

# NanoFabNet

international Hub for sustainable  
industrial-scale Nanofabrication

## NanoFabNet Strategy & Implementation Roadmap for Sustainability in Nanofabrication



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Acronyms Listed in Document	
CEN	European Committee for Standardisation
EC	European Commission
ECHA	European Chemicals Agency
ENM	Engineered Nanomaterial
EU	European Union
EUON	European Union Observatory for Nanomaterials
IEEE	Institute of Electrical and Electronics Engineers
ISO	International Organization for Standardization
LCA	Life Cycle Assessment
LCC	Life Cycle Costing
LCSA	Life Cycle and Sustainability Assessment
NIA	Nanotechnology Industries Association
NM	Nanomaterial
NGO	Non-Governmental Organisation
RA	Risk Assessment
RM	Risk Management
OECD	Organisation for Economic Cooperation and Development
SA	Safety Assessment
SbD	Safe-by-Design
SDGs	Sustainable Development Goals
SSbD	Safe- and Sustainable-by-Design
S-LCA	Social Life Cycle Assessment
UN	United Nations
WTO	World Trade Organisation



## 1. Executive Summary

This report presents the NanoFabNet strategy and implementation roadmap for sustainability in nanofabrication, which consists of a set of actions and recommendations to be implemented at different timescales and by different bodies within the next years to achieve sustainable nanofabrication. This strategy and implementation roadmap is a direct output of the advances and activities performed by the NanoFabNet Project. It is organised into four parallel dimensions, each of them being treated in a chapter of this report: **‘Raising Awareness of Sustainability’**; **‘Compliance with Regulation and Legislation’**; **‘Implementation of Sustainability Indicators’**; **‘Building Support and Engagement for Sustainability Criteria’**. For each of these dimensions, different kinds of actions are proposed, delineated, and classified according to two main categories: (a) short- to middle-term actions, and (b) middle- to long-term actions.

This strategy is intended to feed the **NanoFabNet 5-Years-Strategy** and the **EU 2030 Strategic Plan for Nanofabrication** to be delivered by the NanoFabNet Project by the end of its course.

## 2. Introduction

### 2.1 Context and Sources of the NanoFabNet Strategy & Implementation Roadmap for Sustainability in Nanofabrication

The objective of this report is to define a coherent strategy for sustainability in nanofabrication, and an implementation roadmap of the strategy, which is directly linked with the discoveries and advances in terms of sustainability in nanofabrication made during the course of the NanoFabNet Project.

The development of this strategy has benefited from three different types of sources:

As a first source can be mentioned the first four reports on sustainability in nanofabrication written by the NanoFabNet Project, namely:

- the *‘Report on the Concepts & Disciplines of Sustainability in Nanotechnology & Nanofabrication’<sup>1</sup>*;
- the report on the *‘Detailed Database Entries & Map of the Field of Sustainability in Nanotechnology & Nanofabrication’* (confidential);
- the NanoFabNet *‘Annotated List of hard regulatory Requirements for Nanofabrication’* (confidential); and
- the *‘Report on recommended ‘soft/exploratory’ Sustainability Indicators for NanoFabNet’* (confidential).

In the first report (i.e. *‘Report on the Concepts & Disciplines of Sustainability in Nanotechnology and Nanofabrication’<sup>1</sup>*), the **NanoFabNet Concept of Sustainable Nanofabrication** was introduced, and its three working areas (i.e. (a) Environment, Health and Safety issues, (b) Life Cycle Sustainability issues, and (c) Ethics and Governance issues) were identified and described. In the second report (i.e. *‘Detailed Database Entries & Map of the Field of Sustainability in Nanotechnology and Nanofabrication’*), some organisations and projects worldwide were identified, which are relevant for the definition and implementation of the NanoFabNet concept of sustainable nanofabrication. In the third report (i.e. *‘Annotated List of hard regulatory Requirements for Nanofabrication’*) the main existing legislations are identified and analysed that are able to contribute to the implementation of the NanoFabNet concept of sustainable nanofabrication in the EU, in the US and other countries and regions. In the

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<sup>1</sup> NanoFabNet *‘Report on the Concepts & Disciplines of Sustainability in Nanotechnology & Nanofabrication’* (October 2020) (accessed: 1. January 2022)



fourth report (i.e. *'Report on recommended "soft/exploratory" Sustainability Indicators for NanoFabNet'*) a certain number of indicators, frameworks and voluntary approaches were identified, analysed and classified that are able to contribute to the definition and implementation of the NanoFabNet concept of sustainable nanofabrication.

As a second source can be mentioned the two **NanoFabNet Development Workshops (DWs)**, which were organised and held by the NanoFabNet Project in March 2020 and January 2021, respectively. During the 1<sup>st</sup> Development Workshop, a first sketch of the NanoFabNet concept of sustainable nanofabrication was presented and discussed. During the 2<sup>nd</sup> Development Workshop, the refined NanoFabNet concept of sustainable nanofabrication was described, illustrated (in particular *via* different case studies), and discussed. The needs of the NanoFabNet stakeholders (in particular in terms of discovery of the relevant tools, of information, of public debate and intercultural dialogue) were collected and discussed.

As a third source can be mentioned the complementary literature, through the study and analysis of reports and documents directly relevant for the definition of a strategy for sustainability in nanofabrication, as well as its and an implementation roadmap. The following documents can be highlighted in particular, as they have been of some importance for the writing of this report:

- the report entitled *'Nanosafety in Europe 2015-2025: Towards Safe and Sustainable Nanomaterials and Nanotechnology Innovations'* (Savolainen et al., 2013);
- the report entitled *'Moving Towards a Safe(r) Innovation Approach (SIA) for More Sustainable Nanomaterials and Nano-enabled Products'* (OECD, 2020);
- the *'Mapping study for the development of Sustainable-by-Design criteria'* (Amodio et al., 2021);
- the *First report on the CG sessions, Deliverable D3.1* (SUSNANOFAB, 2021); and
- The concept paper entitled *'International Network Initiative on Safe and Sustainable Nanotechnologies (INISS-nano)'* (Falk et al., 2021).

## **2.2 Development of the NanoFabNet Strategy & Implementation Roadmap for Sustainability in Nanofabrication**

The different sources described above have enabled the NanoFabNet Project to organise its strategy for sustainability in nanofabrication around **four dimensions**, which recur in a consistent manner in all the reflections devoted to the advent of sustainable nanofabrication.

The first dimension consists in **'raising awareness of sustainability'**; it is related to a general need of information concerning sustainability in nanofabrication and its different stakes and methods. During the 2<sup>nd</sup> NanoFabNet Development Workshop, the stakeholders mentioned information dissemination as their first need (prior to training or workshops). They mentioned also the *'discovery and use of the different tools available'* as their first interest in terms of services in ethics (Figure 1).

**Question:** Among the different services in Ethics planned to be offered progressively by the NanoFabNet Hub, are you interested in:

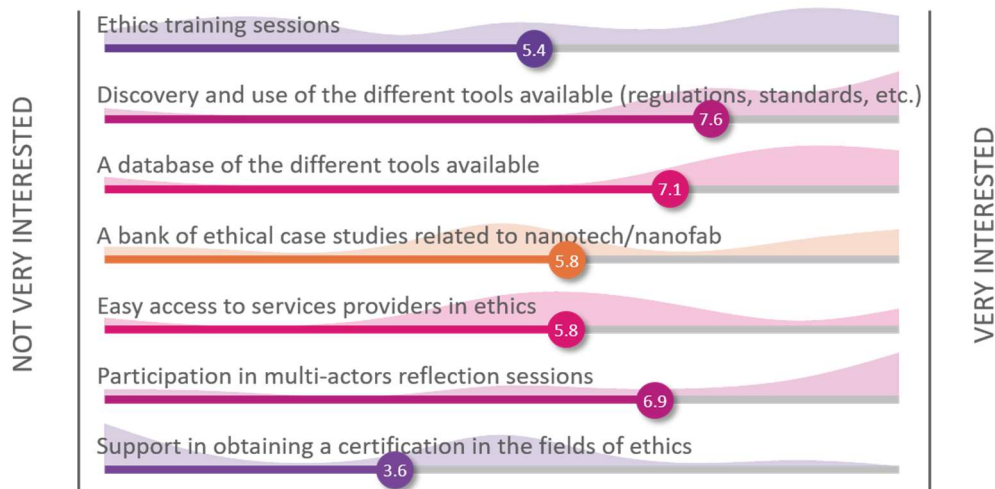


Figure 1: Screenshot of the results of a question posed to the NanoFabNet stakeholders: 'Among the different services in ethics planned to be offered progressively by the NanoFabNet Hub, are you interested in: [...]?'; the question was polled during the 2<sup>nd</sup> NanoFabNet Development Workshop, held on the 20<sup>th</sup> and 21<sup>st</sup> January 2021.

The second dimension consists in '**compliance with regulation and legislation**', as one of the first necessary steps to reach sustainability. During the 1<sup>st</sup> NanoFabNet Development Workshop, the stakeholders indicated that regulation requirements represent one of their main needs to increase confidence in sustainable nanofabrication (Figure 2).

**Task:** Classify these nanofab main issues regarding your needs in validation, harmonisation & standardisation to increase confidence in nanofab.

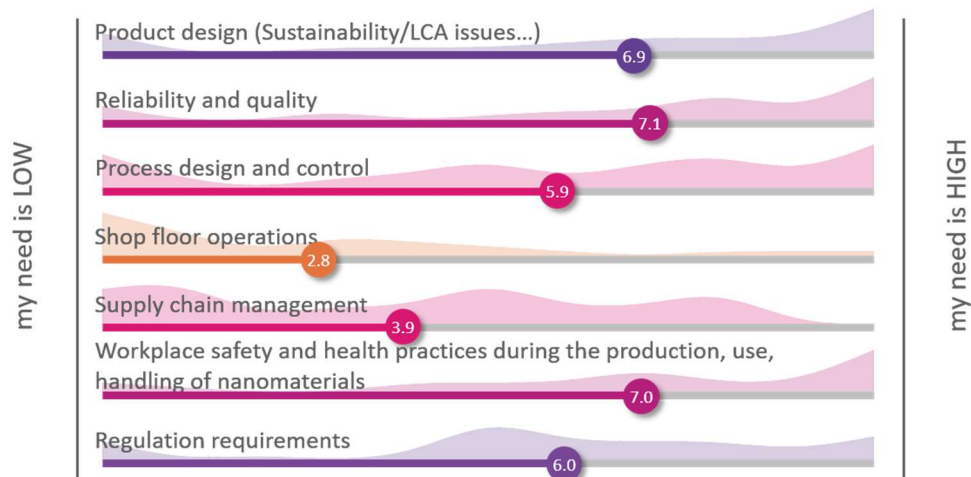


Figure 2: Screenshot of the results of a task asked of the NanoFabNet stakeholders: 'Classify these nanofab main issues regarding their needs in validation, harmonisation & standardisation to increase confidence in nanofab.'; the task was asked to be completed during the 2<sup>nd</sup> NanoFabNet Development Workshop, held on the 20<sup>th</sup> and 21<sup>st</sup> January 2021.



The third dimension consists in the **‘implementation of sustainability indicators’**. During the 2<sup>nd</sup> NanoFabNet Development Workshop, the stakeholders expressed great interest in investigating and applying some indicators-related methods (Figure 3).

**Question:** *What are the methodologies and tools that you would like to further investigate and apply to your business?*

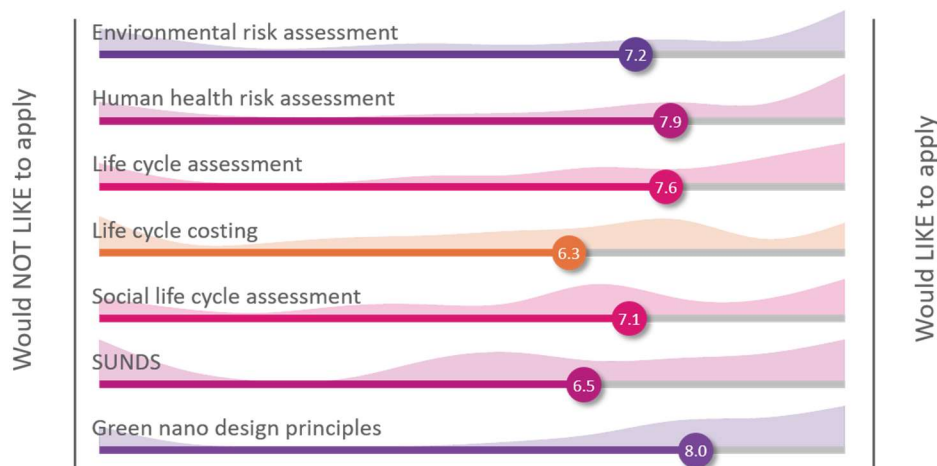


Figure 3: Screenshot of the results of a question posed to the NanoFabNet stakeholders: ‘What are the methodologies and tools that you would like to further investigate and apply to your business?’; the question was polled during the 2<sup>nd</sup> NanoFabNet Development Workshop, held on the 20<sup>th</sup> and 21<sup>st</sup> January 2021.

The fourth dimension consists in **‘building support and engagement for sustainability criteria’**; it encompasses - in particular - a great need in harmonisation of practices, as clearly expressed by the stakeholders during the 2<sup>nd</sup> NanoFabNet Development Workshop (Figure 4).

**Question:** *According to you, what could be the best way to define and share best practice regarding sustainability?*



Figure 4: Screenshot of the results of a question posed to the NanoFabNet stakeholders: ‘According to you, what could be the best way to define and share best practice regarding sustainability?’; the question was polled during the 2<sup>nd</sup> NanoFabNet Development Workshop, held on the 20<sup>th</sup> and 21<sup>st</sup> January 2021.

The dimension discussed above furthermore encompasses an important need in terms of discussion with all stakeholders and with civil society; during the 2<sup>nd</sup> NanoFabNet Development Workshop, an

important role was pleaded for civil society in the developments of nanotechnology and nanofabrication (Figure 5).

**Question:** Concerning the developments of nanotech/nanofab, would you say that civil society:

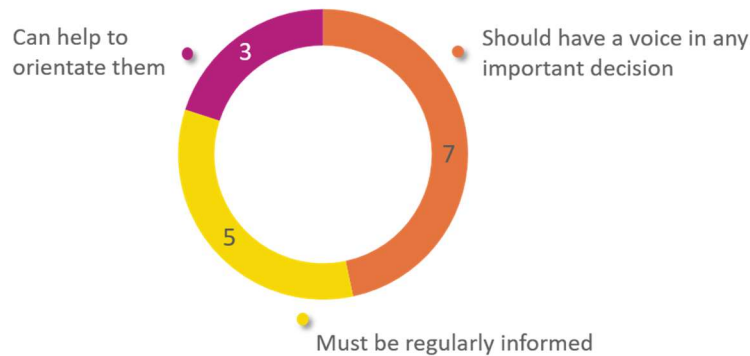


Figure 5: Screenshot of the results of a multiple-choice completion task asked of the NanoFabNet stakeholders: 'concerning the developments of nanotech/nanofab, would you say that civil society: [...]'; the task was asked to be completed during the 2<sup>nd</sup> NanoFabNet Development Workshop, held on the 20<sup>th</sup> and 21<sup>st</sup> January 2021.

## 2.3 Organisation of the NanoFabNet Strategy & Implementation Roadmap for Sustainability in Nanofabrication

The NanoFabNet strategy and implementation roadmap elaborated in this report is organised according to the four parallel dimensions introduced in the previous section; each one of the dimensions is treated in a separate chapter of this report.

Each dimension involves and concerns different kinds of stakeholders, who are sometimes the possible providers of the corresponding actions, and sometimes the target audience of them. There exist, of course, different kinds of links between the different dimensions, which cannot be considered as totally independent of each other:

- The first dimension (*i.e.* 'raising awareness of sustainability') encompasses issues related to the diffusion of information and of trainings towards the different communities of stakeholders, and their internal and external connexions.
- The second dimension (*i.e.* 'compliance with regulation and legislation') encompasses issues related to the compliance of stakeholders with legal requirements and the middle- and long-term evolutions of them.
- The third dimension (*i.e.* 'implementation of sustainability indicators') encompasses issues related to the use and the development of relevant sustainability indicators and the sharing of available sustainability data.
- The fourth dimension (*i.e.* 'Building support and engagement about sustainability criteria') encompasses issues related to the monitoring of sustainability performances, the collective definition of benchmarks, the possible creation of a label in sustainable nanofabrication and the general trends in sustainability governance.

For each of these dimensions, different kinds of actions are proposed, delineated and classified according to two main categories:

1. short- to middle-term actions, and

## 2. middle- to long-term actions.

In the general framework of this NanoFabNet implementation strategy, we adopted the following meaning for the different timescales:

- ‘Short-Term’: one to three years (*i.e.* 2022 to 2025);
- ‘Medium-Term’: three to eight years (*i.e.* 2025 to 2030); and
- ‘Long-Term’: beyond eight years (*i.e.* 2030 onwards).

The different categories of actions and recommendations identified and proposed by NanoFabNet and incorporated within the NanoFabNet strategy and implementation roadmap for sustainability in nanofabrication, can be summarised in the following diagram (Figure 6). The chapters 3, 4, 5, 6 of this report are then detailing respectively the four dimensions mentioned above.

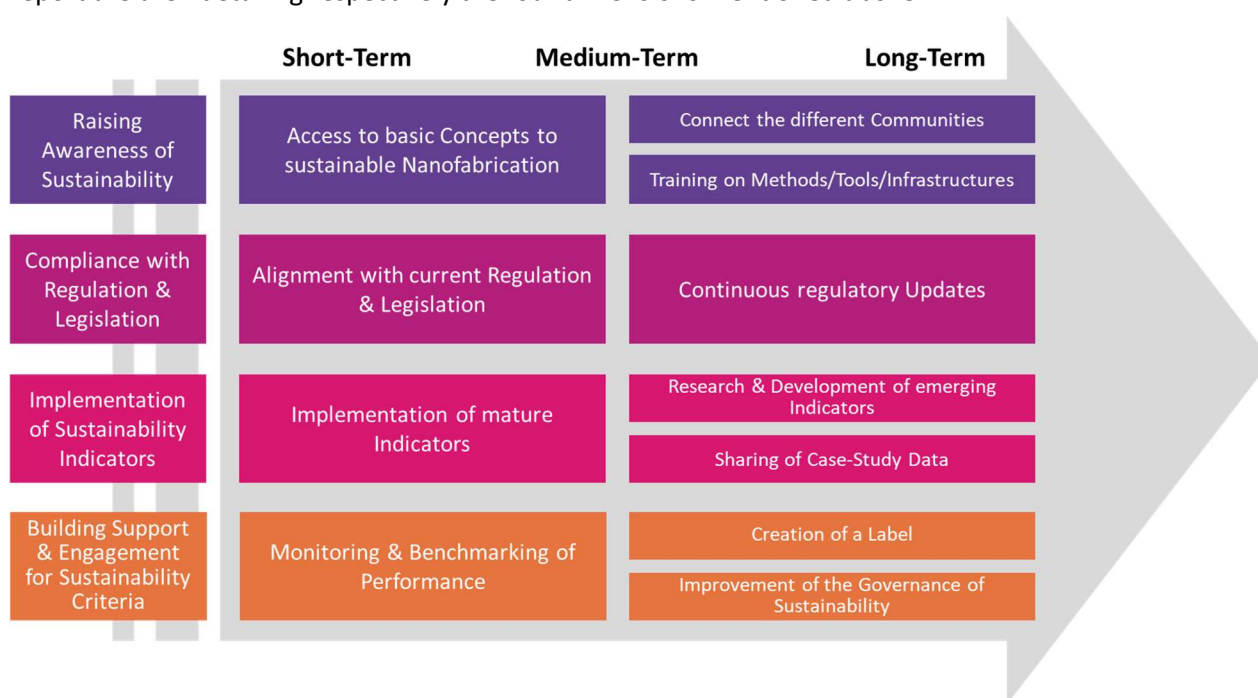


Figure 6: Diagram summarising the actions and recommendations of the NanoFabNet strategy and implementation roadmap for sustainability in nanofabrication.

## 3. Raising Awareness of Sustainability

This dimension deals with the need to raise the awareness of sustainability within the different categories of nanofabrication stakeholders. As a short-term to medium-term action, the creation of a platform providing access to basic concepts of sustainability in nanofabrication is recommended (see section 3.1). As medium-term to long-term actions, the connexion of the different communities and the development of trainings about sustainability in nanofabrication are recommended (see section 3.2).

### 3.1 Short- to Medium-Term Actions in support of Raising Awareness of Sustainability

There exist currently in Europe and worldwide diverse sources of information related to sustainability in nanotechnology and nanofabrication. Information is in particular relayed by organisations and initiatives, such as the EU's *NanoSafety Cluster (NSC)*<sup>2</sup>, the *European Observatory for Nanomaterials*

<sup>2</sup> [NanoSafety Cluster \(NSC\)](#) (accessed: 31. December 2021)



(EUON)<sup>3</sup>, the European Chemicals Agency (ECHA)<sup>4</sup>, the Organisation for Economic Co-operation and Development (OECD)<sup>5</sup>, and the Nanotechnology Industries Association (NIA)<sup>6</sup>, as well as numerous EU-funded research projects. The field furthermore benefits from some initiatives at national level, such as the *Association de veille et d'information civique sur les enjeux des nanosciences et des nanotechnologies (AVICENN)*<sup>7</sup> in France. Nevertheless, these sources are often incomplete, redundant, fragmented, or very specialised; moreover, they tend to focus mainly on issues related to health and environmental risks. It remains thus necessary to develop and generalise information that is relevant and applicable to the wider field of sustainable nanofabrication. The current situation furthermore manifests a need for unification, validation, and - to a certain extent - popularisation or translation/digest of information, to make it accessible and understandable to all stakeholders. Information must also be channelled to achieve full effectiveness.

The provision of access to basic concepts, tools and information related to sustainable nanotechnology and nanofabrication for all stakeholders should be organised, for example through a dedicated web platform. Such a platform could provide the following basic information related to:

- theoretical concepts of sustainability in nanofabrication;
- main players and main principles of sustainability in nanofabrication;
- relevant publications relating to sustainability in nanofabrication (e.g. articles, books, reports, national and international project deliverables, position papers);
- results of national and international projects relating to sustainability in nanofabrication;
- agenda of relevant events relating to sustainability in nanofabrication (e.g. seminars, conferences, webinars, events);
- major regulatory developments relating to sustainability in nanofabrication; and
- key associative events (e.g. actions, publications) in link with nanotechnology and nanofabrication development, in particular related to the dialogue between associations and institutions at national and international levels.

This information could prove useful to all the stakeholders of sustainable nanofabrication (incl. research and innovation communities, industry, politicians and decision makers, standardisation and regulatory bodies, interest groups and NGOs, media, general public). Specific rules in the collection of information and the operation of this platform should be enacted to ensure that the information thus made available is validated, made genuinely accessible and easily appropriated to its recipients, and finally to ensure that it is really intended for a plurality of actors (without of course refraining from imagining differentiated paths for the different audiences within this information).

## 3.2 Medium- to Long-Term Actions in Support of Raising Awareness of Sustainability

### 3.2.1 Connect the different Communities

Achieving sustainable nanofabrication is a collective challenge. Various NanoSafety communities are already existing in Europe, diversely structured according to regions and nations. In general, the different communities of stakeholders that make up sustainable nanofabrication suffer from a lack of internal connexions and mutual interactions. It seems necessary to unify each of these communities around issues specific to nanotechnology and nanofabrication; to develop links between these

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<sup>3</sup> [European Observatory for Nanomaterials \(EUON\)](#) (accessed: 31. December 2021)

<sup>4</sup> [European Chemicals Agency \(ECHA\)](#) (accessed: 1. January 2022)

<sup>5</sup> [Organisation for Economic Co-operation and Development \(OECD\)](#) (accessed: 1. January 2022)

<sup>6</sup> [Nanotechnology Industries Association \(NIA\)](#) (accessed: 1. January 2022)

<sup>7</sup> [Association de veille et d'information civique sur les enjeux des nanosciences et des nanotechnologies \(AVICENN\)](#) (accessed: 1. January 2022)



different communities; and – in turn – to bring together the actors active in the field of sustainability with the actors active in the field of nanotechnology and nanofabrication.

The first step consists in improving the connexions between the actors working on issues specific to sustainability in nanotechnology and nanofabrication within their respective professional communities, both nationally and internationally. The following examples of communities can be mentioned:

- the competent actors in the Life Cycle Assessment (LCA) applied to nanotechnology and nanofabrication (whose mutual links are still embryonic in Europe);
- the service providers in the field of nanosafety and nanosustainability, at both national and European levels (see for example the propositions made in Marcoulaki et al. (2021));
- the different NGOs and interest groups active in the field of nanotechnology and nanofabrication, to promote the common expression of societal expectations and concerns on these topics; and
- those of the technical players in nanotechnology and nanofabrication who are particularly open to sustainability issues.

In support of the success of each of these communities, classic tools could be developed, such as (but not limited to) repositories of actors and projects, repositories of reports, guidance and methodologies, regular meetings, working groups.

The second step consists in promoting and allowing the interaction of the communities thus created, on the one hand with each other, on the other hand with the other stakeholders in nanotechnology and nanofabrication (including research and innovation communities, industry communities, politicians and decision makers, regulatory bodies, general public). These cross- and long-term interactions can - for example - be organised as follows:

- around specific themes;
- through interdisciplinary working groups devoted to the different fields of application and their specific challenges (*e.g.* in medicine, energy, electronics, construction);
- around *ad hoc* requests (for example arising from the requirements associated to the regular regulatory changes); and
- in link with commercial regular trades (such as those between industries and service providers).

The necessary efforts mentioned above can rely on numerous pre-existing associations: for example, in the the general (and non-nano-specific) networks of toxicologists, risk assessors, life cycle sustainability assessment practitioners, ethicists at various regional, national and supra-national levels. Some existing structures dedicated to nanotechnology and nanofabrication at national and international levels (such as, for example, the *C'Nano* network in France<sup>8</sup>, or the *EU NanoSafety Cluster* at the European level) can also be useful as catalysts. The *NanoSafety Cluster*, currently mainly focused on EU-funded research projects, could - in particular - gain by evolving towards a wider connexion of the actors and the various communities present in these projects. It could also be worth considering the creation of new working groups dedicated to life cycle sustainability issues, or ethics and governance issues, within the *NanoSafety Cluster*, to connect the relevant EU-funded projects in these areas.

All these initiatives would help to promote the emergence of authentic communities of sustainable nanofabrication, which could exist at different regional, national and supra-national levels, and benefit from different institutional support (*e.g.* regions, states, Europe, other kinds of *ad hoc* associations) (see for example Shandilya et al. (2020), which discusses the national levels). From these communities

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<sup>8</sup> [C'Nano network](#) (accessed: 31. December 2021)

could emerge, in the long term, propositions for regulations and good practices, capable of guaranteeing the advent of a real sustainable nanofabrication.

### **3.2.2 Trainings on Methods, Tools and Infrastructures**

General information and awareness of the various stakeholders are currently insufficient to promote the advent of sustainable nanofabrication. First, the technical players in nanotechnology and nanofabrication (*i.e.* researchers and industry in particular) must be made more aware and educated about the issue of sustainability concerning their products, processes and services, both in terms of topicality of concerns and of the means and tools to deal with them. Secondly, a wider range of actors (*e.g.* regulators, politicians, media, NGOs) also suffer from a lack of information and long-term awareness to properly exercise their role in the direction of sustainable nanofabrication. Finally, civil society in the broad sense is too often poorly informed; it should be endowed with the appropriate resources to be able to understand the reality and the complexity of situations related to nanotechnology and nanofabrication, and to take a full role in the corresponding debates. The lack of social acceptability today remains a major obstacle to the advent of sustainable nanofabrication, and a concerted approach to information is undoubtedly the first step in trying to overcome it.

There is a need to develop and systematise training courses relating to the various challenges of sustainability in nanofabrication. With regard to the traditional players in nanotechnology and nanofabrication, such trainings should be systematically offered or integrated: in the framework of nanotechnology and nanofabrication training courses (*i.e.* from the Master-level, as well as in the training framework of doctoral students); within Research and Development structures in nanotechnology and nanofabrication; within companies in the nanotechnology and nanofabrication sectors. These trainings should be adapted to the different audiences; they could range from introductions and more general considerations to very specialised trainings for professionals of risk assessment in laboratories and companies. They should be provided by specialists from the different disciplines, in a general spirit of awareness and empowerment of stakeholders. While safety aspects are more commonly covered, it is important to also tackle life cycle sustainability and ethical aspects of sustainable nanofabrication.

The training offers should also be generalised:

- To politicians and decision makers, it is advisable to offer training allowing them to understand the novelty of the challenges of sustainable nanofabrication, and to take relevant decisions.
- To standardisation and regulatory bodies, regular training should be provided on technological advances, and knowledge enabling them to best orientate them (*i.e.* training is, in particular, supposed to be an important aspect of the ‘regulatory preparedness’ concept, as promoted for example by the OECD (2020)).
- To interest groups and NGOs, it is important to provide regular information on advances in science and technology, on toxicological and regulatory news, and on the many related issues.
- For the media, which sometimes tend to disseminate only incomplete information, it is advisable to offer transparent, balanced and contradictory information content.
- Finally, concerning civil society, a very specific effort to disseminate and popularise the state of knowledge available on the various challenges of sustainable nanofabrication should be carried out. Politicians, the media and NGOs can contribute to this, but this duty also falls on researchers, manufacturers, regulators, as well as all stakeholders in sustainable nanofabrication, by all available means (*e.g.* conferences, workshops, media interventions, organisation of public debates and participatory processes).



## 4. Compliance with Regulation and Legislation

Being compliant with regulation and legislation is one of the key steps for industry to manufacture, to place on the market and to use raw materials, technologies, or final products. To do so, a certain number of legal instruments are made available and are usually divided into two categories: binding and non-binding instruments; of these, the legally binding instruments are the ones that define mandatory requirements applicable to certain activity sectors, which are required to be compliant with the provisions of those legal instruments.

Being compliant with legal requirements represents an important challenge for many industries that need to be aware of multiple, constantly evolving legal instruments. To review the current regulatory framework on nanomaterials and identify the legal obligations explicitly applicable to nanomaterials can be the main focus in the short-term actions (see section 4.1) with an emphasis on awareness raising of industry. A continuous regulatory watch on planned or on-going initiatives to anticipate potential (further) regulatory requirements for nanomaterials should be considered for long-term actions (see section 4.2).

### 4.1 Short- to Medium-Term Actions in Support of Compliance with Regulation and Legislation

According to Rauscher (2017), nanomaterials (NMs) are present in many sectors (*e.g.* chemicals, consumer products, environment) and nanotechnology is considered to be a key enabling technology (KET) (Rauscher, 2017). Therefore, NMs are explicitly or implicitly covered by several pieces of horizontal and sector-specific legislations of the EU's regulatory framework. The report '*Support for 3<sup>rd</sup> regulatory review on nanomaterials – environmental legislation*' (Broomfield et al., 2016) pointed out that regulated man-made nanomaterials represent a challenge, since different nanoforms of the same chemical substance can have different properties and most of the existing regulations were designed to deal with the risks of conventional materials. During the last few years and since the EU adopted a definition for a nanomaterial in 2011, however, several EU legislations were amended to explicitly address nanomaterials and include nanomaterial-specific information requirements. Furthermore, even if they are not explicitly mentioned, in principle, nanomaterials, and especially potential risks associated with them, are covered by existing legislation.

In the framework of the NanoFabNet Project, a comprehensive regulatory review of more than 80 pieces of legislation was conducted with the aim to identify the legal instruments with specific requirements for nanomaterials, and was reported in the NanoFabNet report '*Annotated List of hard regulatory Requirements for Nanofabrication*' (confidential). The results of the review identified 15 pieces of legislation with specific provisions for nanomaterials, which cover only few areas as for example chemicals, cosmetics, medical or food areas. 14 other pieces of legislation were identified with provisions that implicitly cover nanomaterials as for example chemicals, plant protection products, waste or water legislations. Besides the legislation available at the European level, five Member States have taken national initiatives to request more information on nanomaterials from industry.

For an industry trying to be compliant with the legal requirements inherent to its activities, the first thing is to be aware about the different current legislations applicable, and to find the correct information and guidance helping it to proceed. At the European level, the first official information source is Eur-Lex website<sup>9</sup>, which is an online gateway to EU law and which provides an official and comprehensive access to EU legal documents. Due to the number of new legislations published every day, using this official information source can be a challenge for industry, and there is thus a need to have a centralised information source. Several data sources already exist, and the regulatory monitoring database provided by NIA (NIA, 2021) can be mentioned as example. But the limitation of

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<sup>9</sup> [Eur-Lex website](#) (accessed: 31. December 2021)

this database is that only the members can easily access to it. Another information source, available at the European level, that can be relevant for industries that need information about their obligations is the EUON<sup>3</sup>, funded by the European Commission and hosted and maintained by the ECHA<sup>4</sup>; it constitutes one of the most complete sources of information on legal obligations in Europe, but also on general information about nanomaterials. The availability of several information sources often represents a challenge for industry to find correct and relevant information. A solution could be the elaboration of a portal to centralise the different sources, and the EUON website could be an interesting starting point. This centralised portal could also refer to the different available guidance available to help in the practical aspects to be compliant with legal obligations.

Finding the relevant information is one of the key points, in order to put in place necessary actions to be compliant with legal obligations. Practical guidance is one of the supports but awareness raising actions are also a support often appreciated by industry and especially by small businesses. This type of action is already in place and webinars organised by ECHA can be mentioned as an example with a webinar organised in 2020 to provide practical tips on how to register nanoforms under the *Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)* regulation<sup>10</sup> (ECHA, 2020). All relevant events could also be made available in the portal mentioned in the previous paragraph.

Besides the need for information, determining exactly what are the obligations of each specific activity of industries is another step to be compliant. Several software tools are already available on the market to help industries to follow what are the current but also new legal texts published relevant for their business. Companies can also ask for service providers to help them on this task. A common aspect of such solutions is that they are paid services. A solution that could be developed is a free decision tool that could be used by companies to better target their obligations. ECHA already provides such a tool, ECHA navigator (ECHA, 2021), for companies that need to determine their obligations under the obligations of the REACH) regulation<sup>10</sup> and the *Classification, Labelling and Packaging (CLP)* legislation<sup>11</sup>. This tool provides clarification on the role in the supply chain, the legal obligations, and provides relevant guidance. The results are based on answers given by a company to a series of questions.

#### **4.2 Medium- to Long-Term Actions in Support of Compliance with Regulation and Legislation**

Besides the need to clearly understand and be compliant with the current legislations in place, industry also needs to follow the on-going and future initiatives related to new developments and improvements of the legislations to define the future constraints that could impact their businesses. The case of the chemicals sector is typically one sector that needs to be aware about future legal developments, in that companies need to follow the developments pertaining to substances that could be forbidden on the European market in the next years and try to develop safer alternatives at the any stage of their business.

In section 4.1 above, we mentioned that several tools were available to support companies on the follow-up of current and new obligations, but we did not consider initiatives on future developments of the legislations; by way of an example for one such initiative, the European Commission already provides a platform entitled '*Have your say*' (EC, 2021a), which allows businesses and also citizens to share their views on up-coming new and revision of an existing regulation or legislations. Following the future regulatory developments and identifying future regulatory constraints, however, needs a time investment not always possible for small businesses.

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<sup>10</sup> [Registration, Evaluation, Authorisation and Restriction of Chemicals \(REACH\) regulation](#) (accessed: 31. December 2021)

<sup>11</sup> [Classification, Labelling and Packaging \(CLP\) Legislation](#) (accessed: 31. December 2021)

The centralised information platform mentioned above could be used as a solution to provide in one place the different information related to the running initiatives concerned with regulation and legislation. One concrete example of an on-going initiative provided by the European Commission is the review of the *'Recommendation on the definition of a nanomaterial'* (2011/696/EU)<sup>12</sup> on the definition of nanomaterials; a stakeholder consultation was concluded on the 30<sup>th</sup> June 2021 to update, test and verify the preliminary findings of this comprehensive review, gathering further evidence and feedback from a wide range of stakeholders who have a role in the application of the harmonised regulatory definition of nanomaterials in the EU (EC, 2021b). The review of this definition was one of the actions of the *'European Chemicals Strategy for Sustainability'* (EC, 2020a) concerning the simplification and consolidation of the legal framework. To achieve consistency of regulatory outcomes, the use of a coherent terminology is indeed a need, in particular to define the substances in question.

## 5. Implementation of Sustainability Indicators

Besides the mandatory requirements for the compliance with regulation, sustainability indicators can be applied by nanotechnology and nanofabrication stakeholders, and monitored to steer the development and the deployment of nanotechnology and nanofabrication. As highlighted in the NanoFabNet *Report on recommended 'soft/exploratory' Sustainability Indicators for NanoFabNet*, there is a variety of sustainability indicators, covering three areas:

- i. *Environment, Health and Safety;*
- ii. *Life Cycle Sustainability (including environmental, economic and social sustainability); and*
- iii. *Ethics and Governance.*

Several related methodologies and tools exist, but with a variable maturity level. Sustainability indicators with a higher level of standardisation and harmonisation can be prioritised in the short-term (see section 5.1), while research development should be made on a longer-term to improve the methods with lower maturity (see section 5.2.1). The wider spread and improvement of related methods can be facilitated with the increased availability of data (see section 5.2.2). This chapter details the roadmap to facilitate and improve this implementation.

### 5.1 Short- to Medium-Term Actions in Support of the Implementation of Sustainability Indicators

#### 5.1.1 Integrate Sustainability Criteria for the Development of new Nanotechnology and Nanofabrication

Since nanotechnologies remain emerging technologies, it is crucial to integrate sustainability criteria within their development stages to ensure that they will contribute to the transition towards a sustainability society. At European level, the *'Sustainable Products Initiative'*<sup>13</sup> is going in that direction and the alignment with '(Safe) and Sustainable-by-Design ((S)SbD)'-criteria might become a prerequisite to enter the EU market. This action should be implemented by technology developers (industry or research organisation), and can be supported by experts in the sustainability areas, internally or externally.

Until now, the concept of 'Sustainable-by-Design' focuses on safety and environmental sustainability (EC, 2021c). This is the case for the 'Green Nano' design principles (University of Bremen, 2016) that were defined to facilitate the sustainable design of nanotechnology-enabled products. These principles

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<sup>12</sup> [Recommendation on the definition of a nanomaterial \(2011/696/EU\)](#) (accessed: 1. January 2022)

<sup>13</sup> [EU Sustainable Products Initiative](#) (accessed: 31. December 2021)



can be used as guidelines, but a more quantitative approach is recommended to better understand the sustainability performances.

At a low Technology Readiness Level (TRL), the online tool *LICARA NanoSCAN*<sup>14</sup> (van Harmelen et al., 2016) can be used to estimate the benefits and risks of a nanotechnology-enabled product. The tool includes environmental benefits (qualitative comparison based on energy and materials flows), economic benefits (qualitative comparison based on purchase price and operational costs), societal benefits (qualitative benefits of the application and of the labour force qualification), public health & environmental risks (estimates of the potential effect and input into the environment), occupational health risks (risk category based on hazard and exposure scores from *Stoffenmanager*<sup>15</sup>), and consumer health risks (risk category based on nanoelement location and exposed consumer population). The scores for each category are normalised (scale 0 to 1) and aggregated (equal weighting factor) to map the net benefits and risks and support the further design. However, a more robust approach based on standardised methodologies to quantify the impacts and risks of nanotechnology applications is recommended. In this regards the OECD report '*Moving Towards a Safe(r) Innovation Approach (SIA) for More Sustainable Nanomaterials and Nano-enabled Products*' (OECD (2020)), based on the review and integration of the work done within two previous reports (OECD (2017) and OECD (2018)), has drawn a lot of principles that are recognised as helpful to evaluate the extent of Safe-by-Design (SbD) implementation in different domains. This document lists a number of risk assessment tools, frameworks and initiatives developed for Safe(r)-by-Design and aids the understanding of the relevant terminologies used in this field. The inventory of risk assessment tools and frameworks should contribute in assisting industries to implement a 'Safe(r) Innovation Approach' for NMs and nanotechnology-enabled products contributing in increasing the awareness of the stakeholders about SbD concepts, as well as increasing the 'Regulatory Preparedness'.

Within the *NanoReg2* project<sup>16</sup>, Salieri et al. (2021) proposed a stepwise approach to integrate an SSbD concept, based on the application of risk assessment, life cycle assessment (LCA) and socio-economic analyses.

Depending on the development stage (*i.e.* from business idea to market entry), the data requirements for the three assessment methodologies and associated tools are detailed. Indeed, the lack of experimental and quantitative data at low TRL implies the use of proxies (*e.g.* characterise human hazard based on a bulk material or similar nanoparticles, use estimates to perform LCA). This framework can be used as starting point, knowing that the sustainable-by-design concept will evolve with the definition of criteria by the European Commission (expected in 2022) and the ongoing research work to improve the approach (incl. future European research projects funded within the Horizon Europe Framework Programme).

### 5.1.2 Sustainability Indicators to support Decisions

The actions described in the previous paragraph were focusing on how to make use of sustainability indicators to integrate sustainability in the development of a new technology, in particular at low TRL. Some of them are qualitative, and they concern mainly technology developers in industry and research. Nevertheless, besides the support to the development of a new technology, sustainability indicators can also be useful to a wider range of stakeholders from industry, regulatory bodies or policy, be it to improve their current practices, to support their strategies and decisions, or for communication purposes. The outcomes of these actions should feed the medium- to long-term actions in terms of research development and data sharing (section 5.2). The specific methods and guidelines that can be used are detailed below for the three sustainability areas.

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<sup>14</sup> [LICARA NanoSCAN](#) (accessed: 31. December 2021)

<sup>15</sup> [Stoffenmanager](#) (accessed: 31. December 2021)

<sup>16</sup> [NanoReg2 project](#) (accessed: 1. January 2022)



## 5.1.2.1 Environment, Health and Safety

Chemical safety is considered a necessary element of the wider concept of sustainability, as described by the United Nations Sustainable Development Goals (among other sources) (OECD, 2020). How to reduce the uncertainties and risks for human and environmental safety along the value chain, keeping high product efficiency is a topic still under discussion also at the *OECD Working Party on Nanomaterials* (WPNM)<sup>17</sup>. The different initiatives proposed to support future decision-making when developing more sustainable products, processes and uses are still far from being completely validated, but their application to different case studies would allow starting to identify gaps in the proposed decisional framework, as well as to better set the applicability domains. A comprehensive review of the existing tools developed to implement the sustainability criteria in the life cycle, with a specific focus on the safety of products at design stage, use stage and end of life, is done in Jantunen et al. (2017). Unfortunately, only few of these tools are covering the whole value chain: *LICARA NanoSCAN*<sup>14</sup>, *SUNDS*<sup>18</sup>, the *GuideNano Tool*<sup>19</sup>, the *Stoffenmanager Nano Module*<sup>20</sup>, and *NanoSafer CB*<sup>21</sup> are among the most complete ones. Others, like the *Precautionary Matrix for Synthetic Nanomaterials*<sup>22</sup>, the *ANSES Control Banding Tool for Nanomaterials*<sup>23</sup>, and the *SbD Implementation platform* (by TEMAS) consider only few stages of the value chain. There are also models that are focused on hazard prediction only (like QSAR, Bayesian Methodology or -mics); these are thus mainly useful at the design stage, while yet other are helpful in understanding the potential risk for the environment, due to the production phase or the end of life (e.g. the outputs of the *NanoRelease project*<sup>24</sup>, the *NanoFATE project*<sup>25</sup>, the *NanoFASE project*<sup>26</sup>) (OECD, 2020). The aforementioned instruments are also easily attributable to the categories of ‘risk assessment’ and ‘occupational safety indicators’ described in detail in the ‘*Report on recommended ‘soft/exploratory’ Sustainability Indicators for NanoFabNet*’ (confidential).

The direct application of these tools might be considered as a short-term action that could help SbD strategy implementation. As previously mentioned, the definition of short-term actions refers to the maturity level of the tool which has been applied. Also, the alignment with well-established regulatory procedures (not binding for the specific test case) and classified in the ‘*Report on recommended ‘soft/exploratory’ Sustainability Indicators for NanoFabNet*’ as a potential ‘hard indicator requirement’ could be classified as short-term action. This is because the application of an already existing set of rules could be faster than the development of a completely new discipline from scratch, but then its implementation might require a lot of time. It should be additionally pointed out that referring to not nanotechnology-specific regulation might lead to an overestimation of the exposure risks (Brouwer et al., 2010), and thus to a wrong decision at the end of the process.

## 5.1.2.2 Life Cycle Sustainability (including environmental, economic and social Sustainability)

Regarding life cycle sustainability, the only standardised methodology for now is LCA (i.e. ISO14040/44:2006 - Environmental management — Life cycle assessment — Principles and framework

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<sup>17</sup> [OECD Working Party on Nanomaterials](#) (accessed: 1. January 2022)

<sup>18</sup> [SUNDS \(Decision support system for risk assessment and management of nano\(bio\)materials used in consumer products and medical applications\)](#) (accessed: 31 December 2021)

<sup>19</sup> [GuideNano Tool](#) (accessed: 31 December 2021)

<sup>20</sup> [Stoffenmanager Nano Module](#) (accessed: 31 December 2021)

<sup>21</sup> [NanoSafer Control Banding \(CB\) tool](#) (accessed: 31 December 2021)

<sup>22</sup> [Precautionary Matrix for Synthetic Nanomaterials](#) (accessed: 31 December 2021)

<sup>23</sup> [ANSES Control Banding Tool for Nanomaterials](#) (accessed: 31 December 2021)

<sup>24</sup> [NanoRelease project](#) (accessed: 31 December 2021)

<sup>25</sup> [NanoFATE project](#) (accessed: 31 December 2021)

<sup>26</sup> [NanoFASE project](#) (accessed: 31 December 2021)





(ISO, 2006), while ISO14075 for social life cycle assessment (S-LCA) is under development<sup>27</sup>. The ISO Standard for LCA remains generic and some further guidance documents can be used, in particular the EU's *Product Environmental Footprint*<sup>28</sup> and the standards CEN/TS 17276 for specific guidelines regarding the LCA application to manufactured nanomaterials (CEN, 2018). LCA is a comprehensive approach with several environmental indicators. The impacts on climate change (e.g. the carbon footprint) are the most evaluated. The availability of data and additional standards (e.g. ISO 14067:2018 on '*Greenhouse gases — Carbon footprint of products — Requirements and guidelines for quantification*') makes this indicator the most mature and easiest to implement, although it still requires a minimum of knowledge of LCA tools. Additionally, circular economy indicators could be used, but there is no consensus regarding their definition. Since they rely on simple calculations (e.g. share of material inflow), they can be used easily but should be complemented with more robust indicators.

Regarding economic sustainability, conventional evaluation of capital and operational expenditures can be done easily, as well as cost-benefit analysis per stakeholder to understand the viability and profitability of a technology or product. The application of life cycle costing (LCC) is not harmonised but can follow the same principles of LCA, associating prices to the input and output flows. The inclusion of external costs is possible (externalities such as future costs for pollutant removal). The assessment of social sustainability (S-LCA) is quite recent and can rely on the UNEP guidelines (UNEP, 2020), a revision of the UNEP-SETAC 2009 guidelines. The impacts (i.e. both positive and negative) on workers, local communities, value-chain actors, consumers and children can be assessed. A drawback, however, is that indicators often remain semi-quantitative (e.g. scale from low to high risk), due to the lack of data. The few S-LCA studies for nanotechnology (Pucciarelli, Traverso & Lettieri, 2021; Subramanian et al., 2018) can be used as examples.

The three sustainability pillars can be integrated *via* life cycle sustainability assessment (LCSA), which is not standardised but can rely on a guiding document from UNEP-SETAC (UNEP-SETAC, 2011). The most common LCSA approach is to perform LCA, LCC and S-LCA separately and interpret and/or aggregate the obtained results, most often using Multi-Criteria Decision Analysis (MCDA).

Only one study (Visentin, da Silva Trentin, Braun & Thomé, 2021) was found for an LCSA application on nanotechnology (synthesis of nanoscale zero valent iron for contaminated site remediation).

The comprehensive evaluation of sustainability can be supported by the *SUNDS*<sup>18</sup> assessment tool (Malsch et al., 2018). It consists of risk assessment and control, environmental and socio-economic assessment modules, as well as a stand-alone self-assessment tool to check compliance of a company's risk management procedures with the *CENARIOS*<sup>TM</sup> tool<sup>29</sup>. Sustainability criteria are aggregated in a similar fashion to for the *LICARA NanoSCAN* tool<sup>14</sup> (i.e. equal weighing for aggregation and visual representation with colour codes).

### 5.1.2.3 Ethics and Governance

Regarding Ethics and Governance in nanotechnology and nanofabrication, some harmonised or standardised frameworks and tools are already existing. First, two nano-specific documents deserve to be mentioned. The 2008 European Commission *Code of Conduct for Responsible Nanosciences and Nanotechnologies Research* (EC, 2008) is organised around a list of basic principles to be promoted: (a) Meaning, (b) Sustainability, (c) Precaution, (d) Inclusiveness, (e) Excellence, (f) Innovation, and (g) Accountability. The (not certifiable) CEN/TS 16937:2016 standard entitled '*Nanotechnologies – Guidance for the responsible development of nanotechnologies*' (CEN, 2016) rests on seven core principles to be implemented: (a) Board Accountability, (b) Stakeholder Involvement, (c) Worker

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<sup>27</sup> [ISO/AWI 14075 - Principles and framework for social life cycle assessment](#) (accessed: 31 December 2021)

<sup>28</sup> [Product Environmental Footprint](#) (accessed: 31 December 2021)

<sup>29</sup> [CENARIOS<sup>TM</sup>](#) (accessed: 31. December 2021)





Health and Safety, (d) Benefits to and Risks for Public Health, Safety and the Environment, (e) Wider Social and Ethical Implications and Impacts, (f) Engagement with Business Partners, and (g) Transparency and Disclosure). These documents can be useful to guide researchers, companies and other stakeholders in their approach to responsibility, even if they remain general and lack criteria and indicators.

In the course of the development of a new nanotechnologies, it is also already possible to perform an upstream Ethical Impact Assessment (EIA). EIA allows to identify and to screen the possible ethical impacts of a developing technology. A current and fully nano-relevant guidance for EIA is in particular given by the *CEN Workshop Agreement: Ethics assessment for research and innovation - Part 2: Ethical impact assessment framework* (CWA 17145-2)<sup>30</sup>. Some recommendations for adapting the CWA 17145-2:2017 to fit into a more-encompassing decision support system for risk governance of nanomaterials are also provided in Malsch et al. (2020). EIA tools and methodologies consist mainly of procedures to be followed, which can include the use of ethics experts or the consultation of stakeholders.

At last, a plurality of non-nanotechnology-specific ethical tools and frameworks can nevertheless be considered as useful for dealing with nanotechnology and nanofabrication. Numerous already existing ethical codes of conduct (e.g. codes related to the international ethical compendium, professional and sectoral ethics codes, industrial codes) can guide stakeholders in their efforts towards a responsible development of nanotechnology and nanofabrication. Concerning OECD publications, among several other ones, the recent *Recommendation of the Council on Responsible Innovation in Neurotechnology* Report (OECD, 2019a) and the *Recommendation of the Council on Artificial Intelligence* Report (OECD, 2019b) provide guidelines and references for dealing with ethical issues in different fields, in which nanotechnology can be involved. The different guidance's used by the European Commission in ethics screening of H2020 funded projects (e.g. on dual use ethical issues, on misuse ethical issues) can also be mentioned. Finally, some sectoral ethical standards can be relevant since they can concern nanotechnology-enabled applications. One can mention in particular, among different other ones, the ethical standards related to autonomous and intelligent systems currently being developed by the Institute of Electrical and Electronics Engineers (IEEE) in the framework of its Ethically Aligned Design Program<sup>31</sup>, and which include standards for ethics by design, data privacy, ethically driven robotics and automation systems.

## 5.2 Medium- to Long-Term Actions in Support of the Implementation of Sustainability Indicators

### 5.2.1 Research and Development of emerging Sustainability Indicators

Even though the LICARA NanoSCAN<sup>14</sup> and SUNDS tools<sup>18</sup> can support the assessment of the sustainability benefits and risks of nanotechnology, research gaps and limitations still need to be tackled to improve the reliability and credibility of the indicators. These developments should be performed by researchers in the sustainability and nanotechnology fields and should lead to a higher standardisation and harmonisation of the methods.

#### 5.2.1.1 Environment, Health and Safety

Although a lot of efforts have been done to collect the large amount of data already available, there are still gaps on information at different stages of the product value chain for nanotechnological applications. First of all, the risk assessment procedure is particularly complex, because of the need of

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<sup>30</sup> [CEN Workshop Agreement: Ethics assessment for research and innovation - Part 2: Ethical impact assessment framework. CWA 17145-2](#) (accessed: 31. December 2021)

<sup>31</sup> [IEEE Ethically Aligned Design Program](#) (accessed: 31. December 2021)

evaluating different aspects not common to other chemicals, for which the procedure could be considered quite consolidated, at least from a theoretical point of view. With specific regards to nanotechnological applications, the list of physico-chemical properties that have to be evaluated is quite broad and the experimental techniques helpful to this purpose are not easily accessible by all the stakeholders. In addition, the settings of exposure scenarios, exposure routes, exposure concentrations need to be evaluated on a case-by-case basis and often require the support of a group of experts. The monitoring of environmental concentrations is not always possible because of the difficulty in distinguishing the emissions from the natural background or because the techniques of analysis are not enough sensitive or appropriate to detect specific substances. The further development of basic experimental techniques would be helpful, not only to increase the knowledge on the new substances, but also to support the development and the implementation of SbD strategies, since they could count on more reliable methods for the collection of the missing information. If experimental techniques are not available, or if their use was itself not sustainable, the adoption of alternative methods to predict hazard, exposure and risk related to nanotechnologies could help in filling the gap. With this regard, OECD (2017) is describing in detail the status of these alternative methods and their field of application.

The engagement of industrial actors in European projects focused on SbD implementation is a relatively simple way to put together the different subjects and to foster the collaboration and the information exchange. On the one hand, industrial actors could gain experience in applying specific tools with the help of people directly involved in the development of such tools. On the other hand, such an exercise would allow the developers to come in close contact with the specific needs of the single industrial sectors, in order to apply the most appropriate strategy to each case. The active participation of the industrial sector to the different surveys administered through various kinds of European initiatives is also an important milestone to strengthen the dialogue among the different stakeholders. In addition, a stronger collaboration among innovators, industry, regulatory bodies in a 'trusted environment' (meant as a physical or virtual place where the confidentiality is ensured (see OECD, 2020)) would be beneficial for a better harmonisation of the basic concepts and the fulfilling of the different requests. The development of new tools and sustainability indicators based on this kind of collaboration would finally combine the efforts of the different stakeholders in the same direction for a more sustainable development of nanotechnologies.

#### **5.2.1.2 Life Cycle Sustainability (including environmental, economic and social Sustainability)**

LCA was applied in more than 200 studies to assess the environmental impacts of nanomaterials or nanotechnology-enabled products. The application of LCA in the nanotechnology field raises some challenges (Hischier, 2021). First, the definition of the functional unit (used to compare equivalent systems) can be critical due to the potential additional functions brought by nanotechnology and the uncertainties related to their characterisation. Then, the low maturity of the technologies implies a lack of representative data to model the life cycle inventory and additional uncertainties regarding upscaling effects or market deployment. In addition, the release of nanoparticles along the life cycle is poorly characterised and the influence of aging processes on the nanoparticle properties should be further investigated. Finally, there is an additional difficulty to model the (eco-)toxicity impacts of nanoparticles, due to the lack of characterisation factors (need to adapt fate and exposure modelling, issues related to the reliability of testing procedures). Besides the improvement of the conventional LCA methodology, developments towards absolute environmental sustainability assessment should be pursued (Ryberg, Andersen, Owsianiak & Hauschild, 2020). This new concept aims at comparing the impacts of the studied system with the so-called planetary boundaries, instead of comparing it with alternative systems providing the same function. Despite the underlying uncertainties (*e.g.* value choices to allocate thresholds to human activities), this approach can better highlight the alignment of (new) technologies with absolute sustainability targets.



Regarding the economic and social sustainability, only a few studies applied LCC, S-LCA or their integration with LCA via LCSA for the assessment of nanotechnology. These methodologies are not yet standardised and ongoing research work should contribute to their improvement and harmonisation. For LCC, specific attention should be made regarding the time differentiation of flows (via discounting) and to assessment of externalities. Regarding S-LCA, methodological sheets for assessment social indicators are being updated following the UNEP 2020 guidelines. The wider spread of S-LCA studies should facilitate its application. Finally, for LCSA, the application of various Multi-Criteria Decision Analysis (MCDA) techniques can improve the interpretation of results. Apart from the aggregation of LCA, LCC and S-LCA indicators, the full integration of social, environmental and economic cause-effect chains is a research path that could consider the influence between the three pillars (Guinée et al., 2011; Schaubroeck & Rugani, 2017).

### 5.2.1.3 Ethics and Governance

In terms of ethics and governance in nanotechnology and nanofabrication, research and development are also expected to provide in the next years more harmonised and standardised tools, methodologies and indicators useful to the different categories of stakeholders. A first need is probably to develop new codes of conduct, which should be both more operational than the current ones (in particular associated to more precise criteria) and more sectoral (in particular adapted to the specificities of the different fields of application of nanotechnology and nanofabrication). New ethical guidelines for research and innovation in nanotechnology and nanofabrication are also expected, both in the form of general ones applying to a broad range of actors and activities, as well as more detailed and practical ones relating to some specific actors and practices (in particular, end-user guidelines for ethical usage of nanotechnology-enabled products and services, and guidelines for ethics-by-design). New ethical standards (both generic and sectoral) adapted to the case of nanotechnology and nanofabrication are also expected. Different ongoing EU-funded research projects (such as *TECHETHOS*<sup>32</sup>) are expected to contribute to these tasks.

Concerning particularly the industrial actors, another important stake is to adapt progressively the Corporate Social Responsibility (CSR) framework to the specificities of nanotechnology and nanofabrication. CSR as a whole has been proved an efficient way for encouraging companies to go beyond profit maximisation, to take into account their social and environmental responsibility, and to develop their activities towards desirable futures. CSR and its different components (e.g. the *UN Global Compact*<sup>33</sup>, the ISO 26000 standard on 'Social Responsibility' (ISO 26000, 2010), the *Global Reporting Initiative*<sup>34</sup>, the framework of the *UN Sustainable Development Goals*<sup>35</sup>) benefit already from well-established tools and indicators. Some nanotechnology companies are already engaged in a general CSR approach; according to Woodson & Do, 2015, this was the case in 2015 for 60% of the top-50 US nanotechnology R&D companies in the water, energy, and agrifood sectors. Nevertheless, it appears that the CSR framework has not yet been specified enough for being really relevant and incentive in terms of nanotechnology and nanofabrication (Subramanian et al., 2016).

### 5.2.2 Sharing of Case-Study Data

In order to expand and improve the use of sustainability indicators, the data generated for the assessment of nanotechnology should be shared systematically and following FAIR (findable, accessible, interoperable and reusable) guiding principles (Wilkinson et al., 2016).

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<sup>32</sup> [TECHETHOS project](#) (accessed: 1. January 2022)

<sup>33</sup> [UN Global Compact](#) (accessed: 1. January 2022)

<sup>34</sup> [Global Reporting Initiative](#) (accessed: 1. January 2022)

<sup>35</sup> [UN Sustainable Development Goals](#) (accessed: 1. January 2022)

The new EU Industrial Strategy as well as the EU's *Chemicals Strategy for Sustainability*<sup>36</sup> and the *Circular Economy Action Plan*<sup>37</sup> (driven by the *European Green Deal*<sup>38</sup> approach) are themselves based on the FAIR concept; they aim to support substitution and elimination of hazardous substances based on Safe and Sustainable-by-Design approaches thus enabling safe and sustainable innovation (Soeteman-Hernández et al., 2019a; EC, 2020b). In response to the need for the collection of data with the opportunity to increase the access to the information following the FAIR principles, the *eNanomapper* platform<sup>39</sup>, developed within the context *eNanomapper project*, provides a computational infrastructure for sharing and managing data on the safety of nanomaterials (Jeliazkova et al., 2015, 2021). The platform comprises several different components, including a public database that contains information on nanomaterials such as toxicological, ecotoxicological, and physio-chemical characterisation data and is proposed to be continuously expanded with data from more EU research projects. In fact, the underlying database has been used by a lot of actors in the nanosafety community and its structure is made to simplify the comparison of data coming from different sources.

All actors (incl. researchers, industry or policy makers) can contribute to data collection and should contribute to increase the acceptance of sustainability criteria, in particular *via* the definition of benchmarks (see section 6.1) or with the help of case-studies.

Some of the existing tools listed in the OECD document (OECD, 2020) have been developed to be applied within specific domains; this is the case for the *GoNanoBioMat* framework<sup>40</sup>, specifically developed in the context of polymeric nanobiomaterials for drug delivery. The framework is built to take into consideration the risks, efficiency and costs related to each step in an iterative manner; therein, it focusses on the design phase, production phase and storage and transport. The EU-funded projects *NANoREG*<sup>41</sup>, *ProSafe*<sup>42</sup> and *NanoReg2*<sup>16</sup>, elaborated a Safe-by-Design concept in order to increase the acceptance of the product at the time of the entry into the market. This is done through an increased communication between innovators and regulatory bodies. The idea is to anticipate some of the requirements foreseen in the registration procedure through the analysis of the production process, safety dossier, safety profile and procedures applied (OECD, 2020).

Even though these models were used to implement Safe-by-Design in particular industrial sectors, their application to concrete scenarios allowed to identify gaps, obstacles, barriers at different levels and this exercise will definitely be helpful to improve these tools and bringing them to a higher level of acceptance, standardisation and maturity.

Regarding life cycle sustainability, there is not yet any dataset to represent a life cycle step of nanotechnology in commercially available LCA tools or databases (the same for LCC or S-LCA). The LCA studies should publish their inventory data in a transparent way, on a gate-to-gate basis (*i.e.* direct material and energy flows for a specific process step). Unfortunately, such data are scarce in literature and are only available for a few nanomaterials (nanosilver, titanium dioxide and carbon nanotubes) (Hischier, 2021). Only a few LCA case studies considered the release of nanoparticles along the life cycle of nanotechnology-enabled products, with significant assumptions due to the lack of data. Similarly, there are no characterisation factors (CFs) for nanoparticles in life cycle impact assessment methods. LCA practitioners should rely on research work where such CF development was carried out, but with a variability of modelling assumptions and data applied. The aggregation of these data and

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<sup>36</sup> [EU Chemicals Strategy for Sustainability](#) (accessed: 1. January 2022)

<sup>37</sup> [EU Circular Economy Action Plan](#) (accessed: 1. January 2022)

<sup>38</sup> [European Green Deal](#) (accessed: 1. January 2022)

<sup>39</sup> [eNanoMapper platform](#) (accessed: 1. January 2022)

<sup>40</sup> [GoNanoBioMat framework](#) (accessed: 1. January 2022)

<sup>41</sup> [NANoREG project](#) (accessed: 1. January 2022)

<sup>42</sup> [ProSafe project](#) (accessed: 1. January 2022)

related CF into – for example - an online platform could facilitate the further research work and integration of CFs for nanoparticles in LCA tools.

Regarding ethics and governance, the sharing of case study data must also be promoted. Besides the ongoing ethical assessment work carried out regularly by the academic world (see for example the journal *NanoEthics* published by Springer<sup>43</sup>), the production of fact sheets and practical case studies, for example in ethics of sustainable nanofabrication, would be worth exploring. A dedicated bank of ethics case studies could be an interesting option, on the model of (or in collaboration with) some already existing ethics case studies collections (for example those from the *Markkula Center for Applied Ethics* at Santa Clara University in the U.S.<sup>44</sup>, from the *Online Ethics Center for Engineering and Science*, hosted by the University of Virginia in the U.S.<sup>45</sup>, from the *Royal Academy of Engineering* in the UK<sup>46</sup>). A regular and comparative watch on emerging ethical questions linked to nanotechnology and nanofabrication should also be organised and widely disseminated, for example on the model of the productions of the past EU-funded *Observatory Nano* project<sup>47</sup>.

The sharing of case study data, in all the dimensions mentioned above, can also probably benefit from the advances on the '*Knowledge and Communication Platform*' concept, such as those summarised in OECD (2020, pp.62-64).

## 6. Building Support and Engagement for Sustainability Criteria

Having shared indicators allowing the most relevant stakeholders (researchers, industrialists, regulators) to assess the sustainability of their nanotechnology-enabled products, processes and uses is essential, but not sufficient. It is also necessary to derive from them shared and accepted criteria, targets and benchmarks related to sustainability, benefiting from a social consensus, and able to give rise to concrete, achievable and incentive objectives (see section 6.1). These could, for example, be embodied in a sustainable nanofabrication label, certain characteristics of which can be anticipated (see section 6.2.1). Access to sustainable nanofabrication furthermore requires the establishment over the long term of a real collective governance of sustainability (see section 6.2.2). This chapter details the roadmap to implement these different recommendations.

### 6.1 Short- to Medium-Term Actions in Support of Building Support and Engagement for Sustainability Criteria

In terms of sustainability, performance monitoring is a comprehensive task that should be developed at all levels. Performance monitoring first includes collecting and sharing as systematically as possible all the indicators listed above (section 5.1) in their application to nanotechnology-enabled products, processes and services. Monitoring of the current and possible effects and impacts of activities related to nanotechnology and nanofabrication should also be developed more widely, which includes, for example, monitoring the impact of natural and artificial nanomaterials in terms of occupational health, public health, environmental preservation, social cohesion. Overall monitoring in terms of sustainability should also include the monitoring of a set of new risks and impacts, such as those called 'soft risks' by the industrial world (*i.e.* societal risks such as public perception, risk debate or media coverage, regulatory risks, product liability risks) (see Widler et al., 2016, p.228). As argued by

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<sup>43</sup> [NanoEthics journal](#) (accessed: 1. January 2022)

<sup>44</sup> [Markkula Center for Applied Ethics](#) (Santa Clara University, United States) (accessed: 1. January 2022)

<sup>45</sup> [Online Ethics Center for Engineering and Science](#) (University of Virginia, United States) (accessed: 1. January 2022)

<sup>46</sup> '[Engineering ethics in practice: a guide for engineers](#)' (Royal Academy of Engineering, United Kingdom) (accessed: 1. January 2022)

<sup>47</sup> [Observatory Nano project](#) (accessed: 1. January 2022)





Soeteman-Hernández et al. (2019b), the use of indices to monitor in particular safety, environmental, societal or economic performance indicators could be also explored, and an index in SSbD could be created akin to the *Dow Jones Sustainability World Index*<sup>48</sup>, the *ARCADIS Sustainable City Index*<sup>49</sup>, or the *Sustainable Society Index*<sup>50</sup>.

Monitoring must then be able to lead to benchmarking. Very generally, a benchmark is a certain target, for which different actors decide that it should be reached. A benchmark concerns often an indicator, and is often associated to a specific metric-reading of it. Benchmarks are particularly important in the implementation of a strategy. A benchmark needs to be measurable, and is best set to be ambitious, yet realistic. Benchmarks in general need to be set both by those who can set them, and by those who can, if needed, impose sanctions related to them (in particular the policy makers). Benchmarks also need to be regularly reviewed, refined or amended, in order to become more ambitious as technologies progress.

In terms of sustainable nanofabrication, it would be interesting to move towards the definition of benchmarks for all the indicators listed above (section 5.1), or at least for a carefully selected number of them. Such benchmarking can first be developed in a comparative manner, by comparing the risks, benefits and additional issues of nanotechnology-enabled products, processes and services to those related to more conventional alternatives. This approach is promoted in different: in particular for applications at low TRL when limited information is available (Trump et al., 2018; Linkov, 2018). For example, regarding life cycle sustainability, the impacts of nanotechnology are generally benchmarked against competitive alternatives, which makes the assessment case specific. There are ongoing initiatives to define benchmarks in several sectors to facilitate the identification of sustainable technologies. For social impacts, some standards are already used for the assessment (*e.g.* comparing the wage of labours with a fair wage value). Besides this, the Taxonomy of the EU Technical Expert Group on Sustainable Finance (EU Technical Expert Group on Sustainable Finance (2020)) defines performance thresholds (in terms of carbon footprint) to identify low-carbon technologies (*e.g.* 100 g CO<sub>2</sub> eq./kWh set for electricity supply technologies). Based on the increased share of sustainability performances data (see section 5.2), the development of such benchmarks for nanotechnology depending on the application sector could be envisioned. Ultimately, benchmarking should also become more general, and it could be interesting to define benchmarks and targets to reach in order to be considered ‘absolutely’ sustainable. The concept of absolute sustainability is already giving rise to research in the field of environmental assessment (see above section 5.2.2), and it should be able to be developed in other areas. The definition of such benchmarks should nevertheless benefit from a social consensus, and from a participatory process aimed at establishing it, which goes beyond the sole competence of the experts. For example, the definition of benchmarks, relative or absolute, in the field of occupational safety, requires the effective participation of the workers themselves and their representatives. The same is true of public health. This is even more true for social impacts with a high ethical and cultural dimension, since they cannot always be captured through quantitative indicators, and the definition of benchmarks related to them is likely to require additional qualitative methods and stakeholder dialogue (Subramanian et al., 2016, p.67).

Where the choices of society, and the applications resulting from nanotechnology and nanofabrication to be adopted or to be proscribed with regard to ethics in certain sensitive fields such as medicine, surveillance, artificial intelligence are concerned, however, the only possible benchmarking is that provided by public debate and dialogue with society. These must be encouraged and developed in all their possible forms at the different national and international levels, as well as informed by the

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<sup>48</sup> [Dow Jones Sustainability World Index](#) (accessed: 1. January 2022)

<sup>49</sup> [ARCADIS Sustainable City Index](#) (accessed: 1. January 2022)

<sup>50</sup> [Sustainable Society Index](#) (accessed: 1. January 2022)



international ethical expertise (such as provided among others by the COMEST<sup>51</sup>, the EGE<sup>52</sup>). With a view to benchmarking, a direct dialogue between companies, civil society and other stakeholders must also be developed, by all available means (e.g. company forums, government initiatives).

## **6.2 Medium- to Long-Term Actions in Support of Building Support and Engagement for Sustainability Criteria**

### **6.2.1 Creation of a Label for ‘Sustainable Nanofabrication’**

It seems legitimate to consider the question of the creation of a label (or a mark, or a certificate) for ‘sustainable nanofabrication’. Such a label could fulfil a dual role: act as an incentive and as a reward for the players accessing this label, and guarantee the validation of their approach and of their implementation strategy in terms of sustainability. During the survey set up in the framework of NanoFabNet WP4, 56% of the stakeholders declared themselves in favour of such a label, and 50% of them declared themselves interested in contributing to its development (NanoFabNet *‘Report on the Challenges & Opportunities in the Validation, Harmonisation & Standardisation of industrial-scale nanofabrication’*<sup>53</sup>, p.38).

Many questions, both theoretical and practical, remain to be resolved and discussed about this topic; these questions include (but are not exhausted by) the following:

- Would such a label be a voluntary initiative open to all players of the nanofabrication community (including research institutes, public bodies, NGOs, sustainability professionals) or only to some nanotechnology and nanofabrication professionals (including industry in the first place)?
- Would this label be applied to products, processes, or institutions themselves?
- Who would be the owner of this label, who would be liable for it, and what would the accreditation process related to this label consist of?

Such a label could be based on the compliance with certain benchmarks (which remain to be precisely defined) related to the sustainability indicators presented above (in the three areas of (i) Environment, Health & Safety, (ii) Life Cycle Sustainability Assessment, (iii) Ethics & Governance). It could also include – as a potentially necessary condition – the certification against a number of already existing standards, to be precisely defined. Several already existing frameworks can be useful as sources of inspiration (even if not as first bricks) for such a label. In particular, the *Responsible Care Initiative* of the chemical industry<sup>54</sup> promotes and helps the implementation of sustainability throughout the value chain of chemical activities, and has developed relevant tools such as a general guidance, a global charter, a self-assessment web tool, an annual awards programme. It remains to be discussed with all stakeholders if, in the profusion of already existing labels, the potential benefit of such a new label can really justify and outperform the efforts and investments needed to create it, to position it as relevant, to maintain it in the long run, and to make it really meaningful (even if only for some actors, such as downstream users in the value chain of nanotechnology and nanofabrication). Other aspects that might be discussed along those lines are (i) the diffusion dimension (regional, national, global, other dimension) of such a label, (ii) the consideration of already ongoing definition-exercises and its

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<sup>51</sup> [World Commission on the Ethics of Scientific Knowledge and Technology \(COMEST\)](#) (accessed: 31. December 2021)

<sup>52</sup> [European Group on Ethics in Science and New Technologies \(EGE\)](#) (accessed: 31. December 2021)

<sup>53</sup> [NanoFabNet ‘Report on the Challenges & Opportunities in the Validation, Harmonisation & Standardisation of industrial-scale nanofabrication’](#) (accessed: 1. January 2022)

<sup>54</sup> [Responsible Care Initiative](#) (accessed: 1. January 2022)

supportive initiatives in similar fields (e.g. CEN TC352, WG1 - *Measurement, characterization and performance evaluation*<sup>55</sup>; INISS-Nano (Falk (2021)), and (iii) the ethical aspects of such a label.

### **6.2.2 Improve the Governance of Sustainability**

Lastly, it is crucial, for the full effectiveness of all the measures listed above, to continue efforts to establish a harmonised and shared system of governance adapted to the different development challenges of nanotechnology and nanofabrication. Different governance frameworks (e.g. risk governance, anticipatory governance, regulatory preparedness, responsible research and innovation) have been mobilised in recent years with the objective of responding to the increasing political and social demand for accountability and openness addressed to emerging technologies, in an overall context in which the social climate and the tolerability or acceptability of different levels of risks or impacts are increasingly determining (Hankin & Read, 2016, pp.41-42). These frameworks share as main features (Idem, p.42):

- i. the application of anticipating techniques (such as horizon scans, foresight, scenario planning) to gain some insight into what might be expected to happen;
- ii. an upstream involvement of society and stakeholders in the collective exploration of the potential long-term global impacts of new technologies (including early discussion and deliberation of the ethical and societal dimensions of it); and
- iii. education, training, sharing of the best available knowledge and practice, as crucial components of all this process.

One of the positive aspects of these incentives has been the dissemination (down to company level) of a general culture of pro-action marked by the development of soft law approaches, codes of conduct, voluntary reporting schemes. At the same time, however, these new models of governance appear to succeed only moderately in disrupting a form of '*de facto* governance' of nanotechnology and nanofabrication (Rip, 2018), which remains a complicated patchwork, where interaction occurs at multiple levels between different institutions (EU, OECD, WTO, ECHA, ISO, CEN, national authorities) and a complex network of national and transnational actors and agents (including politicians, regulators, industry, NGOs, media, the public) (Hankin and Read, 2016, p.45; Malsch et al., 2015). In this situation, it seems reasonable to continue to promote the main characteristics of anticipatory governance (which should now be able to include an authentic 'governance of sustainability' going beyond the simple governance of risk), while making proof of practical innovation and flexibility in its implementation. This is particularly true at the level of anticipation techniques (see for example the recent recommendations of Rios Rojas et al. (2021) on foresight approaches), interaction techniques (as evidenced by the emerging notion of 'trusted environment' promoted in OECD (2020)) or even public engagement techniques (for which, for example, Chilvers and Kearnes (2020) propose new performance criteria based on more reflexivity).

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<sup>55</sup> [CEN TC352, WG1 - Measurement, characterization and performance evaluation](#) (accessed: 1. January 2022)

## 7. Conclusion

This report presents the NanoFabNet strategy and implementation roadmap for sustainability in nanofabrication. It is organised according to four parallel dimensions: 'raising awareness of sustainability', 'compliance with regulation and legislation', 'implementation of sustainability indicators', and 'building support and engagement for sustainability criteria'.

Each of these dimensions encompasses a set of actions and recommendations to be performed according to different time-scales: access to basic concepts, connections of the different communities, training on methods and tools for the first dimension; alignment with current regulation and continuous regulatory update for the second dimension; implementation of mature indicators, research and development of emerging indicators, share case study data for the third dimension; monitoring and benchmarking of performances, creation of a label, and improve the governance of sustainability for the fourth dimension.

The different suggested actions and recommendations cannot be considered as totally independent of each other. They involve and concern different kinds of stakeholders, who are sometimes the possible providers of the actions, and sometimes the target audience of them. This strategy and implementation roadmap thus appears as a collective task, where each category of stakeholders has both a specific and a collective role to play: **interaction** and **engagement** can be mentioned as its key messages to be retained.



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