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Risks and implications for health and the environment associated with products and waste containing nanomaterials: regulatory and management issues in the European framework

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ABSTRACT. Nanomaterials can revolutionize everyday products, but there are still many unanswered questions about the risks they may pose to human health and the environment. Inconsistent definitions and metrological issues are still of concern for manufacturers, importers and distributors who are demanded to comply with strict regulations. It is also likely that the increasing number of nanomaterial-containing products available on the market will vary the chemical and physical properties of the waste produced, which is currently treated in traditional plants without any particular differentiation. Treatment efficiency for nanomaterials-containing waste should then be addressed and the risks of uncontrolled emissions considered. Finally, the risks associated with the use of nanomaterials-containing products may not be sufficiently characterized as current exposure estimation models are not designed for estimating exposure to nanomaterials and they are likely to be affected by large uncertainties. Hence, it would be important for national and international institutions to provide. as soon as possible, harmonized regulations covering all aspects of the life cycle of products and waste containing nanomaterials. This paper is proposed as a starting point for reflection on the main regulatory and management issues associated with products and waste containing nanomaterials, focusing mainly on the European framework.

Key words: nanomaterials, nanomaterials-containing products, waste management, nanomaterials-containing waste, risk assessment.

RIASSUNTO. I nanomateriali possono rivoluzionare i prodotti di uso quotidiano, ma vi sono ancora diversi aspetti da chiarire in merito ai rischi per la salute umana e per l'ambiente. Discrepanze nelle definizioni esistenti e negli approcci metrologici rappresentano un problema per produttori, importatori e rivenditori europei che devono tuttavia confrontarsi a normative stringenti. È inoltre molto probabile che il crescente numero di prodotti contenenti nanomateriali disponibili sul mercato determinerà una variazione delle proprietà chimico fisiche dei rifiuti attualmente trattati in impianti convenzionali, senza particolari differenziazioni. L'efficacia di tali trattamenti dovrebbe pertanto essere verificata, insieme al rischio derivante da emissioni non controllate. Il rischio associato all'utilizzo dei prodotti contenenti nanomateriali potrebbe infine non essere sufficientemente caratterizzato, dal momento che i modelli esistenti non sono appositamente predisposti per quantificare l'esposizione ai nanomateriali e quindi facilmente soggetti ad una considerevole incertezza. Sarebbe dunque importante che le autorità nazionali ed internazionali predisponessero, nel minor tempo possibile, una regolamentazione armonizzata in grado di regolamentare

Introduction

In the last decade there has been a considerable increase in the number of nanomaterials-containing products (NMCP) available on the market (+500%), increasing the market value of nanomaterials (NMs) by at least ten times (1). At the same time, NMs are rapidly becoming a major challenge for regulatory bodies, which are asked to regulate materials whose properties are not yet fully understood. "Nanomaterials are revolutionizing everyday products, with benefits to society, but there are many unanswered questions about the risks they may pose to our health and the environment," said recently Simon Upton, director of Environment Organization for Cooperation and Economic Development (OECD) (1). Inconsistent definitions and metrological issues are still of concern for manufacturers, importers and distributors who are demanded to comply with regulations which are not ready for such an emerging global phenomenon. In addition, the introduction of an increasing number of NMCP in the market will reasonable change the chemical and physical properties of the waste produced. Nevertheless, no particular distinction is made for that waste, which enters the same treatment plants and recovery facilities of traditional waste. It is then reasonable to question whether the traditional disposal techniques may be suitable for nanomaterials-containing waste (NMCW), or there may be additional aspects to be considered to both ensure public health and environment protection. In this paper, we discuss the major issues concerning regulation and management of NMCP and NMCW with a focus on the European framework. In particular, in the first section critical aspects and uncertainties associated with the existing definitions and classification of NMs will be discussed, along with current concerns about the implementation of major regulations and policies. In the second section the discussion will be focused mainly on NMCW and the potential harms deriving from current management and treatments.

Regulatory issues

NM definitions

Several definitions for NM have been proposed by various governments, industries and standard organiza-

tutto il ciclo di vita dei prodotti contenenti nanomateriali. Il presente articolo si propone come spunto di riflessione sulle principali criticità normative e gestionali associate a prodotti e rifiuti contenenti nanomateriali, concentrandosi principalmente sul quadro europeo.

Parole chiave: nanomateriali, prodotti contenenti nanomateriali, gestione rifiuti, rifiuti contenenti nanomateriali, valutazione del rischio.

tions, but they are often inconsistent in their elements and scope, leading to confusion in defining what a NM is (2). For example, in the European Union (EU), the Recommendation on the Definition of Nanomaterials 2011/696/EU defines a NM as any "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 1-100 nm (3) and this definition has been recently included in the European Regulation 1881/2018 (4). Aggregates or agglomerates with particles size comprised between 1-100 nm are specifically included in the definition. Other countries adopted different definitions. For example, the United States Food and Drug Administration (FDA) extends the NM definition to materials up to 1 micron, if the material exhibits properties or phenomena attributable to its dimensions; or else, the Swiss Federal Office of Public Health and Federal Office for the Environment includes substances with primary particles, aggregates and agglomerates up to 500 nm, as well as respirable materials of up to 10 microns with nanometric side branches. The particles size distribution could be defined according to a number percentage, as required in the EU Regulation (4), or by a weight percentage, as suggested by the United States Environmental Protection Agency (EPA). Other definitions do not consider distribution thresholds at all. For example, the Health Canada and the Taiwan Council of Labor Affairs include materials larger than the nanoscale range in all dimensions if they exhibit one or more nanoscale properties/phenomena (2). International Standards ISO/TS 80004-1:2015 and ISO/TS 12901-1:2012 introduce additional definitions, for example: nano-scale (size range from 1 to 100 nm); nano-object (material with one, two or three dimensions in the nanoscale range); and nanomaterial (material with any external dimensions in the nanoscale range, or having an internal or surface structure in the nanoscale range thus including in this generic term also nano-objects and nanostructured materials).

Despite the numerous definitions based on size measurements, harmonized methods for identifying NMs do not currently exist and inconsistencies in size metrology contribute to confound policy and decision-making. It has been demonstrated that a 1% error in a mass or volume distribution measurement at the nanoscale could translate to a > 50% error in a number distribution (5). In addition, for accurate particle size measurements, the sample should meet several requirements (e.g. be homogenous, composed mostly of spherical particles and devoid of aggregates or agglomerates) which may represent the exception rather than the rule. As a result, such measurements will likely be affected by large uncertainties, bringing to confusion during registration of new products, and disparity in commercial requirements. Many questions have been raised about the size limit used for NMs classification and the effectiveness of such approach for the protection of health and the environment, especially for some household products (6). Materials with dimensions even slightly greater than 100 nm might not be classified as NMs for EU regulations and would therefore exempt from many specific requirements (e.g. the obligation to specify the presence of a NM on the cosmetic or biocide product label). This is a major challenge for regulatory bodies, which have to regulate materials on the basis of inconsistent definitions whose possible implications are not yet fully understood.

REACh and CLP

Along with the mentioned definition issues, there are other conceptual regulatory aspects that are still of concern (7,8). In particular, it is under debate whether NMs should be regulated by existing laws, or a new set of harmonized regulations should be prepared. For example, according to the European Regulation 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACh) (9), NMs have to be treated as all the other substances (Article 3.1). Nevertheless, the definition of nanomaterial adopted by the European Commission (3) has resulted in some modifications of the registration dossier: for example, the section related to the substance identity profile requires size range, shape, surface chemistry and specific surface area range for the nanoform. In 2017 the European Chemical Agency (ECHA) has improved its guidelines to help registrants preparing dossiers that cover nanoforms (10), and in the recent Regulation 2018/1881 (4) NMs are recognized to have specific toxicological profiles and exposure patterns and may therefore require specific risk assessment and adequate sets of risk management measures. Such improvements will hopefully clarify REACh registration requirements with regard to NMs and address the knowledge gap on which substances registered under REACh are placed on the market as NMs and in which quantities. It should be noted that the requirements of the Regulation 2018/1881 will enter into mandatory application by 1/1/2020, but some guidelines for the application of the test methods are still not available. To fill this gap, ECHA, in cooperation with Member States and stakeholders, is asked by the Commission to develop new documents.

Moreover, substances, and therefore NMs, should be classified and labelled according to the Regulation 1272/2008 on the Classification, Labelling and Packaging of substances and mixtures (CLP) (11). The manufacturer or the importer is obliged to notify ECHA about the classification and labelling of the NM which is going to be traded and to prepare the Safety Data Sheets (SDS). This requires a lot of available information to the manufacturer or the importer and usually, due to the general lack of knowledge about NMs' toxicological properties, a caseby-case approach will be adopted.

REACh and CLP constitute the European regulatory framework for NMs. However, some member states (e.g. France, Norway, Belgium, Denmark), particularly concerned about safety measures for NMs, have issued their own regulations requiring companies to notify NMs or products containing NMs to their national products register or "nano register". In some cases, manufacturers, importers or distributors are required to register substances when these exceed the threshold of 100 g/y. This is in sharp contrast with the lowest tonnage limit for REACh registration which is set to 1 t/y, also for NMs.

A comparison with the global context shows that, similarly to REACh, EPA considers NMs as chemical substances regulated by the Toxic Substances Control Act (TSCA). TSCA requires manufacturers of new chemical substances to provide specific information to the Agency for review prior to manufacturing or trading in chemicals. This information includes chemical identity, material characterization, physical chemical properties, production volume, use, methods of manufacturing and processing, exposure and release data and existing information concerning environmental and health effects. TSCA applies to solid chemical substances manufactured or processed in a form where any particle, including aggregates and agglomerates, is in the size range of 1-100 nm in at least one dimension and that exhibits one or more unique and novel properties. This law does not apply to chemical substances containing less than 1% by weight of any particles, including aggregates and agglomerates, in the size range of 1-100 nm. These parameters aim to identify chemical substances which undergo the rule, without establishing a definition of nano-scale material (12).

It is clear the need of a global regulatory framework for NMs at international level to ensure a high level of consumer protection, free movement of goods and uniform requirements for manufacturers.

Other EU Regulations

Besides REACh, NMs are specifically considered in other EU regulations (e.g. cosmetics, food, biocides, electrical equipment). For example, according to the EU Regulation 1223/2009 on cosmetic products, a NM is an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm, and the NM content in a cosmetic product must be specified in the label (13). As for food products, according to the EU Regulation 1363/2013, any change in a particular additive used (e.g. the shape or size of the particles added to the food) must be approved before products can be marketed, and several label specifications are also required (14). European legislation on food packaging and in particular Regulation 10/2011 (as amended by Regulation 2015/174), also known as PIM Regulation (Plastic Implementation Measure), allows exclusively the use of approved NMs. As for the use of NMs in biocidal products, the NMs definition given in Recommendation 2011/696/EU and transposed in Article 3 of the Regulation

528/2012, extends the concept of NM to "any natural or manufactured active substance or non-active substance containing particles" (15). Moreover, it asserts that the risk to human health, animal health and the environment has to be assessed separately if NMs are used in a biocidal product. Biocidal products eligible for the simplified authorization procedure should not contain any NM, and, if a treated article contains NMs, the name of all of them must be included in the label followed by the word "nano" in brackets. The inclusion of an ingredient in the label implies measurements which are likely affected by large uncertainties, as mentioned before. Currently, available methods allowing the detection and quantification of NMs embedded in simple matrices are not yet standardised nor generally accepted. Routine application of NMs detection methods on complex matrices, such as in cosmetics or food, still needs considerable development.

The rise of nanotechnology in the consumer marketplace is proved by the creation of several NMCP inventories listing today thousands of products (16). Usually, such inventories miss crucial information on exposure assessment, but there is a growing number of published studies estimating consumer exposure to NMs released during the NMCP use, such as cosmetic powders, sprays, general household products, and products for children (17). In many cases the released amount of the NM from the product matrix is uncertain, influencing the oral or dermal exposure to the NM. Currently, it appears more reliable to estimate oral and dermal exposures to NMs compared to inhalational exposure. Inhalation exposure is more difficult to assess in particular for sprayed applications for which a significant number of experimental parameters (pressure, nozzle size, ventilation, size of experimental chamber, viscosity of sample, analytical measurement techniques, etc.) have to be considered. In general, current exposure estimation models are not designed for estimating NMs exposure and are also likely to be affected by large uncertainties. Moreover, the increasing number of NMCP entering the market will inevitably affect the waste to be disposed of or recycled. This opens the question whether traditional techniques for waste treatment may also be suitable for NMCW.

The management of NMCW

The lack of information is even more critical in the NMCW risks evaluation (18). In a recent official report released in February 2016, the OECD highlighted the urgent need of further research to assess the possible risks to human health and ecosystems caused by the ever-increasing amounts of NMCW (1). In particular, large amounts of NMs are already entering the cycle of waste disposal through traditional landfill, incineration and wastewater treatment plants, without any special design, treatment or precaution. This involves, for example, the possibility that NMs are accumulated in sewage sludge (which can be used as agricultural fertilizer) or in effluents of sewage treatment plants that enter rivers and lakes, as well as in recycled goods. The adoption of the best available techniques (BAT) can be effective in retaining a variable fraction of NMs in sludge and slag, but the uncer-

tainties about the actual collection efficiency and removal of NMs are very large (1). On the other hand, a significant amount of NMs may be released into the environment from systems which do not adopt BAT, reaching the atmosphere as emissions from incineration plants (or from products coming from ashes recovery), or percolating into the ground as landfill leachate, or being released into surface water after traditional sewage treatment. It has been estimated that about 95% of NMs contained in personal care products and cosmetics end up in wastewater treatment plants through the domestic sewage (18), and an higher percentage was observed specifically from washing nano-Ag containing-textile products (18-20). The presence of NMs in sewage sludge and composting products commonly used as fertilizers on agricultural land is a possible concern. In France, about half of the sludge from wastewater treatment is reused for agricultural fertilization (1). Since the NMs are steadily increasing in wastewater, it is reasonable to assume that the amount of NMs in sludge used for agriculture will also increase. Moreover, many critical issues have not yet been considered in depth, for example those associated with the presence of NMs in the soil, their interactions with plants and bacteria and their transfer to surface water. Currently, sludge from water treatment and municipal solid waste are the two main sources of NMCW. In EU countries the main destination of such waste is incineration. In 2014, about 658 million tons of municipal waste were produced in EU, and 145 million tons (22%) were destined to incineration (1). As previously mentioned, the number of NMCP is growing, with TiO₂ and SiO₂ dominating the world market, followed by ZnO, carbon nanotubes (CNT), other metal oxides and Ag. It is estimated that in EU countries, from 2011 to 2014, about 10,000 tons per year of nano- TiO_2 were produced (18) and a large but unknown part of these was destined to incineration (1).

The only study performed at real incineration plants was carried out in 2012 by analyzing the behaviour of cerium oxide (80 nm) added to the waste before and during incineration. Almost all the cerium was recovered from the bottom ash (80%) and fly ashes (19%), and less than 0.1% was released into the atmosphere. The authors conclude that abatement systems based on electrostatic precipitators in combination with wet scrubber can effectively remove most of the nano-metal oxides present in the waste (21). Other authors argue that these systems work efficiently for large particles (> 100 nm), but for smaller particles a wide fraction of NMs (up to 20%) could be released into the atmosphere without being captured by the abatement systems (22).

Along with incineration plants, landfills may become sites of great concern in the next future. A recent study considering waste management in Switzerland shows that most of NMs introduced in the waste cycle ends its life cycle in landfills. In particular, it is estimated that most of the disposed nano-TiO₂ (85%, about 150 t/y) will be collected in landfills as heavy ash (61%) and inert waste (24%). Further studies confirm these predictions providing that over 50% of NMCP (NMs as nano-Ag, nano-TiO₂ and CNT) are supposed to be disposed of in landfills

(20,23). Therefore landfills, which still represent the most common disposal system in the world, could be, in the next future, an extremely critical target site, for evaluation and management of risks associated with NMCW.

With the increasing spread of NMCP it is reasonable to expect a qualitative variation of the waste and therefore of the physico-chemical characteristics of the leachate produced, which presumably represents the primary way of transport of NMs outside of the landfill. The presence of NMs in the waste can increase the complexity of the leachate and its treatment can involve difficulties for the pollution extreme variability. The lack of data also concerns the ability to retain or remove NMs during the leachate treatment processes. Although some studies show certain capabilities of removing some NMs by conventional treatment techniques, other studies show that the NMs in the leachate interferes with the efficiency of treatment, especially if biological processes are adopted for the removal of some pollutants (1). Some authors suggest the use of membrane filtration techniques (eg. nano-filtration) to ensure NMs removal (24). However, the resulting sludge will have to be re-disposed of in landfills, thus enriching the overall load of NMCW. For this reason, the introduction of stabilization processes (eg. vitrification), already used for certain types of hazardous industrial waste, could be a viable method (25). Another important forthcoming issue to be addressed, is the possibility that some of the NMs in the waste can bypass the landfill-surrounding synthetic layers. However, there are no solid data available yet. There is then an urgent need to investigate all the possible risks to health and the environment associated with the disposal of NMCW and in particular with respect to the management and treatment of landfill leachate.

Concluding remarks

There are significant critical aspects associated with the regulation and management of NMCP and NMCW which need to be addressed. The different definitions proposed to classify and regulate NMs can lead to confusion and increase uncertainty for manufacturers, importers or distributors (26). Labelling products and informing consumer on NMs content in product registers or inventories are measures to increase knowledge and traceability of their use (27). However, harmonized method or consolidate procedures for the detection and quantification of NMs in products are not available, and inconsistencies in size metrology still exist. In order to ensure a high level of consumer protection, allowing for free movement of goods and uniform requirements for manufacturers, a global framework for NMs should be developed at international level.

Despite some influent criticisms support the fact that the use of engineered nanomaterials is still rather small and the predicted emissions even smaller (28; 29), with the likely rise of NMCP, it is reasonable to expect a corresponding change in the chemical and physical characteristics of the waste produced. Actually, a relevant amount of NMCW is currently disposed of as traditional waste and not specific managements, codes, classifica-

tions based on the NM content or any particular specific control of emissions, ashes or leachate are adopted. It has been shown that there are stages in the disposal of NMCW that may generate NMs emissions, and these may not be sufficiently characterized. Traditional preventive measures taken for the protection of health and safety of workers could be insufficient for NMs, and this should be investigated. Moreover, in many countries of the world waste incineration is carried out open-air or in plants not equipped with adequate abatement systems and this could lead to the release of relevant amounts of NMs, as well as of traditional pollutants. The same is valid for the disposal of waste in non-controlled landfills. In these cases, there may be uncontrolled contamination of soils and aquifers close to the landfill, or the discharge of contaminated effluent in surface water. Special attention should be directed to the NMs content in the sludge being reused in agriculture, for possible interactions with the soil and the products obtained from its cultivation. Despite of these critical aspects, it is clear that there is an enormous scientific and technical interest on NMs, in particular in the medical field and technology. It would be therefore important that national and international institutions provide soon harmonized regulations concerning all aspects of the life cycle of NMCP and NMCW, in particular the definition of the minimum requirements for analytical characterization of materials. This would contribute to clarify the composition of NMs in products and waste. On the other hand, precautionary practices aimed at containing risks to public health and the environment should be implemented. For example, as for the landfills, the deposition in dedicated cells might be considered especially for those types of waste for which it can be assumed a greater NMs release. This would allow selective control of the leachate, and the assessment of its specific composition. Differentiated treatments or pre-treatments (onsite) could also be considered. In order to ensure protection of the workers involved, it would be reasonable to review safety procedures currently in place, according to risk assessments considering exposure to NMs, especially where these are directly produced or treated. Adequate environmental monitoring with specific attention to size and composition of respirable particles should be adopted. Gravimetric determinations are inadequate for the purpose of occupational risk assessment of NMs. It would also be reasonable to consider the feasibility of biological monitoring to assess exposure for personnel directly involved in the production or treatment of NMCP and NMCW.

Conflict of Interest

None

Data Accessibility

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