ChemCon The Americas 2023

International Conference on Chemical Control Legislation & Trade Aspects

13 – 17 March 2023
San Francisco, USA

Workshop

Global supply chain through the regulatory lens

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by HaskoningDHV Nederland B.V.
P.O. Box 151, 6500 AD Nijmegen, The Netherlands
Tel: +31 (0)88 348 88 88
E-mail: office@chemcon.net
Website: chemcon.net
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Handbook Manual

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Organiser's Message

Dear Ladies and Gentlemen,

San Francisco was the host city for our 30th ChemCon Conference, ChemCon The Americas 2023. Another successful conference in the global series of ChemCon Conferences, which took place from March 13th to 17th, 2023 in San Francisco, USA.

With thanks to the enthusiastic support of the distinguished speakers and partners of ChemCon The Americas 2023, we were able to set up a great event in this wonderful city. More than 180 experts from 23 countries representing over 110 companies, authorities and associations attended our conference sessions and exhibition. Together, they contributed to an inspiring exchange of experiences and discussions about regulatory affairs around the globe.

This hands-on workshop '*Global supply chain through the regulatory lens*' provided useful and in-depth information on EU's Sustainable product initiative, including a digital product passport and global Nanomaterials and RoHS regulations.

For this electronic handbook, we have slightly adapted some papers and presentations in order to provide an easily accessible overview of the content presented in the conference sessions.

We would like to express our gratitude to our partners and supporters - thank you for the joined efforts in making this conference a success. To all speakers and chairpersons - thank you for the wonderful job in preparing and presenting valuable information and insights. And of course, thanks to all the delegates who have participated in ChemCon The Americas 2023. The experiences and views shared by you, allow this platform to continue being the leading international regulatory affairs meeting point for the chemical sector.

If you want to learn more about upcoming events in the series of ChemCon Conferences, please visit our website: www.chemcon.net.

From October 23rd - 27th 2023, Vienna, Austria will be the host city for ChemCon Europe 2023. The next ChemCon Asia will probably take place in 2024 (Spring).

Thank you for your continued interest in ChemCon Conferences. We look forward to meeting you at one of our future conferences.

Yours faithfully,
Tjeerd Bokhout
Conference Director

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  Mark Herwig, Raytheon Technologies

Speakers and Chairman

ChemCon TV

- News Bulletins
- Interviews

Future Events

ChemCon TV

ChemConTV (CCTV) provides you with daily news bulletins and in-depth interviews on key topics, created during our conferences. You can view all bulletins and interviews on our **ChemCon YouTube channel**.

Monday News Bulletin >>

Tuesday News Bulletin >>

Wednesday News Bulletin >>

Thursday News Bulletin >>

Friday News Bulletin >>

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ChemCon TV

Interview on California and other state regulations >>

Interview on Environ. Justice and TSCA implementation >>

Interview on PFAS regulations, with a focus on the EU PFAS restriction proposal >>

Interview on on Safe and Sustainable by Design >>

Interview on data sharing opportunities >>

Interview on the impact of product risk assessment and liability >>

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Future Events

Sustainable Product Initiative including a Digital Product Passport

Christian Gründling, FCIO

EU Sustainable Product Initiative

Chemical Strategy & Sustainable Products

- Non-toxic material cycles

*"minimise the presence of **substances of concern** in products by introducing requirements, also as part of the Sustainable Product Policy Initiative, giving priority to those product categories that affect vulnerable populations as well as those with the highest potential for circularity, such as …"*

*"ensure availability of information on chemical content and safe use, by introducing **information requirements** in the context of the Sustainable Product Policy Initiative and **tracking the presence of substances of concern** through the life cycle of materials and products."*

Christian Gruendling

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EU Sustainable Product Initiative

Circular economy & Sustainable Products

- Sustainable product policy framework

*"In order to make products fit for a climate-neutral, resource-efficient and circular economy, reduce waste and ensure that the performance of front-runners in sustainability progressively becomes the norm, the Commission will propose a **sustainable product policy legislative initiative**."*

*"The core of this legislative initiative will be to widen the Ecodesign Directive beyond energy-related products so as to make the **Ecodesign framework** applicable to the broadest possible range of products and make it deliver on circularity"*

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EU Sustainable Product Initiative

Circular economy & Sustainable Products

"As part of this legislative initiative, and, where appropriate, through complementary legislative proposals, the Commission will consider establishing sustainability principles and other appropriate ways to regulate the following aspects:"

- improving product **durability, reusability, upgradability and reparability**, addressing the presence of **hazardous chemicals** in products, and increasing their **energy and resource efficiency**;
- increasing **recycled content in products**, while ensuring their performance and safety;
- enabling **remanufacturing** and **high-quality recycling**;
- reducing **carbon and environmental footprints**;
- restricting **single-use** and countering **premature obsolescence**;
- introducing a **ban on the destruction of unsold durable goods;**
- incentivising **product-as-a-service** or other models where **producers keep the ownership of the product** or the responsibility for its performance throughout its lifecycle;
- mobilising the potential of **digitalisation** of product information, including solutions such as **digital passports, tagging and watermarks;**
- rewarding products based on their **different sustainability performance**, including by linking high performance levels to incentives.

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EU Sustainable Product Initiative

Circular economy & Sustainable Products

- Priority sustainable products

"Priority will be given to addressing product groups identified in the context of the value chains featuring in this Action Plan, such as electronics, ICT and textiles but also furniture and high impact intermediary products such as steel, cement and chemicals."*

*Further product groups will be identified based on their environmental impact and circularity potential.

"The Commission will also increase the effectiveness of the current Ecodesign framework for energy-related products, including by swiftly adopting and implementing a new Ecodesign and Energy Labelling Working Plan 2020-2024 for individual product groups."

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EU Sustainable Product Initiative

Sustainable Product Initiative: several proposals

"Making sustainable products the norm"

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EU Sustainable Product Initiative

Ecodesign for Sustainable Products Regulation - ESPR

"It's time to end the model of 'take, make, break, and throw away' that is so harmful to our planet, our health and our economy. Today's proposals will ensure that only the most sustainable products are sold in Europe. They allow consumers to save energy, repair and not replace broken products , and make smart environmental choices when they are shopping for new ones."

– **Frans Timmermans**; Executive Vice President

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EU Sustainable Product Initiative

ESPR – Buidling on existing ecodesign approach

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EU Sustainable Product Initiative

ESPR – structure of framework legislation

I. General provisions
II. Ecodesign requirements
III. Digital product passport
IV. Labels
V. Prioritisation, planning and consultation
VI. Destruction of unsold consumer products
VII. Obligations of economic operators
VIII. Conformity of products
IX. Notification of conformity assessment bodies
X. Incentives
XI. Market surveillance
XII. Safeguard procedures
XIII. Delegated powers and committee procedure
XIV. Final provisions

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EU Sustainable Product Initiative

ESPR – general provisions

- Scope
  " any physical good that is placed on the market or put into service, including components and intermediate products"
- Exemptions
  - food & feed
  - (veterinary) medical products
  - living plants, animals and micro-organisms
  - products of human origin;
  - products of plants and animals
    relating directly to their future reproduction

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EU Sustainable Product Initiative

ESPR – ecodesign requirements for products

- durability,
- reliability;
- reusability;
- upgradability;
- reparability;
- possibility of maintenance and refurbishment;
- presence of substances of concern;
- energy use or energy efficiency;
- resource use or resource efficiency;
- recycled content;
- possibility of remanufacturing and recycling;
- possibility of recovery of materials;
- environmental impacts, including carbon and environmental footprint;
- expected generation of waste materials

Additionally: performance and information requirements

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EU Sustainable Product Initiative

ESPR – substances of concern

- SVHC
  - CMR Cat. 1; PBT & vPvB
  - ED Cat. 1, PMT & vPvM
  - equivalent level of concern
- GRA (+ SVHC)
  - Resp. Sens.; STOT RE 1;
  - hazardous to the ozone layer
- SoC (+ GRA + SVHC)
  - CMR Cat. 2; ED Cat. 2; Skin Sens.; STOT SE, STOT RE 2
  - Chronic Aqu. Tox.
- Substances which inhibit circularity

mainly for information

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EU Sustainable Product Initiative

ESPR – information requirements

- tracking of all substances of concern throughout the life cycle of products
  - the name of the substances of concern present in the product;
  - the location of the substances of concern within the product;
  - the concentration, maximum concentration or concentration range of the substances of concern
    - at the level of the product, its main components, or spare parts
  - relevant instructions for the safe use of the product;
  - information relevant for disassembly

Information via digital product passport;
specific requirements and exemptions in specific product legislation possible

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EU Sustainable Product Initiative

ESPR – Digital Product Passport (DPP)

- Information flow currently not suitable to deliver

- Objectives
  - ensure that actors along the value chain, in particular consumers, economic operators and competent national authorities, can access product information relevant to them;
  - facilitate the verification of product compliance by competent national authorities;
  - improve traceability of products along the value chain

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EU Sustainable Product Initiative

DPP – general requirements

- Connected through a data carrier to a unique product identifier
  - data carrier physically present on the product, its packaging or on documentation accompanying the product
  - data carrier and the unique product identifier shall comply with standard ('ISO/IEC') 15459:2015
- Information based on open standards, developed with an interoperable format and shall be machine-readable, structured, and searchable
  - refer to the product model, batch, or item

Access to information based on essential requirements specified in norms & in specific product legislation

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EU Sustainable Product Initiative

DPP – structure and template

Possible Track & Trace identifiers

- Economic operator's name, registered trade name
- GTINumber or equivalent
- TARIC code
- Global location number
- Authorised representative
- Reference of the back-up data repository
- …

Example of potential attributes

- Description of the material, component, or product
- Recycled content
- Substances of concern
- Environmental footprint profile
- Classes of performance
- Technical parameters
- Manuals
- Labels
- …

Different for product groups

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EU Sustainable Product Initiative

DPP – decentalised system with central registry

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EU Sustainable Product Initiative

ESPR – development of specific product legislation

- Prioritisation based on
  - potential for improvement (no legislation yet; disparity of performance)
  - sales and trade volumes
  - environmental impacts, energy use and waste generation
- Product groups in focus (public consultation)
  - End-use products: Textiles and Footwear; Furniture; Ceramic Products; Tyres; Detergents; Bed Mattresses; Lubricants; Paints and Varnishes; Cosmetic Products; Toys; Fishing Nets and Gears; Absorbent Hygiene Products;
  - Intermediary products: Iron and Steel; Non-Ferrous Metals; Aluminium; Chemicals; Plastic and Polymers; Paper, Pulp Paper and Boards; Glass;
  - Horizontal measures: Durability; Recyclability; Post-Consumer Recycled Content

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EU Sustainable Product Initiative

ESPR – development of specific product legislation

Figure III. The 12 shortlisted end-use products.

Figure IV. The 7 shortlisted intermediate products.

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EU Sustainable Product Initiative

ESPR – development of specific product legislation

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EU Sustainable Product Initiative

Existing ecodesign regime – Workplan 2022 - 2024

Existing product rule reviews

Reviewing Heating/cooling product requirements Rescaling energy efficiency label

Estimated impact: 170 TWh/year in 2030

Introducing new rules

Currently unregulated products: smartphones, solar PV systems/panels, printers & scanners

New products to be studied

i.e. Low temperature radiators, electric vehicle chargers, universal external power supplies

Estimated impact: 70 TWh/year in 2030

Circularity requirements - assessment

E.g. reparability scoring systems, recycled content, critical raw materials, durability, firmware, software

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EU Sustainable Product Initiative

Summary

- Strong push for sustainable products in European Union
  - based on Circular Economy Action Plan (and Chemical Strategy for Sustainability)
- New framework in the final legislative process
  - prioritisation for specific product groups underway
- Digital Product passport - new communication tool through the whole life cycle of specific products
  - covering circularity and sustainability aspects

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EU Sustainable Product Initiative

Thank you …

… for your attention!

Christian Gründling ◆ T: +43 5 90900 3348 ◆
E: gruendling@fcio.at

Christian Gruendling

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RoHS Regulations Around the Globe

Meglena Mihova
EPPA

RoHS regulations around the globe

Meglena Mihova

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RoHS regulations around the globe

Current considerations for restriction

- **TBBP-A: restriction proposal under RoHS expected 2023-24**
  - *No drop-in replacement available*
  - *Cost of substitution: premature re-design, risk of forced market withdrawal*
  - *Challenges on screening and analytical methods*
- **MCCP*: restriction proposal submitted under REACH**
  - *Challenges on screening and analytical methods*
  - *No known alternatives can perform all functions of MCCPs*
- **ATO:**
  - *Suitability of alternatives with larger negative environmental impact*

Meglena Mihova

**Medium-chain chlorinated paraffins (MCCP) and other substances that contain chloroalkanes with carbon chain lengths within the range from C14 to C17*

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RoHS regulations around the globe

Restriction of MCCP under REACH

- MCCPs used as **plasticiser** & **flame retardant** in large number of consumer & industrial applications
- **No known suitable alternative exists** which can perform all functions in industrial EEE:
  - **No direct substitution** that can be consistently applied
  - **Different solutions** will need to be **specifically tailored** in each use
  - **Extended time needed** to determine if the **reliability of substitutes** is assured
  - **Product safety third-party certifications of alternatives**
- EEE producers will be **forced to redesign, test and requalify the entire portfolio**.
- **Severe negative impact** anticipated on the **product availability and innovation**.

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RoHS regulations around the globe

MCCP restriction timeline

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RoHS regulations around the globe

Lead prioritised for a ban under REACH Annex XIV

- Lead has a **critical function** in electronics, especially in professional & industrial EEE;
- Exemptions granted under RoHS, but substantial **reduction of quantities**;
- The risk of workers or environmental exposure is properly managed at all life cycle stages;
- The largest use is in aluminium, steel and copper alloys for which there is **no suitable alternatives**.
- **Feb 2023 ECHA Member State Committee: inclusion of lead in Annex XIV with LAD of 36 months & recommends exemption of uses covered by RoHS (**art 58 (2))

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RoHS regulations around the globe

RoHS exemptions: key challenges & concerns

- **Lack of predictability on the timing of submission of exemption requests**
- Consequences **of early exemption renewal requests** not fully considered
- Very short renewal periods – invitation to re- submit improved application
- Keep **consistency of exemption structure:** wording, numbering, timelines
- Lack of transparency, data gathering & proper analysis: **mercury exemptions**
- Challenges related to the transposition of the Delegated Directives in the EU Member States

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RoHS regulations around the globe

Pack	Annex	Requests for renewal of exemptions	Status	Link
21	IV	1; 1(a); 1(b); 1(c); 2; 3; 5; 11; 13; 14; 15; 17; 26; 29; 31(a); 39	Evaluation report published by Biois August 2022	link
22	III	6(a); 6(a)-I; 6(b); 6(b)-I; 6(b)-II; 6(c); 7(a); 7(c)-I; 7(c)-II	Evaluation report published by Oeko-Institut February 2022	link
23	III	4(f); 8(b); 8(b)-I; 9; 9(a)-II; 13(a); 13(b); 13(b)-I; 13(b)-II; 13(b)-III; 15; 15(a);	Evaluation report published by Biois December 2022	link
24	III	5(b); 18(b); 18(b)-I; 24; 29; 32; 34	Evaluation report published by Oeko-Institut February 2022	link
	IV	34		
25	IV	New exemption regarding mercury New exemption regarding DEHP (request withdrawn by applicant)	Evaluation report published by Oeko-Institut July 2022	link
26	IV	New exemption regarding lead	Evaluation report published by Oeko-Institut September 2022	link

RoHS regulations around the globe

RoHS revision: possible REACH – RoHS model

- **RoHS substance restrictions:**

COM/MS identify substances – candidates for RoHS restriction → RAC & SEAC evaluation → COM decision on new RoHS restriction (delegated act)

- **RoHS exemption process:**

Exemption request to COM → RAC & SEAC evaluation → COM decision to grant or renew exemption (delegated act)

Advantages:

- Benefit from SEAC experience on SEA
- Timeline is generally respected
- Use of adequate data generated under REACH
- In line with OSOA principle

Challenges:

- Less familiar with RoHS and waste issues
- Can ECHA manage increasing workload?

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RoHS regulations around the globe

Introducing "Essential use" concept in RoHS

Allow use of hazardous substances when the use is considered essential!

1. **The risk is controlled**
   - Cat 8 & Cat 9 professional & industrial use
2. **Lack of suitable alternatives**
   - Specific technical performance, high reliability, long product lifetime
3. **Necessary for health, safety or critical for functioning of society**
   - Critical function of the substance in the application + uses in critical sectors (Security, pharma, food etc.)

Consideration for cat 8 and 9 industrial derogation based on the "essential use" concept!

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RoHS regulations around the globe

Key recommendations for the revision of RoHS

- General support of the RoHS model, RoHS shall not be merged with other legislation
- Transform RoHS into Regulation to ensure better clarity of scope and implementation timing
- Improvement of RoHS substance identification and exemption processes is needed
- Using ECHA's resources and experience would optimise the process in a cost-effective way
- Consider implementing "essential use concept" in RoHS
- Given the policy context of the Circular Economy and the cost-effectiveness ratio for Cat. 8 & 9 industrial, a thorough analysis of the relevance of adding Cat. 8 & 9 industrial in the scope of future restrictions and introduction of simplified exemption procedure

Meglena Mihova

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RoHS regulations around the globe

ChemCon The Americas

UK RoHS

Meglena Mihova

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RoHS regulations around the globe

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- **UK and EU operate RoHS independently:** UK RoHS covers GB, Northern Ireland follows EU RoHS
- **Key UK RoHS institutions:**
  - DEFRA: policy oversight;
  - Office for Product Safety & Standards Agency: enforcement
- The EU revision of RoHS will not apply or bind the UK. The UK is unlikely to conduct a revision of RoHS nor to introduce new substance restrictions

UK vs EU RoHS key difference: product marking

- The EU CE marking will be replaced by the UKCA marking. Goods placed on the Northern Ireland market will still be covered by CE marking.
- UKCA will be required on most products entering GB from **1 January 2025**. Until then, using CE marking on the GB market will be permitted.

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RoHS regulations around the globe

UK RoHS exemptions - key issues

- **During the Brexit transition period, UK RoHS exemptions were updated when they appeared in the EU Official Journal, since 31 December 2020, UK lists were frozen.**
  - For new exemptions & exemption renewal applications, UK will introduce a fee of £39,721 applicable from 6 April 2023 → risk of market distortion.
  - Separate UK & EU exemption evaluation timelines → need for clarity & coherence to reduce burden (exemptions time lags already visible).
  - Need for clarity & certainty on the exemptions made while still bound by EU law marked as 'transitional cases'.
  - The double exemption applications result in significant burden for industry as companies need to ensure regulatory compliance in both UK & EU to maintain continuity of supply chains.

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RoHS regulations around the globe

Conclusions & recommendations

- Critical policy & regulatory developments in EU and UK in the next two years
- Impact on product design of EEE & market access
- Need to anticipate, assess impacts, strategic planning
- Proactive engagement in the consultation processes & with the relevant competent authorities

Meglena Mihova

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RoHS regulations around the globe
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Thank you!
Meglena Mihova, EPPA
meglena.mihova@eppa.com
Meglena Mihova
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Nanomaterials – Global Definitions and Regulations

Mark Herwig
Raytheon Technologies Corporation

Nano Materials – Definitions & Regulations

ChemCon The Americas

- What
- Why
- Forms & Types
- Definitions w/ Regulatory Perspective

Mark Herwig

3

Nano Materials – Definitions & Regulations

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General Concept:

The engineering, production and/or manipulation of matter with at least one dimension sized from 1 to 100 nanometers.

But then there is significant divergence……..
Scientific, Regulatory, Analytical, Properties, Risk

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Nano Materials – Definitions & Regulations
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Classical Physics
Quantum Mechanics
Novel properties can enable new products / enhance existing products
Material Scientist Dream Space
Head of a Pin 1-2 mm
Human Hair ~50 µm wide
Red & White Blood Cells ~2–5 µm
DNA ~2 nm wide
10-3
10-4
10-5
10-6
10-7
10-8
10-9
10-10
1 millimeter (mm)
MEMS Devices 10–100 µm wide
1 micrometer (µm)
Visible Spectrum
100 nm
Quantum Dot 10-100nm
1 nanometer (nm)
0.1 nm
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Nano Materials – Definitions & Regulations
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Nanotechnology
Nanomaterials
(outer or inner dimensions nanoscale*)
Nanoobjects
(one or more outer dimensions nanoscale*)
Nanostructured Materials
(inner or surface structures nanoscale*)
Nanoparticles
(3 outer dimensions nanoscale*)
Nanofibres
(min. 2 outer dimensions nanoscale*)
Nanoplates
(min. 1 outer dimension nanoscale*)
Composites
Agglo-merates Aggregates
Nano-porous Systems
Nano-foams
Or "platelets"
100 nm
100 nm
100 nm
100 nm
100 nm
100 nm
* nanoscale: size between 1 and 100 nm
Mark Herwig
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Nano Materials – Definitions & Regulations

NOTE 1: This is a "primary particle" depiction.

NOTE 2: Aggregates / Agglomerates can ALSO be manufactured at the nano-scale

NOTE 3: Unique and Novel can include, but is not limited to:

Surface Reactivity: the reactivity at the surface of a reportable chemical substance. It is dependent upon factors such as redox potential, which is a measure of the tendency of a substance to lose or acquire electrons.
Zeta potential: the electrostatic potential near the particle surface.

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Nano Materials – Definitions & Regulations

Nanoscale Materials

Tubes
Wires
Balls
Particles
Composites

As Is / Agglomerated
Coated
Functionalized
Dispersions

Desired Properties
or
Further Processing
Product Incorporation
→ Markets

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Nano Materials – Definitions & Regulations

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surface treatments

Spheroidal

aspect ratio

Platelets

density

Surface area

Crystallinity

Elongated

rigidity

Multimodal shapes

assembly structure

PSD

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Nano Materials – Definitions & Regulations

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Types (EXAMPLES)

"Substances"

- SiO_2
- TiO_2
- Gold / Polystyrene
- Carbon black / graphene
- CNT's
- Tantalum
- Silver
- Ex-foliated clays
- Tungsten / Diamonds
- Ni / Cr / Other nano metals
- Other oxides of Al, Zr, Y, S, Cd, Sn
- Cobalt Chrome
- Cadmium Stannate
- Metallic / Organo-metallic powders of (Cu, Al, Zn, Gr, Ce)

"Materials / Formulations / Articles"

- Ice-phobic Coatings
- Thermal Dissipation technologies
- Super Magnets
- Nano composites / Polymers and other materials
- Dielectrics (various)
- Thermal Barrier Coatings
- Reflective Coatings
- Catalysts
- Photonics / Sensing & Detection technologies
- Membranes / Water Treatment technologies
- Lubrication technologies
- Ceramics / Ceramic Matrix Composites
- Battery / Energy Storage technologies
- Rubber / Elastomer Compounding
- Chemical Sensing
- Nano structures (e.g. graphene layers / zeolites)
- Screen-printing / Films

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Nano Materials – Definitions & Regulations

Particle Size Implications?

Particles: Not an "exact"/"exacting" material science.
Particle size distribution characterization often important

Maybe…..
It depends

Do these PSD's represent a regulated nanoscale material?

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Nano Materials – Definitions & Regulations

US EPA TSCA and nano-scale substances

New Nano Fact Sheet

- **January 23, 2008 "General Approach"** Guidance Document
- Nanoscale under TSCA: chemical substances that have structures with dimensions at the nanoscale -- approximately 1-100 nanometers (nm)
- "Molecular Identity" is key in determining whether a nanoscale material is new or not
- A chemical substance with a molecular identity that is not identical to any substance on the TSCA Inventory is considered to be a new chemical
- There are many "existing" nanoscale materials in the US market
  - Listed (on TSCA Inventory) or under Low Volume Exemption (LVE)
- There are currently a "handful" of SNUR's on nanoscale materials. Mostly carbon-based (e.g. tubes, wires, functionalized)

Subpart E
40 CFR 721

NNI

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Nano Materials – Definitions & Regulations

Nanoscale materials under CEPA

- Long History of regulatory activity on "nano"
- June 2022 consultation: Risk Assessment Framework for Nano Materials (Nano)

ECCC and HC regulators have been using the Health Canada "working definition" (GoC, 2011).
Working definition includes any manufactured substance or product and any component material, ingredient, device or structure if:

- It is at or within the nanoscale in at least one external dimension, or has internal or surface structure at the nanoscale, or;
- It is smaller or larger than the nanoscale in all dimensions and exhibits one or more nanoscale properties/phenomena.

- "nanoscale" means 1 to 100 nanometers, inclusive;
- "nanoscale properties/phenomena" means properties which are attributable to size and their effects; these properties are distinguishable from the chemical or physical properties of individual atoms, individual molecules and bulk material; and,
- a substance is evaluated as an NM if 10% or more by number of its primary particles have at least one internal or external dimension at or within the nanoscale.
- agglomerates and aggregates, regardless of their external dimensions, are considered NMs whenever their constituent (primary) particles meet the definition of an NM.

Approaches for "New" vs. "Existing" are generally the same as in the US. Some "nano's" are SNAc'd!

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Nano Materials – Definitions & Regulations

revised Annex VI of REACH introduces the concept of "nanoform"

a "nanoform" is a form of a natural or manufactured substance containing

- particles, in an unbound state, or
- as an aggregate, or
- as an agglomerate, AND where…..

for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm.

Including also by derogation fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm.

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Nano Materials – Definitions & Regulations

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"Nanoforms" subject to same Registration and Identification obligations as non-nano substances.

New Guidance!

Actors:

- M/I of substances on their own or in mixtures,
- P/I of articles located in the EU where the substance is intended to be released under normal or reasonably foreseeable conditions of use, or
- Only Representatives established in the EU and appointed by a manufacturer, formulator or article producer established outside the EU

HOWEVER,
When an actor in the supply chain purchases the substance and converts it from a non-nanoform into a nanoform, or modifies it from one nanoform to another nanoform, this actor is considered a downstream user (DSU).

ECHA DSU Guidance

Poison Center Notification?

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Nano Materials – Definitions & Regulations

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Asia-Pacific?

- S. Korea, Japan, Taiwan, Australia, New Zealand and others…
- Patchwork of inconsistencies and legal requirements
- More research, controls, regulatory updates over time.

LATAM & MENAT

- Mostly focused on Human Health and Occupational Controls

Conclusion: If you're in the nanoscale material business or you use/incorporate for commercial purposes, you have to understand each jurisdictions requirements – not unlike "regular" chemical substances.

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Thank You!

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Speakers

- **Christian Gründling,** FCIO
- **Mark Herwig,** Raytheon Technologies
- **Meglena Mihova,** EPPA

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Curriculum Vitae

Christian Gründling

FCIO – Association of the Austrian Chemical Industry
Deputy Director
Wiedner Hauptstraße 63
A-1045 Vienna
Austria
+43 5 90 900 3348
gruendling@fcio.at

Christian Gründling graduated as a chemical engineer at the Technical University of Vienna, Austria and worked at the Texas A&M University, USA and the University of Twente, NL during his Ph.D. in the field of heterogeneous catalysis. He graduated in Enschede at the end of 1995.

He started his professional career by selling emission control equipment. In 1997 he joined FCIO – the Association of the Austrian Chemical Industry – as an environmental manager. From 2000 to 2002 he worked for DSM Fine Chemicals Austria as Manager Permitting and External Relations within the health, safety and environment department. In 2002, Christian Gründling re-joined FCIO as a senior expert with emphasis on chemicals policy (i.e., REACH, CLP and GHS), safety and health at the workplace and on transport of dangerous goods.

Since then, he has been closely involved in the legislative development of REACH and CLP in Europe. From the very beginning, he has been involved in numerous conferences and training courses covering these chemical regulations as a lecturer and trainer. Currently, he is deputy director general of FCIO, still with the clear focus on health, safety and environmental issues and chemicals policy. Additionally, he is responsible for the Austrian detergent, cosmetic and aerosol industry.

Curriculum Vitae

Mark Herwig

Raytheon Technologies

Senior Director Global Chemicals Regulations and Risk Management Program

+1 203 224 9713

mark.herwig@rtx.com

Mark is currently employed by Raytheon Technologies Corporation (RTX), one of the largest Aerospace and Defense companies in the world. Mark joined United Technologies Corporation, the predecessor to Raytheon Technologies in October 2017, after nearly 28 years with the General Electric Company. In 2020, United Technologies and Raytheon Company merged to become Raytheon Technologies.

Prior to all of this, Mark fulfilled professional roles in the oil and electrical production/distribution sectors, as well as a little consulting “in his spare time”. Mark’s educational background includes undergraduate work at Clarkson University, graduate work at Rensselaer Polytechnic Institute, both located in the State of New York (USA), and has completed numerous employer sponsored management and executive leadership courses over his career.

He currently serves on the Board of the Chemical Users Coalition, and previously participated in The Conference Board Product Stewardship and Regulatory Affairs Council and was a founding Board Member of the Product Stewardship Society.

Curriculum Vitae

Meglena Mihova

EPPA SA

Managing Partner

meglena.mihova@eppa.com

Meglena Mihova is a Managing Partner at EPPA, specialized in environment, chemicals and trade. She developed specific expertise regarding RoHS, REACH authorization and restriction dossiers.

Meglena has been working on REACH since 2001, and has extensive experience in REACH authorization, restriction dossiers. She helped companies and industry associations to develop and implement successful advocacy strategy which resulted in mitigating risks for prioritization and restriction of substances under REACH and getting positive authorization outcome. Since 2018 she has been supporting industry with SEA, AoA and advocacy strategy in the Microplastics restriction dossier, as well as in the PFAS restriction.

Meglena served 3 years as Vice -Chair and Board member of AmCham EU. Prior to that, she served 6 years as a Chair of the AmCham EU Environment Committee and was active member of the Operations group. She has a Master in European and International law from University Paris II – Assas and from the Institute of High International studies in Paris. She speaks Bulgarian, Russian, English and French.