Concept paper

International Network Initiative on
Safe & Sustainable Nanotechnology

INISS-nano

"This concept paper shall prepare the ecosystem for global collaboration in selected fields of action (see pillars), enabling "collaboration without borders" within joint projects, joint funding initiatives, and any further way of cooperation."

Comments:

Interested colleagues are invited to connect with the coordinators of the initiative. Furthermore, any comments, contributions and remarks that are meant to support INISS-nano are highly welcome and shall be sent to the corresponding author before August 17th 2021 to be taken into account during the revision.

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Content

Abbreviations

ANF – Asia Nano Forum
AOPs – Adverse Outcome Pathways
APMP – Asia Pacific Metrology Programme
ASTM – American Society for Testing and Materials
BIAC – Business at OECD
CEN – European Committee Standardisation
EC – European Commission
ECHA – European Chemicals Agency
ENMs – engineered, manufactured or manmade nanomaterials
EU-US-CoR's – EU-US-Communities of Research
EUON – European Union Observatory for Nanomaterials
EURAMET – EURAMET e.V., European Association of National Metrology Institutes
FAIR(-principles) – findable, accessible, interoperable and reusable
GDPR – General Data Protection Regulation
INIC – Iran Nanotechnology Innovation Council
INISS-nano – international network initiative on safe and sustainable nanotechnology
ISO – International Organisation for Standardisation
JRC – Joint Research Centre
MoAs – Modes of Action
NANTEC – National Nanotechnology Center, Thailand
NRGC – Nanotechnology Risk Governance Council
NSC – European NanoSafety Cluster
OECD – Organisation for Economic Co-operation and Development
OITBs – Open Innovation Test Bed projects
OSHA – European Agency for Safety and Health at Work
RMOs – Regional Metrology Organisations
RRI – Responsible Research and Innovation
SAICM – Strategic Approach to International Chemicals Management
SDS – Safety Data Sheets
SIM – Inter-American Metrology System
TC – Technical Committee
UNEP – United Nations Environment Programme
UNITAR – United Nations Institute for Training and Research
WHO – World Health Organisation
WPMN – OECD Working Party on Manufactured Nanomaterials

1.1 Introduction

The numerous application possibilities of engineered, manufactured or manmade nanomaterials (ENMs) have created immense interest in various industry sectors to invest in this emerging technology. This has resulted in a rapid entry of nanotechnology-based products into the market and has obviated the need of regulation policies to ensure their safe and responsible/sustainable manufacturing, quality control, efficacy and use. In order to be successful in nanotechnology research, commercialisation and regulation, international collaboration is crucial. This works quite well within Europe and the USA; however, international collaboration especially between Europe and Asia is still in its infancy. Since the creation of the EU NanoSafety Cluster (NSC) in 2010[1], the international collaboration is an important activity. The EU-US-CoR's[2] (established 2011) and international exchange-meetings (e.g. with South Korea, 2011 and onwards) are successful examples to be mentioned, however, a single, independent global collaboration platform is still missing.

The "*EU-Asia dialogue on NanoSafety*", organised by members of the EU NanoSafety Cluster and the Asia Nano Forum, started in 2017 as a series of annual conferences, in order to focus on synergies between Asian and European countries in science and research, with respect to (safer) nanomaterials, including standardisation and test guideline development pertaining to them. Based on the proposal of a "network of networks", first presented during the 2nd EU-Asia dialogue on NanoSafety (2018) by Ali Beitollahi (INIC), at the 4th Meeting (2020) a further developed idea of that was shown. Thus, it was decided to move a next step forward, make this collaboration more formal and open it to the world. A group of experts in different aspects of NanoSafety research - already including world-wide partners - started to discuss the goals and content of the initiative entitled "**International Network Initiative on Safe and Sustainable Nanotechnologies" (INISS-nano)**, and how this network could be put into practice.

1.2 Focus and value-added by INISS-nano

Based on the idea of a "network of networks", the "**international network initiative on safe and sustainable nanotechnology" (INISS-nano)** was formed, aiming to bring together science, industry and government from partners all over the world, **not duplicating structures but connecting** with them (e.g. NSC, ANF, EC & JRC, EU-US-CoR's, standardisation bodies (such as CEN, ISO, ASTM, etc.), OECD & BIAC, ECHA). The focus shall be on the **collaboration in different fields pertaining to nanotechnology research in general and nano-safety research in particular**. This shall include collaboration in terms of e.g. training,

[1] https://www.nanosafetycluster.eu
[2] https://us-eu.org/

standardisation efforts, test-guidelines development, metrology, commercialisation, ethical aspects, sustainability, and joint research, supporting governance, regulatory guidance, and of course being open for further joint working items. The added value of INISS-nano shall be the collection and analysis of available information worldwide, always in collaboration with existing organisations or working groups (e.g. definitions and ontologies of nanotechnology; differences between several markets; common strategies on transfer of scientific results into policy; regulation; standardisation; harmonisation of methods, such as risk assessment methodologies). INISS-nano will aim at making this knowledge accessible for the global nano-community, and based on identified gaps and/or bottlenecks to initiate common activities. Joint activities could be (but shall not be limited to) development of joint funding programs, joint research projects and develop common publications, reduce/avoid duplication in research and innovation, exchange programs for students, data sharing, share of common laboratory infrastructure, expert exchange, consultancy services, support the development of harmonised and validated protocols e.g. for characterisation methods; gaining an overview on available certification protocols. Additionally, this initiative has the ambition to support with its scientific knowhow the work of global organisations active in the nano-field, e.g. the OECD, to contribute to international harmonisation and to the development of standardisation documents, such as OECD testing guidelines or ISO/CEN Technical Reports/Specifications. The creation of official bridges with regional metrology organisations (such as EURAMET, APMP, SIM, etc.)[3] will be key, not only to bring metrology expertise on board, but also to help guide the activities of this community. This shall enable INISS-nano to make a real contribution to advancing pre-standardisation and validation in the field of metrology for the benefit of nano-safety issues.

The **following pillars** have been identified by the participants during the 4th EU-Asia Dialogue and further defined during the first meetings of the INISS-nano group (i.e., co-authors of the concept paper) as **important action fields** that shall be in the focus of INISS-nano. The "NanoSafety Dialogue"-events shall be continued and be the place to discuss the output generated so far, to evaluate the progress, and to define a kind of **international nano-community roadmap for the mid- and long-term implementation** of the actions.

[3] https://www.bipm.org/en/liaison/regional/

2.1 Pillar "Harmonisation"

The harmonisation pillar consists of two elements, in which harmonisation on global level shall be addressed within this initiative:

2.1.1 Standardisation efforts

Undoubtedly, standardisation in general and more specifically **nano-safety and characterisation/metrology standards** play a **key role** in further development of safe and responsible nanotechnologies. There is a critical need to harmonise nanomaterials characterisation technologies so that those will deliver quantitative interoperable characterisation data. This is the case for example of EU-H2020 project CHARISMA[4] for Raman spectroscopy or e.g. projects EMPIR nPSize[5], and ISO-G-SCoPe[6] for improved traceability chain of nanoparticle size measurements and graphene characterisation, respectively. Harmonised measurements will facilitate accurate quantitative characterisations of given materials with, e.g. multiple Raman instruments, thus enabling the development of standards. Harmonised characterisations are a key pillar to enable a one-characterisation/one-assessment paradigm.

Furthermore, the Open Innovation Test Bed projects (OITBs), funded under the NMBP-03-2019 (FlexFunction2Sustain[7], INNOMEM[8], NewSkin[9], NextGenMicrofluidics[10]) and NMBP-06-2020 (PHOENIX[11]) shall be also mentioned to have the potential to contribute to characterisation and measurements according to standards. Finally, the process analytical technologies fitting to nanotechnologies are another characterisation competence that is funded by the EC in specific projects, NMBP-08-2019 (CHALLENGES[12], NanoBat[13], NanoPAT[14], NanoQI[15], PAT4Nano[16], RealNano[17]).

Unfortunately, despite considerable international investments on nano-safety and nanomaterials characterization research and the establishment of relevant technical

[4] https://www.h2020charisma.eu/ ; https://cordis.europa.eu/project/id/952921
[5] https://www.bam.de/Content/EN/Projects/nPSize/npsize.html
[6] https://www.euramet.org/research-innovation/search-research-projects/details/project/standardisation-of-structural-and-chemical-properties-of-graphene/
[7] https://flexfunction2sustain.eu/ ; https://cordis.europa.eu/project/id/862156/en
[8] https://www.innomem.eu/ ; https://cordis.europa.eu/project/id/862330/en
[9] https://www.newskin-oitb.eu/ ; https://cordis.europa.eu/project/id/862100/en
[10] https://www.nextgenmicrofluidics.eu/ ; https://cordis.europa.eu/project/id/862092/en
[11] https://www.phoenix-oitb.eu/ ; https://cordis.europa.eu/project/id/953110/en
[12] https://cordis.europa.eu/project/id/861857
[13] https://cordis.europa.eu/project/id/861962
[14] https://cordis.europa.eu/project/id/862583
[15] https://cordis.europa.eu/project/id/862055
[16] https://cordis.europa.eu/project/id/862413
[17] https://cordis.europa.eu/project/id/862442

committees in standardization bodies (ISO/TC229, ASTM/E56, CEN/TC352…) in the past 15 years, there are **not yet many international nano-safety-related published standards**, **nor harmonized (or even standardised) documents needed to implement OECD Test Guidelines**, to support the ever increasing demands of the relevant industries and regulatory bodies. EU-funded projects are underway to support the development of testing guidelines (Gov4Nano[18], NanoMET[19], NanoHarmony[20]). **Addressing these issues demands reinforced international collaboration,** which supports the need of an overarching platform for facilitating enhanced communications, sharing knowledge and infrastructure between the related stakeholders and sharing the burden in terms of resource allocation. Furthermore, such a platform could embrace a large number of international collaborating experts/ responsible bodies (notably from academia and regulatory agencies) by initiating smart and persuading strategies, paving the way towards more harmonized approaches regarding international regulations and laws to be developed in future. Such a globally organised platform, meantime, could also act as an international consulting body or as external liaison to international standardisation bodies such as ISO/TC229, supporting e.g. with its overview about science and research results around the globe.

The proposed networking instrument aiming at boosting nano-safety and nano-characterisation standardisation cooperation will be able to provide the following added values in collaboration with existing platforms/networks/organisations:

- Facilitate and accelerate the development of joint high impact nano-safety and harmonised/pre-standardised nano-characterisation to enable its standardisation, which will eventually benefit the consumer community and governmental risks agencies as well as relevant industrial sectors. This is done through sharing the relevant information related to human resources, infrastructure, knowledge, etc. to blend into consistent agreed harmonised methods – as far as possible, this shall be done in collaboration and via existing infrastructures.
- Support capacity building in the scientific community to take a bolder role in the development of nano-safety and nano-characterisation harmonisation to improve the efficiency of knowledge transfer for the creation of standards. A possible solution for this could be, for example, to develop and communicate on internationally recognised standardisation certificates to acknowledge standardisation work on the basis of the mechanism, already implemented by the EU Graphene Flagship Standardisation Committee[21], and foster CEN Workshop Agreements.
- Make existing documents and work in progress better known to the various stakeholders, including industrialists, with a view to wider use of the documents, to

[18] https://www.gov4nano.eu/ ; https://cordis.europa.eu/project/id/814401
[19] https://cordis.europa.eu/project/id/887268
[20] https://cordis.europa.eu/project/id/885931
[21] https://graphene-flagship.eu/innovation/industrialisation/standardisation/

recruit new experts and to promote cross-fertilisation between different sectors or geographical areas.

- Further enhancement of research and development collaboration in favour of supporting harmonisation and development of new standards by promoting some of the mechanisms already in place (i.e., EU funding opportunities for pre-standardisation metrology activities through the new European Partnership on Metrology (EPM) Programme or Graphene Flagship Validation Service and Standardisation Committee)[22].
- Support inter-lab assessments initiatives, help in the prioritisation of inter-lab comparisons and promote, among others, VAMAS[23] and ASTM/E56 activities in the field.
- Involve the National Metrology Institutes (NMIs) in the process so that the actions of the actors in this community can be aligned with the needs in the field, taking into account the opportunity in EU to build a European Metrology Network in the field of nanomaterials (https://www.euramet.org/european-metrology-networks/?L=0).
- Support better coordination and synergy in test guidelines for regulatory systems through enhancement of international collaboration, i.e., MALTA initiative[24], and successor programs, and/or supporting the Mutual acceptance of data approach.
- Enhance the existing collaboration between international standardization bodies like ISO/TC229, CEN352, etc. as well as national standardization bodies in the area of nano-safety and nano-characterisation standards with the nano-safety community.

2.1.2 Transfer of Science into harmonised Guidance and Standards on a global Scale

From the Creation and Establishment of Safe and Sustainable by Design (SSbD) and Regulatory Preparedness towards implementation

In over a decade of research, the European projects in the NSC have collaborated with partners from around the world to generate fundamental knowledge and data on the intrinsic and extrinsic physicochemical properties of engineered nanomaterials, as well as their key release/exposure pathways, nano-bio/eco interactions, biodistribution, environmental fate, (eco)toxicity and related Modes of Action (MoAs) such as Adverse Outcome Pathways (AOPs). This coordinated effort has formed a solid basis for advancing the research from the consideration of the (regulated) safety of current nanomaterials to the future-oriented sustainability of advanced materials and processes under the novel concept of Safe and

[22] https://graphene-flagship.eu/innovation/industrialisation/validation-service/
[23] www.vamas.org
[24] https://www.bmu.de/en/topics/health-chemical-safety-nanotechnology/nanotechnology/the-malta-initiative/

Sustainable by Design (SSbD)[25]. The NMBP-15[26] (ASINA[27], Sabyna[28], SbD4Nano[29], SABYDOMA[30]) and the NMBP-16[31] projects (SUNSHINE[32], DIAGONAL[33], HARMLESS[34]), and DT-NMBP-12[35]-projects (NanoFabNet[36], SusNanoFab[37]) aim to address new and future generations of materials. This is done in collaboration with a wide range of international partners and collaborators including e.g. USA, Canada, China, South Korea, South Africa, Israel, Brazil and Japan. The NMBP-15- and NMBP-16-projects study the environmental, health and safety (EHS) implications of advanced multi-component and smart nanomaterials, while the DT-NMBP-12 projects aim to form a (digitally established) collaborative space for sustainable nanofabrication as a large-scale high-tech industrial manufacturing process.

The projects' underlying bottom-up generation of scientific knowledge, methods and data(bases), supported by the coordinated effort to foster and establish international, interdisciplinary activities between both academia, public laboratories and industrial players of all sizes, is complemented by a top-down process of ensuring that their results both relevant for regulation and policy making, and implementable by the sustainable nanotechnology community. Finally, the mission of NMBP-35-2020 projects (CHARISMA[4], nanoMECommns[38], EASI-STRESS[39]) are instrumental to harmonize nanomaterials characterization, thus enabling their standardization. Standardized nano-characterisation is a critical need to seamlessly connect characterization with safety assessment.

The process of transferring the state-of-the-art science of sustainable nanotechnology into internationally harmonised and accepted guidelines, standards and policies was pioneered by the NANoREG project[40] and implemented via a number of follow-up projects, which aim to provide policy makers with scientific opinions on how certain challenges could be addressed through policies and guidance documents. The projects thus play a pivotal role in increasing Regulatory Preparedness; their collaborative outreach to both academia, industries and regulators provides a real-world grounding of both the scientific and industrial state-of-the-art

[25] http://doi.org/10.5281/zenodo.4652587
[26] topic: Safe by design, from science to regulation: metrics and main sectors
[27] https://cordis.europa.eu/project/id/862444
[28] https://cordis.europa.eu/project/id/862419
[29] https://cordis.europa.eu/project/id/862195
[30] https://cordis.europa.eu/project/id/862296
[31] topic: Safe by design, from science to regulation: multi-component nanomaterials
[32] https://cordis.europa.eu/project/id/952924
[33] https://cordis.europa.eu/project/id/953152
[34] https://cordis.europa.eu/project/id/953183
[35] topic: Sustainable Nano-Fabrication
[36] https://cordis.europa.eu/project/id/886171
[37] https://cordis.europa.eu/project/id/882506
[38] https://cordis.europa.eu/project/id/952869
[39] https://cordis.europa.eu/project/id/953219
[40] https://cordis.europa.eu/project/id/310584

and increases capacity to anticipate any regulatory concerns to take timely and appropriate action.

The Need for a globally harmonised approach

The process of knowledge transfer from state-of-the-art R&I into relevant, appropriate and implementable policies has been developed and perfected throughout the past Framework Programmes of the European Commission (i.e. FP7 (2007-2013) and FP8=Horizon 2020 (2014-2020)) and is now firmly established and enforced within the European community. International collaborations are both afforded by the complexity of any advanced technology, and commanded by the need for approaches to sustainability that are neither limited to borders, nor defined by hard regulations. However, this relies on the ad-hoc responsibility and outreach capacity of the individual project partners.

The establishment of INISS-nano will relieve the burden and limitation of ad-hoc call-specific international collaborations that are newly established on a case-by-case basis, and that may not be able to allow productive, cross-border collaborations to take place. The proposed INISS-nano could become a permanent collaborative space for the exchange of knowledge and ideas across borders and beyond the immediate regulatory requirements of a single jurisdiction, thus supporting the development of a community for sustainable nanotechnology, based on principles and values that are jointly agreed on a global level. The vision would be harmonisation, the way to achieve this shall be the collaboration.

Furthermore, within the concept of INISS-nano all collaboration partners will respect to consequently follow the FAIR-principles of data.[41,42,43]

[41] FAIR-principles: Wilkinson, M., Dumontier, M., Aalbersberg, I. et al. The FAIR Guiding Principles for scientific data management and stewardship. Sci Data 3, 160018 (2016). https://doi.org/10.1038/sdata.2016.18

[42] https://doi.org/10.1038/s41565-021-00911-6

[43] https://pubs.rsc.org/en/content/articlehtml/2020/nr/c9nr08323e

2.2 Pillar "Support industrial understanding"

INISS-nano is meant to establish a collaboration between the ANF, the NSC and all interested countries globally, in order to expand the common knowledge base for nanomaterials of regulatory significance and to support the needs of various stakeholders including industry. The first meeting of INISS-nano, attended by interested stakeholders from both regions, identified that "supporting industrial understanding" should be one of the four pillars that the initiative should address. In this section we will describe the approach that the INISS-nano can support industrial understanding by first understanding some of the barriers faced by industry and then investigating the viability of some mechanisms to overcome these barriers. The renewed focus of governments in both EU Member States and Asia on sustainability and management of climate change (e.g. EU Chemicals Strategy for Sustainability[44]; Thailand's drive towards a bio-, circular and green (BCG) economy[45]) can assist engagement with programs developed by INISS-nano.

Industry can face a number of barriers to the progress of a product from research through development to commercialisation. Some of these are acceptable, such as regulatory obligations that ensure the safety of products to humans and the environment; in fact, these can even trigger new areas of innovation. However, other barriers, such as poor knowledge transfer are barriers that can and should be reduced. This is of particular importance in a growing sector such as nanotechnology. During the process of conceptualization of INISS-nano a number of barriers has been identified that it is felt the initiative could help to reduce.

Inefficient Knowledge Transfer

Poor dissemination from and among research projects can lead to duplication of work and delay the widespread uptake of the best cutting-edge methods and tools by industry. This barrier could be established both by an approach to dissemination of results by projects that are too narrow or by an unwillingness or inability of industry to adopt new research. It is felt by some (industrial) parties that the disseminated results from these projects are too technically complex to easily utilise at the factory floor level. There is a critical need to devise strategies to foster permeation of knowledge among these communities. The implementation of FAIR-principles across the globe and further use of already installed data platforms (e.g. European Union Observatory for Nanomaterials – EUON[46]) will be taken into account as solutions that will be supported by INISS-nano.

[44] https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf
[45] https://www.nstda.or.th/thaibioeconomy/138-bio-circular-green-economy-to-be-declared-a-national-agenda.html
[46] https://euon.echa.europa.eu/

Inconsistent measures and mechanisms between regions

Encourage aligning of measures and mechanisms in regulation and market access to reduce complexity for multinational companies. The issue of complexity of different regulatory regimes is addressed in the chapter of "legal aspects" in chapter 2.4.2. Beyond that, if there is excessive disparity of the protocols and tools required to meet regulatory obligations, the industry might not recognise where they can use a single set of data across many jurisdictions and see a barrier to expansion where none exists.

A Thai Case-Study - Variable confidence in products using nanotechnology (both from industry and the consumer)

Nanotechnology has been *de facto* present in industry for decades (e.g. catalysis, sensors), but the industry has only recently become aware of it due to an exponential growth of its applications.

- Perceived uncertainty over hazards and risk from nanomaterials and nano-enabled products, leading to the implementation of high regulatory barriers due to regulators needing to take a precautionary approach. A number of governments have found difficulties around the introduction of Genetically Modified Organisms (GMO) into their markets and do not want to face the same issues around nanotechnology. Thus, the support for companies to facilitate the implementation of updated REACH is needed[47].
- In some regions, "*nano*" is regarded positively to such an extent that its use can be associated with premium products. This can lead to this term being used as a marketing tool even where neither nanomaterials nor nano-enabled products are present potentially causing confusion and distrust to the consumer.
- In the communication of the risks and appropriate risk management measures of nanomaterials to the factory floor, which will benefit from making use of EUON.

Governments and regulators across both Asia and the EU are recognising the importance of nanotechnologies and the barriers to its exploitation. For example in the case of Thailand, awareness of nano-safety is an integral part of nanotechnology development. The same can also be said when it comes to safe use of nanomaterials in industry. Safety of workers is a priority and for this reason, the government approved the NanoSafety and Ethics Strategic Plan in 2012. The national plan is designed to be used as a guideline for creating action plans by relevant agencies. To achieve the goal the Plan identified three strategies:
1) the creation and management of knowledge,
2) the development and strengthening of measures and mechanisms for supervision and enforcement, and
3) the strengthening and promotion of public participation.

[47] https://echa.europa.eu/-/updated-guidance-for-registering-substances-in-nanoform

INISS-nano can assist in lowering these barriers and have identified **some approaches** that will be investigated in the next few years:

A Thai Case-Study - The introduction of a labelling standard for products containing nanomaterials

To increase market share both domestically and overseas, some Asian countries have introduced unique and innovative measures. For example, Thai companies have been adopting practices that are internationally accepted. Companies have been requesting to use the **NanoQ** label which is issued by the Nanotechnology Association of Thailand and approved after verification. The label only confirms that the production process utilizes nanoscale materials and has specific properties such as anti-bacterial and water repellent. The label serves to assure consumers' confidence and helps to eliminate fake nano products from the market. For example, Iran (NanoTrust), Malaysia (NANOVerify), and Taiwan (nanoMark) have also implemented similar nano labels and it is under consideration in other countries such as Vietnam. These schemes are focused, inter alia, on ensuring public confidence and fair trade by guaranteeing the authenticity of a product marketed as one containing nanomaterials and are intended to be a label for safety.

In Europe, regulation requires the labelling of nanomaterial ingredients in cosmetics, food and biocides products and there are labelling schemes focused on the environmental sustainability of a product such as the EuroEco Label (see more labels identified in: Mapping study for the development of sustainable-by-design criteria[48]). A Study Group on *Labelling* has been recently formed within CEN/TC 352 *Nanotechnologies* to collect stakeholders' views on this topic before considering the possible production of a document. B2C-labelling and B2B-labelling are currently discussed by the group, which stressed that in order to possibly support B2C labelling the issue of measurements is key to produce reliable information and that more transparency in the supply chain in B2B is needed. The aim of the Study Group could be to develop in the near future a document providing guidance on how to improve the traceability of nanomaterials all along the different value chains by paying attention to the key role of measurements.
We believe INISS-nano is well suited to investigate and assess various existing labelling schemes and to suggest common practices that could be applied with the view to a cross regional label, in particular as a number of the experts involved here are also contributing to the ongoing discussions on the subject of labelling (including the CEN/TC 352 Study Group).

INISS-nano could also support to develop basic concepts and compile what has been of common sense between the involved countries, and to disseminate this information (Concept of Nanotechnology), rather than creating regulations or standards. In a second step, based on

[48] https://ec.europa.eu/info/publications/mapping-study-development-sustainable-design-criteria_en ; page 12ff

the results from the compilation of the knowledge, training for industry should be provided by each country's representative, coordinated and supported by INISS-nano. Within this framework industry from distinct countries can receive oriented understanding and support.

Repository of new research tools from across both regions

Projects from the EU FP7, Horizon2020 and other funding programmes have produced a wide range of tools that can help industry with a range of their development goals, from estimating hazard and risk of new nanomaterials to identifying regulatory obligations, like currently running NMBP-13-2020 risk governance projects (RiskGONE,[49] Gov4Nano[50] and NanoRiGo[51]) and NMBP-14-2020 nanoinformatics projects (NanoInformaTIX[52] and NanoSolveIT[53]), which complement each other on the assessing the safety of nanomaterials and how to serve regulatory decisions. Similar initiatives towards the expanding the development of nanotechnology have been actively pursued within the ANF.

- Applications of nano hybrid resin (GreenEpoxy Technology, Taiwan)
- Water Treatment for Self-Sustaining Toilets (Nanopac, Malaysia)
- Silica-based Solar Coat for Solar Thermal and Solar Photovoltaic application, (NANOTEC, Thailand)
- Commercialization of Nanofibers produced by Hybrid Electrospinning (Amogreentech Co., Ltd. , Korea)

Within each region the dissemination of research is actively pursued. The NSC use to produce an annual review of active EU projects and in Thailand the National Nanotechnology Center (NANOTEC) have initiated the NanoSafety Network for Industry with an aim of utilizing the partnership of 9 state agencies to drive the **NanoSafety and Ethics Strategic Plan 2017-2024**[54] to enhance industrial understanding and awareness of how new nano-enabled products can pose concerns regarding to human health and environmental risks. In addition to using existing industrial standards related to nanotechnology the network is also exploring implementation of other activities such as production of industrial databases, easy to read safety publications, manuals, and applications including organization of seminars and exhibitions. Within the EU, the regulations for Safety Data Sheets (SDS) have been revised to include obligations around nanomaterials.

It is felt that, whilst the OECD Working Party on Manufactured Nanomaterials (WPMN)[55] play a vital role in disseminating information at a high level, knowledge about this research and

[49] https://riskgone.eu/2020/ ; https://cordis.europa.eu/project/id/814425
[50] https://www.gov4nano.eu/ ; https://cordis.europa.eu/project/id/814401
[51] https://nanorigo.eu/ ; https://cordis.europa.eu/project/id/814530
[52] https://www.nanoinformatix.eu/ ; https://cordis.europa.eu/project/id/814426
[53] https://nanosolveit.eu/ ; https://cordis.europa.eu/project/id/814572
[54] https://www.nanotec.or.th/en/wp-content/uploads/2018/09/Nanosafety-Soft-file.pdf ; https://www.nanotec.or.th/en/?page_id=9279 (extension of the plan to 2024)
[55] https://www.oecd.org/env/ehs/nanosafety/publications-series-safety-manufactured-nanomaterials.htm

these tools (i.e., testing guidelines[56]) is not reaching the factory floor effectively between regions. As nanomaterials do not change their fundamental nature between regions there is no reason these tools cannot be utilised by industry across the globe other than through lack of awareness. INISS-nano is an ideal position to both identify testing providers from member's own regions but also to disseminate information about tools developed across the globe **in a manner that can be easily accessed and understood by all parts of a factory**. The INISS-nano feels that facilitating the transfer of information from SDS to the factory floor for nanomaterials in a clear and understandable way is absolutely key to the safe implementation of nanotechnology across the globe and is intrinsically linked to effective dissemination of research and tools discussed previously. It will investigate the best approaches to achieve this goal.

The INISS-nano has strong links to the industrial, research and regulatory communities, meaning that it is ideally placed to support the development of protocols and schemes that promote the safe and sustainable expansion of nanotechnology across regions without the perception of vested interests.

[56] https://www.oecd.org/chemicalsafety/nanosafety/testing-programme-manufactured-nanomaterials.htm

2.3 Pillar "sharing / facilitate sharing of resources/ infrastructures"

There is a growing concern regarding the safety of ENMs and consequently, a lot of scientific effort with considerable resources is now devoted to nano-safety research. Significant advances have been made in the knowledge and understanding pertaining to nano-safety issues, as well as their implementation in guidance documents, good practice guidelines and regulatory procedures. Nevertheless, the high cost of sophisticated laboratory instruments and experimental procedures, as well as the regional differences in terms of regulatory priorities has created a patchwork of activities and output that show little harmonization across political borders. Through a community-based sharing platform, this pillar of the proposal advances the theme of a sustainable solution to overcome some of the challenges with respect to nano-safety research.

Significant efforts have been made possible by progress in several targeted European projects, and in the NSC. Another example are the three NMBP-13 projects (RiskGONE,[49] Gov4Nano[50] and NanoRiGo[51]), which collaborate in order to provide solid procedures for science-based risk governance of ENMs in the Nanotechnology Risk Governance Council (NRGC). While these projects are mere examples of the many efforts to advance the safety and sustainability of nanotechnology and its products around the world, there is no single international platform that could sponsor, promote, and govern a sharing mechanism for laboratory resources at a global scale.

Under the mentioned circumstances, the initiation of INISS-nano, in order to facilitate access for researchers and experts, relevant industries, academic institutions, and research centres to the existing infrastructures including laboratories, instruments and information system platforms seems justifiable. Taking a broader view of the term infrastructure, including relevant information and tacit knowledge, such a platform can not only facilitate access to laboratory services (e.g. caLIBRAte[57]), but it can also make existing data and knowledge pertaining to nano-safety and sustainability accessible[58] to a wider relevant community across the world; in this context, the proposed INISS-nano can indeed improve collaboration, enhance synergy, and advocate harmony among the growing the research community for safe and sustainable nanotechnology worldwide.

Beyond provision of easier access for academic researchers, technologists and industries with nano-safety-related activities with sophisticated instruments and testing facilities, the proposed

[57] https://cordis.europa.eu/project/id/686239
[58] https://cordis.europa.eu/project/id/731032

network can also expose partners to a vast field of cutting edge technologies, protocols, novel ideas, opportunities, recent projects and talents outside their organization, hence resulting in a win-win situation with incentive for all players to join the network. Interactions in this network can also inspire development of novel instruments, infrastructure and know-how which will be much needed in future. As part of the network, a matchmaking mechanism can help connect partners with relevant experts/organizations resulting in a more efficient use of knowledge and skills and more versatile mobility of experts, researchers and perhaps students.

The proposed INISS-nano can help to provide better visibility of nano-safety related infrastructures on a global scale, and thus support the exchange and training of both staff and users. The network can facilitate upgrading the technical knowledge of experts through various targeted short-term virtual or otherwise training programs/workshops; this would culminate in an added value of an improvement of laboratory services for the partner organizations in the field of nano-safety and sustainability research. Another function of the proposed network would be to promote harmonization between laboratories and testing facilities, for example by arranging laboratory comparison schemes (e.g. round-robin tests, technology validation exercises, infrastructure sharing) and harmonization of test guidelines, protocols and procedures.

Similar experiences such as the European NanoFabNet[36] platform and other relevant initiatives around the world can inspire the proper design for sharing facilities that would immensely benefit the community of safe and sustainable nanotechnologies; in particular, NanoFabNet can be invited to be directly involved in this scheme. The suggested partnership can further advance the realization of a **more harmonized safe-and-sustainable-by-design approach across the globe**.

2.4 Pillar "Ethical aspects"

Introduction

International collaboration in nano-safety involves addressing some ethical issues, e.g. protection of the safety of workers and consumers in developing countries, implications for nanotechnology exporters in a situation when there are differences in legal regimes in different world regions and countries, implications for public perception of fake news about nanotechnologies and the related legal framework and other ethical issues and international collaboration in responsible nanotechnology research. However, although the European Agency for Safety and Health at Work (OSHA)[59] has provided some information on safety of workers[60] (last update in 2017), the intention of INISS-nano should not limit to developing countries only as there are still lots of gaps in practical safety (e.g. ultrafine (nano) particles during manufacturing, etc.) across developed countries.

In the following pages, we briefly address these issues and make some suggestions how INISS-nano may help overcome these.

2.4.1 Nano-safety in developing countries

Since 2009, nano-safety has been addressed as an emerging policy issue in the UNEP (United Nations Environment Programme) administered Strategic Approach to International Chemicals Management (SAICM)[61]. This initiative was taken to achieve the sound management of chemicals throughout their life cycle so that, by the year 2020, chemicals were produced and used in ways that minimize significant adverse impacts on the environment and the human health. The objective has not yet been fully achieved.

In 2016, some initiatives taken by UN bodies have been listed in the Nanotechnology and International Law Research Guide[62].

Until 2020, OECD and United Nations Institute for Training and Research (UNITAR) were leading the international cooperation on the emerging policy-issue of nanotechnology. In particular, UNITAR has published guidelines, containing some suggested ideas, for developing-countries´ governments about how to formulate their policy for nanotechnology governance[63]. In addition, UNITAR has organised regional workshops and national projects to address nano-safety all over the world[64]. Furthermore, the World Health Organisation (WHO)

[59] https://osha.europa.eu/en
[60] https://osha.europa.eu/en/legislation/guidelines/guidance-protection-health-and-safety-workers-potential-risks-related
[61] http://www.saicm.org/EmergingPolicyIssues/Nanomaterials/tabid/5475/language/en-US/Default.aspx
[62] https://www.nyulawglobal.org/globalex/Nanotechnology_International_Law1.html#UnitedNations
[63] https://cwm.unitar.org/publications/publications/Nano.aspx
[64] https://unitar.org/sustainable-development-goals/planet/our-portfolio/nanotechnology-

has developed guidelines for occupational health and safety of workers handling nanomaterials[65].

Future work

INISS-nano can target the protection of workers and consumers exposed to nanomaterials in developing countries and thus support international organizations (e.g. the International Labour Organisation) by the following measures:

- Invite policy makers and nano-safety experts from developing countries to all events organised by the NanoSafety Cluster.
- Engage with the coordinators of the UNITAR nanotechnology activities to identify their needs and interests in continuing support and training in nano-safety.
- Advertise research jobs in nano-safety to students and researchers from developing countries, through the network established by UNITAR.
- Promote the UNITAR and WHO guidelines through the NanoSafety cluster newsletter and other media.

2.4.2 Legal aspects

There is currently no specific and direct international legal instrument dealing with nanotechnologies, ENMs or nano-safety. This may be due to the reason that ENMs are nanoscale chemicals and the chemicals related international legal provisions are generally encapsulated within the international environmental law related legal instruments. Moreover, even until 1960s, environmental matters were considered as national issues, and therefore, did not receive concerted international attention. Legal regimes in the fields of environmental protection, occupational health and safety, and consumer protection, etc. are often fragmented between States, international and regional levels such as the European Union which, with some of its Member States, has been during the last 20 years the most proactive organisation to adopt legally-binding instruments dealing with nanotechnology-based products. Some inter-governmental organisations have adopted policy documents which are not legally binding and enforceable. International regulatory approaches can be better understood in the light of the legislative experience of the European Union and its Member States.

One of the drivers of regulatory action is the precautionary principle, which is recognised and incorporated in many international instruments e.g. the Rio Declaration on Environment and Development, and adopted by a vast majority of states across the world, as it incentivises regulators to adopt measures in the absence of scientific certainty[66].

[65] https://apps.who.int/iris/bitstream/handle/10665/259671/9789241550048-eng.pdf?sequence=1

[66] https://www.un.org/en/development/desa/population/migration/generalassembly/docs/globalcompact/A_CONF.151_26_Vol.I_Declaration.pdf

In the European Union, the precautionary principle is enshrined in article 191 of the Treaty of the Functioning of the European Union[67] and has been further interpreted in a 2000 communication from the European Commission[68]. With the emergence of an innovation principle in policy guidelines[69] and in the new European Regulation, the risk of legal uncertainty and stagnation could grow if a balance should be made between the precautionary principle and other principles such as the innovation principle, if they would achieve equivalent legal recognition. Dialogue on a risk of a conflict of legal principles appears to be necessary, in order to unlock potential legal hurdles.

In addition, the legal definition of nanotechnologies remains a significant challenge for regulators. For instance, in the European Union, definitions of nanomaterials are not the same whether we consider the case of cosmetics[70], novel food[71] , biocides[72] or chemical products[73]. Some States have also taken the initiative to adopt nanomaterials registers that add a further level of complexity for all stakeholders. Greater convergence with standardisation efforts is a key element to understand the exact scope of sector-based legislation.
Moreover, most pieces of legislation in the fields of occupational safety – particularly exposure to chemical agents – product liability and consumer protection are technologically neutral and should therefore be interpreted in the light of the specific issues of nano-safety.

Navigating in the legal environment is a challenging task for stakeholders. The case of legal harmonisation appears not to be self-evident for all stakeholders, as some advocate for separate regulatory regimes with their own legal definitions. However, lessons can be drawn from the recent and ongoing regulatory reforms in the European Union where by-design approaches receive greater echo (e.g. circular economy, artificial intelligence), even in legally binding instruments (GDPR for the field of personal data protection)[74].
International dialogue and collaboration such as INISS-nano could focus on the need to better balance the burden of potential liability between the different stakeholders and improve regulatory compliance by focussing on the general interests that should be protected when placing nanotechnology-based products on the market.

[67] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12008E191:EN:HTML
[68] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52000DC000
[69] https://ec.europa.eu/info/sites/default/files/research_and_innovation/knowledge_publications_tools_and_data/documents/ec_rtd_factsheet-innovation-principle_2019.pdf
[70] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20201203
[71] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02015R2283-20210327
[72] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02012R0528-20210329
[73] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.308.01.0001.01.ENG&toc=OJ:L:2018:308:TOC
[74] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02016R0679-20160504

2.4.3 Fake news

The propagation of nanotechnology-related rumours[75] and "fake news"[76] (i.e., harmful misinformation and disinformation) increases with severe risks for society (e.g. discouraging people from COVID 19 vaccination[77]). The information problems propagate for different reasons: Technological factors (e.g. digital platforms making profit from 'any' kind of sharing); Psycho-sociological factors (e.g. confirmation bias, echo chambers and filter bubbles); Political factors (e.g. populisms and polarization); and Media factors (e.g. news avoidance, lack of media literacy[78]). The effects and consequences of fake news include social destabilization, media distrust and suspicion against real science which may ultimately create barrier in the utilisation of science for the betterment of mankind. Hence, debunking false information about nanotechnology is a global need of industry[79] and society[80]. However, among the worldwide organizations in the Fact Checking Network[81] for information evaluation following a strict code of principles[82], only one specializes in science (Science Feedback[83], mainly focusing on climate and health), while others (AFP Fact Check[84] and Reuters Fact Check[85]) are large international news agencies also covering science. Furthermore, very few agencies fact-check in various languages (e.g. the French-language Détecteur de Rumeurs[86], in the Reporters' Lab database[87], or those with a base in Southeast Asia[88]).

Future work

The INISS-nano can contribute in cleaning the "information pollution" by:

- Educating the INISS-nano scientists on how to communicate better-sound science to all (e.g. following the European Science Media Hub[89] initiative). Potential approach → Step 1, evaluation of European experiences in the context of other parts of the world; Step 2, follow European practices in case these fit the context of other regions/countries, considering the presence of cultural variables and other socio-economic/legal differences; Step 3, learn from experiences on the global scale aiming to improve scientific communication.

[75] https://www.timharper.net/the-science-behind-fake-news-and-fake-products/
[76] https://firstdraftnews.org/latest/fake-news-complicated/
[77] https://www.reuters.com/article/idUSKBN28F0I9
[78] Source: https://www.unav.edu/en/web/grupo-investigadores/digital-news-media
[79] E.g.: https://blog.agchemigroup.eu/top-5-myths-on-nanotechnology-exposed/
[80] E.g.: https://sciencemediahub.eu/
[81] https://ifcncodeofprinciples.poynter.org/know-more/the-commitments-of-the-code-of-principles
[82] https://ifcncodeofprinciples.poynter.org/
[83] https://sciencefeedback.co/
[84] https://factcheck.afp.com/
[85] https://www.reuters.com/fact-check
[86] https://www.sciencepresse.qc.ca/detecteur-rumeurs
[87] https://en.wikipedia.org/wiki/List_of_fact-checking_websites#cite_note-36
[88] https://theconversation.com/three-fact-checking-challenges-in-southeast-asia-148738
[89] https://sciencemediahub.eu/

- Organizing world-wide events during the European Media Literacy Week[90] to educate society to media literacy (i.e., the capacity to access, have a critical understanding of, and interact with the media).
- Bringing together international media-literacy stakeholders, taking advantage of the EU Expert Group on Media Literacy[91] which meets annually to a) identify, document and extend good practices in the field of media literacy; b) facilitate networking between different stakeholders, with the aim of cross-fertilisation; c) explore synergies between different policies and support programmes and worldwide media-literacy initiatives.
- Inviting media-literacy stakeholders worldwide to join the European Union Action Plan against Disinformation[92] based on four pillars: I) improving detection[93] , analysis and exposure of disinformation; II) stronger cooperation and joint responses to threats; III) enhancing collaboration with online platforms and industry to tackle disinformation; IV) raising awareness and improving societal resilience.
- Promoting the international harmonization of the legal frameworks related to fighting false information.

2.4.4 Other ethical issues

Much is expected from nanotechnology in terms of sustainable development, and for the achievement of the UN Sustainable Development Goals, particularly in developing countries. Nevertheless, at the same time, the development of nanotechnology globally raises a set of social and economic issues, including the risk of "nano-divide" (e.g. will nanotechnology increase or decrease the gap between industrialized and developing countries?), the impacts on the workforce of developing countries, on the primary materials markets, and on the economy of countries dependent upon them. There are also concerns that, taking advantage of less stringent regulations, the developing countries might be used as testing grounds of nano-enabled products developed by the manufacturers from industrialised countries. More generally, this development questions strongly the respective roles of technology and of politics in addressing the different challenges of developing countries.[94]

The development of nanotechnology applications (in particular in nanomedicine, robotics, information and communication technologies, etc.) raises a set of social and ethical questions, which require the development of ethical impact assessment procedures and tools. The international ethical compendium (including the Universal Declaration of Human Rights) is frequently mentioned accordingly. Nevertheless, there remain cultural differences all over the

[90] https://digital-strategy.ec.europa.eu/en/events/european-media-literacy-week
[91] https://ec.europa.eu/transparency/expert-groups-register/screen/index.cfm?do=groupDetail.groupDetail&groupID=2541
[92] https://digital-strategy.ec.europa.eu/en/library/action-plan-against-disinformation
[93] https://www.euronews.com/2019/01/09/how-can-europe-tackle-fake-news-in-the-digital-age
[94] J.Schummer, "Impact of nanotechnologies on developing countries", in F.Alhoff and alii, Nanoethics: The Ethical and Social Implications of Nanotechnology, Wiley, 2007, pp.291-307

world in the promoted ethical principles and values, and in the interpretation of them, which make such an ethical impact assessment difficult and limited.[95]

The European Commission strategy for the development of nanotechnology comes within the general framework of Responsible Research and Innovation (RRI), with e.g. anticipatory and participatory processes, upstream public and stakeholder engagement. There exists currently an ambition to export this model all over the world.[96] The possibility and legitimacy of such an ambition deserves nevertheless to be questioned, in particular regarding the specificities of nanotechnology.

The INISS-Nano initiative can help to address these issues in organizing works and meetings on these topics with relevant experts and stakeholders, in particular in the general framework of the OECD, UNITAR and UNESCO initiatives.

[95] S.Dalton-Brown, Nanotechnology and Ethical Governance in the European Union and China, Springer, 2015

[96] R.Von Schomberg and J.Hankins (eds.), International handbook on responsible innovation: A global resource, Edward Elgar Publishing, 2019

3 Implementation strategy of INISS-nano

The implementation strategy includes two main parts. The first part shows the options for the organizational implementation of the INISS-nano. The second part lists in the table (action plan) the potential timelines for the implementation of tasks along the proposed actions.

3.1 Organizational implementation of INISS-nano

The success of INISS-nano will depend on the international collaboration. These efforts in the coordination of this collaboration and continuous further development of the initiative need to be structured with a secretariat and thus will request resources.

The following options can be done either one or more of them or any combination of them:

- implementation through existing networks and/or ongoing (European/international) projects;
- governmental funded rotating secretariat;
- secretariat funded within a dedicated project (e.g. a potential new call in Horizon Europe for global participation)

3.1.1 Identity of INISS-nano and organization

A potential organisational form of the network would be as an independent international NGO. Nevertheless, governmental organizations with responsibility or interest in the area of nano-safety are expected to contribute in two ways, by coordinating their respected national bodies to contribute, and by financial and/or in-kind contribution to activities of the network.

The role of national, regional or international public sector institutions in formation of the INISS-nano is crucial as the nature of nano-safety activities demands public sector support and intervention. So, it is expected that at least in the first three years INISS-nano benefit from such support. INISS-nano might also act as an external liaison body to international and regional standardization organizations and help them in achieving their goals.

Regarding the organization of the network, it is suggested that a core founding/steering committee will make strategic decisions of the network and a community of contributors will help in implementation of the programs. The key sponsor and supporter organizations might have a seat in the steering committee; however, it needs to be guaranteed that the committee remains an independent body.

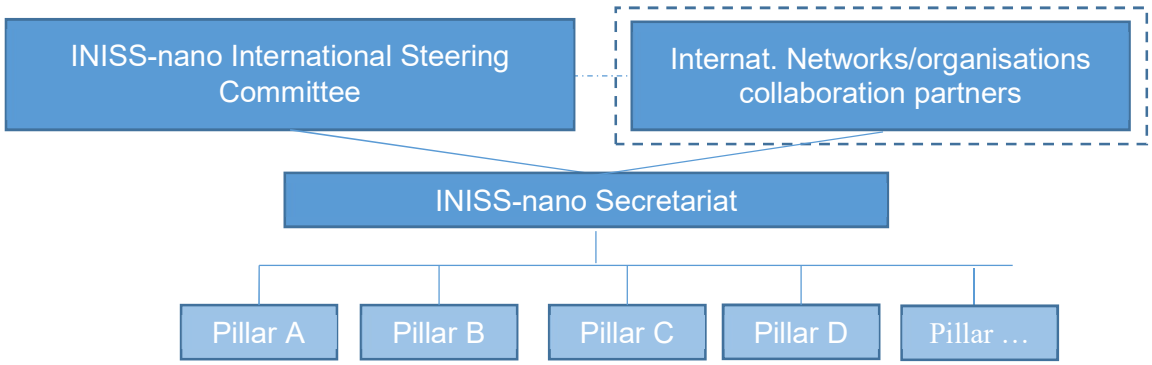

Figure 1: proposed structure for INISS-nano.

A matrix structure (see figure 1) is envisaged to shape the proper work division in the INISS-nano; there will be a few functional pillars dedicated to harmonisation, support industrial understanding, sharing/facilitate sharing of resources/infrastructures, and ethical aspects (other pillars might appear at a later stage) along with several key expertise areas such as nanomedicine, medical devices and materials, agriculture, etc. Working groups for each functional pillar ("pillar A", etc.), including focused experts for each specific area, will be formed, continuously expanded, and will be responsible to link the INISS-nano to the relevant outside networks.

3.1.2 Key strategies of the network initiative

Some key strategies of the network are listed here:

- Nurturing international collaboration and cooperation will be the main target of all activities and programs of the network.
- Implementation of INISS-nano would happen in two parallel paths; a **top-down** track which pursues formal registration and establishment of the network, determine the position of the INISS-nano in the nano-safety ecosystem, and tries to allocate specific initial resources for establishment of the network. It is expected that formal shaping of the network will be ready by the end of the year 2022. The second track would follow a **bottom-up** path in which the founding members and contributors initiate a range of relevant activities and programs through existing platforms and ongoing projects (supported by e.g. EU Horizon2020 projects, Asian and/or international initiatives) where the required resources are already available. The second track shall start by the end of 2021 and shall continue based on each activities' progress. The proposed double track implementation strategy makes sure that while a sound and long-term vision is outlined, feasible useful activities within the network start as soon as possible.

- The implantation will benefit from a decentralised operation with emphasis on voluntary membership and contribution of enthusiastic individuals and organisations. There is a need for delicately designed incentive mechanisms to motivate individuals and institutions to become members and contribute; for example, in infrastructure sharing platforms, incentives and gains, both for those who share their facilities and those who benefit from the shared facilities need to be identified and proper incentive mechanisms need to be devised.

3.1.3 Activities and programs

A list of relevant activities and programs will be compiled by the members through brainstorming sessions. Concurrent programs elsewhere in the world with overlap or similar mandate will be recognised and the possibility of partnership or merge evaluated. A number of programs with higher feasibility/importance will be candidates to go through a prioritisation process. After this selection, the details of the programs will be worked out by the dedicated team including objectives, business model and work division, and shall enable the implementation.

3.1.4 Required resources

INISS-nano requires resources to conduct its activities. These include human resources, infrastructure, and financial resources. Part of these resources will be provided through in-kind contributions of the founding members (mainly human resources and infrastructure) and part of it will be provided through two main financial mechanisms.

The first one shall be through support from international sources (e.g. EC, relevant institutions, etc.) and/or via projects (ongoing and/or new projects). This shall support the initial establishment of INISS-nano. It is expected that the initial establishment of the network and the first 3-5 years of its operation rely mainly on these resources.

The second mechanism deals with resources needed for continuous operation of INISS-nano which is expected to come from membership fees e.g. of INISS-nano-members (states, institutes, organisations, etc.) and in the long run from fee-for-service incomes. However, a dedicated financial planning needs to be conducted, taking into account also the options mentioned in chapter 3.1.

3.2 Action plan (first draft - to be further elaborated after the commenting phase)

Action	Short-term	Medium-term	Long-term
Pre-standardisation / Harmonisation issue (including involvement of	Support the NSC WG-B / WG-G Concept paper	• European Metrology Network on	Collaboration with Regional metrology organizations (RMOs

the metrology community)	regarding the need for implementation Documents to support Regulatory Preparedness in Nanotechnology	nanomaterials/advanced materials topic ● Initiate a collaboration with VAMAS ● Promote already available funding mechanisms *(i.e., dedicated annual calls for proposals regarding pre-standardisation activities within the new European Partnership on Metrology programme*) ● Contribute to identify and prioritize the needs regarding OECD TG implementation documents	like EURAMET, APMP, SIM...) and BIPM
Standardisation	● Communicate on standardisation programme (available and under development documents) ● Produce and disseminate summary reports of CEN/TC 352 and ISO/TC 229 meetings ● Apply for becoming liaison partner of CEN / ISO TC's	● Contribute to the development of an internationally recognised Standardisation Certificates to acknowledge standardisation work (in particular for academia experts) ● Contribute to identify and prioritize the needs regarding standardisation work in order to optimize resource allocation	

4 Timeline and next steps

- 21st of December 2020; (9:00-11:00 a.m. CEST) – 1st virtual meeting - done.
- Continuous broadening of the group - ongoing.
- 9th of April 2021; (9:00-11:00 a.m. CEST) – 2nd virtual meeting - done.
- Revision of the draft concept paper in terms of the pillars, adding legal aspects sub-pillar, adding sub-pillar technical and regulatory focus; adding chapter Implementation strategy till April 28th, 2021 – done.
- Pre-final document "concept paper" – April 29th – done.
- Submission of draft and discussion with the EC-observers – April/May 2021 – done.
- Final round of revisions to the "concept paper" – till May/June 2021 – done.
  - **Publication of the concept paper – June 2021.**
    - Open for comments (till August 17th 2021)
    - Digestion of comments & complementing action plan (3.2) – till 24th of September
    - October 2021 – 3rd virtual meeting[97].
    - Circulation of the final concept paper to the EC and to country representatives - envisaged October/November 2021.
    - further interactions planned to take place during 5th EU-Asia Dialogue event (first half of 2022, in Malaysia); 6th EU-Asia dialogue event (2023, Berlin, Germany; tbc)

[97] Tentative timing: October 1st, 2021, 12-14 CEST.

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- Friedrichs, Steffi (AcumenIST, Belgium)
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5.3 Involved Projects, Initiatives and Partnerships

5.3.1 Projects

BIORIMA
caLIBRAte
CHARISMA
DIAGONAL
EASI-STRESS
Gov4Nano
HARMLESS
ISO-G-SCoPe
LifeLongJoints
NanoCommons
NanoFabNet
NanoHarmony
NanoInformaTIX
nanoMECommns
NanoMET
NanoRiGo
NanoSolveIT
NanoSyn
NanoSyn2
nPSize
RiskGONE
SUNSHINE
(open to further contributions that can be added throughout the commentary phase)

5.3.2 Initiatives/Partnerships

Asia Nano Forum

DBT -TDNBC - DEAKIN – Research Network Across continents for learning and innovation (DTD-RNA)

EU NanoSafety Cluster

EURAMET

(open to further contributions that can be added throughout the commentary phase)

5.4 Citation

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