Mexico – European Union Workshop in Nanosafety

REPORT

Participants: Miguel Bañares, Ruben J. Lazos-Martinez, Flemming R. Cassee (organizer), José Luis Rodríguez-López, Gerardo García-Rivas, Eva Valsami-Jones, Ulla B. Vogel, Iseult Lynch, Carlos Eduardo Lima da Cunha, Rafael Vázquez-Duhalt (organizer), Fabián Fernández-Luqueño, Carmen González, Andrea De Vizcaya-Ruiz (organizer), Zaira Garcia-Carvajal, Gabriel Luna-Bárcenas, Karla Juárez, Danail Hristozov, Ana Lucia Gallego-Hernández, Alejandro Huerta-Saquero, Stela Stoycheva,, Denhi Schnabel, Janeck J. Scott-Fordsmand, Claus Svendsen (remote-participation).

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Centro de Nanociencias y Nanotecnologia, UNAM
Ensenada, Baja California Norte, Mexico

Overall summary

The aim of this workshop was to establish a stronger connection between the Mexican and European research & innovation community within the context of bringing scientific information to the risk assessment, risk management and policy level. Mexico is eligible for participating in the EU in H2020 and FP9 programmes and this meeting is meant to get Mexicans and Europeans acquainted with what already has been achieved and where they can benefit from each other's knowledge (needs) and infrastructures. The following key collaboration summaries have been identified:

1) To formally invite some of the members of EU Nanosafety Cluster to be members of the International Advising Committee of SINANOTOX.
2) To engage SINANOTOX in NSC activities such as training schools, workshop and annual scientific meeting
3) SINANOTOX members to become member of working groups and task forces.
4) To promote the direct contact between the SINANOTOX research groups and their European counterparts vice versa, e.g. by involving Mexican partners in EU project proposals as Mexico is eligible for retrieving funding from the EU.
5) To promote the student and faculty exchanges using the binational CONACyT funds.
6) To promote in CONACyT the opening of a special call for Nanosafety.
7) To invite specific groups from EU Nanosafety cluster to review and enrich the toxicological assays proposed by SINANOTOX members.
8) To connect SINANOTOX with the Malta Initiative
9) To share protocols and standard operating procedures
10) To organize a small workshop or course on data handling and analysis.
11) To organize a meeting to evaluate the one-year activities and results from EU Nanosafety cluster-SINANOTOX conjoint activities on January-February 2020.

More specific recommendations are included in the presentation summaries below.

Presentation summaries

DAY 1

The meeting started on 22 January and the 20 delegates from the EU and Mexico were addressed by Dr. **Fernando Rojas Íñiguez**, director of Centro de Nanociencias y Nanotecnología, Universidad Nacional Autónoma de México who emphasized the relevance of the event and welcomed European representatives of NSC projects to Ensenada and to participate in the Mexico – European Union Workshop in Nanosafety, which represents the trigger for future collaborations to contribute in knowledge and safety perspectives between Mexican researchers working in nanosciences, nanotechnology and nanotoxicology and European Union partners joined in the NSC.

One of the main funding agencies in Mexico, Conacyt, was represented via a video connection by Dr. Héctor de León, acting Director of Technological Development, expressed the fundamental interest of Conacyt to support and engage in the activities related with and uniting European partners of the NSC and Mexican researchers participating in SINANOTOX. Conacyt acknowledges EU R&I Framework Programme, Horizon 2020, as a main vehicle for EU-Mexico partnership, with the potential to further strengthening of cooperation in key strategic sectors of mutual benefit. The EU side acknowledges CONACYT's willingness to participate in the flagships on Nanosafety and Technologies for Global Health Care (safety of medical devices) as well as contribute to the development of the guidelines of the "Malta Project" which involves EU Member States, OECD and the European Chemicals Agency (ECHA). Furthermore, the EU side welcomed the intention of Mexico to join the EU Observatory for Nanomaterials and expand H2020 participation to the field of Nanosafety.

On behalf of the European Commission, **Carlos Eduardo Lima Da Cunha**, policy officer at DG Research & Innovation pointed out that nanomaterials are an increasingly important product of nanotechnologies, being present in several industries, such as healthcare, electronics, food, and cosmetics. Their physical and chemical properties often differ from those of bulk materials. These properties make them extremely relevant for industrial applications, but might also lead to new unforeseen risks. Thus nanosafety emerged as a field to study the potential hazard and risk that nanomaterials might bring to workers, to consumers, and the environment. Currently this is done on a case by case basis, but this strategy is unsustainable as the use of nanomaterials expands, especially as they find their way into consumer products. In this context, and in the context of a global economy, the EU has funded several initiatives to promote and understand the risks regarding nanomaterials and how to mitigate them. However this knowledge needs to be transformed into regulation through internationally accepted testing guidelines and benchmark standards. The EU and Mexico Meeting on Nanosafety was planned as a platform to bring together European and Mexican researchers in the field and to align topics of interest. This initiative aimed also to increase the awareness of Mexican researchers and authorities towards EU-funded projects in the area of nanosafety, and to extend the reach of the current European projects. Within European projects, great emphasis has been put onto round-robin tests to validate testing protocols, an area which Mexican researchers could contribute and bring their expertise. Thus, a stronger relation between EU and Mexico will help promote scientific standards at international organisations, such as the OECD. Finally, the participants were made aware of European initiatives on nanosafety such as the Nanosafety School, and of upcoming European calls on safe by design.

The coordinator of SINANOTOX and local host of this workshop, **Rafael Vázquez-Duhalt** (Centro de Nanociencias y Nanotecnología, UNAM, Ensenada, México) described the newly established nanotoxicology consortium SINANOTOX, in which 6 higher education and research institutions join forces in the interest and to strengthen research in safety and nanomaterial development. This first workshop was an essential tool for SINANOTOX, as a new and starting organization, receiving the information on the organization and activities of the EU Nanosafety cluster, on the different working groups that are involved and on the understanding of task forces. Due to the significant amount of information that was described further meetings and time are needed for a solid integration, yet collaboration possibilities and opportunities are evident. From SINANOTOX perspective the following post-workshop activities are proposed: 1) To formally invite some of the members of the EU Nanosafety Cluster as members of the International Advising Committee of SINANOTOX; 2) to ask all SINANOTOX members to visit the EU NanoSafety Cluster webpage in order to detect working groups and task forces in which they can contribute. SINANOTOX members will be asked to make a report of this activity; 3) to promote the direct contact between SINANOTOX research groups and their European counterparts; 4) to elaborate a "Memorandum of Understanding" between EU Nanosafety cluster and SINANOTOX; 5) to promote the student and faculty exchange using Bi-national CONACyT funds; 6) to promote in CONACyT the opening of a special call for Nanosafety; 7) to invite specific groups from EU Nanosafety cluster to review and enrich the nanotoxicological assays proposed by SINANOTOX members; 8) to organize a Workshop or course on nanotoxicological data handling and analysis; and 9) to organize a meeting to evaluate the one-year activities and results from EU Nanosafety cluster-SINANOTOX conjoint activities on January-February 2020.

Gabriel Luna (Cinvestav - Querétaro, Querétaro, México)
SINANOTOX is an initiative supported by the Nanosciences and Nanotechnology Network of Conacyt.

Rubén Lazos, Centro Nacional de Metrología, Querétaro, México

Contributions of CENAM to joint activities and actions foreseen between Mexico and the European Union:
To share and jointly develop standards, protocols and standard operating procedures; and to invite SINANOTOX to interlaboratory comparison activities organized in the EU, and vice versa.
Harmonized and validated protocols constitute a core concept on metrology and standardization for laboratories performing tests for nanosafety. Harmonization of protocols promotes equivalent reproducible results. It means that results are independent of the laboratory, equipment and personnel used to obtain them. Thus, it brings confidence to the systems of laboratories. International harmonization is a legitimate aim of international standards and documents -like those by ISO and WPMN-OCDE-, supported on regional standards -like CEN-, and implemented through local standards -like NOM and NMX in Mexico-. Every effort is being made to align the protocols at every stage. Nevertheless, a basis for harmonizing protocols is to get them validated. A usually thoughtless assumption is that the documentary standard is correct, so it is always wise to ensure that before issuing it. Protocol validation provides confidence on that the protocol output is really adequate for its intended use. The best way to

accomplish it is by participating on interlaboratory comparisons (ILC). Since these exercises demand considerable resources, it is of the most convenience that laboratories seek to participate in them as much as possible. In order to disseminate the benefits, it is usual to organize similar ILC with the participation of at least one laboratory present in the previous one. It is assumed that reliable measurement standards, as calibrated items and certified reference materials, are used along the comparison and on the routine work. It is recognized that metrology for nanosafety has achieved very important advancements but, also, that relevant gaps are still to be solved. It is highlighted the close interrelation among protocols as documentary standards and metrology to support them. No good protocols can be founded on loose metrology. As summary, one of the elements to achieve reliable laboratory networks for nanosafety is to have globally harmonized and validated protocols, based on sound metrology.

Claus Svendsen UKRI-CEH, Wallingford, United Kingdom NanoFASE

The presentation focused on how we in order to make tangible progress on nano-exposure assessment in the environment and its inclusion in nano-regulation, must drive towards a pragmatic and realistic approach that where possible tries to reduce complexity. There is a need to move focus away from the physical/chemical properties of pristine ENMs and understand the functional and behaviour patterns of ENM in exposure relevant environments, something that is also recognized in the new REACH annexes. In addressing fate and transport in real environments, NanoFASE meets this challenge.

NanoFASE has worked to improve the prediction of environmental distribution, concentration and form (speciation) of nanomaterials, so the hazard testing can be targeted at including the actual exposure relevant particles that organisms will encounter, to allow a more relevant and realistic assessment of potential environmental and human exposure and risks, and an understanding that also facilitates safe product design.

The overarching objective of NanoFASE is to deliver an integrated Exposure Assessment Framework (protocols, models, parameter values, guidance) that:

- Allows all stakeholders to assess the environmental fate of nano releases from industrial nano-enabled products,
- Is acceptable in regulatory registrations and can be integrated into the EUSES model for REACH assessment,
- Allows industry a cost-effective product-to-market process, and
- Delivers the understanding at all levels to support dialogue with public and consumers.

The ambition is to reach a level of ENM Fate and exposure assessment at least comparable with that for conventional chemicals. For that, NanoFASE has developed a set of novel concepts and approaches to underpin the Framework, developed as common themes linking the research, exploitation and dissemination throughout the project. Our vision has been to move from the mainly mass-based lifecycle and release flow approaches towards systems that can account for spatial and temporal variability of ENM release, environmental transport and fate.

The presentation illustrated with examples how our framework incorporates: 1) the behaviour of the actual relevant ENM forms released from ENM products (a distribution of composite bound and free particles); 2) how reactions in waste management and environmental compartments (or "reactors") transform such release-relevant ENMs (integrating environmental speciation with ENM properties); and 3) the consequences of these transformations for transport and fate and among the different environmental compartments including organism uptake and local accumulation of ENMs in some environmental compartments ("environmental sinks" and hot spots). It was also shown how we have worked with ECHA and the OECD WPMN to ensure our framework is supported by standard operating procedures (SOPs), parameter values, models and guidance, and that this is transferred into the OECD WPMN Test Guideline and Guidance Document development program. As well as how we have worked with the CEINT center in the US to build a unified data holding structure for environmental nano fate and behavior data that can link these patterns to uptake and effects in biota.

In NanoFASE we would welcome interactions with Mexican initiatives or groups around environmental fate and exposure assessment, especially related to models, functional fate assays and data.

Denhi Schnabel (Instituto de Biotecnologia, UNAM, Cuernavaca, México) on the use and application of zebrafish. Zebrafish is an excellent animal model in different areas of biomedical research and in toxicological studies. This is due to study several characteristics like the external embryonic development, the small size of the embryos and transparency facilitates *in vivo* real time analysis of detailed cell behavior under the microscope. Zebrafish has most of major organs and tissues as any vertebrate; 70% of the protein coding human genes have a counterpart in the zebrafish genome, and even more interesting is that 84 % of the genes known to be associated with a human disease are present in zebrafish. At the Institute of Biotechnology of the National Autonomous University of Mexico (UNAM) we have set up a zebrafish facility were we produce hundreds to thousands of embryos weekly that are used in our everyday research projects and for teaching purposes too. Besides being an excellent model for the study for developmental biology, it is also a very good model to study diverse diseases that affect humans and for toxicological analysis. In our group we recently established the Fish Embryo Acute Toxicity (FET) Test using the OECD Guidelines for testing the effect on the development of zebrafish embryos for aromatic polycyclic hydrocarbons and organic micro contaminants, found in polluted water. Nevertheless, we are interested in more profound evaluations in the toxicological studies and for this purpose we have set in the laboratory several techniques that allow us to determine the detailed developmental effects at the molecular and cellular level. For example, we established qRT-PCRs and *in situ* hybridization for genes of interest; in addition we can detect DNA damage, oxidative stress, proliferation and cell death in whole embryos. We have several zebrafish fluorescent lines that allow us to determine toxicological damage in the cardiovascular system, the immune system or the germ line. In conclusion in our laboratory we have the methodological and conceptual expertise that allows us to use the zebrafish as a model to evaluate nanoparticle biocompatibility. By participating in the Mexico-European Union Workshop in Nanosafety opportunities to: -Promote the cooperation between the EU Nanosafety Cluster (NSC) and SINANOTOX, focused in education and research, -Work to obtain data of nanomaterials, in terms of their characterization, standard operation procedures for risk assessment, -Determine protocols to evaluate short and long term possible hazard of nanomaterials, -Possibility to participate in courses, schools and meetings, and -To promote CONACyT interest for a special call regarding Nanosafety.

Fabián Fernández Luqueño, Cinvestav-Saltillo, México

The Mexico-European Union Workshop in Nanosafety was an interesting summit in which Mexican and European researchers discussed the scientific finding of risk assessment, risk management, and national and international policies regarding nanotoxicity and nanosafety. I consider it was an excellent opportunity to meet European Colleagues, which generate cutting-edge knowledge, but, also they are all willing to collaborate with Mexican researchers. As soon as possible I will organize my agenda to visit the labs of Claus Svendsen, from the UK, and Carmen Gonzalez from San Luis Potosí, Mexico. I am really sure that this workshop strengthens the national and international collaboration, which will have results in a short and long term to contribute to the human and environmental health, to the legal and economic framework, and to the social well-being. Finally, I want to acknowledge the effort of Rafael Vazquez-Duhalt, Andrea de Vizcaya-Ruiz, and Flemming R. Cassee by the organization of this important workshop and of course, a special thanks to the sponsors.

Alejandro Huerta-Saquero, Centro de Nanociencias y Nanotecnología, UNAM, Ensenada, México

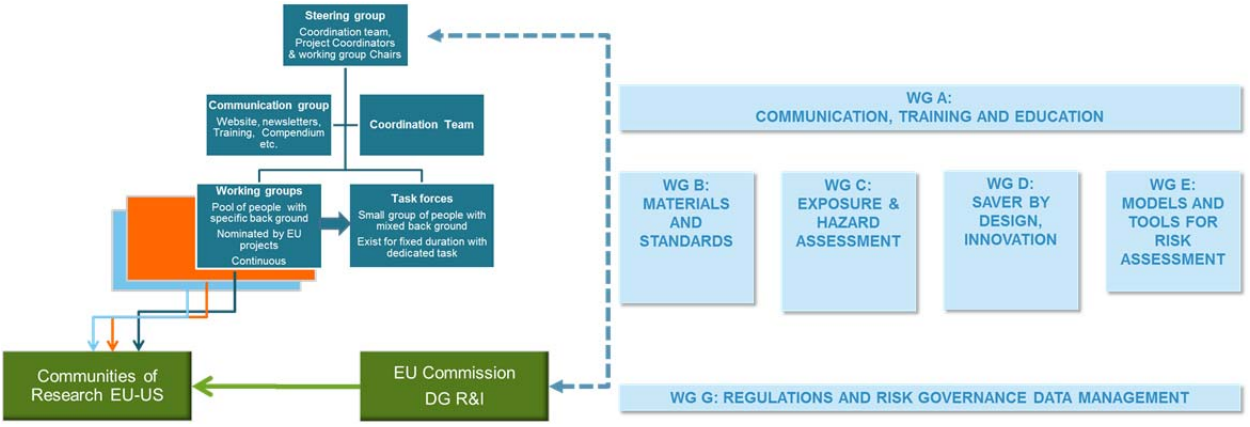
The past workshop between the European Nanocluster and the SINANOTOX focused mainly on the description of the activities concerning the biosafety of the use of nanomaterials. The Mexican groups showed the advances in the methods standardization of biological models for the study of the toxicity of the nanomaterials, while the European groups mainly focused on describing their organization systems and international collaborations in the European zone, emphasizing in the regulation of the use of nanomaterials and risk assessment. The progress in the evaluation of the toxicity of nanomaterials, the regulation of their use and the prediction of possible risks to health and the environment was addressed from different areas, thus, the European Union shows significant advances in the development of evaluation protocols, bioinformatics platforms for the report of results and even the prediction of possible scenarios for the use of certain materials. On the other hand, the large number of groups that are associated in the European Nanocluster gives us a clear vision of the importance of toxicological evaluation of nanomaterials in Europe and serves us as a reference to develop a robust system, focusing at national impact as well as at Latin American impact.

Opportunity areas EU-Mexico:

Search funding for collaborative projects on:

1. The development of hybrid nanomaterials to fight against emerging diseases in Europe and Mexico.
2. Design of hybrid antimicrobial nanomaterials for water disinfection.
3. Design and use of nanoantibiotics (including synergy with antibiotics) to prevent and combat microbial infection outbreaks caused by common social problems (migration, poverty, overcrowding).

Flemming R. Cassee (National Institute for Public Health and Environment & Utrecht University, the Netherlands. Coordination team EU project NanoSafety Cluster) explained the history, structure and function of the European Nanosafetcluster (NSC). The NSC is an initiative of the European Commission Directorate-General for Research and Innovation (DG RTD), which sponsors research in nanosafety. Idea launched Namur (B), 2009, established Boedapest (Hu) 2010. The NSC aims to maximise synergies between European-level projects addressing the safety of NMs and technologies. The NSC functions as a high profile platform for coordination of nanosafety research in Europe. It also provides strategic direction for the EU and member states and enhances synergies between running and newly starting projects. The website is used to preserve the outputs and data from ended projects. Members of the NSC also integrate and synthesize nanosafety knowledge to provide a unified message to stakeholders including regulators, industry and civil society. Members represent academic organisations, industry and (Non-) Governmental organisations from primarily EU countries mostly but also outside Europe. The NSC consists of working groups based on disciplines (chemistry, exposure assessment, human and eco toxicology etc) with an executive body (coordination team). There is a steering committee with representatives of all running projects that is the decision making body, although the NSC is not a legal entity. Task forces are initiated based on a concrete question or problem that can be addressed with a year, very much focussed to apply the knowledge generated within projects and working groups. More information via www.nanosafetycluster.eu.



As the EU commission has invested a vast amount of money into projects and knowledge development, this should now be used to support the development of new and the revision of existing OECD test guidelines and guidance document to accommodate or to allow testing of nanomaterials. The NSC projects are expected to contribute to this via the so called Malta Initiative (MI), named after a meeting of a group of regulators during a conference on Malta. There is a strong focus on the need from REACH.

Initiative and the MI is coordinated by Thomas Kuhlbusch, Federal Institute for Occupational Safety and Health (BAuA), DE. It consist currently about a10 different actions (projects) and the NSC but also other parties including SINANOTOX can contribute with dedicated knowledge or offering round robin testing. Examples of MI projects are specific surface area, dustiness, particle size and size distribution determination of solubility and dissolution rate in water and relevant synthetic biologically fluids, the identification and quantification of the surface chemistry and coatings toxicokinetics and in vitro genotoxicity of manufactured nanomaterials. New members always welcome, please join via: https://www.nanosafetycluster.eu/home/mailing-lists.html (NSC community or join one or more working groups), to attend meetings (usually 2/year), and to propose and participate in the task forces.

Danail Hristozov, Greendecision Srl., spin-off of University Ca' Foscari of Venice.

As one of the Key Enabling Technologies, nanotechnology has emerged in a broad area of industries and applications. From a risk governance point of view, it has become a real challenge to accommodate this technology, correctly and uniformly across all involved regulatory domains (i.e. chemicals, biocides, cosmetics, food, and medicine). By the time regulators became aware of potential omissions in guidance and guidelines addressing the nanospecific nature of chemical substances and products, they were already on the market. As a result, the nanomaterials and nano-enabled products on the market have developed governed by a system in which both regulators and industry lack a sound knowledge-base to ensure their safety.
To address this, the EU H2020 Gov4Nano project will develop and implement an inclusive, credible science and evidence-based risk governance process for future and emerging nanotechnologies. This governance model will be based on appropriate knowledge, concepts of risk perception and transparency about dealing with uncertainties. It will be implemented through a Nanotechnology Risk Governance Council (NRGC), designed and established by the project as a trustworthy and objective international umbrella for the risk governance of nanotechnologies.
To develop and implement the Gov4Nano adaptive and resilient risk governance process, we will explore the potential added value of innovative approaches such as Findable, Accessible Interoperable and Re-usable (FAIR) databases, blockchain technology and implementation of safe-by-design. This new governance model will support

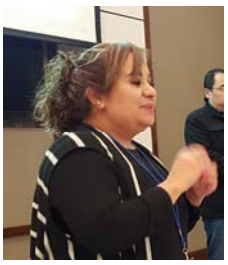
consensus building, prioritization and harmonization of practices amongst stakeholders, with a focus on key aspects such as risk assessment, risk management, risk perception and risk communication, risk-benefit evaluation, risk-transfer, and the societal desirability of nanotechnology applications.It will include knowledge management and data management, efficiently executed through stakeholder involvement.
In addition, Gov4Nano will be the first project actively supporting the objectives of the so-called Malta-Initiative which focuses on a science-based revision of those OECD guidance and guidelines which are relevant for nanotechnology. Additionally, the future route for updating guidance and guidelines will be laid out by the development of a transdisciplinary regulatory research roadmap.

Iseult Lynch, University of Birmingham, United Kingdom, EU project RiskGone
Science-based Risk Governance Of NanotEchnology (RiskGone) is coordinated by Maria Dusinska, Norwegian Institute for Air Research. Engineered nanomaterials (ENMs) are covered by REACH/CLP regulations; the general opinion is that the risk assessment (RA) approach routinely used for conventional chemicals is also applicable to ENMs. However, as acknowledged by OECD and ECHA, the OECD and ISO Test Guidelines (TGs) and Standard Operating Procedures (SOPs) need to be verified and adapted to be applicable to ENMs.

RiskGONE will support the standardization and validation process for ENM by evaluating, optimizing and pre-validating SOPs and TGs and integrating them into a framework for risk governance (RG) of ENMs. The framework will comprise modular tools and will rely heavily on current strategies for the RA of conventional chemicals, complemented by methods for estimating environmental, social and economic benefits. It will incorporate ethical aspects and societal risk perception and will manage acceptable and unacceptable risks through transfer or mitigation. The focus of RiskGONE is to produce nano-specific draft guidance documents for application to ENM RA; or, alternatively, to suggest ameliorations to OECD, ECHA, and ISO/CEN SOPs or guidelines. This will be achieved through Round Robin exercises and multimodal testing of OECD TGs and ECHA methods supporting the “Malta-project”, and on methods not yet considered by OECD. This process will be accelerated by provision of guidance documents for data storage/curation/accessibility optimisation, applied to well-characterized reference ENMs typifying the main physicochemical and toxicological features.
The risk governance framework will be underpinned by state-of-the-art decision-making tools (decision support tools) and risk communication tools to relevant stakeholders, including industry, regulators, insurance companies, and especially to the general public. All aspects of the risk governance framework will be integrated into the RG Cloud Platform, which will facilitate the dynamic integration of scientific evidence as it evolves over time, and advance the handling of scientific uncertainty in the regulatory RA of ENMs.
Finally, a transparent, self-sustained RG council, representing EU stakeholders, member states, industry and civil society, will be established, who will utilise the RiskGone RG framework and cloud platform to support nano-governance in Europe and beyond. The RG framework and methods developed by RiskGONE will be transferred to the RG council, which will act as a science-based governance body for ENMs safety and provide responsible 2-way communication with stakeholders and civil society, based on high quality information. A suitable “home” for the RGC will be found among the different EU agencies to ensure sustainability, independence, and neutrality of the council, which will have to provide, upon request from the European Commission (EC), expert opinion on the risk management of engineered nanomaterials. Importantly, the structure of the RGC will be balanced (tripartite covering regulatory, academic and industry representatives), transparent and inclusive, taking into account stakeholder feedback in reflections and decisions through bi-directional communication.

Janeck J Scott-Fordsmand, Aarhus University, Denmark, EU project NANOtechnology RIsk Governance (NANORIGO) Partners in this project will develop and implement a transparent, transdisciplinary and science-based Risk Governance Framework (RGF) for managing nanotechnology risks regarding social, environmental and economic benefits. A new risk management approach is developed, based on high-quality data and advanced scientific tools, for and with all stakeholders. The RGF will use a life- cycle perspective and integrate available knowledge on ethical, social, environmental and economic concerns into a user-friendly format that can be easily adapted and transferred into regulation for hazard, exposure and risk assessment and management of nanomaterials. It will consist of: (i) risk management strategies based on reinforced tools for guidance and decision-making developed for risk assessment, (ii) validated methodologies to identify potential hazard and exposure, and (iii) a web-based information and communication platform to facilitate access to good quality data and a clear understanding of risks for all stakeholders, and their valuable feedback. A self-sustained European Nanotechnology Risk Governance Council (NRGC) will be installed to implement the RGF, embedded in relevant international structures and in close cooperation with the International Risk Governance Center (IRGC). Case studies will demonstrate the sustainability of solutions and their consistent integration into regulatory applications under real conditions. Bringing all stakeholders together under a common umbrella will allow to share and integrate the most appropriate governance tools, frameworks and plans for future science and regulatory research and foster consistency of management approaches in the EU and synergies internationally. Contact coordinator: Janeck J Scott-Fordsmand, Aarhus University, e-mail: jsf@bios.au.dk

DAY 2



Zaira García, CIATEJ, Guadalajara, México

The Center for Research and Assistance in Technology and Design of the State of Jalisco, AC (CIATEJ in spanish) is a research center belonging to the Coordination of Environment, Health and Food System Public Research Centers (ICC) of CONACyT). For over 40 years we have been active in Research, Technological Development and Innovation (R + D + I), we also offer technological services and training of human resources specialized graduate programs (masters and doctorates), continuing education (training) and research initiation (and undergraduate internships).

The Center specializes in technological and human capital solutions that contribute to improving the competitiveness of the various stakeholders in the agricultural, health, food, environmental, analytical measurements, among others.

In CIATEJ, we have a multidisciplinary team in technology transfer a decisive activity in the emerging knowledge economy that supports entrepreneurs and social actors. Our main partners are from the productive sector and academia,

The collaboration and participation in specific projects for mutual interests are:

1. A diagnosis that shows a way forward for initiatives that stimulate research, development and innovation of nanotechnologies and nanomaterials in Mexico. Focus on Market studies and Roadmaps of Nanotechnology in: a) Food and the feed chain, and the agriculture sector in Mexico; and b) Academic Collaboration (interchange program).
2. Characterization or nanomaterials in the gastrointestinal fluids:

a) Determination of the size in collaboration with Professor Eugenia (Éva) Valsami-Jones of NanoMILE & ACEnano Project coordinator

b) 3D GIT models: Dispersion and ageing protocols to better mimic NMs transformation in the gastro-intestinal tract (GIT) following oral exposure in collaboration with Roel Schins of PATROLS.

Other interest are: Training in Nanosafety and Legal Framework, Publish jointly, Feedback from Europe

Commission and Nanosafety in the Legal topics, Interlaboratory co-workers in order to validate our protocols, Consulting and training programs for the productive sector in Mexico. Specific: Fod-Feed chain and agriculture, and Feedback from Europe Comission about the management of innovations trends in the agri-food sector.

Jose Luis Rodriguez-López, IPICyT, San Luis Potosí, México

The Protein Corona on Nanoparticles in Nanomedicine Applications: their optimal design & issues from materials science characterization.

Dr. Rodriguez-Lopez, from the Advanced Materials Department at IPICYT, presented a study on the bio-functionalization of metallic nanoparticles for potential applications on nanomedicine.

The efficacy of drugs and other therapies related to nanomedicine depends to a large extent on the ability of nanoparticles (NPs) to reach the target tissue. In an ideal sequence of events NPs injected into the bloodstream circulate and reach the target tissue, ligand molecules on the surface of the NPs recognize and bind to specific receptor molecules of the target tissue where the drug they may carry is released in a controlled manner. However, once NPs are injected into a living organism, their surface is modified by the interaction with blood components, mostly proteins, and spontaneously form a structure called 'protein corona' (PC) in a dynamic process governed by the affinities and equilibrium constants of each type of protein to the NPs surface and the composition of the surrounding biological fluids. In this work, we present the structural and analytical characterization of the PC of the complex BSA—AuNPs with a diverse portfolio of materials science techniques, and address some aspects in the implementation for their standardization and interpretation of results.

Dr. Rodríguez-López emphasized that in order to start and increase the collaborations with the EU partners, we should focus primary on:

1- That this first EU-MX interaction bring results such as exchange of researchers, students, projects together, etc. In this sense, his group foresees a potential collaboration with the responsible of the ACEnano H2020 project, Prof. Valsami-Jones. This potential collaboration could be through the program https://royalsociety.org/grants -schemes-awards/grants/international-exchanges/a program that can be taken also for other colleagues from this first EU-MX initiative.

2.- He also emphasized the offer to support the group with all the materials science characterization infrastructure present now at IPICyT, in order to help in the structural and analytical characterization of nano-systems for problems of biomaterials, or nanomedicine.

Flemming Cassee, RIVM, NL, EU project PATROLS

Physiologically Anchored Tools for Realistic nanOmateriaL hazard aSsessment (PATROLS) is an international project combining a team of academics, industrial scientists, government officials and risk assessors to deliver advanced and realistic tools and methods for nanomaterial safety assessment.

PATROLS will provide an innovative and effective set of laboratory techniques and computational tools to more reliably predict potential human and environmental hazards resulting from engineered nanomaterial (ENM) exposures. These tools will minimise the necessity of animal testing and will support future categorisation of ENMs in order to support safety frameworks. To date, hazard assessment studies conducted on ENMs have focused on short-term, high-dose exposures. However, in reality, exposure to nanomaterials is long-term, repetitive and occurs at low doses. 2D cell monocultures are widely used in safety assessment for human health; however, these standard systems fail to represent the complex biological processes that occur within the human body. As a result animal models are relied upon to confirm the hazard data generated. Furthermore, environmental ENM hazard assessment is typically restricted to short-term exposures on a small selection of organisms which lacks

environmental realism in terms of dose delivery, exposure duration and uptake through the food chain.

A similar problem exists in ENM ecotoxicity testing, which is typically restricted to short-term exposures on a small selection of organisms. In contrast, long-term, low-level exposure of ecosystems to ENM will be the reality for many environments. Current approaches lack environmental realism in terms of dose delivery, exposure duration and uptake through the food chain. The latter affects behaviour of top consumers by reducing their activity, feeding rate and changing species interactions

The PATROLS project is establishing a battery of innovative, next generation safety testing tools to more accurately predict the adverse effects caused by long-term ENM exposure in humans and the environment.

We aim to deliver:

- Realistic and predictive 3D tissue models of the lung, gastrointestinal tract and liver for ENM safety assessment, reducing the need for animal testing.
- Innovative methods for safety assessment in ecologically relevant test systems and organisms, selected according to their position in the food chain.
- Creating robust computational methods for ENM exposure and dose modelling, as well as hazard prediction.
- Characterising ENM under relevant experimental conditions dictated by the advanced human and environmental model development.

Carmen González, UASLP, San Luis Potosí, México

Without a doubt, the first meeting of the EU Nanosafety Cluster (NSC) and the Mexican National System for the Toxicological Evaluation of Nanomaterials (SINANOTOX) was encouraging, productive and motivating, since there were great academic-scientific similarities, and important differences in which both parts complement and strengthen experiences around nanomaterials.

The following is a list of proposals / ideas that could strengthen this Europe-Mexico interaction:

1.- One point that I think should be dealt with more particularly is the financial part and the mechanisms through which SINANOTOX members could participate in European calls and vice versa.

2.- Likewise, the collaborations between both parties would be a great advance and even more so if we were to entrust the SINANOTOX members with identifying and contacting the international pairs that work with similar models of experimentation, in order to validate the tests proposals at the National level, a fact that would enhance the internationalization of SINANOTOX.

3.- Learn and get more involved in the mechanisms that the European community has put in place and that allows it to have an advance and synchrony in the various activities that its system contemplates. (eg. assistance to nanotechnology courses, standardization and regulation of nanomaterials, use and disposal of nanomaterials, evaluation, their engagement and social organization (electronic platforms, financing, business plan, sustainability, marketing, etc.)).

4.- Another proposal could be the generation of a book of joint protocols, which would serve as a broader catalog-guide of evaluations of nanomaterials (similar to the one contemplated with SINANOTOX).

5.- Conduct a cycle of virtual seminars Europe-Mexico, to meet the above.

Gerardo Garcia-Rivas, Escuela de Medicina y Ciencias de la Salud, ITESM-Monterrey, México
Nanomaterials have created certain concerns about their potential effects on human health and safety and environmental burden. Special considerations are given regarding susceptible groups of people and vulnerable cardiovascular conditions including: hypertension, cardiovascular risk and heart failure. Accordingly, toxicological studies of nanomaterials have been carried out on cardiovascular system.

In general, silica, titania and silicon nanoparticles can be considered as of relatively low toxicity, however one aspect often ignored concerns with the interaction of nanoparticles with cells from several pathological scenarios. To the best of our knowledge, there is not a systematic investigation of the differential cytotoxic response of healthy and cardiac cells from a pathological setting such as: heart failure, cardiac hypertrophy, and pulmonary arterial hypertension using nanomaterials. Since cardiac cells from an animal model of cardiomyopathy are prone to suffer high levels of oxidative stress, energetic dysfunction and nanoparticle accumulation, it seems important to review the doses of concentration of nanoparticles, to compare the mechanisms of cytotoxicity with healthy cells, and to evaluate the percentage of viability regard to cellular dysfunction. Our group is focused in characterizing the potential toxicity of several nanomaterials (silica, titania, silicon and graphene) on cardiovascular system (at different levels of organization, starting with isolated cardiac mitochondria, adult ventricular myocytes and animal models of cardiac dysfunction. We are conducting three main projects using silica, titania and graphene oxide, that use a combination of biochemical, cellular imaging, ultrasound, and electrophysiological techniques to elucidate the functional and the structural changes in cardiac models expose to nanomaterials.

We have interest in collaborate with Carmen Gonzalez, Flemming Cassee and Andrea De Vizcaya to evaluate the ventricular function and hemodynamics on mice exposed to ultrafine particles. Evaluate the effect of ultrafine particles and nanomaterials in our models of non-ischemic heart failure, stress-induce cardiomyophaty and pulmonary arterial hypertension with healthy animals. This collaboration would be also relevant as part of the Malta Initiative participating in the revision of TG related with in vitro testing and cardiovascular models.

Andrea De Vizcaya-Ruiz, Toxicology Department, Cinvestav, Mexico City, México
Establishment of nanosafety protocols using *in vitro* and *in vivo* animal models is essential to understand their biointeraction and potiental toxicity. At the Department of Toxicology at the Center of Research and Advanced Studies (Cinvestav) we have established protocols and methodologies focused on the understanding of nanomaterials in relevant media, protein corona biointeraction and toxicity testing using *in vitro* and *in vivo* rodent models. Harmonization and collaboration with established protocols on laboratory techniques and computational tools to more reliably predict potential human and environmental hazards resulting from engineered nanomaterial with projects such as PATROLs, and integration with Test Guidelines procedures via Malta Initiative or the Nano Observatory to outreach scientists that are developing or using nanomaterials is a main objective, as well as collaborating with other integrated projects of the NSC that are applying state of the art technologies such as toxicogenomcis and single cell-ICP-MS. Cinvestav and SINANOTOX as a grouped organization can potentially succeed in this active collaboration.

Ulla Vogel, National Research Centre for the Working Environment, Copenhagen, Denmark, representing SmartNanoTox

An adverse outcome pathway (AOP) is structured representation of a casual chain of biological events leading to adverse effects and is considered relevant to risk assessment.

The AOP links in a linear way existing knowledge along one or more series of causally connected key events (KE) between two points — a molecular initiating event (MIE) and an adverse outcome (AO) that occur at a level of biological organization relevant to risk assessment. The linkage between the events is described by key event relationships (KER) that describe the causal relationships between the key events. New AOP can be submitted to the AOP initiative (https://aopwiki.org/).

The identified KEs can be used in hazard assessment of new nanomaterials and they are obvious targets for development of in vitro and in silico assays for hazard assessment, grouping and ranking of nanomaterials.

Several H2020 project including SmartNanotox (http://www.smartnanotox.eu/), PATROLs (https://www.patrols-h2020.eu/), and CaLIBRAte (www.nanocalibrate.eu/home) use the AOP concept.

SmartNanoTox will develop new AOPs and has currently contributed to two AOPs to the AOP framework (https://aopwiki.org/), AOP 173 (Increased substance interaction with the resident cell membrane components leading to lung fibrosis) and AOP 237 (Secretion of inflammatory cytokines after cellular sensing of the stressor leading to plaque progression). In addition, SmartNanoTox will develop in vitro and in silico assays for KEs.

PATROLs focusses on the development of in vitro assay for KEs that are relevant for development of inflammation, fibrosis and cancer in lung and liver.

The development of new AOP for nanomaterial-induced adverse outcomes is highly warranted and this is an area, where Mexico and EU could both contribute.

Stela Stoycheva, YORDAS GROUP, EU project GRACIOUS (https://www.h2020gracious.eu/)

The GRACIOUS Project: Grouping, Read-Across and ClassIficatiOn framework for regUlatory risk assessment of manufactured nanomaterials and Safer design of nano-enabled products

During the presentation a short overview of the project facts, stakeholder consultation activities and current status of the Framework were showcased. In the discussion session opportunities for knowledge exchange and collaboration between EU and Mexican partners were identified.

The project will work continuously with stakeholders in an iterative cycle of design, testing and refinement to ensure that the Framework effectively meets the needs of both regulators and industry.

The GRACIOUS Framework will be underpinned by scientific hypotheses identifying endpoints relevant to grouping and read-across. To generate the knowledge and data needed to identify and test the hypotheses Integrated Approaches to Testing and Assessment (IATAs) covering all domains of relevance for risk assessment: (i) “Lifecycle environmental release and human exposure”, (ii) “What they are: physicochemical identity”, (iii) “Where they go: Environmental fate, uptake and toxicokinetics”, and iv) “What they do: human and environmental toxicity”. The IATAs will reduce, refine and replace (where possible) the need for animal testing by promoting the use of modelling (e.g. in silico, fate, exposure), in vitro and cell-free tests.

To enable the Framework to inform SbD options that retain product functionality, we will apply Stage-Gate thinking which incorporates a risk/cost-benefit analysis to inform decisions on project termination, the need for stage reiteration to improve the safety, and/or progression to the next stage.

GRACIOUS Stakeholder consultation activities:

Stakeholder engagement forms a key aspect of the GRACIOUS project. As the project aims to be of practical value and intends to support regulators and industry decision makers by providing suitable decision-making

methodologies and tools, an effective stakeholder engagement and consultation with target stakeholder groups will ensure alignment of the project outcome to the needs of stakeholders. The GRACIOUS methodology for Stakeholder engagement consists of two main components: formal and informal engagement. Informal stakeholder engagement is delivered as a communication process in which a broader audience is kept informed about the goal of the project, its progress and outputs. These activities are achieved by the means of continuous marketing and dissemination tools such as newsletter subscription, communication via the project website, press releases, direct emails and social media communication. The formal Stakeholder engagement is delivered through constant communication with the developed within the project stakeholder database encompassing all GRACIOUS target groups and its International Advisory Board. A formed group of Stakeholder champions (comprising of members of the consortium representing each stakeholder group) is responsible to communicate actively with key stakeholders and a broader audience as the project progresses, and to elicit feedback from those groups that can be helpful to refine the Framework development.

Current status of the GRACIOUS Framework:
The GRACIOUS Grouping Framework design:

- aligns with EU chemicals legislation (in particular REACH).
- is informed by existing approaches and recommendations on grouping and read-across
- aligns with the industrial innovation process (e.g. Stage-Gate Idea to Launch process)
- is hypothesis-driven and evidence based.

The information and data for justifying the grouping hypotheses are generated via tailored IATAs.
The IATA are comprised of tiers of increasing specificity and complexity to acquire the data needed to justify grouping and read-across.
Grouping considers not only intrinsic properties and (eco)toxicological effects, but also extrinsic (system-dependent) descriptors of exposure, toxicokinetics and environmental fate.
The grouping outcome is influenced by the grouping purpose (regulatory compliance including read-across, innovation/Safe by Design (SbD), identification of precautionary measures, scientific understanding) and context (e.g. inhalation vs dermal, or human vs environment) in order to inform hypothesis generation.
The Frameworks takes the user through a couple of steps to reach a final grouping/read across decision.
To more confidently justify the inclusion of a NF or NFs into a group, more information may be required to assess the similarity between the NFs as postulated by the grouping hypotheses. Generation of this information is guided via an Integrated Approach to Testing and Assessment (IATA). IATAs use both existing information and newly generated information gathered via the most relevant modelling or testing strategies. These IATAs will incorporate all domains of relevance for risk assessment, namely:

- What the nanoforms are (physical and chemical characteristics),
- Where they go (in the environment, within the bodies of humans or other organisms),
- What they do (their hazard to humans and other organisms), and
- Description of the exposure scenarios and the exposure relevant nanoforms for the uses of interest.

DAY 3

Éva Valsami-Jones, University of Birmingham, ACEnano project coordinator. For the future wider acceptability of nanotechnology, a well-founded and robust legislative framework that will ensure safe development of nano-enabled products is needed. The development of such a framework has proven particularly challenging; at the heart of the challenge lies the difficulty in the reliable and reproducible characterisation of nanomaterials given their novelty, variety in properties and forms and dynamic nature, particularly in complex conditions, such as within different biological, environmental and technological compartments.

To resolve this, the ACEnano project, is working towards introducing confidence, adaptability and clarity into nanomaterial risk assessment by developing a widely implementable and robust tiered approach to nanomaterials physicochemical characterisation that will simplify the choice of characterisation methods, and facilitate contextual (hazard or exposure) description and its transcription into a reliable nanomaterials grouping framework.
ACEnano is structured into three phases of instrument and method development: innovation to develop new methods, new means of instrument hyphenation, novel sample introduction, or miniaturised equipment; optimisation of workflows and sample introduction systems; and benchmarking of both existing methods and those developed and optimised within ACEnano. In all cases, full protocols and SOPs, and training materials (video protocols, online tutorials, libraries of representative results…) will be provided, alongside a decision tree to support users (industry, regulators…) in the selection of the most appropriate combination of methods to address their specific analysis or characterisation need.
The presentation focused on some examples where analytical innovation is needed for example in the development of harmonized sample preparation, sample introduction systems, hyphenated analysis enabling the use of different method to simultaneously or sequentially analyse the same sample spot and the use of novel powerful analytical methods such as single-cell inductively coupled plasma mass spectrometry.

Danail Hristozov, University of Venice, Italy, EU projects CALIBRATE/SUN

caLIBRAte project: Currently, most of the existing REACH compliance models and exposure limits are not suited or validated for risk assessment of manufactured nanomaterials. The EU H2020 project caLIBRAte has addressed this by establishing a versatile next-generation nano-risk governance framework for assessment and management of human and environmental risks of manufactured nanomaterials and nano-enabled products. The framework has been founded on thoroughly tested models and stakeholder needs. The goal is that the quality and trust in these models will exceed the current level of most existing REACH tools. These models have been linked into an online nano-risk governance portal, which companies, developers and authorities can access to find tools for risk assessment, prioritisation and management of occupational, consumer and environmental risks associated with manufacturing and use of products containing nanomaterials. The models will be aligned in the framework to support decisions along the research and innovation value chain, from basic research to market launch.

The nano-risk governance portal will be specifically based on a suite of tested and calibrated nano-specific risk prioritisation and control banding tools to perform occupational, consumer, and environmental risk assessment and management during innovation, production and use of nanomaterials and nano-enabled products. Stakeholders have been surveyed to define their requirements and understand their concerns. Comprehensive work has been done to collect and evaluate existing characterization and toxicological test data on a larger suite of nanomaterials as well as human exposure scenarios. New data has been generated to test toxicological hypothesis and close data gaps to reach a comprehensive set of data to be used for model testing. The nano-risk governance portal is expected to be publicly available from September 2019. Our limited understanding of the environmental and health risks from nanotechnologies has raised concerns about the adequacy of their regulation. To address this challenge, the EU FP7 Sustainable Nanotechnologies (SUN) project studied the properties, exposure, hazard and risks not only of pristine nanoparticles, but also of materials released from products, weathered in the environment, and modified for safety by design reasons.

Sustainable Nanotechnologies (SUN) project: In 3.5 years of research in contact with major industries, the scientists have developed and tested an array of methods and tools for estimation of release, in vitro and in vivo toxicity, toxicokinetics, environmental fate and exposure. These efforts culminated in developing the SUNDS online platform (https://sunds.gd/), which supports industries and regulatory agencies in assessing potential risks that may arise for workers, consumers and the environment in order to identify relevant risk management measures. These methods and tools were tested in case studies representing supply chains of real industrial

products: coatings and composites for the energy, transportation and construction industries embedding nanoscale Tungsten Carbide/Cobalt, Copper Oxide, Silica, Titanium Dioxide, organic and inorganic pigments, and multi-walled carbon nanotubes.

This has not only generated an enormous amount of new scientific data and knowledge on release/exposure pathways, (eco)toxicological effects, toxicokinetics and environmental fate, but has also resulted in key discoveries in regard to the interactions between nanomaterials and biological or ecological systems. These results, disseminated in over 160 research papers, have been immediately taken up by industries and regulators and led to developing safer and more sustainable nanotechnology products, some of which have been marketed worldwide.

Miguel A. Bañares, CSIC - Instituto de Catalisis; Madrid; SPAIN, NanoInformaTIX
Development and Implementation of a Sustainable Modelling Platform for nanoinformatics – (NanoInformaTIX): aims to create a comprehensive, sustainable, multi-scale modelling framework for exposure and (eco)- toxicity of Engineered Nanomaterials (ENM) to facilitate cost-effective risk assessment, less reliant on animal testing, and to support the design of safer materials and products. Our approach integrates several relevant EU/US databases with validated nanoinformatics models covering: Materials, Exposure, Physiologically-Based Pharmacokinetics (PBPK), Quantitative-Structure-Activity Relations (QSAR) and Systems Biology modelling and in vitro/in vivo extrapolation to support the prediction of biological effects and exposure of ENM at various stages of their life cycle and product development. NanoInformaTIX will address grouping and read-across for risk assessment and safer product design. NanoInformaTIX will use existing curated data from several completed EU/US projects and from peer-reviewed literature to develop, extend the models and will also consider emerging data from ongoing projects for model validation following the OECD validation principles. This will take the NanoInformaTIX models from TLR4 to TLR6. The NanoInformaTIX modelling framework will be a web-based platform with a user-friendly interface tailored to the needs of different stakeholders (industry, regulators, academia and the civil society). To obtain optimal confidence in the use of the NanoInformaTIX modelling and database framework, all models will be described clearly using agreed standards terminology and implemented on harmonized standard operating protocols based on Good Modelling/Software Design practices. Their applicability domain will be clearly documented and referenced for full transparency and detailed user guidance for each will be provided. NanoInformaTIX will achieve considerable impact by providing the much - needed validated accessible data management modelling framework to predict human and environmental risks, to support the design of sustainable ENM and products.

Iseult Lynch, University of Birmingham, United Kingdom, EU project NanoSolveIT
Innovative Nanoinformatics models and tools: towards a Solid, verified and Integrated Approach to Predictive (eco)Toxicology (NanoSolveIT) is coordinated by Antreas Afantitis, Novamechanics Ltd.
Effective prediction of NMs health and environmental risks requires utilisation of existing or newly generated data to develop innovative predictive hazard assessment models based on refined hazard-correlated endpoints. Achieving this requires establishment of a unified methodology for predicting the risks related to use of NMs, building on a sustainable multi-scale nanoinformatics framework, which links existing and emerging data and integrates, facilitates and advances the current state of the art in silico modelling and predictive toxicology approaches. The proposed NanoSolveIT framework foresees the development of a broad spectrum of diverse but interlinked advanced physics–based, OMICS-based and data-driven (AI, deep learning) models that work synergistically exchanging inputs and outputs. NanoSolveIT aspires to serve as the central nanoinformatics platform at the pan- European level and beyond, supporting development and design of safe NMs and NM-enabled products with the desired functional properties and safety profiles in a cost- and time efficient manner


that relies less on animal testing through utilisation of in silico approaches. Towards this end NanoSolveIT will design, develop and deliver the NanoSolveIT platform, fully integrated within RA and risk governance frameworks.

NanoSolveIT aspires to introduce a ground-breaking in silico Integrated Approach to Testing and Assessment (IATA) for the environmental health and safety of Nanomaterials (NM), implemented through a decision support system packaged as both a stand-alone open software and via a Cloud platform. NanoSolveIT will develop and deliver: (i) a reliable user friendly knowledge-based infrastructure for data hosting, sharing and exploitation, (ii) NM fingerprints, sets of nanodescriptors and properties that can be predictively linked to NM functionality, exposure and hazard, thereby supporting NM grouping, safe-by-design (SbD) and regulatory risk assessment (RA), (iii) innovative methodologies for NMs predictive (eco)toxicology underpinned by artificial intelligence (AI) and state-of-the-art in silico techniques, and, (iv) integration with currently developing multi-scale modelling, RA and governance frameworks developing in EU H2020 funded projects including caLIBRAte and from the Risk Governance projects. NanoSolveIT will deliver a validated, sustainable, multi-scale nanoinformatics IATA, tested and demonstrated at TLR6 via OECD-style case studies, to serve the needs of diverse stakeholders at each stage of the NMs value chain, for assessment of potential adverse effects of NM on human health and the environment. Central to the concept proposed by NanoSolveIT is the EU-US NanoInformatics roadmap, which identified 13 milestones for nanoinformatics to support NMs Risk Assessment, in the short, medium and long term: NanoSolveIT directly addresses all of the NanoInformatics Roadmap milestones, thus directly supporting its implementation and achievement.

Iseult Lynch, University of Birmingham, NanoCommons

The European Nanotechnology Community Informatics Platform: Bridging data and disciplinary gaps for industry and regulators (NanoCommons) is driven by the European nanosafety, nanomedicine and emerging materials research and regulatory communities search for a novel e-infrastructure providing a standardized, reproducible and interoperable way to access all available data, knowledge and analysis and modelling tools that have been adapted and verified as suitable for application to nanomaterials with their myriad challenges even beyond those of chemical risk assessment. The research community spans toxicology and especially predictive toxicology, systems and structural biology, bioinformatics and its subtopics toxicogenomics, cheminformatics, biophysics and computer science, as well as of the EU's chemical manufacturing industries, e.g. pharmaceutical companies, chemical and agrochemical industries and cosmetic industries, and the corresponding regulatory agencies, e.g. the European Medicines Agency (EMA), the European Chemicals Agency (ECHA), the Scientific Committee on Consumer Safety (SCCS), the European Food Safety Authority (EFSA) and the Organization for Economic Cooperation and Development (OECD).

NanoCommons is creating an openly accessible e-infrastructure to facilitate co-creation of a community framework around an agreed set of approaches for data generation, data management and nanoinformatics, and the infrastructure to support reproducible science, and in particular in silico workflows for nanomaterials and beyond, by:

(i) integration and federation of existing NMs characterisation and interaction mechanisms for knowledge, protocols and data (beyond simple toxicity), along with quality assurance criteria and underpinning ontologies,

(ii) compilation, development and expert support of computational tools for mechanistic and statistical modelling, read-across, grouping, safe-by-design and life cycle assessment to the broader user community, and benchmarking of their predictive power; and

(iii) provision of (remote) access to its KnowledgeBase, modelling toolbox and workflow optimisation and supporting expertise to facilitate commercialisation of nanotechnology-derived products.


Thus, the NanoCommons knowledge infrastructure will enable rapid progress beyond the current state of the art in modelling and nano-informatics by providing a stable and expandable bedrock upon which nanoinformatics research projects can build on. NanoCommons' vision is being implemented and delivered via a set of tightly interconnected Networking Activities, Joint Research Activities and Transnational Access to its tools and services. Together, these constitute a framework of knowledge and tools to support assessment of the hazard of NMs, their transformation products and their formulations, for use in advanced materials and product design (safe by design), regulatory assessment of NMs and modelling and education around new and emerging materials and their application as key enabling technologies.

Ideas for future collaboration:

During the discussion session future interaction points have been identified between EU and Mexican partners aimed at fostering knowledge exchange and discussions on the applicability of the GRACIOUS Framework to relevant legislation outside the EU.

In particular, Mexican partners have been invited to participate to upcoming training activities hosted by GRACIOUS and in collaboration with other Horizon2020 projects such as:

- 1st Interprofessional Education Nano Training School: Cutting Edge Approaches for the Risk Assessment and Management of Nano-(bio)materials: From the Lab to the Market: H2020 BIORIMA-GRACIOUS-NanoInformaTIX Training School (https://www.h2020gracious.eu/event/training_school2018), scheduled for 25-29 March 2019.
- A webinar giving an overview of EU Regulations with relevance for nanomaterials (https://www.h2020gracious.eu/event/webinar_a_change_is_reached_for_nanomaterials), taking place on 21 February 2019.
- Nanotox Conference 2021 hosted by Horizon2020 GRACIOUS, BIORIMA and PATROLS projects, to be held in April 2021 in Edinburgh, UK.
- Furthermore, interested Mexican partners were included in the GRACIOUS stakeholder database and their input in the GRACIOUS Framework refinement will be sought in the next rounds of stakeholder consultation activities.