Development of options for changing REACH requirements for nanomaterials and assessment of their consequences for industry, consumer human health and the environment

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Background - Nanomaterials & REACH

European Regulation 1907/2006 on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) entered into operation on 1st June 2008. REACH lays down provisions on substances, which apply to the manufacture, placing on the market and use of substances on their own, in preparations or in articles. It is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment.

Nanomaterials are covered by the "substance definition" of REACH (European Parliament and Council 2006), which addresses chemicals in whatever size, shape or physical state. By 1st December 2010, substances produced and imported in quantities ≥ 1000 tonnes per year in the European Union (EU) had to be registered under REACH. In addition a number of very toxic and "new" (under REACH "non phase-in") substances at lower quantities were registered. All of these registration dossiers held the potential to cover also nanomaterials.

Aims of the NANO Support Project

In December 2010, the European Commission Joint Research Centre (EC JRC) signed an Administrative Arrangement (AA) with the Directorate General Environment (DG ENV) covering the Project *"Scientific technical support on assessment of nanomaterials in REACH registration dossiers and adequacy of available information"* (NANO SUPPORT Project). The specific tasks of this 2-year AA were to:

1) provide a comprehensive assessment and analysis of the availability and quality of data on the properties of nanomaterials in REACH registration dossiers due by December 2010;
2) develop options on how to amend REACH to better address nanomaterials, and;
3) examine the consequences of implementation for industry, consumers, human health and the environment of possible options for changing the REACH requirements for nanomaterials.

Tasks 1 and 2 were carried out by JRC in close collaboration with the European Chemicals Agency (ECHA), while the third task was undertaken by external consultants (BiPRO and Ökoinstitut e.V.).

Assessment & analysis of data on nanomaterials in REACH dossiers

A summary of the approach taken to the assessment and analysis of the availability and quality of data on the properties of nanomaterials in REACH Registration dossiers submitted by the December 2010 deadline is provided in Figure 1.

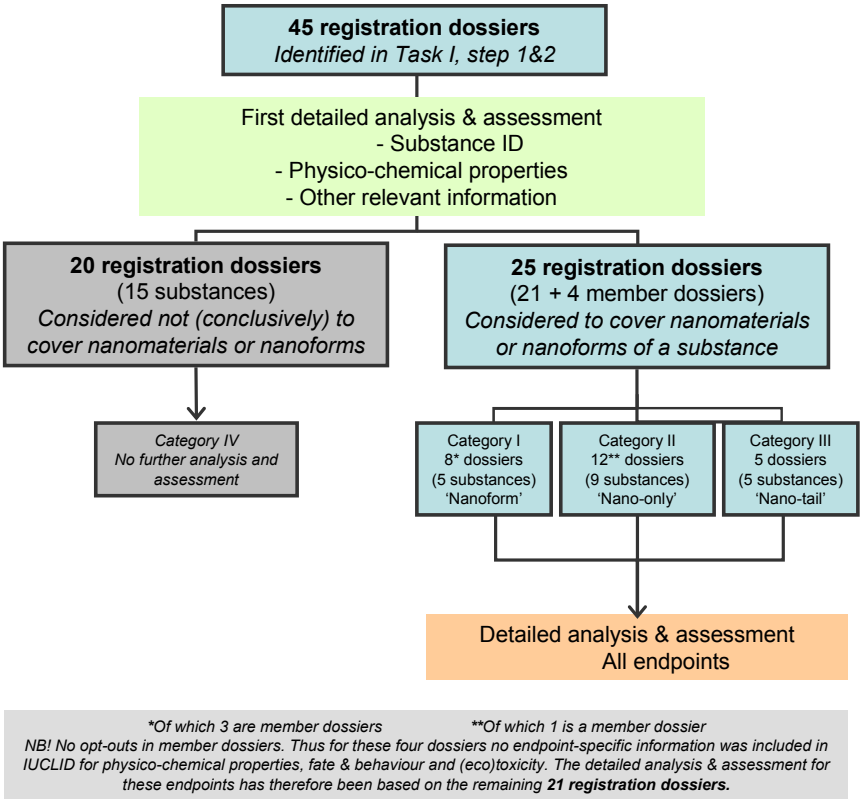

Figure 1: Summary of the assessment & analysis of data on nanomaterials in REACH dossiers

From more than 26,000 submitted registration dossiers, covering 4,700 substances, 45 dossiers (referring to 33 distinct substances) possibly addressing nanoforms or nanomaterials were identified. The selection was based on a combination of automated searches of the International Uniform Chemical Information Database (IUCLID), on knowledge of the substances selected for assessment in the Organisation for Economic Co-operation and Development Working Party on Manufactured Nanomaterials (OECD-WPMN), and other criteria to identify substances considered to include a nanoform. It is possible that other dossiers could be considered to cover nanomaterials or nanoforms, however, they could not be identified as it was often not clear whether nanoforms were included within the scope of the registered substance. In addition, the information provided on the forms or granulometry of the substances often did not allow for identification of particles in the nano-range.

Following an examination of the information on substance identity, state, granulometry and other relevant endpoints, 20 dossiers were excluded from further assessment. This was because they could not conclusively be considered to cover nanomaterials or nanoforms, based on the information provided. The remaining 25 dossiers, covering 19 different substances were identified as likely to cover nanoforms/nanomaterials. These dossiers included three registrations that had explicitly selected "nanomaterial" as the form of the substance in an optional IUCLID field. The further assessment identified three categories of registration dossiers, where:

I. the registrants recognised that nanoforms of particle size < 100 nm were within the scope of the dossier (8 dossiers / 5 substances);
II. substances considered to exist only as nanomaterial without a bulk form (12 dossiers / 9 substances), and;
III. the assessors identified nanomaterials on the basis of the presence of a 'nanotail' in the provided particle size distributions (5 dossiers / 5 substances).

All 25 dossiers were subject to further detailed analysis and assessment of substance identity, physicochemical properties, human health, fate, ecotoxicity, classification and labelling, and the chemical safety report. It should be noted that the assessment was not a compliance check nor

any other formal REACH evaluation of the dossiers and substances analysed. It is recognised that since December 2010 some additional nanomaterials have been registered as either non phase-in substances or phase-in substances for the registration deadline of May 2013, but these were not within the scope of the NANO SUPPORT project.

The examination of the substances' identity and key physicochemical properties (e.g. granulometry, surface area etc.) revealed that the information provided in the dossiers was, in general, not sufficient to identify a nanomaterial or nanoform of a substance. The general observation for other endpoints, such as human health or environment, was that the test materials were usually not well characterised and that different forms could not be distinguished.

Options on how to amend REACH to better address nanomaterials

Based on the result of the assessment described in the previous section, 21 options were developed for adapting REACH to better reflect the properties of nanomaterials. These options refer to five categories: (i) substance identification and physicochemical properties, (ii) general and specific options for human health hazards, (iii) environmental fate, (iv) environmental hazards and exposure assessment, and (v) risk characterisation.

An assessment of the consequences of these options for industry, consumers, human health and the environment during 2012–2022 was carried out by a contractor. As a first step for the definition of the baseline, it was decided that only 9 of these options should be addressed for the assessment of the consequences. The remaining 12 options were, following intensive dialogue with European Chemicals Agency staff[1], eventually considered part of the current requirements (i.e. the baseline) and therefore considered to represent compliance costs.

The 9 options selected for assessment of consequences were as follows:

- Include information on dustiness;
- Require acute toxicity data for the most relevant route of exposure (Annex VII);
- Change particles to '(nano)particles' for repeated dose toxicity studies (inhalation);
- Require non-bacterial in vitro mutation study (Annex VII);
- Consider water solubility in relation to test waiving;
- Specify that long term testing should not be waived based on lack of short term toxicity;
- Specify that algae testing should not be waived based on insolubility;
- Require that testing on soil and sediment organisms is prioritised;
- Require considerations of most appropriate/relevant metrics.

The costs and benefits for human health were assessed quantitatively based on case studies and extrapolation to the whole market for nanomaterials. It was estimated that 500–2,000 substances (including different forms and surface modifications of the same substance) would be placed on the market, at more than 1 tonne/year during 2012–2022.

The costs of the option scenario (nine options) for industry, including testing and updating registration dossiers, were estimated to be €11–73 million, as a cumulative effort until 2022. If grouping and read-across approaches were not taken into account extensively, the costs would rise to €100–600 million.

Human health benefits, e.g. by improving the health of the general population were estimated to be €165 million, on average (with a range of €83–248 million) for cumulative savings for 2012–2042. As health benefits are expected to accrue with significant delays after implementation of the options, a direct comparison with the costs is not possible. All estimations are associated with high uncertainty. Qualitative impacts of the implementation of the options include more transparency on the use and safety of nanomaterials, greater innovation and better possibilities for risk reduction measures.

[1] This is not an official ECHA statement

Summary and impact

The analysis and assessment of REACH registration dossiers showed, that little 'nanospecific' information and experience could be retrieved from 2010 REACH registration dossiers (European Commission 2012). In that context it should be however noted that most of the high tonnage substances exist in different forms/sizes and that the submission, identification and selection of dossiers was done prior to the adoption of the EC recommendation (2011/696/EU) (European Commission 2011) on the definition of nanomaterial. It was therefore up to the registrant to decide how to address different form(s) within the dossier. In addition, the dossiers had to be prepared prior to the publication of ECHA guidance documents including recommendations for nanomaterials (ECHA 2012).

The assessment of the consequences concluded that, based on an implementation of the developed options, additional costs for companies can lead to a reduced uncertainty about potentially adverse effects. These may lead to considerable health and environmental benefits, if combined with appropriate risk reduction measures (BiPRO and Ökoinstitut e.V. 2013)

The results of this project had a direct impact on the European Commission's evaluation of the need to review REACH for nanomaterials within the 2nd Communication of the regulatory aspect of nanomaterials in October 2012. In addition it will have an impact on the forthcoming envisaged modifications of the REACH Annexes, to better address the properties and risks of nanomaterials.

The full final reports of the NANOSUPPORT Project are available to download on the European Commission website. http://ec.europa.eu/environment/chemicals/nanotech/#support

References

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