

## Business model and governance mechanisms



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## EC4SafeNano Project

The European Centre for Risk Management and Safe Innovation in Nanomaterials and Nanotechnologies, EC4SafeNano, is a 2016-2019 Coordination and Support Action, funded by the European Commission. EC4SafeNano is coordinated by INERIS, and operated together by major European risk institutes with the support of numerous associated partners, gathering all stakeholders involved in Nanomaterials and Nanotechnologies (regulators, industry, society, research, service providers...).

A central challenge to ensure the sustainable production and use of nanotechnologies is to understand and effectively control the risks along the industrial innovation value chain. Knowledge about nanotechnology processes and nanosafety issues (hazards, fate, risk...) is growing rapidly but the effective use of this knowledge for risk management by market actors is lagging behind.

EC4SafeNano will promote a harmonized vision of expertise in risk assessment and management for the public and private sectors to enable the safe development and commercialization of nanotechnology. The main objective of EC4SafeNano is to design harmonized services in risk assessment and management and a sustainable structure to deliver these services. For that, the project will gather stakeholder needs and expertise resources. It will demonstrate the efficiency of the proposed solution on case studies.

## Executive Summary

After 3 years of EU funding the EC4SafeNano project has created key tools and gained sufficient experience to develop a proposal for business model and governance of a permanent and self-sustainable centre after the project EU funding.

It is proposed that at the end of EC4SafeNano Project partners would have the capability to decide to become Members of the Centre and pursue its activities to establish a one-stop shop for all kinds of nanosafety related services offered in Europe and a central contact point for questions about nanosafety.

The main missions of the Centre would be:

- to harmonise the methods used for assessment of risks associated to nanomaterials and nanotechnologies;
  - to exchange knowledge and technical expertise in order to identify what information is currently missing and the actions needed to promote collaborative research programmes at European, international level;
- to develop networking activities aimed at sharing knowledge within the nanomaterials' community as a way to enhance and harmonise the overall expertise at European level and beyond.

The main activities of the Centre would include:

- the maintenance of tools (website, databases, etc.) for an efficient interface with external customers, facilitating access to technical information and services;
- the provision of technical expertise and science-based advice to questions raised by stakeholders, including regulatory bodies and competent authorities;
- the organisation of activities, collectively agreed by the members of the Centre as part of a voluntary annual joint programme of activities (JPA), such as interlaboratory studies, expert group meetings on high-priority topics selected by members, position papers, guidance documents, etc.

The Centre would also promote the development of harmonised services, the creation and promotion of EU certification trademarked services, the audit of providers of EU certification trademarked service(s) and training of service providers.

It is proposed that the future Centre should be formed of any juridical entities, except private individuals, from: Service providers; Competent authorities / National reference laboratories; Research centres and academia; Industry stakeholders; Government institutions and Standardisation bodies.

The Centre should have three categories of members: (I) Founding Members, (II) Ordinary and (III) Contributors. Founding and Ordinary Members shall pay a membership fee and have the right to vote. Institutional bodies, Governmental and International Organisations, Standardisation bodies and Non-Governmental Organisations can apply to become Contributors (unless they wish to join as Ordinary Members). They can act as consultants to the General Assembly, but have no right to vote.

The General Assembly is the organ which brings together all members of the Centre and allows each member to express their position. The Centre would be managed by a Steering group, responsible for the management and strategic orientation of the network, assisted by an executive secretariat.

Each Founding Member shall automatically be a member of the steering group for the first three years of the functioning of the Centre. After this start-up phase, membership of the steering group will be achievable only by election.

The Centre shall be financed by subscriptions or other contributions from the Members, under the conditions laid down by the Steering Committee (an in-kind contribution may be allowed, to cover part of the membership fee for Ordinary Members), by the incomes from the contracts and services delivered to the Customers and by the fees paid by Service Providers for registration of their services (knowing that the membership to the Centre already includes the registration of services).

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## Glossary

<i>Terms</i>	<b>Definition</b>
<i>Centre (the)</i>	The legal entity that will be developed as the main outcome of the H2020/EC4SafeNano project, along with its Resources, Services, business model(s), governance procedures and its Members
<i>Certified Service</i>	A Certified Service is a Harmonised Service which has been subject to a certification scheme covered by an EU Certification Mark, agreed by a High-Level Stakeholders Committee, periodically re-evaluated for its consistency regarding the level of knowledge (state of the art).
<i>Chairman</i>	The Chairman is a member of the Steering Committee. The Chairman represents the Centre in the public relations
<i>Contributor</i>	Contributors may participate in the General Assembly and other activities of the Centre with a right to speak and to make proposals, but they shall have no right to vote. Only Institutional bodies, Governmental and International Organisations, Standardisation bodies and Non-Governmental Organisations can apply to become Contributors. Contributors do not pay any membership fee.
<i>Customer</i>	Customers are public institutions (EU agencies, Commission, ministries and agencies of the Member States, international organizations), NGOs, public or private research organisations, all relevant industries or trade associations that are paying directly or indirectly the Centre for the provision of services.
<i>Delegate for assistance to customers</i>	The Delegate for assistance to customers is a member of the Steering Committee to coordinate the preparation of offers by the Centre to customers' demands
<i>EU Certification Mark</i>	In line with Article 83 of the Regulation No. 1001/2017 an EU Certification Mark is an EU trade mark which "is described as such when the mark is applied for and is capable of distinguishing goods or services which are certified by the proprietor of the mark in respect of material, mode of manufacture of goods or performance of services, quality, accuracy or other characteristics, with the exception of geographical origin, from goods and services which are not so certified".
<i>Executive secretary</i>	The Executive secretary is in charge of day-to-day operation and interactions with members
<i>General Assembly</i>	The General Assembly is the organ which brings together all members of the Centre and allows each member to express their position. It determines the general policy of the Centre and it has all powers needed for the realisation of its objectives, and such powers are explicitly delegated to the Steering Committee.
<i>Harmonised Service</i>	A Harmonised Service is a Service in which the technical content is stated to be relevant, efficient, repeatable, reproducible and at the state of the art, by a collective expertise able to deliver a reliable and repeatable result when carried out by different service providers. Harmonization ensures the consistency of the result, allowing the possibility to use different possible Resources. Service providers have to be audited to be able to conduct a Harmonized Service.
<i>Help Desk</i>	The Help Desk is appointed by the Steering Committee with a three-year mandate. The Help Desk is in charge of the organisation and maintenance of the activities related to mapping of needs, mapping of resources and services, catalogue of service, dissemination of the activities of the Centre via the website, the Newsletter;



<i>Terms</i>	<i>Definition</i>
<i>Member of the Centre</i>	A Member of the Centre is a legal entity or a consortium with legal personality contributing effectively to the Centre. The Members pay an annual membership fee and can contribute to all activities of the Centre. A member can be a Founding member or an Ordinary member.
<i>Need</i>	<p>A Need is a Technical demand that is expressed to the Centre by a Customer,</p> <ul style="list-style-type: none"> <li>- asking for registration of a technical Resource or Need that are part of a Service,</li> <li>- asking for Service harmonization i.e. the development of a Harmonized Service or the development of a Certified Service</li> <li>- asking to be trained to use a Harmonized Service</li> <li>- asking to be audited to use an EU Certification Mark developed and offered by the Centre,</li> <li>- asking for the provision of advanced Technical Services and tasking the Centre to propose one service provider or a group of appropriate service providers (within the Members of the Centre) to deliver the Technical Service.</li> <li>- asking for the provision of a collective review of a Service, to be delivered by a group composed of Members and Contributors of the Centre</li> </ul> <p>NOTE: A Need can also be a demand by a competent authority for advise about a new regulation in the field of nanosafety.</p>
<i>Registered technical service provider</i>	Any legal entity or consortium having a legal personality having registered their technical capabilities through the Centre web-portal.
<i>Resource</i>	A Resource is a technical capability such as an instrument, a bench, a laboratory but also a protocol, a SOP or a standard, a training course, a software, a model, ect.
<i>Service</i>	A Service is an activity carried out by a legal entity and/or a consortium with or without legal personality for which one or more Resources are being used in order to address a Customer need. A Service can be a Technical Service, a Harmonized Service or a Certified Service.
<i>Steering Committee</i>	<p>The Steering Committee is composed of no less than three members and no more than nine members.</p> <p>For the first three years of the functioning of the network, all Founding Members shall automatically sit on the Steering Committee.</p> <p>After this three-year start-up phase, the Steering Committee members shall be elected by the General Assembly (Founding and Ordinary members) with a mandate of 3 years.</p> <p>The Steering Committee shall elect the Executive Secretary, the Delegate for Customers' assistance, the Treasurer and the Chairman.</p> <p>The Steering Committee is responsible for the direction (business operational and administrative management) and the strategic orientation of the Centre.</p>
<i>Technical Service</i>	A Technical Service is a technical activity carried out by a legal entity and/or a consortium with or without legal personality for which one or more Resources are being used in order to address a Customer need.
<i>Treasurer</i>	The Treasurer prepares and manages the budget of the Centre. The treasurer reports to the General Assembly on an annual basis.
<i>User of Certified Service</i>	A legal entity or part of a legal entity registered as a service provider, that has been successfully audited regarding its capability to deliver a particular Certified Service. Users are periodically re-audited and they can use the EU Certification Mark to market and perform the Certified Service.

## 1 Why a permanent European Centre for risk management and safe innovation in nanomaterials and nanotechnologies?

A central challenge to ensure the sustainable production and use of nanotechnologies is to understand the risks for the environment, human health and safety associated with this technology and resulting engineered nanomaterials and to identify and implement practical strategies to minimise these risks. Knowledge about nanotechnology-enabled processes and products is growing rapidly thanks to the numerous European and national programmes launched over the last decade, but more effort is needed to improve effective use of this knowledge for risk management.

Regulatory bodies need the most relevant and reliable scientific evidence when making policy decisions in the field of human and environmental health protection.

Gathering information on stakeholder needs, knowledge and tools available, reaching consensus on harmonised protocols for risk assessment & management is crucial to support the implementation of sound risk reduction strategies and safe innovation in both the public & private sectors. To achieve these goals experts from various fields (research centres and academia, industry, public authorities and institutional bodies) should be encouraged to exchange information and work together on a sustainable, long-term basis.

The EC4SafeNano project has been funded by the Commission under the Horizon 2020 programme to prepare the ground for a permanent infrastructure able to bridge the gap in an efficient and sustainable way between the scientific community, the market and the wider stakeholders' community in the field of risk management and safe innovation in nanomaterials and nanotechnologies.

Important results have already been achieved during the project:

- two global surveys have been performed to map the needs as well as the resources available, with the involvement of a large community of stakeholders from industry, regulatory bodies, EC/ Member States, research centres and academia (D1.1 & D2.2);
- three case studies have been carried out to test the capabilities of EC4SafeNano to deliver services requiring collective expertise and benchmarks to the customers and were validated (D4.5 & D4.6);
- inventories have been created (and recently updated) of available tools and methods, training courses, standards and standard operating procedures (SOPs), guidance documents and best practices (D2.3);
- a fit & gap analysis tool has been developed to match identified needs and available resources but also to identify customer needs and new services to be addressed. The tool has been used to analyse and visualise the data from the two above-mentioned surveys (D3.1);
- Catalogue of services (D3.2).

The following chapters provide a proposal for the business model and governance of a permanent and self-sustainable centre after the project EU funding, on the basis of the experience gained during the project.

## 2 Missions

The missions of the EC4SafeNano Centre are the following:

- Understand the needs of all stakeholders along the (innovation) value chain and identify the resources and capabilities available to address these needs.
- Build, test and benchmark a range of existing and new services in order to ensure safer, marketable, regulated and accepted long-lived nano-based products.
- Develop networking activities aimed at sharing knowledge within the nanomaterials' community as a way to enhance and harmonise the overall expertise at European level and beyond.
- Harmonise the methods used for assessment of risks associated to nanomaterials and nanotechnologies, in order to make it possible for the authorities to compare and interpret the data and improve policies and regulations in the field of human and environmental health protection.
- Exchange knowledge in order to identify what information is currently missing or required in terms of monitoring and risk assessment in the field of nanomaterials and nanotechnologies and what are the actions needed to promote collaborative research programmes at European, international level.
- Create a one-stop shop for all kinds of nanosafety related services offered in Europe and a central contact point for questions about nanosafety.

From a more general perspective, the **EC4SafeNano Centre** is qualified to respond to key questions which are currently high on the agenda of competent authorities and policy-makers for the implementation of a European regulatory framework for risk governance in nanotechnology.

Three European projects (GO4nano <https://www.gov4nano.eu/>, NanoRigo, <http://nanorigo.eu/> and Riskgone <https://riskgone.wp.nilu.no/> ) have been recently funded under the H2020 research programme to define solid procedures for consistent risk governance of engineered nanomaterials and nanotechnology. One important objective of these projects is the creation of a European Nano Risk Governance Council (ERGC), a group of individuals with different areas of expertise on nanomaterials tasked to provide governance decisions on the safety of the specific materials. In this context the **EC4SafeNano Centre** will be instrumental in supporting these three projects with a view to the creation of the ERGC.

## 3 Activities

### 3.1 Help Desk

The Help Desk ensures an efficient contact and interface between EC4SafeNano and the external customers. Via the EC4SafeNano website the Help Desk facilitates access to technical information and services such as:

- Mapping of needs, resources and services
- Catalogue of services of the Centre
- Periodic Newsletter

#### 3.1.1 Mapping of needs, resources and services

Via its Help Desk EC4SafeNano ensures the maintenance of an on-line service for mapping of relevant, reliable and up-to-date information on Customers' needs as well as a regular inventory of the risk-assessment and risk-management-related resources and services offered by the Service Providers.

The collection of this information will be organised via voluntary registration through a permanent on-line system available on the EC4SafeNano website:

- Mapping of needs: A tool will be available on the EC4SafeNano website for on-line registration of the needs for nanosafety services identified by the different users / actors (Member States, EU Commission, EU and national agencies, private stakeholders and NGOs) in the field of nanotechnologies and nanomaterials. The centre will provide a periodic summary of the identified Needs per stakeholder (public, private, NGOs), anonymised by default. Access to this service will be part of the benefits of the Members of the Centre. Legal entities willing to register their Needs will not be subject to payment of fees.
- Mapping of resources: Service providers will be invited to register their resources and services on the EC4SafeNano website via a dedicated Registry. Service providers willing to register their resources and services will need to be ready to fill in all the requested fields in the Registry file, including those addressing technical specifications and QA/QC aspects. They will need to agree that the provided information will be publicly available as a searchable database. Registration of services will be subject to payment of an annual fee, knowing that the registration fee necessary to become Member of the Centre already includes free access to registration of services. The amount of the registration fee will be defined on an annual basis and will be modulated according to the home country / region of the service provider.

A strong and well-developed dissemination plan, including workshops, conferences, etc. will enhance spontaneous registration of service providers.

Horizon scanning and periodic surveys are likely to be necessary to complete the information obtained via voluntary registration. The collected information will be stored in the inventory of available tools and methods, training courses, standards and standard operating procedures (SOPs), guidance documents and best practices.

Horizon scanning (including the results of the inventory of needs) can be organised periodically by EC4SafeNano as part of the annual Joint Programme of Activities of the Centre (see below).

### **3.1.2 Catalogue of services, tools and methods**

The EC4SafeNano catalogue is closely connected with the above-mentioned activities, i.e. mapping of needs and inventory of resources and services.

The EC4SafeNano catalogue will be accessible free of charge for all interested users through the EC4SafeNano's website. Users will be able to make multiple-parameter queries to search for available services, methods and tools and organisations able to provide the required services. In this way, EC4SafeNano will be able to promote the services of the registered service providers.

### **3.1.3 Newsletter**

A newsletter will be published periodically (to be defined) to promote the activities of the Centre and to provide an overview of research projects, standardisation activities and other relevant initiatives in the field of nanosafety in Europe and beyond.

## **3.2 Collective expertise and promotion of service capabilities**

The members of the Centre, collectively, can provide technical expertise and science-based advice or answers to questions raised by stakeholders, including regulatory bodies and competent authorities. The Centre is able to manage all activities related to:

- Analysis of "simple" demands, study of the customer's question, hand-over of the right contacts and identification of the required services. The centre will provide a list of members having the capabilities to respond to a given demand, and eventually it should be up to the customer to select an adequate provider.
- Analysis of "complex" demands requiring the joint contribution of more than one member. This involves the preparation of a proposal by one member (project leader) able to provide the requested service using the resources and the collective expertise of the members of the Centre.
- Collective review of services: a collective review of service can be performed by the Centre (review committee appointed by the Steering Committee) when a customer asks (and pays) for the review / validation of a service by a group of experts (members of the Centre). The collective review of a service will evaluate the quality of the delivered project with respect to commonly agreed criteria.

## **3.3 Harmonised and certified services**

The Centre will also promote:

- The development of harmonised services
- The creation and promotion of EU certification trademarked services
- The audit of providers of EU certification trademarked service(s)
- Guidance documents
- Training of service providers.

## **3.4 Annual Joint Programme of Activities (JPA) of the Centre**

Besides the services of the Centre to respond to specific demands, the members of EC4SafeNano discuss and collectively agree on a voluntary annual joint programme of activities (JPA).

Activities which, based on identified needs, can be organised by the Centre as part of its annual JPA include, but are not limited to:

- Interlaboratory studies
- Pre-standardisation activities for the development of harmonised protocols (with a view to the development of standards at CEN / ISO / OECD level, etc.)
- Expert Group meetings on high-priority topics selected by members (two to three events per year).
- Position papers. The results and conclusions of the Expert Group meetings will lead to position papers summarising the position of the Centre on high-priority topics.
- Workshops (one event per year).
- Training of service providers.

The members will also decide whether there is an interest / demand for the organisation of activities associated with the promotion of harmonised and/or certified services (as mentioned under Section 3.3) and the areas / topic(s) where the Centre plans to invest resources for such activities. The activities will be funded with the membership fees paid by the members, by the incomes from the contracts and services delivered to the Customers. Incomes may also be obtained from bidding for national or international funding. More details are provided in Section 6.5. The budget allocated to the Joint Programme of Activities will therefore be defined each year based on the resources available.

## 4 Who should be part of the EC4SafeNano Centre?

Candidate members are all the stakeholders dealing with (engineered) nanomaterials – whether in studying their occurrence and effects or risk assessment and risk management. Among the key members there will be:

- Service providers;
- Competent authorities / National reference laboratories;
- Research centres and academia;
- Industry stakeholders;
- Government institutions and standardisation bodies.

## 5 Added value of a European Centre for Risk management and safe innovation in nanomaterials and nanotechnologies

EC4SafeNano partners already provide a vast quantity of scientific results for the European research area and are involved in large EU-funded project, thereby providing new methodologies for time- and cost-effective Europe-wide risk management and safe innovation.

However, the ambition of EC4SafeNano, rather than simply passively collating information, is to focus and strengthen the efforts of all participants in this field, in Europe and in the wider world. Its ultimate aim is to increase their capabilities, responsiveness and efficiency to the point at which they become, collectively, the global one-stop shop for all issues raised around safety of nanomaterials and products.

### 5.1 *What will be the benefit for your organisation as a member of EC4SafeNano?*

- Fast and easy access to the available information on institutes, projects and experts in the field of nanosafety and nanotechnologies in Europe and beyond:
  - thanks to its close links with the scientific community and reference laboratories in different countries, the Centre will be able to provide a systematic and updated overview of the needs, methods and resources available for a more effective support to public authorities and stakeholders
  - it will be possible to establish quicker contact with other partners in order to find the answer to a question, or rapidly put together a sufficient number of laboratories interested in starting a common action / work on a given priority topic
  - it will be easier and faster for stakeholders to find - in Europe and beyond - institutes, projects and experts suitable for collaborative research initiatives in the field of nanotechnologies
- Opportunities to launch initiatives for harmonisation of methods and services:
  - Thanks to the action of a European Centre, approaches for risk assessment and risk management will become more easily harmonised at European level, thereby reducing the effort and cost of development by single laboratories at the national level.
- A higher guarantee of the quality of the services provided thanks to a collective review of services:
  - A service provider or a customer can ask for support from the Centre to review a service. EC4SafeNano will set up a Task Force (i.e. a group of experts, members of the Centre) to review and validate a service delivered by the service provider.
- Active involvement at an early stage in the debate on highly strategic topics.
- A bigger voice speaking to the EC and other public institutions:
  - As an independent and competent forum of experts, the Centre will have a higher visibility and credibility toward the European Commission services and institutional bodies, compared to individual organisations, to answer questions about topics of concern, research needs and priorities for future regulations.
  - Organisation of regular Expert Group meetings and Position Papers which will contribute to boost the promotion of new research projects in priority fields.
  - A close link with policy-makers at national and European level will help to ensure that current policy development takes account of research outcomes.



A summary of the benefits that each type of stakeholder is expected to get by becoming a member of the EC4SafeNano Centre is reported in the table below.

Table 1: *Main benefits for your organisation as a member of EC4SafeNano*

Type of stakeholder	Benefits for your organisation as a member of EC4SafeNano
Service providers	<ul style="list-style-type: none"> <li>- Fast and easy access to the available information on institutes, projects and experts in the field of nanosafety and nanotechnologies in Europe and beyond</li> <li>- A higher guarantee of the quality of the services provided thanks to a collective review of services</li> <li>- Opportunities to promote and participate in initiatives for harmonisation of methods and services</li> <li>- Active involvement at an early stage in the debate on highly strategic topics</li> </ul>
Competent authorities / National reference laboratories	<ul style="list-style-type: none"> <li>- Fast and easy access to the available information on institutes, projects and experts in the field of nanosafety and nanotechnologies in Europe and beyond</li> <li>- Opportunities to promote and participate in initiatives for harmonisation of methods and services</li> </ul>
Research centres / academia	<ul style="list-style-type: none"> <li>- Enhanced opportunities to establish quicker contact with other partners and put together a sufficient number of organisations interested in working on a given priority topic</li> <li>- Active involvement at an early stage in the debate on highly strategic topics Have a bigger voice speaking to the EC and other public institutions</li> <li>- Participation in Expert Group meetings and Position Papers which will contribute to boost the promotion of new research projects in priority fields.</li> </ul>
Industry stakeholders	<ul style="list-style-type: none"> <li>- A higher guarantee of the quality of the services provided thanks to a collective review of services</li> <li>- Fast and easy access to the available information on institutes, projects and experts in the field of nanosafety and nanotechnologies in Europe and beyond</li> </ul>
Government institutions and standardisation bodies	<ul style="list-style-type: none"> <li>- Opportunities to promote initiatives for harmonisation of methods and services</li> <li>- Thanks to the action of a European Centre, approaches for risk assessment and risk management will become more easily harmonised at European level, thereby reducing the effort and cost of development by single laboratories at the national level</li> <li>- Access to highly qualified services providers</li> </ul>

## 6 Governance of the EC4SafeNano Centre

### 6.1 Members

It is foreseen that the Centre will be formed of any legal entities, except private individuals, from the four groups of stakeholders mentioned below:

- i. National Competent Authorities and Reference Laboratories,
- ii. Research centres and Academia,
- iii. Industry and private sector,
- iv. Non-Governmental Organisations and Institutional Bodies.

The Centre will consist of:

- i. Founding Members (Voting Members),
- ii. Ordinary Members (Voting Members),
- iii. Contributors.

#### 6.1.1 Founding members

Founding Members are:

- the members who create the Centre by signing its articles of association.

Founding Members shall pay an annual membership fee. During the first three years following the creation of the Centre, Founding Members shall pay an extra membership fee (in the order of max 10,000€) in order to help the start-up phase. After this first phase, Founding Members and Ordinary Members shall pay an identical membership fee, unless otherwise decided by the Steering Committee.

Each Founding Member shall automatically be a member of the Steering Committee for the first three years of the functioning of the Centre. After this start-up phase, membership of the Steering Committee will be achievable only by election.

Founding Members shall have the right to vote pursuant to the general rule 'one member one vote'.

Each Founding Member shall have full access rights to all products of the Centre under the conditions defined in the Centre's Internal Regulations (to be defined by the Steering Committee).

#### 6.1.2 Ordinary members

Ordinary Members shall pay an annual membership fee.

Ordinary Members shall have the right to vote pursuant to the general rule 'one member one vote'.

Ordinary Members shall have full access rights to all products of the Centre under the conditions defined in the Centre's Internal Regulations.

### **6.1.3 Contributors**

Institutional bodies, Governmental and International Organisations, Standardisation bodies and Non-Governmental Organisations can apply to become Contributors.

Contributors do not pay any membership fee.

Contributors may participate in the General Assembly and other activities of the Centre with a right to speak and to make proposals, but they shall have no right to vote.

### **6.1.4 Admittance of new members**

Admittance of new members can be done further by an application for membership. The application shall be sent in writing to the Executive Secretary at the address of the Centre. Membership (Ordinary Members only) shall start upon payment of the membership fee and full acceptance of the articles of association and Internal Regulations.

## **6.2 Organs of the Centre**

The management of the Centre is ensured via following organs:

- The General Assembly
- The Steering Committee (which includes the Executive Secretary, the Chairman, the Treasurer and the “Customers’ assistance Delegate”) which would serve as board of directors of the Centre.
- The Help Desk

### **6.2.1 The General Assembly**

The General Assembly (GA) is the organ which brings together all members of the Centre and allows each member to express their position. It determines the general policy of the Centre and it has all powers needed for the realisation of its objectives, and such powers are explicitly delegated to the Steering Committee. The Voting Members shall be represented in the General Assembly by their legal representatives or by any other representative by means of a written proxy.

The General Assembly shall convene every year.

The General Assembly can take decisions - by a majority of votes of the Voting Members present or represented at the General Assembly annual meeting - on the following issues:

- Approval of removal of members or Executive Secretary on the grounds of poor performance (vote);
- Election of members of the Steering Committee (vote);
- Approval for admission of members with the status of Founding Members (vote);
- Approval of the Annual Report (financial and activities) (vote);
- Approval of the annual audited accounts (vote);
- Recommendation and comments on the Centre’s Strategy and the Annual Joint Programme of Activities or JPA (consultation);
- Modification of the address of the registered seat (vote);
- Modification of the internal regulations (vote);
- Any other decision stated on the agenda (vote or consultation).

### 6.2.2 The Steering Committee

The Steering Committee shall be composed of no less than three members and no more than nine members.

For the first three years of the functioning of the network, all Founding Members shall automatically sit on the Steering Committee.

After this three-year start-up phase, the Steering Committee members shall be elected by the General Assembly three-year mandate.

Each Voting Member of the General Assembly shall be entitled to vote for candidates from the different groups of stakeholders.

The Steering Committee is elected by the GA (Founding and Ordinary members) with a mandate of 3 years.

The Steering Committee shall elect among its members the Executive Secretary, the Delegate for Customers' assistance, the Treasurer and the Chairman. They shall serve for three (3) years (renewable mandate). The Steering Committee is responsible for the operational and administrative management and the strategic orientation of the Centre.

The Steering Committee shall meet at least twice a year. One meeting should be organised to discuss the approval of the annual Joint Programme of Activities and Budget of the Centre. A second meeting should be organised to discuss the progress of the work and the preparation of the annual General Assembly meeting.

The tasks of the Steering Committee include, but are not limited to, the following:

- Ensuring the overall direction and co-ordination of the Centre;
- Admission or exclusion of new members;
- Appointing the Help Desk among the candidate applicants (three-year mandate, renewable);
- Defining the Annual Programme of Activities, taking into account the proposals and comments of the Members and registering per project which Members will participate in the specific activities;
- Choosing the members to be appointed for the realisation of the different tasks of the Annual Programme of Activities;
- Planning, monitoring and controlling the budget;
- Ensuring that the Centre's objectives are met;
- Approving the General Assembly meeting agenda drawn up by the Executive Secretary;
- Defining and approving the first Internal Regulations, including the list of criteria for the appointment of the member(s) in charge of the preparation of project proposals for customers' demands;
- Auditing and approving the provisional budget;
- Deciding, together with the adoption of the budget, on the amount and due date of the membership fees;
- Appointing Executive Secretary, Chairman and Treasurer;
- Administrative management of the day-to-day business of the Centre and, if applicable, supervision of the Executive Secretary;
- Timely preparation of the Annual Report and Annual Accounts for approval by the General Assembly;
- Ensuring that any Member of the centre can have access to relevant documentation regarding the activities of the centre.

Representatives of the Steering Committee should strive for consensus on all matters. Only in the absence of consensus, for a motion to be passed a two-thirds (2/3) majority of the votes cast is required.

#### **6.2.2.1 Executive Secretary**

The Executive Secretary is a member of the Steering Committee (mandate 3 years, renewable).

The Executive Secretary reports directly to the Steering Committee and is responsible for the day-to-day operation of the Centre and the proper running of interactions between the members.

The Executive Secretary shall:

- Prepare and organise the General Assembly meetings;
- Convene the Steering Committee and chair the meetings;
- Prepare the minutes of the meeting of the Steering Committee meetings;
- Collect the proposals from the Steering Committee and the General Assembly for the preparation of the Annual Programme of Activities;
- Prepare the Annual Programme of Activities, in collaboration with the Steering Committee, based on the input of the General Assembly (proposals of the members);
- Appoint the experts mandated by the Steering Committee to produce the planned deliverables (Expert Group meetings, workshops, organisation of interlaboratory studies, etc.);
- Ensure communication with external stakeholders (exchange of information about projects and initiatives in the various sectors and in the various countries);
- Receive applications for membership;
- Manage the day-to-day accounting operations.

#### **6.2.2.2 Chairman**

The Chairman is a member of the Steering Committee (3-year mandate, renewable). The Chairman shall chair the General Assembly meeting.

The Chairman shall:

- Convene the General Assembly;
- Prepare the minutes of the meeting of the General Assembly;
- Implement the decisions made by the Steering Committee;
- Represent the Centre in public relations with external organisations and institutions in collaboration with the Executive Secretary;
- Ensure specific communication with the Commission.

#### **6.2.2.3 Treasurer**

The Treasurer is a member of the Steering Committee (3-year mandate, renewable).

The Treasurer shall:

- Inform the Steering Committee on the financial situation of the Centre and ensure proper accounting and management of the Centre's property;
- Prepare and manage the budget.

#### **6.2.2.4 Delegate for Customers' assistance**

The Delegate is a member of the Steering Committee (three-year mandate, renewable).

The Delegate shall:

- Follow the list of criteria defined in the Internal Regulations of the Centre, for the appointment of the member(s) in charge of the preparation of project proposals for customers' demands;

- Inform the members about the demands of the customers (launch of a call for proposals);
- For simple demands, select among the candidates (or the proposals submitted by the candidates) the member or a list of members having the capabilities to prepare the offer and deliver the service (eventually it should be up to the customer to select an adequate provider);
- For complex demands, appoint a Task Force of qualified Members of the Centre (project leader and members with specific tasks in the project) that should be in charge of the preparation of the offer and delivery of the service.
- Present to the annual General Assembly meeting a detailed report of the services delivered by the Centre, including the list of the organisations appointed for the delivery of the services and the criteria applied for the selection of candidates.

### 6.2.3 Help Desk

The Help Desk is a member (or a group of members) of the Centre appointed by the Steering Committee with a three-year mandate. The candidate organisations need to apply for the task of Help Desk.

The tasks of the Help Desk are remunerated by the Centre. The annual budget allocated to the Help Desk is decided by the Steering Committee on an annual basis as part of the approval of the budget.

### 6.3 Preparation of the Joint Programme of Activities

The activities of the Centre shall be planned and organised on the basis of the Annual Programme of Activities to be proposed for each calendar year, following four main steps:

1. Consultation of the members of the Centre to invite their proposals and comments
2. Discussion of the proposals at the annual General Assembly meeting;
3. Survey among the members to vote the proposals and identify those with higher level of interest
4. Submission of the draft Annual Programme of Activities to the Steering Committee for formal adoption no later than 20 December of the previous year.

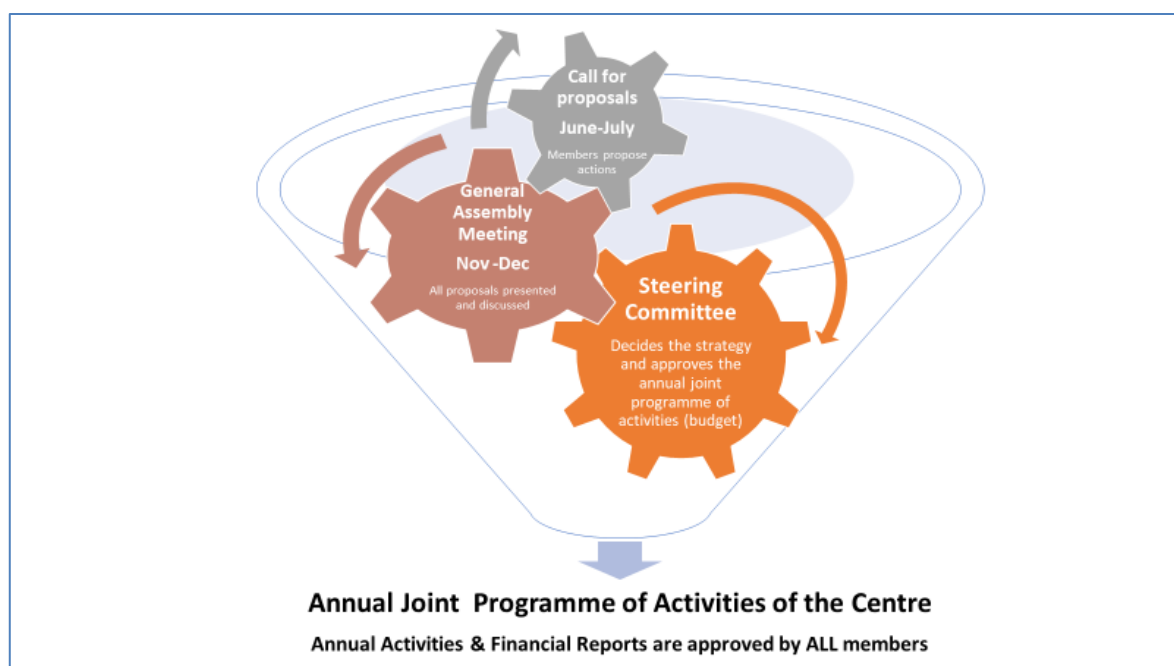


Figure 1: Governance mechanism for the preparation of the annual Joint Programme of Activities

## 6.4 Preparation of projects / contracts for external customers

When a Customer asks the Centre to deliver a service, the Delegate will apply the following procedure:

The Delegate for Customers' assistance informs the members and launches a call for proposals to respond to the demand(s) of the customers.

For simple demands the Delegate selects and appoints among the candidates (or among the proposals submitted by the candidates) the organisation that will prepare the offer and deliver the service or a list of members having the capabilities to respond to the demand of the customer.

For complex demands - which require the joint contribution of more than one member - the Delegate appoints a dedicated Task Force of members and contributors which will be in charge of preparing the offer (project leader and members with specific tasks in the project) and delivering the service.

For the appointment of the member(s) in charge of the preparation of the project proposals, the Delegate will follow the criteria approved by the Steering Committee, as part of the Internal Regulations of the Centre. The criteria will include, among others, cost, time for the delivery of the service, proven expertise of the candidates.

A review of the service by a Committee of Review will be possible upon demand of the Customer.

The experts of the Committee of Review are nominated by the Steering Committee.

Each service will be charged with an extra fee (given % of the cost of the contract), to be paid to the Centre. The members contributing in the deliverables review process will then be reimbursed by the Centre (lump sum defined based on the number of projects reviewed in one year).

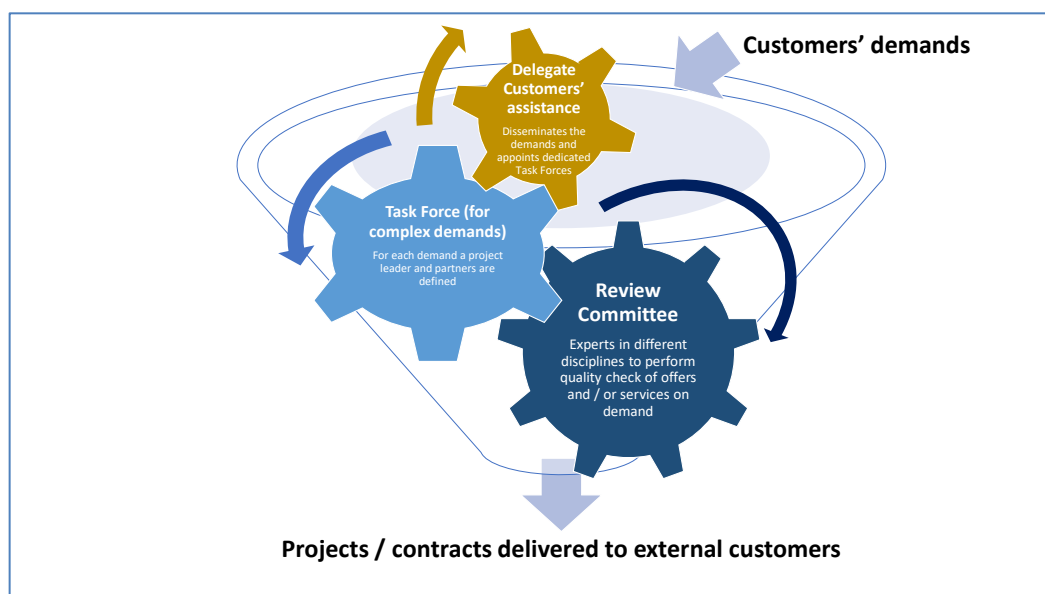


Figure 2: Governance mechanisms for the preparation of contracts and services for external customers

## 6.5 Financing

The Centre shall be financed by subscriptions or other contributions from the Members, under the conditions laid down by the Steering Committee, by the incomes from the contracts and services delivered to the Customers and by the fees paid by the service providers for registration of their services (knowing that the membership to the Centre already includes the registration of services).

The main incomes of the Centre are:

- Membership fees from founding and ordinary members (annual fee): the subscription fee;
- Registration fee of service providers to promote their services via the Centre: the service providers must pay a specific fee (annual fee) for registration of their services on the on-line webpage (database of services) of the Centre

- o the amount of the registration fee should be differentiated taking into account criteria such as: the value of services that is offered; the home country of the service provider (e.g. GDP per capita).
- Incomes from services provided by the Centre / provision of technical expertise and science-based answers to questions raised by stakeholders / training and audits / certification services<sup>1</sup>:
  - o A fee is applied (a given percentage of the cost of contract) to each contract. This income covers the administrative work, the study of the Client's question and selection of the member(s) in charge of making the proposals.
  - o A fee is applied for a review of the proposed service, upon demand of the Customer.

The amount and terms of such payments shall be established by the Steering Committee.

The annual membership fee covers the period from 1 January to 31 December.

There shall be no reimbursement of the membership fee if a member decides to withdraw from or is excluded from the network before the end of a year for which it has paid the subscription fee.

Subject to the agreement of the Steering Committee, an in-kind contribution may be allowed, to cover part of the membership fee for Ordinary Members.

In-kind contributions can be proposed for the following items:

- Organisation of Expert Group meetings and workshops;
- Organisation of interlaboratory trials;
- Other types of contribution, subject to the approval of the Steering Committee.

A member willing to provide an in-kind contribution will need to address a formal request to the Steering Committee, describing the contribution proposed.

The acceptance or not of the offer of an in-kind contribution shall be decided on a case-by-case basis by the Steering Committee. The Executive Secretary shall notify the applicant in writing of the decision of the Steering Committee.

The Steering Committee shall be responsible for judging whether the in-kind contribution actually made is of the promised quality. If the provided in-kind contribution does not meet the promised standard, the member involved shall pay the full membership fee.

The tasks of the help desk and of the Steering Committee are remunerated by the Centre, as follows:

**Help Desk:** fixed annual budget for maintenance of the website, databases, catalogue of services, newsletter, plus an additional budget defined on an annual basis depending on possible new tasks approved by the Steering Committee as part of the annual Joint Programme of Activities.

**Steering Committee:** they commit for their role at their own cost for human effort. An annual remuneration (defined as an annual lump sum) shall be paid by the Centre to cover travel costs for participation in SC meetings, etc.

**Executive secretary, Chairman and Treasurer** shall receive an additional annual remuneration (defined as an annual lump sum) to compensate for extra human effort and travel costs in addition to the SC tasks. The rest is provided as in-kind contribution.

**Customers' assistance Delegate:** shall receive an annual remuneration (defined as an annual lump sum).

**Experts of the Committee of Review:** shall receive a remuneration (annual lump sum, proportional to the number of services / projects reviewed).

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<sup>1</sup> In the first years the harmonised services need to be built by the Centre. Afterwards for some of them it might be possible to file an application to obtain an EU certification trademark which could be owned by the Centre. So in the starting phase of the Centre these activities will not generate income but hopefully they will after some years.



### 6.6 Budget

Each year and together with the Annual Programme of Activities a Budget for the next financial year, including a proposal on how it will be financed, shall be formally adopted by the Steering Committee.

The overall cost of the annual programme should fall within the total of anticipated receipts, while respecting a safety margin recommended by the Steering Committee.

To this purpose, each year and together with the Annual Programme of Activities a draft budget for the next financial year, including a proposal on how it will be financed, shall be prepared by the Executive Secretary and the Treasurer. The Steering Committee shall examine it, amend it as they see fit and formally adopt it.

The Steering Committee shall, together with adoption of the Budget, decide on the amount and due date of the membership fees.

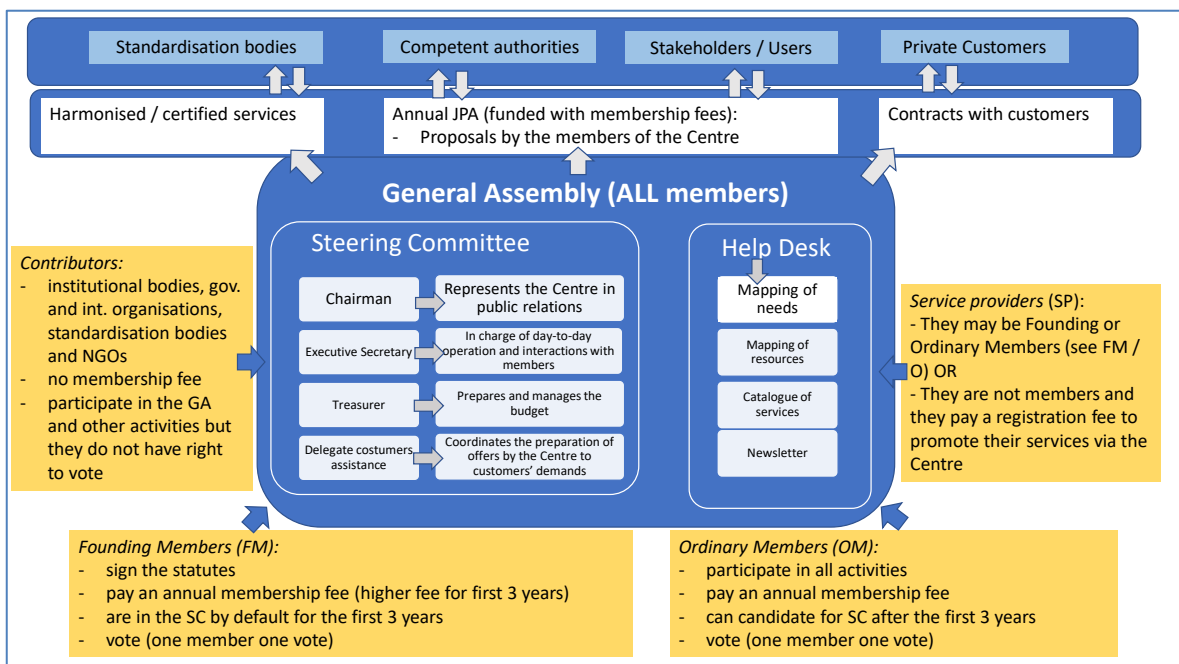


Figure 3: Governance mechanisms and business model of the EC4SafeNano Centre