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Publishable Executive Summary

Deliverable 7.9 “Final version of policy document”, is the final report containing the policy recommendations regarding the developed activities in PureNano project, namely, topics related to nanotechnology issues and wastewater treatment processes. Thus, policy landscape along with policy recommendations provided in this Deliverable, to contribute to new standards development in the specific technological area that PureNano initiates. This deliverable is based on Deliverable 7.8 “First version of policy document” and includes amendments on the existing text and regulations and new additions in order to be updated until November 2022.

With the enormous amount of legislation and regulations that cover many aspects of the industry, defining the specific actions to direct the development activities towards existing standards as well as proposing of new standards is an important task of this project.

The initial analysis of the standardization landscape performed early during the project, **along with the updated analysis presented hereafter**, aimed at providing ground for policy recommendation development with the final target of contributing to new standards developments in specific topics, promoting the inclusion of the outcomes of the project in new or future standards that can be easily used by the European or international industry, increasing this way the impact of the project.

This document provides information for the elaboration of new standard documents related to four major topics that are fundamental for the project and the acceptance of its results in the target market. Up to now, standards related to the H&S aspects of NPs use in the workplace as well as disposal and recycling standards and the environmental impact of NPs use are not sufficient to address the growing use of nanomaterials and the concern regarding their fate and impact on human health and the environment.

Moreover, the plating industry and the related waste water treatment, being the target market of the PureNano project, are specifically addressed in this document providing an information on the current policy landscape, the need for Best Available Techniques for industrial waste water treatment and policy recommendations that can be applied in the specific needs of the plating industry.

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Abbreviations and acronyms

BAT	Best Available Techniques
EPA	Environmental Protection Agency
EUON	European Union Observatory for Nanomaterials
H&S	Health & Safety
HSE	Health, Safety and Environmental
IRGC	International Risk Governance Council
ISO	International Organization for Standardization
IUCN	International Union for Conservation of Nature
MNPs	Magnetic nanoparticle
NMs	Nanomaterials
NOAAs	Nano-objects and their aggregates and agglomerates
OECD	Organization for Economic Co-operation and Development
OEL	Occupational exposure Limits
OSHA	Occupational Safety and Health Administration
SCENIH	Scientific Committee on Emerging and Newly Identified Health
R	Risks
TC	technical Committee
WHO	World Health Organization
WPMN	Working Party for Manufactured Nanomaterials

1. Introduction

Deliverable 7.9, depicts the implemented work under Task 7.4. This Task aimed at contributing to the generation of new standards in order to facilitate future replicability and reuse of the results and reduce market acceptance risks as well as to promote circular economy. Moreover, promoting the research results to be included into future standards can facilitate the market uptake of the innovations. Furthermore, standardization system constitutes itself an efficient and fast information and knowledge transfer structure. The bidirectional implication of correspondent technical committees at international, European and national levels allows any information provided to reach an immediate widespread dissemination, focused to the interested stakeholders in every country.

There is the need of specific standards that ensure safe, integrated and responsible nanotechnology production and utilization in waste water treatment plants in the plating industry and in the industry in general. The present document is an attempt to present the needs described above, the current policy landscape and to propose actions and policy recommendations that could help to better integrate nanotechnology into industrial applications.

2. Standards related to the H/S safe use of NPs in the workplace

Due to the numerous advantages, a great development on the use of nanotechnologies is expected in the coming years, which will increase the number of workers exposed to nanoparticles². Currently, specific regulatory occupational exposure assessments (OELs) for nanomaterials (NMs) have not been established by the EU or by any national authority and it is expected that it may take a long time before deriving OELs for all highly diverse frequently used NMs. This is mainly due to the still existing large gaps in knowledge on particle toxicology, the high diversity of the newly developed, and used, NMs, the uncertainties about their hazardous nature and the on-going discussions on the metrics to be used for the nano-OELs e.g. mass-based or particle number based³. Therefore, due to the lack of uncertainties that still exist around NMs, their management in the workplace thus becomes a challenge for regulators, industry heads and occupational safety professionals. A certainty that exists is that a safe, integrated and responsible nanotechnology production and utilization strategy is necessary.

2.1 Risk management standards landscape

Technological developments, such as nanotechnologies, have to face different kind of factors and influences, internal (organizational) and external (from stakeholders), that create uncertainty about whether or not they could achieve the objectives for what they were created⁴. The effect of these risk could be managed though their identification, analysis and evaluation in order to satisfy a control criterion. To support this processes, different strategies and methodology for risk management have been presented in international standards. Particularly, the ISO 31000:2018 standard is the main reference regarding how to achieve risk management in a systematic way⁵. However, the specifics on how to respond to the uncertainties associated with nanotechnology, particularly as it is emerging technologies and which we have little information, require greater attention for its management⁶.

² EU Commission (2012) Communication from the commission to the European parliament, the council, the economic and social committee and the committee of the regions: Second Regulatory Review on Nanomaterials {SWD(2012) 288 final}

³ Mihalache R, Verbeek J, Graczyk H, et al (2017) Occupational exposure limits for manufactured nanomaterials, a systematic review. *Nanotoxicology* 11:7–19

⁴ Harri Jalonen, 'The Uncertainty of Innovation: A Systematic Review of the Literature', *Journal of Management Research* 4, no. 1 (2012): 1

⁵ ISO, ISO 31000: 2018 Risk Management–Principles and Guidelines (Geneva, Switzerland: International Organization for Standardization, 2018)

⁶ Gary E. Marchant, Douglas J. Sylvester, and Kenneth W. Abbott, 'Risk Management Principles for Nanotechnology', *Nanoethics* 2, no. 1 (2008): 43–60.

For nanotechnologies, international H&S standards and related documents including technical specifications, technical reports and guidance materials are being developed through the International Organization for Standardization (ISO), specifically by the technical Committee (TC) 229: Nanotechnologies and through the OECD Working Party for Manufactured Nanomaterials (WPMN) ⁷. At the EU level, the H&S standard development is led by the European Committee for Standardization, more precisely by the technical committee (CEN/TC) 352 on nanotechnologies and supported by “CEN/TC 137 - Assessment of workplace exposure to chemical and biological agents” and “CEN/TC 195 - Air filters for general air cleaning”. The role of these bodies compasses the understanding of what effects nanotechnology might have on health and the environment, including standards focused on the following areas: *terminology and nomenclature; metrology and instrumentation, including specifications for reference materials; test methodologies; modelling and simulations; and science-based health, safety, and environmental practices* ⁸. Some aspects related to the standardisation of nanotechnologies that are still under development include: 1) clear definition of nanotechnology and requirements for users, 2) support legal issues (e.g. exposure assessment, hazard identification, labelling, Safety Data Sheets (SDS/MSDS); 3) promote H&S practices within organisations; and 4) define criteria for conformity assessment.

Table 1 shows the approximate number of published standards related to:

- 1) Nanotechnology concepts and vocabulary (e.g. ISO/TR 11360:2010 Nanotechnologies — Methodology for the classification and categorization of nanomaterials);
- 2) Nanomaterials characterisation, including physico-chemical characterization (e.g. ISO/TR 10929:2012 Nanotechnologies — Characterization of multiwall carbon nanotube (MWCNT) samples);
- 3) Hazard identification, including safety and toxicity parameters (e.g. ISO/TR13014:2012 Nanotechnologies — Guidance on physico-chemical characterization of engineered nanoscale materials for toxicologic assessment); **two updated releases (ISO/TS 21633 & 23034) are involved by 2021 concerning toxicity and uptake of nanomaterials by living organisms (health and safety)**
- 4) Exposure assessment (e.g. ISO/TR 18637:2016 Nanotechnologies — Overview of available frameworks for the development of occupational

⁷ OECD, Nanosafety at the OECD: The First Five Years 2006–2010 (Paris, France: Organisation for Economic Co-operation and Development, 2011); ISO, ‘Technical Committees: ISO/TC 229 Nanotechnologies’, 2020, <https://www.iso.org/committee/381983.html>

⁸ CEN, ‘CEN/TC 352 - Nanotechnologies’, 2020, https://standards.cen.eu/dyn/www/f?p=204:7:0::::FSP_ORG_ID:508478&cs=1A6FDA13EC1F6859FD3F63B18B98492ED

- exposure limits and bands for nano-objects and their aggregates and agglomerates (NOAAs);
- 5) Risk management and/or assessment frameworks (e.g. ISO/TR 12885:2018 Nanotechnologies — Health and safety practices in occupational settings); and
 - 6) Other aspects such as waste management, product labelling and life cycle assessment (e.g. ISO/TS 13830:2013 Nanotechnologies — Guidance on voluntary labelling for consumer products containing manufactured nano-objects).

The total number of ISO standards published by this committee is 133 (November 2022), of which 53% have focused on aspects of characterization of the NMs.

Since the first version of policy analysis (D7.8), 21 ISO/TC 229 standards have been added⁹, while, in total, 48 standards being under reviewed, 40 under development and 36 have been withdrawn.¹⁰ In addition, 19 CEN/TC (137 & 195) standards have been also added especially focusing on methods and equipment to limit exposure and hazard effects on processing nanomaterials.

However, many of these published standards indirectly provide valuable information for risk management.

For their part, CEN and OECD have focused on developing standards that directly respond to H&S aspects, mainly exposure assessment. Current publications by OECD WPMN programme are guidance documents rather than standards. Since the previous update (D7.8), the OECD has further published 14 reports, No.92-1005 (Dec. 2020-Oct. 2022).¹¹, with the last published on Oct. 2022 being aligned with the SSbD principles. Whilst OECD does publish standards and is pioneering in the nanotechnology field, there are no relevant published standards on H&S aspects, and it is expected the publication of future standards by OECD ¹².

⁹ <https://www.iso.org/committee/381983/x/catalogue/p/1/u/0/w/0/d/0>

¹⁰ <https://statnano.com/news/68696/ISO-Published-12-Nanotechnology-Standards-in-2020>

¹¹ <https://www.oecd.org/env/ehs/nanosafety/publications-series-safety-manufactured-nanomaterials.htm>

¹² IOM SAFENANO, 'Current Nanotechnology Standardisation Activities', 2020, <https://www.safenano.org/KnowledgeBase/Standards.aspx>

Table 1. Published standards and guidelines on nanotechnologies by international and European standardisation and policy development bodies (as for November 2022)

Standardization body Standard category	ISO/TC 229	CEN	OECD –	ISO/TC 229
Nanomaterials characterization	60+10	10+3	5	
Concepts and vocabulary	21+4	13	-	
Exposure assessment	6+1	13+14	13+4	
Hazard identification	19+2	3+2	9	
Risk management framework	4	3	7+4	1 (IEC)
Others (Product C&L / Lifecycle, SSbD)	2	7	+2	
Health & safety	+4	-	+4	
Total (by Nov. 2022)	112+21	49+19	34+14	1

2.2 Risk Governance

As mentioned above, standardisation and regulation on health, safety and environmental (HSE) management for nanotechnologies is still on going and are key for risk governance.

The latter refers to “*both the institutional structure and the policy process that guide and restrain collective activities of a group, society or international community to regulate, reduce or control risk problems*”¹³.

International Risk Governance Council (IRGC), referring to nanotechnology, as an important and rapidly growing field that raises more complex and far-reaching issues than many other innovations, thus, posing significant challenges to risk governance structures and processes¹⁴.

Nanotechnology HSE risk concerns if not governed by proper risk assessment and management approaches, may significantly hamper the great potential of nanotechnology to deliver industrial, energy, environmental, health, and other benefits¹⁵.

According to the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) report¹⁶, the relevance of standardisation and regulation can be

¹³ Renn, O., & Klinke, A. (2013). A framework of adaptive risk governance for urban planning. Sustainability, 5(5), 2036-2059

¹⁴ <https://irgc.org/issues/nanotechnology/nanotechnology-risk-governance>

¹⁵ Isigonis, P., Afantitis, A., Antunes, D., Bartonova, A., Beitollahi, A., Bohmer, N., ... & Doak, S. (2020). Risk Governance of Emerging Technologies Demonstrated in Terms of its Applicability to Nanomaterials. Small, 16(36), 2003303.

¹⁶ A. Albom et al., ‘Risk Assessment of Products of Nanotechnologies’, Report of the Scientific Committee on Emerging and Newly Identified Health Risks–SCENIHR. European Commission Health & Consumers DG, Brussels, 2009.

helpful in tackling some of the following issues when applied to nanotechnology risk governance: 1) expand traditional standards frameworks to cover nanotechnologies appropriately; 2) increase knowledge regarding the hazardous properties of NMs, 3) adapt and recommend H&S measurement and methods applied to NMs; 4) to better of the effectiveness of workplace controls, and 5) ensuring consistency internationally. The following subsections discuss the advancement and challenges regarding the risk governance of NMs.

2.3 Risk governance approach

As nanomaterials are increasingly being regulated by the EU and by individual EU Member States, due to the increasing application in multiple industry sectors, the EU has adopted specific measures within several directives and regulations for the control of risks from nanomaterials, as it has realised that their hazardous characteristics can be different to the same substances as bulk materials. However, the governance framework(s) for nanotechnologies, including engineered nanomaterials is(are) under development.

Chemical safety assessment, exposure and hazard assessment guidelines and standards rely on well-established risk concepts and methodologies, which have been validated for conventional chemicals and which are used in the regulatory context, such as REACH. Up to today, however, the fulfilment of the information requirements for nanomaterials safety assessment, such as for REACH registration, is still hampered due to the lack of validated OECD TG/GD. Furthermore, key guidance documents from implementing agencies such as the ECHA R-series for REACH chemical safety assessment have been updated or amended with nano-recommendations following dedicated REACH Implementation Projects (RIP1-3) in the past decade and guidance appendices have been issued until recently due to amendment of REACH Annexes to address nano-form substances (Commission Regulation (EU) 2018/1881). **Another supporting EU legislation in 2022 (DIRECTIVE (EU) 2022/431) was published amending the Directive 2004/37/EC concerning the protection of works and the exposure risks related to carcinogenic, mutagenic and reprotoxic (CMR) substances, e.g. Nickel and Cobalt and their compounds.¹⁷ The CMR chemicals are also classified for their hazardous effects, without excluding their use at nano or larger scales. The updated legislative framework aims to set limitations on the exposure of workers to CMR substances to minimize health and safety impacts at workplaces.**

Furthermore, many efforts focused, and progresses have been made, in recent years towards achieving adapted internationally validated OECD guidelines and guidance documents (TG/GD) with applicability to NMs and to advance the adaptation and validation of the risk governance framework. The systemic efforts

¹⁷ <https://echa.europa.eu/oels-activity-list>

on risk governance of the last decade are being consolidated in the various running projects such as RiskGONE, NANoRIGO and Gov4Nano; OECD TG/GD harmonisation and validation is on its way supported by projects such as NanoHarmony and the OECD Malta Initiative. Thus, it seems that the nanotechnology field has arrived at a sufficient level of maturity that allows harvesting scientific background and to translate it into a form of regulatory relevance with international consensus. OECD's recent report (2020-2022) focuses on the tools and models to investigate exposure at occupational and consumers level to nanomaterials and their capacity for risk and safety assessment in manufacturing. The existing and lately updated contexts of CEN/TC 137 can be complementary to both REACH and risk management legislation by setting the rules and methods for sampling chemical and biological agents, airborne particles and vapors in workplace air. The latest updates on CEN/TC 195 provide tests in the fields for effective ventilation and removal. ISO has also embedded (in 2021) the aspects for cellular uptake and toxicity (in-vitro) of nanomaterials.

2.4 Risk governance actions and policy recommendations

There are three types of actions that are required for a responsible development of a risk governance framework. First, research and transparency in information. The diversity of organizations at the international and European level, as well as the efforts at the individual level of certain organizations, requires constant consolidation of experiences and results, in order to add synergies in information exchanging, advance the research process and make the outputs of invested budgets even more profitable. For this, it is important to increase the existing knowledge networks and the access to them through advanced information and communication systems that are easily accessible as tools. This would avoid atomization and duplication of efforts and serve as a basis for progress and information to society. Furthermore, it is in the interest of the different sectors that there are sufficient public funds to investigate the potential risks of NMs, preventing market dynamics from generating risks and accidents. Significant research investment is still needed to address nanomaterials standardization and support revision of test guidelines for NMs. A long-term aim of the risk governance council must thus include continuous monitoring, investigation and understanding of NMs behavior and risks, i.e., in one word, governance². Another way to continue providing centralized information, it is through the support of the different institutional bodies responsible for providing objective and reliable information on the markets and safety aspects of nanomaterials especially in the EU (e.g. European Union Observatory for Nanomaterials - EUON).

The second type of action refers to government regulation. Governments must ensure the health of workers, consumers and the environment, and for this the regulation of NMs constitutes a central aspect. In the absence of sufficient information, the precautionary principle should be the guide. For this, the

establishment of a regulatory framework in line with social expectations and needs is recommended. An important step is the obligation to report. Given the weakness of the regulations and legislation in force, it is recommended to adopt measures to provide citizens with the necessary and mandatory information that indicate safety and environmental sustainability actions for the selection and rational use of products that contain materials considered nano during their life cycle.

The third type of action that could be implemented are voluntary certifications, or voluntary codes of conduct. These are statements of companies and associations of companies, or even governments directed to the consumer, with the purpose of publicizing a certain responsible behaviour in the production processes (e.g. the use of Safe-by-Design strategies and processes once they have been standardized). Although these are proactive measures, their implementation as a voluntary measure is not a guarantee for the majority of the population. It is for this reason that in mid-2007 more than one hundred non-governmental organizations, unions and other civil organizations launched the declaration called Principles for the Supervision of Nanotechnologies and Nanomaterials¹⁸. There it is argued and justified in favour of public policies recognizing and / or adopting eight principles regarding nanomanufactured products and NMs.

¹⁸ ICTA. (2007). Principles for the oversight of nanotechnologies and nanomaterials. International Center for Technology Assessment

3. Environmental impact of the NPs use

3.1 Fate and behavior of nanoparticles in the environment

Due to their unique properties (e.g., extremely small size and high surface-volume ratio), the impacts and toxicity of NMs on the environment with respect to their interaction with biological substances are still relatively poorly described¹⁹. During the life cycle of these materials (production, use and disposal) nanoparticles (in a free or aggregated state) can be released into the environment. This release may raise concerns regarding health and the environment. For this reason, uncertainty about hazards, exposures, and risks in the emerging green nanotechnology field, including uncertain ecological impacts, environmental soundness, fouling properties, low detection limits, high expenses, regeneration, and environmental deposition, make it imperative to adopt a dynamic precautionary management approach before all of the evidence is completed²⁰.

The destiny of NMs in the environment is controlled by the combined effects of their physicochemical properties, and their interactions with other pollutants. After NMs are discharged into the environment, they accumulate in different environmental matrices (e.g. air, water, soil, and sediments)¹⁹. There are still large knowledge gaps with respect to NMs' environmental fate specially after release into the air, due to the exposure to the sunlight and UV wavelengths, due to physical transformations or due to the gravitational settling velocities resulting in different ways of deposition. With regard to soil, nanomaterials pass through pores and adhere to soil particles. Due to their high surface area, vast aggregates of NMs can be immobilized by sedimentation, filtration, or straining in smaller pores. The fate of NMs in the aquatic system is thus affected by various processes, for example, accumulation, disaggregation, diffusion, interaction with other components (and aquatic organisms), biological degradation and abiotic degradation.

Some of the identified key transformation processes of NMs that influencing their environmental fate and behaviour are: a) Oxidation; b) Photochemical degradation; c) Dissolution, d) Reduction; e) Precipitation; f) Speciation – complexation; g) Adsorption; h) Desorption; i) Biotransformation, j) Agglomeration; k) Sedimentation²¹.

In summary, there are concerns about NMs' potential harmful effects on the environment and human health. There are reasons to believe that use of NMs is increasing. The results of preliminary studies revealed that these structures are

¹⁹ Kabir, E., Kumar, V., Kim, K. H., Yip, A. C., & Sohn, J. R. (2018). Environmental impacts of nanomaterials. *Journal of Environmental Management*, 225, 261-271

²⁰ Lavicoli, I., Leso, V., Ricciardi, W., Hodson, L. L., & Hoover, M. D. (2014). Opportunities and challenges of nanotechnology in the green economy. *Environmental Health*, 13(1), 78

²¹ Hartmann, N., Skjolding, L., Hansen, S., Kjølholt, J., Gottschalck, F., Bau, A. (2014) Environmental fate and behaviour of nanomaterials, Environmental Project No. 1594

affecting the environment by a number of routes, e.g., 1) by increasing the pollution level of air, water, and soil, 2) by accumulating in the environmental system (which may pose both short term and long term effects), and 3) by affecting the life-cycle of living systems present in environment.

3.2 Environmental policy landscape regarding nanomaterials

New technology or products should go through extensive testing for adverse environmental and health consequences before introduction. Kriebel et al.²² outlined the precautionary principles for environmental decision making as “1) taking preventive action in the face of uncertainty; 2) shifting the burden of proof to the proponents of an activity; 3) exploring a wide range of alternatives to possibly harmful actions; and 4) increasing public participation in decision-making”. However, such principles were not followed before the introduction of NMs, leaving uncertainty about the dangers versus advantages of NMs. After a decade of critical revisions, EC recently admitted that NMs are “difficult to regulate” because of their complexity and lack of knowledge²³.

The European Commission has stated that the existing regulations are applicable, for example the REACH Regulation. **ECHA collaborates with the EC, Industry associations and NGOs to competent authorities, the European Commission, NGOs and the OECD to assist in the implementation of the EU chemicals legislation in contexts of nanomaterials manufacturing, use and waste management.**

3.3 Policy recommendations

The majority of studies on the effect on NMs on environment are based on short-term effects. The future studies with special focus on accelerated or long-term effect of NMs, if carried out, can help in estimating the exact toxicological profile of these structures on environment. Such studies should also be included in the future research to prepare disposal regulations of NMs.

The proper guidelines and regulations for the use and disposal of NMs should be prepared to avoid any future complications. Therefore, it is very important to conduct proper life cycle evaluation and risk assessment analyses for NMs before wide application. Nanomaterials at their end of life constitute the least studied waste. There is a great lack of knowledge about analytical methodologies that can determine them in the natural environment, so there are only forecasts and speculations of their presence and destination, as well as the physical and chemical effects that they can exert on living beings, as transporters of other contaminants or the different additives they may contain.

²² Kriebel, D., Tickner, J., Epstein, P., Lemons, J., Levins, R., Loechler, E. L., ... & Stoto, M. (2001). The precautionary principle in environmental science. *Environmental health perspectives*, 109(9), 871-876

²³ OECD Environment Directorate, 2014. *Ecotoxicology and Environmental Fate of Manufactured Nanomaterials: Test Guidelines*. Expert Meeting Report. Series on the Safety of Manufactured Nanomaterials

Increasing knowledge in this field is a major challenge that we must address in future policy. By reducing the huge gaps in knowledge about the nature of interactions of NMs, we will have proper guidelines regarding the processing, applications, and regulation of NMs in the future. The CEN methods and tests related to effective filtering of air environments in manufacturing have a dual positive effect on both minimizing exposure of workforce in hazardous compounds and the limitation of such emissions in the environment.

To this end, the OECD guidelines also offer a harmonized strategies for NPs emissions and exposure and recommendations for measurements and instrumentation. These can include different types of control techniques and personal protection equipment need to be considered over the various work places and tasks of workforce involved in manufacturing and handling of NPs.

Key actions are also highlighted concerning the different zones of measuring/sampling and analyzing NPs. These mainly consist of the emissions zones (some centimetres from source); the breathing zone (30 cm of radius from workers respiratory system); the background zone (2-3 m from potential NPs sources); and the supply air, namely, the air inflow through the ventilation system. Accordingly, sampling should be targeted in line with the above zones and samples can be appropriately handled and treated for elemental composition and SEM analysis; direct reading instruments are also proposed as best practices for real-time monitoring and taking actions.²⁴

²⁴ Lovén K., Franzén S.M., Isaxon C., Messing M.E., Martinsson J., Gudmundsson A., Pagels J., Hedmer Maria, 2021. Emissions and exposures of graphene nanomaterials, titanium dioxide nanofibers, and nanoparticles during down-stream industrial handling. *Journal of Exposure Science & Environmental Epidemiology*, 31:736–752. <https://doi.org/10.1038/s41370-020-0241-3>

4. Waste water treatment in the plating industry

4.1 Waste in the plating industry

The surface treatment industry produces significant quantities of metal hydroxide sludge. The European Union alone produces about 1,000,000 tons/year of hydroxide sludge thus reducing waste generation at source is an imperative goal²⁵.

The pollutants generated by the surface treatment activities, with the related waste, quantitatively modify the natural constituents of the receiving environments. The impact of these pollutants on ecosystems manifests itself in various ways. Indeed, some pollutants, such as metals, depending on their chemical form and the quantity disposed, can be highly toxic to living beings. For this reason, the disposal of concentrated plating baths can cause very serious accidental pollution since the specific lethal dose of metals for many species can be exceeded resulting to their death. They also involve the risk of long-term toxicity, due to the accumulation of non-metabolized or non-eliminated substances.

The impact of these pollutants affects the choice of an appropriate purification system and the destination of the waste. In fact, an effluent that respects the limit values set by the regulations in force, even if it has a greatly reduced acute toxicity compared to untreated wastewater, is not entirely harmless: it still contains (even if at very low concentrations) metal ions and other pollutants that cannot be completely eliminated by the applied treatments.

There is thus the need to pay particular attention to metal pollution, taking into consideration their persistent toxic character and the phenomena of biological accumulation.

On the other hand, metals are important raw materials, not renewable but infinitely recyclable, and their careful and conscious use can allow their recovery and recycling, achieving two objectives: to improve environmental protection together with the competitiveness of businesses.

The imminent implementation of the new integrated approach in all the countries of the European Union is part of this framework to the prevention and control of environmental pollution. **Directive 2010/75/EU – 24 November 2010 (repeal IPPC directive n 96/61/EC of 24 September 1996)** already implemented in Italy with **Legislative Decree 59 of 18 February 2005 (repeal Legislative Decree no. 372 of 4 August 1999)**. This type of approach, for surface treatment activities, consists in dealing comprehensively with all the harmfulness and risks associated with production activities.

²⁵ Trattamenti delle superfici, Depurazione delle acque, 1a edizione italiana della 2a edizione francese, Autore e editore della versione tradotta e adattata per l'Italia, AIFM – Associazione Italiana Finiture dei Metalli; ISBN: 2-9506252-2-3

Best Available Techniques (BAT) Reference Document for Waste treatment of the Industrial Emissions, Directive 2010/75/EU (Integrated Pollution Prevention and Control) introduces the notion of "best available techniques", intended to determine the limit values for the emissions that can be imposed, on a certain technological basis, on industrial companies²⁶. Furthermore, its adoption for regulatory purposes allows to support innovation, through the application, as widespread as possible in a well-defined economic context, of pollution prevention or de-pollution processes that are certainly capable of making progress both for environment and for the competitiveness of businesses.

4.2 Waste water treatment policy landscape

The issue by the Council of the European Union of Directive 96/61/EC of 24 September 1996, also known as the IPPC directive, introduced a new integrated approach for the protection of the environment and the health of citizens, aims at preventing, reducing and, as far as possible, eliminating the pollution coming from the productive sectors, considering the environment no longer separated into three distinct areas: air, water and soil, but as a single entity to be protected. **This directive has been repealed by Directive 2010/75/EU of the European Parliament and of the Council - 24 November 2010.**

The directive introduced the concept of emission limit values referring to technological, management and economic evaluation standards derived from the so-called BAT, i.e. the best available techniques, where the term "techniques" includes not only the technologies of production processes but also the techniques of plant design, management, maintenance and decommissioning.

The term "available" means all the techniques currently applicable both from the technological point of view and from the aspect of economic compatibility, within the framework of an overall evaluation of cost-benefits.

At European level, **Directive 2010/75/EU – 24 November 2010 (repeal the Community legislation 1836/93/EEC of June 29th 1993, also on eco-audit (EMAS certification))** reserves the possibility for companies to voluntarily participate in an environmental management and audit system. Entrepreneurs can also opt for the recognition of their environmental management system, obtaining the ISO 14001 certification.

Since the protection of the environment is now an essential objective, the eco-audit approach and ISO 14001 certification represent the tools for an active integration of environmental aspects in the management of the company. In this context, the application of internal procedures aimed at formalizing the environmental parameters and the involvement, at all levels, of the company's staff are proof of the entrepreneur's responsible commitment.

²⁶ A. Pinasseau, B. Zerger, J. Roth, M. Canova, S. Roudier. Best Available Techniques (BAT) Reference Document for Waste Treatment Industrial Emissions, Directive 2010/75/EU Integrated Pollution Prevention and control, 2018

Additionally, the European Union (EU) Water Framework Directive (2000/60/EC) (EU, 2000) applies to the management of water quality, including wastewater. The Framework Directive on Waste uses the '3R's' approach – reduce, recycle, reuse – as well as the precautionary and polluter pays principles (2008/98/EC) (EU, 2008)²⁷.

New EU rules²⁸ have been discussed (Brussels, 26 October 2022) in order to address the management of remaining pollution and cover the gaps of the existing legislative framework toward the zero-pollution EU ambition by 2050. The revision of the urban wastewater treatment target to EU health and environment protection through (i) Energy- and climate-neutral sector, (ii) Treatment of toxic micropollutants, (iii) Improvement of the access to sanitation, (iv) Improvement of monitoring health parameters. Last but not least, existence of viruses concentrations due to COVID-19 increases concerns for monitoring health parameters.

Although the Water Framework Directive is undoubtedly a major policy progression and is delivering environmental improvements, the Directive could have played a greater role in delivering coherent and sustainable water management in Europe. Why the great expectations that came with the Water Framework Directive have not yet been fully realized could be due to its interpretation, reviewing its intent, how it was applied and due to the administrative challenges. Undoubtedly, the legislation applicable to industrial activities in general, and to surface treatments in particular, has its origin in various national and regional laws, in Community directives or regulations and in international conventions and it is for such reasons that it can often appear complex. On the other hand, the multiplicity of provisions in force is the result of a progressive development of a regulatory framework, the density of which is a guarantee of effective pollution prevention, in all its various aspects ²⁹.

Despite three decades of European efforts to introduce and set minimum standard requirements for wastewater treatment, there are still some aspects to be tackled in order to guarantee a higher effectiveness of the directives. As far as industrial wastewater treatment is concerned, a bottleneck for high-end water recycling systems, which usually involve membrane technologies and consume substantial amount of energy, has been noted. In the near future, the main challenge that may face water reuse is likely to be the development of novel processes that consume less energy and/or enhance energy recovery. However, the efforts should not only focus on the best available technology that may not be economically feasible but

²⁷ Common implementation strategy for the water framework directive and the floods directive, Guidelines on Integrating Water Reuse into Water Planning and Management in the context of the WFD Document endorsed by EU Water Directors at their meeting in Amsterdam on 10th June 2016

²⁸ https://ec.europa.eu/commission/presscorner/detail/en/QANDA_22_6281

²⁹ N. Voulvoulis, K. Dominic Arpon, T. Giakoumis, The EU Water Framework Directive: From great expectations to problems with implementation Nikolaos Voulvoulis, Karl Dominic Arpon, &, Theodoros Giakoumis; Science of The Total Environment, Volume 575, 1 January 2017, Pages 358-366

to a fit-for-purpose approach which will allow meeting the circular economy principles.

4.3 Policy recommendations

Public-private and multi-stakeholder partnerships are necessary for scaling up technological innovation, resources and action. There should be an integrated approach to economic, social and environmental dimensions, innovative business models, effective public water policies and regulation. Wastewater is a valuable resource of water (e.g. industrial reuse) and material (e.g. secondary raw materials) and industries should be encouraged to recycle their wastewater and to treat it to meet standards set for ultimate wastewater reuse.

As a starting point for capacity building of wastewater treatment plant employees, wastewater managers should make assessments concerning the adequacy of local labor and expertise available for health and environmental control aspects, adequate operation and maintenance of wastewater treatment plants. Different types of training programmes and training material should be developed and technical trainers' availability as well as available sources of funding for workshop should be assessed.

The continuous evolution of the available technologies for wastewater treatment leads towards new opportunities to meet specifics of circular economy. Wastewater managers along with industries should invest on technologies that allow the recovery of secondary raw materials in the end of the treatment process and on technologies that incorporate recycled materials or by-products of other processes. The integration of innovative technologies for wastewater treatment most of the times require an adequate adjustment of the facilities and proper training. Industries and waste water managers should be provided with incentives for investing on such innovative technologies but should be also obtain derogation from certain legislative obligations during the early stages of the novel technology implementation in their plants.

Individual design is necessary to address the characteristics of any specific plant but there are a number of common treatment steps for liquid effluents of electroplating plants. For small facilities, the possibility of sharing a common wastewater treatment plant should be considered.

BREFs are also continuously updated to set new limitations and targets on the cost-, energy- and environmentally-effective operation of EU Industries including wastewater management and metal/plastic surface treatment.

On June 2022, the KoM for the review of the Best techniques for the surface treatment of metals and plastics has taken place posing key challenges

Where the consideration of industry and the means to collect data have been posed and set.

Still, the Best Available Techniques reference documents raises concerns on the chemical treatments of plating baths and rinsing water to effectively recover, reuse and recycle solutions and components in the metal/plastics surface

industry; e.g. Re-use/recycling of rinsing water; Cleaning and regeneration of phosphate solutions; Cleaning and regeneration of the chromate and phosphate bath ; regeneration of sulphuric acid anodising solutions. ³⁰

³⁰ <https://eippcb.jrc.ec.europa.eu/reference>

5. Disposal and recycling standards for Nanowaste

5.1 Nanowaste

Nanotechnology and its products have launched a new era in industrial scale production but have also triggered difficulties in waste management due to nanowaste (waste containing nanomaterials) that may have different forms varying from pure nanomaterials to surfaces and substances contaminated by nanomaterials or liquids and solids containing nanomaterials. **The potential impact is different depending on the disposal site, meaning, water, air, soil.**

Nanomaterials could pose a threat for both the human health and the environment and the existing waste treatment plants are not adequate for the removal of nanomaterials. As nanotechnology applications are becoming more present, the amount of nanowaste is difficult to be estimated and the available data on the treatment of nanowaste or its behavior in treatment plants are not sufficient to determine the actions required for the treatment of nanowaste. Partially, this can be attributed to the lack of international classification of the risk levels of nanowaste and to the introduction of nanotechnology as a green technology.

It is thus of paramount importance the creation of policies and regulations related to the disposal of nanowaste and legislation is required for the sale of nanomaterial-containing products and their further disposal after use even though the most desirable outcome is the recycling of nanomaterials.

5.2 Nanowaste policy landscape

International organizations such as the Organisation for Economic Co-operation and Development (OECD) and the International Union for Conservation of Nature (IUCN) along with several governments are taking actions for the development of suitable and efficient regulations and policies although a more unified approach would be required in order to tackle such an issue. Joint effort including coordinated research activities, experience and knowledge sharing, guidelines developed for nanomaterials producers, users and waste managers would bring one step forward the nanowaste management agenda ³¹.

The International Organization for Standardization (ISO) developed a series of standards (ISO/TS 80004, now in force ISO/TS 80004-1:2015, is expected to be replaced by ISO/DIS 80004-1) motivated by health, safety, and environmental concerns which describe vocabulary for nanotechnology and its applications. This was one of the very first attempts to unify the field and introduce uniform standards and legislations. Another standard, the ISO/TR 13121:2011 which relates to Nanomaterial risk evaluation had as an aim to identify, evaluate, address

³¹ Bartłomiej Kołodziejczyk, Carnegie Mellon University and IUCN CEM, Nanotechnology, Nanowaste and Their Effects on Ecosystems: A Need for Efficient Monitoring, Disposal and Recycling. Brief for GSDR – 2016 Update

and communicate the potential risks of developing and using nanomaterials, in order to protect the health and safety of the public, consumers, workers and the environment³². However, to date, there are no standards that relate specifically to the safe disposal or recycling of nanomaterials probably due to the large variety of nanomaterials and nanoparticles implicating thus varying approaches.

Recently, OECD along with other national and international organizations released five new reports that describe their efforts. The US Environmental Protection Agency (EPA), US Occupational Safety and Health Administration (OSHA) and World Health Organization (WHO) are funding studies on the health and environmental risks posed by nanomaterials and the UK's Royal Society of Engineering along with the European Commission are currently developing rules to protect humans and the environment from nanomaterials and nanowaste³². However, there is still much to be done.

Latest news from ECHA (Helsinki, 15 November 2021) noted that despite the limited knowledge about nanomaterials in wastes, any existing data are valuable. To this end, based on REACH, there are obligations from manufacturers and importers to report and monitor any nanoform of chemical substances.

In the same context, the G20 Insights³³ – Policy area: 2030 Agenda – there are identified needs for effective disposal and recycling of nanowastes. The ISO/TS 80004 series and ISO/TR 13121 are also setting the guidelines; however, a great intensification and more funding for lifecycle and commercialization of nanotechnology and safe disposal of nanowastes are highly proposed.

5.3 Policy recommendations

Evaluating protocols and developing new disposal and recycling processes for nanowaste and products containing nanomaterials is essential. For this reason, research grants and funding should be allocated and provided, and more attention should be paid to the development of nanowaste disposal procedures and nanotechnology life-cycle.

A single procedure for nanowaste disposal will not be sufficient due to the broad range of existing nanomaterials that have different properties. Understanding the properties of the specific nanowaste before developing effective disposal practices should be a priority for developing effective disposal practices that are tailored to each material individually.

Companies producing nanowaste should guarantee deactivation of the waste prior to disposal and new nanomaterials should be released to the market only after the development of appropriate disposal procedures approved by government agencies.

Where possible, nanowaste should be recycled.

³² Thomas Faunce, Bartłomiej Kolodziejczyk Nanowaste: Need for Disposal and Recycling Standards, April 27, 2017

³³ <https://www.g20-insights.org/>

Specific nanomaterials might be chemically active or toxic under particular environmental conditions occurring in different parts of the world so each country should develop their own standards and disposal procedures based on their individual needs and geographical conditions.

Unified international policies and guidelines are also needed so international stakeholder, scientist and policy makers' engagement is required in order to enhance expertise, issues and solution exchange.

Consumers and the general public should be aware of the health and environmental consequences of nanowaste so awareness-raising and communication campaigns should be organized.

Based on ECHA, the manufacturers and importers of nanomaterials should report the quantity and quality of the nano and non-nano form chemicals.³⁴ This will enable the identification of volumes and facilitate strategic planning for nanowastes management. Due to lack of data, the G20 strategy highlights the need for the evaluation of toxicity and safe disposal of nanowastes in a continuous basis. In this scope, G20 also identifies challenges, where actions are required, including the development of ³⁵:

- Instrumentation for exposure assessment
- Methods for the toxicity evaluation
- Models for the prediction of environmental and human health impacts; including engineered nanomaterials (whole life cycle)
- Research programs for associated risks analysis.

³⁴ <https://echa.europa.eu/-/despite-limited-information-on-nano-waste-existing-data-is-valuable-for-waste-operators>

³⁵ https://www.g20-insights.org/wp-content/uploads/2017/05/Agenda-2030_Nanowaste-1.pdf

6. Conclusions

Deliverable 7.9 is the final version of policy recommendations related to the PureNano project. It addresses the major topics that are fundamental for the acceptance and integration of the PureNano technology to the waste water treatment in the plating industry.

International H&S standards and related documents including technical specifications, technical reports and guidance materials are being developed for nanotechnologies and translating scientific background it into a form of regulatory relevance with international consensus is what is currently needed. Here, three types of actions required for a responsible development of a risk governance framework are presented.

Environmental impact and toxicity of nanomaterials are still poorly described and understood. Since nanomaterials can be released to the environment at any stage of their life cycle and there is still uncertainty about the hazards and risks, it is fundamental that existing regulations adapt to the specific issues of nanomaterials and consider as well their long-term effects on the environment. Certain recommendations on that directions are provided in this document with the hope that proper guidelines will be developed in the near future.

Specifically, for the plating industry, the choice of an appropriate purification system and the destination of the waste is affected by the pollutants and in particular metals, contained in the waste water. Additionally, metals are important raw materials and their careful and conscious use can allow their recovery and recycling improving environmental protection and business competitiveness. However, some aspects of industrial wastewater treatment still need to be tackled in order to guarantee a higher effectiveness of the directives and the focus should be on best available technologies that allow meeting the circular economy principles.

Finally, as nanotechnology applications generate considerable amounts of nanowaste, regulations related to the disposal of nanowaste and of nanomaterial-containing products are essential. Although actions for the development of suitable and efficient regulations and policies are being taken, up to date, there are no standards that relate specifically to the safe disposal or recycling of nanomaterials. For such reasons, recommendations that aim at unified international policies and guidelines are provided here.