NIA
Nanotechnology
Industries Association

Member Regulatory Priorities

May 28, 2020
1500 CEST

Claire Skentelbery
David Carlander

Webinar will start at 1500 CEST
Recorded for Member access
Ask questions and use chat function throughout

Agenda topics

- CARACAL activities
  - Nanomaterials and REACH – An ECHA Update
  - Member State, association and NGO comments
  - Next dates
- REACH nanoform updates:
  - ECHA/Cefic/Eurometaux/NIA webinar final Q&A responses
  - ECETOC app and eREACHnano website
- Carbon NanoTubes
  - EPA SNUR proposal
  - SIN list inclusion and potential response from NIA Input from Members
- Advanced Materials – the position of nano
  - Introduction to AM positioning in policy, standards and regulation
  - NIA contribution and activities for a Member position Input from Members
- EUON publications
  - Latest 'nanopinions' and publications – NIA response as EUON stakeholder Input from Members
- Green Deal chemicals strategy roadmap consultation Input from Members
- NIA's new H2020 projects – NanoHarmony, SusNanoFab
- NIA Regulatory Affairs position Action for members

All materials linked to NIA or originating site

CARACAL 'Nanomaterials and REACH – An ECHA Update'


EUROPEAN COMMISSION
ENVIRONMENT DIRECTORATE-GENERAL
Circular Economy and Green Growth
Sustainable Chemicals

ECHA
EUROPEAN CHEMICALS AGENCY

DIRECTORATE-GENERAL INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMES
Chemicals and Consumer Industries
REACH
Chemicals

Brussels, 17/03/2020
Doc. CA/20/2020

34th Meeting of Competent Authorities for REACH and CLP

31 March – 1 April 2020

Concerns: Nanomaterials and REACH – An ECHA Update

- March 31 meeting cancelled with exception of nanomaterials topic
- ECHA publication from March 17
- 86 unique submissions for 34 substances covering nanomaterials received by Jan 1, 19 subsequent
- Lower than expected from market reviews
  - *Wide divergence in numbers predicted (200-2000)*
- 45% failed completeness
  - *NIA point – wide variety of reasons, often basic administrative*
  - *Justification of sets*
  - *Missing lead dossier*
- Challenges beyond technical on confidentiality issues of novel nanoforms within a consortium
- Actions to support implementation
  - *Two hosted webinars (NIA active in both)*
  - *Temporary action to enable completion of Annex VII and VIII where test methods not available for required end points*
  - *Improved applicant support*
  - *Guidelines update (not before Q2 2021)*
- ECHA questions for discussion

All CARACAL documents in public domain through CIRCABC – need profile but free to access

Responses to ECHA: MS, NGO & associations

DE: Are registrants considered experienced? What is learned from the completed dossiers? Train the trainers requested for national agencies, it may not be updates but registrations that are missing, perhaps lack of awareness of end point requirements for nanoforms in IX and X, practical examples are urgently needed, testing facilities are a bottleneck

FR: Categories with nanoforms between R-nano and REACH considered similar at 300, late update of IUCLID was not helpful, limited national enquiries – recommends more ECHA interaction with associations, suggests that ECHA could write directly to dossier holders where nanoforms are foreseen

European Environmental Bureau: « unacceptable » figures on dossier updates, potential obligation for EU-wide registry, enforcement to remove materials from incomplete dossiers from market, is lack of dossiers due to non-compliance?, nanoforms should be registered individually if a set cannot be justified, make use of existing tools such as REACH Dossier Improvement Action Plan to improve compliance

Cefic/Eurometaux: Time and flexibility for completion, waive data generation until standards and tests are defined, further work with industry for SIEFs or consortia, constant guidance update and regular webinars etc., focus enforcement now to companies unwilling to update.

Other MS provided comments – selection here reflects message

Questions from ECHA in report

1. Did we overestimate the number of substances having nanoforms on the internal market? We invite Member States and Stakeholders to share their views on the potential reasons why.

2. To what extent is the current situation a reflection of difficulties faced by registrants in meeting the new information requirements? What additional action would be needed to mitigate such challenges?

3. Or, is the current situation due to a lack of awareness by registrants? If so, what initiatives seem appropriate to further increase awareness, e.g. at national level?

Addressing ECHA questions

From Cefic/Eurometaux

1a. Low rates of dossier update

- *Confidentiality* e.g. surface treatments, requirement to opt out for specific NF where data required that was not relevant before and is not in place, not possible to build sets accurately in IUCLID
- *Missing IT tools* Late availability of IT tools (7 week installation and test)
- *Late guidance publication* with 1 month to compliance
- *Narrow interpretations* of nanoforms and sets in guidance (examples needed)
- *Novel situations* complexity of lead vs co-registrant data provision for NF
- *TCC failure* is high, suggesting lack of clarity and no way of validating before submission
- *CRO availability* is low

1b. Over-estimation of expected updates

- Differing calculation methods, incorrect entries in EUON plus inclusion of 75 materials not within REACH, divergence between REACH and national registries,

Addressing ECHA questions (2)

2. Extent of current situation a reflection of difficulties for registrants in meeting new requirements?

- Answer 1a and general comments for substantial difficulties
- Consider industry alternatives for grouping and justification
- Review guidance as more experience gained
- Example/case study dossier updates
- Methods must be widely available for companies

3. Lack of awareness and suitable initiatives

- Not lack of deadline awareness for producers – complexity, NF identification more the challenge
- Perhaps lack of awareness downstream users transitioning into producers following NF modifications
- Regular webinars with ECHA and continuous follow up is recommended

Provisional upcoming CARACAL dates

23-24 June and/or 7–8 July 2020 21-22 September 2020

14-15 December 2020

ECHA Nanoform support

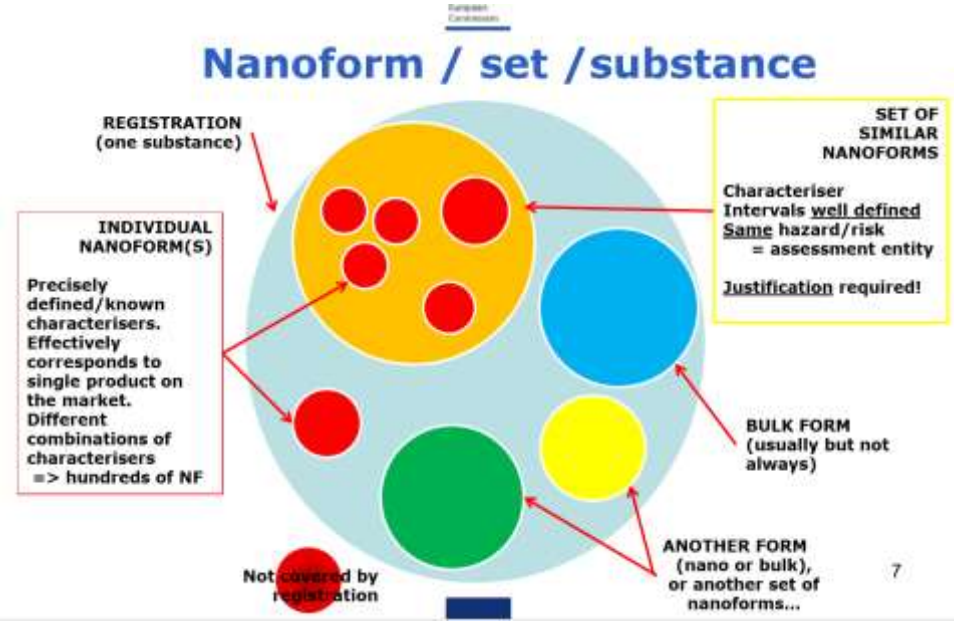
ECHA participated in 2 webinars on NF dossier updates:

- 24 February "Registering nanoforms: practical advice“: Short recommendations, relevant info, appropriate methods – short Q&A

Recording, slides and Q&A HERE.

- 30 March (with Cefic, NIA and Eurometaux): Reflections from EC, case study from Solvay, questions. No official Q&A summary released yet

Slides from ECHA and Solvay HERE.



ECHA Q&As: Summary to Members

If a substance has wide size distribution as it is produced and put on the market, how to deal with narrow size distributions as expected by ECHA?	Could ECHA give more guidance on how to determine an appropriate ‘set of similar nanoforms’, and the evidence that would be considered good enough to justify it? Advice and examples on data types and parameters to justify a ‘set of similar nanoforms” would be welcome.
We are facing massive technical limitations for numerous endpoints already for substance characterisation which cannot be ignored plus e.g. TEM capacity is just not enough there. How to proof the limited capacity? We still struggle with the characterisation for a lot of substances. If there are no meaningful data, what should be submitted? Just put something into IULCLID to fulfil the formalism?	ECHA will publish the Guidance on HH not before Q2 2021 and the Guidance on ENV not before Q4 2021. The documents provided in the EUON page are not sufficient to guide registrants, specially those with less resources to understand or choose what will be more appropriate to test nanoforms. Can in those cases ECHA give ad hoc guidance?
ECHA will publish the Guidance on HH not before Q2 2021 and the Guidance on ENV not before Q4 2021. The documents provided in the EUON page are not sufficient to guide registrants, specially those with less resources to understand or choose what will be more appropriate to test nanoforms. Can in those cases ECHA give ad hoc guidance?	Slide 8 says Nanoforms in a set should have "same" toxicity. Our understandings from previous webinars by ECHA has been that justification should be provided as to why nanoforms of a set can have their (eco)toxicity be performed jointly. This is not the same as "same" (eco)toxicity. ECHA or the commission should clarify.
Does ECHA accept the inclusion of nanoforms within one set which contradict the limitations of set formation set out in the Guidance if the registrant can show that the hazard, exposure and risk assessments can be performed jointly?	How do you allocate a “set” to a substance that fulfills the criteria, but was not designed to be nano and has a primary particle size distribution in the 1 to 100 nm range (so every size present).
How does ECHA suggest to proceed if a co-registrant claims not to produce nanoforms but does not provide any proofs for this?	How to proceed if the LR only supports nanoforms and we have a bulk form? Can we assume the nanoform as the worst case and use the studies from the LR dossier as read-across or even directly?

Support tool for NF sets development - ECETOC

April 22: Joint NIA ECETOC webinar presented novel web platform, enabling individual registrants to submit data on intended nanoforms & platform proposes sets & justification, plus recommendations for additional data to support justification.

GOAL: SUPPORT THE FORMATION OF SETS OF NFS BY CREATING A TOOL THAT IMPLEMENTS THE ECHA GUIDANCE IN A TRANSPARENT AND EVIDENCE-BASED MANNER.

- Guide the registrant on when additional measurements are necessary to support a set of NFs.
- Establish generic numerical cutoffs for sufficient similarity for each property under consideration.
- The documentation by the tool shall serve as justification that the assessment can be performed jointly for a set.

Webinar recording and slides HERE
EUON Nanopinion HERE

DATA CONSIDERED TO SUBSTANTIATE SIMILARITY

Tier	Type of data	Relevance to sets of NFs	Relevance to gn PSLT
Tier 1 Column 1 data Basic data	Intrinsic material properties	Sufficient to define 'same set of NFs'	
Tier 2 Column 2 data (alternative methods)	Extrinsic properties / functionality	triggered if potentially within 'same set of NFs', but not sufficiently substantiated by above	Sufficient to define 'PSLT'
Tier 3 Column 3 data (animal testing)	In vivo data	*	triggered if potentially PSLT but not sufficiently substantiated by above

Current status and plans

- Test phase almost complete (easy to use for trained persons, straightforward)
- ECHA due to respond in next days
- Peer review publication under development
- Target autumn launch with training support

Support tool for nanomaterials – eREACH Nano

www.ereachnano.dk

- Formally mentioned in CARACAL responses
- NIA has previously provided feedback on industrial value
- Initiated through Nordic Council of Ministers
- Norway, Sweden, Finland and Denmark - N-Nano project
- Give guidance on how to deal with nanoforms (materials) for their REACH registration
- Teach and quiz for understanding of your position

Carbon Nanotubes – EPA TSCA

April 5: significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA). The SNURs require persons who intend to manufacture (defined by statute to include import) or process any of these chemical substances for an activity that is proposed as a significant new use by this rule to notify EPA at least 90 days before commencing that activity *Pre-manufacture Notice (PMN)*

Results of chronic aquatic toxicity testing, with natural organic matter (NOM) as the dispersant, may be potentially useful to characterize the environmental effects of the PMN substance.

The PMN states that the use of the PMN substance will be as a chemical intermediate to manufacture functionalized carbon nanotubes by oxidation with nitric acid; an additive in rubber polymers to improve mechanical/physical/chemical/ electrical properties; an additive in resin polymers to improve mechanical/ physical/chemical/electrical properties; an additive in metals to improve electrical/thermal properties; an additive in ceramics to improve mechanical/electrical/thermal properties; a semi-conductor, conductive, or resistive element in electronic circuitry and devices; an electric collector element or electrode in energy devices; a photoelectric or thermoelectric conversion elements in energy devices; a catalyst support element or catalytic electrode for use in energy devices; an additive for transparency and conductivity in electronic devices; and an electro- mechanical element

TSCA requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Use of a National Institute for Occupational Safety and Health (NIOSH)-certified respirator with an Assigned Protection Factor (APF) of at least 50 where there is a potential for inhalation exposure;
- Use of the PMN substance other than as allowed in the TSCA Order;
- Waste streams from manufacture, processing, and use must be disposed of only by incineration or landfill;
- No predictable or purposeful release of a manufacturing, processing, or use stream associated with any use of the PMN substance into the waters of the United States.

Comments close June 3: CLICK HERE for EPA source and comments
NIA happy to submit comment on behalf of Members

Nanomaterials on the SIN list: CNTs open the door

November 2019: ChemSec « *carbon nanotubes are Carcinogenic, Persistent and probably Toxic to Reproduction"*

Criticism of rationale for inclusion, with only intrinsic properties considered

- *Chemical Watch article*
- *Nature Nanotechnology correspondance*

Carbon nanotubes added to the SIN List as a nanomaterial of Very High Concern

Long term risk for nanomaterials:

- Broad inclusion of a nanomaterial despite significant diversity in physchem properties – wide target impact
- Dis-incentivises safe by design for nanomaterials and products

Discussion with NIA Members

Position Paper?

- Aim: Communicate diversity of hazard within a substance and forms
- In line with REACH amendments, focus on nanoforms rather than generic sub-set of a substance
- Identify nanoforms characteristics associated with higher hazard and possibly where risk likely to be greater in use
- Safe by Design to address diversity of hazard inherent to nanform diversity
- CNT is a good example and it extends to all nanomaterials in future

Advanced Materials – the position of nano

- ‘Advanced materials’ increasing focus of policy and potential regulation – strategic term
- Nano is not automatically advanced:
  - Complex structures/coatings
  - Hybrid materials
- When does ‘Advanced’ become ‘old school’?

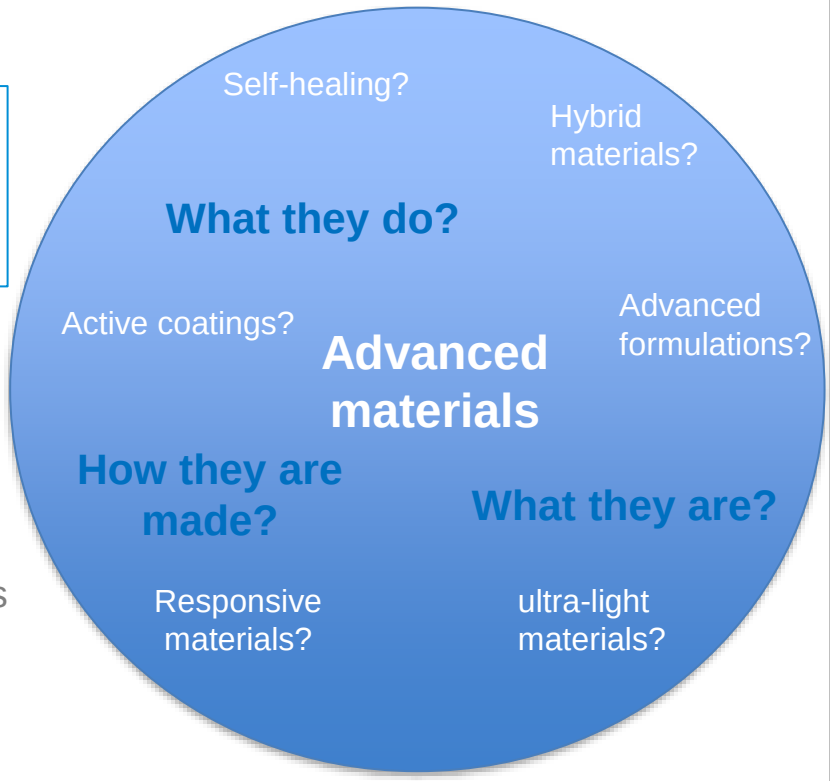
Important for nano and NIA

Guide robust policy and terminology development for AMs
Ensure nanomaterials are correctly positioned
Guide Horizon Europe focus for nano

German government hosted NanoDialogue May 2019

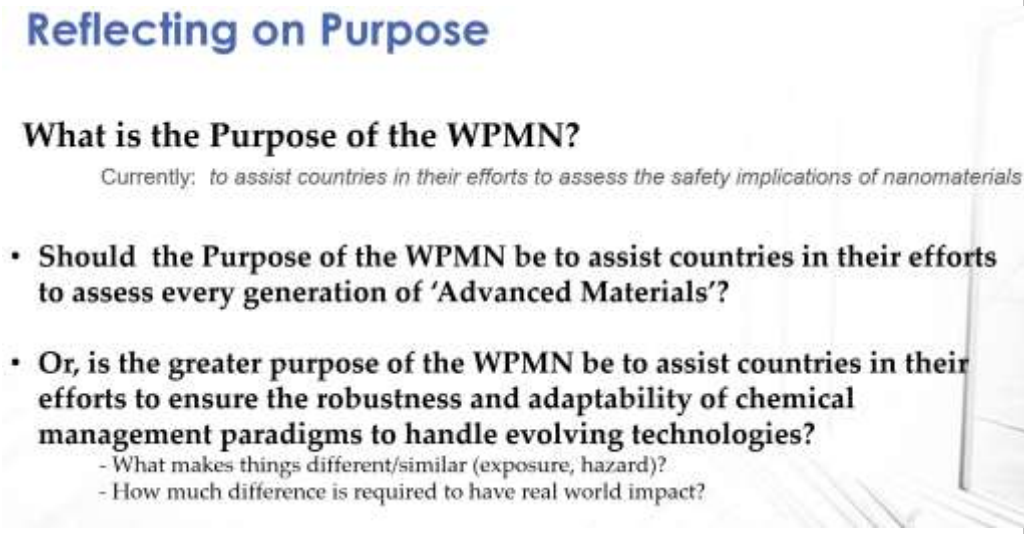
(3D-printing, High-performance-polymers in lightweight construction, Organic electronics, Active materials in food packaging, Functional Textiles)

- Complexity through variety of combinations
- Need to understand and manage within existing regulations
- Definitions need to be clear – size, substance, volume, application….
- Position for recycling (circular economy and green deal)
- What is relevant for legislation



OECD Working Party for Manufactured Nanomaterials (WPMN)

- December meeting – Paris
- Define ‘normal’ in order to understand ‘advanced’
- Identify differentiating features
- Avoid perception issues
- Not always linked to risk
- Ongoing progression vs fixed material definition



NIA contribution

OECD Online Conferences on Advanced Materials
June 16 and September 15th - online

Supported by the German Environment Agency (UBA) and the German Ministry of the Environment, Nature Protection and Nuclear Safety (BMU)

Attendees: Nanotechnology expert group

- June meeting objective: Discuss possibilities to structure the field and to identify types of advanced materials as of relevance with regard to chemical safety.


Advanced materials - online conferences
Identification of action needs on chemical safety
Approaches for structuring the field, prioritisation and assessment

Invitation

10:45 **Overview of advanced materials**

Advanced materials options to cluster and approach suggested by the project, overview of the different types of advanced materials - Results from the research activities
Bernd Giese, Institute of Safety/Security and Risk Sciences (ISR)

Advanced Materials - an industrial perspective from nanomaterials
Claire Skentelbery, Nanotechnology Industries Association (NIA)

- September meeting objective: Focus on chemical safety challenges, including to hazard and exposure assessment approaches and tools, that advanced materials in general or particular types of advanced materials may pose.

The learnings and results of the two online conferences will be an input to the **3rd Thematic Conference (5th and 6th of May, 2021 in Berlin)** focusing on recommendations on chemical safety of advanced materials.

NIA Member contribution

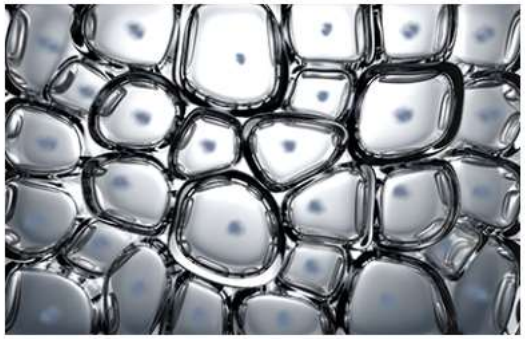
Requested NIA contribution for June 16:

- How does industry categorise advanced materials?
- How do they use terms and/or what are principles and approaches to deal with (groups of) advanced materials?
- How do they characterise their materials?

Short survey for NIA Members. Proposed questions – review today, feedback and finalise for Monday.

- Is the term ‘advanced material’ used within your strategy, positioning or branding?
- What is your understanding of ‘advanced materials’?
- Do you consider your company to work with advanced materials?
- If yes, what characteristics/performance makes them ‘advanced’
- Do ‘advanced’ materials introduce any new safety or hazard concerns that need to be understood
- Are current regulations suited to manage ‘advanced’ materials, or will they need to be updated to include new provisions for ‘advanced’ materials e.g. hybrid?

EU Observatory for Nanomaterials (EUON)



Are nanomaterials getting under your skin?

20 May 2020

A recent study has analysed existing research on whether nanomaterials used in consumer products and at workplaces are absorbed through the skin. The study calls for more comparable and high-quality data through well-organised and structured research programmes that follow OECD test guidelines.

6 April 2020

Female fertility data lacking for nanomaterials

A study commissioned by the EU Observatory for Nanomaterials found a lack of data on female fertility. Studies on reproductive performance were also scarce. The study calls for more coordinated tests and follow up of outcomes when concerns are identified.

07 April 2020

Carbon Nanotubes – First nanomaterial of high concern on the SIN List

Anna Lennquist, Senior Toxicologist, International Chemical Secretariat (ChemSec)

NIA as EUON stakeholder:

- Hit and miss on quality control
- Ambiguous on message allowed to be implied e.g. silver ions and skin penetration – given the target audience os not expert
- Comments from Members?

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COMMUNICATION

Chemicals – strategy for sustainability (toxic-free EU environment)

Roadmap for implementing strategy to reduce risks from production and use of chemicals

FULL DETAILS

- Three page document
- Problem at which initiative addressed
- Basis for EU intervention
- What it will achieve and how
- Better regulation
- Evidence base and data collection
- Citizen consultation

Feedback (7)

26 May 2020 | Company/business organisation

Green Chemical Design Limited (United Kingdom)

I write as a chemist with many years of EU regulatory experience, working for industry and regulatory agencies. I also have a strong interest in research and development (R&D) that leads to new chemicals. The Roadmap sets out clearly some highly desirable objectives, many of which have been stated and agreed to by all stakeholders in the last decades. There have even been studies about why there has been insufficient movement on the green...

28 May 2020 | Public authority

UK House of Commons Environmental Audit Committee (United Kingdom)

The House of Commons Environmental Audit Committee undertook an inquiry in 2019 into "Toxic chemicals in Everyday Life" and published a Report including conclusions and a series of recommendations to the UK Government. The Committee's conclusions on product safety may be of particular interest (see chapter 5 as well as chapter 3 which covers furniture and furnishings specifically). All of the publications relating to the inquiry, including...

ROADMAP	
Roadmaps aim to inform citizens and stakeholders about the Commission's work in order to allow them to provide feedback and to participate effectively in future consultation activities. Citizens and stakeholders are in particular invited to provide views on the Commission's understanding of the problem and possible solutions and to make available any relevant information that they may have.	
TITLE OF THE INITIATIVE	Chemicals strategy for sustainability
LEAD DG – RESPONSIBLE UNIT	DG ENV- B2 Sustainable Chemicals
LIKELY TYPE OF INITIATIVE	Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions
INDICATIVE PLANNING	Q3 2020
ADDITIONAL INFORMATION	-
This Roadmap is provided for information purposes only and its content might change. It does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content. All elements of the initiative described by the Roadmap, including its timing, are subject to change.	

NIA action: Consultation response

Not high impact policy doc

However…….NIA and nano should be visible and engaged

Propose:

- NIA drafts a statement in response
- Member feedback invited
- Final statement developed and submitted
- Deadline June 20

NIA new projects

SusNanoFab (susnanofab.eu)

Integrated EU strategy, services and International coordination activities for the promotion of competitive and sustainable nanofabrication industry

- Analysis of nanofabrication ecosystem
- Roadmap to identify:
  - High priority future common research,
  - Standardisation gaps and actions
  - Strategic cooperation actions
- Development of the SUSNANOFAB digital platform
  - Data exchange with other pan-European initiatives
- Repository of best practices
- Identification of:
  - Knowledge & skills gaps and training needs of nanofabrication stakeholders
  - Technology and service needs and planning and deploying brokerage services

NanoHarmony (nanoharmony.eu)

Towards harmonised test methods for nanomaterials

NanoHarmony will focus on OECD TGs and GDs for eight nanomaterial test endpoints prioritized with ECHA, NMEG, Industry and the Malta Initiative and considering OECD WPMN priority recommendations.

- Bioaccumulation testing in fish
- *In vivo* toxicokinetic studies
- Concentrations in biological samples
- Solubility and dissolution rates in water and biologically-relevant fluids
- Surface chemistry and coatings
- Dustiness testing
- Intestinal fate from oral ingestion
- Short term toxicity studies

SOP development, refinement & inter-lab testing

Expert workshop – November 3-5
Become a stakeholder to contribute
Welcome webinar July 7
NIA will communicate all opportunities

NIA Reguatory Affairs position

Essential experience:
- REACH
- Wider regulatory background in chemistry/toxicology
- Knowledge of key actors
- Chemicals policy development knowledge

Core role:
- Proactive scouting and review of nano-relevant global regulatory development across all sectors
- Prioritisation of updates and actions for NIA Members
- Analysis and explanation of regulations and changes
- Participation within expert groups and committees
- Responding to Member regulatory concerns and priorities and outreach to the wider industrial community
- Maintenance of NIA documentation and reporting of regulatory priorities and development

Team role:
- Participation in EU projects
- News creation for website and social media
- Networking across sectors
- Public speaking for NIA
- Part of NIA Membership expansion

General:
- Half time, with potential for full time
- Preferred in Brussels but remote position possible
- Flexible working structure and times
- Part of small but dynamic team across 3 countries
- Employee or freelance possible
- Target start date – early autumn
- Must be able to freely work and travel within the EU

That’s all folks!

Thank you for participation and inputs

Recording and slides available shortly

Also in website Member area

Formal summary of items for Member response

Thank you again to David