



RISK GOVERNANCE AND RESEARCH & INNOVATION PRIORITIES IN NANOTECHNOLOGIES

***UPDATE ON REGULATORY CONTEXTS AND CURRENT POLITICAL
DEVELOPMENTS AND BRIEFING REPORT FOR GoNANO WHITE
PAPERS***

Deliverable 5.2

GoNano has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement 768622.



Work Package:	WP5
Deliverable number:	5.2
Partner responsible:	OeAW
Deliverable author(s):	Ulrike Bechtold, Daniela Fuchs (Austrian Academy of Sciences); David Azoulay (Centre for International Environmental Law); Corentin David (Centre for International Environmental Law); Daniela Pimponi (Airi - Italian Association for Industrial Research); Andrea Porcari (Airi),
Contributor(s):	Florian Ortis (Austrian Academy of Sciences); Daan Schuurbiers (De Proeffabriek); Vanessa Moore (European Institute of Women's Health); Harald Throne-Holst (Oslo Metropolitan University); Craig Richmond (RMIT Europe); Lenka Hebáková, Marek Pour, Iva Vancurova (Technology Centre of the Czech Academy of Sciences); Anne Dijkstra (University of Twente); Helle Henriksen and Lise Bitsch (Danish Board of Technology Foundation), Elvio Mantovani (Italian Association for Industrial Research)
Quality assurance:	Lise Bitsch (Danish Board of Technology Foundation)
Planned delivery date:	30 September 2019
Actual delivery date:	31 October 2019
Dissemination level:	PU

TABLE OF CONTENT

Executive summary	4
1. Introduction.....	5
1.1. Purpose, scope and structure.....	5
1.2. Methodology	6
2. Nanotechnology Policy Context	7
2.1. EU policy framework for nanotechnology.....	7
2.2. Nanotechnology policy frameworks in GoNano partner countries	9
3. Nanotechnology risk governance and regulations.....	25
3.1. General overview	25
3.2. Nanomaterials in food.....	36
3.3. Nanomaterials under the medical devices regulation	39
3.4. Nanotechnology and energy	40
4. Research and innovation priorities on nanotechnologies.....	42
4.1. European Union H2020	42
4.2. Nano governance in H2020 projects (status quo and outlook)	45
5. Synthesis and conclusions	60
5.1. Points of reference for the White Papers (GoNano Del. 5.3).....	62
6. References.....	64
Annex: Data Management Plan.....	68

EXECUTIVE SUMMARY

The report provides an updated overview of both recent developments and debates regarding risk governance and regulations of nanotechnologies, and research and innovation priorities by European policies (H2020) in addition to the focus on ETPs in Del. 5.1, and supplemented by concrete project examples on European level.

The aim is to ensure continuous alignment of GoNano activities with the regulatory and policy context.

This report is Deliverable 2 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 GoNano pilot studies and relevant policy initiatives and debates.

1. INTRODUCTION

1.1. PURPOSE, SCOPE AND STRUCTURE

The report explores risk governance and regulatory issues and research and innovation priorities related to nanotechnologies, with a focus on the three pilot sectors of the GoNano project (food, health and energy).

This report is Deliverable 2 of Work Package 5 “Governance and Policy Outreach and Alignment” (Task 5.1 “Policy Monitoring and Alignment”) of GoNano and serves to ensure alignment of GoNano activities with the current regulatory and policy context, specifically regarding the design of the White papers and business case (WP5). It is an updated version of Deliverable 5.1 (published in September 2018).

Nanotechnology is the prominent term to describe the variety of research and innovations related to the manipulation of matter in the nanometer range.¹ 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.

Thus, 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.

The geographical focus of this report is primarily on the EU level, including priorities stated in Horizon 2020.

In detail, the report looks at:

- a) *Risk governance, regulatory issues and debates*: an overview of existing regulatory policies and current debates on the governance and regulation of nanotechnologies, both in general in the three selected sectors (EU and national level). This includes recent debates by policy makers and regulators, industrial and research actors, and civil society organizations in the area of risk governance of nanomaterials, in particular concerning updates of REACH. The aim is to capture the main priorities, positions and controversial issues of different R&I players and societal groups.
- b) *Research and innovation priorities*: an overview of strategic and investment priorities of policy (EU Commission) and industry stakeholders (ETPs). The analysis focuses on strategy developments, action plans or roadmaps as well as dedicated funding initiatives and programmes.

The report aims to provide a structured overview on the main issues of the debate on nanotechnology development, in order to provide useful insights to perform stakeholder engagement in the field. As far as concern GoNano, the report will inform the development of the White Papers (Del. 5.3) and

¹ 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”

business case (Del. 5.4) on Responsible Research and Innovation approaches for stakeholder engagement and co-creation on nanotechnologies.

The analysis provided in this report does not claim to be comprehensive.

1.2. METHODOLOGY

The report is based on desk research, on peer-reviewed and grey literature and online resources (e.g. existing legislation, strategy documents of the European Commission and H2020 documents and calls) as well as by input from the experience of GoNano partners.

This report is an update of the first screening report Del. 5.1, and thus a similar structure is used.

For reasons of efficiency and due diligence, the original text is left unchanged as far as necessary and valid. Most significant updates include:

- In section 2.1, the revisions of the REACH Annexes which were adopted in December 2018, and information on the upcoming Horizon Europe framework programme (in particular regarding the NMBP work programme).
- In section 2.2, updated initiatives and activities regarding all countries have been included.
- Section 3 was thoroughly updated.
- Section 4 has been completely revised, replacing the mapping of ETPs priorities, with an analysis of research projects on risk governance.
- Section 5 has been completely revised, in order to inform the design of the three GoNano White papers on Responsible Research and Innovation approaches for stakeholder engagement and co-creation on nanotechnologies

A reference to Del. 5.1 will indicate where parts of the text largely remain the same (e.g. parts of Chapter 2). Other parts (e.g. the reports on EU and national governance on nano) have been updated individually by partners where necessary (Chapter 3) or were fundamentally rewritten (Chapter 4 and 5).

2. NANOTECHNOLOGY POLICY CONTEXT

Nanotechnology is one of the enabling technologies identified in research and innovation policy in many countries since the late 1990s. Japan, China and the US have been the first countries to provide strategic support to the development of nanotechnologies. Since around the year 2000, nanotechnology has increasingly become the subject of R&I and regulatory debates and initiatives in Europe, starting in Member States such as the Germany and the UK, and then at the level of the European Union and in other Member States. At the same time, other international organizations such as OECD, UNESCO or ISO as well as various NGOs increasingly paid attention to the debate. This chapter gives a brief overview on the nanotechnology policies in terms of foci, key documents, 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 (N&N) 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
- b) developing world-class infrastructure
- c) promoting the development of skills and business competencies 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.

Nanotechnologies already 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. Part of the debate focus on environmental, health and safety issues (EHS) and ethical, legal and social aspects (ELSA), in the context of the broader concept of Responsible Research and Innovation.

The Directorate-General for Research and Innovation² plays a crucial role in coordinating and supporting research and development in N&N, and from the sixth Framework Programme on has provided financial and funding support (see section 4.1 in Del. 5.1 for more details). In recent years, **nanotechnologies have been integrated in the European Commission's strategy and action plan for**

² http://ec.europa.eu/research/industrial_technologies/nanoscience-and-technologies_en.html [2019-10-18]

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)³, 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.⁴
- A Member States Group on KETs⁵ has been set up to improve collaboration between European and national/regional level actors.
- 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 programmes⁶.

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.

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 NanoDiode⁷ and Nano2all⁸ 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 Cluster⁹, 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. 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

³ http://ec.europa.eu/growth/industry/policy/key-enabling-technologies/european-strategy/high-level-group_en [2019-10-18]

⁴ <http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2962> [2019-10-18]

⁵ <http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2950> [2019-10-18]

⁶ https://ec.europa.eu/growth/industry/policy/key-enabling-technologies/european-strategy_de [2019-10-18]

⁷ <http://www.nanodiode.eu/> [2019-10-18]

⁸ <http://www.nano2all.eu/> [2019-10-18]

⁹ <https://www.nanosafetycluster.eu/> [2019-10-18]

Work (EU-OSHA)¹⁰. OSHA looks at the exposure to nanomaterials at the workplace¹¹ and respective risk perception and risk communication strategies¹².

Looking at the sectors considered by GoNano, EHS issues and ELSA have been highly debated concerning the **application of nanotechnologies in food**. The European Food Safety Authority (EFSA)¹³ supports the European Commission with risk assessments on nanotechnologies in food and feed¹⁴, respective guidance and public consultations¹⁵. In addition, 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)¹⁶ also published various documents concerning EHS of nanotechnologies¹⁷.

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).

Specific regulatory provisions and guidance documents are included in cosmetics, food, chemicals and biocides and Medical Devices regulations.

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 European Chemicals Agency (ECHA)¹⁸. In order to facilitate this process ECHA has published several guidances for safety assessment of nanomaterials¹⁹. The European Chemicals Agency (ECHA) also hosts the European Observatory for Nanomaterials (EUON)²⁰. Section 3 provides further details on regulation of nanomaterials at EU level.

2.2. NANOTECHNOLOGY POLICY FRAMEWORKS IN GoNANO PARTNER COUNTRIES

Several EU Member States are active in the governance of nanotechnologies since a long time (European Commission, 2017c, 8). This section provides an updated overview on national

¹⁰ <https://osha.europa.eu/en/emerging-risks/nanomaterials> [2019-10-18]

¹¹ https://osha.europa.eu/en/tools-and-publications/publications/literature_reviews/workplace_exposure_to_nanoparticles/view [2019-10-18]

¹² https://osha.europa.eu/en/tools-and-publications/publications/literature_reviews/risk-perception-and-risk-communication-with-regard-to-nanomaterials-in-the-workplace/view [2019-10-18]

¹³ <http://www.efsa.europa.eu/en/topics/topic/nanotechnology> [2019-10-18]

¹⁴ <http://www.efsa.europa.eu/en/supporting/pub/1393e> [2019-10-18]

¹⁵ <http://www.efsa.europa.eu/en/press/news/180112> [2019-10-18]

¹⁶ https://ec.europa.eu/health/scientific_committees/emerging_en [2019-10-18]

¹⁷ http://ec.europa.eu/health/scientific_committees/emerging/opinions/scenihr_opinions_en.htm#nano [2019-10-18]

¹⁸ <https://echa.europa.eu/home> [2019-10-18]

¹⁹ <https://echa.europa.eu/regulations/nanomaterials> [2019-10-28]

²⁰ <https://euon.echa.europa.eu/home> [2019-10-28]

nanotechnology governance initiatives, 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.²¹ After the end of the programme and to this day, nanotechnology research and industrial development have been integrated to the programme “Production of the Future” of the Austrian Ministry for Transport, Innovation and Technology, handled by the Austrian Research Promotion Agency (FFG)²².

Discussions on environmental, health and social issues of nanotechnologies and specific regulatory discourses started to go public 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) (Jakl et al. 2009, accepted by the cabinet in 2010) marks the starting point for co-ordinated political action on nanotechnology risk governance in Austria. The ÖNAP was initiated by the BMLFUW (Federal Ministry of Agriculture, Forestry, Environment and Water Management; today BMNT, Federal Ministry for Sustainability and Tourism) and prepared by four working groups (on health, environment, economy, science). In these working groups, stakeholders and representatives from the administration, NGOs, and science met on a regular basis (Kurath et al., 2014); representatives of Nanotrust²³ (of the Institute of Technology Assessment of the Austrian Academy of Sciences) were represented in all four working groups. The plan contains fifty recommendations in the fields of environment, health and occupational safety. Fundamental to these recommendations is the demand for establishing a transparent public communication strategy that is based on two different pillars: (1) the Nanoinformation Platform (NIP, since 2011) and the (2) website “nanoinformation.at” (since 2012) which provides information on different areas (health, food and nutrition, work safety etc.) and offers the opportunity to answer consumers’ questions in relation to nanotechnology.

The ÖNAP identified different fields of action such as 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. Because of these expert discussions, the website Nanoinformationsportal (nanoinformation.at) was established. In 2013, the informal working

²¹ <https://ec.europa.eu/growth/tools-databases/kets-tools/policy/policy-profiles-kets-austria/initiative/austrian-nano-initiative> [2019-10-18]

²² <https://www.ffg.at/en/production-future-calls> [2019-10-18]

²³ <https://www.oewaw.ac.at/ita/en/projects/nanotrust/overview/> [2019-10-18]

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.

Ever since 2011, a working group “Nano-Arbeitswelt” (nano in the workplace) initiated by ITA and AUVA (Allgemeine Unfallversicherungsanstalt, the Austrian Workers’ Compensation Board), continuously works on questions on workplace safety in the context of nanomaterials.

Additionally, the head of the NanoTrust project also chairs the standardization committee 052.73 “Nanotechnology” which has been established to discuss the international developments in the area of nanostandards (CEN and ISO). It aims to increasingly involve Austrian sciences and research in the international work on norms.

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 Czech Academy of Sciences²⁴ 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 Republic²⁵ (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: Nanoprogress²⁶ is a cluster of more than 40 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 five universities that are active in the field of advanced materials, of which some are nano – based. The Nano Association of the Czech Republic²⁷ 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 applications of the nanotechnologies, organising a range of events (Czech Nano Days) across the Czech Republic and abroad supported by the state Business and Investment Development Agency CzechInvest²⁸ and the foreign trade agency CzechTrade.

²⁴ Czech Academy of Science <http://www.avcr.cz/en/about-us/mission-of-the-cas/> [2019-10-18]

²⁵ Technology Agency of the Czech Republic <https://www.tacr.cz/en/homepage/> [2019-10-28]

²⁶ Nanoprogress <https://www.nanoprogress.eu> [2019-10-28]

²⁷ Nano Association <http://www.nanoasociace.cz/en/> [2019-10-18]

²⁸ CzechInvest <https://www.czechinvest.org/en> [2019-10-18]

Nanomedicine is one of the most developed nano-based sector in the Czech Republic. It is undoubtedly due to the technology of production of nanofibers by electrospinning invented in 2003 and further developed 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 tissue engineering developments based on nanofibers, in vitro expansion 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/micro particles and nano-fibrous systems (Inocure).

Several companies are active in the area of energy, in particular with regard to use of nanomaterials for components for solutions in energy-efficient buildings and especially for batteries. The latter area is represented by the HE3DA company, which has reached high TRL levels in development of high capacity /low cost batteries, secure with respect to danger of fire burst.

DENMARK

The Danish Ministry of Higher Education and Science²⁹ provided a consolidated overview of the most important research areas of the future as seen from the perspectives of businesses, organisations, ministries, Danish knowledge institutions as well as a wide variety of other stakeholders (RESEARCH2025)³⁰. In this overview as well as in the RESEARCH2020 Strategic Research Horizons catalogue³¹ nanotechnology is highlighted as a priority area for the country and the importance of nanotechnologies for addressing important societal challenges such as health, energy and environment is emphasised.

Nanomedicine is underlined 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 technology³². Regarding energy, The Danish Environmental Protection Agency³³ 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 nanotechnology³⁴. In addition, the Danish Technological Institute established the first production machinery for production of nanoparticles for fuel cells³⁵.

Regarding risk issues, 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.

²⁹ <https://ufm.dk/en> [2019-10-18]

³⁰ https://ufm.dk/en/publications/2018/filer/forsk25_katalog_eng_enkelt.pdf [2019-10-18]

³¹ <https://www.ufm.dk/en/publications/2012/files-2012/research2020.pdf> [2019-10-18]

³² [http://www.sum.dk/Aktuelt/Publikationer/~media/Filer%20-%20Publikationer i pdf/2007/Nanoteknolog_Sundhed.ashx](http://www.sum.dk/Aktuelt/Publikationer/~media/Filer%20-%20Publikationer%20i%20pdf/2007/Nanoteknolog_Sundhed.ashx) [2019-10-18]

³³ <http://eng.mst.dk> [2019-10-18]

³⁴ <https://www2.mst.dk/Udgiv/publikationer/2007/978-87-7052-647-0/pdf/978-87-7052-647-0.pdf> [2019-10-18]

³⁵ <https://www.teknologisk.dk/ydelser/danmarks-foerste-nano-fabrik-er-klar-til-produktion/33056?cms.query=nano> [2019-10-18]

Our knowledge of potential health effects from brand new, manufactured nanoparticles is much restricted – not only because of the limits in scientific knowledge - but also because in numerous contexts they show different physico-chemical properties than known materials. There is also limited knowledge of the so-called cocktail effects, which is the term for the combined effects that can be caused by exposure to – typically smaller doses of – several different substances. Greater knowledge of the link between physico-chemical properties, harmful effects and exposure can be used in prevention measures, including for developing new materials without potentially harmful effects. Therefore, there is huge commercial interest in developing cost-effective solutions for substituting such substances³⁶.

The responsibility for risks associated with nanotechnology and nanomaterials is distributed among different ministries and agencies. Between 2012 - 2015 the Ministry of Environment and Food carried out the initiative Better Control of Nanomaterial³⁷, aiming to promote a better understanding of the possible exposure pathways and potential harmful effects of nanomaterials (Nano2All, 2016). As part of the initiative, the Environmental Protection Agency under the Ministry of Environment and Food has established a national register of nanomaterials³⁸.

FRANCE³⁹

Today France's population is the fourth most informed in the EU and the first most concerned with Austria about nanoparticles in food⁴⁰. France also seems to be one of the EU countries where nanomaterials get the most coverage in mainstream media⁴¹. France has developed several governance approaches to nanomaterials in the past.

In 2007, the Grenelle Environment Forum committed to a national public debate on nanotechnologies and nanomaterials⁴². In order to prepare this debate, a nano "task-force" was created but a report in 2013 commissioned by five ministers found that this task force did not deliver as expected⁴³.

From 2009 to 2010, a national public debate was held resulting in several engagements from the French government. The debate was highly controversial, and a number of public meetings had to be cancelled because of demonstrators protesting against the frame of the discussions. The first concrete

³⁶ https://ufm.dk/en/publications/2018/filer/forsk25_katalog_eng_enkelt.pdf, page 163-166. [2019-10-18]

³⁷ <https://www2.mst.dk/Udgiv/publications/2015/12/978-87-93352-89-6.pdf> [2019-10-18]

³⁸ <http://mst.dk/service/publikationer/publikationsarkiv/2015/dec/better-control-of-nanomaterials/> [2019-10-18]

³⁹ France is no GoNano partner country. However, as the progress of the nano regulation debate and its recent developments in France are highly informative also for a wider European context (see below), we have decided to shortly discuss the milestones of the debate here.

⁴⁰ Special Eurobarometer Wave EB91.3.

https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/Eurobarometer2019_Food-safety-in-the-EU_Full-report.pdf [2019-10-18]

⁴¹ Researching for the term "nanomaterials" in the research section of newspapers yields: 77 results for Le Monde (France), 36 for BBC (UK), 29 for El Pais (Spain), 22 for Die Zeit (Germany), 7 for Kleine Zeitung (Austria), 2 for De Telegraaf (The Netherlands) ...

⁴² <http://veillenanos.fr/wakka.php?wiki=DebatPublicNationalNanoFrance20092010> [2019-10-18]

⁴³ <http://veillenanos.fr/wakka.php?wiki=TaskForceNanoFrance> [2019-10-18]

measure adopted pursuant to this forum was the creation, in 2012 of a **compulsory register for nanomaterials**. The first of its kind in the world⁴⁴. France was then followed by Belgium and Denmark both in 2014⁴⁵. In the French register, each batch of nanomaterial is given a registration number that follows the batch throughout the supply chain⁴⁶. Every year, the French government publishes a report which includes aggregated numbers by sectors, but which does not allow the public to identify specific products containing nanomaterials. The primary objective of the register is to help the regulator identify the amount and nature of nanomaterials on the French market and assess the need for further regulatory initiatives, studies have identified additional benefits such as increasing information flow across the supply chain, as well as increased awareness of workers working with nanomaterials.

The national plans for health and environment⁴⁷ from the second plan on (2009-2013), nanomaterials were mentioned as an emerging risk for human health and the environment⁴⁸. Action 46 is nano specific: “Strengthen regulation, monitoring and the expertise and prevention of risks on nanomaterials.” and this action only, amounted to 1.6 million euros⁴⁹.

The preparatory work for the 4th national plan for health and environment started on the 21st of March 2019 and shall be released officially at the beginning of 2020.

Four priorities have been set for the next period:

- A better knowledge on the exposure and the effects on the environment and health of populations.
- Inform, communicate and train professionals and citizens.
- Increase the number of concrete actions conducted on the ground.
- Reduce exposure and environmental inequalities

This preparatory work is conducted by the health-environment group, a consultative body on emerging risks, including nanomaterials. **One of the many governance approaches** of the French government is a dialogue committee called “nanomaterials and health”⁵⁰. It gathers from one to four times a year to disclose their work on nanomaterials. This committee brings together different stakeholders who can demonstrate nano specific knowledge with the French agency for food, environmental and occupational health & safety⁵¹. The committee started its work in 2012.

The government environmental roadmap, adopted in 2016, includes nanomaterials in its objective 12a, point 3⁵². **At the end of 2017**, the national health strategy for 2018-2022 was launched specifically mentioning nanomaterials as an emerging risk. **France supports** the June 2018 Berlin declaration as well (with Germany, Austria, Switzerland, Liechtenstein and Luxembourg) asking as one of its main

⁴⁴ <http://veillenanos.fr/wakka.php?wiki=DeclarationObligatoireNanoFrance#FrancePilote> [2019-10-18]

⁴⁵ <http://veillenanos.fr/wakka.php?wiki=DeclarationObligatoireNanoFrance> [2019-10-18]

⁴⁶ [Articles L.523-1 and followings](#)

⁴⁷ PNSE = Plan national santé environnement

⁴⁸ <http://veillenanos.fr/wakka.php?wiki=NanoPnse2Pnse3> [2019-10-18]

⁴⁹ <https://www.ecologique-solidaire.gouv.fr/sites/default/files/PNSE2.pdf> p.69 [2019-10-18]

⁵⁰ «Nanomatériaux et santé»

⁵¹ ANSES: Agence Nationale de Sécurité sanitaire de l'alimentation, de l'environnement et du travail.

⁵² [https://www.ecologique-solidaire.gouv.fr/sites/default/files/Conférence environnementale FRTE 2016.pdf](https://www.ecologique-solidaire.gouv.fr/sites/default/files/Conférence%20environnementale%20FRTE%202016.pdf) [2019-10-18]

requests for a cross-definition of nanomaterials in EU regulations. This declaration was transmitted to the European council. **The latest regulatory development** in France is the ministerial order of April 17th, 2019 suspending the marketing authorization for food containing additive E171 (titanium dioxide - TiO₂) for a year starting from the 1st of January 2020⁵³. The parliament had previously approved this suspension in Article 53 of law n° 2018-938 of the 30th of October 2018. This prohibition in food on the French territory follows a long reviewing process by ANSES who made a recommendation at the European level (see European part).

With regard to finance, the national agency on research⁵⁴ funding public and public-private research in France has played a significant role in funding researches in nanotechnologies since its creation in 2005. In 2011, the call for projects in nano research amounted to around 100 million euros. In 2013, it declared supporting more than 400 projects⁵⁵. Unfortunately, their latest report dates back to 2013.

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 market, 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, 2018⁵⁶). 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).

⁵³ https://www.legifrance.gouv.fr/affichTexte.do;jsessionid=DBC533A6FB27E821A6A56C77D1155A54.tp_lgfr25s_2?cidTexte=JORFTEXT000038410047&dateTexte=&oldAction=rechJO&categorieLien=id&idJO=JO_RFCONT000038409666 [2019-10-18]

⁵⁴ ANR = Agence Nationale de la recherche.

⁵⁵ <http://veillenanos.fr/wakka.php?wiki=AnrNano> [2019-10-18]

⁵⁶ Health and Safety Authority, 2018. Nanotechnology [Online]. Available: <http://www.hsa.ie/eng/Chemicals/Nanotechnology> [2019-10-28].

Ireland benchmarks well internationally based on 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 affecting or is set to influence 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, pharmaceuticals & biotech, transportation, as well as typical Made in Italy sectors (e.g. textiles, furnitures, cultural heritage)⁵⁷.

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.

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 in 2018 the book Exposure to Nanomaterials in Occupational Settings^{58,59}

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

⁵⁷ „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 DOI 10.12910/EAI2015-027

⁵⁸ www.nano.lab.it [2019-10-19]

⁵⁹ <https://www.inail.it/cs/internet/comunicazione/pubblicazioni/catalogo-generale/pubbl-esposizione-nanomateriali-luoghi-lavoro.html>

recently published a national platform on safety of nanomaterials. In February 2019 ISS launched an cross-department structure to act as a national reference point for risk assessment of nanomaterials.

The National Federation for Chemical Industry (Federchimica) leads a Nano Product Stewardship working group.

Italy is partner of the EU H2020 projects: Gov4nano “Implementation of Risk Governance: meeting the needs of nanotechnology” started the 1st of January 2019 and RiskGone “Risk Governance of Nanotechnology”.

With regard to the issue of “Open Innovation”, in 2016, the 10th Commission on Productive activities of the Italian Chamber of Deputies promoted a study on Industry 4.0 and the model to be applied in the Italian context to support the digitalization of the Italian industrial production chains. The final document set “Open Innovation” as one of the five pillars for the Italian Strategy (and further Plan) for Industry 4.0. Coherently with these pillars and the Italian Industry 4.0 National Plan, the Ministry for the Economic Development adopted a new instrument (in May 2019) to push SMEs to have Innovation Managers supporting Innovation processes and Technological/digital transformation through the introduction of an “enabling technology or factor” and Open Innovation is one of the enabling factors.

The Italian Industries Association of Milano Monza e Brianza AssoLombarda, the Italian association of StartUps Italia Startup and the independent platform for innovation Smau, promoted a national “Observatory on Open Innovation and Corporate Venture Capital”, to select and promote concrete and successful models for Open Innovation, in order to share them inside the Italian industrial and innovation ecosystem.

Additionally to these endeavors, in order to protect and support companies having a strong commitment to creating societal value, the Italian regulatory framework provides the possibility to create B-Corps (Benefit Corporations) since 2016.

More specific on co-creation, the Italian Ministry for Education, University and Research and the Italian Agency for New Technologies, Energy and Sustainable Development (ENEA) take part to the European H2020 project Expand (“Enhancing co-creation in JPI Urban Europe through widening Member State and stakeholder participation”). The project aims at exploiting co-creation in order to support the implementation of the JPI Urban Europe Strategic Research and Innovation Agenda, developing a Stakeholder Involvement Platform (SIP) to facilitate the dialogue between the different stakeholders across Europe. On a national level, co-creation was also widely exploited for the development of the projects included in the winning bid book of the Matera 2019 Capital of Culture⁶⁰.

In June 2019, Airi released an updated version of the report about Responsible Research and Innovation implementation in Italy, based on an agreement between Airi and Cnr (National Research Centre) to promote RRI in Italy. The report provides the national framework of RRI implementation in both the public and industrial R&I and some recommendations for the development of an Italian Roadmap for RRI.

Sapienza University of Rome coordinates the European Project Fit4RRI aiming at mainstreaming RRI and Open Science by providing training tools and actions and promoting the diffusion of advanced

⁶⁰ <https://www.matera-basilicata2019.it/en/processes/co-creation.html> [2019-10-28]

governance settings to embed RRI and OS in Research Institutions. The project will also exploit co-creation methodologies in Italian organizations.

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 a key player in nanotechnology among European 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). Programmes on the possible risks and societal dimensions of nanotechnologies accompanied these programmes such as the NanoNed Technology Assessment flagship and the NanoNextNL Risk Analysis and Technology Assessment programme. In 2010, the Commission “Societal Dialogue on Nanotechnology” organised a national public dialogue on nanotechnologies,⁶¹ building on the Rathenau Institute’s social dialogue activities since 2003.⁶²

The NanoNextNL Risk Analysis and Technology Assessment (RATA) programme considered new and existing risks as well as broader societal impacts of nanotechnology. The programme developed tools for the detection of nanomaterials and understanding the mechanisms of (eco) toxicity.⁶³ NanoNextNL allocated a significant portion of its budget to Responsible Research and Innovation.

The Netherlands played a significant role in operationalizing the concept of “Safe-by-Design” in nanotechnology, both through the work of the NanoNextNL RATA-programme, and through contributions to the European-funded NANoREG⁶⁴ and NanoReg II⁶⁵ projects. The National Institute for Public Health and the Environment (RIVM) has played a key role in these developments, also through the national Nanotechnology Knowledge and Information Centre (KIR nano).⁶⁶ These concepts will be developed further in three European projects that recently received funding under NMBP-13-2018 on risk governance in Nanotechnology⁶⁷: GOV4NANO, coordinated by the RIVM, NANORIGO and RISKGONE (for project details and references see table 1 in section 4.2).

In 2018, the Dutch government continued to promote the concept of Safe-by-Design. The Ministry of Infrastructure and Water Management announced a programme for Safe-by-Design, with the aim to “incorporate health and safety considerations from the earliest stages of innovation, because safe and

⁶¹ <https://www.nemokennislink.nl/partners/nanopodium/> [2019-10-18]

⁶² <https://www.rathenau.nl/en/digitale-samenleving/nano-netherlands> [2019-10-18]

⁶³ <http://www.nanoreg.eu/> [2019-10-18]

⁶⁴ <http://www.nanonextnl.nl/safebydesign/> [2019-10-18]

⁶⁵ <http://nanoreg2.eu/> [2019-10-18]

⁶⁶ <https://www.rivm.nl/nanotechnologie/kennis-en-informatiepunt-risico-s-kir-nanotechnologie> [2019-10-18]

⁶⁷ <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/nmbp-13-2018> [2019-10-18]

healthy products and processes are a necessary condition for realizing a circular economy («Safe at the front end», Safe-by-Design)” [translation DS].⁶⁸

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,⁶⁹ which made 7 million Euro available for innovation in dedicated sectors in the period 2012-2015), the cabinet decided 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 so-called ‘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;⁷⁰ The Quantum/Nano-Revolution;⁷¹ Smart Industry;⁷² Circular Economy;⁷³ Sustainable Production of Safe and Healthy Food;⁷⁴ Personalised Medicine⁷⁵ and Energy Transition.⁷⁶

In April 2019, the Dutch government identified nanotechnology as one of the key enabling technologies that determine the future success of the so-called ‘mission-driven topsector- and innovation policy’ of The Netherlands. In September 2019 the kick off⁷⁷ was organized of the new Nano4Society programme that has a time span of 15 years and a budget of 400 million Euros.

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 (Nano2021⁷⁸) and biotechnology (BIOTEK 2021⁷⁹). 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).

⁶⁸ <https://zoek.officielebekendmakingen.nl/kst-34775-XII-2.html> [2019-10-18]

⁶⁹ <https://www.topsectoren.nl/> [2019-10-18]

⁷⁰ <https://wetenschapsagenda.nl/route/materialen-made-in-holland/> [2019-10-18]

⁷¹ <https://quantum-nano.nl/projects/> [2019-10-18]

⁷² <https://wetenschapsagenda.nl/route/smart-industry/> [2019-10-18]

⁷³ <https://wetenschapsagenda.nl/route/circulaire-economie-en-grondstoffenefficiëntie-duurzame-circulaire-impact/> [2019-10-18]

⁷⁴ <https://wetenschapsagenda.nl/route/duurzame-productie-van-veilig-en-gezond-voedsel/> [2019-10-18]

⁷⁵ <https://wetenschapsagenda.nl/route/personalised-medicine-uitgaan-van-het-individu/> [2019-10-18]

⁷⁶ <https://wetenschapsagenda.nl/route/energietransitie/> [2019-10-18]

⁷⁷ <https://fhi.nl/minacned/agenda/1460/> [2019-10-18]

⁷⁸ <https://www.forskningsradet.no/en/about-the-research-council/programmes/nano2021/> [2019-10-28]

⁷⁹ <https://www.forskningsradet.no/en/about-the-research-council/programmes/biotek2021-----bioteknologi-for-verdiskaping/> [2019-10-28]

In 2012, the Norwegian Government launched its National Strategy for Nanotechnology⁸⁰. 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.

The RCN tried out a new measure called 'needs identified research'. The intention is to grant funds to research projects that answers knowledge needs identified by the users themselves. This model was based on measures developed by National Institute of Health Research, "Priority Setting Partnerships" and "Commissioned Research". The needs identification is supposed to enable clinicians, patients and carers to work together to identify problem areas that could be answered by research. In a 2-step application process, the users had influence on the choice of which pre-proposals that would be invited to submit a full application for a 2nd Round. In an evaluation report⁸¹ the RCN concludes that the users (patients and relatives) had genuine influence on what should be prioritized, and that the process was rather resource demanding. The RCN recommends to develop specific guidelines for application process for this measure.

The Norwegian Minister of Climate and Environment was one of the signatories on a letter to the Commission on initiatives on EU chemicals policy⁸². The letter was sent in July 2018 and expressed concerns regarding potential delay of several initiatives, among these were the safety of nanomaterials. The signatories urged the relevant Commissioners to further advance EU chemicals policy and present proposals based on the already adopted 7th Environmental Action Program (EAP).

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, their 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 Swan⁸³ has its latest entry on nanotechnology in 2012, additionally reflecting the declining interest. When searching through the

⁸⁰

https://www.regjeringen.no/contentassets/5aa4911bcb474c0da4f21d1dcbc47ecb/63867_nanostrategi_web.pdf [2019-10-18]

⁸¹ Behovsidentifisert forskning om CFS/ME – BEHOV-ME. Administrativ sluttrapport og egenevaluering – Kortversjon.

<https://www.forskningsradet.no/contentassets/0a02fa10831441aba55ab3b807e18164/sluttrapport-behov-me-kortversjon.pdf> [2019-10-18]

⁸² Date: 27th of July 2018 Subject: Commission initiatives on chemicals and circular economy

<https://www.regjeringen.no/contentassets/50a9a90ba6584bdb88e70b3e17a46187/20180727-letter-to-cion-on-outstanding-eu-chemical-policy.pdf> [2019-10-18]

⁸³<https://www.svanemarket.no/english/>; <https://www.svanemarket.no/search/?q=nanoteknologi>

webpages of the Norwegian Environment Agency, we find that the latest entry on nanotechnology is from 2016. 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. 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 and have tried out various measures for inclusion of the public in various stages of research.

SPAIN

Regarding the national governance of science and technology in Spain, the Ministry of Science, Innovation and Universities (MICINN)⁸⁴ assumes the responsibility for fostering research and innovation, and the management of international relations in this area. None of the main policy documents on research, development and innovation focusses exclusively on nanotechnology; 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 2013–2020.⁸⁵ 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&I in Spain. An example of this can be seen in the Aragon Strategy of Research, Development and Innovation for Intelligent Specialization 2015, where nanotechnology features very strongly and is identified as a key enabling technology (KET).⁸⁶

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) has published various guides related to health and safety and nanomaterials^{87,88,89}. There are some regional level initiatives, such as the Competence Centre for Environment, Health and Safety

⁸⁴ <http://www.ciencia.gob.es/portal/site/MICINN/> [2019-10-18]

⁸⁵ Spanish Strategy of Science, Technology and Innovation 2013–2020
http://www.idi.mineco.gob.es/stfls/MICINN/Investigacion/FICHEROS/Spanish_Strategy_Science_Technology.pdf [2019-10-18]

⁸⁶ Estrategia RIS3 Aragón <https://www.aragon.es/-/ris3-aragon-estrategia-de-investigacion-e-innovacion-para-una-especializacion-inteligente> [2019-10-29] and
<https://www.aragon.es/documents/20127/674325/Estrategia%20RIS3%20Aragon%20mayo%202015.pdf/379c5127-df93-9510-2d55-ca53c7c275a2> [2019-10-29]

⁸⁷ Seguridad y salud en el trabajo con nanomateriales
<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> [2019-10-18]

⁸⁸ Riesgos derivados de la exposición a nanomateriales en distintos sectores: Construcción
<http://www.insht.es/InshtWeb/Contenidos/Documentacion/Riesgos%20derivados%20nanomateriales%20construccion.pdf> [2019-10-18]

⁸⁹ Riesgos derivados de la exposición a nanomateriales en el sector de la automoción
<http://www.insht.es/InshtWeb/Contenidos/Documentacion/FICHAS%20DE%20PUBLICACIONES/EN%20CATALOGO/Higiene/Riesgos%20nanomateriales%20automocion.pdf> [2019-10-18]

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&I 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 Plan⁹⁰ 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 with regard to nanomaterials⁹¹, 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 Ordinance⁹², the Ordinance on Biocidal Products⁹³, the Plant Protection Products Ordinance⁹⁴ 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 definition⁹⁵ 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:

⁹⁰ OPFSP, SECO, OFEV. Rapport du Conseil Fédéral du 9 avril 2008 : plan d'action, nanomatériaux synthétiques. Berne: DFI, DFE, DETEC, 2008.

⁹¹ OFSP, OFEV, OSAV, OFAG, SEFRI, SECO, Swissmedic. Plan d'action Nanomatériaux synthétiques : Deuxième rapport du Conseil fédéral sur l'état de mise en œuvre, les effets et le besoin de réglementation. Berne : DFI, DETEC, DEFR, 2014.

⁹² Ordonnance du 5 juin 2015 sur la protection contre les substances et les préparations dangereuses (Ordonnance sur les produits chimiques, OChim)

⁹³ Ordonnance du 18 mai 2005 concernant la mise sur le marché et l'utilisation des produits biocides (Ordonnance sur les produits biocides, OPBio)

⁹⁴ Ordonnance du 12 mai 2010 sur la mise en circulation des produits phytosanitaires (Ordonnance sur les produits phytosanitaires, OPPh)

⁹⁵ «Définitions», Office fédéral de la santé publique <https://www.bag.admin.ch/bag/en/home/gesund-leben/umwelt-und-gesundheit/chemikalien/nanotechnologie/rechtsetzung-und-vollzug/definitionen-begriffe.html> [2019-10-28]

« 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 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 devices⁹⁶ 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.”

Nanomaterials are regulated under existing procedures for authorization and notification procedures⁹⁷. 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 issue an EC certificate, where appropriate. 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 hazardous⁹⁸. 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 micrometres are subject to mandatory notification since March 2018.

⁹⁶ Loi fédérale du 15 décembre 2000 sur les médicaments et les dispositifs médicaux (Loi sur les produits thérapeutiques, LPT^h)

⁹⁷ «Droit en vigueur», Office fédéral de la santé publique
<https://www.bag.admin.ch/bag/en/home/gesund-leben/umwelt-und-gesundheit/chemikalien/nanotechnologie/nano-im-alltag/rechtliches-in-kuerze.html> [2019-10-28]

⁹⁸ «Droit en vigueur», Office fédéral de la santé publique
<https://www.bag.admin.ch/bag/en/home/gesund-leben/umwelt-und-gesundheit/chemikalien/nanotechnologie/nano-im-alltag/rechtliches-in-kuerze.html> [2019-10-28]

Current Swiss legislation does not contain any specific declaration requirements for nanomaterials, except for biocidal products, foodstuffs and cosmetic products⁹⁹. 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.

⁹⁹ «Droit en vigueur», Office fédéral de la santé publique
<https://www.bag.admin.ch/bag/en/home/gesund-leben/umwelt-und-gesundheit/chemikalien/nanotechnologie/nano-im-alltag/rechtliches-in-kuerze.html> [2019-10-28]

3. NANOTECHNOLOGY RISK GOVERNANCE AND REGULATIONS

3.1. GENERAL OVERVIEW

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

The question of whether and how to regulate nanomaterials has been discussed in the European Union (EU) for over a decade. It was first raised during the EU parliamentary debates that would lead to the adoption of the EU flagship regulation on chemicals, 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 experiences and attitudes of individual organizations and stakeholders about risk of nanomaterials and as well impacts 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 the first jurisdiction in the world to provide nano specific legal provisions to address health and safety concerns of nanomaterials.

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).

Nowadays, nanomaterials are explicitly covered under sectoral regulations on Cosmetics¹⁰⁰; Food¹⁰¹; Biocides¹⁰²; and Medical Devices¹⁰³, and covered as well by REACH¹⁰⁴ 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 have been and continue 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, shape, its specific novel properties or a combination of these (see also above). Starting from 2014, the ISO published a series of standard documents providing definitions for different terms related to nanotechnologies (ISO/TS 80004-series¹⁰⁵). These emerging definitions were often formulated for specific purposes (CIEL et al., 2015).

¹⁰⁰ 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.

¹⁰¹ 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.;

¹⁰² 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.

¹⁰³ 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.

¹⁰⁴ 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

¹⁰⁵ <https://www.iso.org/committee/381983/x/catalogue/p/1/u/0/w/0/d/0> [2019-10-18]

The absence of generally accepted legal definitions has played a significant role in delaying the establishment 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 a legal definition of nanomaterials. However, despite the adoption (in 2011) of a recommendation for the definition of nanomaterials there is still a diversity of legal definitions across regulatory sectors. In particular, the Cosmetic regulation defines Nanomaterials as

“insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm.”¹⁰⁶

This definition gave rise to a number of questions relating to individual substances and whether they fall under the nano definition of the Cosmetic regulation.

An example is Synthetic Amorphous Silica (also known as SAS), which manufacturers argued, is soluble and should therefore not be considered a nanomaterial when used in Cosmetics. In order to clarify this technical question, the Scientific Committee on Consumer Safety (SCCS) published in June 2019¹⁰⁷ an opinion on the matter. The opinion states that none of the SAS materials considered, whether hydrophilic or hydrophobic, can be regarded as soluble under the nanomaterial definition of the cosmetics Regulation. SAS used in cosmetics therefore falls under the definition of nanomaterials for uses in cosmetics. SAS can also be used as a food additive (under the number E551). However, no opinion was sought in relation to whether the same material would also be considered a nanomaterial under the legal definition of nanomaterials applicable in the food sector.

European commission recommendation on the definition for nanomaterials.

The 2011 European Commission’s recommendation¹⁰⁸, 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.

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 %.”¹⁰⁹

¹⁰⁶ Scientific Committee on Consumer Safety, Opinion on solubility of amorphous Silica (SAS), adopted on 20-21 June 2019. Available at: https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_228.pdf [2019-10-18]

¹⁰⁷ Scientific Committee on Consumer Safety, Opinion on solubility of amorphous Silica (SAS), adopted on 20-21 June 2019. Available at: https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_228.pdf [2019-10-18]

¹⁰⁸ Commission Recommendation of 18 October 2011 on the definition of nanomaterial, Off. J. EU 2011, L275, 38.

¹⁰⁹ Commission Recommendation of 18 October 2011 on the definition of nanomaterial, Off. J. EU 2011, L275, 38. Point 2.

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.”¹¹⁰

“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.”¹¹¹

This EU definition is thus based on size, 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 Centre (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 (see Rauscher et al., 2019, in addition to the 2017 report mentioned above¹¹²). 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. Therefore, they use distinct definitions:

As already described, the definition in the cosmetic regulation 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

¹¹⁰ Commission Recommendation of 18 October 2011 on the definition of nanomaterial, Off. J. EU 2011, L275, 38. Point 3.

¹¹¹ Commission Recommendation of 18 October 2011 on the definition of nanomaterial, Off. J. EU 2011, L275, 38. Point 5.

¹¹² Available at: <https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/overview-concepts-and-terms-used-european-commissions-definition-nanomaterial> [2019-10-18]

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.”¹¹³

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 regulation¹¹⁴ and the Medical devices regulation¹¹⁵ include a definition of nanomaterials based on the Commission’s recommendations (Azoulay and Tuncak, 2014).

The currently amendment of REACH annexes aims to adapt it to the specificities of nanomaterials, and currently includes a definition based on the Commission’s recommendation.

To ensure conformity across regulations, the recommendation seeks to enable a coherent crosscutting 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).

Given the failure to do so during the past seven years, it remains to be seen whether this harmonization could take place in the future. In the meantime, each sector continue to deal with the definition included in the sectoral regulations. As indicated above with the SAS case, the challenge is that it means that a similar material could be considered nano under one legislation (when it is used in Food for example), but not under another (when used in cosmetics for example). This adds complexity for the producer of the substance who does not necessarily know how, or in which product their customers will use it.

3.1.2. REACH REGULATION (CHEMICALS)

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.

¹¹³ 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.

¹¹⁴ 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)

¹¹⁵ 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).

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, because it covers all substances, regardless of shape, size or physical state.¹¹⁶ However, since 2018 there were no specific provisions for nanomaterials in REACH. For example, some aspects of nanoparticles, such as effects of associated particles like agglomerations and aggregates, or shape specific hazardous aspect, seem not adequately considered. In addition, REACH is not designed to address substances and particles generated at the workplace (so called Process Generated NanoParticles - PGNPs). However, these are an essential missing element in many actual risk assessments. Of course, these risks are covered under the Framework Directive, and the Chemical Agents Directive, but these directives do not focus on specific substances.

Quite recently, ECHA declared that REACH has so far failed to effectively ensure the safety on nanomaterials on the market (Chemical Watch, 2018). A policy process to update REACH annexes to insert nano specific provisions started already 2013 and ended in 2018.

During the process, 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).

In the end, on the 3rd of December 2018, the European Union adopted amendments to the annexes of REACH. This revision includes nano specific provisions and “clarifies” the information registrants (producers or downstream users) must provide in their registration dossier.

The new provisions use the same definition of nanomaterials as the original EU commission recommendation for the definition of nanomaterials currently under review (see section 3.1.1).

From the 1st of January 2020, registrants will be required to provide specific information to register the NMs on the market, whether they are registered separately from the bulk form of the substance or as one single substance.

More specifically registrants are required to provide:

- Specific physicochemical properties of NMs on the market to allow characterization of nano forms;
- The uses (the manufacture and use information provided for regular substances applies to Nanoforms (NFs) of the substance);

¹¹⁶ 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.

- The safe handling techniques and their relevance to the NFs;
- The potential risks to human health and the environment (obligation then to consider the whole life cycle when considering the dose humans and the environment might be exposed to); and
- The risk control methods and their relevance to the NFs.

It will force the industry to assess that the nanomaterials they use are safe for Human Health and the environment, while justifying every choice they made in their application for specific Nanoforms.

This **registration** obligation applies to manufacturers and importers when **1 ton per year or more** of this substance is produced. A **chemical safety report** also has to be provided by the manufacturer or importer when **10 T per year or more** of the substance are produced or imported.

This chemical safety report has to specify whether and which different NFs have been characterized as part of the registration and if they are covered by the Chemical Safety Assessment. This chemical safety report documents the Chemical Safety assessment undertaken by the applicants that demonstrate the risks from the exposure to a substance (see earlier remarks on PGNPs).

If the NF of a substance fulfil the criteria for dangerous/ hazardous substances, then an exposure assessment and risk characterization shall be completed. According to the CAD (Chemical Agents Directive), the employer is responsible to carry out a risk assessment and evaluation in case of working with chemical substances or in case of potential exposure to hazardous substances.¹¹⁷

Several issues remain uncertain regarding the registration of the NFs of particles: To begin with, the characterization of the particle as to whether it is considered nano or not: the definition is based on the percentage of particles under a certain size. However, no guidance is given on how to assess the size of a particle or which technique to use. It is then up to the manufacturer to decide which technique and depending on that technique it might determine that the particle is in its NF or not. Determining then if it needs nano-registration.

This regulatory uncertainty might be solved by the updated guidelines of ECHA (see below).

Another issue is that these Annexes provide the possibility for the registrants to register **groups** of NFs in “sets of nanoforms” that are defined by their boundaries. Possible only if scientifically justified, the molecular structural similarities cannot be alone used to justify the grouping for instance. The hazard of these groups’ particles cannot vary within the group.

These groups are thought to prevent the registrants from having to give the information required for the characterization of each particle. Instead, the registrants would be allowed to give the information of the set of nanoforms. However, ECHA in its guidance determines that correct and unambiguous characterization of the particles that are included in each set of nanoforms are a prerequisite. This

¹¹⁷ Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC).

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01998L0024-20140325&from=EN>
[2019-10-18]

possibility was debated for a long time during the annex revision negotiation process and questions remain in relation to the justifications required to group several nanoforms into a single set.

In addition to what was previously mentioned, ECHA has updated its test guidelines in May 2017. The industry follows the REACH guidelines usually relying on the OECD's international test guidelines. They contain appendices addressing the registration of nanomaterials. The update of these guidelines including the guidelines on the new annexes of REACH should intervene in 2020 to match the entry into force of the annexes.

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 differences of views between DG Environment and DG Growth, who share the responsibility for the implementation of REACH.¹¹⁸

An example of implementation of REACH: nano - TiO₂

After a national review in accordance with the REACH and CLP provisions, on the 20th of May 2015, France proposed the classification of titanium dioxide (TiO₂) as a carcinogen 1b under the CLP regulation. ECHA's Committee for risk assessment (RAC)¹¹⁹ has reviewed the French report and proposal and proposed, in 2017, to classify this substance as potential carcinogen (category 2).

In the classification process, which is strictly based on hazard assessment and has no direct consequence other than labelling, it is the REACH committee that adopts the classification decision based on a proposal by the Commission. In this particular case, and for the first time since the entry into force of REACH, the Commission decided to put forward a proposal that would derogate from the RAC recommendation and would only apply to certain forms of TiO₂ or would dispense with actual labelling of the classified substance. After several iterations of the Commission proposal, the REACH committee did not manage to adopt a decision.

Due to a procedural change, the decision is now back into the hands of the Commission who will propose a delegated act addressing the classification proposal for TiO₂. Once this act is adopted by the Commission, the EU Parliament and Council will have three months to object to the decision. Should they decide not to object, the Commission's proposal would then be considered definitively adopted.

No delegated act has been proposed at the time of writing and no proposal should be expected before the new commission is installed and starts working in earnest.

¹¹⁸ David Azoulay, "Nano Regulation – ComMission : Impossible ?", *Chemical Watch*, November, 2014, <https://chemicalwatch.com/21979/nano-regulation-commission-impossible>; «Quelles réglementations autour des nanos ?», VeilleNano, <http://veillenanos.fr/wakka.php?wiki=ReglementationsNano> [2019-10-18]

¹¹⁹ <https://echa.europa.eu/-/titanium-dioxide-proposed-to-be-classified-as-suspected-of-causing-cancer-when-inhaled> [2019-10-18]

3.1.3. THE QUESTION OF NANO REGISTERS

For the past ten years, a number of stakeholders have been complaining¹²⁰ 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 ecotoxicologists have also asked similar questions to be able to define research protocols that are relevant to real world situation¹²¹.

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,¹²² to private market research,¹²³ 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.¹²⁴ 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 as well as on the methodology and relevance of market studies.¹²⁵

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).

¹²⁰ See for example: Eugenie Samuel Reich, *Nano rules fall afoul of data gaps*, in *Nature*, 480,160–161 (08 December 2011), available at <https://www.nature.com/news/nano-rules-fall-foul-of-data-gap-1.9548>

¹²¹ See for example Section on Key Data Gaps of the Report on Environmental exposure to nanomaterials – Data Scoping Study by Milieu, available at https://ec.europa.eu/environment/chemicals/nanotech/pdf/exposure_nanomaterials.pdf

¹²² See for example the database established by the Danish Eco Council: <http://nanodb.dk/> [2019-10-18]

¹²³ See for example; BCC research, *The Maturing nanotechnology Market: Products and applications*, (2016) available for 2750 US\$.

¹²⁴ “Home”, European Observatory on Nanomaterials, accessed April 11, 2018, <https://euon.echa.europa.eu/> [2019-10-18]

¹²⁵ <https://chemicalwatch.com/56883/echa-launches-eu-nanomaterials-observatory?q=EUON>

Since the publication of the First monitoring report (Del. 5.1), the EUON published three main reports:

- Critical review of the relevance and reliability of data sources, methods, parameters and determining factors to produce market studies on manufactured nanomaterials on the EU market (July 2018)¹²⁶
- Literature study on the uses and risks of nanomaterials as pigments in the European Union (September 2018)¹²⁷
- Ex-post evaluation of the European Union Observatory for Nanomaterials (July 2019)¹²⁸

3.1.4. **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.

Nanomaterials in cosmetics

The Cosmetic Products regulation “establishes rules to be complied with by any cosmetic product made available on the market”.¹²⁹ 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 market¹³⁰ even when the bulk form of the substance has been previously authorized (Azoulay and Tuncak, 2014).¹³¹

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).

¹²⁶

https://euon.echa.europa.eu/documents/23168237/24095696/170718_critical_review_of_market_studies_nanomaterials_final_report_en.pdf/ec77f39e-0918-5984-d7b1-654e3b1f14da [2019-10-18]

¹²⁷

https://euon.echa.europa.eu/documents/23168237/24095696/070918_euon_nanopigments_literature_study_report_en.pdf/58977ab1-1059-4b41-f003-18ae9d7a157c [2019-10-18]

¹²⁸

https://euon.echa.europa.eu/documents/23168237/24095696/050719_evaluation_nano_observatory_en.pdf/04466705-48a8-b759-b719-5a503b180034 [2019-10-18]

¹²⁹ 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.

¹³⁰ 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).

¹³¹ 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.

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 Ombudsman (European Ombudsman, 2018).

Nanomaterials under the Biocidal products regulation

This regulation contains a definition based on the Commission recommendation, 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.¹³² 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).

¹³² 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

This regulation also seeks to provide information on the presence of nanomaterials to consumers by setting up a labelling system.¹³³ 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).¹³⁴

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 sector¹³⁵, 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.

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

Novel Food regulation

The Novel Food Regulation ¹³⁶ “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 below¹³⁷.

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

¹³³ 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

¹³⁴ 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

¹³⁵ 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

¹³⁶ 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.

¹³⁷ Quel encadrement des nanomatériaux dans l'alimentation en Europe? [Online]. Available: <http://veillenanos.fr/wakka.php?wiki=ReglementationNanoAlimentationEurope> [11/04 2018].

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).¹³⁸

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,¹³⁹ 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.

Food additives regulation

This regulation¹⁴⁰ 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 regulation¹⁴¹ provides for a case-by-case assessment of substances in 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.

¹³⁸ 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

¹³⁹ Agir pour L'environnement: Des analyses révèlent la présence de nanoparticules dans les aliments (2016), https://www.agirpourenvironnement.org/sites/default/files/communiqués_presses/Rapport%20LNE_P156452.DMSI_001-VC.pdf [2019-10-18]

¹⁴⁰ 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.

¹⁴¹ 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).

Active and intelligent food contact materials regulation

This regulation¹⁴² 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 consumer regulation

This regulation¹⁴³ 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)¹⁴⁴: Labelling consist of adding the word nano in brackets next to the name of the ingredient in the ingredients' list (Azoulay and Tuncak, 2014).

As mentioned in the French part of this Report, TiO₂ will be banned from foodstuff in France as of first of January 2020 for a year. This ban was adopted based on a recommendation following a scientific evaluation by ANSES (French Agency for Food, Environmental and Occupational Health & Safety) which undertakes the testing of products/ substances and gives recommendations to the French regulators based on these studies.

The ministerial order was notified to the European Commission on 26 April 2019. This order was preceded by a note from the French authorities sent to the European Commission on 15 February 2018, which requested the adoption of interim protective measures provided for by Article 53 of Regulation (EC) No178/2002. In accordance with Article 54 of Regulation (EC) No178/2002, where a Member State officially informs the Commission of the need to take emergency measures and where the Commission has not acted in accordance with Article 53, the Member State may adopt interim protective measures. These measures may be maintained until Union measures are adopted.

Discussions have taken place during the meeting of the Standing Committee On Plants, Animals, Food and Feed (SCOPAFF) of May 2013, with presentations by both ANSES and EFSA, who recently published an opinion on the ANSES study (published 13 May 2019¹⁴⁵) as well as an opinion on physicochemical characterization of E171 (published on 12 July 2019¹⁴⁶). No decision has been reached at the time of writing.

¹⁴² 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.

¹⁴³ 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.

¹⁴⁴ 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.

¹⁴⁵ <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.5714> [2019-10-18]

¹⁴⁶ <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.5760> [2019-10-18]

3.3. NANOMATERIALS UNDER THE MEDICAL DEVICES REGULATION

The medical devices regulation¹⁴⁷ 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.¹⁴⁸ 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.¹⁴⁹ Such devices must be labelled.¹⁵⁰ For special devices in class III and class IIb, a clinical evaluation assessments conducted by an expert panel must be carried out.¹⁵¹ 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.¹⁵²

¹⁴⁷Regulation (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.

¹⁴⁸ 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

¹⁴⁹ 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

¹⁵⁰ 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.

¹⁵¹Regulation (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

¹⁵² 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/> [2019-10-18]

Other regulations, including regulation on the authorisation and supervision of medicinal products for human and veterinary use,¹⁵³ the directive on Good clinical practice,¹⁵⁴ or the regulation on clinical trials on medicinal products for human use¹⁵⁵ also apply to healthcare product although none of these regulations include nano-specific provisions.

The field of medicines 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 diseases. 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 application of nanotechnologies to medical sector.

3.4. NANOTECHNOLOGY AND ENERGY

Nanotechnology is relevant for many areas of the energy sector, such as photovoltaic, wind energy, or battery technologies (see section 4.4 of Del. 5.1).

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**

Although not nanospecific, the following directives are also essential:

¹⁵³ 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

¹⁵⁴ 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"

¹⁵⁵ 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

- The Framework Directive: COUNCIL DIRECTIVE of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (89/391/EEC)
- The CAD: COUNCIL DIRECTIVE 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)
- The Carcinogens Directive: DIRECTIVE 2004/37/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC)

Regulation also exists in form of Ecodesign¹⁵⁶ for heaters and fluorinated greenhouse gas¹⁵⁷ (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”¹⁵⁸, especially the “stability of the incentive regime”.

¹⁵⁶ https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/ecodesign/space-heaters_de [2019-10-18]

¹⁵⁷ https://ec.europa.eu/clima/policies/f-gas_en [2019-10-18]

¹⁵⁸ <https://www.rhc-platform.org/publications/> Common Implementation Roadmap for Renewable Heating and Cooling Technologies, p. 45. DOI: 10.13140/2.1.1309.4082 [2019-10-29]

4. RESEARCH AND INNOVATION PRIORITIES ON NANOTECHNOLOGIES

As outlined in Del. 5.1, nanotechnology is increasingly becoming a horizontal technology, i.e. a general-purpose enabling technology or even a “new way of manufacturing” that is of high relevance for a wide range of industry sectors and applications (European Commission, 2017c). For example, inorganic nanoparticles and nanomaterials are applied in such diverse sectors as textiles, health care, agriculture, electronics, or renewable energy to improve materials and functionalities¹⁵⁹.

This chapter will explore research and innovation priorities with regard to nanotechnologies reflected in the European Commission’s framework programme H2020, and will discuss in more detail recent initiatives and projects on nanotechnology risk and innovation governance. The focus lies on all GoNano sectors and provides an overview on ongoing research for nanotechnology governance activities - current or to come - stirred by the European Commission (status August 2019).

4.1. 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. 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 billion¹⁶⁰. H2020 is dedicated to and structured in three pillars: Excellent Science, Industrial Leadership and Societal Challenges (see Figure 1). In addition, funding is provided through the crosscutting 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. (as already outlined in Del. 5.1)

¹⁵⁹ <https://www.nanowerk.com/nanotechnology-applications.php> [2019-10-18]

¹⁶⁰ <http://ec.europa.eu/programmes/horizon2020/en/what-horizon-2020> [2019-10-18]

NMBP in Horizon 2020

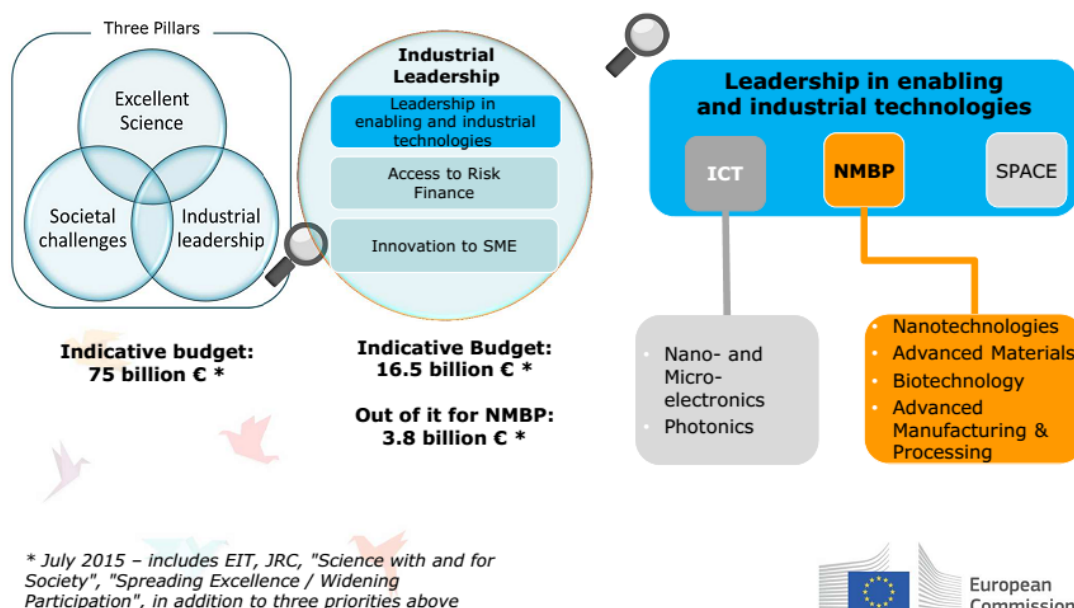


Figure 1: NMBP in Horizon 2020, Source: Presentation by Helene Chraye (EC)¹⁶¹

Due to their cross-sectional character, research and development of nanotechnologies may be funded under all three pillars (and crosscutting areas), but nanotechnologies are explicitly targeted under the second pillar “Industrial Leadership” under the theme “**Leadership in enabling and industrial technologies**” (LEIT) (see Figure 1). 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 markets¹⁶². 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. For the calls in 2019, there will be approx. € 545 million available, for 2020 approx. € 572 million^{163,164}.

¹⁶¹ http://www.kpk.gov.pl/wp-content/uploads/2017/07/20170912-NMBP-02-HeleneChraye_KE-short.pdf [2019-10-18]

¹⁶² <https://ec.europa.eu/programmes/horizon2020/en/area/key-enabling-technologies> [2019-10-18]

¹⁶³ <https://www.kowi.de/en/kowi/calls-2018/nanotechnologies-advanced-materials-biotechnology-and-advanced-manufacturing-and-processing-2018-2020.aspx/page-1/> [2019-10-18]

¹⁶⁴ 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

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”¹⁶⁵.

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

An important funding instrument are the **open innovation test beds** (see table below) 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”¹⁶⁶. 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:

nanotechnology, photonics and micro- and nano -electronics); broadening the KET ‘biotechnology’ to ‘Life Sciences technologies’; adding two new main fields, namely: artificial intelligence and digital security and connectivity.

See: https://ec.europa.eu/research/industrial_technologies/pdf/re_finding_industry_022018.pdf [2019-10-18]

¹⁶⁵ <http://ec.europa.eu/programmes/horizon2020/node/1306> [2019-10-18]

¹⁶⁶ <http://ec.europa.eu/programmes/horizon2020/node/1306> [2019-10-18]

behaviour of multi-component nanomaterials; and Regulatory science for medical technology products as upcoming calls (Kopp, 2014).

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 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 FETFLAG-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."¹⁶⁷

In summary, nanotechnologies are explicitly supported as a key enabling technology for industrial competitiveness, particularly in the areas of healthcare, energy and environment, manufacturing and electronics and ICT. Beyond that, nanotechnologies may play an important role in fostering excellent and groundbreaking 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.

4.2. NANO GOVERNANCE IN H2020 PROJECTS (STATUS QUO AND OUTLOOK)

With the continuous advance of nanomaterials in various sectors of industry and the increased consciousness for potential risks, nanomaterials can pose to health and the environment, the need for a Europe-wide science-based approach to governance and regulation of nanomaterials remains at focus of attention. Over the past years, progress has been made on the assessment of risks for human

¹⁶⁷ <https://ec.europa.eu/programmes/horizon2020/en/h2020-section/nanotechnologies> [2019-10-18]

health and the environment and therefore established a basis for projects focusing on the governance and regulation of nanomaterials. A focus on ethical, legal and societal aspects (ELSI) of the increased application of nanotechnology to ensure responsible research and innovation as well as establishing dialogue with citizens and stakeholders involved in research, production, commercialisation, use and recycling of nanomaterial is of utmost importance to develop a sustainable and applicable framework for nano governance at all steps of the innovation chain.

The NMBP work programme 2018 - 2020 includes several topics related to nano governance. The call for the foundation of tomorrow's industries covers topics such as the establishment of open innovation test beds, advancement of material characterisation and computational methods supporting science-based risk-benefit assessment and projects emphasising on governance and regulatory aspects. For 2018, the whole budget covering the call for the foundations of tomorrows industries contains 149 million euros including 30 million alone for the topics NMBP-13 and NMBP-14 concerning risk governance of nanomaterials and nanoinformatics for predictive toxicology modelling. For the entire call, 122.6 million euros are allocated for 2019 and 161.5 million euros for 2020.¹⁶⁸

According to the European Commission, managing the risks posed by nanotechnology requires a framework comprising the three layers of scientific research, regulatory research to translation of findings to regulation and a market layer concerned with the implementation in industry. As of July 2019, there are currently five projects to be found in the EU project data base CORDIS¹⁶⁹ working explicitly on governance and regulatory frameworks, namely caLIBRAte, EC4SafeNano, Gov4Nano, NANORIGO, and RiskGone. Common objective of these projects is to link various interest groups, engage them in dialogue and provide tools or platforms for safe and responsible innovation. Gov4Nano, NANORIGO and RiskGone have been officially launched in January 2019 under the topic NMBP-13-2018 - Risk Governance of nanotechnology (RIA). Projects delivering to this topic should ideally cover tools for managing possible risks regarding social, environmental and economic benefits and provide high quality data for industry and regulator decision-making to ensure a self-sustained and science-based risk governance council. The three projects involved will be focusing on the establishment of a risk governance framework for nanomaterials and nano-enabled technology addressing issues such as environmental, social and economic impact. Ideally, a permanent and self-sustained Risk Governance Council recruiting its members from public authorities, research institutions, civil society and industry with the task of decision-making based on risk-benefit assessment and prepared for future challenges will result from the collaboration. An important point in RiskGONE will be developing guidelines and procedures to characterise the environmental and health impact of engineered nanomaterials by verifying or adapting existing testing protocols given by REACH and integrating those tools into the governance framework. Gov4Nano will set its focus on the improvement of infrastructure supporting risk assessment such as databases, also aiming to harmonise

¹⁶⁸ https://ec.europa.eu/research/participants/data/ref/h2020/wp/2018-2020/main/h2020-wp1820-leit-nmp_en.pdf [2019-08-22]

¹⁶⁹ Cordis, the European Commission's database covering its active and concluded research projects and their results, was searched for projects working on governance and regulation, or actively supporting such interests. The database was searched using key words related to the topic of nano governance and headings given in the European Commission's work programmes for the years of 2014 to 2020. <https://cordis.europa.eu/> [2019-10-18]

protocols for characterisation and identifying relevant parameters for the testing of hazards posed by nanomaterials. Additionally, Gov4Nano will explore risk perception in civil society and the insurance industry and evaluate public acceptance and how to raise awareness for nanotechnology. Based on the principles of participation and inclusiveness, all stakeholders will be involved to oblige all needs. The project NANORIGO will additionally work on a web-based information and communication platform to facilitate access to quality data and conduct case studies to investigate the consistency of regulatory solutions under real conditions.

A project currently ending is caLIBRAte funded under the topic NMP-30-2015 - Next generation tools for risk governance of nanomaterials. The project resulted in a NanoRisk Governance Portal to assess and manage risks for health and environment, based on different models and methods providing tools for decision support and surveillance of occupational, consumer and environmental risks. Data accessibility and predictive modelling for risk governance are being evaluated in cooperation with the NanoSafety Cluster and the other Horizon2020-funded projects NanoCommons, NanoSolveIT and NanoinformaTIX. Moreover, caLIBRAte engaged into horizon scanning and analysing stakeholder needs and perspectives concerning nano governance. As the three recently launched projects, caLIBRAte also evaluated existing tools for risk, exposure and hazard assessment.

A second project coming to terms in 2019 is EC4SafeNano funded under the topic NMBP-27-2016 - Promoting safe innovation through global consolidation and networking of nanosafety centres and strengthening the European industry through cooperation in nanosafety. Overall aim of the project was the establishment of a self-sufficient Centre for Risk Management and Safe Innovation mapping stakeholder interests and providing guidance on available tools, best practices and infrastructure. The project consisted of work packages on stakeholder demands concerning knowledge, tools and services for safety management, evaluating resources and overcoming barriers concerning data collection and distribution for risk assessment and safe innovation, providing a catalogue of available services and identify missing ones, addressing legal and economic aspects and involve all stakeholders in networking.

Several projects aim to support the formation of a governance framework. This ideally covers risk assessments and communication, achieved by extensive collection of data and curation of open access data bases on hazard, exposure, health and environmental impact of nanomaterials as well as bridging gaps between laboratory methods and computational simulations to support EU regulatory bodies and international partners. Various projects concerned with the integration of existing databases and modelling software into a single framework are currently under way. The Horizon2020 projects caLIBRAte, GRACIOUS, NanoInformaTIX, NanoREG II as well as RiskGONE together with the concluded FP7 projects ENPRA, MARINA, NanoGenoTox, NANoREG and NanoTest contribute to the eNanoMapper database on toxicology data of engineered nanomaterials, also a FP7 project (<https://search.data.enanomapper.net/index.html>). The projects GRACIOUS and NanoREG II hereby approach the topic of environmental, health and safety impact assessment by working out grouping strategies for nanomaterials based on physicochemical properties to ensure time-efficient testing. Another approach followed by PATROLS is the shift from short-term, high dosimetry human exposure and eco toxicity testing to long-term low-dosimetry testing. PATROLS aims to provide a more effective set of laboratory techniques and computational tools to predict hazards posed by engineered nanomaterials by bringing together scientists from academia and industry, government officials and risk assessors.

A number of NMBP-projects such as BIORIMA and REFINE are concerned with risk assessment and contribution to a regulatory framework concerning applications of nanomaterials in medical products and devices. REFINE furthermore states its mission to establish a consortium for the advancement of regulatory science in biomaterials and nanomedicines consisting of regulators, manufacturers, scientists and end-users. This consortium's purpose will be to identify regulatory challenges and define an action plan, verify and improve testing strategies for bio distribution and quality assurance of nanomedicines and thus contribute to a more efficient testing framework of novel materials beyond the project.

The project NanoFASE (2015-2019) funded by NMP-28-2014 - Assessment of environmental fate of nanomaterials as an offspring of the FP7 project NanoFATE (2010-14) developed an Exposure Assessment Framework to explore accumulation, transformation and transport processes of engineered nanomaterials in living organisms and the environment providing a full life-cycle assessment from synthesis to waste management. NanoStreeM, which was funded under ICT-25-2015 - Generic micro- and nano-electronic technologies established a multidisciplinary consortium to assess and communicate risks of nanomaterials in the semiconductor industry and assist governance and safety regulation on this sector. PANDORA, funded under MSCA-ITN-2015-ETN - Marie Skłodowska-Curie Innovative Training Networks (ITN-ETN), will educate young scientists on the topic of immunosafety. The INFRAIA-1-2014-2015 - Integrating and opening existing national and regional research infrastructures of European interest-funded project EUNCL brings together a consortium consisting of eight distinct reference laboratories throughout Europe and one in the US providing a testing infrastructure for the preclinical physical and chemical as well as biological characterisation covering bio-distribution, metabolism, pharmacokinetics and immunology of nanomaterials for medical applications.

A safe-by-design approach along the innovation chain was worked on by PROSAFE and NanoREG II, the latter containing two work packages of the project covering guidelines for the implementation of the concept and its demonstration and verification. Both projects support the principles to support risk assessment, management and governance outlined by the FP7 project NANoREG, which worked on a common approach to regulatory testing of manufactured nanomaterials from 2007 to 2013.

To counter challenges with the transfer of innovation from scientific research to industry and barriers in the step from pilot production to large-scale industrial production, the call for Nanotechnologies, Advanced Materials, Advanced Manufacturing and Processing, and Biotechnology covers the establishment of Open Innovation Test Beds for safety testing, materials characterisation and open access pilot lines. These programmes aim to ensure the participation of small and medium enterprises in the innovation process and foster co-creation. Projects such as MDOT, NanoPilot, SAFE-N-MEDTECH and TBMED set their focus on innovation of nanomaterial-based products in the medical sector ideally assisting in early-stage product development, pilot line production and characterisation of materials, providing the infrastructure for safety assessments and support in commercialisation and compliance with regulation, as well as assistance with up-scaling production and commercialisation. Similar concepts exist for innovation in the development of materials for the electronics industry and battery production, i.e. CORNET, LEE-BED and TEESMAT, and the production of novel composite materials by CO-PILOT, NANOLEAP, OASIS, OptiNanoPro and PLATFORM. Various projects in this sector further work on the provision or development of tools for materials modelling and act as platforms for knowledge exchange. Some projects such as IZADI-NANO2INDUSTRY or MDOT try to establish manufacturing and characterisation standards to ensure safe production and quality goods in their

respective field of industry; others explore material's life cycles and sustainability, i.e. NanoTextSurf and NECOMADA.

A couple of projects researching in the medical, health care, food, electronics and composite or metals manufacturing sectors plan co-creation with partners in industry to ensure knowledge transfer and up-scaling of production, but do not actively engage in dialogue with the public. As one of Europe's biggest research initiatives and one of the currently active Future Emerging Technologies programmes starting out in 2014 and a core project of Horizon2020, the Graphene Flagship deals with establishing the carbon-based 2D-material graphene on the European market and in society takes action in stakeholder dialogue and co-creation to enable graphene's uptake in various industries such as electronics, biomedicine and automobile. The project provides a platform for discussion among researchers and partners from industry by organising workshops to guide future innovations. The project NOBEL funded under topic NMBP-16-2017 - Mobilising the European nano-biomedical ecosystem aims to support innovation of nanotechnology and cooperation among its stakeholders in the medical sector. NOBEL is coordinated by the European Technology Platform Nanomedicine and runs the Healthtech Translation Advisory Board (TAB) providing tools for mentoring, characterisation and pilot production during development and commercialisation for industry and academy in cooperation with other Horizon2020 projects such as EUNCL.

A project funded as Coordination and Support Action to promote the adoption of NMBP Key Enabling Technologies is CLUSTERNANOROAD, which resulted in a road map based on case studies conducted to identify success factors in stimulating innovation in this sector. NANO2ALL, which ended this year, worked on a responsible approach to innovation in nanotechnology stating its objectives as raising awareness and increasing public trust by establishing a platform for mutual dialogue and ultimately provide recommendations on strengthening public engagement. A project concerned with raising public awareness for nanotechnology and the breadth of the topic was SeeingNano operated from 2014 to 2016 under the topic NMP-31-2014 - Novel visualization tools for enhanced nanotechnology awareness. The project's objective was the development of good-communication practice and visualisation tools.

Several projects are currently working on the implementation and lifting of barriers for the concept of Responsible Research and Innovation (RRI) but none are explicitly concerned with nanotechnology. One of those is MARINA, which aims to establish the concept of RRI in marine research addressing societal needs and citizen's perspectives and has cooperated with nanomaterials-related projects to transfer lessons learned.

Table 1 provides an overview on nano-related projects with regard to different fields and emphases (risk governance framework, EHS research, Platform for coordinated action, dialogue and RRI, toxicology and materials modelling¹⁷⁰), with short summaries of each of the projects.

¹⁷⁰ Some of these projects do not necessarily address nanoparticles and nanomaterials explicitly, but may include aspects relevant for nanoinnovation and regulation.

Table 1: Overview on nano risk related projects funded by the EC (period 2015-2022)

Project name	Project title	Webpage	Start	End	Short summary
Risk governance frameworks					
caLIBRAte	Performance testing, calibration and implementation of a next generation system-of-systems Risk Governance Framework for nanomaterials	http://www.nanocalibrate.eu/home	May 1, 2016	October 31, 2019	Objective is establishment of Risk Governance Framework to assess and manage risks for health and environment as a web-based 'system-of-systems' based on different models and methods to ensure screening of risks and trends in nanotechnology (horizon scanning) and provide decision support, risk surveillance and guidance by revision, calibration and demonstration of existing models.
EC4SafeNano	European Centre for Risk Management and Safe Innovation in Nanomaterials Nanotechnologies	http://www.ec4safenano.eu/	November 1, 2016	October 31, 2019	Objective is the establishment of a research centre from several networks at the interface of research organisations, industry, regulatory bodies and civil society to ensure the understanding and addressing of the interests of all stakeholders along the value chain, mapping those interests and evaluate possible services, and develop rules for governance as well as ensuring self-sufficiency of the programme.
Gov4Nano	Implementation of Risk Governance: meeting the needs of nanotechnology	https://www.gov4nano.eu/	January 1, 2019	December 31, 2022	First implementations for a transdisciplinary operational Nano Risk Governance Council as objective international umbrella organisation will be explored based on an already established governance frameworks by the International Risk Governance Council. A self-sustainable NanoSafety Governance Portal will be established, bringing together progressive nanosafety governance tools for dialogue and risk perception including knowledge management and data management with stakeholder participation. Approaches such as Findable, Accessible Interoperable and Re-usable databases, data-hackathons, blockchain technology and implementation of Safe-by-Design to achieve adaptive and resilient risk governance will be explored.
NANORIGO	Establishing a Nanotechnology Risk Governance Framework	http://nanorigo.eu/	January 1, 2019	February 28, 2023	Objective is the development and implementation of a transdisciplinary and science-based Risk Governance Framework for the social, environmental and economic impact of nanotechnology. The framework will consist of risk management strategies based on reinforced tools for guidance and decision-making developed for risk assessment, validated methods to identify hazards and exposure and a web-based information and communication platform to facilitate access to good quality data and a clear understanding of risks for all stakeholders. The project works towards the establishment of a European Nanotechnology Risk Governance Council which implements the framework. Case studies will be conducted to demonstrate sustainability and integration into regulation under real conditions.
RiskGONE	Risk Governance of Nanotechnology	https://riskgone.wp.nlu.nl/	January 1, 2019	February 28, 2023	Objective is to strengthen EU safety governance of engineered nanomaterials by revising and adapting the current guidelines and procedures (test and standard operation procedures) given by REACH, ISO, OECD through round-robin exercise and multimodal testing. A risk governance council representing EU stakeholders, member states, industry and civil society communicating topics concerning characterisation of materials, environmental and social impact, economic assessment and risk reduction, transfer and communication will be established. Together with Nanorigo and Gov4Nano, a framework for the establishment of a European Risk Governance Council are going to be investigated.

Environment, Health and Safety issues					
ACEnano	Analytical and Characterisation Excellence in nanomaterial risk assessment: A tiered approach	http://www.acenano-project.eu/	January 1, 2017	December 31, 2020	The project focuses on the establishment of a framework for the reproducible characterisation of nanomaterials to improve nanomaterial's grouping according to health and environmental risks.
BIORIMA	BIOMaterial Risk MAnagement	https://www.biorima.eu/	November 1, 2017	October 31, 2021	Objective is to establish an integrated risk assessment framework for nanomaterials used in Advanced Therapy Medicinal Products and Medical Devices. Project will curate data on nano-biomaterials as well as engineered nanomaterials, implementing a data base concerning exposure, hazard and risk to human and environment and further support the standardisation and regulation of nanomaterials.
EUNCL	European Nanomedicine Characterization Laboratory	http://www.euncl.eu/	May 1, 2015	December 31, 2019	EUNCL consists of nine key reference facilities working on the improvement and provision of analytical support in nanomedicine development and towards a harmonisation of testing protocols.
GRACIOUS	Grouping, Read-Across, Characterisation and classification framework for regulatory risk assessment of manufactured nanomaterials and Safer design of nano-enabled products	https://www.h2020gracious.eu/	January 1, 2018	June 30, 2021	Objective is to create a framework for assessment of nanomaterial's risks to health and environment by grouping materials according to similarities to minimise testing expenditures and move away from case-to-case assessments. To better support regulators and industry, stakeholders will be continuously involved.
PROSAFE	Promoting the Implementation of Safe by Design	http://www.prosafe.org/	February 1, 2015	April 30, 2017	Aim is to improve the characterisation of nanomaterials by data collection on toxicology testing, exposure monitoring and disposal of waste materials. The project resulted in a joint document concerning physicochemical characterisation, exposure, bioaccumulation, ecological effects, human health effects and risk assessment. A white paper evaluating previous projects and giving advice on the implementation of efficient governance and regulation of nanomaterials including proposals for the harmonisation of testing methods and improvement of data management was also published.
NanoREG II	Development and implementation of Grouping and Safe-by-Design approaches within regulatory frameworks	http://www.nanoreg2.eu/	September 1, 2015	February 28, 2019	Objective of the project was to establish Safe-by-Design as fundamental pillar in research, screening and commercialisation of novel nanomaterials by identifying testing strategies, exposure scenarios, evaluating grouping strategies, designing and implementing a regulatory approach to deal with a diverse array of nanomaterials, develop and adapt technical and organisational tools and overcoming barriers of SbD-concepts. Documents and reports on strategies for grouping, guidelines for the Save Innovation Approach, on the implementation of Save-by-Design and on the promotion of dialogue among stakeholders were published.
NanoStreeM	NANOMaterials: STRategies for Safety Assessments in advanced Integrated Circuits Manufacturing	http://www.nanostreem.eu/	January 1, 2016	December 31, 2018	Aim was to collect data on nanomaterials and research directions in the nanoelectronics industry, identify gaps in knowledge and methodology and to promote open communication and informed decision-making with and among stakeholders to ensure better governance and outreach. The project produced reports on nanomaterials important for the semiconductor industry and risk assessment methodologies.

NanoFASE	Nanomaterial FATE and Speciation in the Environment	http://www.nanofase.eu/	September 1, 2015	August 31, 2019	Objective is establishing an integrated Exposure Assessment Framework and improve existing tools. The fate of engineered nanomaterials in the environment and the modifications undergone by the material as well as the distribution in soil, water and animals was investigated. The project resulted in reports concerning pathway analyses and nanomaterials accumulation and transformation in soil and water.
PANDORA	Probing safety of nano-objects by defining immune responses of environmental organisms	https://www.pandora-h2020.eu/	January 1, 2016	December 31, 2019	Project is funded as a training network to educate scientists on impact assessment of engineered nanoparticles on health by studying immune response in various organisms (immuno-nanosafety). Research will be conducted with partners from industry.
PATROLS	Physiologically Anchored Tools for Realistic nanomaterial hazard assessment	https://www.patrols-h2020.eu/	January 1, 2018	June 30, 2021	Objective is to bring together academics, industrial scientists, government officials and risk assessors to deliver advanced laboratory techniques and computational tools for risk assessment in nanotechnology to further support nanosafety frameworks.
REFINE	Regulatory Science Framework for Nano(bio)material-based Medical Products and Devices	http://refine-nanomed.com/	December 1, 2017	November 30, 2021	Objective is to propose a regulatory framework for risk assessment in nano-based medical products and devices. This will lead to the facilitated classification of novel nanobiomaterials, ensure the design of safe products and efficient testing and support regulators. A consortium including all stakeholders will be established to bridge gaps between existing science and regulatory methods and address harmonisation and testing.
SiNFONiA	Safety in Nanomaterials & Nanotechnology	n.a.	June 1, 2019	May 31, 2023	Research on nanosafety will be conducted.
Platform for coordinated action, dialogue and RRI ¹⁷¹					
AceForm4.0	Activating Value Chains for EU leadership in FORMulation Manufacturing 4.0	https://formulation-network.eu/	October 1, 2016	September 30, 2018	Project worked on innovation and commercialisation of formulated products, designing a road map and an implementation plan by engaging stakeholders and supporting knowledge exchange.
CIMULACT	CITIZEN AND MULTI-ACTOR CONSULTATION ON HORIZON2020	http://www.cimulact.eu/	June 1, 2015	March 31, 2018	Project's objective was to engage stakeholders and citizens in co-creation to ensure research agendas based on actual societal needs and visions by providing recommendations and policy options in active H2020 programmes, building up capacities for engagement in research and innovation, engaging citizens and stakeholders in dialogue and revealing the benefits of citizen consultation.

¹⁷¹ Projects of this category marked in grey indicate an explicit focus on stakeholder engagement.

CLUSTER NANO ROAD	Driving Europe's NMBP economy - Cross-cluster innovation and value creation through validated NMBP collaborative strategies and roadmap	https://cluster.nanoroad.eu/	September 1, 2016	February 28, 2019	Objective was to develop and implement specialisation strategies in the nanomaterials and biomaterials sector key stakeholders along the innovation chain. Case studies were conducted to map good practices and coordinate innovation action and shape strategic priorities for future cooperation by addressing. Project resulted in a guide on good practice, a report on regional RIS3 activities and roadmap for future action.
EnTIRE	Mapping Normative Frameworks for Ethics and Integrity of REsearch	http://entire.consortium.eu/	May 1, 2017	April 30, 2021	Objective of the project is to foster stakeholder engagement, compare Research Ethics and Research Integrity practices among different countries and develop practices from case analyses, as well as establish an open access online platform based on the research results.
FIT4RRI	Fostering Improved Training Tools For Responsible Research and Innovation	https://fit4rri.eu/	May 1, 2017	April 30, 2020	Project aims to improve RRI implementation with training in RRI tools and strategies as well as promote advanced governance for RRI.
JERRI	Joining Efforts for Responsible Research and Innovation	https://www.jerri-project.eu/jerri/index.php	June 1, 2016	May 31, 2019	Project investigated state of RRI in Europe, looked at barriers for the concept and thought to deliver an action plan for implementation established with the help of case studies conducted.
MARINA	Marine Knowledge Sharing Platform for Federating Responsible Research and Innovation Communities	https://www.marinaproject.eu/	May 1, 2016	April 30, 2019	Project explores RRI approach to sea-related topics and how to promote participation as well as understanding concerns and barriers on the adoption of RRI. Project further aims to develop an RRI-road map highlighting best practices and limitations transferable to issues concerning RRI and nanotechnology.
NANO2ALL	Nanotechnology Mutual Learning Action Plan For Transparent And Responsible Understanding Of Science And Technology	http://www.nano2all.eu/	October 1, 2015	March 31, 2019	Project aimed at establishing a platform for dialogue on responsible research during the value-chain. The project resulted in various reports on current and future trends in RRI regarding nanotechnology and management of two-way communication with stakeholders.
NanoDiode	Developing Innovative Outreach and Dialogue on responsible nanotechnologies in EU civil society	http://www.nanodiode.eu/	July 1, 2013	June 30, 2016	The NanoDiode project establishes a programme for outreach and dialogue to support the responsible development of nanotechnologies in Europe. The consortium brings together a range of stakeholders including industry, civil society organisations, research-ers from the natural and the social sciences and artists.
NewHorizon	Excellence in science and innovation for Europe by adopting the concept of Responsible Research and Innovation	https://newhorizon.eu/	May 1, 2017	April 31, 2021	The project organises 19 social labs consisting of societal actors concerned with the detection of barriers and the implementation of RRI in different parts of H2020.
NMP TeAm 4	Improving the services of the NMP NCP Network through Transnational Activities 4	http://www.nmpteam.eu/	January 1, 2017	March 31, 2020	Project is the offspring of TeAm 1, 2, 3, all working on communicating information and assisting participation on NMP programmes in H2020, thus it supports and coordinates national contact points on key enabling technologies programmes. Project aims at increasing outreach to stakeholders and provide tools for projects involved in H2020.
NOBEL	Mobilising the European nano-biomedical ecosystem	https://nobel-project.eu/	October 1, 2017	September 30, 2020	The project is coordinated by the European Technology Platform Nanomedicine and works towards common innovation in the medical sector in Europe through linking of stakeholders, setting-up roadmaps

					for emerging medical technologies and provide tailored support to industrial partners during development and market implementation of novel products.
RRI-Practice	Responsible Research and Innovation in Practice	https://www.rri-practice.eu/	September 1, 2016	August 31, 2019	Project aimed to identify drivers and barriers for RRI implementation and conducted several case studies.
SeeingNano	Developing and Enabling Nanotechnology Awareness-Building through the Creation and Exchange of enhanced Communication and Visualisation Tools and Guidance for 'Seeing at the Nanoscale'	http://www.seeingnano.eu/	December 1, 2014	November 30, 2016	Project created new visualisation tools to enhance public nanotechnology awareness and understanding related to technological, socio-economic and safety aspects.
SISCODE	Society in Innovation and Science through CODEsign	https://siscodeproject.eu/	May 1, 2018	April 30, 2021	Project focuses on Public Engagement and Responsible Research and Innovation and promote the concept of co-creation among researchers and policy makers and to detect favourable conditions for co-design.
SUPER_MORRI	Scientific Understanding and Provision of an Enhanced and Robust Monitoring system for RRI	https://www.super-morri.eu/super-morri/index.php	January 1, 2019	December 31, 2023	new project on RRI
SYNAMERA	Synergies in Nanotechnologies, Materials and Production in the European Research Area	http://www.synamera.eu/	May 1, 2015	April 31, 2017	Project aims to coordinate european, national and regional stakeholders and funding authorities using the ERANET tool.
TeRRitoria	Territorial Responsible Research and Innovation Through the involvement of local R&I Actors	https://cordis.europa.eu/project/rcn/221619/factsheet/en	February 1, 2019	January 31, 2022	new project on RRI
Toxicology modeling					
EU-ToxRisk	An Integrated European 'Flagship' Program Driving Mechanism-based Toxicity Testing and Risk Assessment for the 21st Century	http://www.eu-toxrisk.eu/	January 1, 2016	December 31, 2021	Project aims to develop new methods on toxicology testing of chemicals and nanomaterials by reducing animal-testing and economic expenditure focusing on omics-based approaches

HISENTS	High level Integrated SEnsor for NanoToxicity Screening	https://hisen.ts.eu/	April 1, 2016	May, 31, 2019	Project will establish a high-throughput platform providing toxicity screening for risk assessment. Aim is to bring together a multidisciplinary team to generate new screening tools, improve the profiling of nanomaterial's hazards and allow a faster characterisation of toxicological mechanisms of nanomaterials, thus contribute to nanosafety, regulation and the Nano Safety Cluster.
NanoCommons	The European Nanotechnology Community Informatics Platform: Bridging data and disciplinary gaps for industry and regulators	https://www.nanocommons.eu/	January 1, 2018	December 31, 2021	Objective is to establish a framework for the characterisation and interaction mechanisms of nanomaterials integrating computational tools for risk assessment, decision support and quality control criteria. The project aims to create a tool for mechanical and statistical modelling, grouping, safe-by-design and life cycle assessment and bring together interests from regulators, industry and consumers.
NanoGenTools	Developing and implementation of a new generation of nanosafety assessment tools	http://www.3.ubu.es/nanogentools/	January 1, 2016	December 31, 2019	Objective is establishing a collaborative knowledge-based network to provide solutions for assessment of toxicological properties of nanomaterials using HTS and omics-related tools, create a database including physical, chemical and biological properties and thus improve bioinformatic methodologies for toxicity prediction and improve the safe-by-design concept.
NanoInformaTIX	Development and Implementation of a Sustainable Modelling Platform for NanoInformatics	http://www.nanoinformatics.eu/	January 1, 2019	February 28, 2023	Objective is the establishment of a web-based sustainable Nano-Informatics framework by bringing together multiple EU and US databases with validated nanoinformatics models. Data concerning methods for engineered nanomaterial design, (eco-)toxicity and exposure and biodistribution will be collected and managed to obtain a modelling and database framework for the demands of different stakeholders such as industry, civil society, academia and regulators. Project aims at supporting the development of safe-by-design engineered nanomaterials and facilitate risk-assessment.
NanoSolveIT	Innovative Nanoinformatics models and tools: towards a Solid, verified and Integrated Approach to Predictive (eco)Toxicology	https://nanosolveit.eu/	January 1, 2019	February 28, 2023	Objective is to introduce an Integrated Approach to Testing and Assessment for the safety and environmental impact of engineered nanomaterials through the development and integration of innovative tools to support industrial and regulatory risk governance. The project will deliver knowledge-based infrastructure for data exchange and aims to provide characterisation of nanomaterials by functionality, exposure and hazards and develop methodologies for the prediction of toxicology of nanomaterials, thus supporting risk assessment and a safe-by-design approach.
PANBioRA	Personalized And/Or Generalized Integrated Biomaterial Risk Assessment	https://www.panbiora.eu/	January 1, 2018	December 31, 2021	Project will provide solutions for risk assessment including anti-body response, toxicity for cell and genome and systematic and local effects on tissue of biomaterials by standardising the evaluation of biomaterials to support its application in personalised diagnostics.
SmartNanoTox	Smart Tools for Gauging Nano Hazards	http://www.smartnanotox.eu/	March 1, 2016	February 28, 2020	Project explores respiratory toxicity of nanomaterials through in vivo, in vitro and in silico methods to identify interactions and pathways in the human body after exposure.
STARNANO	Spheroids as a Tool to Assess Realistic long term effects of mixtures of nanomaterials and chemicals		February 1, 2018	January 31, 2020	Project will explore hazards posed by nanomaterials interactions with common materials in environment by conducting long term studies on cell cultures to assess longterm effects and intra-cellular fate of nanomaterials. Furthermore, project will support safe and sustainable use of nanomaterials in industry and support REACH.

ToxEcoGraphene	Assessment of ecocorona acquired by Graphene Family Nanomaterials during exposure to biofilms and fate following uptake		May 1, 2018	April 30, 2020	Aim is to characterise environmental processes graphene-related nanomaterials undergo by developing protocols and methods to investigate materials fate and transport in environment, to determine toxicity for humans and environment and to assist risk assessment in production.
Materials modeling					
EMMC-CSA	European Materials Modelling Council	https://emm.c.info/	September 1, 2016	August 31, 2019	
INTERSECT	Interoperable Material-to-Device simulation box for disruptive electronics	http://intersect-project.eu/abstract/	January 1, 2019	January 31, 2022	Project aims at bridging gap between academia and industry by proving materials modelling software.
MarketPlace	Materials Modelling Marketplace for Increased Industrial Innovation	https://www.the-marketplace-project.eu/	January 1, 2018	December 31, 2022	Objective is to create an open web-based Materials Modelling and Collaboration Platform as a central hub for materials modelling in european manufacturing industry linking several databases and simulation tools as well as promoting exchange of knowledge an topics along the value chain.
MMAMA	Microwave Microscopy for Advanced and Efficient Materials Analysis and Production	https://www.mmama.eu/	November 1, 2017	October 31, 2020	Objective is the development of Scanning Microwave Microscopy technology to measure material and interface properties of nano-patterned surfaces applicable in coatings, photovoltaic cells and semiconductor circuits. This should lead to the development of an open access platform for nanoscale characterisation and standard operating procedures.
NANO2DAY	MULTIFUNCTIONAL POLYMER COMPOSITES DOPED WITH NOVEL 2D NANOPARTICLES FOR ADVANCED APPLICATIONS	http://nano2day.eu/	May 1, 2018	April 30, 2022	Objective is to develop multifunctional composite materials by incorporating Mxene nanosheets into the matrix. Project will explore electronic and mechanical properties and establish modelling tools for such composites.
Oyster	Open characterisation and modelling environment to drive innovation in advanced nano-architected and bio-inspired hard/soft interfaces	http://www.oyster-project.eu/	December 1, 2017	November 30, 2021	Objective is to establish tools and methodologies for the evaluation of nano-enabled products i.e.nano-patterned topologically functionalised surfaces, in adhesion and friction applications. Besides modelling and characterisation of materials in cooperation with european and international partners, industrial manufacturing and commercialisation will be another aim.
ReaxPRO	Software Platform for Multiscale Modelling of Reactive Materials and Processes	https://www.scm.com/about-us/eu-projects/reaxpro-multiscalere	January 1, 2019	February 28, 2023	Objective is to bring together and improve various existing software tools for materials modeling, primarily concerned with simulation of catalytic processes from the molecular up to the reactor's scale, and distribute these tools through European Materials Modelling Marketplace.

		actormodeling/			
SimDOME	Digital Ontology-based Modelling Environment for Simulation of materials	https://simdome.eu/	January 1, 2019	January 31, 2023	Project will develop an industry-ready software framework for (nano)materials testing in several sectors of industry, improving an adapting existing software from previous EU-funded projects and providing up-scaled software through European Materials Modelling Marketplace.
VIMMP	Virtual Materials Market Place		January 1, 2018	December 31, 2021	Project will deliver an open-source, web-based marketplace covering materials models, software tools and training services, leading to an easier communication among stakeholders concerned with materials modelling and boosting European manufacturing industry.
Open Innovation Test Beds					
CORNET	Multiscale modelling and characterization to optimize the manufacturing processes of Organic Electronics materials and devices	https://www.cornet-project.eu/	January 1, 2018	September 30, 2020	Objective is to establish an Open Innovation Environment for manufacturing, characterisation and modelling of organic electronics nanomaterials and devices. Project aims to establish a platform and database assisting producers with protocols and standards and upscaling production, as well as providing legal and commercial support.
CO-PILOT	Flexible Pilot Scale Manufacturing of Cost-Effective Nanocomposites through Tailored Precision Nanoparticles in Dispersion	http://www.h2020copilot.eu/	January 1, 2015	December 31, 2017	Objective was to implement open access infrastructure for the development of novel multifunctional nanocomposite materials on a pilot scale. Focus of the project was on dispersion and online monitoring techniques.
IZADI-NANO2INDUSTRY	Injection moulding, casting and coating PILOTS for the production of improved components with nano materials for automotive, construction and agricultural machinery	http://www.izadinano2industry.eu/	November 1, 2015	October 31, 2018	Building up on previous EU-funded projects, objective was to develop pilot lines for the production of nanomaterials-improved products such as thermoplastics, metallic coatings and castings and promote a safe-by-design approach, conduct assessments of environmental and health impact and to contribute to manufacturing and characterisation standards.
LEE-BED	Innovation test bed for development and production of nanomaterials for lightweight embedded electronics	https://www.dti.dk/specialists/innovation-test-bed-for-development-and-production-of-nanomaterials-for-lightweight-embedded-	January 1, 2019	December 31, 2022	Project establishes single-entry Open Innovation Test Bed to evaluate technological and economic possibilities and risk-benefit-assessment of nanomaterials in light-weight electronic devices, perform pilot projects and assist with the knowledge transfer to industry.

		electronics-lee-bed/38965			
MDOT	Medical Device Obligations Taskforce	https://www.cidetec.es/en/projects/nanomedicine-9/medical-device-obligations-taskforce-3	January 1, 2019	December 31, 2023	Objective is to establish an Open Innovation Test Bed for medical technology safety testing. Project will support companies with risk assessment, act as a platform for data exchange, development of advanced testing methods and clinical trials.
NANOFACTURING	The Development of Medium- and Large-Scale Sustainable Manufacturing Process Platforms for Clinically Compliant Solid Core Nanopharmaceuticals	http://nanofacturing.eu/	February 15, 2015	January 31, 2019	NANOFACTURING aimed to implement new manufacturing processes and improve supply chains in european nanomedicine sector by assisting in early stage trials, large-scale production set-up to commercialisation. The focus was on the manufacturing and scale-up of glycan-coated gold particles.
NANOLEAP	Nanocomposite for building constructions and civil infrastructures: European network pilot production line to promote industrial application cases	http://www.nanoleap.eu/	January 1, 2015	June 30, 2018	Objective was to develop a network of specialised pilot lines for nanocomposite production for the construction and engineering sector and further support industrial manufacturing and commercialisation.
NanoPack	Pilot line production of functional polymer nanocomposites from natural halloysite nanotubes: demonstrating controlled release of active antimicrobials in food packaging applications	https://www.nanopack.eu/	January 1, 2017	December 31, 2019	
NanoPilot	A Pilot Plant for the Production of Polymer based Nanopharmaceuticals in Compliance with GMP	http://www.nanopilot.eu/homepage	January 1, 2015	June 30, 2019	Objective was to establish a pilot plant for the production of three different polymer-based nanopharmaceuticals. The project further focused on evaluating economic impact and possible large scale production as well as performing safety assessments.
NanoTextSurf	Nanotextured surfaces for membranes, protective textiles, friction pads and abrasive materials	http://www.nanotextsurf.eu/	November 1, 2017	October 1, 2020	Objective is to improve existing pilot lines for manufacturing of nanotextured surfaces based on nanostructured biomaterials for the application in functional textiles, membranes and abrasive and friction materials. The project will aim to up-scale the manufacturing process and thereby assess economic feasibility, environment risks and life cycle.
NECOMADA	Nano-Enabled Conducting Materials Accelerating Device Applicability	http://necomada.eu/	January 1, 2017	December 31, 2019	Objective is to develop and improve nano-enabled multi-functional electrically conductive adhesives and printable conductor inks, to deliver production methods ready for up-scaling and validate market performance, to develop an open access pilot line and platform to counter technical and commercial challenges, as well as co-develop sustainable life-cycle strategies.

NFFA-Europe	NANOSCIENCE FOUNDRIES AND FINE ANALYSIS - EUROPE	https://www.nffa.eu/	September 1, 2015	August 31, 2020	Projects aims to develop a platform to conduct multidisciplinary research on nanomaterials from synthesis to characterisation and simulations by providing free-of-charge access to analytical facilities and high performance computing facilities.
OASIS	Open Access Single entry point for scale-up of Innovative Smart lightweight composite materials and components		January 1, 2019	August 31, 2022	Project will develop pilot lines for the production of nanoenabled multifunctional composite materials. The project will assist with technical issues such as modeling, characterisation, toxicological and life cycle assessment, and non-technical issues, i.e. business planning and innovation coaching.
OptiNanoPro	Processing and control of novel nanomaterials in packaging, automotive and solar panel processing lines	http://optinopro.eu/	October 1, 2015	September 30, 2018	Objective is to explore application of nanocomposite materials and develop approaches to integrate nanotechnology in production lines for packaging, automotive and photovoltaics industry by providing online dispersion and monitoring systems. Stakeholders from all steps of the supply and value chain will be working together to integrate new nanotechnologies into existing production lines and assist in evaluating nanosafety and commercial issues.
PLATFORM	Open access pilot plants for sustainable industrial scale nanocomposites manufacturing based on buckypapers, doped veils and prepregs	https://cordis.europa.eu/project/rcn/194436/factsheet/en	February 1, 2015	January 31, 2018	Objective was to develop open access pilot lines for the production of carbon-based nanomaterials for application in composites for aerospace or automotive industry. Project is based on previous EU-funded programmes and offers facilities for the development of novel materials and support with commercialisation and assist process and materials characterisation, and further work with regulators to ensure nanosafety.
SAFE-N-MEDTECH	SAFETY TESTING IN THE LIFE CYCLE OF NANOTECHNOLOGY-ENABLED MEDICAL TECHNOLOGIES FOR HEALTH	n.a.	April 1, 2019	March 31, 2023	Project aims to establish a coordinated Open Innovation Test Bed for nanotechnology in the medical sector. An open access platform will be established to provide companies and reference laboratories with information regarding the development, testing, assessment and market implementation of nanotechnology-based medical and diagnosis devices.
SUN-PILOT	Subwavelength Nanostructure Pilot		January 1, 2018	December 31, 2021	Project will establish a platform for pilot production for sub-wavelength nanostructure manufacturing techniques with potential to upscale production for applications in optical systems in electronics, medicine and security technology.
TBMED	A testing bed for the development of high-risk medical devices	https://www.tbmed.eu/about/objectives	January 1, 2019	February 28, 2023	Project establishes a single entry point Open Innovation Test Bed for the development of high risk medical devices consisting of several laboratories to ensure support at all points of the value chain, from pre-clinical testing, characterisation and safety assessment, through pilot projects to scale-up industrial manufacturing.
TEESMAT	OPEN INNOVATION TEST BED FOR ELECTROCHEMICAL ENERGY STORAGE MATERIALS	https://www.teesmat.eu/teesmat/	January 1, 2019	August 31, 2022	Project works on an Open Innovation Test Bed for the development of high performance battery solutions assisting with the development and demonstration of novel materials characterisations, data analytics. The established test bed aims to accelerate innovation, reduce development cost and ensure compliance with regulation.

5. SYNTHESIS AND CONCLUSIONS

This second policy screening presented in this report serves as background information for the three White papers and policy and industry briefs on Responsible Research and Innovation approaches for stakeholder engagement and co-creation on nanotechnologies to be developed in GoNano (Del. 5.3 and 5.4, as well as info box on GoNano process and interrelation of outcomes below). The following synthesis and suggestions are derived from the analysis presented in this report and deliverable 5.1.

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 groundbreaking 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 with regard 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.

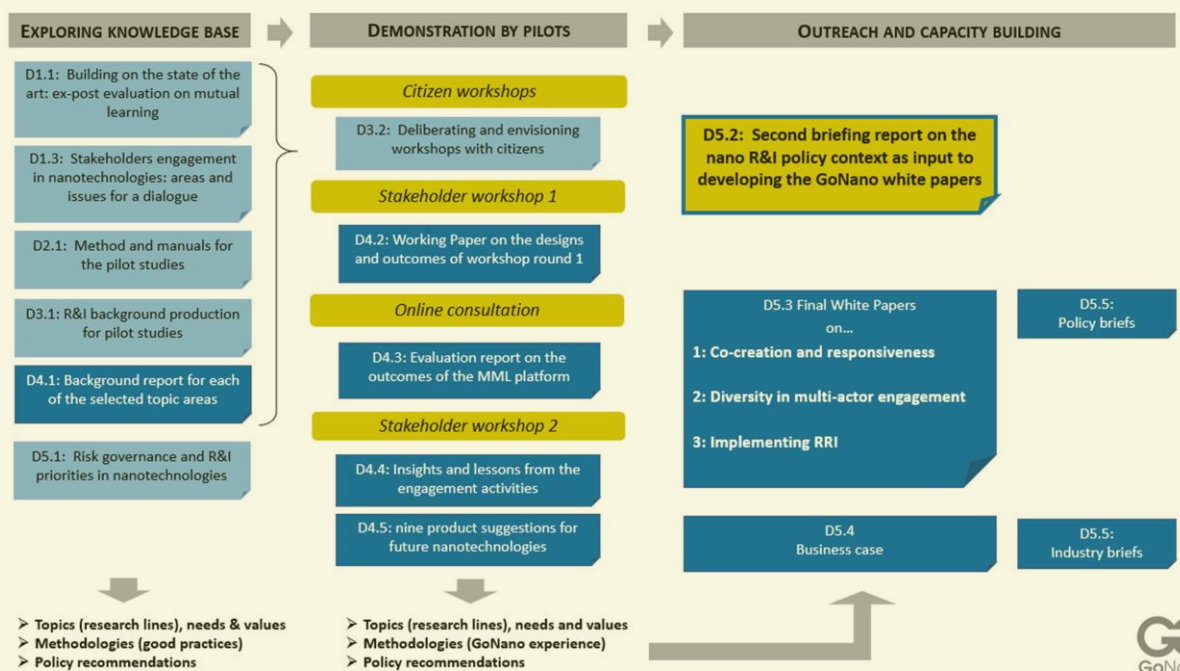
This also relates to what Swiestra and te Molder (2012) called “hard” and “soft” impacts of nanotechnologies. The defined “hard impacts” as *“those impacts that are quantifiable, represent non-controversial values and have a direct causal link to the technology, such as adverse health impacts, pollution, safety or privacy. ‘Soft’ impacts, by contrast, are qualitative in nature, relate to contested values and are ‘mediated’ rather than directly caused by the technology. They typically concern the domain of our daily routines, life style, aspirations, expectations, but also the moral domain of norms, values, virtues and responsibilities”* (Swiestra and te Molder, 2012). They suggest that nanotechnology

governance should consider both hard and soft impacts. Whereas the first have received ample attention, attention for the soft impacts is much harder to realise.

This ambiguity served as an important issue in the pilot studies. While taking promising sectors and among them, promising research achievements as starting point for the GoNano co-creation process, the challenge of an “in-built tendency towards a technology-fix position, in which nanotechnologies are framed as the (only) solution to a range of problems” remained. However, GoNano aimed to counter such tendencies by explicitly addressing diverse values and needs of citizens (e.g. in the citizen consultations conducted by GoNano).

Workflow as relevant for the GoNano White Papers

The three White Papers are a core outcome of the GoNano projects and will provide the basis for both the policy briefs and an industry briefs. Their focus is defined within the DoA. The following flow chart provides an overview of embeddedness of the three white papers within GoNano and other Go Nano tasks.



Description of Workflow

GoNano builds on the three pillars of exploring existing knowledge bases, an empirical demonstration of co-creation by pilot areas and outreach and capacity building. These pillars are cross-cutting with regard to work packages, indicating the close interrelation between each GoNano step.

Del. 5.1 and Del. 5.2 show the regulatory context and background with regard to public engagement that provides the backbone for setting up the co-creation process as well as the White Papers that address pressing issues for implementing co-creation in a wider sense. The White Papers, again, are the basis for concrete recommendations towards policy and industry as a resource for the policy and industry briefs, as well as the business case.

5.1. POINTS OF REFERENCE FOR THE WHITE PAPERS (GoNano Del. 5.3)

In the following, potential points of reference for each GoNano White paper are outlined. However, as the White Papers are currently under development and co-creatively written, minor changes with regard to content and lines of argumentation may occur.

REFLECTIONS FOR WHITE PAPER 1: CO-CREATION & RESPONSIVENESS

Co-creation as developed in GoNano, among other approaches, can be understood as one instrument to enhance responsiveness of researchers and scientists to societal challenges. An exploration of responsiveness in the area of nanotechnology sciences and identifying challenges and ways to address them, is the aim of White Paper 1. The potential connection between Del. 5.2 and White Paper 1 is therefore threefold:

First, with regard to White Paper 1, this report outlines the frame in which responsiveness is likely to take place. The existing regulatory state-of-the-art with regard to nanotechnology that stakeholders need to obey to, and the novel approaches on risk governance that are being explored by EU initiatives, could lead to specific understandings of how responsiveness can be enacted within a broader scientific institutional background.

Second, with regard to challenges that are rooted within the way of how research is being performed and responsiveness is being enacted - both at institutional and individual level-, the variety of national strategies in terms of public engagement activities indicates huge differences with regard to potential and established scope of doing so. This report highlights the variety of these strategies, particular regarding socio-political conditions in GoNano partner countries.

REFLECTIONS FOR WHITE PAPER 2: CULTURE, COMMUNICATION AND GENDER MULTI-ACTOR ENGAGEMENT EXERCISES

As issues of (cultural) diversity are currently hardly addressed in the policy landscape with regard to nanospecificity, the GoNano White Paper will aim at identifying links that could be valuable here. GoNano specifically set out to develop a multi-actor engagement process taking into account differences in culture, communication practices and gender. White Paper 2 explicitly takes on the issue of gender and diversity in multi-actor engagement exercises on a practical level. The white paper develops recommendations for policy-makers for supporting a focus on these issues, and provides recommendations and examples for organisers wanting to be more mindful of said issues. The White Paper's recommendations include an empowering way of communication, finding a two-way communication between actors within the co-creation process; the role of diverse every-day life settings to address technology contexts in a vivid way; and to challenge the ways of thinking about technologies especially with regard to imagined roles and assumptions and avoiding an "in-built tendency towards a technology-fix position" as outlined in the conclusions of Del. 5.1 (Del. 5.1, 55).

REFLECTIONS FOR WHITE PAPER 3: IMPLEMENTING RRI

White paper 3 takes on the challenge of implementing RRI along the value chain in order to address challenges with regard to specific innovation lines.

First, this report could provide an informative background exploring conditions under which the different actors along the value chain operates. It is shown that priorities with regard to aspects of RRI may vary according to national background and/or position within the value chain.

Second, with regard to research funding, ideas of value chain approaches are in line with the scope of other EU projects and potentially the scope of regulators. Hence, embedding the White Paper 3 in a wider perspective on EU funding activities (see table 1) clearly argues in favour of continuation of ideas on how to discuss responsibility within the nanotechnology field.

Third, White Paper 3 might need to analyse gaps in implementation regarding the regulatory context for nanomaterials (e.g. REACH regulation). In particular, the issue of definitions may add complexity for the producers of the substance who might not be able to anticipate in which ways customers will actually use their products. As a result, this might pose a clear obstacle to implement RRI along the value chain level.

6. REFERENCES

- AZOULAY, D. 2011. Nanotechnology Legislation. *In*: BOSSELMANN, K., FOGEL, D. & RUHL, J. B. (eds.) *Berkshire Encyclopedia of Sustainability 3/10: The Law and Politics of Sustainability*. Great Barrington: Berkshire Publishing Group LLC.
- AZOULAY, D. & TUNCAK, B. 2014. Swedish Society for Nature Conservation Report: Managing the Unseen: Opportunities and Challenges with Nanotechnology. Stockholm: Naturskyddsföreningen.
- BECK, U. 1986. Risikogesellschaft. Auf dem Weg in eine andere Moderne, Frankfurt am Main, Suhrkamp.
- CHARRIÈRE, A. & DUNNING, B. 2014. Timeline: Nanotechnology. Policy and Regulation in Canada, Australia, the European Union, the United Kingdom, and the United States. Ottawa: University of Ottawa.
- CHEMICAL WATCH. 2018. *Echa says it cannot verify if nanomaterials are being used safely* [Online]. Available: <https://chemicalwatch.com/63212/echa-says-it-cannot-verify-if-nanomaterials-are-being-used-safely?q=nanomaterials+ECHA+registration> [Accessed 11/04 2018].
- CIEL, ECOS & OEKO INSTITUTE 2015. Nanomaterials Definition fact sheet.
- CRANN INSTITUTE 2018. Impact Assessment Report 07-16. Dublin: Trinity College Dublin.
- ECHA EUROPEAN CHEMICALS AGENCY. *REACH Guidance for nanomaterials published* [Online]. Available: <https://echa.europa.eu/-/reach-guidance-for-nanomaterials-published> [Accessed 11/04 2018].
- EUROPEAN COMMISSION 2004a. Communication by the Commission: Toward a European Strategy for Nanotechnology. *In*: OFFICE FOR OFFICIAL PUBLICATIONS OF THE EUROPEAN COMMISSION (ed.). Luxembourg.
- EUROPEAN COMMISSION 2005. Communication from the Commission to the Council, the European Parliament, and the Economic and Social Committee. Nanosciences and nanotechnologies: An action plan for Europe 2005-2009. *In*: OFFICE FOR OFFICIAL PUBLICATIONS OF THE EUROPEAN COMMISSION (ed.). Luxembourg.
- EUROPEAN COMMISSION 2008. Commission Recommendation on A code of conduct for responsible nanosciences and nanotechnologies research & Council conclusions on Responsible nanosciences and nanotechnologies research. Brussels: European Commission.
- EUROPEAN COMMISSION 2012. Communication: A European strategy for Key Enabling Technologies – A bridge to growth and jobs'. *In*: COMMISSION, O. F. O. P. O. T. E. (ed.). Luxembourg.
- EUROPEAN COMMISSION. 2017a. *Definition of a nanomaterial* [Online]. Available: http://ec.europa.eu/environment/chemicals/nanotech/faq/definition_en.htm [Accessed 11/04 2018].

- EUROPEAN COMMISSION 2017b. Horizon 2020 - Work Programme 2018-2020. Nanotechnologies, Advanced Materials, Biotechnology and Advanced Manufacturing and Processing. Brussels: European Commission.
- EUROPEAN COMMISSION 2017c. NanoData Impact Assessment. Energy, Health, ICT, Manufacturing, Photonics. Synthesis Report. Brussels: European Commission, Directorate-General for Research and Innovation.
- EUROPEAN ENVIRONMENTAL BUREAU. 2016. *New initiative on nanomaterials will not improve transparency* [Online]. Available: <http://eeb.org/new-initiative-on-nanomaterials-will-not-improve-transparency/> [Accessed 11/04 2018].
- EUROPEAN OMBUDSMAN. 2018. Recommendation of the European Ombudsman in case 1336/2017/JAS on the European Commission's refusal to grant access to its catalogue of nanomaterials used in cosmetics, as well as to related notifications from cosmetics manufacturers [Online]. Available: <https://www.ombudsman.europa.eu/cases/recommendation.faces/en/91138/html.bookmark> [Accessed].
- FORFÁS 2010. Ireland's Nanotechnology Commercialisation Framework 2010 – 2014. Dublin: Forfás.
- HANDFORD, C. E., DEAN, M., SPENCE, M., HENCHION, M., ELLIOTT, C. T. & CAMPBELL, K. 2014. Nanotechnology in the AgriFood industry on the island of Ireland: applications, opportunities and challenges. Cork: SafeFood.
- JAKL, T., HANSLIK, S., MÜHLEGGGER, S., POGANY, A., PÜRGY, R., SUSNIK, M. & ZILBERZSAC, A. 2009. Austrian Nanotechnology Action Plan. Wien: Lebensministerium.
- The regulation of Nanotechnology", Chemical Watch Webinar, 2014. Directed by KOPP, F.
- KURATH, M., NENTWICH, M., FLEISCHER, T. & EISENBERGER, I. 2014. Cultures and strategies in the regulation of nanotechnology in Germany, Austria, Switzerland and the European Union. *Nanoethics*, 8, 121-140.
- NANO2ALL 2016. Current RRI in Nano Landscape. Deliverable 5.1. Nano2All.
- RAUSCHER, H., RASMUSSEN, K. & SOKULL-KLÜTTGEN, B. 2017. Regulatory Aspects of Nanomaterials in the EU. *Chemie Ingenieur Technik*, 89, 224-231.
- RAUSCHER, H., ROEBBEN, G., MECH, A., GIBSON, N., KESTENS, V., LINSINGER, T.P.J., RIEGO SINTES, J. 2019. An overview of concepts and terms used in the European Commission's definition of nanomaterial, EUR 29647 EN, European Commission, JRC, doi:10.2760/459136, JRC113469.
- RCN 2005. Nanoteknologier og nye materialer: Helse, miljø, etikk og samfunn. Nansjonal forsknings- og kompetansebehov // Nanotechnologies and new materials: Health, environment, ethics and society. National needs for research and competence. In Norwegian. . Oslo: Research Council of Norway.
- RHC 2012. Strategic Research Priorities for Cross-cutting Technology. Brussels: European Technology Platform on Renewable Heating and Cooling.

SAVOLAINEN, K., BACKMAN, U., BROUWER, D., FADEEL, B., FERNANDES, T., KUHLBUSCH, T., LANDSIEDEL, R., LYNCH, I. & PYLKKÄNEN, L. 2013. Nanosafety in Europe 2015-2025: Towards Safe and Sustainable Nanomaterials and Nanotechnology Innovations. Helsinki: Finnish Institute of Occupational Health.

SWIERSTRA T., TE MOLDER, H. (2012). Risk and Soft Impacts. In: Roeser S., Hillerbrand R., Sandin P., Peterson M. (eds). Handbook of Risk Theory. Springer, Dordrecht.

LEGISLATION (CHRONOLOGICAL ORDER)

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.

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"

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

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.

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

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.

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.

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

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) 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.

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 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.

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.

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.

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: DATA MANAGEMENT PLAN

The present report is based on the collection and analysis of publicly available information from:

- Scientific and non-scientific publications,
- Legal texts,
- Official websites of, among others, EU institutions, Non-governmental organisations, websites of national ministries.
- All information sources are referenced and listed in the report. No further data was collected, stored or analysed for this report.