

Workshop Report

Stakeholder Dialogue meeting European Union Observatory for Nanomaterials

9 March 2018

European Commission DG GROW, Brussels

1 Summary

ECHA arranges an annual workshop for its stakeholders to discuss current and future development of the European Union Observatory for Nanomaterials (EUON).

This year, the event focussed on giving an update on the EUON since its launch in 2017 and giving the floor to stakeholders to share their views and expectations on the future development of the observatory.

2 Presentations and discussion

Welcome

Jukka Malm, ECHA

Jukka Malm introduced the day and welcomed participants to the second stakeholder workshop. He also gave a brief background of the observatory and the scope of the workshop. He explained that the observatory is constantly being developed with more studies, databases and eventually REACH data on nanomaterials if the REACH information requirements are updated.

He acknowledged that some of the stakeholders would have preferred a mandatory register instead of an observatory. He reminded that the workshop should focus on how to best work together to make EUON more useful within existing limitations.

EUON state of play

Abdel Sumrein, ECHA

Abdel Sumrein presented the current status of the observatory and how it will be developed in the coming months. He highlighted the published cross-link with the Commission's list of cosmetics and ECHA's dissemination database as an example of synergies between different legislations.

He highlighted the launch of two databases, the eNanoMapper and NanoData, planned for June and the possible future integration of national inventories on nanomaterials to the EUON. He also mentioned studies on pigments and on EU markets expected to be published in May 2018.

Discussion

Participants stressed that for the EUON to be transparent, it should not only highlight

scientific information that is already available but also fill data gaps; what is missing and still needs to be generated.

Integration with other information providers such as DANA, or US websites was also discussed. ECHA confirmed that currently a link exists on EUON to many external sources, however, the assessment of what data sources should be added as links will never be completed. A standing encouragement remains for all participants to highlight if they believe sources are missing.

Some participants expressed concern that the pigments study was requesting for a lot of information at a time when companies were struggling with other deadlines such as the REACH 2018 registration deadline. This prevented them from providing meaningful input on time. ECHA took note and agreed to consider other legal obligations and/or give longer commenting periods when conducting future studies.

EUON and data from EU research projects

Georgios Katalagarianakis, European Commission, RTD

Georgios Katalagarianakis explained EU nano safety research policy highlighting the Nano Safety Cluster. He stressed the importance for research to match with regulatory objectives.

His presentation highlighted the need for a harmonised data structure and model for nanomaterials to avoid a “data dump” and establish a reliable and searchable data storage. Some of the key questions posed in the presentation included what is the critical data needed and is this data available, finding common grounds or transparency about the models and tools being used for generating data, getting agreement on ontology and domains and what is the regulatory value of the generated data?

Discussion

Participants asked how the work in harmonising data and the work of the risk governance council would align with the observatory. Georgios explained that much of the output generated by the research is too complex but that the observatory could summarise it through web articles and link to various databases.

What EUON should deliver to regulators – Member State view

Monique Groenewold, RIVM

Monique Groenewold highlighted 5 regulatory needs from the Dutch perspective:

- **Transparency:** from surveillance and accountability (e.g. openness about the availability of safety information) of industry to consumers’ right-to-know and freedom of choice
- **Traceability:** enabling safety information flows along value chains, regulatory enforcement and adequate responses in case of calamities
- **Monitoring:** enabling priority setting in e.g. risk research, assessment, management and policy
- **Knowledge** of what is on the market
 - a complete overview of nanomaterials and nanoproducts
 - what nanomaterials and in what volumes
 - at which work floors
 - in which products
- **User-friendly and easily accessible** database(s) to understand risks (of use)

She stressed the following concerns in the EUON's contribution to more transparency in nanomaterials on the market: a broad range of sources and primarily no new data will be generated, many nanomaterials may remain under the radar as they are under REACH tonnage levels, exempted from national registries or under confidentiality claims. She expressed the need for more detail and ready-to-use information on the potential health impacts of nanomaterials for consumers.

In order to ensure that the EUON will fulfil its aims and purpose, she explained that it is key to continue urging the European Commission to provide necessary preconditions such as:

- An update of REACH Annexes
- A harmonised and unequivocal EU definition of nanomaterials
- (Financial) future commitment of the European Commission

Discussion

Participants asked why the Netherlands did not establish a national inventory of materials on the Dutch market. According to Monique, Dutch ministries always preferred a solution where this information would be collected at EU level as having several different registries may further complicate EU-level harmonisation.

Participants asked whether the REACH annex revision would answer some of the questions such as traceability for example. Monique explained that REACH tonnage levels will be too high to bring enough data on some of the lower volumes of nanoforms – it may help but some of the issues will remain.

French national register for nanomaterials: lessons learned

Damien De Geeter, French Ministry for an Ecological and Solidary Transition

Damien De Geeter explained the French national register for nanomaterials. The register was established in 2009 for better traceability of substances, improving information to consumers and workers and to provide more data for risk assessment.

He explained that the register is mandatory for producers and importers in France and from distributors to the last professional user, with an exemption for military uses. A declaration to the register needed to be made for above 100 grams of the substance, making it lower than the tonnage thresholds in REACH.

According to him, limited access to the data in the register was given only for French regulatory and research agencies due to confidentiality concerns. He explained that the data was being used for risk assessment and exposure on a national level.

He showed the most frequent uses for nanomaterials reported in their register with agriculture being at the top of the list.

Discussion

Participants asked how the register was used to communicate about nanomaterials to consumers. Damien explained that the Ministry publishes an annual report but no other actions were currently being undertaken.

Proposals on the regulatory governance of nanomaterials

Aida Ponce del Castillo, European Trade Union Institute (ETUI)

Aida Ponce del Castillo highlighted that the observatory was not the best option from the trade union perspective after discussions on EU level. She explained that it uses existing data and is purely based on voluntary contributions which are not enforceable.

According to her, ECHA should focus on getting sufficient quality information on nanomaterials through the REACH registration process with the need for transparent, scientific information on risks available in all endpoints of the registration dossier.

Her presentation outlined five key development proposals:

- Make information about nanomaterials public and visible
- Prioritise nanoforms
- Establish mandatory safety data sheets for nanoforms
- Include labelling of nanomaterials in the same way as for cosmetics
- Compile and harmonise data from national registries and disseminate it through EUON

Discussion

Participants discussed the use of information from national registries and other data sources on the EUON. Abdel Sumrein mentioned the ambition to compile data from publically available sources and connect them with REACH. Jukka Malm mentioned that the observatory also builds on information coming from other pieces of legislation, adding value by combining and explaining the synergies between them. He also stressed that to be able to use research data to comply with information requirements under REACH, the substance identity must be clear including the substance composition. Without this, it is challenging to translate the data into usable components in safety information and/or worker protection.

Aida Ponce del Castillo mentioned that the EUON could also be made more useful for workers by using data from national inventories.

Industry expectations for the EUON and how industry can contribute

Claire Skentelbery, Nanomaterials Industry Association (NiA)

Claire Skentelbery presented industry expectations for the EUON and how they can contribute. She highlighted that the constantly changing and undefined regulation of nanomaterials creates uncertainty among industry together with the lack of clear technologies to generate data for regulatory purposes. A further challenge are multiple regulatory agencies dealing with nanomaterials causing fragmented sources of information. According to her, the primary message is risk and creates caution for users and consumers, leading to an unpredictable market access for industry.

She stressed that EUON needs to provide high quality, scientific data that is curated and does not become a voice for lobbying.

She gave suggestions for further developing the EUON to meet industry needs including case studies on nanomaterials and nano-enabled product development, nano safety assessment tools linked to databases, links to standards for nanomaterials assessments

and a calendar of events where EUON is present as an umbrella for nanotechnology forums or topics.

Discussion

Discussions focussed on the current legal frameworks for submitting information about nanomaterials. Industry participants mentioned that companies were having issues under REACH with no straightforward answer on defining nanoforms. Jukka Malm explained that the revision of the REACH Annexes to include nanomaterials and the revision of OECD guidelines will bring more certainty.

Participants also highlighted a disparity of what is required for REACH versus national registers.

Discussions then focussed on whether the EUON would be in a position to publish case studies from specific interest groups and maintaining its reliability and transparency. Participants agreed that as long as the content was curated and presented with all benefits and concerns in a balanced way, this could be done through the ECHA Newsletter for example.

Participants discussed whether the current regulatory regimes are fit for regulating new generations of nanomaterials including self-replicating, intelligent materials. It was mentioned that a study by DG Environment on “advanced materials” could be promoted on the EUON.

Closing remarks

Jukka Malm concluded the meeting by thanking the participants for their active contribution to the discussions, the efforts made by the presenters to prepare slides and to DG Grow for providing the venue. He reminded that the observatory needs all partners and stakeholders to develop it further and called on all participants to act as multipliers and help ECHA to further promote it.

Annex 1 - Agenda

Stakeholder Dialogue meeting European Union Observatory for Nanomaterials

9 March 2018

European Commission DG GROW, Brussels

9.30	Welcome Jukka Malm, Deputy Executive Director, ECHA <i>EUON state of play</i> Abdel Sumrein, ECHA	
9.50	Stakeholder Reflections <i>EUON and data from EU research projects</i> Georgios Katalagarianakis, European Commission, RTD <i>What the EUON should deliver to regulators: Member State view</i> Monique Groenewold, RIVM <i>French national register for nanomaterials: lessons learned</i> Damien De Geeter, French Ministry for an Ecological and Solidary Transition Q&A	
11.20	Coffee break	
11.45	Stakeholder Reflections <i>Proposals on the regulatory governance of nanomaterials</i> Aida Ponce del Castillo, ETUI <i>Industry expectations for the EUON and how industry can contribute</i> Claire Skentelbery, NiA Q&A	
13.00	Closing remarks ECHA	
13.30	End of the meeting	

Annex 2– List of participants

	First name	Last name	Organisation
1	Peter	Baricic	European Commission - DG GROW
2	Katrine	Bom	Danish Environmental Protection Agency
3	Nathalie	Buijs	MedTech Europe
4	Jorge	Costa-David	European Commission - DG EMPL
5	Damien	De Geeter	Ministry for an Ecological and Solidary Transition
6	Olivier	de Matos	ECETOC
7	Maria Chiara	Detragiache	Orgalime
8	Jana	Drbohlavova	European Commission - DG RTD
9	Adam	Elwan	ECHA
10	Magdalena	Frydrych	Bureau for Chemical Substances
11	Irantzu	Garmendia	European Association of Chemical Distributors
12	Monique	Groenenwald	RIVM
13	Celia	Gryspeirt	IMA-Europe
14	Jean-Paul	Heine	Toyota
15	Jenny	Holmqvist	ECHA
16	Georgios	Katalagarianakis	European Commission - DG RTD
17	Andrej	Kobe	European Commission - DG Environment
18	Jukka	Malm	ECHA
19	Laia	Perez Simbor	ETRMA
20	Aida	Ponce Del Castillo	ETUI
21	Erica	Poot	European Commission - DG RTD
22	Laia	Quiros Pesudo	European Commission - JRC
23	Blanca	Serrano Ramon	Cefic
24	Claire	Skentelbery	Nanotechnology Industries Association
25	Christine	Spirlet	International Zinc Association
26	Abdel	Sumrein	ECHA
27	Marko	Susnik	WKÖ
28	Marie-Noelle	Valla	Total Lubrifiants
29	Edward	Xuereb	MCCAA

Annex 3 - Presentations

Click on the image to open the full presentation.





 Rijksinstituut voor Volksgezondheid
en Milieu
Ministerie van Volksgezondheid,
Welzijn en Sport

***What the EUON should
deliver to regulators***

Monique Groenewold
*Head of Knowledge & Information
Centre Risks of Nanotechnology*
RIVM

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European Union Observatory for Nanomaterials
9 March 2018

**The French national register for
nanomaterials:
lessons learned**

Damien De GEETER
**Ministry for an Ecological and
solidary transition**
**Directorate General for Risk
Prevention**
Chemical Products Unit
2018 March 09




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Stakeholder Dialogue
European Union Observatory for Nanomaterials EUON
March 9th, 2018

**Proposals on the regulatory
governance of nanomaterials**

Aida Ponce Del Castillo
Foresight Unit
European Trade Union Institute

etui.

NIA
Nanotechnology
Industries Association

**Industry expectations for EUON and how
industry can contribute**

9 March 2018

Claire Skentelbery
Director General
Nanotechnology Industries Association [aisbl](http://aisbl.org)

nanotechia.org

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