



Revision of REACH Annexes to address nanoforms of substances

+ Review of definition of nanomaterial (2011/696/EU)

NIA Workshop, April 2018

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EUROPEAN
COMMISSION

Brussels, XXX
[...](2017) XXX draft

COMMISSION REGULATION (EU) .../...

of XXX

amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council
on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
as regards Annexes I, III, VI, VII, VIII, IX, X, XI, and XII to address nanoforms of
substances

(Text with EEA relevance)

Content

- *REACH - Process*
- *Impact assessment & proposal*
 - **Main elements, with summary of comments**
- *Discussion to date*
- *Review of definition*
 - **Public consultation coming up 😊**

Process

- *2012/13: Announcement of possible revision*
- *2013-17: Proposal development, impact assessment*
 - **Public consultation, discussions with stakeholders**
- *March 2017: Committee - 1st presentation of main elements (non-paper)*
- *9 October 2017: Commission draft proposal*
- *Oct, Dec 2017, Feb, Mar, Apr 2018: Committee discussion*
- *2018 : EP and EC scrutiny, Commission adoption*
- *[1 Jan 2020] Mandatory application*

IA Report in a nutshell

- **61 pages (144 total), 16 Appendixes**
- **Context, Problem Definition, Objectives**
- **Policy Options**
- **Analysis of Impacts**
 - **Economic, Health, Environment, Animal testing**
- **Comparing the Options (incl. 'preferred option')**
- **Appendixes**
 - **Background (REACH, public consultations, nanoform concept) and procedural**
 - **Analysis of impacts**
 - **Details of measures, assumptions, cost methodology**
 - **Sensitivity analysis**

POLICY OPTIONS

1	No change (<i>very specific interpretation used in cost analysis</i>)*
2	Clarifying the existing information requirements (current requirements according to ECHA)*
3	Soft law measures
4	Scientific-technical recommendations tailoring information requirements
5	Reduced information requirements
6	Exhaustive information requirements

* Some interpretation required : changes pre- & post- BoA Decision A-11-2014 in 2017

IA challenges and approach

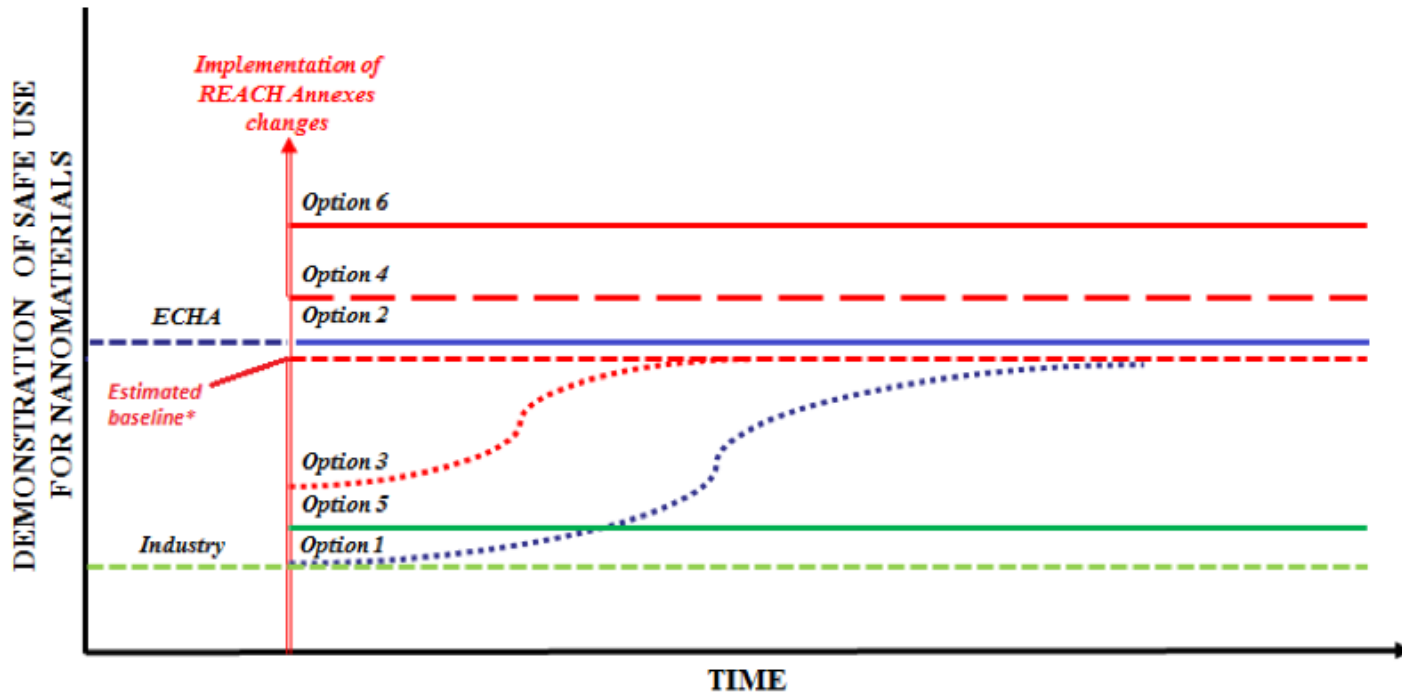
- *Restricted scope of the exercise*
- *Baseline supported with the BoA decision A-011-2014*
- *Cost estimations are very sensitive to the underlying assumptions*

Concepts of 'nanoform' and associated 'set of nanoforms' was used as principal element of the assessment. A large number of assumptions was made.

ASSESSMENT OF IMPACTS

- *Economic, Health, Environment, and animal use*
 - **Costs quantified**
 - **Benefits mostly qualitative- general findings on benefits of chemicals regulation on substances can be applied**
- *For options 2 to 6, 52 measures were identified and individually assessed (including cost and animal use)*

Description of options, evolution...



Preferred option

- IA has led to a better understanding of the consequences of specific measures
- To increase efficiency of the solution, some measures have been slightly modified compared to what was proposed initially, and measures constituting the different options as set out originally have been combined.
- **Preferred option is compiled as a mixture of all measures of option 2 and few measures of option 4 and 6.**
- **In discussions with MS in REACH committee, some measures are being modified/reconsidered**

Cost per nanoform (in 1000 €)

per tonnage band, use of alternative information methods possible

	1 ^a	1 ^b	Estimated baseline ^e	2	3	4 (including 2)	5	6 (including 2 and 4)	Preferred (Mix)
>1000 tonnes	772	77	1049	1157	1049	1256	458	2256	1234
100-1000 tonnes	538	77	777	814	770	939	375	1736	901
10-100 tonnes	183	37	334	359	334	471	40	869	413
1-10 tonnes (Full Annex VII)	78	20	162	187	162	246	20	463	235
1-10 tonnes (Only Phys-chem)	37	9	62	87	62	89	9	463 ^d	128^d
1-10 tonnes ^a	49	12	91	116	91	137	12	466	159
Weighted Average	358	47	516	565	516	642	212	1254	628

Under revision based on changes in RC!

Grand total cost (in million €)

per tonnage band, use of alternative information methods possible

	1 ^a	Estimated baseline ^d	2	3	4 (including 2)	5	6 (including 2 and 4)	Preferred (Mix)
>1000 tonnes	36	482	532	482	578	211	1038	568
100-1000 tonnes	43	426	426	426	519	207	960	498
10-100 tonnes	9	84	90	84	118	10	217	103
1-10 tonnes (Full Annex VII)	5	38	44	38	58	5	109	55
1-10 tonnes (Only Phys-chem)	5	35	49	35	50	5	264 ^b	73^b
1-10 tonnes	10	73	93	73	110	10	373	127
Total	107	1065	1165	1065	1325	437	2588 ^c	1297^c

Under revision based on changes in RC!

IAR conclusions - preferred option

- *Most coherent with REACH and ensures legislation is fit for nanomaterials as for any other chemical*
- *Most cost-effective option that would attain the objective to ensure adequate demonstration of safe use for nanomaterials*
- *Animal use: option is "slightly above neutral" compared to baseline – subject to interpretation*

Elements

- *Transitional provision – mandatory [1 Jan 2020]*
- *Fulfilling information requirements [Annexes VI, III & VII-XI]*
 - **Inclusion of 'definition' of nanoform [NF] and *nanoform characterisation requirement***
- *Clarification statements [Annex I, XII]*
 - **If NF are covered by the registration, they must be addressed, assessment and conclusions documented and appropriate risk management measures identified**
- *Specific scientific-technical considerations [VI-XI]*
 - **Make the existing information requirements in Annexes VI to XI effective and applicable for NF**

Annex VI (introductory guidance, nanoform)

Fulfilling information requirements for substances with nanoforms (A VI-XI)

- Link the concept of nanoform, based on the Commission recommendation of the definition of nanomaterial*, with the existing information requirements for substances
- Include minimum characterisation information on size, shape, surface treatment and surface area of the nanoparticles as part of substance identification for nanoform or set of nanoforms.

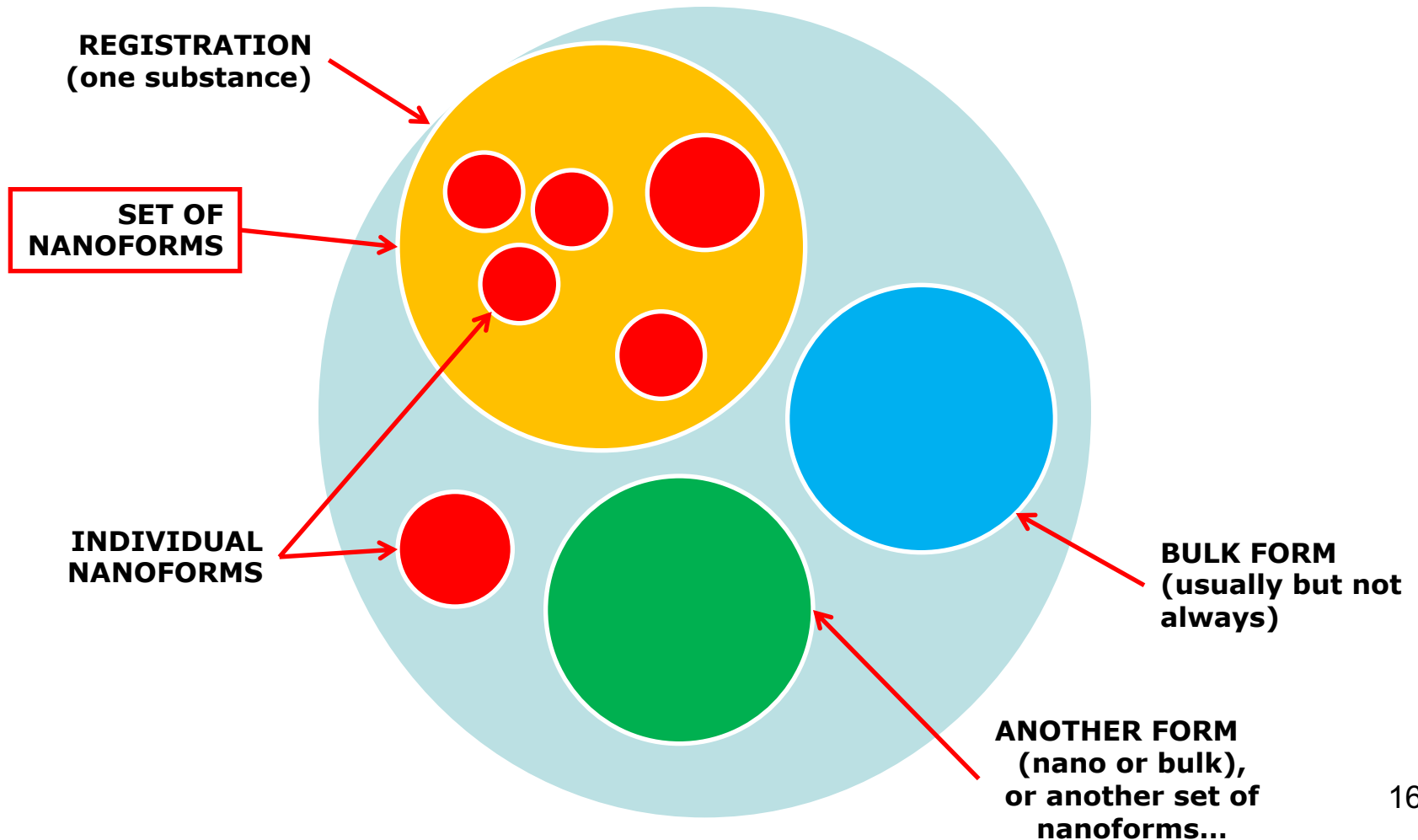
Also enables to establish relevance and adequate scope of the hazard information and chemical assessment

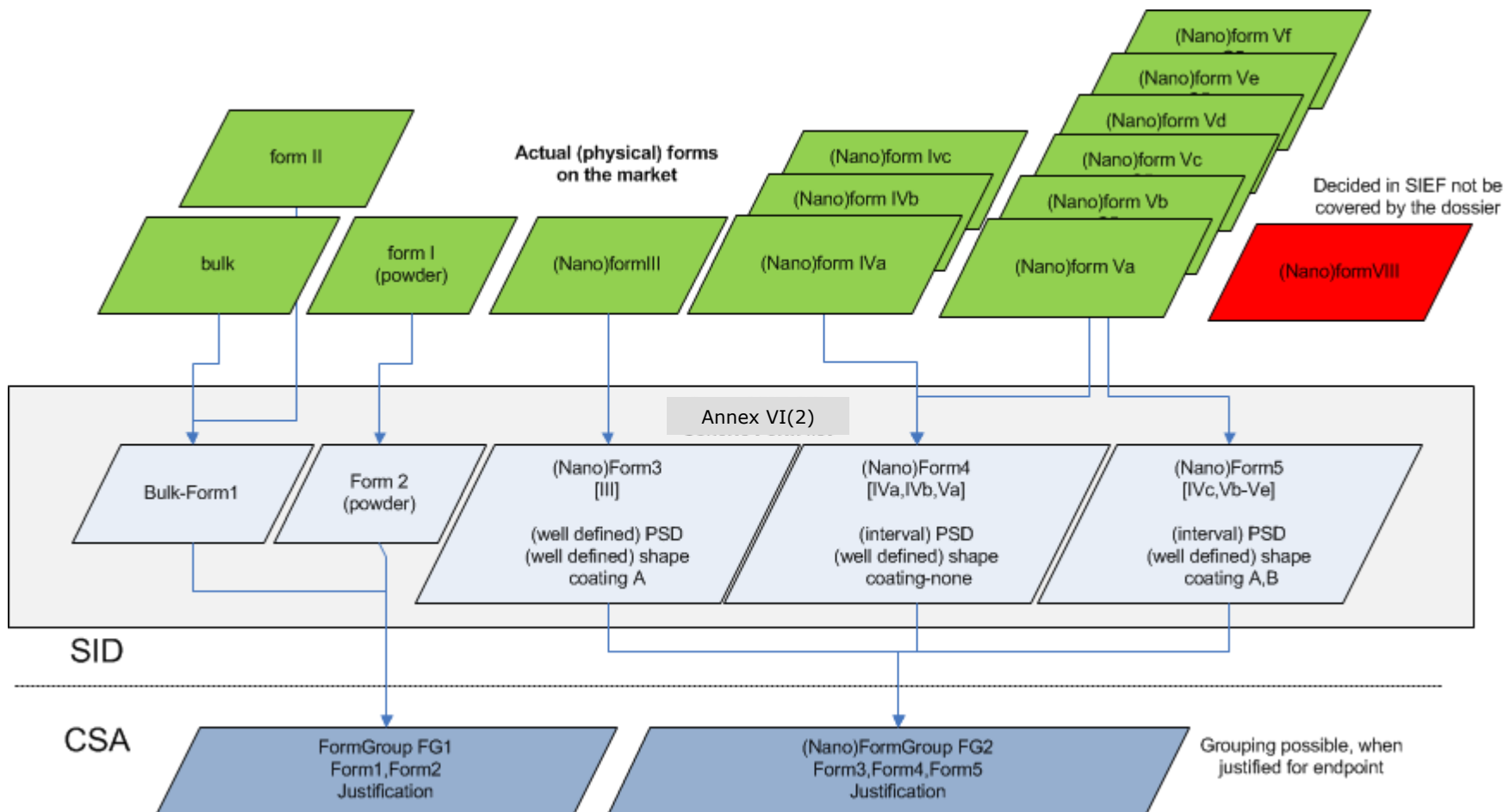
****2011/696/EU. Review in progress. To be replaced by the revised Recommendation as soon as available***

Discussions in the REACH committee

- *Annex II (Safety Data Sheet)*
 - **Ensure consistency of provisions**
- *Clarity (Annex VI)*
 - **What is a nanoform? or Set or no set?**
- *Information requirements*
 - **Basic Physico-chem set of information**
 - Dissolution rate
 - Agglomeration behaviour (dispersion stability)
 - **Request relevant information**
 - Acute toxicity / appropriate route
 - Triggers/waivers/short-long term

Nanoform concept





2011/696/EU Review

- *Delay in one step before last : public consultation*
- *After 12w consultation, analysis of feedback ->*
 - **Decision on revision and its individual elements**
- *Following Commission's adoption*
 - **Uptake in respective regulations (own processes)**
 - **Further conditions might still apply**

Principal elements to be consulted upon...

Similar but not the exactly the same...

- *Materials, not products or components*
- *Definition based on (sizing of) identifiable constituent **solid particles**, external size 1-100nm*
- *Nanostructured materials excluded*
- *Particle number size distribution, 50% threshold (**only**)*
- *Supplementary definitions (particle, agglomerates, aggregates)*

Further changes considered...

- **VSSA**
 - As way to **exclude** material as nanomaterial ($<5 \text{ m}^2/\text{cm}^3$)
 - Guidance decision tree may include VSSA as a way to demonstrate material is a nanomaterial
- ***Materials explicitly included :***
 - Considering to replace existing derogation (fullerenes, graphene flakes and single wall carbon nanotubes) with inclusion of counting also **thin ($1 < \text{nm}$) particles of elongated or plate-like shapes**
 - Views on this solution (or its alternatives) will be sought in the consultation, including
 - *Identification of thus 'newly' included materials and their use*
 - *Impact of such inclusion, based on uptake in the regulation (e.g. cosmetics)*