12. Internationaler Behördendialog
Regulation von Nanomaterialien

REACH-Anpassungen aus der Sicht der EU-Kommission; Planungen und Aktivitäten im Nano-Observatory

Otto Linher, Europäische Kommission, DG GROW

- **Review of nanodefinition**
- **Update of REACH Annexes**
- **Execution of M461 (Standardisation activities)**
- **ECHA's activities (NanoObservatory EUON, guidance on nanomaterials)**

Review of nanodefinition – current definition

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:en:PDF

"Nanomaterial" means a natural, incidental or manufactured material 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.

By derogation from point 2, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials.

Review of nanodefinition – scientific background

1st JRC Report: Compilation (2014)

http://publications.jrc.ec.europa.eu/repository/bitstream/JRC89369/lbna26567enn.pdf

2nd JRC Report: Assessments (2014)

http://publications.jrc.ec.europa.eu/repository/bitstream/JRC91377/jrc_nm-def_report2_eur26744.pdf

3td JRC Report: Recommendations (2015)

http://publications.jrc.ec.europa.eu/repository/bitstream/JRC95675/towards%20review%20ec%20rec%20def%20nanomaterial%20-%20part%203_report_online%20id.pdf

NANODEFINE – final report (2017), NANODEFINER

http://www.nanodefine.eu/

http://www.nanodefine.eu/index.php/nanodefiner-e-tool

Review of nanodefinition – discussed changes

change "particles" to "solid particles";

change "containing" to "consisting of";

change "in an unbound state" to "on their own";

introduction of the term "identifiable constituent particle" in the context of aggregates and agglomerates;

Review of nanodefinition – discussed additional changes

deletion of the point 5. of EU recommendation (the material with specific surface area (VSSA) by volume 60 m^2 / cm^3 or more can be considered as nanomaterial),

adding the criterion that ***materials having VSSA smaller than 5 m^2/cm^3 are not considered as nanomaterials.***

Review of nanodefinition – discussed changes

- *By derogation from point 2, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials.*

- *Alternatives for changes: to keep existing scope,*

to delete derogation, to extend derogation by including all similar materials (particles longer than 100nm with diameter <1nm or plate-like shaped particles thinner than 1nm with other two dimensions over 100nm), possibly excluding 2D materials with lateral size >100micrometers

Review of nanodefinition – Where we are?

The draft changes to the Recommendation, considered on the basis of the information compiled in the review, will be subject of an online public consultation ***(summer 2018?)****.*

COM Intention: To use this recommendation (or its main elements) in REACH and across all legislation dealing with nanomaterials (cosmetics, medical devices, food, food additives, electronics, food contact materials, worker protection, biocides, pesticides ….) .

Update of REACH Annexes – main drivers

- *nanomaterials can have different (eco)toxicological profile than bulk forms (big area/volume ratio)*
- *to improve transparency in the registration dossiers which cover nanoforms of a substance (better characterisation and link to relevant hazard and risk data)*
- *to reflect properties and behavior of nanomaterials in specific (eco)toxicological endpoints (e.g. triggers for data waiving)*
- *to reflect exposure to nanomaterials*

Update of REACH Annexes – process

- *2012-13: Announcement of possible revision*
- *2013-17: Proposal development, impact assessment*
- *9 Oct. 2017: Commission draft proposal*
- *2017: Public consultation*
- *26 Apr. 2018: REACH Committee vote (unanimous)*
- *3 months EP and EC scrutiny, then Commission adoption*
- *Annex II (safety data sheets) is not part of this revision and nanomaterials will be included in the frame of changes for CLP*
- ***1 Jan. 2020: Mandatory application***

Update of REACH Annexes - Annex VI (guidance on fulfilling information requirements)

- **characterisation of the nanoforms of a substance** (minimum requirements are particle size distribution, shape, surface area and surface treatment) added to the substance identification data
- **definition of nanoform** based on the Commission recommendation of the definition of nanomaterial*
- **definition of set of similar nanoforms** - set consists of the nanoforms where the hazard assessment, exposure assessment and risk assessment of these nanoforms can be performed jointly, the borders of a set are defined by the above characteristics.

2011/696/EU. Review in progress. To be replaced by the revised Recommendation as soon as available

Update of REACH Annexes – main changes in the initial COM proposal

- New information requirements (Annex VI, III & VII-XI)
  - **dustiness included in Annex VII (under 7.14 bis)**
  - **further information on phys. chem. properties (Annex IX)**
  - **request on the toxicokinetics studies for nanoforms (Annex VIII, 8.8)**
  - **characterisation of nanoform in Annex VI**

- Clarification statements (Annex I, VI,XII)
  - **NF covered by the registration must be addressed**
  - **Assessment & conclusions documented and appropriate risk management measures identified**

- Specific scientific/technical considerations (Annex VII-XI)
  - **for NFs insolubility, K_{ow} or soil adsorption coefficient cannot be used as data waivers in the same way as for classical substances**
  - **in some cases require more detailed results from test methods (8.6.1-2)**

Update of REACH Annexes –changes in resulting from discussions in the REACH Committee

- considering dissolution rate in water, aquatic and biological media (under water solubility in 7.7)

- considering dispersion stability when K_{ow} is not available (under K_{ow} in 7.8)

- considering the inhalation route of administration for nanoforms as standard route (Annex VII, 8.5.1)

- Long term ecotox (VII 9.1.1, VIII 9.1.3) for nanoform also in the case of low dissolution rate

- Further information on phys.chem. properties on nanoforms in Annex VIII (not IX)

Execution of the M461 (*Standardization activities regarding nanotechnologies and nanomaterials)*

Examined areas under mandate M/461

- methodologies for nanomaterial characterization
- sampling and measurement of workplace, consumer and environment exposure
- methods to simulate exposures to nanomaterials
- health, safety and the environment

Topics identified for standardisation under M461:

- measurement of dustiness (5 ENs)
- efficiency of filtration (1 EN, 1 TS)
- workplace exposure (4 ENs)
- guidance/protocols on characterisation, waste, life cycle assessment (5 TS)

Execution of the M461 (*Standardization activities regarding nanotechnologies and nanomaterials)*

CEN/TC 352 Nanotechnologies

(TS) **"Nanotechnologies – Guidance on measurands for characterizing, evaluating nano-objects and materials that contain them" (publicly available)**

(TS) "Nanotechnologies – Guidelines for aspects of Life Cycle Assessment specific to nanomaterials"

(TS)"Nanotechnologies – Guidance on detection and identification of nano-objects in complex matrices"

(TS) "Nanotechnologies – Guidelines for determining protocols for the explosivity and flammability of powders containing nano-objects (for transport, handling and storage)"

(TS) " Nanotechnologies – Guidelines for the management and disposal of waste from the manufacturing and processing of manufactured nano-objects"

Execution of the M461 (*Standardization activities regarding nanotechnologies and nanomaterials)*

CEN/TC 195 Air filters for general air cleaning

(EN) Test method to measure the efficiency of air filtration media against spherical nanomaterials in 20-500 nm size range,

(TS) Test method to measure the efficiency of air filtration media against spherical nanomaterials in 20-30 nm size range,

Execution of the M461 (*Standardization activities regarding nanotechnologies and nanomaterials)*

CEN/TC 137 Assessment of workplace exposure to chemical and biological agents

(EN)"Measurement of dustiness of bulk nanomaterials - Part 1 : General guidance and requirements"

(EN)"Measurement of dustiness of bulk nanomaterials - Part 2: Rotating drum method"

(EN)"Measurement of dustiness of bulk nanomaterials - Part 3: Continuous drop method"

(EN)"Measurement of dustiness of bulk nanomaterials - Part 4: Small rotating drum method"

(EN)"Measurement of dustiness of bulk nanomaterials - Part 5: Vortex shaker method"

Execution of the M461 (*Standardization activities regarding nanotechnologies and nanomaterials)*

CEN/TC 137 Assessment of workplace exposure to chemical and biological agents

(EN) "Workplace exposure - Characterization of ultrafine aerosols/nanoaerosols - Determination of number concentration using condensation particle counters" (publicly available)

(EN) "Workplace exposure - Guidance document for the assessment of exposure to inhaled manufactured nanoparticles"

(EN)"Workplace exposure - Guidance on metrics to be used for the measurements of exposure to inhaled nanoparticles (nano-objects and nanostructured materials) such as mass concentration, number concentration and surface area concentration"

(EN)"Workplace exposure - Guidance document of assessment of dermal exposure to manufactured nanoparticles"

ECHA activities: Guidance on nanomaterials

- *New practical guide: How to prepare registration dossiers that cover nanoforms;*
- *New guidance on grouping and read-across between nanoforms;*
- *Nano specific Appendices to the guidance on information requirements and chemicals safety assessment, covering:*
  - *Update of the information requirements for human health and for the environment;*
  - *New guidance for read-across and grouping between nanoforms.*
- *Will be updated shortly to reflect the adapted REACH Annexes.*

Link: https://echa.europa.eu/-/reach-guidance-for-nanomaterials-published

EU Observatory on nanomaterials – why?

Originate from a request by the EU Parliament resolution in 2009, and COM 2nd regulatory review on nanomaterials 2012

Based on an impact assessment COM concluded observatory is the most cost-effective option to increase transparency on nanomaterials on the market

Observatory is one part of several policy actions on nanomaterials – each element has its role to play

EUON aims

Provide objective and reliable information on the market and safety of nanomaterials in the EU

- **Collect and analyse information from a wide variety of existing sources**
- **Supplement existing information with external studies**
- **Present information on uses and safety of nanomaterials in a friendly way**

EUON - 1 year old

EUON launched June 2017

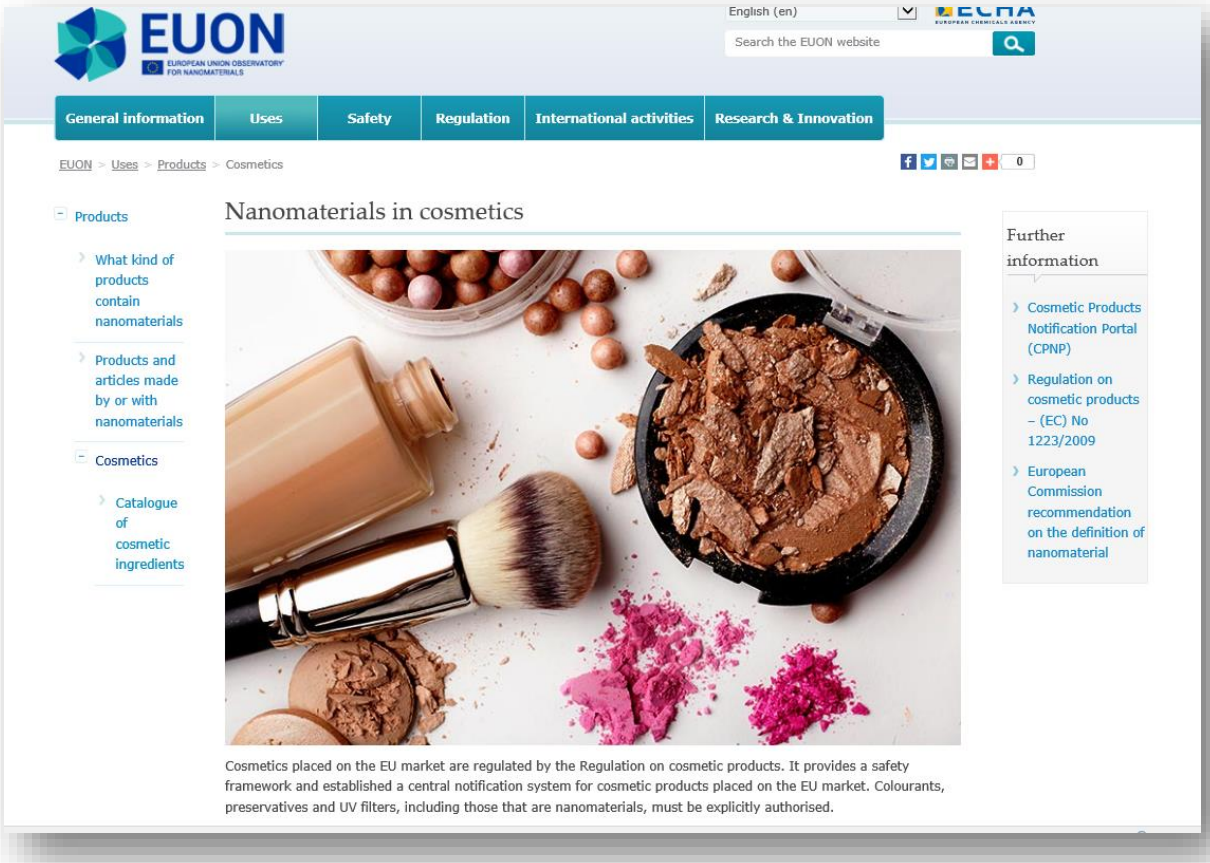
- **Make use of synergies with existing information**
- **Provide narrative content on key areas of nanomaterials**
  - Uses
  - Safety
  - Regulation
  - Research and development

euon.echa.europa.eu

Additional improvements

Information on cosmetics

- **Find what nanomaterials are used in cosmetics**



EC/List name	EC	CAS	Type	Name
Trisodium 5-hydroxy-1-(4-sulphophenyl) -4-(4-sulphophenylazo)pyrazole-3-carboxylate	217-699-5	1934-21-0	Colourant	ACID YELLOW 23 / CI 19140
				BARIUM SULFATE / CI 77120
				CARBON BLACK / CI 77266
				CI 77288
				CI 77491
				CI 77499
				CI 77510
				CI 77891
				COPPER / CI 77400
				GOLD / CI 77480
				PIGMENT RED 57 / CI 15850
				PIGMENT RED 57:1 / CI 15850
				SILVER / CI 77820
No EC/List name available	425-950-7	187393-00-6	UV filter	BIS-ETHYLHEXYLOXYPHENOL METHOXYPHENYL TRIAZINE

Trisodium 5-hydroxy-1-(4-sulphophenyl)-4-(4-sulphophenylazo)pyrazole-3-carboxylate

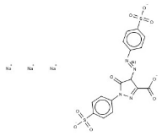
↓Other names: Regulatory process names [2] IUPAC names [9]

Substance identity

EC / List no.: 217-699-5

CAS no.: 1934-21-0

Mol. formula: C16H9N4Na3O9S2



Hazard classification & labelling

According to the notifications provided by companies to ECHA in REACH registrations no hazards have been classified.

How to use it safely

- ECHA has no data from registration dossiers on the precautionary measures for using this substance.
- Guidance on the safe use of the substance provided by manufacturers and importers of this substance.

About this substance

This substance is manufactured and/or imported in the European Economic Area in 10 - 100 tonnes per year.

This substance is used by consumers, in articles, by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing.

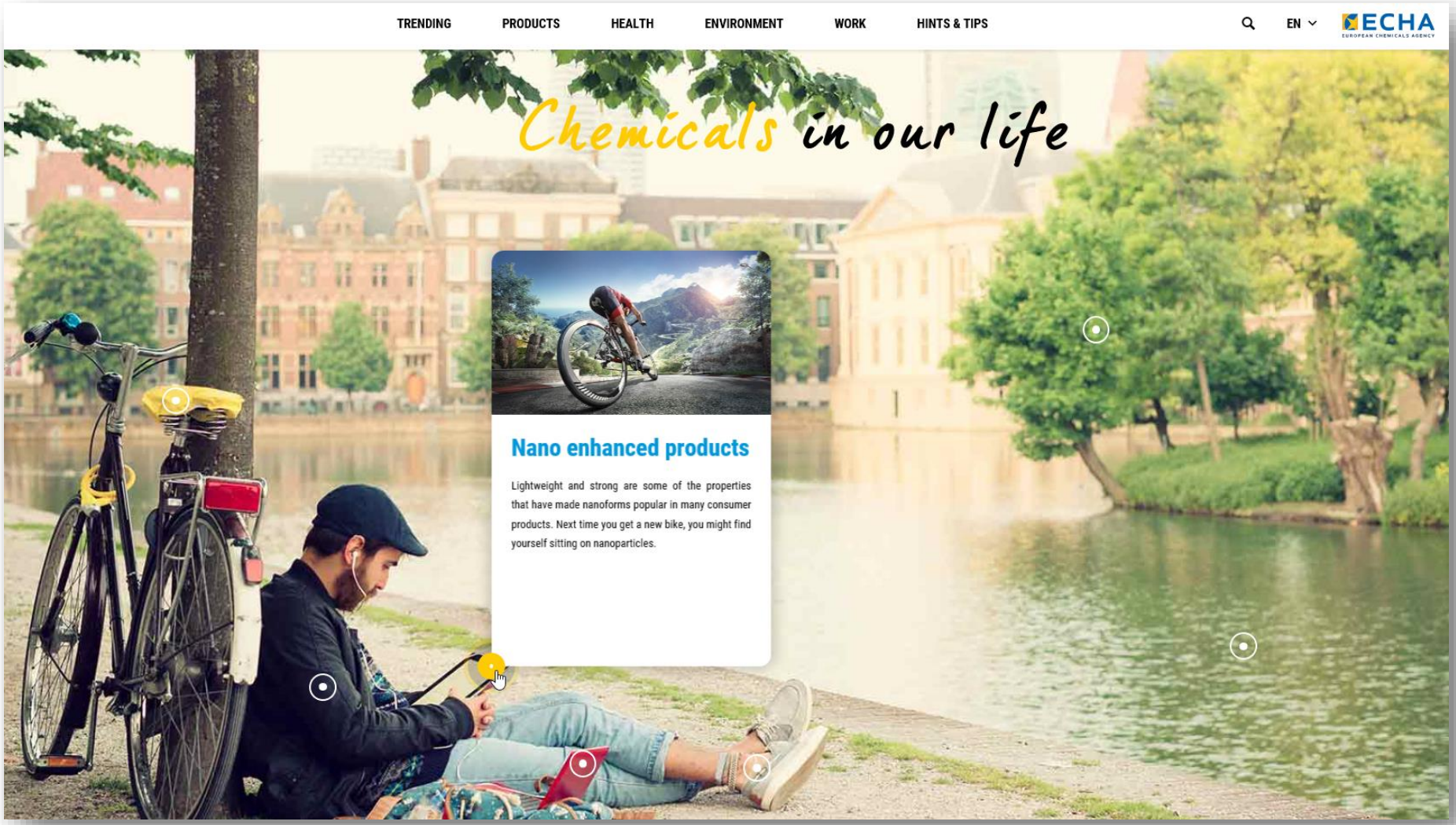
Consumer Uses

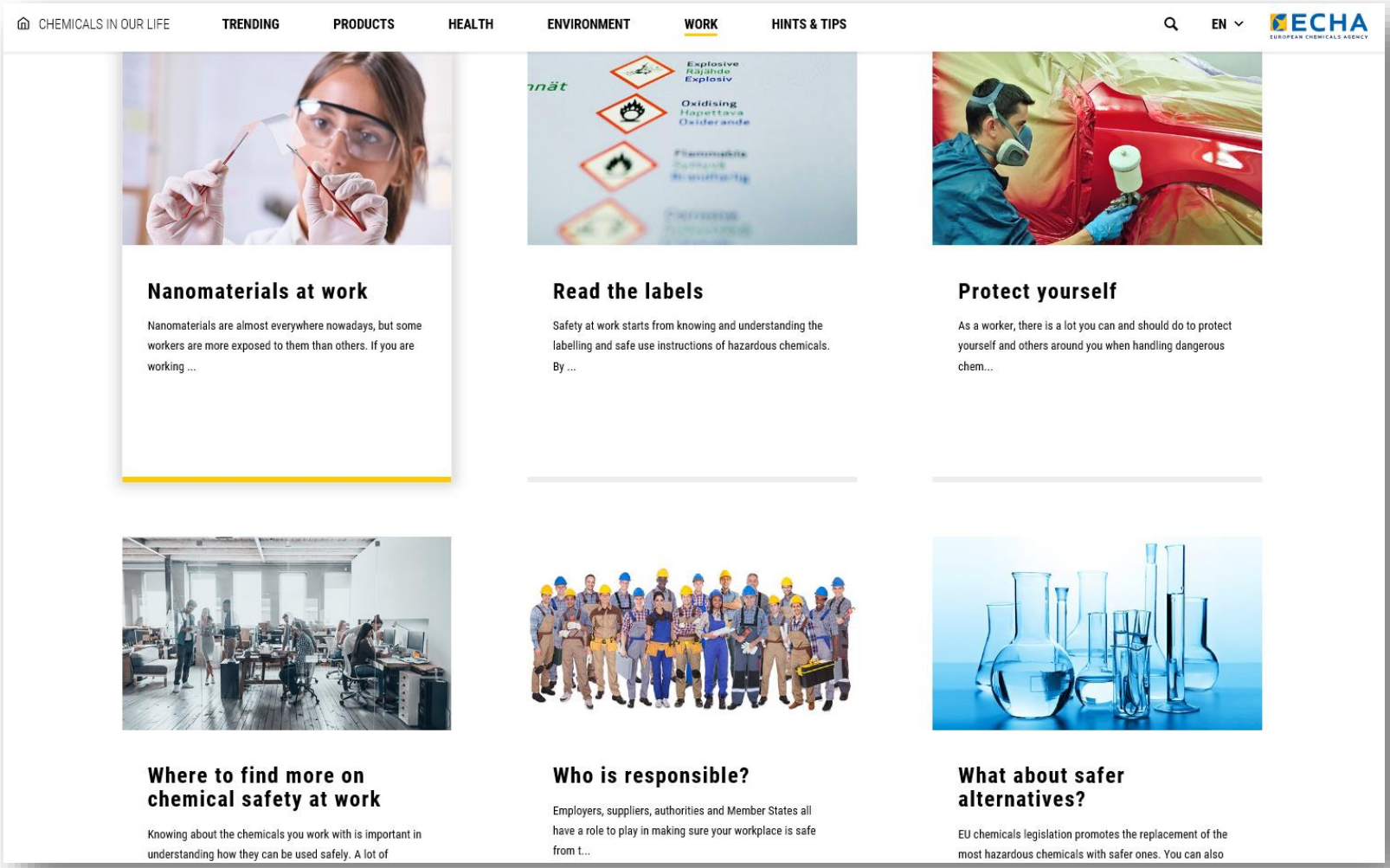
This substance is used in the following products: cosmetics and personal care products, inks and toners, biocides (e.g. disinfectants, pest control products), washing & cleaning products

Launch of consumer microsite

Dedicated website with information for consumers: launched on 15 March, World Consumer Rights Day

chemicalsinourlife.echa.europa.eu


TRENDING
PRODUCTS
HEALTH
ENVIRONMENT
WORK
HINTS & TIPS
EN
ECHA
Chemicals in our life
Nano enhanced products
Lightweight and strong are some of the properties that have made nanoforms popular in many consumer products. Next time you get a new bike, you might find yourself sitting on nanoparticles.


CHEMICALS IN OUR LIFE
TRENDING
PRODUCTS
HEALTH
ENVIRONMENT
WORK
HINTS & TIPS
EN
ECHA
Nanomaterials at work
Nanomaterials are almost everywhere nowadays, but some workers are more exposed to them than others. If you are working ...
Explosive
Räjähde
Explosiv
Oxidising
Hapettava
Oxiderande
Read the labels
Safety at work starts from knowing and understanding the labelling and safe use instructions of hazardous chemicals. By ...
Protect yourself
As a worker, there is a lot you can and should do to protect yourself and others around you when handling dangerous chem...
Where to find more on chemical safety at work
Knowing about the chemicals you work with is important in understanding how they can be used safely. A lot of
Who is responsible?
Employers, suppliers, authorities and Member States all have a role to play in making sure your workplace is safe from t...
What about safer alternatives?
EU chemicals legislation promotes the replacement of the most hazardous chemicals with safer ones. You can also

Planned new content

New sections/text on different areas

- **Potential benefits of nanomaterials**
  - Medicines
  - Food/feed
  - Environment
  - ….
- **Nanomaterials in different regulations**
- **Nanomaterials in the workplace**

EUON 2nd phase: additional data

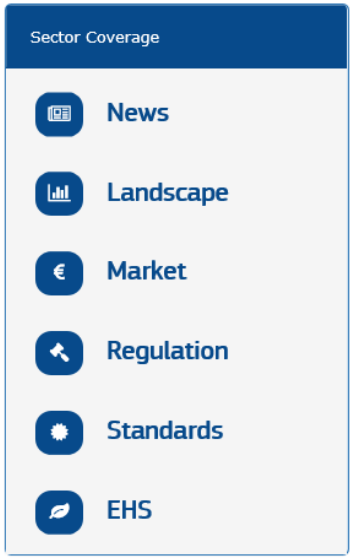
New data sources:

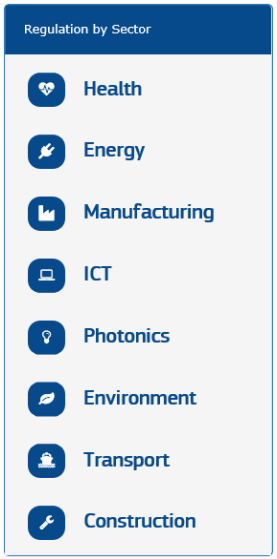
- **NanoData to enable dissemination of information on safety, markets, innovation**
- **Information from EU-funded research projects (eNanoMapper)**
- **Links with national registries for details on specific substances in specific markets**
- **Harvesting new information on nanomaterials from other EU sources (EFSA, EMA, EU-OSHA, EEA), Commission services, and other legislations**

NanoData

Available information on Nano Data, e.g.:

- **Products**
- **Publication**
- **Patents**
- **Organizations**
- **R&D and Innovation**

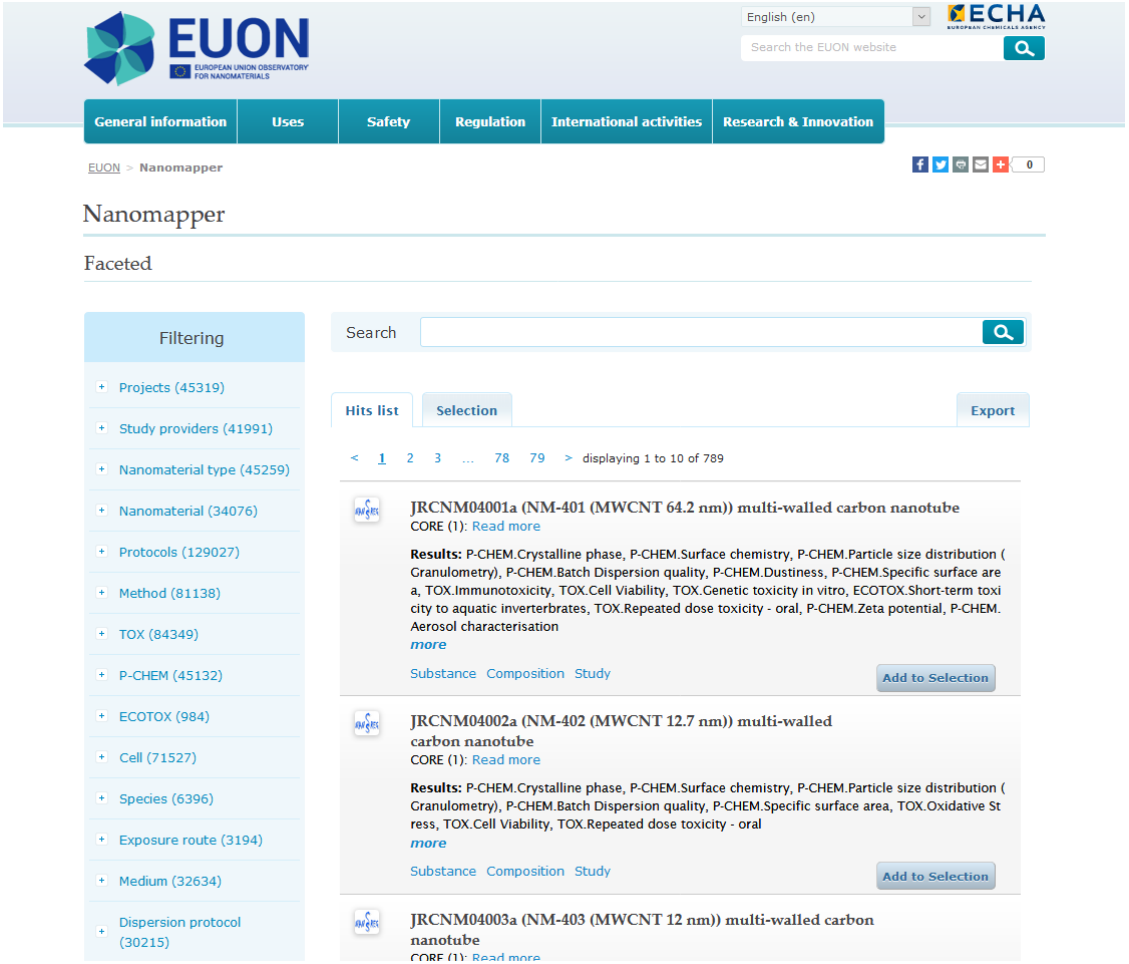




eNanoMapper

eNanoMapper provides ontology and databases for managing data from EU funded research projects on health and safety of nanomaterials

User can search, display, and filter data from different research projects



EUON: external studies

EUON has conducted two external studies on nanomaterials

- **Literature study of risks in the use of well known pigments in consumer products and for workers**
- **Parameters and data sources used to produce market studies and their relevance and reliability**

Studies completed, results to be published soon

Nano-Observatory – build up in three phases

1st Phase -2017– make use of synergies

- New web-content for professionals and consumers
- Mainly easily available basic information
- New micro-site for consumers
- New search functionality on our dissemination site

2nd Phase – 2018 – expansion of content – launch 12/6/2018

- More edited content for different audiences
- Linking with national inventories
- Linking with (or hosting) databases on research and innovation (NANODATA, eNanoMapper)
- external studies (e.g. study on nano-pigments in consumer products), new studies are scheduled
- More structured information from other legislations

3rd Phase – 2019 – full operation

- More edited content for different audiences
- New IT solutions?
- And more to come…

Thank you for your attention.

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