

Welcome!

Regulatory priorities and meet new Member VITO

The webinar will start at 15:00

**Please put yourselves on mute to improve the
sound quality during presentations**

**Ample time will be allowed for questions and
discussion!**

**You can use the chat function and directly ask
questions during the discussion periods**

Agenda

- 1500 – 1530: NIA - Regulatory priorities in July 2017
- 1530 – 1600: VITO, new NIA Member – research and nanotechnology expertise
- All slides shared with attendees following the webinar

NIA Regulatory Update July 2017

NIA Webinar

5 July 2017, 15:00 CEST

Claire Skentelbery

Director General

and

David Carlander

Director Regulatory Affairs

Topics for Regulatory priorities

- **Catalogue of nanomaterials in cosmetics**
- **ECHA**
 - Recent guidance publications
 - Board of Appeal:
 - TiO₂
 - SiO₂
 - TiO₂ under CLP
 - EU Observatory for Nanomaterials
- **SE Register**
- **Definition and REACH Annexes updates**

Catalogue of nanomaterials in cosmetics (1)

- Regulation (EC) N° 1223/2009 on Cosmetic Products
- **Since 2013:** pre-market notification of nanomaterials
*“nanomaterial” means an **insoluble or biopersistent and intentionally manufactured** material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm ‘*
Article 2.1 k)
- In 2014... **2017:**
‘ the Commission shall make available a catalogue of all nanomaterials used in cosmetic products placed on the market’
Article 16.10 a)
- The Catalogue was published on **15 June 2017**
 - NB: dated 31/12/2016!

Catalogue of nanomaterials in cosmetics (2)

Colorants

	Name ⁷	Category of cosmetics	Exposure	Rinse-off	Leave-on
1	ACID YELLOW 23 / CI 19140	Body or face paint, including carnival make-up	Dermal	x	
	ACID YELLOW 23 / CI 19140	Eye shadow	Dermal		x
	ACID YELLOW 23 / CI 19140	Lip stick	Dermal		x
	ACID YELLOW 23 / CI 19140	Nail varnish / Nail make-up	Dermal		x
2	BARIUM SULFATE / CI 77120	Nail care products	Dermal		x
	BARIUM SULFATE / CI 77120	Nail hardener	Dermal		x
	BARIUM SULFATE / CI 77120	Nail varnish / Nail make-up	Dermal		x
3	CARBON BLACK / CI 77266	Body or face paint, including carnival make-up	Dermal	x	x
	CARBON BLACK / CI 77266	Bath / shower products	Dermal	x	
	CARBON BLACK / CI 77266	Eye contour products	Dermal		x



- List of substances, by **type of use, category, exposure**, and differentiates **rinse-off** and **leave-on** substances
- **43 nanomaterials** (12 colorants, 6 UV-filters and 25 other functions)
- Less than 1% of the total cosmetic products notified contain nanomaterials
- Regular updates foreseen

**Discussion
Comments
Questions
Thoughts**

Recent ECHA updates of nano guidance and best practice, published 25th of May

- [Nano-specific Appendix to Chapter R.6 of the Guidance on Information Requirements and Chemical Safety Assessment \(QSARs and grouping of chemicals\)](#)
- [How to prepare registration dossiers that cover nanoforms - best practices](#)
Recommendations for distinguishing between different nanoforms of a substance, and how to report information on nanoforms consistently in the dossiers. Originally intended to be a guidance, but as a consequence of the Board of Appeal decision for TiO₂ (Case A-011-2014), this is now a best practice document.
- Appendices for nanomaterials to Chapter R.7a, R.7b and R.7c of the Guidance on IR&CSA (Endpoint specific guidance) provide nano-specific advice for registrants to meet the information requirements set out in Annexes VI-XI to the REACH Regulation.
 - [Appendix to Chapter R.7a for nanomaterials](#) - Recommendations for **physico-chemical endpoints**
 - [Appendix to Chapter R.7b for nanomaterials](#) - Recommendations for **ecotoxicological endpoints** for nanomaterials (**general advice**, fate and specific endpoints)
 - [Appendix to Chapter R.7c for nanomaterials](#) - Recommendations for **ecotoxicological endpoints** for nanomaterials (**specific advice** and specific endpoints)

ECHA Board of Appeal – Synthetic Amorphous Silica (SAS)

- Decisions published today 5 July 2017 (cases A-014-2015 and A-015-2015)
- Two appeals for the same ECHA decision requesting information on SAS
- Evaluation by the Netherlands Competent Authority
- Decision requested information on the physicochemical properties and uses of different types of SAS and surface treated SAS
- Requests were annulled as it was not clear how the information would be used to clarify the potential concerns which in any case had not been sufficiently demonstrated.
- One request in the contested decision – for information on the inhalation toxicity of one type of SAS, following repeat exposure - was upheld
 - 90 day inhalation toxicity study in rats to be provided within 2 years

ECHA Board of Appeal – TiO₂

- Decision adopted 2 March 2017 (case number A-011-2014)
- BoA decision follows REACH text!
- BoA annuls ECHA decision to ask for more information related to ‘substance identity’
 - **Note!** Decision is not related to ‘substance evaluation’!

 EUROPEAN CHEMICALS AGENCY BOARD OF APPEAL	A-011-2014	1 (14)
DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY		
2 March 2017		
<i>(Dossier evaluation – Compliance check – Substance identity – Nanomaterials – Nanoforms)</i>		
Case number	A-011-2014	
Language of the case	English	
Appellants	Huntsman P&A UK Limited, formerly Tioxide Europe Limited, United Kingdom Cinkarna Metalurško-kemična Industrija Celje d.d., Slovenia	

Outcome

- Registrant decide on substance ID
- ECHA can not request information outside REACH text specifications for Substance Identity

ECHA TiO₂ under Classification, Labelling and Packaging Regulation (CLP)

- TiO₂ assessment (not nano specific!) provided by ANSES (FR) in May 2016 for Harmonised Classification and Labelling proposal for TiO₂ as Carcinogen cat 1B (via the inhalation route)
- Discussion held in ECHA Risk Assessment Committee (RAC) in March and June 2017:

**RAC conclusion is Carcinogen category 2
(via the inhalation route)**

- ECHA RAC adoption in September by written procedure
- Final decision lies with EC



EU Observatory for Nanomaterials (1)



- Outcome of the 2014 *Study to Assess the Impact of Possible Legislation to Increase Transparency on Nanomaterials on the Market*
- Hosted and managed by ECHA
- First version launched on ECHA's 10th Anniversary (June 2017)



<https://euon.echa.europa.eu/>

EU Observatory for Nanomaterials (2)



- General information on nanomaterials including:
 - Uses, Safety, Regulation, International activities (at OECD, WHO, UN and SAICM), Research and innovation
- EU-ON will host more information in the future
- NIA is part of a stakeholder panel
 - Aim to complete several studies per year. Pigments in consumer products is 2017 target
 - Key databases being reviewed, eNanoMapper, NanoData
 - Links to national registries
 - Data from connected agencies (EMA, EFSA)
 - Info needed from NGOs, Member States, workers and consumer associations
 - Aims to be active at global level
 - Most important to be a neutral provider of data

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Swedish registration of nanomaterials in the Swedish Products Register

- Swedish plans for a nanomaterial register based on the existing provisions of the Swedish Products Register.
 - Chemical products
 - **No threshold, but more information required above 100kg**
 - Similar information to French r-nano.fr
 - Retrospective registration, 28 February for previous year
 - Exemptions
 - Turnover less than 5M SKR (540k €)
 - R&D less than 1000 kg
 - Entry into force: likely **2019**

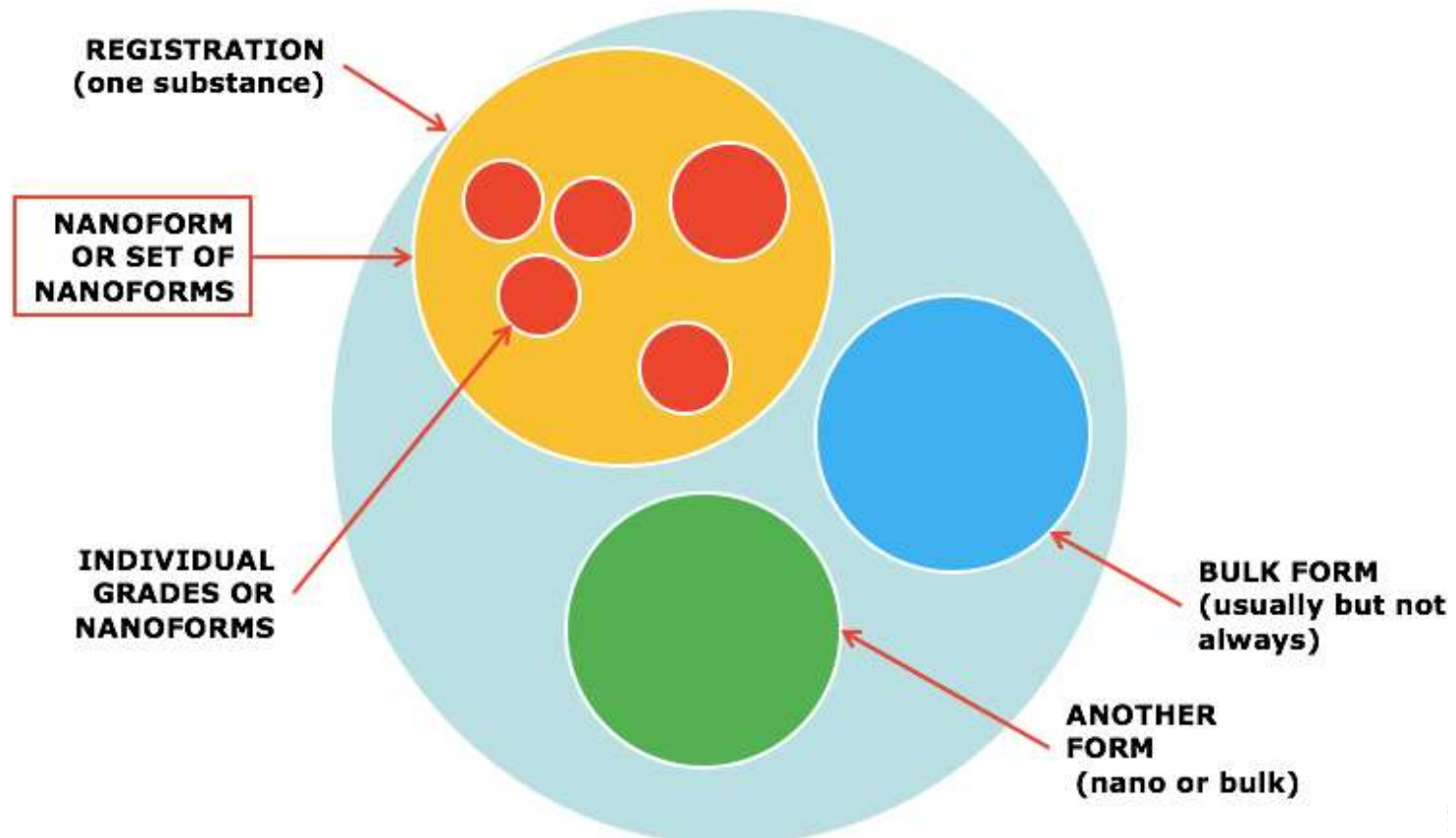


**Discussion
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Revision of Definition and REACH Annexes updates

- Definition: Public consultation (8 weeks) expected to be published shortly.... (EC timing...)
 - Once adopted by EC (end 2017?) uptake into other regulations expected (e.g. REACH, food, cosmetics...)
- EC Non-paper for modifications of REACH Annexes expected to be discussed again at upcoming REACH Committee Meeting in July.
 - However, still no official proposal from the EC

Nanoform concept for REACH Annexes



**Discussion
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NIA support to Members in 2017

- Monthly Regulatory Digest
- Quarterly review and discussion webinars
- Specific Member reporting on headline topics
- Joint activities with other associations - EUCAR
- New services for autumn:
 - Nanotechnology Innovation Council: Joint horizon scanning for high potential research
 - Global Regulatory Working Group: Joint efforts to address challenges of market access or operation across regulatory territories
- Annual symposium – save the date April 10, 2018, Brussels

***Thank you
from the NIA team***

Claire Skentelbery

Director General

claire.skentelbery@nanotechia.org

and

David Carlander

Director Regulatory Affairs

david.carlander@nanotechia.org