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ORIGINAL PAPER

The European and Member States' Approaches to Regulating Nanomaterials: Two Levels of Governance

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Abstract The nanotechnologies and nanomaterials sector is a huge and growing industry. The amount of legislation already in place and still to be produced in order to regulate it will be very substantial. What process is used to produce such regulation? The answer is that very diverse regulatory approaches are and will be used. The approach taken by the European Commission diverges from the one taken by the European Parliament. Moreover, at national level, Member States add their own contribution to the process. This article attempts to describe the landscape and various regulatory actions that have been undertaken by all these actors in the European Union. It first describes the role played by the European Commission and Parliament. It then looks at specific regulatory initiatives from a more sectoral perspective: Cosmetics, Food information, Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment, Waste Electrical and Electronic Equipment and Biocides. The third part of the paper describes some major national initiatives, in particular those concerning the establishment of reporting systems for nanomaterials, mixtures, articles and consumer products containing them, as an example of how to improve the current governance in the EU and to prevent the risks to human health and the environment. The fourth part gives the perspective of the European Trade Union Confederation. Finally it presents some conclusions and policy recommendations, taking into consideration the diversity of regulatory approaches.

Keywords Nanomaterials · Nanotechnologies · European nanomaterials governance · Nano-regulation · Harmonised databases · Reporting systems

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Introduction

Regulating nanomaterials and nanotechnologies, which many assumed would be a very technical endeavour, given the scientific nature of the subject, has become a highly political exercise, with the main actors in EU governance (European Commission, European Parliament and Member States) pulling and pushing in different directions.

The way the EU approaches the regulation of nanotechnologies can be a great opportunity to learn how to regulate new and emerging technologies through a '*proactive approach*'. If the whole process becomes more content orientated and less political, numerous useful lessons will certainly be drawn.

The question is whether the currently diverging approaches of the EC, EP and Member States will eventually converge in a coherent and complementary approach. To try and shed light on the issue, the article describes the EC and EP's approaches, gives an overview of the regulatory outcomes in the field of nanomaterials for the 2004–2013 period and, finally,

describes the contrasting approach adopted by MS in their national initiatives.

EC and EP: Two Diverging Approaches

The regulatory state of play around nanomaterials is complex and difficult to understand. The process that theoretically started in 2004 has been slow, heavy and marked by contrasting approaches: EU institutions have diverging positions, a good number of Member States call for a well-defined and strict regulation, industry wants little or no regulation [1] and civil society stakeholders, including citizens organisations, environmental NGOs and trade unions call for the application of the precautionary principle and for a strict regulation [2]. In addition, the pace of scientific and technological development is much faster than the rather slow regulatory process.

The Regulatory Approach of the European Commission

In 2004, the European Commission set out its strategy on nanotechnologies and nanosciences in a Communication entitled "Towards a European strategy for Nanotechnology" [3]. At the time, the strategy stated that because of the nature of nanotechnologies, existing regulation should be examined and probably revised and that "a proactive approach should be taken".

However, the Commission's Communications of 2008 and 2012 on Regulatory Aspects of Nanomaterials concludes that current regulation covers in principle the potential health, safety and environmental risks associated to nanomaterials since these are similar to normal chemical substances. This Communication (and associated Staff Working Paper) was produced after a review of several pieces of legislation related to nanomaterials but which did not include occupational health and safety legislation. On this, the Commission expects data by 2014 [4, 5]. Generally speaking, the Commission is in favour of "better regulation" and would rather avoid new regulation for nanotechnologies, which it sees as more costly, in particular for SMEs, and hampering industrial innovation.

More recently, in 2013, the Commission has launched a public consultation on the options of possible amendment of REACH annexes for the registration of nanomaterials. This will be accompanied by an impact assessment.

A Contrasting Approach in the European Parliament

The European Parliament (EP) has an important role to play in the discussion, if only because it has a completely different view from the European Commission. As the representative of European citizens, the EP insists on adopting a safe, responsible and integrated approach to nanomaterials regulation. The EP's Resolution of 24 April 2009 on Regulatory Aspects of Nanomaterials specifically states the need for a clear and specific regulatory framework for nanomaterials and their potential health, safety and environmental problems [6].

The Parliament justifies this approach because the old paradigms such as voluntary actions and the implementation of current law have failed. It believes that new paradigms should be adopted as circumstances change and that effective governance should be based on information, transparency and specific legal provisions. It specifically disagrees with the European Commission's views and states in its Resolution that:

- Current legislation does not cover in principle the relevant risks relating to nanomaterials,
- The protection of health, safety and the environment needs mostly be enhanced by improving implementation of current legislation (Paragraph 3), and
- The concept of a *"safe, responsible and integrated approach"* to nanotechnologies advocated by the European Commission is being jeopardised "*by the lack of information on the use and on the safety of nanomaterials that are already on the market, particularly in sensitive applications with direct exposure of consumers*" (Paragraph 4).

In particular, the Parliament calls on the Commission to pursue concrete legislative changes and to focus on several key aspects.

First, it should review all relevant legislation. Specifically, the Commission should review REACH concerning inter alia:

- simplified registration for nanomaterials,
- consideration of all nanomaterials as new substances,
- a chemical safety report with exposure assessment for all registered nanomaterials,
- notification requirements for all nanomaterials placed on the market on their own, in preparations or in articles (paragraph 11).

Second, it should compile an inventory of the different types and uses of nanomaterials on the European market, respecting justified commercial secrets, and make this inventory publicly available. At the same time, it should report on the safety of these nanomaterials. (paragraph 16)

Overview of European Regulatory Activities in the Field of Nanomaterials (2004–2013)

The first deliverable that the European Commission has produced following the Parliament Resolution of 2009 (see above) has been a Recommendation on the definition of the term "nanomaterial", applicable to all EU legislation concerned [7].

Based on scientific advice from the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and the Joint Research Centre (JRC) as well as on the inputs of the different stakeholders, the recommended definition relies on an approach that considers the size of the constituent particles of a material, rather than hazard. It defines a nanomaterial as "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 %. Fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials."

Other important legal provisions referring to nanomaterials have been adopted in five legal instruments, covering the following areas: Cosmetics; Food information; Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment; Waste Electrical and Electronic Equipment; and Biocides.

- **Regulation (EC) No 1223/2009 on cosmetic products**

  This regulation includes specific provisions related to nanomaterials. Article 2, 1(k) incorporates the definition of nanomaterial as an insoluble or biopersistant material on the scale from 1 to 100 nm [8]. The regulation came into force on 1 January 2013. A notification requirement for cosmetic products containing nanomaterials prior to being placed on the market is provided for by Article 16. The notification shall contain the identification of the nanomaterial -size, physical and chemical properties- contained in cosmetic products, the toxicological profile, safety data and exposure conditions. The same provision in paragraph 10 (a) foresees an explicit publicly available catalogue of all nanomaterials used in cosmetic products placed on the market, to be made available by 2014.

  For labelling, article 19 states that the ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients, followed by the word "nano" in brackets.

- **Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (Recast)**

  In December 2008, the European Commission proposed to revise the directive on electrical and electronic equipment in order to reduce administrative burdens, extend the scope of the ban to more products and ensure coherence with new policies and legislation on chemicals and the new legislative framework for the marketing of products in the European Union.

  After several amendments to the Commission's proposal, on 2 June 2010, the European Parliament's Committee on the Environment, Public Health, and Food Safety issued the Final Report on Recast containing a number of provisions relating to nanomaterials [6] which were not accepted by the Council. The text of the Parliament included the definition of nanomaterials; a prohibition of nanosilver and long multi-walled carbon nanotubes in electrical and electronic equipment; the notification of all applications of nanomaterials in electrical and electronic equipment (EEE) to the Commission within 24 months; the assessment by the Commission of the safety of nanomaterials in EEE based on the notifications received and other safety data, and the labelling of EEE that contains nanomaterials that can lead to exposure of consumers.

  The Council adopted the Recast Directive on 27 May 2011, including a provision on nanomaterials that reads as follows:

"As soon as scientific evidence is available, and taking into account the precautionary principle, the restriction of other hazardous substances,

including any substances of very small size or with a very small internal or surface structure (nanomaterials) which may be hazardous due to properties relating to their size or structure, and their substitution by more environmentally friendly alternatives which ensure at least the same level of protection of consumers should be examined" [9].

- **Directive 2002/96/EC on waste electrical and electronic equipment (recast)**

  The text has been in the recast process since 2011. The proposal for the revised waste electrical and electronic equipment (WEEE) directive will set a new binding target for the collection of electrical and electronic equipment and might incorporate provisions on nanomaterials.

  The European Parliament adopted its second reading position on 19 January 2012 [10]. The text incorporates a provision on nanomaterials that calls the Commission to control possible risks to human health and the environment resulting from the treatment of WEEE containing nanomaterials. The Commission is moreover invited to evaluate whether amendments to Annex VII, which refers to selective treatment for materials and components of waste electrical and electronic equipment, are necessary to address nanomaterials contained in EEE.

  The European Commission issued an Opinion accepting the amendments adopted by the European Parliament in its second reading on the proposal for a recast WEEE Directive in April 2012, and the directive entered into force in August 2012 [11].

- **Regulation (EU) No. 1169/2011 on the provision of food information to consumers**

  In July 2011, the European Parliament adopted its Second Reading Position on the proposed legislation on the provision of Food Information to Consumers [12]. This new Regulation changes provisions on labelling and consolidates two Directives into one piece of legislation: Directive 2000/13/EC on labelling, presentation and advertising of foodstuffs, and Directive 90/496/EEC on nutrition labelling for foodstuffs.

  The Regulation incorporates new information to ensure consumer information and freedom of choice for food products containing nanomaterials. It also contains the definition of the term "nanomaterial" recommended by the Commission in its Recommendation.

  The Regulation mandates that all ingredients present in the form of nanomaterials should be listed in the List of Ingredients, followed by the word "nano" in brackets (Article 18, 3).

- **Regulation on biocidal products**

  The Regulation concerning the making available on the market and the use of biocidal products was adopted in May 2012 [13]. It is the responsibility of the European Chemicals Agency to manage the authorisation process biocidal products.

  The European Commission's definition of the term "nanomaterial" has been incorporated into the text (Article 3, 1z). The Commission shall nonetheless be empowered to adapt the definition of the term in view of technical and scientific progress (Article 3, 5).

  The regulation bans the most dangerous chemicals and recognises the potential hazards posed by nanomaterials. The text clarifies how active substances may be authorised and states that approval of an active substance shall not cover nanomaterials except where explicitly mentioned (Article 4).

  Annex II provides for the obligation to explain the scientific appropriateness of the standard test methods, or their adaptation to nanomaterials, in order to respond to their specific characteristics.

  Article 19 specifies the conditions for granting an authorisation. When nanomaterials are used in biocidal products, the risk to the environment, human and animal health have to be assessed separately.

  Article 25 states that there is no simplified authorisation procedure for biocidal products containing nanomaterials.

  When test methods are applied to nanomaterials, an explanation shall be provided of their scientific appropriateness for nanomaterials, and of the technical adaptations or adjustments that have been made in order to respond to the specific characteristics of these materials (Annex III).

  The regulatory text also has provisions concerning labelling for placing treated articles on the market. The rules require that the name of all nanomaterials contained in biocidal products be indicated, followed by the word "nano" in brackets (Article 58, 3d).

For the monitoring of biocidal products and treated articles which have been placed on the market, Member States have to submit to the Commission a report every 5 years on the implementation of Regulation, focusing in particular on the use of nanomaterials in biocidal products and the potential risks. (Article 65,3d).

Member States

Despite the various legislative initiatives developed at European level, the revision and implementation of current European legislation for nanomaterials will be a long and protracted process. As a consequence, Member States have gone into a direction that defers from the Commission's. Several Member States believe that REACH is not enough to regulate nanomaterials and that these should be strictly regulated. They are opting for stricter rules on their own and in doing so are challenging the Commission's position.

The system based on voluntary reporting schemes by companies or databases of products containing nanomaterials developed by other actors (such as consumer associations) is not an effective solution in this context. Despite their usefulness and contribution, such databases have considerable limitations and regulators, public authorities or the public cannot use them for adequate traceability purposes.

Several Member States recommend adopting rules that would require producers and manufacturers to submit information on nanomaterials and products containing them (including quantities, uses and potential risks). According to these countries, adopting a harmonised database at EU level would be ideal. However, since no such project seems to be coming from the EC, initiatives have been launched at national level.

- **France**

  The Environment Act of 2009 (known as the *Grenelle law)* [14] creates a framework for the surveillance of emerging technologies, including nanotechnologies. This process started by sounding out public opinion, with a public discussion on the risk of nanomaterials conducted in 2009 across France [15].

  A reporting system (*"Déclaration des substances à l'état nanoparticulaire"*) is established under the Grenelle II law of 2010 [16, Article 185]. Companies must report: identity of the registrant, identity of the substance (chemical identification of the substance, particle size distribution by number, agglomeration, aggregation, surface, etc.), quantity of nanoparticle substance produced, distributed or imported, uses and identity of professional users. There are also provisions for protecting information and safeguarding confidentiality.

  The objectives of the reporting system are threefold: to get a better understanding of which nanomaterials are manufactured, imported or put on the market in terms of identity, quantity and uses; to create traceability along the supply chain, starting from the producer, distributor, importer and professional user; and to gather knowledge regarding the risks of nanomaterials and information to the public.

  The terms of the French reporting system were set out by Decree 2012–232 published in the Official Journal on 19 February 2012 [17]. As of 1 January 2013, the annual declaration of the production, distribution and import of nanomaterials, with a minimum threshold of 100 g, is to be managed by the French Agency for Food, the Environment and Occupational Health and Safety (known by the French acronym "ANSES").

- **Belgium**

  In 2010, the Belgian EU Presidency concluded that it was necessary to have coordinated and integrated measures in favour of risk management, information and monitoring. The aim was to achieve harmonised compulsory databases of nanomaterials -and products containing them- for traceability, market surveillance, gaining knowledge for better risk prevention and for the improvement of the legislative framework. Belgium also stressed that REACH should be adapted to nanomaterials, through effective amendments, and that the labelling of products containing nanomaterials should be regulated [18].

  These measures were deemed essential in order to protect workers, the health of consumers and the environment, and at the same time guarantee the development of a secure and sound economy based on innovation and industrial applications acceptable to society, and to create quality jobs [19].

  Having in mind public health as a priority, Belgium envisages establishing a database of substances in the nanoform (according to the EC definition of nanomaterials), preparations and products present on the Belgian market, which could be harmonised with other national databases (France

and Denmark). In January 2012, the Belgian administration commissioned a legal study for the implementation of a registry in Belgium. The final report, published in 2013, explores potential options for a Belgian registry and integrates the views of the industry on providing data to simulate a traceability exercise, as well as the views of the civil society stakeholders who participated in the process [20, 21]. Based on the various options given by the report, the Belgian government drafted a royal decree which has been notified to the European Commission. Comments can be submitted by Member States until October 2013, after which date the legislation will be passed. The draft decree requires manufacturers, distributors or importers of substances at the nanoscale to register their products via an online website. The declaration will contain information on the characteristics of the substance, the annual quantity put on the market, its uses and the identity of professional downstream users, respecting confidential information.

Trade unions, environmental and consumer associations have played a key role in the process in Belgium, in supporting the establishment of a registry for nanomaterials and products containing them. These actors expect to benefit from the information declared, emphasizing the benefits for the industry, and insisting on the need to guarantee the right of all citizens to know what they work with, buy and consume [22].

- **Denmark**

  Several projects have been initiated in Denmark to research and generate knowledge about the possible environmental and health effects of nanomaterials. Surveys conducted on nanotechnological consumer products sold in Denmark have shown how difficult it was to identify nanomaterials in finished products [23]. The Danish Environmental Protection Agency added funds to the 2012 budget in order to focus on the regulation of nanomaterials and the identification of substances to be placed on the national list of "unwanted" substances [24].

  As part of the Danish Action Plan for chemicals, the authorities have proposed an information requirement scheme for nanomaterials (substance identity, characterisation, physicochemical properties, toxicity, fate and behavior, as well as ecotoxicity), which could at a later stage be incorporated into a guidance or legislation [25]. They also propose amending the Danish Chemicals Act to enable the Environment Ministry to establish a database of nanomaterials, mixtures and products containing or releasing nanomaterials. A Ministerial Order is expected to be enacted containing the detailed rules in 2014.

- **The Netherlands**

  In 2011, citing the absence of concrete actions by the European Commission, the Dutch government requested that an adequate legal framework be established for the EU [26, 27]. It noted that products incorporating nanomaterials are on the market without having been the subject of a proper risk assessment and that, therefore, traceability had to be ensured.

  In the Note issued by the Dutch government on safety of nanomaterials, the Netherlands calls the Commission to adapt the current legislation (so as to improve its application to nanomaterials), and to propose legislation on registration of nanomaterials or, alternatively, implement a market surveillance scheme. The Dutch government favours a mandatory registration of nanomaterials and products with nanoscale features, which should take place at EU level [28, 29]. The aim is to collect data in order to identify exposure scenarios and develop an adequate risk assessment for nanomaterials and products containing them.

  The policy line pursued by the Dutch government is to achieve a coherent and harmonised approach for regulating nanomaterials in the EU. Different ministries have coordinated their actions in a structured nanotechnology governance platform, bringing together other national authorities and incorporating the diversity of stakeholders in the discussions.

- **Norway**

  The Norwegian Ministry of Environment issued a communication aimed at the European Commission, European Parliament and the Council of the European Union [30]. Norway wants to contribute to the data harmonisation initiatives of other Member States and believes there is a lack of mechanisms in REACH to deal with nanomaterials.

  In concrete terms, Norway points out that proper legislation must:

  – Ensure chemical safety assessment for all nanomaterials, including exposure scenarios and safety assessment.

- Have a mandatory registration of nanoform substances, including information on coated materials.
- Lower the registration thresholds for nanomaterials so that they could be covered in REACH.
- Establish registration deadlines specific for nanomaterials, independently from the bulk form.
- Include in the legislation specific data requirements for nanomaterials such as surface area, form, reactive surface, grain size distribution and optical properties.

- **Sweden**

  The Swedish Chemical Agency (KEMI) is a supervisory authority under the Ministry of Environment whose objective is to aim for a non-toxic environment. KEMI has looked at the overall deficiencies in nanomaterials regulation, such as the lack of a definition, the inadequacy of REACH and the need for a reporting system, and published a draft proposal to amend REACH and better regulate nanomaterials [31].

  Published in 2013, the text considers REACH as the framework to regulate nanomaterials, but only if it considers nanomaterials as substances "on their own". It also requires the registration of nanomaterials under KEMI, specific information requirements, the adoption of the regulation on Classification, Labelling and Packaging of substances and mixtures (CLP) and the convention factor for the tonnage range for nanomaterials.

The European Trade Union Confederation's Perspective on Nanotechnologies and Nanomaterials

In the debate on nanotechnology regulation, civil society stakeholders in Europe have had a significant impact and shown particular interest for certain aspects of the process, in line with the interests they defend. Trade unions have been very active and focused more particularly on the implications of nanotechnologies and nanomaterials for workers in the field.

Workers are at the forefront of the industry and are key actors in the development of materials in laboratories, their manufacturing, production and transportation. They are also heavily involved and potentially negatively affected by end-of-life processes, namely disposal, reuse and recycling. Those processes are associated with difficult working conditions, almost inexistent safety measures and a lack of scientific data about the health impact of such activities. In sum, workers are involved at all levels of all work processes, with different exposure situations, and in all sectors of the industry, which justifies their interest in the regulatory process [32].

Workers are represented in the EU institutional system by the European Trade Union Confederation (ETUC). The ETUC has contributed to the nanotechnology debate in various discussion groups involving the European Commission and Member States competent authorities responsible for REACH and nanomaterials. At the beginning of 2013, the European Chemicals Agency (ECHA) created a nanomaterials working group to discuss scientific challenges. The ETUC is a member of that group, together with other civil society stakeholders and industry organisations.

For ETUC, nanotechnologies present certain advantages but also raise certain concerns. In terms of employment and economic development, ETUC recognizes the potential benefits to society in creating new and decent jobs. As a Key Enabling Technology, nanotechnologies can boost the European economy and contribute to solving environmental problem. However, in terms of occupational health and safety, working with nanomaterials combines traditional risks and exposure to new hazards, related to the use of technologies and materials that have only very recently been developed.

The Executive Committee of the ETUC adopted two resolutions on nanotechnologies and nanomaterials. The first one was adopted in 2008. The second one came out in 2010, as a result of new developments in the technology and scientific knowledge [33, 34]. The resolutions present four key messages, which can be implemented by adapting the legal text and the annexes in REACH regulation:

Application of the precautionary principle

The precautionary principle, a key driver of REACH, is also a key demand for the ETUC in the regulation of nanomaterials. Given past experiences with ultra-fine dusts and asbestos, the ETUC finds that the principle '*no data, no market*' should be applied for nanomaterials: *"Products should not be manufactured without their potential effects on human health and the environment being known unless a precautionary*

approach has been applied and made transparent to the workers".

Manufacturers should be obliged to determine whether insoluble or biopersistent nanomaterials can be released from their products at all stages of their life cycle. To do this, additional testing requirements are needed to identify respirable, biopersistent, fibrous nanomaterials of asbestos-like dimensions and corresponding toxicity.

In the same line of argumentation, the precautionary approach finds its application via the '*no data, no exposure*' principle, meaning that where no data on hazards is available, workers must not be exposed and processes have to be performed in closed systems.

The ETUC also wants workers exposed to nanomaterials to be registered, similarly to what already happens under the Chemicals Agent Directive (CAD). This implies recording nanomaterials used at the workplace, duration and levels of exposure, personal protective measures used, as well as the concentration of nanoparticles. Exposure records need to be associated to health surveillance programmes for workers during and after their work life, thus generating useful and exploitable epidemiological data.

Adoption of stricter provisions across EU legislation

ETUC considers that REACH is the adequate framework to regulate nanomaterials and collect all necessary information related to nanomaterials. Since nanomaterials are different from ordinary chemicals substances, ETUC proposes that REACH registration requirements for nanomaterials be amended: registration of production volumes under 1 tonne per year, obligation to produce a chemical safety report for nanomaterials independently of the tonnage, obligation to produce safety data sheets.

Concerning the definition of the term nanomaterial, Article 3 in REACH should be adapted and the definition should be implemented. On this, the ETUC contributed its own proposal when the EC launched its public consultation of 2010. The ETUC definition suggests that there should be a distinction between a substance in the nanoform and a substance in the bulk form. To do so, the parameters used to identify the nanoform of a substance should be size, primary particle size distribution and shape of the material.

Also, the ETUC definition of the term nanomaterial recommends that all engineered substances in the nanoform be considered as new substances. As such, they must be registered [35].

Concerning risk assessment, the Chemicals Agent Directive 98/24/EC is in principle applicable. However it should be tailored for nanomaterials by asking employers to put in place risk reduction measures appropriate for nanomaterials when the danger is not known. Additionally, insoluble or hardly soluble nanomaterials should be considered as hazardous chemical agents, unless their release from the matrix can be excluded.

Finally, the ETUC demands traceability of nanomaterials through the development of harmonised mandatory registers of nanomaterials or articles containing them. This ETUC demand is in line with the European Parliament's view and with the national proposals described in this paper.

Nanomaterials' regulation should be based on scientific knowledge

As a core demand, the ETUC wants to know that substances are safe and that there are no risks. Until now, the current state of registration dossiers of nanoforms within ECHA has shown the lack of scientific information [36]. Therefore the safety of the nanomaterials has not been sufficiently demonstrated. This is the reason why the ETUC insists on an adequate characterization of nanomaterials, in order to get the correct scientific information.

The ETUC proposes to use the primary particle size distribution (PPSD) as the main physical parameter to distinguish a substance in the nanoform, based on the number of particles with size rather than the mass in the volume.

Effective participation of civil society stakeholders

The ETUC believes that sufficient funds have to be made available to ensure proper civil society stakeholder's participation, from both the EU Commission and Member States. More specifically, the Commission should set a percentage commitment to allocate sufficient funding for societal and ethical concerns.

Conclusions and Recommendations

As described in the article, the governance of the nanotech sector has been affected by a high level of institutional divergence. This is not extraordinary but

still disappointing. With nanotechnology being a new enabling technology, EU institutions should have set aside their differences and adopted a truly innovative legislative approach, for the good of the industry, workers, citizens and the environment.

The Commission has decidedly opted for an approach based on current community legislation applying to nanomaterials, in line with the deregulatory approach that it has been promoting recently. The recent Regulatory Fitness and Performance Programme, which aims to get rid of overly complicated or outdated EU directives, makes sense for regulations that have not been sufficiently updated or are somehow disconnected from reality, but is not applicable to new and emerging technologies. Those require clear, adequate and forward-looking legal provisions.

Additionally, the fact that the Commission has adopted an approach whereby it avoids a co-decision procedure with Parliament puts in doubt the legitimacy of the decision-making process. If the EU Parliament is not involved, citizens and civil society are not well represented and the democratic process becomes diluted. More attention should be paid to the more inclusive approach promoted by the Parliament, who is asking for strict and up to date legal provisions and putting specific emphasis on human health, the environment and the long term impact nanomaterials will have on society.

Member States, the third actor in the process, are exercising their national powers by pushing forward their own regulatory initiatives. This is exemplified by the different mandatory or voluntary nanomaterials databases that they are developing. Member States are asking for a reporting system for the whole EU and since no such scheme is coming from the European Commission, they are moving forward on their own, hoping to eventually steer the European Commission towards an harmonised European database in the future.

Given the context described above, some recommendations can be made:

> First, and very practically, the Commission's definition of "nanomaterial" needs to be integrated across the different existing regulations and implemented. This is still a challenge but, if done successfully, it will serve as a testament to good governance.
>
> Secondly, the regulation of nanomaterials and nanotechnologies needs a process that is more consistent, less divergent and which involves social partners more effectively. Social dialogue can be the way out of the current lack of convergence. It has proven its effectiveness in Europe and could be used to bridge existing gaps between regulatory actors. In particular, workers and their representatives need to be more involved. They have a hands-on knowledge of production processes and can inject useful data and practical evidence into the regulatory process.
>
> Thirdly, workers safety needs to become more of a priority in the regulatory process. In the Second Regulatory Review on Nanomaterials, the Commission made an assessment of the adequacy and implementation of current EU legislation to nanomaterials but overlooked the key aspect of occupational health and safety, mentioning only a final assessment of the occupational health and safety regulation to be made in 2014. The Commission should meet this important deadline, address specific occupational health and safety issues (such as the linkage of REACH and the Chemicals Agent Directive provisions) and look into useful measures such as exposure scenarios for nanomaterials as part of the chemical safety assessment, safety data sheets, exposure records and long term medical surveillance of workers exposed to nanomaterials.

The European Trade Union Confederation (ETUC) believes that nanomaterials require a stricter regulatory approach, which effectively ensures the safety of workers. It proposes various amendments to REACH and its annexes, as well as to other EU legislation, such as Chemicals Agent Directive. It also insist on the need to apply two key principles to nanomaterials: '*no data, no market*' and '*no data, no exposure*'.

Fourthly, an effective nano-regulation would benefit from truly complementary approaches. This means implementing and revising current EU legislation (incorporating the recommended definition of the term "nanomaterials" in REACH and applying the precautionary principle underpinned in REACH), while at the same time establishing a reporting system for nanomaterials and products containing them, so as to collect information without having to rely only on the REACH timelines.

Finally, the Commission should listen to messages coming from the European Parliament and the Member States whose initiatives have been described above. Doing so will lead to a more harmonised legislation

and help avoid multiple versions of databases. It will also lead to a more robust and inclusive regulatory process for nanomaterials, which can serve as a good example for regulating future emerging technologies.

This case of nanomaterials regulation is an interesting example of how EU policy is being developed. In regulating emerging technologies, one would expect a harmonised, transparent and consistent approach based on the principles that are underpinned by the EU Treaty. The present regulatory process is far from that, marked by very antagonistic approaches, and Europe runs the risk of missing a golden opportunity to regulate and promote a robust nanosector.

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