NanoFabNet

international Hub for sustainable industrial-scale Nanofabrication

NanoFabNet Validation, Harmonisation & Standardisation Action Plan

NanoFabNet Report

NanoFabNet

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Acronyms Listed in Document	
ASTM	American Society for Testing Material
CEN	European Committee for Standardisation
CHADA	CHAracterisation DAta
DW	Development Workshop
EC	European Commission
EMN	European Metrology Network
EURAMET	The European Association of National Metrology Institutes
FAIR	Findability, Accessibility, Interoperability, and Reuse
GFSC	Graphene Flagship Standardisation Committee
GFVS	Graphene Flagship Validation Service
IEC	International Electrotechnical Commission
INISS-Nano	International Network Initiative on Safe and Sustainable Nanotechnologies
ISO	International Standard Organization
LCA	Life Cycle Analysis
NMI	National Metrology Institute
NNCI	National Nanotechnology Coordinated Infrastructure
NSC	NanoSafety Cluster
OECD	Organization for Economic Cooperation and Development
OITB	Open Innovation Test Bed
SOP	Standard Operating Procedure
TC	Technical Committee
VAMAS	Versailles Project on Advanced Materials and Standards
WP	Work-Package

1. Executive Summary

The NanoFabNet aims to create a strong international hub for sustainable nanofabrication. Its structure, business model, detailed strategies and action plans are designed, agreed and carried by its international stakeholders during the project duration, in order to yield a self-sustaining collaboration platform: the NanoFabNet Hub.

The NanoFabNet will be a one-stop-shop for all matters and concerns pertaining to sustainable nanofabrication and its successful incorporation into the complex, large-scale high-value industries by bringing together governmental and academic laboratories with large industries and SMEs. The diverse communities will be brought together and served through activities of the NanoFabNet Hub, a registered organisation, consisting of different levels of both formal and informal contribution- and association-models, which will allow both registered organisations and individual experts to choose their optimum level of engagement.

This report presents the **NanoFabNet Validation, Harmonisation & Standardisation Action Plan**, built as a follow-up to the detailed analysis of the challenges posed by any validation, harmonisation and standardisation efforts in sustainable nanofabrication, as given in the previous NanoFabNet report *"Challenges & Opportunities in the Validation, Harmonisation & Standardisation of industrial-scale nanofabrication"*, published in July 2021.[1] In addition, a *NanoFabNet* vision regarding proposals for action to meet these challenges is also being developed.

The Action Plan defines the **NanoFabNet Vision** regarding future activities in harmonisation, validation and standardisation and points out those issues that need to be addressed, in order to establish and maintain a productive, collaborative community in the highly interdisciplinary field of 'sustainable nanofabrication'. The report furthermore suggests a timeline, in which the issues should be address (i.e. short-, medium-, and long-term), and makes recommendations pertaining to the specific activities that should be taken by different stakeholders in the field of sustainable nanofabrication; specific recommendations are provided to the NanoFabNet Hub, in that the relevant issues will be readily incorporated into the '**NanoFabNet 5-Years-Strategy**', to form a central part of the offerings and services of the NanoFabNet Hub to the community of sustainable nanofabrication.

[1] *NanoFabNet* Report "*Challenges & Opportunities in the Validation, Harmonisation & Standardisation of industrial-scale nanofabrication*" (2021): https://www.nanofabnet.net/wp-content/uploads/2021071.pdf

2. Introduction – The Development of the Action Plan

The NanoFabNet aims to bring together the wider communities active in any aspects of 'sustainable nanofabrication', by providing them with a space, in which a diverse range of interdisciplinary collaborations can be formed; in doing so, it identified six main fields that the NanoFabNet Hub needs to address through services and activities (i.e. **NanoFabNet Service & Activity Fields (SAFs)**), as illustrated in Figure 1:

- (Identity & Mapping of) 'Sustainable Nanofabrication';
- Database of 'Sustainable Nanofabrication' (incl. the 'digital twin' of the NanoFabNet Hub);
- Communication & Information Sharing;
- Technology Validation, Harmonisation & Standardisation;
- Infrastructure, Knowledge & Skills; and
- International Cooperations & Collaborations (incl. collaborations with EU-funded projects).

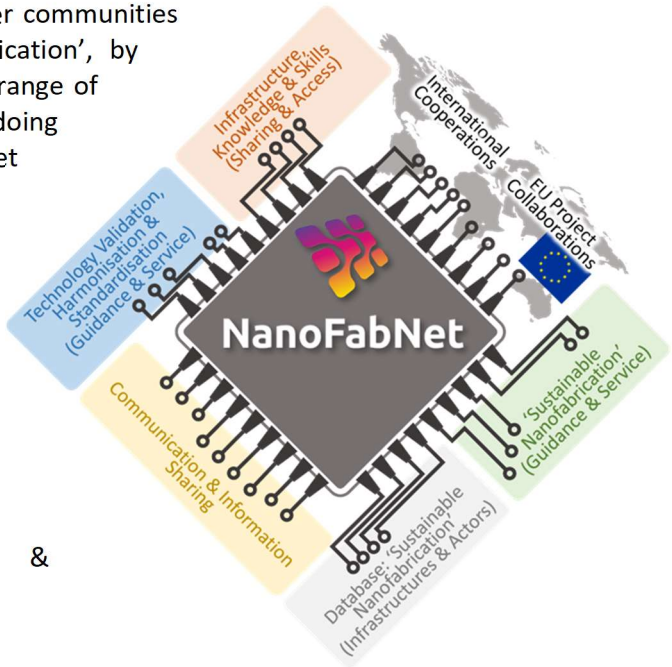

Figure 1: Illustration of the six main Service & Activity Fields of the NanoFabNet.

This report provides a map and recommendations for the time-critical tackling of issues pertaining to the *technical validation, harmonisation and standardisation of sustainable nanofabrication* processes and products, in order to guarantee their adoption into high-tech R&I and industrial manufacturing processes. The report lists the relevant issues that have been identified through the detailed analyses and stakeholder interactions on the topic of *Validation, Harmonisation & Standardisation Actions*, carried out by the NanoFabNet Project[2]:

- The 1st NanoFabNet Hub Development Workshop (DW) held on 4th March 2020;
- A survey carried out between September 2020 and February 2021, which resulted in 57 high-value contributions from 13 countries;
- The 2nd NanoFabNet Hub DW held on 20th and 21rst January 2021;
- The kick-off meeting of the new **EMN AdvanceManu** (European Metrology Network for Advanced Manufacturing)[3] held on 11th and 12th October 2021, of which the NanoFabNet is an official partner; and
- Discussion with various experts contributing to EU or international major initiatives, such as **EuroNanoLab** project[4] (focus on EU nanofabrication / academics clean rooms facilities), US National Nanotechnology Coordinated Infrastructure (**NNCI**)[5], European Nanomedicine

[2] NanoFabNet - International Hub for sustainable industrial-scale Nanofabrication; EU Horizon2020 Grant Agreement No. 886171: https://cordis.europa.eu/project/id/886171.

[3] European Metrology Network (EMN) for Advanced Manufacturing: https://www.euramet.org/european-metrology-networks/advanced-manufacturing/?L=0

[4] EuroNanoLab : http://euronanolab.eu/

[5] NNCI: https://nnci.net/

Characterization Laboratory (**EU-NCL**)[6], the **REFINE**[7] project (focus on nanomedicine and nanomedicinal products), European Centre for Risk Management and Safe Innovation in Nanomaterials & Nanotechnologies (**EC4SafeNano**[8] / risk assessment services providers), Graphene Flagship Validation Service (**GFVS**)[9] and Graphene Flagship Standardisation Committee (**GFSC**)[10], NanoSafety Cluster (**NSC** / in particular WG-B on Materials and Standards)[11], **INISS-Nano** (International Network Initiative on Safe and Sustainable Nanotechnologies)[12], **CEN/TC 352** Nanotechnologies[13], **ISO/TC 229** Nanotechnologies[14], **ASTM/E56** Nanotechnologies[15] or the Versailles Project on Advanced Materials and Standards (**VAMAS**)[16].

During the two NanoFabNet DWs, the consortium invited the stakeholders to participate in interactive sessions that allowed the participants to discuss the actions and services that could be implemented or proposed by the Hub to respond to the needs they expressed. Different questions had been prepared to collect the points of view of each participant in real time via an online polling tool[17]. It should be noted that during the 1st NanoFabNet DW it appeared that **characterisation issues came out on top in terms of importance to accompany the development of nanomanufacturing and the associated sustainability issues** (for more details, see the relevant NanoFabNet report)[1]. Between the 1st and the 2nd NanoFabNet DW, a detailed online poll with expert stakeholders in the field of harmonisation, standardisation and validation was conducted,[18] yielding nearly 60 individual answers, and indicating strong trends in opinions. A corresponding session of the 2nd NanoFabNet DW was thus organised specifically on the harmonisation, validation and standardisation issues associated with the characterisation topic, in order to identify actions to be considered. Figure 2 provides a schematic overview of the underlying process.

[6] EU-NCL: https://cordis.europa.eu/project/id/654190/fr

[7] Regulatory Science Framework for Nano(bio)material-based Medical Products and Devices project: http://refine-nanomed.eu/

[8] EC4SafeNano: http://www.ec4safenano.eu/

[9] GFVS: https://graphene-flagship.eu/innovation/industrialisation/validation-service/

[10] GFSC: https://graphene-flagship.eu/innovation/industrialisation/standardisation/

[11] NSC: https://www.nanosafetycluster.eu/nsc-overview/nsc-structure/working-groups/

[12] International Network Initiative on Safe and Sustainable Nanotechnologies (INISS-nano). Zenodo, Falk A. *et al.* (2021). https://doi.org/10.5281/zenodo.5004929

[13] CEN/TC 352 Nanotechnologies: https://standards.cencenelec.eu/dyn/www/f?p=205:7:0::::FSP_ORG_ID:508478&cs=105D77E18D80442539DAD7D6A6B7EC5FA

[14] ISO/TC 229 Nanotechnologies: https://www.iso.org/committee/381983.html

[15] ASTM Committee E56 on Nanotechnology: https://www.astm.org/COMMIT/E56/

[16] VAMAS : http://www.vamas.org/

[17] Mentimeter: https://www.mentimeter.com/

[18] SURVIO: https://www.survio.com/en/

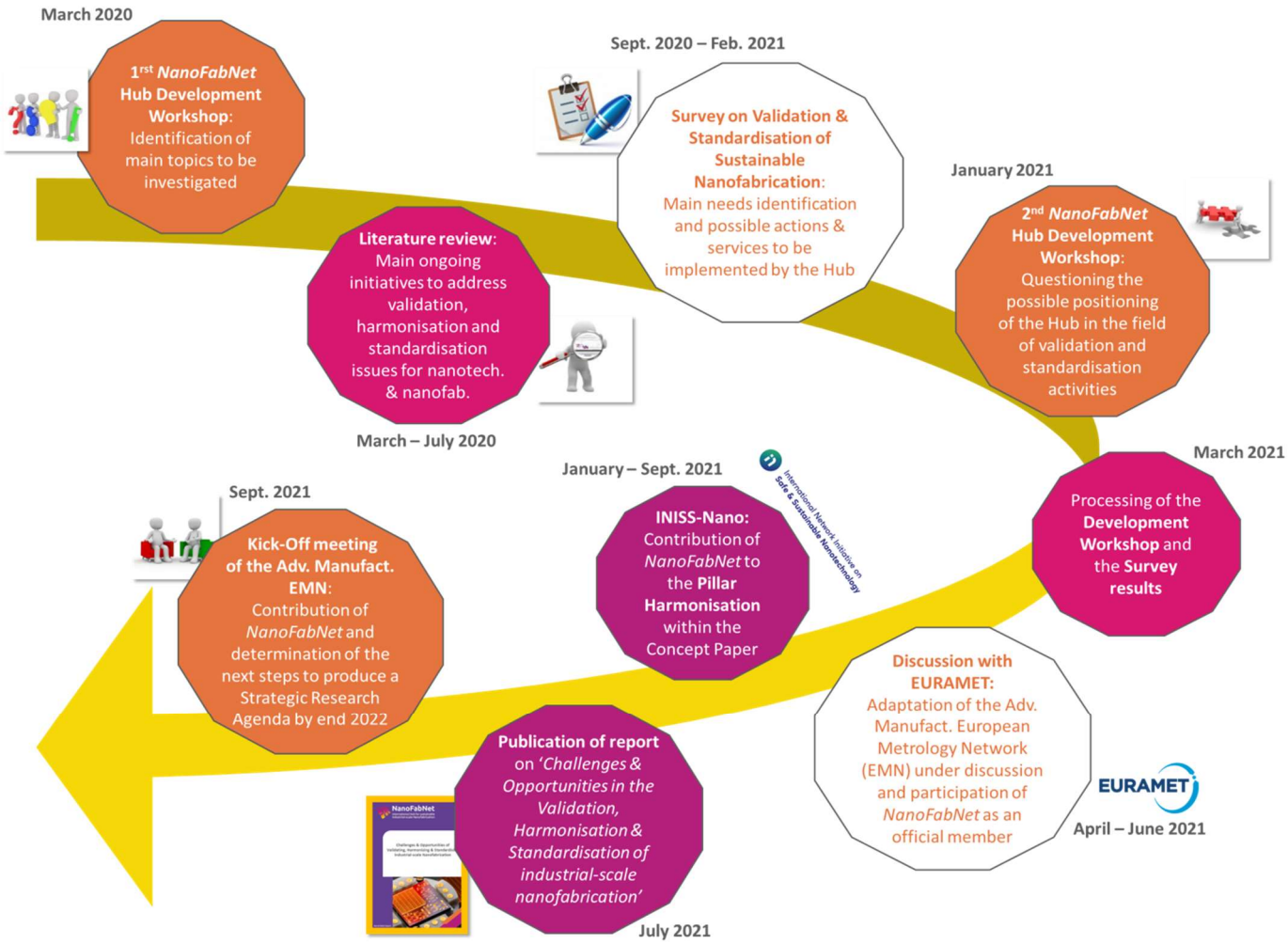

Figure 2: Schematic representation of a process put in place by the NanoFabNet, in order to identify stakeholder needs and actions and services to be offered by the NanoFabNet Hub in the field of validation, harmonisation and standardisation to support sustainable nanofabrication.

The Action Plan proposed in this document responds to the cross-cutting needs and corresponding opportunities identified in the *NanoFabNet* report on the challenges and opportunities in the validation, harmonisation & standardisation of industrial-scale nanofabrication[1], refined through the findings gathered within complementary *NanoFabNet* public reports (*Common Challenges & Opportunities in sustainable Nanofabrication*[19] and *Nanofabrication Competence Map: Infrastructures, Knowledge and Skills - Proposal for a new Nanofabrication Taxonomy*[20]).

The Action Plan defines the **NanoFabNet Vision** regarding future activities in harmonisation, validation and standardisation; the relevant services and activities addressed to the NanoFabNet Hub itself will be readily incorporated into the '**NanoFabNet 5-Years-Strategy**' to form a central part of the Hub's offerings and services to the community of sustainable nanofabrication, as **the lack of harmonisation and standardisation appears as the most important barrier to the introduction of nanofabrication in the industrial ecosystem** (Figure 3).

[19] *NanoFabNet* Report *"Common Challenges & Opportunities in sustainable Nanofabrication"* (2021): https://www.nanofabnet.net/wp-content/uploads/20210803_NanoFabNet_Report_Common-Challenges-of-sustainable-Nanofabrication.pdf

[20] *NanoFabNet* Report *"Nanofabrication Competence Map: Infrastructures, Knowledge and Skills - Proposal for a new Nanofabrication Taxonomy"* (2021): https://www.nanofabnet.net/wp-content/uploads/20210809_NanoFabNet_Nanofabrication-Competence-Map.pdf

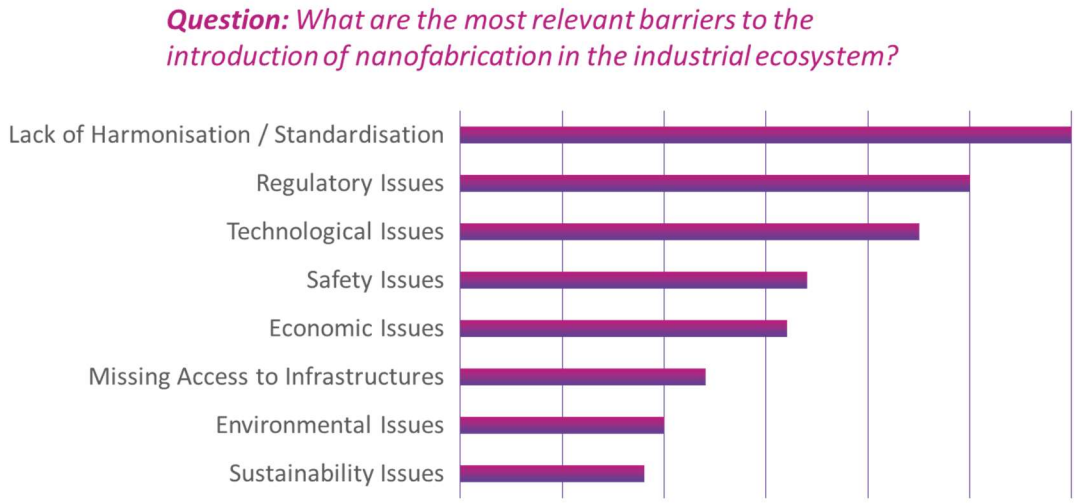

Figure 3: Schematic representation of the results of a NanoFabNet stakeholder poll regarding the 'most relevant barriers to the introduction of nanofabrication in the industrial ecosystem'; the polling was conducted during the 2nd NanoFabNet Development Workshop, held on the 20th and 21st January 2021 with ca. 120 registered participants.

3. NanoFabNet Vision

3.1 General Philosophy of the Action Plan

The NanoFabNet Hub will support the wider community of sustainable nanofabrication in tackling those issues currently holding back innovations in and advancements of sustainable nanofabrication products and processes. To achieve this, the NanoFabNet Validation, Harmonisation & Standardisation Action Plan has identified the relevant issues and developed suggestions for specific actions that should be conducted, in order to adequately address the issues.

The Action Plan provides a **short description of the action**, makes detailed recommendations on the responsible body that should conduct the action, identifies the main target group that would benefit from the action, and suggests the most appropriate **timeline**, in which the action should be conducted. Table 1 provides an outline of the format, in which the suggested actions are listed in this Action Plan; the resulting table-format will be used in a synthetic way throughout this Action Plan to present the different actions proposed by the Hub to move a step forward regarding the main challenges identified regarding validation, harmonisation or standardisation issues and thus to support the implementation of sustainable nanofabrication.

Table 1: Template for the identification and discussion of an action in this Action Plan, providing examples for (a) responsible bodies, (b) target groups, and (c) suggested timelines.

[Type = Validation/Harmonisation]	**Action N°X**	**[Title of the Action]**
	Short Description of the Action	[Description of the action]
	Responsible Body/ies (that should conduct the action)	[list of (stakeholder) groups and organisations relevant to the community of 'sustainable nanofabrication'; e.g.: ▪ [NanoFabNet Hub; NanoFabNet Hub & its individual Members; NanoFabNet Hub Members] ▪ [specific harmonisation bodies]

		▪ [specific standardisation bodies]
	Target Group (benefitting from the action)	[list of (stakeholder) groups and organisations benefitting from concerted actions of/within the 'sustainable nanofabrication' community, e.g.: ▪ Nanotechnology/nanofabrication professionals ▪ Public bodies (governmental/NGOs) ▪ Metrology/characterisation testing professionals ▪ Safety Assessment, Life Cycle Sustainability Assessment, and Ethical Assessment professionals (theoretical and lab-based)]
	Suggested **Timeline**	[indication of most appropriate the NanoFabNet-identified timeline, e.g.: ▪ Short-term: one – three years (i.e. 2022 – 2025) ▪ Medium-term: three – eight years (i.e. 2025 – 2030) ▪ Long-term: beyond eight years (i.e. 2030 onwards)]

The services and activities provided by the NanoFabNet will include, but not be limited to the provision of access to the necessary skills, information, technical resources and collaborations in multiple fields pertaining to the advancement of sustainable nanofabrication. While some of these services and activities will be limited to organisations and/or individuals, who have subscribed to become members of the NanoFabNet Hub, thereby confirming to adhere to agreements that govern and safeguard communications, collaborations and information exchanges within the NanoFabNet Hub, the overarching remit of the NanoFabNet is to interact with the wider nanofabrication and nanotechnology community (e.g. nanofabrication facilities, characterisation/metrology players, proficiency testing organisers, standardisation bodies, sustainability professional, certification and accreditation bodies, European Commission bodies and/or its member states).

The services and activities proposed in this Action Plan address the cross-cutting challenges identified around validation, harmonisation and standardisation issues with a focus on the following guiding questions:

- Does the relevant action concern validation, harmonisation or standardisation topics?
- For which target group is the action envisaged?
- Who will/should be involved (e.g. stakeholder/entity, network, project) and what role of the Hub? Depending on the action considered it could be indeed directly delivered by NanoFabNet or will require collaborations with external bodies and/or stakeholders);
- By what timescale will the action be implemented (i.e. short-term actions: 2022-2025, Medium-term actions: 2025-2030, long-term actions: 2030 onwards (as illustrated in the in Figure 4))?

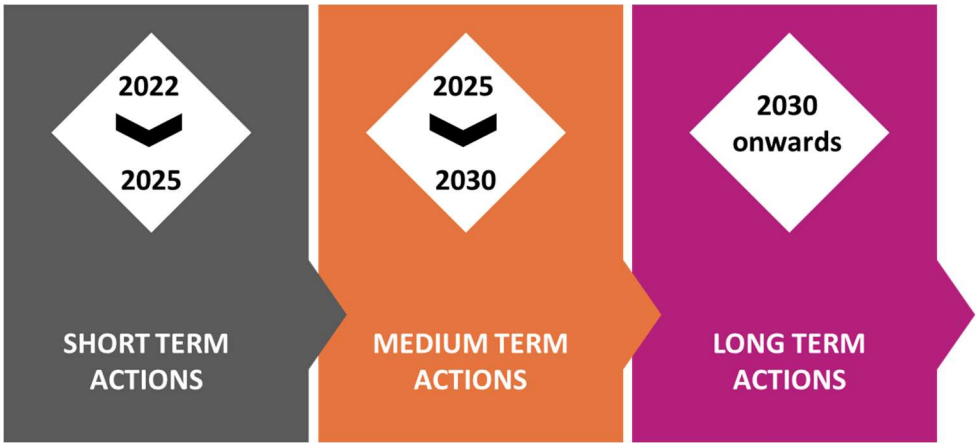

Figure 4: Illustration of the different timescales considered for the actions discussed in this Action Plan.

3.2 Ensuring the Sustainability of the Hub

The NanoFabNet Hub will be officially created and launched in 2022. It will benefit from the analytical and development work carried out by the NanoFabNet Project, enabling it to identify and prioritise the actions to be launched, in order to offer its future services and activities in line with the expectations of the stakeholders, who have been interviewed so far. In order to ensure the economic sustainability and resilience of the Hub, it is necessary that its long-term actions and mode of operation can be adapted to changes and emerging needs in the community. A continuous process plan has been drawn up to allow the wider nanofabrication and nanotechnology community to express new expectations, and the NanoFabNet to adapt its role, activities and services within this, thus enabling the Hub to arrange timely changes in the service offering by exploring, evaluating and forecasting the technological advances in the field of sustainable nanofabrication with regard to the need for their validation, harmonisation and standardisation.

Different tools and activities that could be used in combination will be implemented to continuously monitor and collect stakeholder needs to update the Hub long-term actions:

- **Needs Assessment Surveys:**

  Needs Assessment Surveys will be completed and submitted online by new members with the registration form, enabling the identification of potential matches for customers to the services of the Hub members. Very useful information will be collected from it to identify new needs.

- **Regular surveys among the NanoFabNet Members**:

  The *NanoFabNet* Members will be questioned at least once a year by means of a web-survey in order to evaluate the adequacy of the proposed actions with their expectations/needs. This will also allow to detect what their new needs might be and to identify potential trends. Short bilateral interviews between the *NanoFabNet* Core-team and each member will also be implemented every year to allow members to propose ways of improvement in terms of functioning or types of actions/services.

- **Invitation of NanoFabNet Members to topical NanoFabNet Focus-Groups**:

  Focus-groups will be set up according to the topics and opportunities to feed the discussions within the Hub and provide useful and relevant input to adapt its activities.

- **Workshops with the Contributions of external Stakeholders**:

  At least one workshop will be organised each year for *NanoFabNet* Members. It will facilitate exchanges between members and with the NanoFabNet Core-Team. External stakeholders will be invited in a spirit of openness to explore themes or issues not addressed within the Hub.

Real-time survey tools will be used on this occasion to ask Members and stakeholders about their interests in new activities and/or services.

- **Bibliometric Studies & Trend-Analyses**:

  Bibliometric studies (scientific publications, patents) may be carried out on topics considered important, in order to catch trends and enable an evaluation of the evolution of topics of interest in the scientific and technical community.

3.3 Provision of a Framework and Conditions to support sustainable Nanofabrication

The many consultations carried out within the framework of the NanoFabNet Project have made it possible to highlight that the issue of trust (between economic actors along the value chains, between economic actors and public authorities, between economic actors and civil society) was central to the acceptance of these innovations and thus to the deployment of a real sustainable nanofabrication in the wider high-tech industries; especially large-scale industrial players noted that a form of 'guarantee' or independent endorsement of the quality of a specific service as a central requirement to collaborations and cooperation in new areas. It was clearly identified that the issues of **validation, harmonisation and standardisation were key to the provision of conditions and tools necessary for the establishment of trust between all stakeholders**. This includes the following elements:

- **Harmonisation of the terminologies** used for (a) instruments, and (b) processes is one of the most important prerequisites to enable nanofabrication platforms to act as a network, and aspire to virtual, distributed infrastructures.
- **Comparability and reliability of characterisation/testing data** are key, since the topic of characterisation underpins all issues around nanofabrication (R&D, process optimisation, quality control, demonstration of performances/added-value, risk assessment, regulatory requirements); to support this, a gradual move towards **accreditation of laboratories according to ISO/IEC 17025 standard**[21] was required, in order to **validate/ensure that the laboratory had control over its measurement process**. This, in turn, necessitates that **available standards and/or good practice guidelines**, are (a) brought to the knowledge of the relevant laboratories, and (b) are understood and applied in a manner, in which the relevant laboratory can assess its ability to carry out the type of characterisation in question by participating in inter-laboratory comparisons or proficiency testing.

  The NanoFabNet Project has been working to address point (a) by developing a database of standards and reference guides which will be accessible to Hub members to enable them to quickly identify the reference methodologies to be applied and to thus move a step forward towards ultimately achieving (b) by bringing VAMAS and the European Association of National Metrology Institutes (EURAMET)[22] into the NanoFabNet community. The involvement of the NanoFabNet in the new AdvanceManu EMN will enable it to work with the European metrology community on this point in the months and years to come.
- **Certified training on nanofabrication** appears as a relevant mechanism to validate the expertise of stakeholders in the field and support transfer between academia and industry. The development of shared standards should support this process (cf. the ASTM series of International Standard Guide for Nanotechnology Workforce Education).
- **Harmonisation and validation (and later standardisation) of EHS/OHS practices, criteria and requirements**, but also of the tools and methodologies needed to objectify these issues on the basis of reliable, comparable and recognised data.

[21] ISO/IEC 17025 (2017): *General requirements for the competence of testing and calibration laboratories*

[22] EURAMET: https://www.euramet.org/

4. *NanoFabNet* Validation, Harmonisation & Standardisation Action Plan

Figure 5 illustrates the feedback obtained from stakeholders at the occasion of the 2nd NanoFabNet DW and sheds light on the actions the NanoFabNet should initiate and the place it should occupy in the landscape to support the implementation of sustainable nanomanufacturing and all the stakeholders involved.

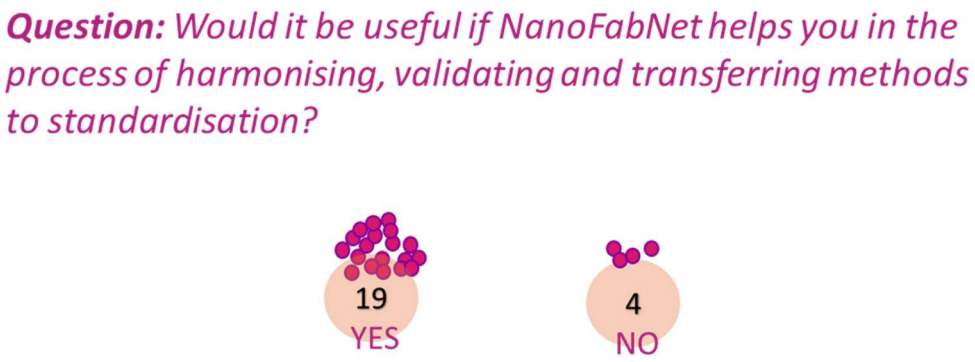

Figure 5: Screenshot of answers to the question 'Would it be useful, if NanoFabNet helps you in the process of harmonising, validating and transferring methods to standardisation', polled during the 2nd NanoFabNet Development Workshop (20th to 21st January 2021).

An indicative (but not limiting) list of actions that will be implemented by the NanoFabNet to respond to the challenges and needs identified during multiple stakeholder consultations is provided in Figure 6. **The majority of the actions aim at moving a step forward regarding harmonisation issues** whether it be for questions of terminology, taxonomy, data formats, criteria and tools to be deployed in the framework of sustainability assessment or characterisation & testing methods.

Stakeholders expect the NanoFabNet to focus on pre-standardisation activities in order to have a **Single-Entry Point to discuss standardisation request**, which **also provides a framework for validating methods and tools prior to standardisation** and the **regular dissemination of state of the art information** on ongoing activities in this field and on available reference documents and guides (see outcomes of the NanoFabNet's survey on Figure 7). A detailed discussion of each action is provided in Chapter 4.

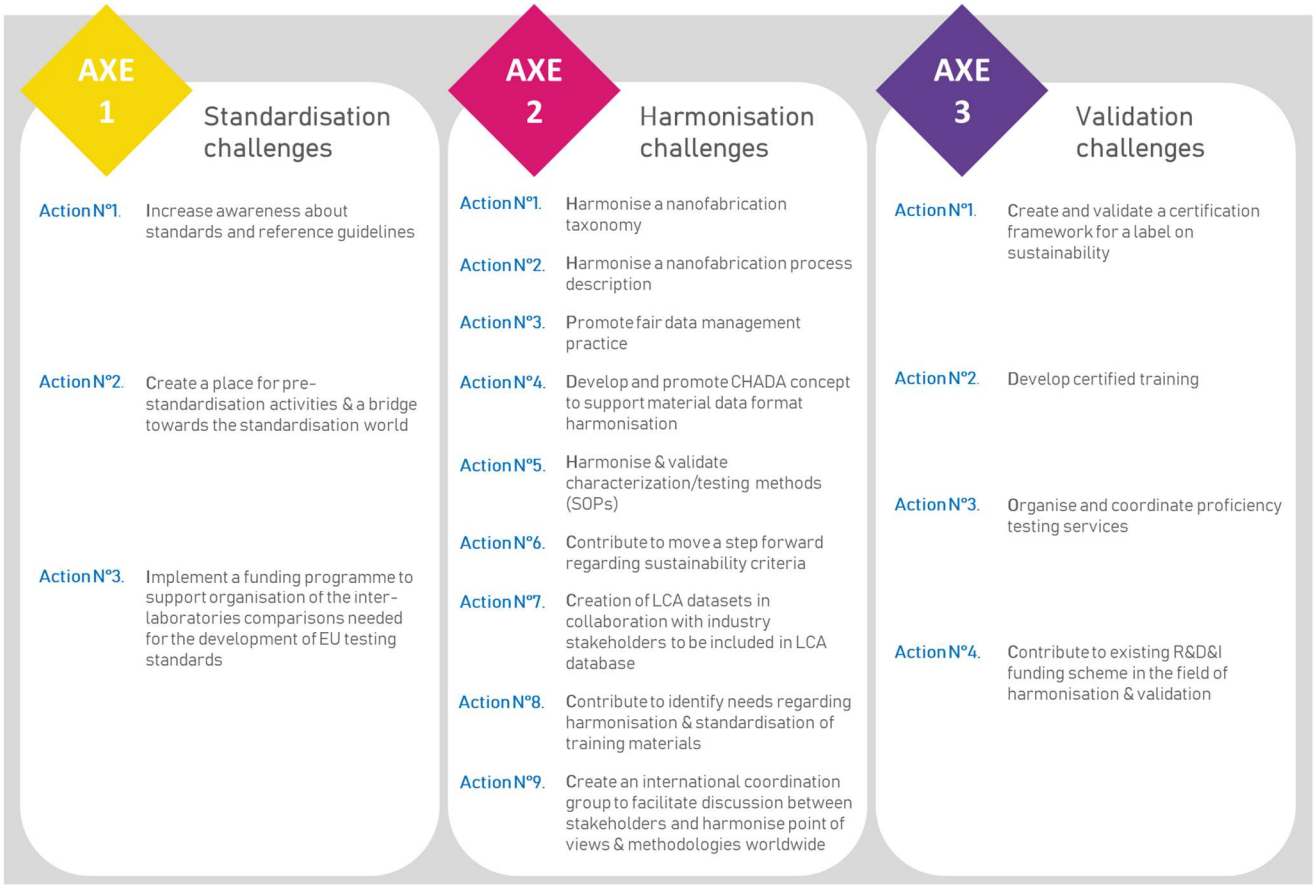

Figure 6: Listing of the NanoFabNet Actions to address challenges in the fields of standardisation, harmonisation and validation topics.

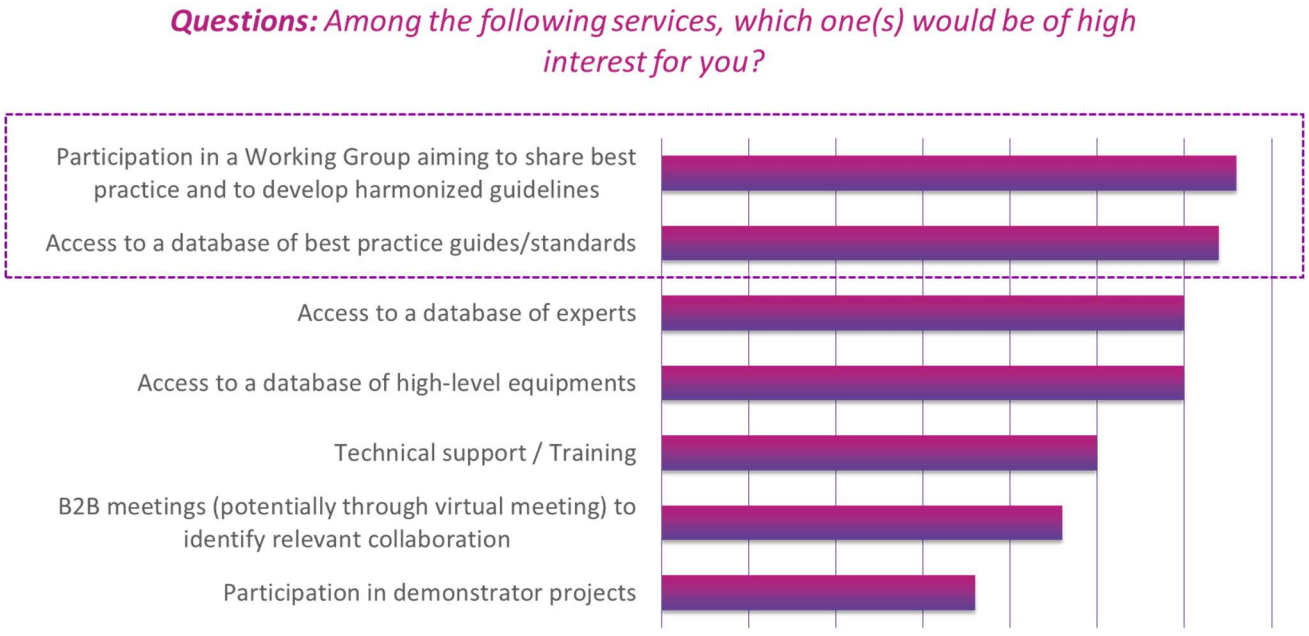

Figure 7: Screenshot of an answers to the question 'Among the following services, which one would be of high interest to you', polled during the 2nd NanoFabNet Development Workshop (20th to 21st January 2021). The dotted frame indicates the two top priorities identifies by the respondents.

4.1 NanoFabNet Actions to address Standardisation Issues

This Section discusses a list of actions corresponding to the NanoFabNet stakeholders' expectations regarding the standardisation area. A NanoFabNet survey of the wider identified community of sustainable nanofabrication provides an illustration of the stakeholders' need for information on standardisation activities (see Figure 8); Table 2 to Table 4 below describe the resulting priority actions developed by the NanoFabNet presents some outputs from the NanoFabNet survey.

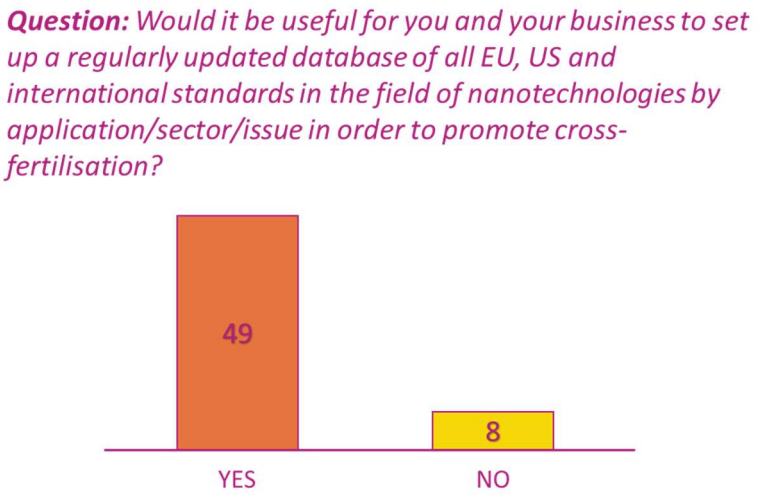

Figure 8: Screenshot of an answers to the question 'Would it be useful for you and your business to set up a regularly updated database of all EU, US and international standards in the field of nanotechnologies by application/sector/issue […]?', polled as part of a NanoFabNet survey regarding the need of sharing information on available standards and reference guidance.

Table 2: Standardisation Challenges – Action N°1: Increase awareness about standards and reference guidelines

Standardisation Challenge	**Action N°1**	**Increase awareness about standards and reference guidelines**
	Short Description of the Action	• 'Standardisation Database' (available through the NanoFabNet Platform) • Periodic report providing an insight regarding on-going activities within standardisation bodies • Consultancy services to help identify relevant guidance / documents
	Responsible Body/ies (that should conduct the action)	• NanoFabNet Hub & its individual Members
	Target Group (benefitting from the action)	• Nanotechnology/nanofabrication professionals • Public bodies (governmental/NGOs) • Metrology/characterisation testing professionals • Safety Assessment, Life Cycle Sustainability Assessment, and Ethical Assessment professionals (theoretical and lab-based)
	Suggested **Timeline**	• Short-term: one – three years (i.e. 2022 – 2025)

In the nanofabrication landscape, many players interact with each other. Beyond EuroNanoLab[4], several Open Innovation Test Beds (OITB) have emerged in recent years to provide access to multiple expertise and different nanofabrication facilities through pilot lines (NEWSKIN[23], PHOENIX[24], OASIS[25]). Few of them, however, have any knowledge of the world of standardisation and the associated processes. This considerably hampers the actions that could be taken to standardise products specifications, nanofabrication process description or characterisation methods for instance.

Table 3: Standardisation Challenges – Action N°2: Create a place for pre-standardisation activities & a bridge towards the standardisation world

Standardisation Challenge	**Action N°2**	**Create a place for pre-standardisation activities & a bridge towards the standardisation world**
	Short Description of the Action	• Set up a **Single-Entry Point** to manage the standardisation requests (e.g. NanoFabNet) • NanoFabNet to provide information and guidance about the standardisation process with the aim to firmly establish the NanoFabNet organisation as standard Project Leader (already possible in CEN/TC 352[13]) in the medium term to facilitate the development of standards and improve the transfer of R&D&I outcomes in standardisation • Document Position (cf. Concept Paper NSC[11] WG-B/WG-G)
	Responsible Body/ies (that should conduct the action)	• NanoFabNet Hub together with regulatory bodies, OITB, OECD, CEN, ISO, IEC
	Target Group (benefitting from the action)	• Nanotechnology/nanofabrication professionals • Public bodies (governmental/NGOs) • Metrology/characterisation testing professionals • Safety Assessment, Life Cycle Sustainability Assessment, and Ethical Assessment professionals (theoretical and lab-based)
	Suggested **Timeline**	• Short-term: one – three years (i.e. 2022 – 2025) • (review and possible continuation) Medium-term: three – eight years (i.e. 2025 – 2030)

The provision of standardised and validated measurement tools and procedures is essential to address all the issues associated with sustainable nanofabrication. The development and standardisation of processes, such test methods, however, requires a detailed assessment of the metrological performance of the method (i.e. intra-laboratory repeatability, inter-laboratory reproducibility) through the organisation of inter-laboratory comparisons; this enables the documentation of its quality and leads to high-quality laboratory data. This process is hampered by the difficulty to

[23] NEWSKIN: Innovation Eco-system to Accelerate the Industrial Uptake of Advanced Surface Nano-Technologies (https://www.newskin-oitb.eu/)

[24] PHOENIX: Pharmaceutical Open Innovation Test Bed for Enabling Nano-pharmaceutical Innovative Products (https://www.phoenix-oitb.eu/)

[25] OASIS : Smart lightweight composite materials and components (https://project-oasis.eu/)

implement outside EU-funded projects, consequently limiting the possibilities of having characterisation or test methods transferred to EU standardisation, especially as many laboratories refuse to participate for lack of funding.

The implementation of a funding programme similar to the **Inter-laboratory Study Program** of the American Society for Testing Material (ASTM)[26] (cf. the report on the *Challenges & Opportunities in the Validation, Harmonisation & Standardisation of industrial-scale nanofabrication*[1]) at the EU level would assist EU stakeholders in developing the necessary characterisation and testing standards, for which the prospect of implementing an inter-laboratory study was either administratively daunting or financially impossible. This would support the CEN committees in their efforts to produce precision statements for their test methods, so as to incorporate at least a repeatability statement, by helping them designing processes, such as an inter-laboratory study, identifying potential samples, soliciting volunteer laboratories, collecting and analysing data.

Table 4: Standardisation Challenges – Action N°3: Implement of a funding programme to support organisation of the inter-laboratory comparisons needed for the development of EU testing standards

Standardisation challenge	**Action N°3**	**Implement of a funding programme to support organisation of the inter-laboratory comparisons needed for the development of EU testing standards**
	Short Description of the Action	• Produce Position Paper • Interact with international initiatives (e.g. INISS-Nano[12], or the International Network4Sustainable Nanotechnology[27]) to support international collaboration actions in the defined field • Exchange with the EC to set up such funding mechanisms
	Responsible Body/ies (that should conduct the action)	• NanoFabNet Hub together with CEN, EC, EURAMET[22], NSC[11], EMN Advanced Manufacturing[3]
	Target Group (benefitting from the action)	• Public bodies (governmental/NGOs) • Metrology/characterisation testing professionals
	Suggested **Timeline**	• Medium-term: three – eight years (i.e. 2025 – 2030) • (review and possible continuation in the) Long-term: beyond eight years (i.e. 2030 onwards)

[26] ASTM : https://www.astm.org/

[27] International Network4Sustainable Nanotechnology: https://network4sustainablenano.org/

4.2 NanoFabNet Actions to address Harmonisation Issues

Figure 9 illustrates the role that stakeholders expect the NanoFabNet to play, i.e. to **be an antechamber to standardisation**, in order to carry out different harmonisation/pre-standardisation actions, especially in the field of characterisation; it is particularly noteworthy that "*None*" was a possible answer to the question shown in Figure 9 and that none of the participants chose to select it.

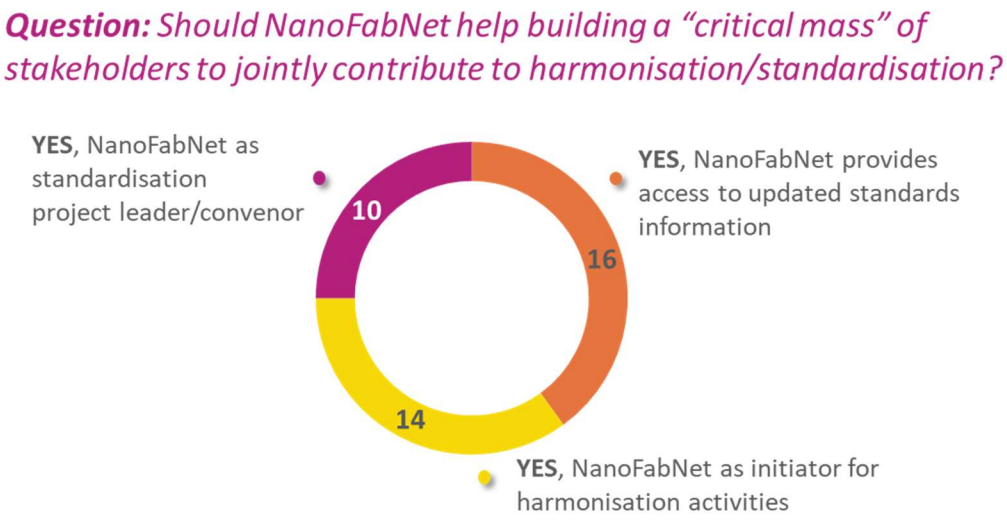

Figure 9: Screenshot of answers to the question 'Should NanoFabNet help build a 'critical mass' of stakeholders to jointly contribute to harmonisation/standardisation?', polled during the 2nd NanoFabNet DW (20th to 21st January 2021).

The actions discussed in Table 5 to Table 8 have been developed by the NanoFabNet Project to meet the stakeholder expectations on the different challenges associated to harmonisation issues with nanofabrication and nanotechnologies, as mentioned in the reports *Challenges & opportunities in the validation, harmonisation & standardisation of industrial-scale nanofabrication*[1] and *Nanofabrication Competence Map: Infrastructures, Knowledge and Skills - Proposal for a new Nanofabrication Taxonomy*[20].

The proposal of the taxonomy of nanofabrication equipment needs to be reviewed and updated by the community of nanotechnology/nanofabrication professionals (see Table 5). A strategy on how to disseminate this concept and convince the nanofabrication community about its usefulness will be developed by the NanoFabNet.

Table 5: Harmonisation Challenges – Action N°1: Harmonise a nanofabrication taxonomy

Harmonisation Challenge	**Action N°1**	**Harmonise a nanofabrication taxonomy**
	Short Description of the Action	• Review and disseminate the NanoFabNet taxonomy through EuroNanoLab and the main EU Nanofabrication facilities
	Responsible Body/ies (that should conduct the action)	• NanoFabNet together with EuroNanoLab, NNCI, CEN & ISO
	Target Group (benefitting from the action)	• Nanotechnology/nanofabrication professionals
	Suggested **Timeline**	• Short-term: one – three years (i.e. 2022 – 2025) Repeated Reviews & Updates (in correspondence with Action N°2): • Medium-term: three – eight years (i.e. 2025 – 2030) • Long-term: beyond eight years (i.e. 2030 onwards)

Once the taxonomy of the nanofabrication equipment has been disseminated, the development of a more detailed harmonisation of nanofabrication process description will follow. Initial case studies (focusing on process transfer between multiple cleanrooms) will be performed within EuroNanoLab and a proposal for revision of actual ISO/TS 80004-8[28] will be filled based on their outputs. As outlined in Table 6, the NanoFabNet will help facilitate the interaction between EuroNanoLab and NNCI on the one hand, and between nanofabrication facilities and the standardisation bodies (CEN & ISO) on the other.

Table 6: Harmonisation Challenges – Action N°2: Harmonise a nanofabrication process description

Harmonisation Challenge	**Action N°2**	**Harmonise a nanofabrication process description**
	Short Description of the Action	• Facilitate the interaction with standards bodies to revise ISO/TS 80004-8:2020 Nanotechnologies — Vocabulary — Part 8: Nanomanufacturing processes • Support EuroNanoLab on the basis of the initiated case studies and ensure the relay to the standardisation world (in particular within CEN/TC 352 to increase activities at EU scale)
	Responsible Body/ies (that should conduct the action)	• NanoFabNet Hub together with EuroNanoLab, NNCI, CEN & ISO
	Target Group (benefitting from the action)	• Nanotechnology/nanofabrication professionals
	Suggested **Timeline**	• Medium-term: three – eight years (i.e. 2025 – 2030) Repeated Reviews & Updates (in correspondence with Action N°1): • Long-term: beyond eight years (i.e. 2030 onwards)

A feedback-loop will be maintained between the repeated reviews and updates of Harmonisation Challenges - Action N°1 and Action N°2; since application of the suggested taxonomies and descriptions will provide the ultimate test for its usability, accuracy and completeness.

[28] ISO/TS 80004-8:2020 Nanotechnologies — Vocabulary — Part 8: Nanomanufacturing processes

Since the development of FAIR (Findability, Accessibility, Interoperability and Reuse) approaches for data management is key both for nanofabrication itself and in terms of risk assessment; NanoFabNet will contribute to give visibility to ongoing initiatives in the field, and in particular to actions carried out by the Implementation Networks AdvancedNano[29] and GO NANOFAB[30] (see Table 7 and Table 8).

Table 7: Harmonisation Challenges – Action N°3: Promote FAIR data management practice

Harmonisation Challenge	**Action N°3**	**Promote FAIR data management practice**
	Short Description of the Action	• Use the large audience of NanoFabNet to disseminate FAIR principles and related information (e.g. events, project) • Integrate FAIR principles already in internal data management procedure to allow the provision of the data to customers as part of quality control of a specific service or ready to be used in proficiency testing. • Provide checklist for standardised reporting of nanofabrication data including requirements for characterisation data. • Coordinate generation of community-agreed metadata standards as central aspect of data FAIRness.
	Responsible Body/ies (that should conduct the action)	• NanoFabNet Hub together with NanoSafety Cluster (AdvancedNano[29]) and EuroNanoLab (GO NANOFAB[30])
	Target Group (benefitting from the action)	• Nanotechnology/nanofabrication professionals • Public bodies (governmental/NGOs) • Metrology/characterisation testing professionals
	Suggested **Timeline**	• Short-term: one – three years (i.e. 2022 – 2025) • (review and possible continuation in the) Medium-term: three – eight years (i.e. 2025 – 2030)

[29] GOFAIR Implementation Network AdvancedNano: https://www.go-fair.org/implementation-networks/overview/advancednano/

[30] GOFAIR Implementation Network GO NANOFAB: https://www.go-fair.org/implementation-networks/overview/go-nanofab/

Table 8: Harmonisation Challenges – Action N°4: Develop and promote CHADA concept to support material data format harmonisation

Harmonisation Challenge	**Action N°4**	**Develop and promote CHADA concept to support material data format harmonisation**
	Short Description of the Action	• Use the large audience of NanoFabNet to disseminate CHADA concept and information • Provide guidance on minimal information requirements, structure and harmonised terminology specifically for nanofabrication method reporting (nanofabrication CHADA templates) • Provide feedback and requirements for semantically annotated CHADAs for better automatic processing and computer readability
	Responsible Body/ies (that should conduct the action)	• NanoFabNet Hub & its individual Members • NanoFabNet Hub together with an external body • Safety Assessment, Material Modelling, Material Characterisation and Life Cycle Sustainability Assessment communities
	Target Group (benefitting from the action)	• Nanotechnology/nanofabrication professionals • Public bodies (governmental/NGOs) • Metrology/characterisation testing professionals
	Suggested **Timeline**	• Short-term: one – three years (i.e. 2022 – 2025) • (review and possible continuation in the) Medium-term: three – eight years (i.e. 2025 – 2030)

Figure 10 gives an overview of the NanoFabNet stakeholders' expectations regarding the role that the Hub should play in the field of harmonisation/pre-standardisation of characterisation methods.

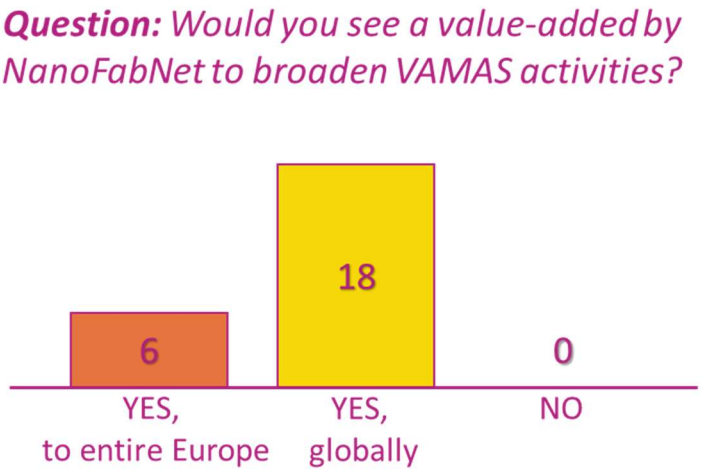

Figure 10: Screenshot of answers to the question 'Would you see a value-add by NanoFabNet to broaden VAMAS activities?', polled during the 2nd NanoFabNet DW (20th to 21st January 2021).

VAMAS currently brings together actors from several countries around the world to work on the pre-standardisation of characterisation methods in the field of advanced materials, in particular through inter-laboratory comparisons. However, this important initiative is not sufficiently visible to European stakeholders who could both contribute to the inter-laboratory comparisons carried out, but also express their needs in terms of methods to be developed and harmonised (more details on this initiative are given in the report *Challenges & Opportunities in the Validation, Harmonisation & Standardisation of industrial-scale nanofabrication* [1]) (see Table 9).

Table 9: Harmonisation Challenges – Action N°5: Harmonise & validate characterisation/testing methods (SOPs)

Harmonisation Challenge	**Action N°5**	**Harmonise & validate characterisation/testing methods (SOPs)**
	Short Description of the Action	• Bring together characterisation laboratories in focus group to harmonise characterisation SOPs • Identify needed Inter-Laboratory Comparisons (ILC) and prioritisation according to EU needs • Gather and share information on ongoing ILCs to facilitate the identification of participating expert laboratories • Organise ILC to validate SOPs (similar actions to the EUROLAB[31] ones) • Interaction with VAMAS[16] (information sharing and providing input to) • Contribution to the EMN Advanced Manufacturing[3] and to the delivery of its Strategic Research Agenda (SRA) • Provide a database with information on existing collections of SOPs and/or providing a central repository for nanofabrication SOPs.
	Responsible Body/ies (that should conduct the action)	• NanoFabNet & its individual Members • NanoFabNet Hub together with regulatory bodies, testing services providers, national characterisation platform, EURAMET, VAMAS
	Target Group (benefitting from the action)	• Nanotechnology/nanofabrication professionals • Public bodies (governmental/NGOs) • Metrology/characterisation testing professionals
	Suggested **Timeline**	• Short-term: one – three years (i.e. 2022 – 2025) • (review and possible continuation in the) Medium-term: three – eight years (i.e. 2025 – 2030)

The following Action N°6 (see Table 10) deals with the harmonisation of sustainability criteria. It must be undertaken in coherence with the *'NanoFabNet Strategy & Implementation Roadmap for Sustainability in Nanofabrication'*, such as presented in the corresponding NanoFabNet report. In this report, different tracks for helping to such a harmonisation are explored, in particular the use of

[31] EUROLAB: European Federation of National Associations of Measurement, Testing and Analytical Laboratories (https://www.eurolab.org/)

relevant mature or emerging indicators in the different sustainability areas (Environment, Health & Safety, Life Cycle Sustainability, Ethics & Governance). The Action is supported by Action N°7 (see Table 11).

Table 10: Harmonisation Challenges – Action N°6: Contribute to move a step forward regarding sustainability criteria

Harmonisation Challenge	**Action N°6**	**Contribute to move a step forward regarding sustainability criteria**
	Short Description of the Action	• Organise discussion within a dedicated Focus Group with interested members regarding the harmonisation of sustainability criteria • Production of a Position Paper • Initiate an action on this topic within standardisation bodies (CEN/TC 352 & ISO/TC 229) • Co-develop activities on international collaboration (e.g. within the harmonisation pillar of INISS-Nano[12])
	Responsible Body/ies (that should conduct the action)	• NanoFabNet member(s) • NanoFabNet Hub together with EC, OECD/WPMN, CEN, ISO, nanosafety communities (e.g. NSC[11]) and international initiatives, such as INISS-Nano[12] (specifically in the harmonisation pillar, but also beyond e.g. sharing facilities, ethical aspects, etc.)
	Target Group (benefitting from the action)	• Nanotechnology/nanofabrication professionals • Public bodies (governmental/NGOs) • Safety Assessment, Life Cycle Sustainability Assessment, and Ethical Assessment professionals (theoretical and lab-based)
	Suggested **Timeline**	• Short-term: one – three years (i.e. 2022 – 2025) • (review and possible continuation in the) Medium-term: three – eight years (i.e. 2025 – 2030)

Table 11: Harmonisation Challenges – Action N°7: Creation of LCA dataset in collaboration with industry stakeholders to be included in LCA database

Harmonisation Challenge	**Action N°7**	**Creation of LCA datasets in collaboration with industry stakeholders to be included in LCA database**
	Short Description of the Action	• Bring together LCA practitioners and industry to harmonise inventory flows characterisation for nanofabrication (e.g. nanoparticles emissions) • Identify gaps and provide requirements for extension to existing and new databases for managing and sharing nanofabrication data according to the standards developed above. • Publication of transparent datasets, based on industrial case studies, in accordance with LCA database rules (e.g. Product Environmental Footprint, ecoinvent, GaBi)

	Responsible Body/ies (that should conduct the action)	• NanoFabNet Hub together with LCA database managers & database providers
	Target Group (benefitting from the action)	• Nanotechnology/nanofabrication professionals • Public bodies (governmental/NGOs) • Sustainability professionals
	Suggested **Timeline**	• Medium-term: three – eight years (i.e. 2025 – 2030)

A need for training materials reflecting new developments of equipment taxonomy and harmonised process description will be evaluated (Table 12). The evaluation will be done within EuroNanoLab expert groups first; in the second stage, it will be extended to all target groups. Update of training materials will be then prioritised based on the output of this evaluation.

Table 12: Harmonisation Challenges – Action N°8: Contribute to identify needs regarding harmonisation & standardisation of training materials

Harmonisation Challenge	**Action N°8**	**Contribute to identify needs regarding harmonisation & standardisation of training materials**
	Short Description of the Action	• Evaluation of needs with key nanofabrication initiatives • Prioritisation of training materials updates • Involvement and contribution to the WG-A "Training and Education" of the NSC[11] • Steering of a reflection within CEN/TC 352 Nanotechnologies • Interaction with ASTM to coordinate activities in the field and to share the burden
	Responsible Body/ies (that should conduct the action)	• NanoFabNet & its individual Members • NanoFabNet together with CEN, ISO, IEC and ASTM
	Target Group (benefitting from the action)	• Nanotechnology/nanofabrication professionals
	Suggested **Timeline**	• Short-term: one – three years (i.e. 2022 – 2025) • (review and possible continuation in the) Medium-term: three – eight years (i.e. 2025 – 2030)

The issues surrounding nanofabrication must be shared at the international level, in order to propose harmonised approaches. The NanoFabNet's contribution to setting up international initiatives, such as the INISS-Nano[12], will support this process (see Table 13).

Table 13: Harmonisation Challenges – Action N°9: Create an international coordination group to facilitate discussion between stakeholders and harmonise point of views & methodologies worldwide

Harmonisation Challenge	**Action N°9**	**International coordination to facilitate discussions between stakeholders**
	Short Description of the Action	• Contribute to the development of organisational frameworks within international initiative, such as the INISS-Nano[12] • Involve NanoFabNet stakeholders in specific actions of international initiatives, such as the INISS-Nano[12] or the International Network4Sustainable Nanotechnology[27], in order to support international collaboration actions in the defined fields
	Responsible Body/ies (that should conduct the action)	• NanoFabNet & its individual Members
	Target Group (benefitting from the action)	• Nanotechnology/nanofabrication professionals • Public bodies (governmental/NGOs) • Metrology/characterisation testing professionals • Safety Assessment, Life Cycle Sustainability Assessment, and Ethical Assessment professionals (theoretical and lab-based)
	Suggested **Timeline**	• Short-term: one – three years (i.e. 2022 – 2025) • (review and possible continuation in the) Medium-term: three – eight years (i.e. 2025 – 2030)

4.3 NanoFabNet Actions to address Validation Issues

The validation process aims to establish the compliance of any activity output as compared to inputs of the activity. It is used to provide information and evidence that the transformation of inputs produced the expected and right result. This concerns questions of skill or process control as well as characterisation methods.

Validation issues appeared as key to stakeholders who have been questioned through a corresponding NanoFabNet survey or different sessions of the 2nd DW; the importance of validation issues mainly concerns the **validation of expertise or efforts made within the entities to move towards sustainable nanomanufacturing**, with a strong focus on characterisation and testing method issues. Figure 11 illustrates the expectations of stakeholders regarding the need to organise in a coordinated way and according to reference standards:

A. Proficiency testing to validate testing laboratories expertise regarding a specific protocol, in particular with a view to an accreditation process according to the ISO/IEC 17025 standard[21]; and
B. Inter-laboratory comparison to validate metrological performances of new measurement/characterisation methods or procedures.

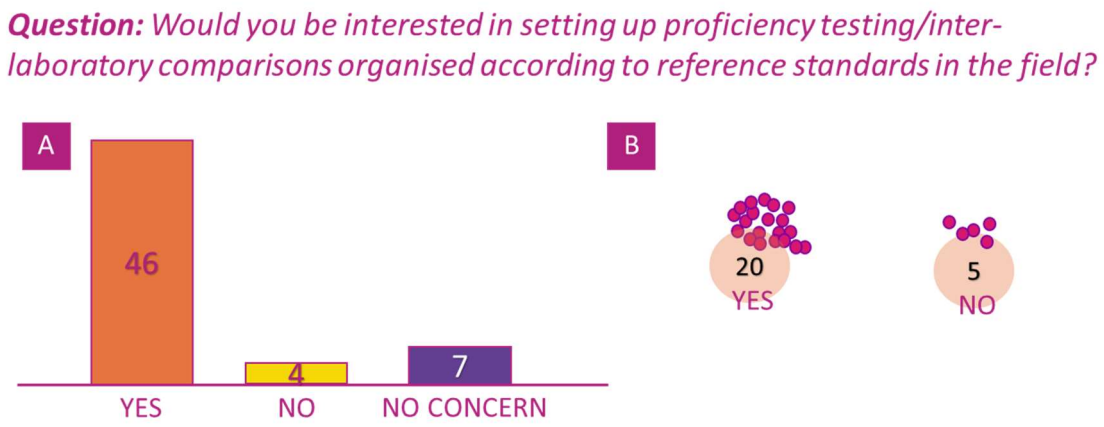

Figure 11: Screenshot of answers to the question A: 'Would you be interests in setting up proficiency testing/interlaboratory comparisons organised according to reference standards in the field?', polled as part of a NanoFabNet survey regarding the topic of proficiency testing and inter-laboratory comparisons, and B: 'Would you be interested in participating in inter-lab comparisons to validate methods/SOPs?', polled during the 2nd NanoFabNet DW (20th to 21st January 2021).

The following list of actions (see Table 14 to Table 17) responds to these expectations, as mentioned in the NanoFabNet report on the *Challenges & opportunities in the validation, harmonisation & standardisation of industrial-scale nanofabrication*[1].

Action N°1 has been proposed in coherence with the "*NanoFabNet Strategy & Implementation Roadmap for Sustainability in Nanofabrication*", such as presented in the corresponding NanoFabNet report. The creation of a label on sustainability can allow the actors to validate their approach and strategy towards sustainability (see Table 14). Such a label could be based on certain benchmarks and already existing standards, to be precisely defined. The relevance of such an initiative remains to be carefully discussed with the concerned stakeholders.

Table 14: Validation Challenges – Action N°1: Create and validate a certification framework for a label on sustainability

Validation Challenge		
	Action N°1	**Create and validate a certification framework for a label on sustainability**
	Short Description of the Action	• Develop a certification framework with NanoFabNet members according to harmonised criteria (including benchmarks and already existing standards) to enable them to validate their commitment to this path and for marketing purpose
	Responsible Body/ies (that should conduct the action)	• NanoFabNet & its individual Members
	Target Group (benefitting from the action)	• Nanotechnology/nanofabrication professionals • Public bodies (governmental/NGOs) • Safety Assessment, Life Cycle Sustainability Assessment, and Ethical Assessment professionals (theoretical and lab-based)
	Suggested **Timeline**	• Medium-term: three – eight years (i.e. 2025 – 2030) • (review and possible continuation in the) Long-term: beyond eight years (i.e. 2030 onwards)

In order to allow seamless transfer of users between different nanofabrication facilities, a system of harmonised user certificates will be developed (Table 15). The certificates will serve as a proof that the user has the necessary theoretical background and is capable to independently work with specific technology. Holders of such certificate can obtain faster/easier access to facilities, which will be accepting it. Pilot action is planned within EuroNanoLab partners.

Table 15: Validation Challenges – Action N°2: Develop certified training

Validation challenge		
	Action N°2	**Develop certified training**
	Short Description of the Action	• Support to develop and raise awareness regarding the certificate to be developed within EuroNanoLab to serve as a proof that the user has necessary theoretical background and is capable to independently work with specific technology
	Responsible Body/ies (that should conduct the action)	• NanoFabNet Hub together with EuroNanoLab
	Target Group (benefitting from the action)	• Nanotechnology/nanofabrication professionals (Users of open access research infrastructures)
	Suggested **Timeline**	• Medium-term: three – eight years (i.e. 2025 – 2030) • (review and possible continuation in the) Long-term: beyond eight years (i.e. 2030 onwards)

Laboratories proposing characterisation activities must be able to demonstrate their ability to master different characterisation methodologies, in order to produce reliable and comparable data (see Table 16). This concerns both laboratories housed within nanofabrication facilities, as well as

characterisation platforms or measurement service providers, within the latter cases the potential desire to be accredited according to the ISO/IEC 17025 standard.[21]

Table 16: Validation Challenges – Action N°3: Organise and coordinate proficiency testing services

Validation Challenge	**Action N°3**	**Organise and coordinate proficiency testing services**
	Short Description of the Action	• Proposes the organisation of regular proficiency testing according to the requests received by the Hub
	Responsible Body/ies (that should conduct the action)	• NanoFabNet Hub with EMN Advanced Manufacturing[3]
	Target Group (benefitting from the action)	• Nanotechnology/nanofabrication professionals • Public bodies (governmental/NGOs) • Metrology/characterisation testing professionals
	Suggested **Timeline**	• Short-term: one – three years (i.e. 2022 – 2025)

Table 17: Validation Challenges – Action N°4: Contribute to existing R&D&I funding scheme in the field of harmonisation & validation

Validation Challenge	**Action N°4**	**Contribute to existing R&D&I funding scheme in the field of harmonisation & validation**
	Short Description of the Action	• Identify topics relevant for harmonisation & validation in the field of nanofabrication within existing funding schemes (e.g. analytical methods, characterisation methods) • Create topic description to address the identified topics in close collaboration with international collaborators (e.g. co-creation within INISS-Nano[12] or the International Network4Sustainable Nanotechnology[27]) • Incorporate the described topics into funding schemes • Disseminate information regarding pre-normative calls for proposal from the European Partnership on Metrology (EPM)
	Responsible Body/ies (that should conduct the action)	• NanoFabNet Hub together with the EMN Advanced Manufacturing[3]
	Target Group (benefitting from the action)	• Nanotechnology/nanofabrication professionals • Public bodies (governmental/NGOs) • Metrology/characterisation testing professionals
	Suggested **Timeline**	• Short-term: one – three years (i.e. 2022 – 2025) • (review and possible continuation in the) Medium-term: three – eight years (i.e. 2025 – 2030)

5. Conclusions

The NanoFabNet report "*Challenges & opportunities in the validation, harmonisation & standardisation of industrial-scale nanofabrication*"[1] provided a detailed analysis of the cross-cutting issues in the fields of validation, harmonisation and standardisation to deploy a real sustainable nanofabrication. The findings showed that the lack of harmonisation and standardisation is the most significant barrier to the introduction of nanofabrication in the industrial ecosystem, rendering the Action Plan provided in the present report all the more important.

The sixteen actions identified and discussed in this Action Plan range from activities to be implemented together with other key networks and/or entities to services directly delivered by the NanoFabNet. The emphasis is on positioning the NanoFabNet as a pre-standardisation structure to link different communities and actors to bodies in which this harmonisation work can be carried out (CEN, ISO, IEC, OECD, VAMAS).

This Action Plan will be readily incorporated into the '**NanoFabNet 5-Years-Strategy**' to form a central part of the offerings and services of the NanoFabNet Hub to the community of sustainable nanofabrication. Various actions have already been put in place over the last few months that testify to the installation of the NanoFabNet in the nanofabrication landscape: the NanoFabNet is already an official member of CEN/TC 352[13] and of the AdvanceManu EMN[3]; it contributed to the drafting of a Concept Paper within the NSC[11], and to bringing EuroNanoLab[4] actors closer to the work in progress within ISO/TC 229[14], and is actively involved in a number of international initiatives, such as the INISS-Nano[12] or the International Network4Sustainable Nanotechnology[27].

NanoFabNet

international Hub for sustainable industrial-scale Nanofabrication