RISK GOVERNANCE AND RESEARCH & INNOVATION PRIORITIES IN NANOTECHNOLOGIES

FIRST BRIEFING REPORT WITH A FOCUS ON FOOD, HEALTH AND THE ENERGY SECTOR

Deliverable 5.1

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CONTENT

EXECUTIVE SUMMARY

The present report provides an overview of the current policy context, recent developments and debates regarding risk governance and regulations of nanotechnologies in Europe as well as the main research and innovation priorities by European policies (H2020) and industries (European Technology Platforms). The report is Deliverable 1 of Work Package 5 "Governance and Policy Outreach and Alignment" (Task 5.1 "Policy Monitoring and Alignment") of the project GoNano and serves to ensure a strong degree of policy alignment of the project, specifically between the design of the pilot studies and relevant policy initiatives and debates.

The screening of R&D policies and industry priorities shows that nanotechnologies are supported to improve industrial competitiveness and to tackle several societal challenges. Two of the areas covered by GoNano, i.e. health and energy, play an important role in the H2020's support for nanotechnologies. Research and innovation of nanotechnologies have also entailed a range of new debates and institutions to deal with the uncertainties and potential side-effects of this technology. The screening of EU risk governance reveals that many risk and regulatory issues are still unresolved and will likely continue to exist. Therefore, it is a key task of the pilots to avoid a technology-fix position, in which nanotechnologies are framed as the (only) solution to a range of problem and risk and regulatory issues are understood as easily manageable. Rather than presuming that complete knowledge on the impacts of nanotechnologies can be acquired and regulated accordingly, the pilots should raise questions along the line of "which uncertainties and risks are we willing to take in exchange of the benefits of nanotechnologies for food, health and energy?"

In respect to the three pilot sectors, food, health and energy, the report provides the following conclusions: The envisioned applications of nanotechnology in the food industry appear rather limited and in the short-term are related to food safety and security and food packaging. In the longer-term, nanotechnologies are expected to be used to realize functional foods. Debates on EHS issues and regulations, however, are particularly pronounced in the food sector with a range of sectoral regulations explicitly addressing nanotechnologies.

The health sector is expected to experience major advancements thanks to nanotechnology. In therapeutics nanotechnologies offer the possibility for a precise control on the release of drugs, reduce the side effects of therapies and to maximise the personalization and efficacy of therapies. Nano-electronics are expected to contribute to more efficient, fast and site-specific, minimally invasive diagnostic and monitoring systems. Nano-assisted regenerative medicine is targete at improving tissue regeneration, develop cell-based therapies and new intelligent biomaterials. Also in the health sector, a range of EHS, unresolved uncertainties and risks to human health are debated and included in existing and new regulations.

The energy sector is expected to benefit from nanotechnology mainly in terms of new structural and functional materials and devices, in particular for energy production (e.g. advanced photovoltaics), energy storage (batteries), and various applications for energy saving. A large group of applications in different sectors can be found that will allow to enhance energy efficiency, reduce energy in industrial processes, improve power distribution and miniaturize energy supply systems. So far, no specific regulations concerning nanotechnologies exist for the energy sector.

1. INTRODUCTION

1.1 GONANO: ADVANCING RRI AND SOCIETAL DIALOGUE ON NANOTECHNOLOGIES

Over the past 20 years, nanotechnologies have given rise to great expectations based on new research opportunities in areas as diverse as energy, healthcare, electronics, food, transportation and construction and promising global competitiveness as well as a remedy for societal challenges such as health, climate change or energy demands. At the same time, new demands for risk governance have emerged against the backdrop of concerns about the safety and unintended consequences of the use of nanomaterials on health or the environment.

Almost from the beginning, the governance of nanotechnologies has been closely linked to the discourse on Responsible Research and Innovation (RRI) (Rip, 2014). After the widespread public debate and refusal of agri-biotechnology, actors in science, politics and industry had become more attentive for potential controversies, uncertainties and risks of emerging technologies and aimed to guide the technological development more responsibly from the outset. The US National Nanotechnology Initiative (2000) adopted "responsible development" as one of their four strategic goals (Owen et al., 2012). Similarly, in the document "Towards a European Strategy for Nanotechnology" the European Commission defined 'responsible development' as a deliberative process based on the idea that nanotechnology could be guided by "ethical principles [which] must be respected and, where appropriate, enforced through regulation" (European Commission, 2004b, de Saille, 2015). Subsequently the European Commission developed recommendations concerning the Code of conduct for and the council conclusions on Responsible Nanosciences and Nanotechnologies Research (European Commission, 2008). In 2008 the Royal Society, Insight Investment and the Nanotechnology Industries Association (NIA) developed the "Responsible Nano Code for business", supported by companies in Europe, the US and Asia (Insight Investment et al., 2008). The now established term 'Responsible Research and Innovation' was initially coined in 2007 in a constructive technology assessment workshop on nanotechnology in the Netherlands (Robinson, 2009). This prompted a wide range of initiatives on RRI, related to nanotechnologies as well as many other different technologies and fields that have been conducted in the last decade, in particularly in Europe[1]. As part of the implementation of RRI, public dialogue initiatives were initiated (and are being held) on the national and EU levels to ensure the early dialogue with society, involving researchers, stakeholders, policy-makers and the general public. Deliverable 1.1 of the GoNano project provides an overview on the main public and stakeholder engagement projects in Europe and summarizes the main lessons learned from these initiatives.

The H2020-funded project *GoNano "Governing nanotechnologies through societal engagement"* (2017-2020) [2] follows these initiatives in fostering societal dialogue on nanotechnologies for RRI. The project enables co-creation between citizens, civil society organisations, industry, researchers and policy makers across Europe to align future nanotechnology applications with societal needs and concerns. GoNano aims at demonstrating how researchers and innovators can work with publics and professional stakeholders to create novel suggestions for future nanotechnology products. The goal

[1] https://ec.europa.eu/programmes/horizon2020/en/h2020-section/responsible-research-innovation
[2] http://gonano-project.eu/

is to co-create concrete product suggestions within the areas of food, health and energy, illustrate new opportunities for innovation and develop policy recommendations. More specifically the objectives include:

- Aligning nanotechnologies with societal needs and values.
- Policy recommendations and in support of a responsive research and innovation system and co-production of knowledge.
- Increased confidence of stakeholders that new technologies respond to societal needs and values.

1.2 Purpose, scope and structure of the 1st Briefing Report

Within GoNano the present report serves to ensure a strong degree of policy alignment of the project, specifically between the design of the pilot studies and relevant policy initiatives and debates, including priorities of the European Union and European Technology Platforms. The Report provides a first overview of the current policy context, recent developments and debates regarding regulation and risk governance of nanotechnologies in Europe as well as on the main R&I priorities by European policies and industries. This 1st briefing report is deliverable 1 of Work Package 5 "Governance and Policy Outreach and Alignment" (Task 5.1 "Policy Monitoring and Alignment").

The geographical focus of this report is primarily on the EU level, including priorities stated in Horizon 2020 and by the European Technology Platforms (ETPs) and regulatory debates and initiatives at the European level. In terms of technology, the focus of the first screening is on nanotechnologies. Nanotechnology is the prominent term to describe the variety of research and innovations related to the manipulation of matter in the nanometer range.[3] However, a clear distinction from prior technology approaches is not always feasible (or useful). Hence, nanotechnology research and applications may occur even without being explicitly named as such. For the screening and monitoring we generally aim for those policy initiatives and debates that are explicitly labelled as "nano" as well as those initiatives that embed "nano" among other (emerging) technologies, such as key enabling technologies in H2020. More specifically the first screening looks at priorities, initiatives and debates in the three pilot sectors food, health and energy. The thematic focus of the first screening is twofold: a) on risk governance and regulatory issues and debates and b) on research and innovation priorities.

a) *Risk governance, regulatory issues and debates:* includes an overview of existing regulatory policies and current debates on the governance and regulation of nanotechnologies in general and in the three sectors in particular (mainly EU level, selected national level). This includes recent debates around nanomaterials and respective definitions in the context of the update of REACH but also soft laws in the area of risk governance and prominent initiatives by non-state actors. With 'key policy debates' we aim at capturing the positions and strategic priorities of

[3] A formal definition of nanotechnology is provided by the ISO/TS 80004-1:2010, where nanotechnology is defined as: *"the application of scientific knowledge to manipulate and control matter in the nanoscale to make use of size and structure-dependent properties and phenomena distinct from those associated with individual atoms or molecules or with bulk materials"*

different actor groups, the main issues and themes, as well as potential controversies associated with the identified regulatory initiatives and debates.

b) *Research and innovation priorities:* include strategic and investment priorities of policy (EU Commission) and industry stakeholders (ETPs). In this context, the screening particularly focusses on strategy developments, action plans or roadmaps as well as dedicated funding initiatives and programmes.

The report does not claim to provide comprehensive information and analysis, but rather to provide a structured overview on the main issues and debates in order to support the citizen and stakeholder dialogues in the pilots.

The information presented in this report was gathered by the means of desk research, including the screening of websites (for example of relevant ETPs or of the European Commission) and the analysis of key documents (e.g. existing legislation, strategy documents of ETPS and the European Commission and H2020 documents and calls) as well as by input from GoNano partners.

The report is structured in the following way: Chapter 2 provides an introduction and overview over policy frameworks on nanotechnology, including recent developments and main institutions at the EU level as well as cursory insights on the role and state of nanotechnology governance in GoNano partner countries. Chapter 3 is dedicated to nanotechnology risk governance and regulation and gives an overview over the main current issues and debates, specifically in the three pilot sectors. Chapter 4 analyses European research and innovation priorities for nanotechnologies in the context of the EU Commission H2020 programme and the relevant European technology platforms. Chapter 5 summarizes the main insights from the first screening and suggests themes, issues and potential applications to be addressed in the three pilot studies. The Annex provides a list of resources on nanotechnology policies, regulations and activities at the European level and at the level of GoNano partner countries.

2. NANOTECHNOLOGY POLICY CONTEXT

Since the late 1990s nanotechnology has been recognized as a key enabling technology by research and innovation policy in many countries. Japan, China and the US have been the first countries to provide strategic support to the development of nanotechnologies. Simultaneously regulatory and risk governance debates started to emerge. Since around 2000 nanotechnology has increasingly become the subject of R&I and regulatory debates and initiatives in Europe, starting in single Member States such as the UK and Germany and then followed by institutions and activities at the level of the European Union. At the same time, other international organizations such as OECD, UNESCO or ISO as well as NGOs increasingly paid attention to nanotechnologies. This chapter gives a brief overview on the nanotechnology policies in terms of foci, key documents and institutions with a major emphasis on the EU level (section 2.1) and some cursory insights on the role and status of nanotechnology policies in the nine GoNano partner countries (section 2.2).

2.1 EU POLICY FRAMEWORK FOR NANOTECHNOLOGY

The European Commission's document "Toward a European Strategy for Nanotechnology" (European Commission, 2004a) marks the beginning of a comprehensive approach and strategy on nanosciences and nanotechnologies at the EU level. The document laid out the multiple challenges and objectives in governing nanosciences and nanotechnologies that define EU activities up until today:

a) increasing and better coordinating R&D in the area of nanosciences and nanotechnologies,
b) developing world-class infrastructure for nanotechnology research,
c) promoting the development of skills and business competencies necessary to successfully exploit nanotechnology,
d) promoting an environment conducive to commercialization of nanotechnologies so that research is translated into economic benefits,
e) integrating societal implications of nanotechnology in the R&D process from an early stage,
f) generating data required for risk assessment so that potential health, safety, environmental and consumer risks can be assessed, monitored and if necessary addressed,
g) engaging in international-level activities to further these objectives.

Nowadays, nanotechnologies concern a wide range of EU policy areas and institutions related to research, innovation and industrial policies, as well as infrastructure, education and international cooperation. Moreover nanotechnologies are discussed under the framework of Responsible Research and Innovation and, crucially, in terms of environmental, health and safety issues (EHS) and ethical, legal and social aspects (ELSA).

The Directorate-General for Research and Innovation[4] plays a crucial role in coordinating and supporting research and development in nanosciences and nanotechnologies, and from the 6th Framework Programme on has provided financial and funding support for nanoscience as well as

[4] http://ec.europa.eu/research/industrial_technologies/nanoscience-and-technologies_en.html

industrial innovations and applications (see section 4.1 for more details). In recent years, nanotechnologies have been integrated in the European Commission's strategy and action plan for key enabling technologies (European Commission, 2012). In order to ensure the successful implementation of the KETs strategy several advisory groups have been set up: A High-Level Group (HLG)[5], consisting of representatives from research and industry associations, is advising on the implementation of the KETs action plan. The Advisory Group for Nanotechnologies, Advanced Materials, Biotechnology and Advanced Manufacturing and Processing (NMBP) assists the European Commission in the preparation of legislative proposals and policy initiatives in the area of NMBP.[6] A Member States Group on KETs[7] has been set up to improve collaboration between European and national/regional level actors. The Member States group advises the Commission on the implementation of the EU KETs policy; ensures coherence with national and regional KETs policies; acts as national KETs ambassadors; and promotes the development of KETs policies to help the Commission identify barriers to trade for KET-based products. The Commission Internal coordination groups (the KETs Interservice Group and the Leadership in Enabling and Industrial Technologies Group of Horizon 2020) ensure coherence between all KETs-related programmes[8].

From the beginning, the European Commission has linked nanotechnologies to the emergence of Responsible Research and Innovation as a new governance approach for the EU's R&D policies. The 'Code of Conduct for Responsible Nanosciences and Nanotechnologies Research' (European Commission, 2008) promotes integrated, safe and responsible nanosciences and nanotechnologies research in Europe for the benefit of society as a whole. The intention of this document is to guide the actions of Member States in the formulation and implementation of both innovation and regulatory research strategies in individual jurisdictions. The Code of Conduct foresees the review of its recommendations every two years and a monitoring by the Member States of the extent to which relevant stakeholders have adopted and applied it (Nano2All, 2016). In order to develop nanotechnology in a way that responds to the needs and concerns of European citizens, a wide range of EU-funded dialogue and communication projects were launched dialogue projects and initiatives have been initiated. Examples of recent initiatives include the NanoDiode[9] and Nano2all[10] projects and the present project GoNano, all funded under the Commission's NMBP programme.

Alongside the strategic support for advancement in nanosciences and the industrial development of nanotechnologies, EHS issues and ELSA have become focus of attention of a wide range of EU institutions. In the framework programmes, the European Commission devoted relevant funding to EHS issues, and (though to a lesser extent) ELSA. EU activities on EHS issues of nanotechnologies are brought together within the Nanosafety Cluster[11], that produced the research strategy 'Nanosafety in Europe 2015-2025: Towards Safe and Sustainable Nanomaterials and Nanotechnology Innovations' (Savolainen et al., 2013), outlining the focal points of nanomaterial safety research for Horizon 2020.

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[5] http://ec.europa.eu/growth/industry/policy/key-enabling-technologies/european-strategy/high-level-group_en
[6] http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2962
[7] http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2950
[8] https://ec.europa.eu/growth/industry/policy/key-enabling-technologies/european-strategy_de
[9] http://www.nanodiode.eu/
[10] http://www.nano2all.eu/
[11] https://www.nanosafetycluster.eu/

The DG for Employment, Social Affairs and Inclusion is particularly concerned with health and safety issues of nanomaterials at work and is supported by the European Agency for Safety and Health at Work (EU-OSHA)[12]**.** OSHA looks at the exposure to nanomaterials at the workplace[13] and respective risk perception and risk communication strategies[14].

Looking at the sectors considered by GoNano, EHS issue and ELSA have been highly debated concerning application of nanotechnologies in food. The European Food Safety Authority **(**EFSA**)**[15] supports the European Commission with risk assessments on nanotechnologies in food and feed[16], respective guidance and public consultations[17]. Also, the European Parliament has been particularly concerned with nanotechnology in food products and has called for safety assessments and labelling of food products containing nanomaterials in the context of the Novel Food Regulation. The European Commission Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)[18] is a further advisory body for the European Commission, providing "opinions on emerging or newly-identified health and environmental risks and on broad, complex or multidisciplinary issues requiring a comprehensive assessment of risks to consumer safety or public health and related issues not covered by other Community risk assessment bodies". SCENIHR also published various documents concerning EHS of nanotechnologies[19].

Closely related to the activities in EHS issues are a range of regulatory issues and debates. Over the past decade, the European Commission has reviewed existing regulatory frameworks on their applicability to nanomaterials in order to propose adaptations of EU regulations in relevant sectors (see chapter 3). In 2009, the European Parliament and European Union Council approved an updated European Cosmetics Regulation that requires manufacturers of new cosmetic products that contain nanomaterials to notify the EC and provide information six months before the product is released on the European market (Charrière and Dunning, 2014). In 2011, the European Union published a directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment. This European Union directive calls on member states to examine the substitution of nanomaterials in electronic and electrical equipment for other substances as a precautionary measure against potential negative human health impacts that might result from exposure (Charrière and Dunning, 2014).

At the core of recent regulatory debates are the REACH Regulation, the Classification, Labelling and Packaging (CLP) and the Biocidal Products Regulation (for more detail on these debates see chapter 3). A range of agencies and advisory bodies support the implementation of these regulations. Notably, EU REACH guidelines require the filing of a materials safety assessment dossier with the

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[12] https://osha.europa.eu/en/emerging-risks/nanomaterials
[13] https://osha.europa.eu/en/tools-and-publications/publications/literature_reviews/workplace_exposure_to_nanoparticles/view
[14] https://osha.europa.eu/en/tools-and-publications/publications/literature_reviews/risk-perception-and-risk-communication-with-regard-to-nanomaterials-in-the-workplace/view
[15] http://www.efsa.europa.eu/en/topics/topic/nanotechnology
[16] http://www.efsa.europa.eu/en/supporting/pub/1393e
[17] http://www.efsa.europa.eu/en/press/news/180112
[18] https://ec.europa.eu/health/scientific_committees/emerging_en
[19] http://ec.europa.eu/health/scientific_committees/emerging/opinions/scenihr_opinions_en.htm#nano

European Chemicals Agency (ECHA)[20]. In order to facilitate this process ECHA has published a safety assessment best practice guide for nanomaterials under REACH (2014). The European Chemicals Agency (ECHA) also hosts the European Observatory for Nanomaterials (EUON)[21]. Within ECHA a Nanomaterials Expert Group (NMEG) was established in order "to seek common ground among experts on scientific and technical issues relating to the implementation of REACH, CLP and the Biocidal Products Regulation (BPR) for nanomaterials"[22]. A further advisory group is the "Competent Authorities for Registration, Evaluation, Authorisation and restriction of CHemicals (REACH) and Classification, Labelling and Packaging (CLP)" (CASG nano), established in 2008, under the aegis of DG Environment. The advisory group cooperates with the Commission and the European Chemicals Agency in the implementation of the REACH and CLP Regulations.

2.2 NANOTECHNOLOGY POLICY FRAMEWORKS IN GONANO PARTNER COUNTRIES

In several EU Member States, the governance of nanotechnologies started in advance of the EU level, some countries even launching early joint projects with industry (e.g. Germany, the Netherlands and the UK) (European Commission, 2017c, 8). Over the past decades, the policy cooperation between the EU and the Member States has frequently shown a mutual influence, sometimes from the national level to the EU level, particularly for the larger Member States (e.g. the UK and Germany), and sometimes from the EU to the MS level (e.g. on fostering societal dialogues on nanotechnologies) (European Commission, 2017c, 9). Within this section, we give a short overview on the respective nanotechnology governance frameworks and debates in the nine GoNano partner countries.

AUSTRIA

The Austrian Nano initiative marks an important starting point for nanotechnology policy in Austria. The Nano initiative funded nanotechnology research projects from 2004-2011, coordinated measures on the national and regional levels and was supported by several ministries, federal provinces and funding institutions.23 After the end of the programme and to this day, nanotechnology research and industrial development have been integrated into the programme "Production of the Future" of the Austrian Research Promotion Agency (FFG)24.

Discussions on environmental, health and social issues of nanotechnologies and respective regulatory discourses began later than in other countries and mainly reacted to international activities (Kurath et al., 2014). From 2007 on, the project NanoTrust, conducted by the Institute of Technology Assessment (ITA), has played an important role in the knowledge and risk governance of nanotechnologies and nowadays forms the central hub for the administrative and stakeholder debate on nanotechnologies in Austria. The Austrian Nanotechnology Action Plan (ÖNAP) (2009) was the starting point of co-ordinated political action on nanotechnology risk governance in Austria. The ÖNAP was prepared by working groups from the BMLFUW nanotechnology platform, on which

[20] https://echa.europa.eu/home
[21] https://euon.echa.europa.eu/home
[22] https://echa.europa.eu/regulations/nanomaterials/nanomaterials-expert-group
[23] https://ec.europa.eu/growth/tools-databases/kets-tools/policy/policy-profiles-kets-austria/initiative/austrian-nano-initiative
[24] https://www.ffg.at/en/production-future-calls

stakeholders and representatives from the administration, NGOs, and science met on a regular basis (Kurath et al., 2014). The plan contains fifty recommendations in the fields of environment, health and occupational safety. Fundamental to these recommendations is the demand for (public) dialogues and transparency among all stakeholders including the breaking down of scientific knowledge into generally understandable language (Jakl et al., 2009). Identified fields of action were the review and securing of legal frameworks (especially when it comes to occupational safety and consumer protection), the possible need for labelling or registry, and the coordination of international legal developments as well as strengthening voluntary measures (Kurath et al., 2014). As a follow-up to the ÖNAP, in 2012 the NanoInformationsPlatform (NIP) was established for the exchange of information on nanogovernance and regulation within the administration and with the public. As a result of these expert discussions the website Nanoinformationsportal (nanoinformation.at) was established. In 2013 the informal working party coordinating the NIP became institutionalised as the "Austrian Nano Information Commission (NIK)", managed by the Federal Ministry of Health, and chaired by the NanoTrust project leader. The NIK is defined as an advisory body for the federal government on the health and societal relevant aspects of nanotechnology.

CZECH REPUBLIC

The Czech Republic does not have a dedicated strategy for nanotechnology research and innovation, but nanotechnologies are included under the priority "*Sustainability of energetics and material resources"* in the implementation plan of the *National priorities for oriented research, experimental development and innovation* (2012-2030) (Nano2All, 2016). From 2006-2012, the Academy of Sciences supported nanotechnology research and development through the funding programme '*Nanotechnologies for Society*'. The programme brought together academia and commercial enterprises and aimed at the development of nano products for the benefit of society (Nano2All, 2016). Currently, the most relevant national funders for nano research and innovation are the *Technology Agency* of the Czech Republic (funds are mostly given to applied research, experimental development, and innovation), the *Czech Science Foundation* (which funds basic scientific research) (Nano2All, 2016), and the *Ministry of Health of the Czech Republic* (supporting partly the field of nanomedicine).

On the industrial side, several research and industry networks and associations foster research and industrial collaboration on nanotechnologies: Nanoprogress is a cluster of more than 30 companies and 2 RTOs (Technical University Liberec, Centre for the Development of Engineering Research (VÚTS). CzechImplant is a cluster of 14 companies (more than half research-performing) and 5 universities that are active in the field of advanced materials, of which some are nano – based. The Nano Association of the Czech Republic has 19 members (companies) and aims at better representing, both nationally and internationally, the strengths and capabilities of Czech companies in business, research, and education. Its project "Czech Is Nano" promotes the outcomes of the research and everyday application of the nanotechnologies, organising a range of events (Czech Nano Days) across the Czech Republic and abroad.

Nanomedicine is one of the most developed nano-based sector in the Czech Republic. It is undoubtedly due to the technology of production of nanofibres by electrospinnig invented in 2003 at the Technical University Liberec, subsequently commercialized as ´NanoSpider´ by the Elmarco company. Today, a range of research and development activities address nanomedicine, for example

the development of body organs by usage of nanofibers, in vitroexpansion and cultivation of cells (NanoPharma), wound healing with hyaluronic acid, pharmaceutical ingredients, implants of peripheral nerves (Contipro) or developing drug delivery and scaffolding systems based on nano/microparticles and nanofibrous systems (Inocure). Several companies are active in the area of energy, particularly in regard to nanomaterials for batteries and nanomaterials as components for solutions in energy-efficient buildings.

DENMARK

The Danish *Research 2020 Strategic Research Horizons* policy document, issued by the Ministry of Higher Education and Science[25], highlights nanotechnology as a priority area for the country and emphasises the importance of nanotechnologies for addressing important societal challenges such as health, energy and environment[26].

The Ministry of Higher Education and Science has established the framework to foster closer collaboration between technical companies that use, or potentially will use nanomaterials, the Danish universities and independent Danish research and technology organisations[27]. Regarding risk, the Ministry of Higher Education and Science recognizes that the need for more reliable, specialized and advanced methods of measurement for categorizing nanomaterial and production processes is standing in the way for upscaling the production of nano- and microstructures[28].
Regarding health, *Research 2020 Strategic Research Horizons* underlines nanomedicine as potentially revolutionary for the treatment of cancer and other diseases. The strongest area of focus within medical research in nanotechnology is diagnostic and drug delivery technology[29]. Regarding energy, The Danish Environmental Protection Agency[30] recognizes the need for development of nanotechnology within the energy sector with the aim of utilise the potentials for green energy production. Nevertheless, it is important to balance this utilisation with caution regarding environmental risks associated with nanotechnology[31]. In addition, the Danish Technological Institute established the first production machinery for production of nanoparticles for fuel cells[32].
The responsibility for risks associated with nanotechnology and nanomaterials is distributed among different ministries and agencies. In general, many of the available reports on risks associated with nanotechnology are more than 5-10 years old. In 2012 the Ministry of Environment and Food developed the action plan: *Better Control of Nanomaterial*, aiming to promote a better understanding of the "*possible exposure pathways and potential harmful effects of nanomaterials*

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[25] https://ufm.dk/en
[26] https://www.ufm.dk/en/publications/2012/files-2012/research2020.pdf
[27] https://ufm.dk/forskning-og-innovation/indsatsomrader/forsk2025/indkomne-indspil/videninstitutioner/gts-institutter/dansk-fundamental-metrologi/dansk-fundamental-metrologi-nano-og-materialeteknologi?searchterm=nano
[28] https://ufm.dk/forskning-og-innovation/indsatsomrader/forsk2025/indkomne-indspil/videninstitutioner/gts-institutter/dansk-fundamental-metrologi/dansk-fundamental-metrologi-nano-og-materialeteknologi?searchterm=nano
[29] http://www.sum.dk/Aktuelt/Publikationer/~/media/Filer%20-%20Publikationer_i_pdf/2007/Nanoteknolog_Sundhed.ashx
[30] http://eng.mst.dk
[31] https://www2.mst.dk/Udgiv/publikationer/2007/978-87-7052-647-0/pdf/978-87-7052-647-0.pdf
[32] https://www.teknologisk.dk/ydelser/danmarks-foerste-nano-fabrik-er-klar-til-produktion/33056?cms.query=nano

(Nano2All, 2016). As part of the initiative, the Environmental Protection Agency under the Ministry of Environment and Food has established a national register of nanomaterials[33].

IRELAND

Despite its small size, Ireland's investments in nanotechnology have proven to be very successful. Government, academia and industry investment have together made nanotechnology a success story in terms of economic growth and employment for Ireland, as well as sustained a huge scientific/research output. This research output is often but not exclusively led by the main nanotechnology centres in Ireland: Crann (Centre for Research on Adaptive Nanostructures and Nanodevices) in Trinity College Dublin (TCD), Tyndall National Institute, University College Cork (UCC) and AMBER, a collaboration between TCD, UCC and Royal College of Surgeons Ireland (RCSI). Looking only at Crann/AMBER, their work over the past decade has simulated 14,279 jobs in the wider Irish economy and have generated €505 million in gross national output (Crann Institute, 2018).

In terms of governance, nanomaterials are covered by the existing legislation for the manufacture, import, or use of chemical substances. Also relevant is REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals), the overarching European regulation on the manufacture, placing on the marker, or use in preparation or in articles, of substances. Regarding risk assessment and control measures, employers are advised to apply a hierarchy of controls in order to protect their workers from nanomaterials, in the absence of specifically developed occupational monitoring methodologies. Likewise, a 'cautious approach' is recommended relating to the uncertainty associated with the effect of nanotechnology on human health, owing to the information gap in nanomaterial risk management (Health and Safety Authority, 2018). Nevertheless, governance and regulation are important issues in Irish research; positive evaluations are based on the assumption that for example the novel-food technology represented by nanotechnology will be adequately regulated (Handford et al., 2014).

Ireland benchmarks well internationally on the basis of normalised publications, patents and quality of research; however, it has to work hard to make an impact on the global stage. Overall, nanotechnology is already impacting or is set to impact all sectors of Irish business and industry in a deep and meaningful way. Ireland's small size can, and should, be turned into an advantage through sharper focus, more efficient use of funds, fewer obstacles, and higher quality standards. In the meantime, the governance and commercial use of nanotechnology in Ireland can benefit from starting with a relatively clean slate but at the same time being able to learn from best practices of other nations (Forfás, 2010).

ITALY

Interest and activities in nanotechnologies, are a relevant feature of the Italian R&D landscape. All major universities and public research institutions, as well as leading national industries and high tech SMEs are involved. Key sectors of application include chemistry & materials, electronics & ICT,

[33] http://mst.dk/service/publikationer/publikationsarkiv/2015/dec/better-control-of-nanomaterials/

pharmaceuticals & biotech, transportation, as well as typical Made in Italy sectors (e.g. textiles, furnitures, cultural heritage)[34].

Investment in the field are both public and private though public funding coming from different sources (EU, national and regional) has still a fundamental role. Private spending nevertheless gains ground, as shown by the increasing commitment of some of the largest industrial groups in the country.

In Italy, there is no specific national funding programme or strategy fully dedicated to nanotechnologies. However, Italy is amongst the first countries in terms of funding received by the Horizon 2020 (NMBP Work Programme), with several research projects specifically on nanotechnologies. The main governmental instrument for R&D planning and funding is the National Research Programme (PNR) 2014-2020 managed by the Ministry of Education, University and Research (MIUR). The PNR for 2014 - 2020 is strongly aligned with Horizon 2020, focusing on major societal challenges and covering various research areas. In the framework of the PNR 2014-2020, under the theme of Industrial leadership, there is a specific funding line for nanotechnology and nano-electronics R&D.

Research centres and academia with specific activities on nanotechnologies are also funded through regional funds, including so called "Excellence centres" focusing on nanotech, established by the MIUR in the past years.

Regarding the responsible development of nanotechnologies, the Italian Workers' Compensation Authority (INAIL) published, in 2011, a "White Book on occupational health and safety effects of engineered nanomaterials", and is working on a specific methodology for risk management and communication of nanomaterials[35]. The Ministry of Health and the National Institute of Health (ISS) are cooperating at international level on the safety of nanomaterials within the NanoReg, Prosafe and EU nanosafety cluster initiatives, and recently published a national platform on safety of nanomaterials[36]. The National Federation for Chemical Industry (Federchimica) leads a Nano Product Stewardship working group. Regular conferences and workshops on RRI aspects of nanotechnologies are held with the participation of national R&I players from both the private and public sector.

THE NETHERLANDS

The Netherlands is at the forefront of nanotechnology developments and is the largest player among the medium-sized economies (Nano2All, 2016). The Dutch government has funded significant national programmes for nanotechnologies in the past. The Dutch Cabinet Vision '*Van Klein naar Groots'* (2006) positioned nanotechnologies as an opportunity for innovation and economic growth, resulting in research and innovation programmes such as NanoNed (2005-2009) and its successor NanoNextNL (2011-2016). These programmes were accompanied by programmes on the possible risks and societal dimensions of nanotechnologies (such as the NanoNed Technology Assessment

[34] „Priority Industrial Technologies in Italy: Innovation for the Future", Airi, 2016 - ISBN 978-88-9893-507-9 and „L'importanza industriale delle nanotecnologie e dei nanomateriali", Energia, Ambiente e Innovazione, 1-2/2015 - DOI 10.12910/EAI2015-027

[35] www.nano.lab.it

[36] www.nanotecnologie.iss.it

flagship and the NanoNextNL Risk Analysis and Technology Assessment programme). Risk Analysis and Technology Assessment (RATA) considered new and existing safety issues associated with nanotechnology within the frameworks like the Stage-Gate innovation model (Beukers and Polman, 2017). This includes tools for the detection of nanomaterials and understanding the mechanisms of (eco) toxicity as well as regulatory oriented projects like the NANoREG[37] project. It also developed "Safe-by-Design" tools for research and development toolbox aimed at a timely dialog between the relevant stockholders[38]. NanoNextNL allocated 18% of the overall programs budget to Responsible Research and Innovation.

Driven by the Cabinet Vision '*Van Klein naar Groots'* and the *Nanotechnology Action Plan,* a number of institutions have been established, such as the Nanotechnology Knowledge and Information Centre (KIR nano), which is part of the National Institute for Public Health and the Environment (RIVM) (Nano2All, 2016). The National Nanomedicine Platform, also hosted by RIVM, brings together researchers, policy-makers, industry and civil society actors interested in nanomedicine research and regulations Cabinet Vision '*Van Klein naar Groots'*. The Sounding Board on Risks of Nanotechnology has also been created and provides advice on nanotechnology risks Cabinet Vision '*Van Klein naar Groots'*.

After a period where there have been no large national nanotechnology funding programmes (nanotechnology was not identified as a dedicated sector in the so-called topsector-policy of the Ministry of Economic Affairs[39], which made 7 million Euro available for innovation in dedicated sectors in the period 2012-2015), the newly formed cabinet may decide to renew funding for nanotechnologies. The cabinet decided in 2017 to invest an additional 400 million in research and innovation. Investments are expected to follow the 'routes' of The National Science Agenda, which aims to set out the future of Dutch science and technology along 25 different 'routes'. Relevant routes for nanotechnologies include: Materials: Made in Holland[40]; The Quantum/Nano-Revolution[41]; Smart Industry[42]; Circular Economy[43]; Sustainable Production of Safe and Healthy Food[44]; Personalised Medicine[45] and Energy Transition[46].

In 2010, the Commission "Societal Dialogue on Nanotechnology" was established to organise a national public dialogue on nanotechnologies (2010-2011). This work was complemented by the Rathenau Institute´s social dialogue activities since 2003 (Nano2All, 2016). In terms of EHS concerns and risk governance of nanotechnologies, the Dutch government further promotes the concept of Safe by Design. The Ministry of Infrastructure and Water Management announces a programme for Safe by Design in its 2018 budget, with the aim to: *"incorporate health and safety considerations*

[37] http://www.nanoreg.eu/
[38] http://www.nanonextnl.nl/safebydesign/
[39] https://www.topsectoren.nl/
[40] https://wetenschapsagenda.nl/route/materialen-made-in-holland/
[41] https://wetenschapsagenda.nl/route/quantumnanorevolutie/
[42] https://wetenschapsagenda.nl/route/smart-industry/
[43] https://wetenschapsagenda.nl/route/circulaire-economie-en-grondstoffenefficientie-duurzame-circulaire-impact/
[44] https://wetenschapsagenda.nl/route/duurzame-productie-van-veilig-en-gezond-voedsel/
[45] https://wetenschapsagenda.nl/route/personalised-medicine-uitgaan-van-het-individu/
[46] https://wetenschapsagenda.nl/route/energietransitie/

from the earliest stages of innovation, because safe and healthy products and processes are a necessary condition for realising a circular economy («Safe at the front end», Safe-by-Design)"[47] *[translation DS]*. The National Institute for Public Health and the Environment (RIVM) has been a front-runner in developing the concept of Safe-by-Design through European projects such as NANoREG and NanoReg2. This will continue to take shape through European networks such as the NanoSafetyCluster and through national initiatives.

NORWAY

The Norwegian Research Council (RCN) has been one of the frontrunners together with UK, Germany and the Netherlands on implementing ELSA and RRI as specific requirements in its research programmes on Nanotechnology (Nano2021) and biotechnology (BIOTEK 2021). The RCN issued the report "Nanotechnologies and new materials: Health, environment, ethics and society. National needs for research and competence" as early as 2005. The report was co-written with The National Committee for Research Ethics in Science and Technology (NENT) and the Norwegian Board of Technology (RCN, 2005).

In 2012, the Norwegian Government launched its National Strategy for Nanotechnology[48]. Following this strategy the Norwegian government will maintain its targeted R&D focus on nanotechnology through the separate programme NANO2021, administered by the Research Council of Norway. The activities of this programme will follow the strategy's three priorities: basic knowledge development, innovation and commercialisation, and responsible technological development. In regard to the last point, the ambition was 1) to increase the funding for EHS and ELSA to a top international level; 2) to facilitate the integration of EHS and ELSA in technological development projects that include nanotechnology; 3) to use the ECs "Code of Conduct for Responsible Nanosciences and Nanotechnologies Research" as a guideline for national R&D; and 4) to cooperate with the Norwegian Board of Technology to promote increased societal dialogue and societal involvement in the technological development in the nano-area.

Despite the prominence of the NANO2021 programme, nanotechnology is not high on the Norwegian public agenda. The Norwegian Board of Technology has dedicated web resources on nanotechnology. However, the latest entry was in 2014. This could be taken as an indication that there is limited public interest in the issues. The official environmental label, The White Swan[49] has its latest entry on nanotechnology in 2012, additionally reflecting the declining interest. When searching through the webpages of the Norwegian Environment Agency, we find that the latest entry on nanotechnology is from 2016. And that appears to be the only entry from that year. In some kind of contrast to this: Norwegians were among those European countries who claimed to know the most about nanotechnology in the latest Eurobarometer on this subject.

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[47] https://zoek.officielebekendmakingen.nl/kst-34775-XII-2.html
[48] https://www.regjeringen.no/contentassets/5aa4911bcb474c0da4f21d1dcbc47ecb/63867_nanostrategi_web.pdf
[49] http://www.svanemerket.no/search/?q=nanoteknologi

In conclusion, there appears to be little public interest and debate on regulatory and societal issues in Norway, but the Research Council of Norway is rather active in promoting RRI.

SPAIN

Regarding the national governance of science and technology in Spain, the Secretary of State of Research, Development and Innovation, within the Ministry of Economy and Competitiveness has responsibility for fostering research and technology in general. The Secretary is supported by the Council of Scientific, Technological and Innovation Policy in charge of the general coordination of the scientific and technological research and innovation. These two entities are advised on policy level by the Advisory Council on Science, Technology and Innovation. None of the main policy documents on research, development and innovation focusses specifically on nanotechnology R&D and innovation; however, the nanotechnology field is identified as a priority. For example, nanoelectronics and nanotechnology are listed as essential enabling technologies in the Spanish Strategy of Science, Technology and Innovation 2013–2020.[50] Additionally, the Spanish government has agreed with the various regions to design and implement research and development policies on nanotechnologies in a coordinated way, which also suggests a high relevance of this field to R&D and innovation in Spain.

Concerning risk assessment procedures on nanotechnologies, there are no national governing bodies specifically tasked in this area; however, the INSHT (National Institute for Occupational Health and Safety) published a guide on *health and safety at work with nanomaterials* in 2015[51]. There are some regional level initiatives, such as the Competence Centre for Environment, Health and Safety Issues on Nanotechnology created by the Basque government, but a more common approach is the development and implementation of institute-specific protocols and guidelines on nanosafety by individual research centres and higher education institutes. In summary, nanotechnology is an important aspect of the R&D and innovation strategy in Spain, which is reflected in general policy and safety documentation; however, a controlling body and absolute authority on the subject is yet to emerge.

SWITZERLAND

The Federal Office for Public Health is in charge of the issue of nanomaterials in Switzerland. A National Action Plan[52] for synthetic nanomaterials was adopted in 2008 to clarify which work was needed in Switzerland to ensure the safe use of nanomaterials. The action plan aims to create a solid legal basis for the regulation of nanomaterials and to promote cooperation and dialogue amongst different actors. The implementation of the action plan has led to the development of guidelines for the use and management of nanomaterials and various ordinances have been revised to include specific provisions for nanomaterials. Meetings with civil society, consumers, academia and industry were held as part of the action plan. In 2014, the Federal Council decided on the future steps to take

[50] http://www.idi.mineco.gob.es/stfls/MICINN/Investigacion/FICHEROS/Spanish_Strategy_Science_Technology.pdf

[51] http://www.insht.es/InshtWeb/Contenidos/Documentacion/FICHAS%20DE%20PUBLICACIONES/EN%20CATALOGO/Higiene/2015%20Seguridad%20y%20salud%20en%20el%20trabajo%20con%20nanomateriales/SST%20con%20nanomateriales.pdf

[52] OPFSP, SECO, OFEV. *Rapport du Conseil Fédéral du 9 avril 2008 : plan d'action, nanomatériaux synthétiques.* Berne : DFI, DFE, DETEC, 2008.

with regard to nanomaterials[53], identifying the need to develop new methods for the characterization of nanomaterials, as well as the need to adapt legal provisions to the specificities of nanomaterials.

InfoNano is the Confederation's central information platform for nanotechnology. It provides information on the benefits and risks of nanomaterials and the progress of the National Action Plan. This platform aims to promote dialogue, research and the adaptation of Swiss legislation to the challenges raised by nanomaterials.

The Chemicals Ordinance[54], the Ordinance on Biocidal Products[55], the Plant Protection Products Ordinance[56] and the legislation on foodstuffs and cosmetics all include specific provisions on nanomaterials. Further specific legal adaptations for nanomaterials will be developed as part of the implementation of the National Action Plan.

Like in the European Union, there is no single definition[57] for nanomaterials in Switzerland. The sectoral ordinances give slightly different definitions depending on the field in which they apply. The Chemicals Ordinance and the Plant Protection Products Ordinance provide this definition:

> « Nanomaterial: A material containing particles in an unbound state or as an aggregate or as an agglomerate, where one or more external dimensions is in the size range 1-100 nm, or a material where the specific surface area by volume is greater than 60 m2/cm3. A material is only considered to be a nanomaterial if it is deliberately produced to utilise the properties arising from the defined external dimensions of the particles it contains, or from the defined surface area by volume of the material. Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm are considered to be nanomaterials."

The ordinance on medical devices[58] defines the nanoparticle as:

> "Nanoparticle: at least one dimension in the size range 1-1,000 nm and a function or mode of action based on nanotechnological properties."

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[53] OFSP, OFEV, OSAV, OFAG, SEFRI, SECO, Swissmedic. *Plan d'action Nanomatériaux synthétiques : Deuxième rapport du Conseil federal sur l'état de mise en œuvre, les effets et le besoin de réglementation.* Berne : DFI, DETEC, DEFR, 2014.

[54] Ordonnance du 5 juin 2015 sur la protection contre les substances et les préparations dangereuses (Ordonnance sur les produits chimiques, OChim)

[55] Ordonnance du 18 mai 2005 concernant la mise sur le marché et l'utilisation des produits biocides (Ordonnance sur les produits biocides, OPBio)

[56] Ordonnance du 12 mai 2010 sur la mise en circulation des produits phytosanitaires (Ordonnance sur les produits phytosanitaires, OPPh)

[57] « Définitions », Office fédéral de la santé publique, accessed April 12, 2018, https://www.bag.admin.ch/bag/fr/home/themen/mensch-gesundheit/chemikalien/nanotechnologie/rechtsetzung-und-vollzug/definitionen-begriffe.html

[58] Loi fédérale du 15 décembre 2000 sur les médicaments et les dispositifs médicaux (Loi sur les produits thérapeutiques, LPTh)

Nanomaterials are regulated under existing procedures for authorization and notification procedures[59]. The authorisation procedure for plant protection products requires the producer or importer to provide data allowing the identification of nanomaterials.

The use of nanomaterials in foodstuffs, cosmetics and everyday objects is regulated. New nanomaterials must be authorised by the Federal Office for Food Safety and Veterinary Affairs before they are placed on the market. In order to be authorised, the substance must not present any risk to human health and it must not give rise to deception. The same rules apply to applications for authorisation of packaging materials containing nanomaterials and/or in contact with foodstuffs. Nanomaterials in food and cosmetic products are subject to a four-year declaration requirement to inform consumers.

Nanomaterials that meet the definition of new substances under the Chemicals Ordinance are subject to a notification requirement.

Medical devices are evaluated by the manufacturer under his own responsibility. Where products present high risks, a conformity assessment body should be used. When all conformity requirements are met, the manufacturer must draw up a declaration of conformity and the assessment body might, where appropriate, issue an EC certificate. Applications for Authorisation or adaptation of medicinal products in Switzerland must state whether the medicinal product contains nano-particles.

The Chemicals Ordinance requires producers and importers to provide guidance on the identity, classification and labelling of nanomaterials classified as hazardous[60]. Since December 2012, additional identification information must be provided for nanomaterials. Biopersistent nanomaterials in fibrous or tubular form with a length of more than 5 micrometers are subject to mandatory notification since March 2018.

Current Swiss legislation does not contain any specific declaration requirements for nanomaterials, except for biocidal products, foodstuffs and cosmetic products[61]. For chemicals and plant protection products, labelling depends on the classification. Dangerous substances and preparations shall be labelled and provided with warnings on the risks and protective measures to be taken. In addition, the name of the dangerous substance must be mentioned on the label. These labelling requirements also apply to nanomaterials and preparations containing them.

There are currently no emission and immission limit values for nanomaterials, nor occupational exposure limit.

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[59] « Droit en vigueur », Office fédéral de la santé publique, accessed April 12, 2018, https://www.bag.admin.ch/bag/fr/home/themen/mensch-gesundheit/chemikalien/nanotechnologie/rechtsetzung-und-vollzug/geltendes-recht.html

[60] « Droit en vigueur », Office fédéral de la santé publique, accessed April 12, 2018, https://www.bag.admin.ch/bag/fr/home/themen/mensch-gesundheit/chemikalien/nanotechnologie/rechtsetzung-und-vollzug/geltendes-recht.html

[61] « Droit en vigueur », Office fédéral de la santé publique, accessed April 12, 2018, https://www.bag.admin.ch/bag/fr/home/themen/mensch-gesundheit/chemikalien/nanotechnologie/rechtsetzung-und-vollzug/geltendes-recht.html

3. NANOTECHNOLOGY RISK GOVERNANCE AND REGULATIONS

3.1 GENERAL OVERVIEW

This section provides a general overview on the state of nano risk governance, the respective regulatory frameworks and debates.

The question of whether and how to regulate nanomaterials has been ongoing in the European Union (EU) for over a decade. The question was first raised during the EU parliamentary debates that would lead to the adoption of the EU flagship regulation on chemical, REACH (which stands for Registration, Evaluation, Authorisation and restriction of Chemicals), in 2006. During the last decade, there have been a great variety of positions on this question, from considerations that nanomaterials are no different than other chemicals and should therefore not be the object of any specific legal provision, to calls for moratorium on the use (and development) of nanomaterials.

Most of the strategic positioning however falls between those two extremes and is generally linked to philosophical positioning towards risk, and one's understanding of the impact of regulation on innovation processes. The question is further complicated by enduring knowledge gaps about nanomaterials properties and reduced time between scientific discovery and market entry (Azoulay, 2011).

The EU launched its first strategic approach to nanotechnologies in 2004 with the Communication from the European Commission (the Commission) "Towards a European strategy for nanotechnology" which aimed to put nanomaterials on the institutional agenda (European Commission, 2004a). This was followed by the adoption of an Action Plan for Europe 2005-2009 (European Commission, 2005).

The EU was also the first jurisdiction in the world to provide nano specific legal provisions to address health and safety concerns of nanomaterials. Nowadays, nanomaterials are explicitly covered under sectoral regulations on Cosmetics[62]; Food[63]; Biocides[64]; and Medical Devices[65], and covered as well by

[62] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products, Off. J. EU 2009, L342, 59.

[63] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. Off. J. 2008, L354, 31.; Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food, Off. J. EU 2009, L135, 3.; Commission Regulation (EU) No 10/2011 of 14 January 2011 on Plastic Materials and Articles Intended to Come into Contact with Food, Off. J. EU 2011, L12, 1.; Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the Provision of Food Information to Consumers, Amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and Repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004, Off. J. EU 2011, L304, 18.; Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on Novel Foods, Amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001, Off. J. EU 2015, L327, 1.;

[64] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 Concerning the Making Available on the Market and Use of Biocidal Products, Off. J. EU 2012, L167, 1.

the EU flagship Chemical regulation on the Registration, Evaluation, Authorisation and restriction of Chemicals (REACH[66]) through specific guidance documents.

3.1.1 DEFINITION

Because nanoscience and nanotechnology have emerged rapidly, the vocabulary used in the contributing disciplines is not always consistent and there has been and continues to be serious challenges in defining nanomaterials (NMs). However, providing a legal definition of nanomaterials is the necessary first step of designing and adopting nano specific regulatory provisions.

Various countries, organizations, and institutes have developed legal, scientific or working definitions of "nanotechnology" and nanotechnology-related terms (e.g., "nanomaterials") based on the material size, its specific novel properties or a combination of both. Starting from 2014, the ISO published a series of standard documents providing definitions for different terms related to nanotechnologies (ISO/TS 80004-series[67]). These emerging definitions were often formulated for specific purposes (for more details on the various approaches to the legal definition of nanomaterials, see for example CIEL et al., 2015).

The absence of generally accepted legal definitions has played a significant role in delaying the creation of a regulatory framework, in the EU and elsewhere, addressing specific issues related to nanomaterials and nanotechnologies (Azoulay, 2011).

The EU is currently one of the very few jurisdictions with legal definitions of nanomaterials, with various pieces of legislation including distinct definitions. Despite the adoption (in 2011) of a recommendation for the definition of nanomaterials, as a guide to harmonise those different definition, there is still a diversity of legal definitions across regulatory sectors.

European commission recommendation on the definition for nanomaterials.

The 2011 European Commission's recommendation[68], defines nanomaterials as follows:

> "'*Nanomaterial' means 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.*

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[65] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, Off. J. EU 2017, L117, 1.

[66] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, Off. J. EU 2006, L396, 1

[67] https://www.iso.org/committee/381983/x/catalogue/p/1/u/0/w/0/d/0

[68] Commission Recommendation of 18 October 2011 on the definition of nanomaterial, Off. J. EU 2011, L275, 38.

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 %."[69]

The recommendation also indicates that:

"Fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials."[70]

''A material should be considered as falling under the definition in point 2 where the specific surface area by volume of the material is greater than 60 m2/cm3. However, a material which, based on its number size distribution, is a nanomaterial should be considered as complying with the definition in point 2 even if the material has a specific surface area lower than 60 m2/cm3."[71]

This EU definition is thus size based without consideration of their possible properties or hazards (Kopp, 2014).

The practical implementation of this definition relies on the possibility to verify by measurement whether a material meets the definition's criteria. Yet, an analysis by the Joint Research Center (JRC) shows that measurements tools currently available cover the requirements to a varying degree and that validated methods and practical guidance are still needed (Rauscher et al., 2017). The Commission's recommendation has been under review since 2014 with support from JRC. At the time of writing, the Commission only contemplates minor adaptations to it (European Commission, 2017a).

Different sectoral regulations, different definitions

The European Chemicals Regulatory Framework consists of several horizontal and sector-specific legislations. The rules established by each sectoral piece of EU legislation apply only to the subject matter and scope.

Most of the regulatory provision addressing nanotechnologies in sectoral regulations were adopted before the adoption of the Commission's recommendation and therefore use distinct definitions:

The cosmetic regulation defines nanomaterials as "*insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale*

[69] Commission Recommendation of 18 October 2011 on the definition of nanomaterial, Off. J. EU 2011, L275, 38. Point 2.
[70] Commission Recommendation of 18 October 2011 on the definition of nanomaterial, Off. J. EU 2011, L275, 38. Point 3.
[71] Commission Recommendation of 18 October 2011 on the definition of nanomaterial, Off. J. EU 2011, L275, 38. Point 5.

from 1 to 100 nm."[72] It therefore only covers those materials that are intentionally manufactured at the nanoscale and which are insoluble or biopersistent.

The various sectoral regulations relating to food (e.g.: Novel food, and Food information to consumers) regulate only engineered nanomaterials (as opposed to those occurring naturally). They are defined as "[…] *any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale.*

Properties that are characteristic of the nanoscale include:

- those related to the large specific surface area of the materials considered; and/or

- specific physico-chemical properties that are different from those of the non-nanoform of the same material."[73]

This definition displays no clear size boundaries ("in the order of") and focuses only on engineered nanomaterials (Rauscher et al., 2017).

Other sector-specific legislations, such as the Biocidal Products regulation[74] and the Medical devices regulation[75] include a definition of nanomaterials based on the Commission's recommendations (Azoulay and Tuncak, 2014).

The currently discussed project to amend REACH annexes to adapt it to the specificities of nanomaterials currently also includes a definition based on the Commission's recommendation.

To ensure conformity across regulations, the recommendation seeks to enable a coherent cross-cutting definition. The Commission planning is to work on harmonizing the sector specific definitions of nanomaterials, based on the Commission's recommendation but also and taking into account the sector specific needs (Rauscher et al., 2017). The harmonization of definitions would ensure that a material, identified as a nanomaterial in one sector will also be treated as such in other sectors (European Commission, 2017a).

[72] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products, Off. J. EU 2009, L342, 59. Article 2 al. 1 lit. k.
[73] Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on Novel Foods, Amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001, Off. J. EU 2015, L327, 1. Article 3 (2) lit. f.
[74] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 Concerning the Making Available on the Market and Use of Biocidal Products, Off. J. EU 2012, L167, 1. Article 3, al. 1 let. (z)
[75] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, Off. J. EU 2017, L117, 1. Article 2 (18).

Given the failure to do so during the past 7 years, it remains to be seen whether this harmonization could take place in the future. In the meantime, each sector must continue to deal with the definition included in the sectoral regulations.

3.1.2 REACH CHEMICALS REGULATION

REACH is the primary EU regulation on chemicals and was adopted to ensure a high level of protection of human health and the environment while enhancing competitiveness and innovation.

Reach is based on the "no data no market" principle, and primary understanding that adequate information regarding each substance provides the basis for identifying and implementing risk management measures when needed. Information requirements are based on production volume with the registration of substances with the highest production volume requiring most information.

REACH is assumed to be the regulatory cornerstone for addressing the health, safety and environmental risks of nanomaterials. In particular, REACH registration is described as the ideal tool to fill the problematic knowledge gap on nanomaterials because REACH covers all substances, regardless of shape, size or physical state.[76] There are, however, no specific nano provisions in REACH.

The European Chemical Agency (ECHA), in charge of REACH implementation has tried to facilitate the registration of nanomaterials, for example by setting up the ECHA nanomaterials working group (NMWG) composed by member states' experts, the European Commission, ECHA and other accredited stakeholders and by developing Guidance on Information Requirements and Chemical Safety Assessment (IR & CSA) (ECHA European chemicals agency). However, because of the lack of nano specific provisions in the regulation, ECHA considers that REACH has so far failed to effectively ensure the safety on nanomaterials on the market (Chemical Watch, 2018).

Based on this recognition, a policy process to update REACH annexes to insert nano specific provisions has been ongoing since 2013. It is expected to conclude in the first semester of 2018 but was not finalized at the time of writing. The proposed amendment includes a definition of nanomaterials based on the Commission's recommendation, a clarification of the information requirements for the registration of substances in the nanoform in the various tonnage bands, and is supposed to enter into force in 2020.

The process of revision of the EU regulatory framework - Whether the review of the Commission's recommendation on the definition for nanomaterials, or the revision of REACH annexes – has been subject to a number of delays in the past 5 years. These delays are mainly caused by enduring

[76] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, Off. J. EU 2006, L396, 1. Article 3 al. 1.

differences of views between DG Environment and DG Growth, who share the responsibility for the implementation of REACH.[77]

3.2.3 THE QUESTION OF NANO REGISTERS

For the past ten years, a number of stakeholders have been complaining about the lack of information available on nanomaterials on the market. Regulators have argued that in order to adopt adequate regulation, they need key information relating to what nanomaterials are on the market, in what quantity, and in what products. Consumers and workers have been asking similar questions to allow consumer choice and occupational safety measures, while a number of toxicologist and eco-toxicologists have also asked similar questions to be able to define research protocols that are relevant to real world situation.

While there was hope that the REACH regulation would provide responses to these questions, it has so far failed to do so, and stakeholders have resorted to various tools to address these questions from inventories of products based on manufacturers claim,[78] to private market research,[79] to setting up mandatory registers (as is currently the case in France, Belgium, and Sweden).

The lack of available information and multiplication of national initiatives triggered a debate at the EU level, and after several years of debate and public consultations, the Commission decided to forgo an EU nanomaterials register (as was requested by most member states and stakeholders) and opt for an EU Nanomaterials Observatory (EUON) under the auspices of ECHA.[80] The EUON, which started its operation in June 2017, is a web platform that will first collect existing information relating to nanomaterials and will package it to target different audiences. In later years, ECHA has committed to work on better integrating information from various sources, and improving the search functions of its website. ECHA has also launched two studies to support the development of the EUON on nano pigments and on the methodology and relevance of market studies.[81]

It should be noted that public interest organizations have decided to boycott participation in the development of the EUON, arguing that because the EUON will only repackage existing information it will do nothing to inform citizens and experts, and is therefore a waste of taxpayer's money (European Environmental Bureau, 2016).

3.2.4 SECTORAL REGULATIONS

This section shortly discusses important sectoral regulations of nanomaterials, excluding the sectors food, health and energy, which are covered in separate sections below.

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[77] David Azoulay, "Nano Regulation – ComMission : Impossible ?", *Chemical Watch,* November, 2014, https://chemicalwatch.com/21979/nano-regulation-commission-impossible ; « Quelles réglementations autour des nanos ? », VeilleNano, accessed April 11, 2018, http://veillenanos.fr/wakka.php?wiki=ReglementationsNano

[78] See for example the database established by the Danish Eco Council : http://nanodb.dk/

[79] See for example ; BCC research, *The Maturing nanotechnology Market : Products and applications*, (2016) available for 2750 US$.

[80] "Home", European Observatory on Nanomaterials, accessed April 11, 2018, https://euon.echa.europa.eu/

[81] https://chemicalwatch.com//56883/echa-launches-eu-nanomaterials-observatory?q=EUON

Nanomaterials in cosmetics

The Cosmetic Products regulation "establishes rules to be complied with by any cosmetic product made available on the market".[82] This regulation was the first piece of legislation in the world to include nano specific provisions including a legal definition, a labelling requirement, prior authorisation and notification, as well as an obligation for the Commission to publish and regularly update a register of all nanomaterials used in cosmetic products.

Nanomaterials for cosmetic use are subject to special procedures (Rauscher et al., 2017).

Prior Authorisation: When nanomaterials are used in cosmetic products as UV filters, preservatives and colorant, they must be positively authorized prior to their placing on the market[83] even when the bulk form of the substance has been previously authorized (Azoulay and Tuncak, 2014).[84]

Prior notification: When used for any purpose other than the three mentioned above (UV Filter, preservative and colorant), the use of nanomaterials must be notified by the producer or importer six month before the placement of the cosmetic product on the market (Azoulay and Tuncak, 2014). This notification must include:

- Identification of the nanomaterial
- Nanomaterial characterisation:
    - Size of the particles
    - Physical and chemical properties
    - Exposure data: estimation of quantity of nanomaterial in cosmetic products intended to be placed on the market per year
    - Toxicology profile
    - Safety data
    - Reasonably foreseeable exposure conditions (Rauscher et al., 2017).

Labelling requirement: The Cosmetic regulation was also the first legal text providing for a labelling requirement for products containing nanomaterials. All nanomaterials (regardless of their function) must be mentioned in the ingredients' list followed by the word "nano" in parenthesis. The objective of this requirement is to allow consumers to make informed choices when buying a product (Rauscher et al., 2017).

The regulation also tasks the Commission with an obligation to regularly update and make available a catalogue of all nanomaterials used in cosmetic products since January 2014. The Commission however delayed publication of the first version of the catalogue until 2017 and denied several access-to-information requests in the meantime, which was considered maladministration by the EU Ombusdman (European Ombudsman, 2018).

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[82] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products, Off. J. EU 2009, L342, 59.
[83] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products, Off. J. EU 2009, L342, 59. Article 14 c), d) and e).
[84] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products, Off. J. EU 2009, L342, 59. Article 16 .

Nanomaterials under the Biocidal products regulation

This regulation contains a definition based on the Commission recommendation of definition, an approval procedure, a specific safety assessment system for substances containing nanomaterials and labelling provisions for nanomaterials (Rauscher et al., 2017). It obliges producers and importers of active and non-active substances in biocides and biocidal products to apply for authorization before putting the products on the market (Azoulay and Tuncak, 2014).

The approval of a substance does not cover its nanoform except when explicitly mentioned. There can be no simplified procedure for biocides containing nanomaterials (Rauscher et al., 2017).

Nanomaterials must undergo specific risk assessments. For biocidal products containing nanomaterials, a separate risk assessment must be conducted to see the impacts on human health, animal health and the environment.[85] When doing tests on nanomaterials to obtain approval of an active substance or authorization for a biocidal product, an explanation must be provided about the adjustments of the test in relation to nanomaterials and the appropriateness of the test procedure for nanomaterials (Rauscher et al., 2017).

This regulation also seeks to provide information on the presence of nanomaterials to consumers by setting up a labelling system.[86] Names of all nanomaterials present in a biocidal product have to be listed on the label with the mention "(nano)". Furthermore, and this goes beyond other regulations' labelling schemes, producers of biological products including nanomaterials have the obligation to identify "any specific related risk" (Azoulay and Tuncak, 2014).[87]

This regulation is considered the most robust nano specific provisions of all EU sectoral regulation. It is relevant and applicable for biocidal application in the agricultural sector[88], food packaging sector and consumer products sector.

3.2 NANOMATERIALS IN FOOD

The agro-food industry is highly regulated with particular focus on food safety and quality, as these factors can influence consumer health nationwide. A comprehensive framework of different regulations cover this sector, including food labeling, nutrition and health claims to prevent misleading claims and ensure fair completion on the market.

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[85] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 Concerning the Making Available on the Market and Use of Biocidal Products, Off. J. EU 2012, L167, 1. Article 19 al.1 let. f

[86] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 Concerning the Making Available on the Market and Use of Biocidal Products, Off. J. EU 2012, L167, 1. Article 69

[87] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 Concerning the Making Available on the Market and Use of Biocidal Products, Off. J. EU 2012, L167, 1. Article 58 al.3 *in fine* and Article. 69 al.2 let. b

[88] Nano pesticides is covered by Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

Several EU regulations related to food safety include provisions addressing nanomaterials:

Novel Food regulation

The Novel Food Regulation [89] "lays down rules for the placing of novel foods on the market within the Union". Use of engineered nanomaterials (see definition in the section above) is considered as producing a novel food and therefore subject to the novel food regulation. Food additives in the nanoform are regulated by the Food additives regulation mentioned below (VeilleNanos).

The regulation includes a definition of nanomaterials, an approval procedure, a safety assessment system and labelling and guidance provisions on nanomaterials. The labelling of novel foods containing nanomaterials is however prescribed under the regulation on the provision of food information to consumers regulation (Rauscher et al., 2017).

Nanomaterials, when in contact with food, must be explicitly authorized and specific risk assessments must be conducted. The regulation calls for clear criteria for the assessment of the safety risks arising from novel food. Nanomaterials are specifically addressed: when a test method is applied to nanomaterials, there should be a clear explanation of the appropriateness of the method for nanomaterials and, if relevant, a description of the technical adjustments made to fit nanomaterials' features (Rauscher et al., 2017).[90]

The European Food Safety Authority (EFSA) is in charge of this subject matter. EFSA's scientific committee developed guidance on risk evaluation of nanomaterials in the food and feed chain and provides recommendations on how to assess applications from industry to use engineered nanomaterials in food and food contact materials. The aim is to facilitate harmonization of practices, improve information sharing and accomplish synergies in risk assessments between EFSA and member states (Rauscher et al., 2017).

It should be noted that implementation of the nano specific provisions for food, in particular in relation to labelling seems to be limited. In France, the only country where enforcement activities have taken place and where NGOs tested un-labelled food products for the presence of nanomaterials,[91] both activities concluded of a poor to inexistent implementation of the labelling requirement by producers and distributors. It should also be noted that questions relating to the definition (i.e., confusion about what definition applies; technical difficulties to implement the existing definition; or expectation that the applicable definition will be revised in the short term) are often put forward to explain the implementation gaps.

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[89] Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on Novel Foods, Amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001, Off. J. EU 2015, L327, 1.

[90] Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on Novel Foods, Amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001, Off. J. EU 2015, L327, 1. Article 10 para. 4

[91] Agir pour L'environnement: Des analyses révelent la présence de nanoparticules dans les aliments (2016), https://www.agirpourlenvironnement.org/sites/default/files/communiques_presses/Rapport%20LNE_P156452.DMSI_.001-VC.pdf

Food additives regulation

This regulation[92] mandates the European Food Safety Agency (EFSA) to carry out a new evaluation of additives previously authorised but whose particle size has been modified by the use of nanotechnologies. EFSA adopted new guidelines for the evaluation of food additives in 2012 that provide specific information for the characterisation of nanomaterials (Rauscher et al., 2017).

Plastic Food contact materials regulation

This regulation [93] provides for a case by case assessment of substances in the nanoform (which are not specifically defined). The regulation further provides that substances in the nanoform shall only be used if explicitly authorised and mentioned in the specifications in Annex 1 of the regulation.

Active and intelligent food contact materials regulation

This regulation[94] includes an approval procedure and safety assessment provisions and also provides for a case by case assessment of substances in the nanoform (Rauscher et al., 2017).

Provision of food information to consumers regulation

This regulation[95] provides for a specific definition of nanomaterials and a labelling requirement for all ingredients, including food additives, present in food products in their nanoform (Rauscher et al., 2017)[96]: Labelling consist of adding the word nano in brackets next to the name of the ingredient in the ingredients' list (Azoulay and Tuncak, 2014).

3.3 NANOMATERIALS UNDER THE MEDICAL DEVICES REGULATION

[92] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. Off. J. 2008, L354, 31.
[93] Commission Regulation (EU) No 10/2011 of 14 January 2011 on Plastic Materials and Articles Intended to Come into Contact with Food, Off. J. EU 2011, L12, 1. Preamble para. 27 and Article 9 (2).
[94] Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food, Off. J. EU 2009, L135, 3. Preamble para. 14.
[95] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the Provision of Food Information to Consumers, Amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and Repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004, Off. J. EU 2011, L304, 18.
[96] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the Provision of Food Information to Consumers, Amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and Repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004, Off. J. EU 2011, L304, 18.

The medical devices regulation[97] is the only regulation dealing with health products that contains specific nano provisions. It provides a definition of nanomaterials and contains approval procedure, safety assessment and labelling provisions on nanomaterials (Rauscher et al., 2017).

This regulation stresses the need for special care when devices contain nanomaterial that can be released in the user's body. Special care must be taken when using nanoparticles with high or medium potential for internal exposure. Such devices should be subject to the most stringent conformity assessment procedures.[98] Devices consisting of or containing nanomaterials are ranked class III if they present a high or medium potential for internal exposure; class IIb if they present a low potential for internal exposure and class IIa if they present a negligible potential for internal exposure.[99] Such devices must be labelled.[100] For special devices in class III and class IIb, a clinical evaluation assessments conducted by an expert panel must be carried out.[101] The critical factor in classifying devices consisting of or containing nanomaterials is the potential for nanomaterials to be in contact with membranes within the body. Devices presenting a high or medium risk of such a contact will be in the highest risk class and subject to the most stringent conformity assessment procedures and clinical evaluation assessment procedures when going through an authorization process.[102]

Other regulations, including regulation on the authorisation and supervision of medicinal products for human and veterinary use,[103] the directive on Good clinical practice,[104] or the regulation on

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[97]Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, Off. J. EU 2017, L117, 1.

[98] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, Off. J. EU 2017, L117, 1. Preamble para.15 and Article 52 and Article 54 and Annexes IX, X and XI

[99] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, Off. J. EU 2017, L117, 1. Annex VIII 7.6 Rule 19

[100] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, Off. J. EU 2017, L117, 1. Annex I 23.2 and 10.4.5.

[101]Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, Off. J. EU 2017, L117, 1. Article 54

102 Lynn L. Bergeson and Carla N. Hutton, "EU Addresses the Use of Nanomaterials in Medical Devices," Nano and Other Emerging Chemical Technologies, Bergeson & CampbellPC, last modified April 11, 2017, https://nanotech.lawbc.com/2017/04/eu-addresses-the-use-of-nanomaterials-in-medical-devices/

[103] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the **authorisation and supervision of medicinal products for human and veterinary use** and establishing a European Medicines Agency

[104] Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for **good clinical practice** as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products"

clinical trials on medicinal products for human use[105] also apply to healthcare product although none of these regulations include nano-specific provisions.

The field of Nanomedicines raises a multitude of ethical, social and legal questions. Ethical questions include privacy, autonomy (i.e. regarding brain implants) and the patient's right to decide whether to be informed about diagnosable but incurable deceases. Social issues may be increased costs of the social security system due to an ageing population or the shift from centralized hospitals to general practitioners for diagnosis. These questions also arise in the medical sector in general and the sector is therefore highly regulated.

3.4 NANOTECHNOLOGY AND ENERGY

Nanotechnology is relevant for many areas of the energy sector, such as photovoltaic, wind energy, battery technologies, etc. (see section 4.4).
In the EU, none of the regulations relevant to the energy sector includes nano specific provisions. A number of those are however still relevant, and all of those pieces of legislations would have to be complied with by a new nano application regardless of specific nano provisions.
Relevant pieces of the regulatory framework include:

- Directive 2013/39/EU of the European Parliament and of the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards **priority substances in the field of water policy**.
- Directive 2014/52/EU of the European Parliament and of the Council of 16 April 2014 amending Directive 2011/92/EU on the **assessment of the effects of certain public and private projects on the environment**
- Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the **control of major-accident hazards involving dangerous substances**, amending and subsequently repealing Council Directive 96/82/EC
- Directive 2013/39/EU of the European Parliament and of the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards **priority substances in the field of water policy**

Regulation also exists in form of Ecodesign[106] for heaters and fluorinated greenhouse gas[107] (F-gas) for gas. Regulatory instability is seen as a problem for investments in this sector, "whose returns must be commercially competitive with existing investments in more polluting technologies"[108], especially the "stability of the incentive regime".

[105] Regulation No 536/2014 of the European Parliament and of the Council on **clinical trials on medicinal products for human use**, and repealing Directive 2001/20/EC
[106] https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/ecodesign/space-heaters_de
[107] https://ec.europa.eu/clima/policies/f-gas_en
[108] RHC Common roadmap, p. 45

4. RESEARCH AND INNOVATION PRIORITIES ON NANOTECHNOLOGIES

4.1 OVERVIEW ON R&I PRIORITIES

Nanotechnology is increasingly becoming a horizontal technology, i.e. a general-purpose enabling technology or even "new way of manufacturing" that is of high relevance for a wide range of industry sectors and applications (European Commission, 2017c). For example, nanoparticles are applied in such diverse sectors as textiles, health care, agriculture, electronics, or renewable energy to improve materials and functionalities (see Figure below).

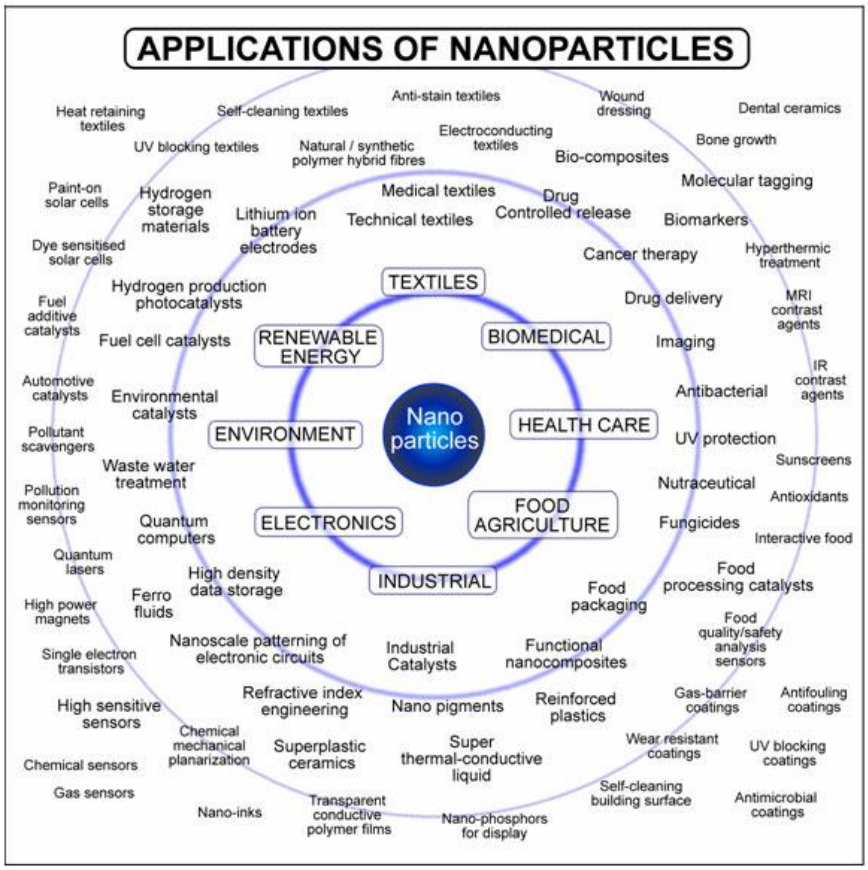

FIGURE 1: SECTORS AND APPLICATIONS OF NANOPARTICLES; SOURCE: NANOWERK[109]

While a number of products are already introduced in sectors such as chemical & materials, ICT/electronics, health care, energy, environment and for different type of consumer product, many applications of nanotechnologies are still in an early concept phase and therewith subjects of public and private support strategies.

This section provides an overview on research and innovation priorities in regards to nanotechnologies. It includes general nanotechnology priorities as reflected in a) the European Commission's framework programme H2020 and b) the European Technology Platforms. The focus is

[109] https://www.nanowerk.com/nanotechnology-applications.php

on all sectors and provides the context for the more detailed analysis of the R&I priorities concerning nanotechnologies in food, health and energy that are discussed in the following sections. The analysis illustrates the current status, i.e. as of spring 2018.

EUROPEAN UNION H2020

The framework programmes are the EU's main instruments to support research and innovation in Europe. Nanosciences and Nanotechnologies have been explicitly supported from the 6th Research Framework Programme (2002-2006) on. In the 6th Framework Programme € 1.3 billion were allocated for the advancement of nanotechnology and new materials (Nano2All, 2016). Through the EU's 7th Framework Programme for Research and Technological Development (2007-2013) € 3.4 million were dedicated to initiatives that promote European competitiveness and support a transition to a knowledge-based economy through nanotechnology and nanosciences (Charrière and Dunning, 2014). While both, the 6th and the 7th Framework Programmes were largely oriented at basic research and exploration, with H2020 the EU aims towards applications and market readiness of nanotechnologies (European Commission, 2017c, 14).

Horizon 2020 is the European Union's 8th Framework Programme on Research and Technological Development, covering the period 2014-2020 and including a budget of around € 80 billion[110]. H2020 is dedicated to and structured in three pillars: Excellent Science, Industrial Leadership and Societal Challenges (see Figure 2). In addition, funding is provided through the cross-cutting schemes: spreading excellence and widening participation, science with and for society, non-nuclear direct actions of the JRC, the EIT. H2020 is implemented through biennial Work Programmes in which specific research topics and respective calls are published.

[110] http://ec.europa.eu/programmes/horizon2020/en/what-horizon-2020

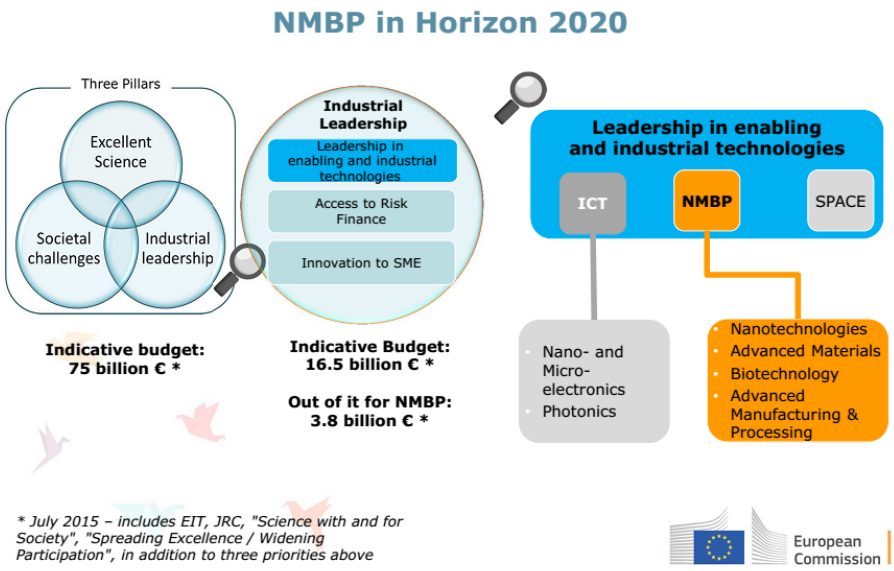

Figure 2: NMBP in Horizon 2020, Source: Presentation by Helene Chraye (EC)[111]

Due to their cross-sectional character, research and development of nanotechnologies may be funded under all three pillars (and cross-cutting areas), but nanotechnologies are explicitly targeted under the second pillar "Industrial Leadership" under the theme **"Leadership in enabling and industrial technologies" (LEIT)** (see Figure 2). The LEIT programme focuses on the innovation aspect of funding demonstration and pilot projects, which are supposed to support market introduction and acceptance of products and services and to strengthen European industry in this domain.

Nanotechnologies are listed as one of **six key enabling technologies** (KETs) (the other five are: nano- and micro-electronics, photonics, advanced materials, advanced manufacturing and processing and biotechnology). KETs are investments and technologies that will allow European industries to retain global competitiveness and capitalise on new markets[112]. Nanotechnologies are grouped with advanced materials, biotechnology and advanced manufacturing & processing under the acronym NMBP. For all four technologies, H2020 focuses on research, development and innovation with a strong industrial dimension and in a partnership approach. The total budget for NMBP in Horizon 2020 is € 3.8 billion. In October 2017, the European Commission published the current Work Programme 2018-2020 for "Leadership in Enabling and Industrial Technologies – Nanotechnologies, Materials, Biotechnologies and Production". The overall budget for the 2018 call is approx. € 534 million. For the calls in 2019 there will be approx. € 545 million available, for 2020 approx. € 572 million[113][114].

[111] http://www.kpk.gov.pl/wp-content/uploads/2017/07/20170912-NMBP-02-HeleneChrye_KE-short.pdf
[112] https://ec.europa.eu/programmes/horizon2020/en/area/key-enabling-technologies
[113] https://www.kowi.de/en/kowi/calls-2018/nanotechnologies-advanced-materials-biotechnology-and-advanced-manufactoring-and-processing-2018-2020.aspx/page-1/
[114] The High Level Strategy Group on Industrial technologies has recently proposed an update of the KETs list, confirming the existing six KETs while merging four of them into two broader categories (materials and nanotechnology, photonics and micro- and nano -electronics); broadening the KET 'biotechnology' to 'Life Sciences technologies'; adding two new main fields, namely: artificial intelligence

Following the declaration of the European Commission, *"[t]he Horizon 2020 programme aims to bridge the gap between nanotechnology research and markets, and to realise the potential contribution to sustainable growth, competitiveness, environment, highly skilled jobs and increased quality of life. A number of barriers need to be addressed, in order to leverage large scale market introduction* ***of innovative, safe and sustainable nano-enabled products****. Horizon 2020 activities addressing this challenge will therefore implement the next steps towards the deployment and market introduction of lightweight, multifunctional, economical and environmentally friendly nano-enabled products for different applications, by scaling up laboratory experience to industrial scale and by demonstrating the viability of a variety of manufacturing technologies*[115].

In order to foster upscaling the Work Programme mainly focusses on (infra) - structural and systemic support while giving only few indication on envisioned applications in specific sectors or areas.

An important funding instrument are the **open innovation test beds** that "provide the development and upscaling of advanced materials and nanotechnologies, combining digital, chemical and physical advances for innovative new products and services" (European Commission, 2017b). Open test beds are physical facilities offering technology access and services to advance from validation in a laboratory (TRL 4) to prototypes in industrial environments (TRL 7). The call addresses six technology domains:

- lightweight nano-enabled multifunctional materials and components,
- safety testing of medical technologies for health,
- nano-enabled surfaces and membranes,
- bio-based nano-materials and solutions,
- functional materials for building envelopes, and nano-pharmaceuticals production (European Commission, 2017b).

As another support for methodological advancements, the Work Programme also calls for the further advancements in materials characterisation and computational modelling to support industrial products.

Moreover, *"Horizon 2020 aims to advance scientific knowledge of the* ***potential impact of nanotechnologies*** *on health or on the environment, and to provide tools for risk assessment and management along the entire life cycle"*[116]. Hence under the header 'Governance, Science-Based Risk Assessment and Regulatory Aspects' the Work Programme lists risk governance of nanotechnologies, nanoinformatics: from materials models to predictive toxicology and ecotoxicology, Safe by design, from science to regulation: metrics and main sectors, Safe by design, from science to regulation: behaviour of multi-component nanomaterials and Regulatory science for medical technology products as upcoming calls (Kopp, 2014).

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and digital security and connectivity. See:
https://ec.europa.eu/research/industrial_technologies/pdf/re_finding_industry_022018.pdf

[115] http://ec.europa.eu/programmes/horizon2020/node/1306
[116] http://ec.europa.eu/programmes/horizon2020/node/1306

Nanotechnologies are also directly linked to the **Factories of the Future** (FoF) /Transforming European Industry sections, where priority is given to nanotechnologies in additive manufacturing in order to aggregate multiple materials within a single process, while improving or expanding their functionality, and enhancing their performance. Moreover, nanotechnologies are explicitly referred to medical technology innovations and clean energy through innovative materials (see sections below).

Nanotechnologies research and development activities may also be funded in the context of the programmes "**Future and Emerging Technologies**", "FET Open" (bottom-up) or "FET Proactive" (topic-related), if they deal with risky, visionary and interdisciplinary topics concerning the development of future technologies. Nanotechnology is explicitly mentioned in the FETPROACT-01-2018 Working Programme as an example for potential high-risk / high-reward research and innovation projects in regards to disruptive micro-energy and storage technologies. Nanotechnology is also explicitly mentioned in the ETFLAG-01-2018: Preparatory Actions for new FET Flagships in the context of ICT and Connected Society and in the context of Health and the Life Sciences where "disruptive technologies to revolutionise healthcare are connected to nanotechnologies.

The previous sections have already indicated the importance of nanotechnologies for issues like health, energy, climate and transport. Hence, nanotechnologies may also play a role in **addressing Societal Challenges** (i.e. the third pillar). The respective Working Programmes do not explicitly call for nanotechnology solutions, but the European Commission expects that "[n]*anotechnologies, […], will help address key societal challenges such as climate change, reducing carbon emission, developing renewable energies, more efficient use of resources and addressing medical needs of an ageing population."*[117]

In summary, nanotechnologies are explicitly supported as a key enabling technology for industrial competitiveness, particularly in the areas healthcare, energy and environment, manufacturing and electronics and ICT. Beyond that, nanotechnologies may play an important role in fostering excellent and ground-breaking science in Europe and in addressing several Societal Challenges. Two of the areas covered by GoNano, i.e. health and energy, play an important role in the Framework Programme's support for nanotechnologies. Food is occasionally mentioned but does not appear as a focus sector. This is also reflected in a stakeholder analysis conducted by the European Commission (European Commission, 2017c) in which the impact of the FP on nanotechnology-based solutions for global challenges was seen as weakest for food security and strong for secure, clean and efficient energy and transport.

European Technology Platforms

In order to derive strategic priorities of industry stakeholders for nanotechnology research and development we draw on the relevant European Technology Platforms (ETPs). ETPs are industry-led stakeholder fora recognised by the European Commission. ETPs develop research and innovation agendas and roadmaps for action at EU and national level to be supported by both private and public funding. They mobilise stakeholders, including economic stakeholders highly oriented at technology,

[117] https://ec.europa.eu/programmes/horizon2020/en/h2020-section/nanotechnologies

innovation or research on specific sectors or areas, and stakeholders from Universities, research institutes, manufacturers as well as local, regional, national and European associations and authorities, to deliver on agreed priorities and share information across the EU. ETPs are independent and self-financing entities[118].

Currently, 41 ETPs exist, grouped under the research areas: bioeconomy, energy, environment, ICT, production and processes, transport and cross-cutting initiatives (for a complete list see https://ec.europa.eu/research/innovation-union/index.cfm?pg=etp)**.** Several ETPs explicitly address nanotechnologies.

The cross-cutting ETP initiative Nanofutures coordinates activities of the respective ETPs in regard to nanotechnologies. NANOfutures is a *"multi-sectorial, cross-ETP, integrating platform with the objective of connecting and establishing cooperation and representation of Technology Platforms that require nanotechnologies in their industrial sector and products. NANOfutures and its operative branch NANOfutures association act as a "Nano-Hub" by linking JTIs, associations, ETPs with expert groups in a collaborative environment"*[119]. NANOfutures identifies the key nodes in strategic nanotechnology related-activities and develops strategies to address nanotechnology challenges with an intersectorial approach. The platform is oriented at and structured along cross-sectoral issues such as communication, critical raw materials, regulation, standardization, etc. (for a complete list of all working groups see http://nanofutures.info/groups). The Nanofutures Roadmap 2012 (Nanofutures, 2012)provides indications for general research and innovation priorities. As reflected in the Roadmap Nanofutures particularly focusses on nano-enabled value chains , i.e. the set of actions along the value chains that are feasible thanks to nano-enabled materials and technologies (Nanofutures, 2012). The Roadmap further points to the importance of designing, modelling and testing of materials and issues of safety and sustainability. Overall, the Roadmap identifies eight main areas of applications and respective lead markets for nanotechnologies and lists respective examples of final nano-enabled products: energy, transportation, construction&building, medicine&pharma, ICT, textile&sports, consumer goods, and packaging (Nanofutures, 2012). Similar to H2020, the sectors energy and health play a much more important role for nanotechnology applications and products than the food sector in the Roadmap.

4.2 NANOTECHNOLOGY AND FOOD

This section provides an overview on policy as well as industry priorities and investment activities in regards to nanotechnology research and applications in the food sector along the question "What are the most discussed and supported research issues and potential applications?"
The overall key challenges set by the ETP Food for Life strategic agenda that need specific solutions (also through technology development) are:

- Consumer engagement, consumer behaviour and perception of food
- Demographic changes
- Resources (securing a continued supply of high quality raw materials)

[118] https://ec.europa.eu/research/innovation-union/index.cfm?pg=etp
[119] http://nanofutures.info

- Sector maturity (revitalize the sector, through innovation, diversification, better addressing of consumer needs, etc.) (ETP 'Food for Life', 2016).

As described above, in the EU H2020 programme nanotechnologies are hardly directly related to the food sector. In regards to the European Technology Platform, the ETP Food for Life[120] is part of Nanofutures, but has only a few references to nanotechnologies in its Strategic Research and Innovation agenda in 2016 (ETP 'Food for Life', 2016). Few indications of relevant applications of nanotechnologies in the food and agrifood area are provided in strategic agenda of other ETPs, such as Nanofutures, Eumat and Sustainable Chemistry.

Three research and application areas are particularly relevant for the application of nanotechnologies in the food and agrifood sectors: safety and security, packaging, nutrition properties. An overall view of potential applications in the food and agrifood sectors, linked to expected social benefits and challenges, and research priorities and needs is reported in **Fejl! Henvisningskilde ikke fundet.**

SAFETY AND SECURITY

Nanotechnologies can contribute to new and faster analytical and screening methods to assess the chemical safety in food. Miniaturized analytical systems, such as lab-on-chip realized using micro Electro-Mechanical Systems (MEMS), could improve the assessment of chemical safety, in particular for complex food matrices or new ingredients (ETP 'Food for Life', 2016).

A further important contribution of nanotechnologies to food and agri-food comes from the water treatment and supply, in order to provide drinkable and affordable water to a larger part of human population and to recycle, reuse and reduce water waste. Nanoactivated photocatalysts (Nanofutures, 2016) could be used for water purification in order to secure rapid and low cost drinking water. In addition, nanostructured surfaces with increased selectivity towards trace contaminants for water management could be developed for water recycling and reuse enabling wastewater treatments with lower energy consumption.

PACKAGING

Currently nanotechnologies are particularly discussed in the context of more *sustainable packaging* systems (ETP 'Food for Life', 2016, Nanofutures, 2012, Nanofutures, 2016). Nanomaterials could contribute to reducing the amount of material needed and prolonging its total lifecycle time (ETP 'Food for Life', 2016).

The use of micro, nano, and smart bio-materials are expected to provide packaging systems with superior performances and improved environmental impact during the full life cycle. Possible applications include biodegradable packaging, micro and nano transparent polymers and packaging with improved gas-barrier properties. Smart packaging solutions, i.e. packaging that provide information about the quality of the contained food, could be realized using nano-enabled devices (e.g sensors to monitor and record temperature) (ETP 'Food for Life', 2016). Similarly, nano-coatings could improve mechanical, thermal, electrical, barrier and chemical properties. Food packaging thereby could become self-healing, self-cleaning, high-gloss, antiscratching, syperhydrophobic,

[120] http://etp.fooddrinkeurope.eu/about-us/about.html

corrosion-resistent, anti-fouling, stain-resistant, anti-odor, anti-microbial, conducting and water-repellent. Overall, these properties could be used to realize so called “customer specific” packaging solutions.

Nanotechnologies may also enable lightweight packaging through new, lighter materials. This would enhance design efficiency of packaging and minimise energy and material consumption. Energy reduction in packaging processes and reduced packaging weight could also be realised through a Injection Stretch Blow Moulding (ISBM) (Nanofutures, 2016), a production process for polymer-made objects. The use of this technique in combination with nanomaterials could help to realize smart and functionalized packaging (e.g. with plastic with counterfeiting properties).

NUTRITION PROPERTIES

Nanoscale approaches might also yield new insides into the structure of ingredients, for example to improve food processing systems used to fractionate food raw materials into functional ingredient classes (ETP ‘Food for Life', 2016). The possibility to have minimally processed, highly functional ingredients will reduce the use of additives and processing aids. Nano-encapsulation or nano-micelles are structures that allow to incorporate new ingredients with specific nutritional properties in specific matrix phases, and could be a building block for new functional foods (ETP ‘Food for Life', 2016).

Overall, with these potential applications, nanotechnologies address several societal challenges pointed out in the EU2020 strategy and Sustainable Development Goals:

- EU2020: 2) Food security, sustainable agriculture and forestry, marine and maritime and inland water research, and the Bioeconomy and 5) Climate action, environment, resource efficiency and raw materials
- SDGs: 2) End hunger, achieve food security and improved nutrition and promote sustainable agriculture, 6) Ensure availability and sustainable management of water and sanitation for all, 12) Ensure sustainable consumption and production patterns, 13) Take urgent action to combat climate change and its impacts.

Table 1: Research and application areas for nanotechnologies in the food sector

Social Drivers: Ensuring food safety, drinkable water availability, reducing food and material waste, saving energy and CO2 emissions in food value chain				
Research Priorities	**Technological Solutions/Challenges**	**Key enabling nanotechnology properties**	**Examples of specific applications**	**Market requirements/ societal challenges**
Safety and Security	Advanced analytical and screening methods (e.g. MEMS)	Fast screening methods	Lab-on-chip for food screening	Assess chemical safety especially in complex food matrices
	Nanostructured surfaces	Providing functional properties to the surfaces (e.g. sensing, rself-cleaning, anti-microbial, etc.)	Food production systems with self-cleaning and anti-microbial properties; Systems to detect trace contaminants in water management	Food production; water recycling and reuse, waste water treatments with lower energy consumption
	Photocatalysts	More efficient photocatalysis systems	Photocalysts for water purification	Rapid and low cost drinkable water
Packaging	Micro, nano, smart bio-materials	Superior performances and improved environmental impact during the full life cycle, long lasting, gas-barrier	Biodegradable packaging, micro and nano transparent polymers and packaging with improved gas-barrier properties	Customer specific packaging solutions, Smart packaging (monitoring quality of food)
	Nanocoatings	improved mechanical, thermal, electrical, barrier and chemical properties:	Self-healing, self-cleaning, high-gloss, anti-scratching, superhydrophobic, corrosion-resistant, anti-fouling, stain-resistant, anti-odor, anti-microbial, conducting, water-repellent systems	Customer specific packaging solutions
	Lightweight materials	Improved structural properties	Lightweight packaging	Enhanced design efficiency, minimise energy and material consumption
	New technologies and materials for Injection Stretch Blow Moulding (ISBM)	Smart and funtionalized properties to packaging material	packaging production (e.g. for plastic bottles)	Reduce energy in packaging production processes; reducing packaging weight and CO2 emissions (due to energy and transport)
Nutrition properties	functional ingredients, nano-encapsulation, nano-micelles	Select ingredients properties	Functional foods	Reduce the use of additives and processing aids

4.3 NANOTECHNOLOGY AND HEALTH

This section provides an overview on policy as well as industry priorities and investment activities in regards to nanotechnology research and applications in the health sector along the question "What are the most discussed and supported research issues and potential applications?"

Nanomedicine is one of the most promising sectors for applications of nanotechnology. For the European Commission, *"[n]anomedicine, the application of nanotechnology to human healthcare, offers numerous potential pathways to improving medical diagnosis and therapy and even to regenerate tissues and organs. It can provide personalised yet more affordable healthcare while at the same time offering an improved quality of life for everyone. Nanomedicine is also a strategic issue for the competitive position of the healthcare industry in Europe".*[121] Consequently, there is a strong reference to the health sector in the current NMBP Work Programme. The interlocking of advancements in nanotechnologies and the health sector is also reflected in the ETP Nanomedicine that advocates a focus "towards clearly identified clinical applications, not being confined to basic research" (ETP Nanomedicine, 2006) and argues that an improved handover between the stakeholders is an essential need for successful Nanomedicine (ETP Nanomedicine, 2013). Nanomedicine research and applications are envisioned and realized in three broader areas: (i) therapeutics, including targeted drug delivery and theranostics, (ii) diagnostics and imaging: efficient, fast and site-specific monitoring, and (iii) regenerative medicine, including implants and in-vivo and ex-vivo regeneration (see Table 2a-c) (ETP Nanomedicine, 2016).

THERAPEUTICS: TARGETED DRUG DELIVERY AND THERANOSTICS

Targeted drug delivery is one of the more developed areas in nanomedicine, few drugs are already available on the market, and others are expected in the mid to long term. The research should yield improved targeting agents that are efficient and can be used safely with living cells. These may include targeting agents produced randomly and filtered out via high throughput selection and multi-target approaches to deal with cell heterogeneities.

Targeted delivery also allows combining specific targeted therapies based on specific targeted diagnostic tests. The theranostics represents the transition from conventional medicine to a precise and personalized medicine approach. Nanotechnology, in this case, enables the combination of diagnosis, drug delivery and treatment response monitoring into a single agent.

Examples of promising research could be manifold. Targeted delivery of specific nanoparticles into tumours stimulates the production of cancer biomarkers, allowing for earlier diagnosis and less burdensome treatment. The encapsulation of existing chemotherapy drugs in nanoparticles allowing personalized therapeutic treatments and more localized delivery, and reducing side effects on the body's healthy tissue.

In the field of imaging, nano-engineered theranostic nanoparticles enable very high resolution and an accurate mapping of lesions with multimodal imaging and multiple therapy possibilities.

[121] http://ec.europa.eu/research/industrial_technologies/nano-in-healthcare_en.html

The usage of nanomedicine for atherosclerosis is in a much earlier phase. Here, the two main fields of application are nanoparticles for diagnostics and treatment of atherosclerosis and the nano-coating of stents.

For diabetes, nanomedicine could allow the delivery insulin in the form of nanoparticles, opening up new non-invasive application routes like sprays or pills. In addition, new nano-based sensor systems for non-invasive and pathless monitoring of glucose levels in blood are under development, as well as immune protective nano-coatings to prolong the survival of transplanted pancreatic islets.

The development of new antibiotics is another field where the methods of nanomedicine could be applied. An example is the development of a system to treat a certain type of bacterial infections in the lung, determining the type of antibiotic needed and treating it by inhalable medicine utilizing nano-carriers, new formulation and delivery-strategies for antibiotics based on peptides in the treatment of lung/skin infections and burn wounds.

Nanoparticles are also considered a promising route for the diagnosis and treatment of the Alzheimer's disease due to their ability to cross the blood-brain barrier (BBB). However, further development is necessary to make them a viable solution for clinical treatment.

For the diagnosis of arthritis, superparamagnetic iron oxide nanoparticles could be used as nano-contrast agents improving the MRI signal.

In the fight against infectious diseases, the methods of nanotechnology are particularly promising for early detection and diagnosis of rapidly spreading epidemics like Ebola. This is especially relevant for countries with less developed healthcare infrastructure, which would otherwise lack the tools to distinguish the illnesses of patients with non-specific symptoms like fever. There are also hopes that targeted delivery of drugs using nanomedical approaches (like nanoemulsions) could improve the treatment of malaria.

Other examples of novel systems include miniaturized nano-devices, acting like pumps. Together with sensors these devices could allow for controlled delivery of drugs, activated by environmental conditions in the body. Possible techniques include Microelectromechanical systems (MEMS) or implantable biochips.

Key fundamental research priorities include the study of absorption of nanostructures into cells, their uptake and recycling as well as their bio-distribution within the body. In order to rule out potential serious consequences on the living organism a throughout safety evaluation has to be performed.

DIAGNOSTICS /IMAGING: EFFICIENT, FAST AND SITE-SPECIFIC MONITORING

This area typically includes analytical systems for both *in vitro* and *in vivo* analysis. For *in vitro* diagnostics, promising systems include the development of integrated multifunctional devices allowing for fast and cheap medical diagnostics. An example are high throughput screening systems, enabling fast (bio) sample preparation, miniaturization and multiplexed analysis in the detection process. All types of imaging systems, such as optical, electron or x-ray microscopy, are continuously improving in terms of sensitivity, flexibility (use for different substrates and in different conditions) and reliability of the analysis, also thanks to advanced nano-electronics systems.

Regarding *in vivo* diagnostics, improvements are expected in terms of sensitivity, accuracy and miniaturization of systems. Examples are nano-enabled probes[122], endoscopes and catheters, providing minimally invasive diagnostic systems. Bottlenecks of new detectors will be signal acquisition, data analysis and data management. In addition, the devices should feature improved instrumental biocompatibility through (nano) surface functionalization together with remote control capabilities.

Note that the diagnostic technologies used in combination with therapeutic approaches (theranostics) are reported in the previous paragraph.

REGENERATIVE MEDICINE

This field focuses on the development of systems able to replace lost or impaired body functions (ETP Nanomedicine, 2016) such as engineering of artificial skin, cartilage and bones for autologous implantation. The research is based on the attempt to simulate the repair process occurring in nature ("biomimesis[123]").

The ETP Nanomedicine's vision is "the development of cost-effective disease-modifying therapies for in situ tissue regeneration". Regenerative medicine also looks for biocompatibility of implants, through the development of efficient strategies based on nanotechnology to disrupt and prevent biofilm formation associated with a number of infectious diseases and implant-associated infections as well as through nano-functionalization of surfaces and intelligent, non-toxic, biodegradable or bioactive materials.

Intelligent biomaterials are artificial biomaterial scaffolds designed to support cell and tissue growth. The aim of these systems is to mimic the structure of organs and therefore provide a closer match of the artificial scaffold to their natural counterpart. Examples of technologies used to this end include nanofabrication, (3D) bioprinting technology, stem cell seeding, recruiting, activation, functionalisation, cell printing and bioactive nanoparticle coatings.

For example, smart nanobiomaterials may be used for personalised regeneration of osteoarticular tissues (bones, cartilages, tendons, joints) (European Commission, 2017b), affected by severe degenerative and/or inflammatory processes.

Another important element of regenerative medicine are bioactive signaling molecules, which are naturally present in cells and trigger regenerative events at molecular level. The understanding of the natural molecular interactions leading to regenerative pathways is essential for achieving progress in this field. Nanotechnology may assist in the development of activation and spatio-temporal control sequences of tissue regeneration.

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[122] Label free detection reduces the invasiveness of sample preparation and makes it easier to keep cells alive

[123] Defined as „study of the structure and function of biological systems as models for the design and engineering of materials and machines" (http://www.biomimeticsummit.com/about-us/what-is-biomimesis/)

Cell based therapies offer another approach to regenerative medicine. Instead of implanting artificial scaffolds, the goal is to utilize the self-repair potential observed in adult stem cells. Nanotechnologies can aid this process by 1. identifying signaling systems in order to leverage the self-healing potential of endogenous adult stem cells, and 2. developing efficient targeting systems for adult stem cell therapies.

While providing answers and solution for a market request of personalization of health treatments, target or site specific delivery of drugs and developing predictive medicine, thanks to nanotechnologies medicine will be able to give answers to several societal challenges pointed out in the EU2020 strategy and several Sustainable Development Goals:

- EU2020: 2) Health, demographic change and wellbeing;
- SDGs: 3) Ensure healthy lives and promote well-being for all at all ages.

Table 2a: Research and application areas for nanotechnologies in the health sector (Therapeutic)

Social drivers: Atherosclerosis and other Cardio-vascular Diseases, Cancer, Neuro-degenerative and other neurological disorders, Infectious diseases, Diabetes and Endocrine disorders, Arthritis and Osteoarticular pathologies			
Technological Solutions/Challenges	**Nanotechnology properties**	**Examples of specific applications**	**Market requirements/ societal challenges**
Research Priorities: Therapeutics: targeted drug delivery and theranostics			
Nano-enabled site-specific targeting	Biodegradability, biocompatibility, bioavailability, specificity, functionalization, hydrophilicity, Nanosized, Photoactive, lipidic	Site specific delivery of neuro active molecules	Personalized, targeted specific, site-specific, predictive
Nanoparticles and nanoformulations with triggered release		Tailor-made pharmacokinetics	
Controlled release strategies		local drug delivery for efficient use of antibiotics and dose-control	
Biodegradable and biocompatible semi-invasive nano-devices		controlled drug delivery, delivery of anti-inflammatory drugs to manage cellular and tissue response	
Nano-formulations and surface functionalization of nanoparticles with peptides		highly targeted drugs for crossing the Blood-Brain Barrier (BBB)	
Polymeric biodegradable hydrophilic nano-particles, nano bubbles, proteins		Target multi-drug-resistant bacteria	
Inorganic/organic nano-carriers		Loading with photosensitizers for photodynamic therapies	
Lipid nanoparticles		Vehiculisation of biological molecules for wound healing	
Nanoformulation of small molecules and biologicals		Regulate disease progression, avoid rapid clearance, inactivation /promotion of specific interactions with targeted organs/systems/cells; protect the cargo against inactivation and to cross significant biological barriers	
Nanotechnologies for spraying		Insulin delivery to nose or lungs	
Engineered theranostic nanoparticles		Nanoparticles for local control of tumour in combination with radiotherapy; Multimodal imaging and multiple therapy possibilities	
High precision optical nano-thermometry		Improved nanoparticle-based hyperthermia treatments	
Nano-formulations for imaging-guided drug delivery of nanosized systems		Endovascular theranostic and plaque imaging; personalised therapeutic treatments of tumours	
Photoactive nanomaterials		improved targeted delivery of agents for photodynamic therapy	
lipidic/micellar nanoparticles		Enhanced cancer cell targeting	

Table 2b: Research and application areas for nanotechnologies in the health sector (Diagnostic/imaging)

Social drivers: Atherosclerosis and other Cardio-vascular Diseases, Cancer, Neuro-degenerative and other neurological disorders, Infectious diseases, Diabetes and Endocrine disorders, Arthritis and Osteoarticular pathologies			
Technological Solutions/Challenges	**Key enabling nanotechnology properties**	**Examples of specific applications**	**Market requirements/ societal challenges**
Research Priorities: Diagnostic/imaging: Efficient fast and site-specific monitoring			
Nanostructured sensors	High sensitivity, High degree of multiplexing and quick response times	Predicting cardiovascular risks, diagnosis, prognosis, monitoring therapeutic efficacy	Personalized, targeted specific, site-specific, predictive
High throughput screening tools, based on nanostructured sensors		Tumour cells or DNA isolation, localisation, quantification, characterisation and sequencing	
Nanoparticle tracers and nano-contrast agents	Bisospecific, targeted	Early stage diagnosis, prognosis, monitoring disease progress and quantification of therapeutic agents and concomitang imaging	
Nano-gels, nano-carriers, composite nanoparticles as contrast agents		Radiotherapy precision and efficacy, inhibite immune response	
Imaging nanoparticles labelled with cells			
Identification and use of novel biomarkers		Integrated screening systems for genetic rare diseases	
Nano-enabled endoscopes and catheters	Minimally invasive or non-invasive, accurate, biospecific	Minimally invasive diagnostics and therapy	
Nano enabled devices		Non-invasive and pathless monitoring of glucose levels in blood, insuline delivery, insulin and glucose measurement; ex-vivo detection methods (i.e. mutation screening)	

Table 2c: Research and application areas for nanotechnologies in the health sector (Regenerative medicine)

Social drivers: Atherosclerosis and other Cardio-vascular Diseases, Cancer, Neuro-degenerative and other neurological disorders, Infectious diseases, Diabetes and Endocrine disorders, Arthritis and Osteoarticular pathologies			
Technological Solutions/Challenges	**Key enabling nanotechnology properties**	**Examples of specific applications**	**Market requirements/ societal challenges**
Research Priorities: Regenerative medicine			
Intelligent, non-toxic, biodegradable, bioactive materials	Smart, biodegradable, bioactive, nanofunctionalized, porous, biocompatible, biodegradable, biomimetic, biocompetent, imunostealth, immunoprotective, hydrophilic, nanostructured, 3D-printed	vascular grafts, drug eluting stens, medical adhesives and sealants	Personalized, targeted specific, site-specific
Porous biomaterials with biocompatibility and targeted biodegradability		Mimick the mechanical properties of nerves	
Nanofunctionalization of surfaces, nanocoatings to disrupt/prevent biofilm formation, Bacterial free nanomaterials		Reduce infection deseases and implant-associated infections	
Funcionalised 2D and 3D biomimetic, biocompetent, immunostealth materials		Spatial and temporal control over release of biochemical factors for artificial pancreas	
Nanotechnologies to deliver immunoprotection / Immunoprotective		Minimise immune response against transplanted cells/tissues	
Smart biomimetic cartilage		Implants disposing of a zonal structure, high stability and high water content	
Highly hydrophilic polymers coated		improve biocompability, lubrication and reduce the wear in prosthesis	
Nanoformulations and functionalized nanoparticles for stem cells		Stem cells recruitment, mobilisation and homing at site of injury, Targeted in-vivo activation of stem cell production	
3D printing of scaffolds, bioactive cells and nano-biomaterials		Neural stem cell encapsulation; stem cell immobilisation at site of injury; induce bone, joint and tissue regeneration	
Functionalized/intelligent bioscaffolds		Promote generation of revascularisation (e.g. with hydrogels)	
Biopolymers, functionalized biomaterials and intraluminal micro/nanostructures		Mimicking the peroperties and physical dimensions of the nervous tissue for peripheral and central nerve regeneration	
Nano-electrodes for stimulation		Induce regeneration in neurodegenerative deseases, combined with intelligent feedback loops using nano-sensors	
Soft nanomaterials		Bone regeneration, rheumatoid arthritis and crohn's disease	
Novel biomaterials, scaffolds, nanoformulated promotors for cell therapy		get faster and safer cell cultures, engineered tissues and allow cell transplantation to the patient	

4.4 NANOTECHNOLOGY AND ENERGY

This section provides an overview of policy as well as industry priorities and investment activities in regards to nanotechnology research and applications in the energy sector.

For the European Commission *"[n]anotechnology's great sustainability promise is to bring about the much needed power shift in renewable energy"*[124]. Consequently, several calls in the LEIT Work Programme explicitly refer to nanotechnology and energy. In regards to industry priorities, several ETPs, including the renewable heating and cooling European technology platform (RHC-ETIP), ETIP PV, NanoFutures and SusChem relate nanotechnologies to advancements in the energy sector. Nanotechnologies are expected to contribute to better and more decentralised energy storage solutions and the advancement of renewable energy production (photovoltaics, wind energy and renewable heating and cooling). In addition, nanotechnologies may contribute to multiple applications that serve energy production, storages and savings (see Table 3**Fejl! Henvisningskilde ikke fundet.**).

ENERGY STORAGE

A key issue for energy is the possibility to use advanced materials, including nanomaterials, to improve the energy storage possibilities. The main issues driving innovation in this sector are the need for very quick charge, higher energy and power density as well as a longer life cycle and the possibility to recycle materials of storage systems. Nanomaterials such as carbon nanotubes (CNT), graphene, carbon nanofibers, carbon nanohorns (CNH) are expected to exhibit high intrinsic conductivity and high energy intensity and thereby could potentially lead to optimised batteries and supercapacitors (i.e. advanced capacitors that have higher energy storage capacity than conventional ones), and are able to discharge over longer time periods. The NMBP Work Programme particularly emphasizes non-automative battery storage for decentralised renewable energies. The WP calls for *"more price competitive, better performant and highly safe battery storage solutions, with improved lifetime by lowering the cost and capital expenditure through development of less expensive and more performant materials (e.g. novel advanced electrode materials, including nanostructured and 2D materials and electrolytes), chemistries, packaging and cell design and battery component production processes*" (European Commission, 2017b).

Another important application of nanomaterials could be new flexible and wearable devices with very fast charge that will be embedded in textiles[125].

Another crucial application for nanomaterials in energy storage is H2 storage, as energy at peak periods can be converted into chemical energy in the form of H2 via electrolysis. In this case, new catalytic processes and catalysts, allowing for H2 generation and conversion into storage mediums are needed, as these operations require transient (dynamic) processes (while conventional processes are usually operated at steady state). Dealing with hydrogen, new noble metal-free electrode materials are being considered for efficient and cost-effective processes, while Metal-Organic

[124] http://ec.europa.eu/research/industrial_technologies/nano-in-energy-environment_en.html

[125] Graphene Magazine, Issue10, January 2018

frameworks (MOFs) seem to offer storage capacities that go significantly beyond the addition of carbon (SusChem, 2017).

PHOTOVOLTAICS

In the field of photovoltaics, the usage of nanotechnology is particularly interesting to produce solar energy harvesting systems with higher energy conversion efficiency. The PV technologies can be divided into two main types of approaches for PV energy conversion. The first type is energy conversion by the photoelectric effect in single-bandgap materials, where the energy conversion efficiency is restricted by the Shockley-Queisser[126] limit. In contrast, approaches using a range of techniques to circumvent the Shockley-Queisser limit are summed as novel or advanced PV technologies because achievable conversion efficiencies and production costs cannot be reliably estimated.

Nanotechnologies could provide benefits for both two types of approaches, and almost all type of PV technologies, including:

- First and Second generation photovoltaics, based on mono and poly crystalline silicon, thin film amorphous silicon
- Third generation (advanced photovoltaics), based on novel techniques, such as quantum dots cells, organic cells, polymer cells, multi-junction solar cells, Dye-sensitized Solar Cells (DSSC)
- Concentrator photovoltaics (CPV) technologies: Concentrating solar power (CSP) technologies, such as parabolic mirrors, solar power tower, parabolic trough.

Improvements of efficiency in PV systems can broadly be categorized into two approaches: tailor the properties of the active (photoelectric) layer to better match the solar spectrum or modify the solar spectrum directly without changing the active layer, such as in concentrator photovoltaics (CPV). Nanomaterials are seen as promising tools in both cases. However, it is expected that these new developments will first reach CPV where the natural light intensity is amplified by optical systems and focused on the PV cell. The required area of such cells is smaller and is therefore easier to warrant more expensive production techniques per square meter.

In the development of novel active layers, nanotechnology can allow a secondary lower/higher bandgap or partially recuperate higher-than-bandgap energies of photons before they thermalize to the bottom of the energy band (PhotoVoltaic, 2011). Development in this area focuses on low dimensional nanostructures like quantum wells, wires or dots.

Tailoring the solar spectrum can be performed by up or down-conversion of photon energies. In these systems a high-energy photon is converted into two low-energy photons (down-conversion) or vice versa (up conversion). The resulting photons can be photoconverted more efficiently by a

[126] An upper limit on the conversion efficiency based on the solar irradiation profile reaching earth and physical processes in materials where the photoelectric effect occurs

conventional PV cell. This effect requires high light intensities[127] and may be achieved using metallic nanoparticles. Because the active layer of the PV cell remains unchanged, these techniques are easier to combine with existing PV technology.

Light management by plasmonic effects is expected to provide low cost improved light coupling and absorption to photoactive layers, for ultra-thin silicon solar cells. Together with tuned nanostructured substrates concepts for stable cells are expected to reach an efficiency coefficient of 17% by 2025 (PhotoVoltaic, 2011).

Nanowires are nearly one dimensional structures which can be made of wide range of materials including conducting and non-conducting materials. Due to their large length-to-width ratio they have unusual physical properties and may help to improve the efficiency of organic dye solar cells by increasing the surface available for electron transport.

Currently expensive vacuum chambers are needed for the deposition of device layers. Novel non-vacuum techniques like nanoparticle printing could help to reduce costs and further increase the competiveness of PV panels with other methods of energy production.

In sum, the photovoltaic production is generally a cost driven industry. It is at constant competition with other energy production methods and the cost per kWh is therefore a key figure in nearly all applications. In the short term, novel technologies and techniques requiring nanomanufacturing are therefore most likely to be successful in specific applications (e.g. aerospace industry) where cost per square meter is not the main selection criterion. In medium term, the combination of nanotechnologies with conventional PV panels may be one of the driving factors for higher conversion efficiencies. Only in the long term, nanomanufactured active panels could possibly compete with conventional panels in high volume markets.

WIND ENERGY

Weight reduction is one of the most important goals for wind energy. The development of cost effective new lightweight materials on the basis of nanocomposites, with excellent stiffness/weight ratio, will enable larger sized blades, thus allowing increasing the power and the energy produced at low/medium speeds. An example could be new bio-based materials for sandwich panels that can be used as core materials for blades.

A second challenge is to improve the corrosion resistance to extend the lifetime of components and reduce maintenance effort, thus reducing lifetime costs. New protective coatings can also guarantee UV light resistance, self-cleaning and anti-fouling and icing properties, to extend operation in harsh environments such as offshore wind farms (SusChem, 2017).

RENEWABLE HEATING AND COOLING

The renewable heating and cooling European technology platform (RHC-ETIP)[128] points to nanotechnology as a way to improve properties of materials and surfaces, affecting properties such

[127] Up and down conversion is a non-linear physical phenomenon of second order requiring high intensities to occur with noticeable probabilities

as weight, friction, viscosity, conductivity, thermal conductibility and others. Examples of application in the near term include nano-coatings in solar heating systems, which are expected to reduce friction losses during fluid flow (ESTTP, 2006), and in heat exchangers as anti-microbial coating (RHC, 2012).[129]

MULTI-APPLICATION

There is also a heterogeneous group of innovations enabled by nanotechnologies that will improve the energy production and distribution as well as reduce energy consumption in a large number of different applications (see Table for a list). Nanotechnology will allow to produce improved flexible printed technologies/devices (Nanofutures, 2016), such as OLED (organic light-emitting diode) technology, opening new design possibilities to extend the application of these energy saving light sources. Nano-electronics will enable a wide range of applications, such as more efficient power distribution and supply solutions to lower energy consumption in automotive sector, using hybrid and electrical power trains. Nanotechnology will also lead to the production of multifunctional materials, with embedded sensing and communication features. 3D printing will enable a rapid and cost-effective production of printed devices for power supply or components for hybrid optics and circuits on flexible substrates. Optical photonics integrated on silicon (Silicon Photonics) (ETP Nanomedicine, 2006) will help to miniaturize high speed applications by reducing costs and power with respect to the interconnections. Nanosensors could help realizing decentralised management of renewable energy grids.

Besides more efficient distribution and power transmission systems, nanomaterials could be used to build smart glass and electrochromic windows capable of maximising the use of solar power to heat buildings.

A new class of nanomembranes could be used for carbon capture at fossil fuel power plants, while nanotacalysts could optimise fuel production.

In conclusion, nanotechnologies are expected to answer to a vast group of European societal challenges concerning the energy field and various sustainable development goals:

- EU2020: 3) Secure, clean and efficient energy, 4) Smart, green and integrated transport, 5) Climate action, environment, resource efficiency and raw materials;
- SDGs: 7) Ensure access to affordable, reliable, sustainable and modern energy for all, 9) Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation, 11) Make cities and human settlements inclusive, safe, resilient and sustainable, 12) Ensure sustainable consumption and production patterns, 13) Take urgent action to combat climate change and its impacts.

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[128] http://www.rhc-platform.org/about-us/background/

[129] http://www.european-coatings.com/Raw-materials-technologies/Technologies/Antifouling-treatment-for-heat-exchangers

Table 3: Research and application areas for nanotechnologies in the energy sector

Social Drivers: Energy saving or preventing energy waste, CO2 emission saving, Competitive low carbon/clean energy production, maximise clean energy production and transport efficiency, efficient and clean energy storage and conservation.				
Research Priorities	**Technological Solutions/Challenges**	**Key enabling nanotechnology properties**	**Examples of specific applications**	**Market requirements/societal challenges**
Storage	Advanced materials such as graphene, carbon nanofibers, nanotubes, nanohorns, nanoonions	High intrinsic conductivity, high energy density	Batteries and supercapacitors for hybrid and electric vehicles or for houses using renewable power sources, , textiles with embedded flexible energy storage devices; wearable electronics	Efficiency, reliability, customization of systems
	MOFs (Metal-Organic frameworks) materials	storage capacities that go significantly beyond the addition of carbon	H2 storage and purification systems	Chemical energy storage
Advanced Photovoltaics & CPV	Novel nanostructured active layers for PV cells		Quantum wells, wires, dots to improve efficiency of the active layer	recuperate higher-than-bandgap energies
	Nanowires	increased surface available for electron transport	Organic dye solar cells	Improve PV efficiency
	Plasmonic materials/devices	Improved light coupling and absorption to photoactive layers, light management	Ultra thin Silicon solar cells, thin film organic photovoltaics (OPV), improved CPV systems	Low cost, increased in efficiency through light management
	Nanoparticle printing		Deposition of device layers in non-vacuum environment	Reduce production costs
	Nanoelectronics devices		Improved inverters, storage devices	PV system efficiency
Wind	Bio-based materials for sandwich panels		Sandwich core materials for wind turbine blades	Enhance wind turbines efficiency
	protective coatings	UV-resistant, self-cleaning, anti-fouling, anti-icing	Components protection of offshore wind farms	Reducing lifetime costs
Renewable heating and cooling	Nano-coatings	Drag reducing and anti-microbial coatings	Reduce friction and biofilm formation in heat exchangers	Reduce energy losses

Research Priorities	Technological Solutions/Challenges	Key enabling nanotechnology properties	Examples of specific applications	Market requirements/societal challenges
Multi-application	Printed devices		Printed power supply systems	Low cost power supply
	3D printed components	advanced nano-lithography, Directed Self Assembly	Printed hybrid optics (LED&lighting), Circuits on flexible substrates, fast prototyping and production of complex electronic devices.	Energy efficiency, fast-prototyping
	Novel Lighting systems	Better quality of light, large area light sources, new form factors	OLED lighting	Energy efficiency
	New technologies and materials for Injection Stretch Blow Moulding (ISBM)	Improved production efficiency	Packaging production (e.g. plastic bottles)	Reduce energy in production; reduce packaging weight and CO2 emissions
	Nano-electronics components/devices	Efficiency of power distribution and transformation, User personalization	Digital power conversion; efficient power supplies, switching power supplies, devices for regenerative energy (solar, wind, water), Efficient ("in-situ") power supplies and management; power distribution infrastructure for electric mobility; hybrid and electrical power trains	Smart and efficient power distribution and management; lower emission in transport systems
	Optical photonics integrated on Si	high speed communication at low cost and low power	High-speed intensive computing, data communication, telecom and high-end storage	Energy efficiency
	Nanocoatings, nanostructured surfaces	improved mechanical, thermal, electrical, barrier and chemical properties: self-healing, self-cleaning, high-gloss, anti-scratching, super-hydrophobic, corrosion-resistant, anti-fouling, stain-resistant, anti-odor, anti-microbial, conducting, water-repellent	Pipelines, Coatings for thermal management (cooling and IR reflection); improved clean energy production systems	Energy costs reduction.
	Nanopigments	Increased luminosity and long after glow for safety applications	Safety signs, safety way guidance systems, underground stations, tunnels	Reduce energy costs in safety systems
	Multifunctional materials with embedded electronics	embedded sensing/actuation functions or electronics		
	Lightweight materials	Structural properties	Engines, batteries (including their packaging)	Minimise energy consumption, enhance design efficiency
	Nanocomposite	Structural properties	friction/wear reduction for energy sector, heat recovery, additives for fuels with enhanced chemical to thermal energy conversion properties	Reduce energy costs
	Nanofluids	Low viscosity, thermal capacity	Improved fluids for transport systems (power train) and manufacturing equipment	Reduce energy costs

5. SYNTHESIS AND CONCLUSIONS

The first policy screening presented in this report serves as input to the pilots in the three sectors, food, energy and health, in terms of potential themes, i.e. nanotechnology applications, to discuss as well as the related EHS and regulatory debates and positions. The following synthesis and suggestions are derived from the analysis presented in this report. The partners implementing the pilots may very well choose other applications to discuss based on the available stakeholders and the related research foci in the respective countries.

5.1 GENERAL SYNTHESIS

Over the past decades, nanotechnologies have transformed from an emerging technology to a key enabling technology. In European policies, they are explicitly supported to improve industrial competitiveness, particularly in the areas of healthcare, energy and environment, manufacturing and electronics and ICT. They are seen as well important to tackle several societal challenges, and in particular secure, clean and efficient energy and transport. Beyond that, nanotechnologies are expected to play an important role in fostering excellent and ground-breaking science (e.g. EC Future Emerging Technologies - FET programme). Two of the areas covered by GoNano, i.e. health and energy, play an important role in the Framework Programme's support for nanotechnologies. Food is occasionally mentioned but does not appear as a focus sector.

While many nanotechnology products are already developed and partially marketed, other initial promises have proven to be unfulfilled hypes. Many of the envisioned applications have still not left the laboratories or even visioning phase. On the other side, also many of the initial fears have proven to be unwarranted, in particular in regards to public acceptance or the lack thereof. Today, nanotechnologies present a paradigmatic case of the ambivalent character of technologies in the risk society (Beck, 1986): Nanotechnologies are presented as a driver for industrial competitiveness, economic growth and prosperity and, with increasing emphasis, as a potential solution to a wide range of the so-called Grand Challenges, including health, environment and energy issues. Following this framing, the imperative to innovate and market nanotechnologies becomes inevitable. On the other side, nanotechnologies increase uncertainties and risks for societies, ranging from questions of how to define nanotechnology to questions of the impacts of nanotechnologies on humans and the environment. Consequently, the development of nanotechnologies has entailed a range of new institutions (organizations, regulations, standards and rules) that deal with the uncertainties and potential side-effects of this technology. As our discussion has demonstrated, many risk and regulatory issues are still unresolved. If nanotech will indeed be the revolution it is claimed to be, then its regulation cannot be business-as-usual.

It is a key task of the pilots to recognize this ambiguity throughout the pilots without leaning to either side. Since the pilots start from promising nanotechnology applications in the three sectors and strive for co-creating nanotechnology product visions, the pilots already have an in-built tendency towards a technology-fix position, in which nanotechnologies are framed as the (only) solution to a range of problems. To counter this tendency, pilots may focus on particular applications but may also allow for or even encourage openness in terms of thinking about

alternatives to nanotechnologies, particularly in citizen deliberations. In regards to issues and debates concerning environmental, health and social issues of nanotechnologies, this report has demonstrated that these issues are not easily resolved. A range of uncertainties and regulatory gaps still exist and will likely continue to exist. In the pilots, it is important to acknowledge this situation and to avoid the impression of an "easy fix" of these issues. Rather than presuming that we can acquire complete knowledge on the impacts of nanotechnologies and regulate them accordingly, we should raise questions along the line of "which uncertainties and risks are we willing to take in exchange of the benefits of nanotechnologies for food, health and energy?"

After these general considerations, in the following we shortly synthesize the insights for the three sectors and provide respective suggestions for the pilots.

5.2 SUGGESTIONS FOR THE FOOD PILOT

The envisioned applications of nanotechnology in the food industry appear rather limited, particularly when compared to the sectors health and energy. In the Food area the main applications are related to food safety and security and food packaging. These applications are expected to be developed in a shorter time. In a longer-term, nanotechnologies are expected to be used also to realize functional foods, allowing to modify food nutrition properties and thus reducing the need for additives or processing aids or to develop novel ingredients. In contrast to the limited applications, debates on EHS issues and regulations are particularly pronounced in the food sector with a range of sectoral regulations explicitly referring to nanotechnologies.

For the citizen and stakeholder deliberations in the food pilot, areas of focus could be: the use of nanotechnologies to improve quality (safety and security aspects) in food, agri-food, and drinkable water management (short-term application); use of nanotechnology for functional foods (long-term).

5.3 SUGGESTIONS FOR THE HEALTH PILOT

The health sector is expected to experience major advancements thanks to nanotechnology, in particular in therapeutics, diagnostics and regenerative medicine. The main applications in therapeutics are related to the possibility to have a precise control on the release of drugs in time and space, reduce the side effects of therapies and to maximise the personalization and efficacy of therapies. Nano-electronics are also expected to contribute to obtain more efficient, fast and site-specific, minimally invasive diagnostic and monitoring systems. Finally, nano-assisted regenerative medicine is targeted at improving the tissue regeneration, develop cell-based therapies and new intelligent biomaterials to reduce risks associated to implants. Also in the health sector, a range of EHS, unresolved uncertainties and risks to human health are debated and included in existing and new regulations.

For the citizens participating in the health sector pilot, areas of focus could be: the use of nanotechnologies for the cure of important diseases, such as cancer (e.g. targeted delivery of drugs); the use of nanotechnologies to create fast, and accessible diagnosis solutions for different diseases, such as pandemic and genetic rare diseases (short to mid-term); 3D printing of scaffolds, bioactive cells and nano-biomaterials (short to mid-term); the use of functionalized nanoparticles for targeted

in-vivo activation of stem cell production for regenerative medicine (mid-term to long-term) and many others.

5.4 SUGGESTIONS FOR THE ENERGY PILOT

The energy sector is expected to benefit from nanotechnology mainly in terms of new structural and functional materials and devices, in particular for energy production (e.g. advanced photovoltaics), energy storage (batteries), and various applications for energy saving. Few applications are found in order to enhance performances of wind energy and renewable heating and cooling, while a large group of applications in different sectors can be found that will allow to enhance energy efficiency, reduce energy in industrial processes, improve power distribution and miniaturize energy supply systems. So far, no specific regulations concerning nanotechnologies exist for the energy sector.

For the citizens participating in the energy sector pilot, areas of focus could be: wearable technologies, including energy storage and energy harvesting systems, such as advanced photovoltaics (short-term to mid-term); H2 storage systems (mid to long-term) and many others.

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7. RESOURCES

In the following, the main web resources on nanotechnology governance and policies are listed, with a focus on the European Union and the GoNano partner countries.

EUROPEAN COMMISSION

Directorates Generals with dedicated websites on nanotechnologies:

- DG Research &Innovation – Website on Nanoscience and Nanotechnologies: http://ec.europa.eu/research/industrial_technologies/nanoscience-and-technologies_en.html
- DG Environment – Website on Nanomaterials: http://ec.europa.eu/environment/chemicals/nanotech/index_en.htm

EU Agencies with dedicated websites on nanotechnologies:

- European Chemical Agency (ECHA)
  - Website on nanomaterials https://echa.europa.eu/regulations/nanomaterials
  - Nanomaterials Expert Group: https://echa.europa.eu/regulations/nanomaterials/nanomaterials-expert-group
  - European Observatory for Nanomaterials (EUON): https://euon.echa.europa.eu/
- European Agency for Safety and Health at Work: https://osha.europa.eu/en/emerging-risks/nanomaterials
- European Food Safety Authority (EFSA): http://www.efsa.europa.eu/en/topics/topic/nanotechnology/

Advisory institutions

- European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR): https://ec.europa.eu/health/scientific_committees/emerging_en
- European NanoSafety Cluster: https://www.nanosafetycluster.eu/
- High-Level Group (HLG) on key enabling technologies: http://ec.europa.eu/growth/industry/policy/key-enabling-technologies/european-strategy/high-level-group_en
- Member States Group on KETs: http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2950

EUROPEAN TECHNOLOGY PLATFORMS

European Technology Platforms with reference and relevance for nanotechnology:

- Nanofutures: http://nanofutures.info
- ETP nanomedicine: https://www.etp-nanomedicine.eu/public
- Nanoelectronics: http://www.eniac.eu/web/index.php

- European Technology Platform for Micro- and Nano Manufacturing (MINAM): http://www.minamwebportal.eu/
- European Technology Platform Photonics: https://www.photonics21.org/
- European Road Transport Research Advisory Council: http://www.ertrac.org/
- ETP Industrial Safety http://www.industrialsafety-tp.org/
- ETCP Innovative Built Environment: http://www.ectp.org/index.php
- European Technology Platform Manu*future:* http://www.manufuture.org/
- European Technology Platform for Advanced Engineering Materials and Technologies http://www.eumat.eu/
- SusChem, European Technology Platform for Sustainable Chemistry: http://www.suschem.org/
- ETP Fibres Textile Clothinghttp://www.textile-platform.eu/
- ETIP Renewable Heating and Coolinghttp://www.rhc-platform.org
- ETIP Photovoltaichttp://www.etip-pv.eu/about-us.html
- Food for Lifehttp://etp.fooddrinkeurope.eu/about-us/about.html
- Food and Drink Europe: http://www.fooddrinkeurope.eu/our-actions/topic/nanotechnology/

NGOs

NGOs (European or international scope) with dedicated websites and activities on nanotechnologies:

- Center for International Environmental law (CIEL): http://www.ciel.org/project-update/safe-development-of-nanotechnologies/
- Center for Food Safety: https://www.centerforfoodsafety.org/issues/682/nanotechnology
- ECOS – Network of European Environmental NGOs, specialized in standardisation and technical product policies: http://ecostandard.org/category/activities-on-nanotech/
- ETC Group: http://www.etcgroup.org/issues/nanotechnology
- IPEN: http://ipen.org/toxic-priorities/nanotechnology

Trade Unions

Trade Unions (European or international scope) with dedicated websites and activities on nanotechnologies:

- European Trade Union Confederation: https://www.etuc.org/issue/nanotechonologies
- European Trade Union Institute (ETUI): http://www.etui.org/Topics/Health-Safety-working-conditions/Nanotechnologies

Industry Associations

Industry Associations (European or international scope) with dedicated websites and activities on nanotechnologies:

- CEFIC (European Chemical Industry Council): http://www.cefic.org/nanomaterials
- NIA Nanotechnology Industry Association: http://nanotechia.org/

OECD

- Website on nanotechnology: http://www.oecd.org/sti/nano/
- Working Party on Manufactured Nanomaterials (WPMN): http://www.safenano.org/knowledgebase/standards/working-party-on-manufactured-nanomaterials/
- Working Party on Nanotechnology (WPN): http://www.oecd.org/sti/sci-tech/oecdworkingpartyonnanotechnology.htm

OTHER

- Asia Nano Forum: https://www.asia-anf.org/
- Asia Pacific Nanotechnology Forum (APNF): http://www.apnf.org/
- Chemicalwatch (News website): https://chemicalwatch.com/
- Nanowerk (information portal) https://www.nanowerk.com/
- Technology Law Source (Law firm) International Risk Governance Council (IRGC): http://www.irgc.org/issues/nanotechnology/
- The Innovation Society (consulting company): http://innovationsgesellschaft.ch/en/
- https://www.technologylawsource.com/articles/nanotechnology/

PARTNER COUNTRIES

Austria

- Austrian Ministry for Transport, Innovation and Technology: https://www.bmvit.gv.at/innovation/nanotechnologie/index.html
- NanoTrust: a project series by the Institute of Technology Assessment at the Austrian Academy of Sciences, dealing with nanotechnology governance: https://www.oeaw.ac.at/ita/en/projects/nanotrust/overview/
- Nanoinformationsportal: https://nanoinformation.at/ (in German only)
- Platform NanonetStyria: http://www.nano-net.at/ (in German only)
- Network BioNanoNet: https://www.bionanonet.at/

Czech Republic

- CzechInvest, Investment and Business Development Agency https://www.czechinvest.org/en/Key-sectors/Nanotechnology
- The Nano Association of Czech Republic http://www.nanoasociace.cz/en/about-us/

Denmark

- Danish Ministry of the Environment, website on nanomaterials: http://eng.mst.dk/chemicals/chemicals-in-products/nanomaterials/
- The Nanodatabase, developed by the Danish Consumer Council and the Danish Ecological Council in cooperation with the Technical University of Denmark (DTU) Environment http://nanodb.dk/
- University institutes:
    - Aarhus University: http://inano.au.dk/

- The Technical University of Denmark: http://www.nano.dtu.dk/english
- University of southern Denmark: https://www.sdu.dk/en/nanosyd
- Copenhagen University: http://nano.ku.dk/english/

Italy

- National Institute of Health, online platform on responsible development of nanotechnologies - https://nanotecnologie.iss.it/
- Italian Workers Compensation Authority- NanoOSH Italia network - https://appsricercascientifica.inail.it/nanotecnologie/?pag=whitebook
- Italian Association for Industrial Research, Committee on Nanotechnologies and Key Enabling Technologies - http://www.airi.it/category/temi-di-ricerca/nanotecnologie/

Netherlands

- Dutch government, website on nanotechnology: https://www.government.nl/topics/nanotechnology
- **The National Institute for Public Health and the Environment (in Dutch: RIVM)**: https://www.rivm.nl/en/Topics/N/Nanotechnology (focus on safety and risks assessment)
  - Risks of Nanotechnology Knowledge and Information Centre (KIR nano): https://www.rivm.nl/en/Topics/N/Nanotechnology/Risks_of_Nanotechnology_Knowledge_and_Information_Centre_KIR_nano
- **National Science Agenda**: https://wetenschapsagenda.nl/national-science-agenda/?lang=en. Relevant 'routes' of the National Science Agenda:
  - Materials: Made in Holland: https://wetenschapsagenda.nl/route/materialen-made-in-holland/
  - The quantum/nano-revolution: https://wetenschapsagenda.nl/route/quantumnanorevolutie/
  - Personalised Medicine: https://wetenschapsagenda.nl/route/personalised-medicine-uitgaan-van-het-individu/
  - Energy Transition: https://wetenschapsagenda.nl/route/energietransitie/
  - Sustainable Production of Safe and Healthy Food: https://wetenschapsagenda.nl/route/duurzame-productie-van-veilig-en-gezond-voedsel/
  - Smart Industry: https://wetenschapsagenda.nl/route/smart-industry/
  - Circular Economy: https://wetenschapsagenda.nl/route/circulaire-economie-en-grondstoffenefficientie-duurzame-circulaire-impact/
- **Netherlands Organisation for Scientific Research NOW, Domain Applied and Technical Sciences** of the (http://www.stw.nl/nl/nano) runs most of the large nano-related funding programmes in the Netherlands, including:

- **NanoLabNL**, a Dutch national facility for nanotechnology research, offering the use of facilities and expertise to universities, research institutes, start-ups and industry: http://www.nanolabnl.nl/
- **NanoNextNL**, the Dutch national research and technology programme for micro and nano technology (2011-2016): http://www.nanonextnl.nl/
  - The NanoNextNL programme also included a theme on **Risk Analysis and Technology Assessment (RATA)**: http://www.nanonextnl.nl/themes/risk-analysis-and-technology-assessment/, combining research on human and environmental health risks with technology assessment.
- **NWO-nano**, a funding programme by the Domain Applied and Technical Sciences of the Netherlands Organisation for Scientific Research NWO. The programme was launched in 2010, making a total of 10 million euros available for nanotechnologies research: http://www.stw.nl/nl/node/4658.

- The TechNano Fund of the **Netherlands Enterprise Agency (in Dutch: RVO)**, a seed fund for early growth nano- en high-tech companies: https://www.rvo.nl/subsidies-regelingen/seed-capital/totaaloverzicht-seedfondsen/technano-fund.
- **NEMO Kennislink**, the online knowledge database of the NEMO Science Museum in amsterdam, has a section on nanotechnologies, see: https://www.nemokennislink.nl/vakgebieden/nanotechnologie/ (in Dutch)
- **Nanocentre:** http://www.nanocentre.nl/index.aspx?id=262, a website providing information to companies on how to innovate safely with nanotechnologies

Norway

- Research Council of Norway; Innovation in enabling technologies; programme Nano2021: https://www.forskningsradet.no/prognett-nano2021/Home_page/1253969916222; dedicated pages on RRI of the NANO2021 programme in the RCN : https://www.forskningsradet.no/prognett-nano2021/RRI/1254018429223
- PhD network: http://www.nano-network.net/
- The Norwegian Board of Technology: https://teknologiradet.no/nanoteknologi/
- Universities:
  - https://www.ntnu.edu/studies/mtnano
    http://www.uio.no/studier/emner/matnat/kjemi/MENA1001/index-eng.html
- Nanomat: http://nanomat.no/ (in Norwegian only)

Spain

- Spanish Nanomedicine Platform: www.nanomedspain.net

Switzerland

- ETH Zürich, nanotechnology group: http://www.nano.mavt.ethz.ch/ ; micro& nanosystems: http://www.micro.mavt.ethz.ch/ ; nanometallurgy: http://www.met.mat.ethz.ch/