Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Eidgenössisches Departement des Innern EDI
**Bundesamt für Gesundheit BAG**
Direktionsbereich Verbraucherschutz

# REACH Regulations

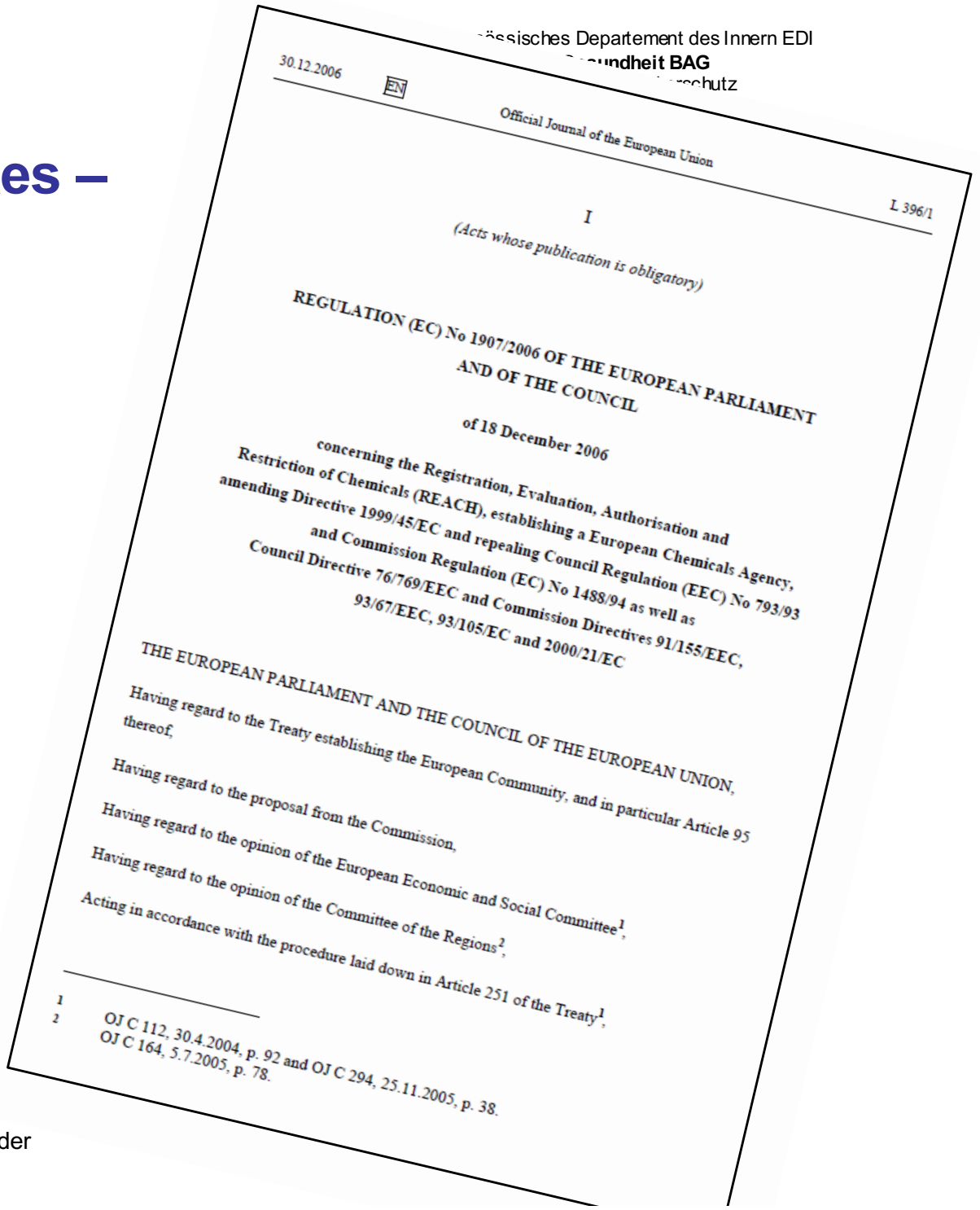
Christoph Studer
Federal Office of Public Health

Contactpointnano Workshop

## Get ready for the future - understanding new regulations for nano-enabled products

7 December 2018

# REACH Annexes – Status quo



30.12.2006 EN Official Journal of the European Union L 396/1

I

*(Acts whose publication is obligatory)*

**REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**of 18 December 2006**

**concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee[1],

Having regard to the opinion of the Committee of the Regions[2],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[1],

1 OJ C 112, 30.4.2004, p. 92 and OJ C 294, 25.11.2005, p. 38.
2 OJ C 164, 5.7.2005, p. 78.

# REACH standard information requirements

The requirements below have to be adapted, waived or increased, according to the rules given in columns 1 and 2 of annexes VII to X and according to annexe XI.

**≥ 1000 t/year (annexes VII + VIII + IX + X)**

**100-1000 t/year (annexes VII + VIII + IX)**

**10-100 t/year (annexes VII + VIII)**

**1-10 t/year (annexe VII)**

**Physico-chemical properties**

- State of the substance at 20°C and 101.3 kPa
- Melting/freezing point
- Boiling point
- Relative density
- Vapour pressure
- Surface tension
- Water solubility
- Partition coefficient n-octanol/water
- Flash-point
- Flammability
- Explosive properties
- Self-ignition temperature
- Oxidising properties
- Granulometry
- Stability in organic solvents and identity of relevant degradation products (if substance stability is considered to be critical)
- Dissociation constant
- Viscosity

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**10-100 t/year (annexes VII + VIII)**

**1-10 t/year (annexe VII)**

**Toxicological information**

- Skin irritation or skin corrosion *(in vitro)*
- Eye irritation *(in vitro)*
- Skin sensitisation
- Mutagenicity (*in vitro*, gene mutation bacteria)
- Acute toxicity (oral route)

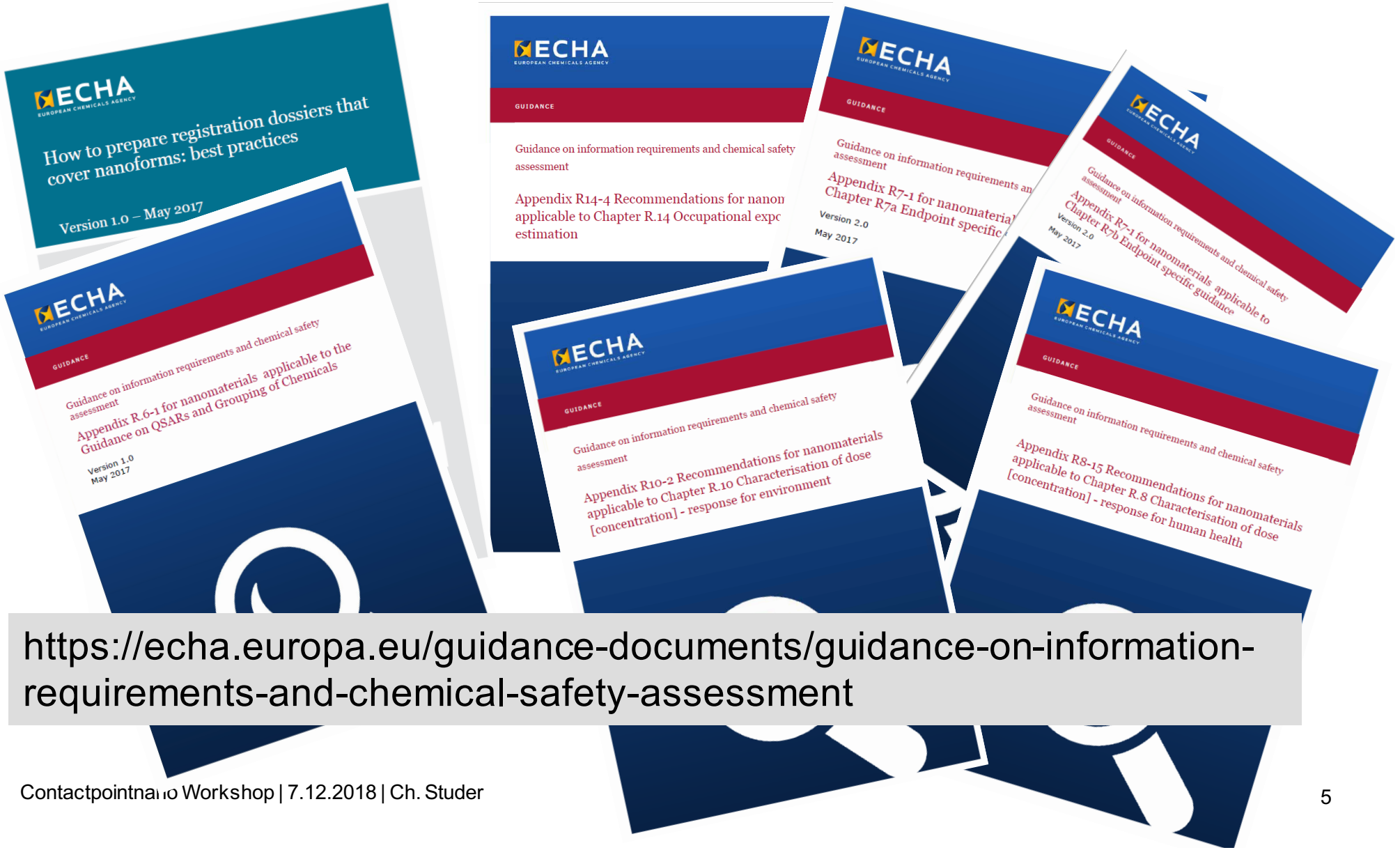
- Skin irritation (*in vivo*)
- Eye irritation (*in vivo*)
- Mutagenicity (*in vitro*, cytogenicity mammalian cells or micronucleus)
- Mutagenicity (*in vitro*, gene mutation mammalian cells)
- Acute toxicity (inhalation)
- Acute toxicity (dermal route)
- Repeated dose toxicity (28 days, one species)
- Reproductive toxicity (screening, one species)
- Toxicokinetics (assessment from available information)

- Repeated dose toxicity (28 days, one species)*
- Repeated dose toxicity (90 days, one species, rodent)
- Reproductive toxicity (pre-natal development, one species)
- Reproductive toxicity (two generations, one species)

- Reproductive toxicity (developmental, one species)
- Reproductive toxicity (two generations, one species)*
- Carcinogenicity study

** These studies have to be carried out if they have not been completed for the lower tonnage band because of waiving*

# Guidance Documents on Nanomaterials under REACH




https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

# Update of REACH Annexes – main drivers

- nanomaterials can have different (eco)toxicological profiles than bulk forms (big surface/volume ratio, different uptake mechanisms compared to soluble substances…)
- to reflect properties and behavior of nanomaterials in specific (eco)toxicological endpoints (including triggers for data waiving)
- to reflect exposure to nanomaterials
- to improve transparency in the registration dossiers which cover nanoforms of a substance (better characterisation and link to relevant hazard and risk data)

# 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**

Verordnungsentwurf:
http://ec.europa.eu/transparency/regcomitology/index.cfm?do=search.documentdetail&Dos_ID=15915&ds_id=56122&version=2&page=1&AttLang=de

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

- **Definition of "nanoform" of a substance:** based on the Commission recommendation on 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 their characteristics
- **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)

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

# Definition of nanoforms:

On the basis of the Commission Recommendation of 18 October 2011 on the definition of nanomaterial, **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.

# Update of REACH Annexes – main changes
## (Commission draft proposal, 2017)

- New information requirements (Annex VI, III & VII-XI)
  - Characterisation of nanoform in Annex VI
  - 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)
- Clarification statements (Annex I, VI,XII)
  - Nanoforms covered by the registration must be addressed
  - Assessment & conclusions documented and appropriate risk management measures identified
- Specific scientific/technical considerations (Annex VII-XI)
  - for nanoforms insolubility, Kow 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 Annex VII 7.7)
- considering dispersion stability when Kow is not applicable (under Kow in Annex VII 7.8)
- considering the inhalation route of administration for nanoforms as standard route (Annex VII, 8.5.1)
- considering long term ecotox (Annex VII 9.1.1, VIII 9.1.3) for nanoform also in the case of low dissolution rate in relevant test media
- further information on phys.-chem. properties on nanoforms in Annex VIII (not IX)

# ECHA activities: Guidance on Nanomaterials

- 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.
- Documents will be updated shortly to reflect the adapted REACH Annexes

# Registration of nanomaterials under REACH

## EU-ECHA*

### Identity of nanomaterials:

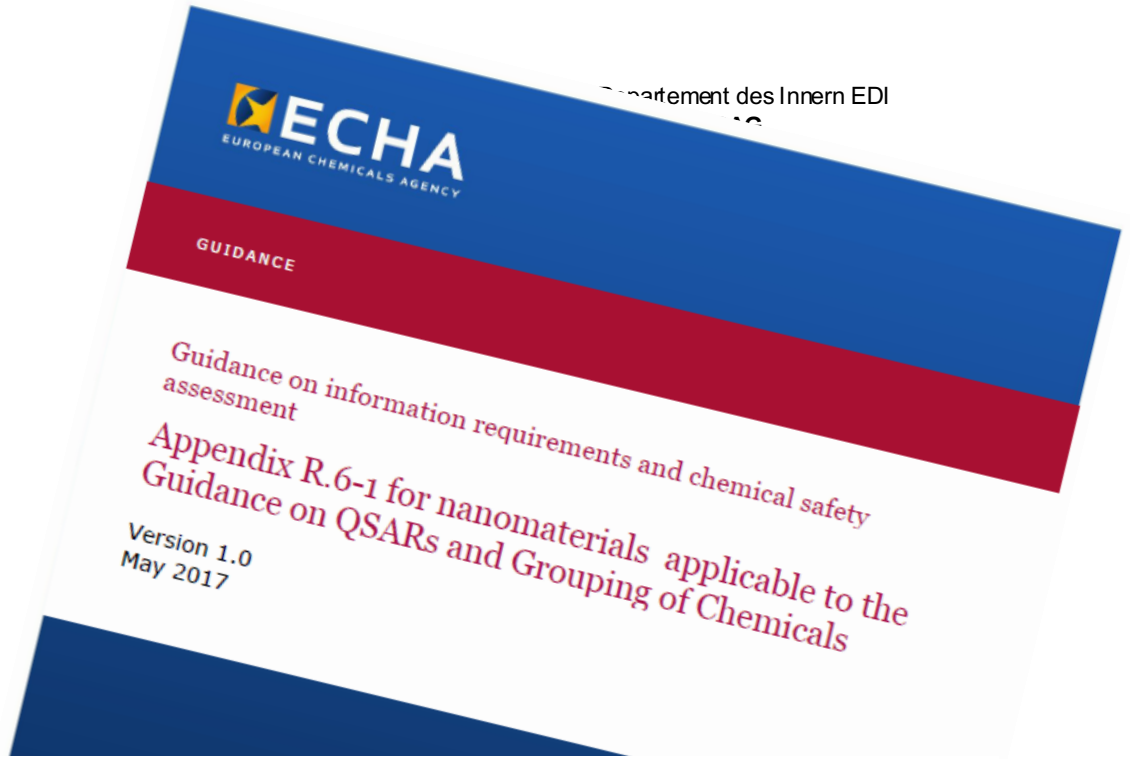
- The chemical composition of the core is determining the identity. Different sizes, forms and coatings are regarded as **«nanoforms»** of this chemical.
- Nanomaterials where the core contributes < 80% to the total weight are normally regarded as discrete chemicals.


### Minimal dataset for the registration of «nanoforms»:

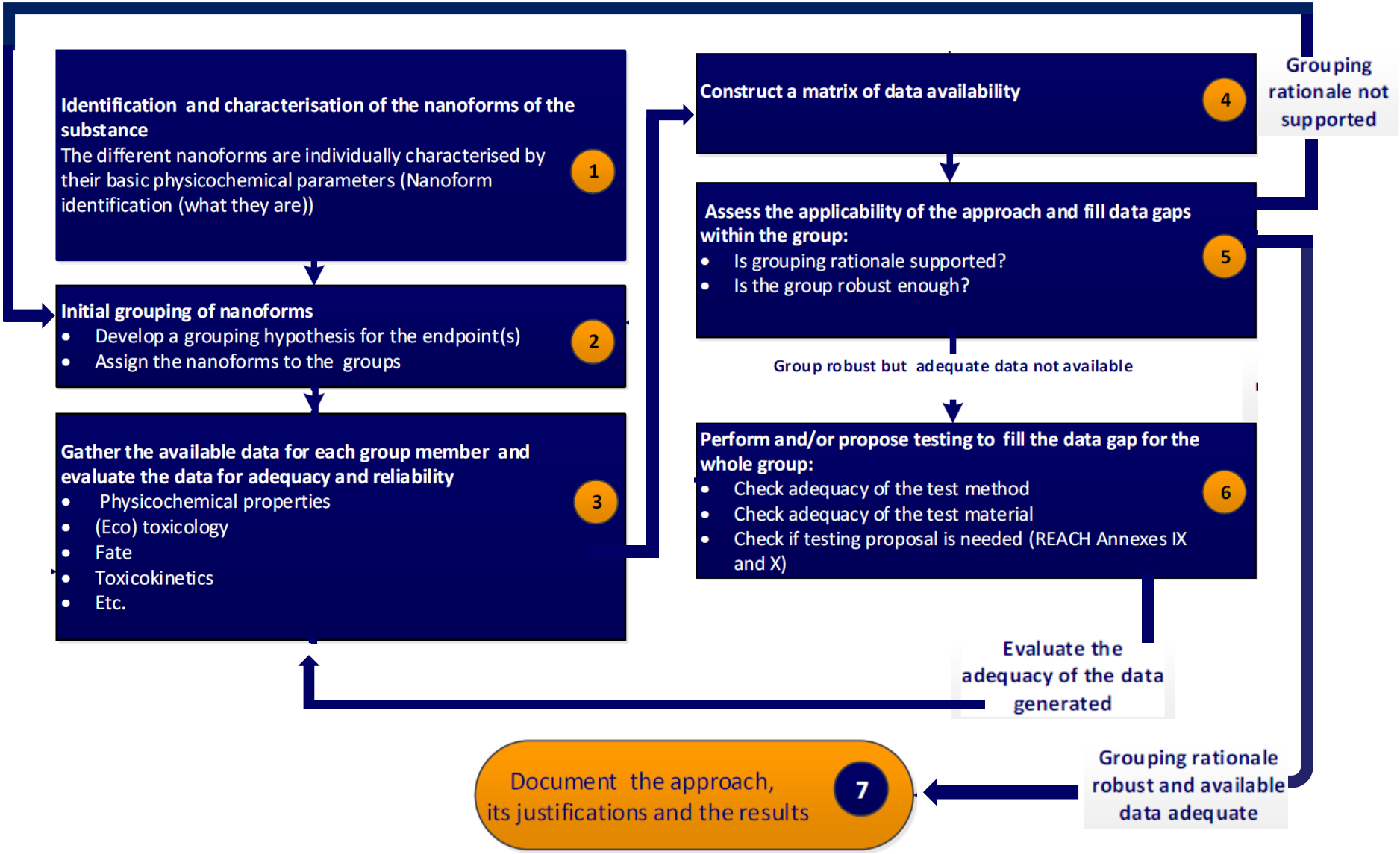
- Size, form and surface chemistry (at least: chemicals used for surface treatment).
- Grouping and read-across approach for data on toxicity and fate.

* Guidance on information requirements and chemical safety assessment; Appendix R.6-1 for nanomaterials applicable to the Guidance on QSARs and Grouping of Chemicals (May 2017);
How to prepare registration dossiers that cover nanoforms: best practices (May 2017)

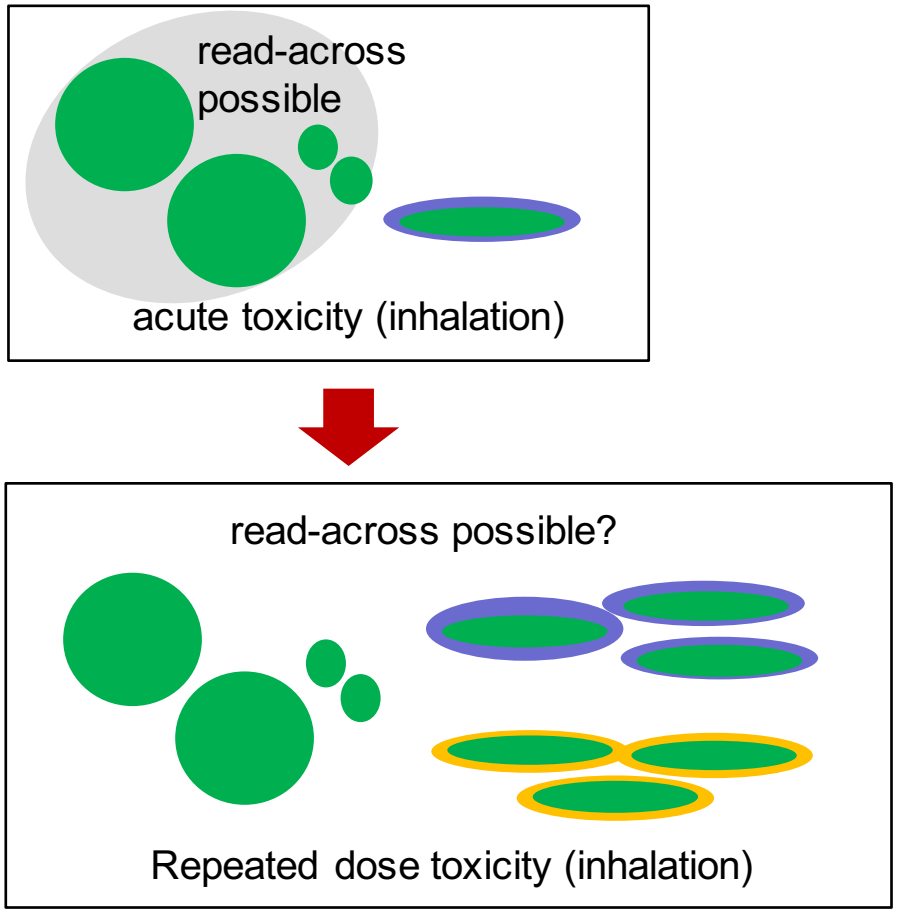
# ECHA Guidance




This chapter outlines the general principles on how information on physicochemical properties and toxicological behaviour should be gathered and combined with expert judgement to provide a scientific rationale for the grouping of nanoforms, as well as guidance on how to document and justify each grouping approach. By seeking similarities in physicochemical properties and toxicological behaviour between different nanoforms, mainly using physicochemical parameters and/or *in vitro* screening methods, it may be possible to develop a robust scientific explanation, which supports the assumption of similar hazard properties within a defined group of nanoforms. Once the grouping approach has been successfully applied, available hazard information can be read-across to all nanoforms within the defined group. In all cases, the hazard information should be robust enough for the purposes of hazard identification, classification and labelling (C&L) and/or risk assessment.


Identification and characterisation of the nanoforms of the substance
The different nanoforms are individually characterised by their basic physicochemical parameters (Nanoform identification (what they are))
1
Initial grouping of nanoforms
• Develop a grouping hypothesis for the endpoint(s)
• Assign the nanoforms to the groups
2
Gather the available data for each group member and evaluate the data for adequacy and reliability
• Physicochemical properties
• (Eco) toxicology
• Fate
• Toxicokinetics
• Etc.
3
Construct a matrix of data availability
4
Assess the applicability of the approach and fill data gaps within the group:
• Is grouping rationale supported?
• Is the group robust enough?
5
Grouping rationale not supported
Group robust but adequate data not available
Perform and/or propose testing to fill the data gap for the whole group:
• Check adequacy of the test method
• Check adequacy of the test material
• Check if testing proposal is needed (REACH Annexes IX and X)
6
Evaluate the adequacy of the data generated
Grouping rationale robust and available data adequate
Document the approach, its justifications and the results
7

# Read-across between nanoforms




**1-10 t/year**
total market volume of all nanoforms of a chemical including bulk

**10-100 t/year**

- Additional information requirements for all nanoforms
- For the new nanoforms information requirements from the lower tonnage band are needed as well

# Chemicals Legislation in Switzerland (Chemicals Ordinance)

## Autonomous monitoring

Manufacturers have to assess the risk of substances and formulations for human health and the ecosystem (Art.5 ChemV).

Requirements of adequate

- packaging
- labeling
- exposure assessment (scenarios) for chemicals if market volume >10t/a
- Safety Data Sheets

**Requirements apply to the non-nanoscale chemicals and to nanomaterials**

# Notification of new chemicals including nanomaterials

Manufacturers have to deliver data on toxicity and fate for non-nanoscale chemicals and nanomaterials to the authorities (tonnage threshold > 1t/a). Additional data for the characteriastion of nanomaterials needed:

- chemical composition, mean particle size and shape (mandatory)
- particle size distribution, specific surface area, crystal structure, aggregation status, surface coatings and functionalisation (if available).

## Reporting of dangerous chemicals and preparations

All non-nanoscal chemicals and nanomaterials classified as «dangerous» according to GHS must be registerd by manufacturer (no tonnage threshold). Public Product register: https://www.rpc.admin.ch/rpc/public/index.xhtml?lang=en&winid=1057559

## Reporting of biopersistant HARNs

Reporting of biopersistant nanotubes and nanofibers with a length > 5µm have to be reported.

# Danke für’s Zuhören!