Policy recommendations

According to a recent report by the OECD, nanotechnologies and nanomaterials will play an important part in the ‘next production revolution’, which will occur through the confluence of diverse technologies such as digital technologies, new materials and new processes.1 The key question of how to best regulate the nano-industry has been the subject of a long battle. Despite most EU Member States being in favour of a regulatory approach to monitoring, the European Commission chose to establish the ‘EU Observatory for Nanomaterials’. This Policy Brief provides information about this Observatory, how it is being developed, its limitations and why it is not an ideal option. It suggests a different monitoring scenario, based on rules which would ensure transparency, improve the ability of national authorities to track different types of nanomaterials along the supply chain, make (nano) information visible, and guarantee an adequate exchange of information on safety at all stages. Finally, it urges policy-makers to make use of foresight and ethics to address fast-moving technological convergence and the new frontiers of science and technology.

1. Introduction

Nanotechnology is technology on a very small scale. This technology exploits the advantage that the properties of certain materials are changing to a scale which makes them useful in specific applications. Nanomaterials are now found in cosmetics, computer chips, sensors, paints or TV screens; they are used to lighten materials and to deliver drugs, as anti-microbial agents in textiles, etc.

The nanoscale ranges from about 1 nm to about 100 nm. Below 1 nm we refer to the molecular scale and above 100 nm to the bulk. Nanoparticles, because they are so small, can cross cell membranes and enter the human body, where they may accumulate and trigger toxic or adverse effects, such as carcinogenicity, sensitisation, irritation, etc. Trade unions, consumer and environmental organisations have raised these concerns and believe research must continue so as to enable a better understanding of these issues.

Manufactured nanomaterials (MNM) vs other nanoparticles

When we talk about nanotechnology and nanomaterials, the discussion focuses primarily on the ‘newly’ manufactured nanomaterials used in all sorts of mixtures and final products. However, other sources of nanoparticles exist and need to be taken into consideration (welding fumes, diesel engines, electro motors, etc). These can release nanoparticles into the atmosphere, and cause damage to air quality, particularly affecting those with respiratory problems and causing a particular sub-set of problems to workers. We know from epidemiologic research into air pollution that the smaller the particles, the further they can penetrate into any living organism and the more hazardous they can be (Li et al. 2016).

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Background to the regulatory process

REACH is the EU regulation that deals with the registration (via individual dossier), evaluation and authorisation of chemicals in the European Union. It is managed by the European Chemicals Agency (ECHA). When REACH was negotiated, nanomaterials were not yet part of the EU industrial landscape and were not included in its scope.

When it was decided that they needed to be tackled, an expert group co-chaired by DG Environment and DG Growth was created. From the beginning of these regulatory discussions, trade unions, environmental associations and consumer groups asked for legislation to be adopted, as well as for meaningful engagement in a genuine discussion about potential risks, transparency and traceability (ETUC 2008 and 2010, CFDT 2014, IndustriALL 2014).

Despite lengthy discussions and various proposals from various Member States, the Commission decided to launch a public consultation to identify and develop the most adequate means to increase the transparency of nanomaterials on the market (2014). Various policy options were put on the table and, eventually, the Commission found that establishing a European nano-observatory (EU-ON) was much cheaper, more flexible and less burdensome to implement than setting up an EU-wide nano-registry.

Various Member States, the trade union movement and consumer and environmental organisations were of the opinion that ensuring transparency and traceability could only be guaranteed by knowing in which products nanomaterials were applied. For that reason, they were in favour of a nano-registry, where mandatory information about which products contained what type of nanomaterials would be recorded and stored. The objective was to understand and give direct information on exposure to nanomaterials.

2. Insufficient nano-safety information for workers at the workplace

Workers’ protection as regards health and safety in the EU is governed by the occupational health and safety directives. Among those, one key directive, the Chemical Agents Directive (CAD), deals with the risks arising from exposure to hazardous chemical agents in the workplace. It states that employers must assess and manage the risk posed by all chemical agents present in the workplace but does not indicate how.

REACH deals with the registration of chemical substances when these are introduced to the European market. It obliges companies to produce a document, the Safety Data Sheet (SDS), which contains information on the characteristics of the substance, its hazards, precautions for safe handling and toxicological information, among others. With that, employers can manage the risks that the substance might pose for workers.

Unfortunately, despite the existence of these two pieces of regulation, some safety information is still missing. For example, REACH does not currently specify that hazards information must be submitted for nanomaterials even where the properties of the material have changed.

3. Adapting REACH to improve the information of workers at the workplace

Currently, for most manufactured nanomaterials, the hazards that must be considered in the REACH registration dossier are not established sufficiently well, which is one reason why REACH needs to be adapted. However, any proposed modification to REACH can only be incorporated within REACH after 2018. Even if that indeed takes place, it will still take many years before information becomes readily available.

Currently, little information can be found in safety data sheets, leaving the employer in the product chain to guess if any risk-mitigating measures must be considered for the workplace. When dealing with uncertain risks, a precautionary approach should be applied; employers should be able to assess whether the measures they are putting in place are sufficient or not.

The absence of risk information in safety data sheets is one of the main reasons why trade unions, environmental associations and consumer groups are in favour of a nano-registry, similar to those already established in several Member States such as France, Belgium, Denmark and Sweden (countries which make up a large part of the EU nano-market).

4. A less than ideal scenario: the EU Observatory for Nanomaterials

The decision to establish the Observatory was chosen by the Commission after it had carried out an impact assessment. Through a Delegation Agreement, the Commission entrusted ECHA with the creation, management and maintenance of the Observatory.

The main reasons behind the choice were that, apart from ‘doing nothing’, this was the option with the lowest financial burden for industry and that it was a voluntary measure, hence not associated with any obligation to cooperate. Another reason that was taken into consideration was that industrial representatives claimed that the financial costs of setting up a European registration system would hamper innovation and competition (CEFIC 2014). This can be contested, as some Member States have set up national registries from which the EU could have benefited in terms of information already collected.

The Delegation Agreement signed with ECHA to establish the Observatory will be implemented in three phases.

The first phase was launched in June 2017. It will gather existing basic information that ECHA already has on its website. The second phase will take place in 2018 and will focus on the compilation and consolidation of research data from different sources, and making it more widely available. The last phase is foreseen for 2019, when the Observatory is expected to become fully operational. Although ECHA will remain focused on its main expert audience, it will try to have more edited content for other audiences and possibly include IT functionalities.2

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5. Will the EU Observatory for Nanomaterials offer solutions to the governance and regulatory issues surrounding nanomaterials?

An Observatory itself cannot offer regulatory solutions and merely restructures existing information. As such, this is an ontological question; given its nature, an Observatory can only be used to observe already-existing information.

From the beginning, several problems have been visible. The Observatory is not going to solve the lack of access to relevant safety information for nanomaterials, that REACH does not actually apply to nanomaterials and that safety data sheets are not mandatory for nanomaterials. For example, when employers are required to assess the risk associated with each chemical agent present in the workplace, they must know whether nanomaterials are present in the products used or produced in the workplace. They must also be informed about the possible adverse effects of the product if these are not reported in a safety data sheet.

The Observatory will draw most of its information from ECHA’s registration dossiers of nanomaterials, which are often insufficiently complete. Indeed, existing scientific information on the hazards of specific MNMs (and exposure levels) are frequently not entered in registration dossiers, although REACH requires that all relevant information must be included. A good example is titanium dioxide, frequently used in paints, varnishes, inks, coatings, plastics, surface treatments, etc. Recent research has focused on the risks of titanium dioxide in nanoform (Laurent et al. 2017) but the reaction from industry is that this has already been marketed over a very long time and no complaint has ever been received. Industry argues that there is no risk associated with it and, consequently, does not feel required to communicate its presence in products covered by REACH.

The Observatory will also not be in a position to verify the reliability of available information and may not be supplied with new risk information if any becomes available in the future.

6. Improving the Observatory

What is needed is to ensure that the Observatory works as an additional tool to ECHA’s main activity, encouraging companies to register their nanomaterials, requiring additional information and ensuring that enough funding is available to validate that information continuously. ECHA should focus on its core business by demanding registration dossiers of sufficient quality on nanomaterials or the nanoform of substances under REACH. The Observatory should support ECHA by making information on risks and health effects more widely available to employers.

Relevant scientific information already available on the risk assessment of MNMs should indeed be included, assessed and publicly available in registration dossiers, without waiting for current standard tests and methods to be adapted and made fit for MNMs.

7. Tackling the unknown: the need to evaluate uncertain risks in the workplace

The employer is responsible for a safe workplace, but workers need to be confident that such is the case. Since receiving relevant hazard information through safety data sheets is problematic, risk evaluation (as defined by the Chemical Agents Directive) should take place and focus on measures to reduce exposure in the workplace, even if it is not scientifically fully established that the substance actually poses a defined hazard. In that case, we talk about a concern and a precautionary approach is applied. This has led to the development of a set of precautionary components (van Broekhuizen 2011). The starting point in using this set is a link between sufficient hazards data and exposure or emission; no data – no exposure or no data – no emission. Another building block is increased transparency and communication about the presence of MNMs within the complete product chain.

It is essential to know the numbers of workers exposed as well as their working conditions. Consequently, we propose to apply in all Member States the set of precautionary components developed by van Broekhuizen (2011), using information produced by the European Trade Union Confederation; industry federations like EFFAT, IndustriALL and the Nordic Federation of Building and Wood Workers; and national unions such as the French CFDT, FNV in the Netherlands and the Belgian unions (CGSLB, CSC, FGTB), as well as Istas, the research institute of the Spanish trade union CCOO (CFDT 2014; CSC et al. 2013; EFFAT 2013; ETUC 2008, 2010; IndustriALL et al. 2014; NFBWW 2015).

Equally, the broad union approach is to build a framework to trace where nanomaterials are being produced and how they are used in different sectors and areas of application, as well as how to dispose of them (ETUI Nanodiode project 2016). For instance, agricultural workers in the fields or waste workers in landfills are the most vulnerable workforce exposed to nanomaterials and very few nanosafety measures/research studies have focused on them.

As already mentioned, exposure to MNMs is not the only concern in the workplace. Quite a number of other sources of emissions of nanoparticles have been identified nowadays. That is why opting for the proposed precautionary approach makes sense as it allows the inclusion of these other exposure sources and their association with nano-specific limit values (NFBWW 2015). Additionally, worker exposure registries at company level should be established. This approach has been applied in the Netherlands in the Guidance on Working Safely with Nanomaterials and Nanoproducst produced by employers, employees and the Dutch government (van Broekhuizen et al. 2017). Another example is the French EpiNano programme, carried out by the French Public Health Agency aimed at companies who have registered nanomaterials under the French declaration system (Chami et al. 2016).

These initiatives are in line with what trade unions have signalled, particularly the need for comprehensive education on nanomaterials and their use (ETUI 2016). This should also include the lack of updated and accurate information in workplaces on the identification of nanomaterials, their proper use and disposal, undisclosed (confidential) information on the composition of

8. Going beyond the Observatory: proposals for alternative governance solutions

As mentioned earlier, the Observatory will largely depend on the information provided in the REACH registration dossiers, with all the problems this entails. Therefore, greater priority should be given to include substances in nanoform in the substance evaluation process carried out by ECHA.

Secondly, available scientific information must be visible in the public part of the REACH registration dossier, and in a transparent manner. Currently, little to no scientific information is accessible in the public part of the registration dossier of a substance in nanoform. This leads to the conclusion that this available information has been left out of the registration dossier by the (lead) registrant for specific reasons. Unfortunately, this does not count only for substances in nanoform but for many other “normal” substances too.

A third recommendation is related to providing transparency of safety-related information. This can be done by applying Article 32.1.d of the REACH regulation. According to this Article, the supplier should provide recipients with relevant information to enable appropriate risk management measures. Then, a safety data sheet must be issued for the downstream user concerning nanomaterials applied in mixtures where any amount has been added intentionally. For each applied nanomaterial and for each hazard endpoint based on the available information in the REACH registration dossier, the safety data sheet should state clearly if this information is conclusive, non-conclusive or does not merit classification in connection with the specific hazard endpoint.

This Policy Brief also recommends that, for MNMs that do not need to be registered according to REACH, the downstream user should receive the common name of the substance with the addition of the word ‘nano’ in brackets (nano), as is currently mandatory in the Cosmetics Regulation.

Knowledge about nanomaterials is being produced in many ways and participatory cross-fertilisation is needed. National registers of nanomaterials are requesting information on safety. This information, together with more information produced by workers (on their exposure) and other civil society actors should be disseminated and shared, which will legitimise public engagement.

With the recent push for technological convergence – and the increased reliance on digital technologies, artificial intelligence, robots, new materials and new processes – nanotechnologies are again at the forefront of European industry, and regulating them will be essential in order to accompany the ‘new production revolution’ (OECD 2016). This revolution is happening at speed and society has difficulties in keeping up with the pace. For that reason, there is a need for anticipatory work on societal and ethical issues in order to shape the future of these convergent technologies.

References


IndustriALL et al. (2014) Joint declaration of the social partners of the European chemical industry (EGE and IndustriALL) on REACH and the inclusion of nanomaterials in its annexes, Brussels.


