EUON is relying for a large extent on the data management and control in the underlying sources, the EUON can only provide useful and trustworthy information when information sources maintain high and up-to-date data quality. REACH is an important source of information for the EUON, and so far ECHA has published several guidance documents that will help registrants preparing REACH dossiers that cover nanoforms. However, these guidance documents have limited legal power as long as

nanospecific requirements are not included in the REACH Annexes. Consequently, REACH can currently only provide limited information on nanospecific properties, studies and risk assessment aspects. In addition, a horizontal regulatory definition of nanomaterials is lacking. Even though the EC has introduced its own recommendation of a definition of nanomaterial in 2011 [29], this is not legally binding and ambiguous, resulting in (slightly) different definitions in the different sources for the EUON (e.g. in cosmetics, biocides and food regulations). Varying definitions in the underlying sources hamper comparisons of the available information from these sources (e.g. it may result in materials being a nanomaterial in one source and not in another). Therefore, several stakeholders point out that a regulatory (horizontal) definition of nanomaterials and an update of the REACH Annexes to accommodate nanomaterials are key to make the EUON fulfil its purpose.

Another key element is the financial means provided. The delegation agreement between the EC and ECHA covers an initial period of five years which means that the EC allocates the necessary budgetary resources for ECHA to implement the tasks of setting up and maintaining the EUON until 2020. It is already stated above that the limited budget for the EUON is expected to generate limitations in what can be achieved within these five years. In addition, the lack of further commitment (beyond 2020) also raises questions and concerns about the sustainability of the EUON.


In order to ensure that the EUON will fulfil its aims and purpose, it is key to continue urging the EC to provide necessary preconditions such as an update of the REACH Annexes, a harmonised and unequivocal EU definition on nanomaterials, and (financial) future commitment of the EC. Without these key elements the EUON will rather emphasise any uncertainties on (safety of) nanomaterials instead of minimizing the uncertainties (e.g. by clearly showing lack of details in the information that should improve transparency).

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