Stakeholder-Dialog

Nanomaterials:

Communication of information along the industry supply chain

Frankfurt am Main, March 5 2008

Dialog Documentation

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Introduction

The stakeholder dialog "Nanomaterials: Communication of information along the industry supply chain" on March 5 2008 is part of the dialog series, which is being jointly implemented since 2005 by the German chemical industry association Verband der Chemischen Industrie e.V. (VCI) and the foundation Stiftung Risiko-Dialog, St. Gallen. This dialog series is entitled "Responsible handling and use of nanomaterials". At the event on industrial health and safety in 2007, VCI and the stakeholders decided to take up the issue of "safety data sheets" as a central element in the communication of information and to find out which specific requirements arise in connection with nanomaterials. VCI had elaborated a proposal for "Guidance for the passing on of information along the supply chain in the handling and use of nanomaterials, via the safety data sheets", which was now presented for discussion to the stakeholders. This Guidance supplements existing VCI documents, such as the "Questionnaire for the review of safety data sheets" (May 2004) and the "Guidance safety data sheet" (June 2007). This basis enables chemical companies to systematically describe in safety data sheets the specific characteristics and information for the handling and use of nanomaterials. Additionally, a compilation of published relevant Guidance documents in English language was made available in March 2008 (Responsible Production and Use of Nanomaterials; download http://www.vci.de). There are also German-language versions of most Guidance documents.

The following report documents contributions to discussions and supplementary proposals from stakeholders. They will be included in the further work on safety data sheets.

Presentation of the VCI Guidance "Communication of information along the industry supply chain for nanomaterials"

- Dr. Heinz-G. Schäfer, Verband der Chemischen Industrie e.V.

Dr. Schäfer presents the Guidance and explains its structure and recommendations, which are based on the VCI documents "Questionnaire for the review of safety data sheets" (May 2004) and "Guidance for a Tiered Gathering of Hazard Information for the Risk Assessment of Nanomaterials" (February 2008). The Guidance refers to the draft definition for intentionally manufactured nanomaterials by the Technical Committee 229 "Nanotechnologies" of the International Organization for Standardization (ISO). Special focus is given on those sections of the safety data sheet (SDS) which are of special relevance to nanomaterials (industrial health and safety, environmental protection, uses). In the following fields, the recommendations go beyond the legal requirements of the European REACH Regulation:

- Gathering of further physicochemical data for risk assessment;
- In individual cases (special toxicity, high exposure potential), gathering of HSE information beyond REACH Annex VII - according to Annexes VIII, IX and X;
- Minimization of exposure at the workplace until specific thresholds are laid down for nanoparticles or for certain nanomaterials.

Furthermore, VCI recommends member companies to provide information on surface modification (e.g. hydrophobic/hydrophilic properties), surface charge, general chemical functionality) and to give special attention to potential aerosol uses. Moreover, it must be examined whether measures for limiting exposure are adequate in the light of physicochemical properties.

Inter alia, the following items of information should be invariably gathered regarding physicochemical properties:

- Impurity profile
- Surface chemistry/coating (only to the extent as appropriate and needed for the risk assessment and filling in the SDS)
- Water solubility
- Partition coefficient n-octanol / water (where relevant, e.g. for coated nanomaterials)
- Morphology, crystalline phase, shape, surface structure (qualitative description)
- Particle size and size distribution
- Agglomeration and aggregation in native material and in preparation (qualitative description)
- Specific surface area
- Known catalytic activity

The safety data sheet should be used for the communication of information also where the substance or the preparation is not classified as dangerous.

Identification of nanomaterials in the supply chain

- Dr. Anja Klauk, EU Commission, Directorate-General Enterprise

Dr. Klauk highlights in her talk that the term "Nano" is not explicitly mentioned in the REACH Regulation. Within REACH, nanoscale uses are covered under the respective substances, with Annex I section 5.1.1 and the REACH Implementation Project (RIP) explicitly pointing to the specific form of substances and to information about their chemical properties. Also Annex VI of Council Directive 67/548/EEC and, at a later stage, the GHS Regulation refer to substance-specific properties depending on the respective form, so that nanomaterials are included in registrations and thus covered by EU legislation. Dr. Klauk emphasizes that REACH prescribes the classification of materials and the elaboration of SDSs, without volume thresholds.

Dr. Klauk informs that an overview of the approach to nanomaterials in EU legislation will be published shortly ("Report on Regulatory Aspects of Nanotechnologies"). Furthermore, still this year a Commission working group will look more deeply into nanomaterials within REACH.

The fact that the following criteria are currently not yet explicitly included in the VCI Guidance on safety data sheets is critically discussed:

- Specific parameters to be monitored, such as thresholds for workplace exposure and/or biological thresholds;
- Measures for the limiting and the monitoring of exposure of workers and of the environment.

With the currently available measuring techniques and measuring methods and due to the lack of thresholds for exposure to nanomaterials, such information would still cause problems at the present stage. For implementation, some available methods for the determination of hazard and exposure and for risk assessment need to be adapted. Relevant activities are currently being performed at OECD and ISO levels.

Regarding point 7 "Handling and storage" it is critically noted that – additionally to the possibly necessary recommendation of avoiding aerosols – further operational procedures and protection measures should be recommended for examination.

What instruments are available for communicating information?

- Dr. Barbara Richter, Bayer MaterialScience AG

Dr. Richter emphasizes the relevance of intensive dialogs with stakeholders and the inclusion of product safety and occupational health and safety issues in the development of new and innovative products – in order to achieve acceptance for products based on nanomaterials. Equally important is harmonization between companies, regarding criteria for the standardization of test methods for risk assessment purposes.

The safety data sheet is a vital communication instrument for Bayer MaterialScience, especially in context with occupational health and safety and environmental protection. The SDS is supplemented by information from the company, such as e.g. technical instruction sheets and scientific publications. Safety-relevant information is also communicated at congresses, trade fairs and on the company homepage. Furthermore, direct talks – especially with customers – are useful for passing on information.

On the example of Baytubes® (dispersion), Dr. Richter highlights how information about restrictions of uses (e.g. "no spray applications") can be documented in the SDS. Resorting to examples, she explains how the following items of information can be presented clearly and comprehensibly:

- Information on acute toxicity (dermal, oral or inhalative), with details on experimental setup, followed methods and results
- Information on primary skin irritation, mucous membrane irritation and sensitizations
- Genotoxicity test and mutagenicity test
- Environment-specific information on biodegradability, toxicity to fish, daphnia, algae and bacteria

Dr. Richter states the necessity of following standardized tests, according to OECD requirements.

Panel discussion about talks given in the morning

In the panel discussion, the participants bring forward questions and first proposals regarding the VCI Guidance. The following points are given special attention:

- The VCI Guidance is a guideline for all companies organized within VCI – it has a high degree of bindingness and can serve as orientation in jurisdiction. However, VCI has no direct influence on the implementation of recommendations in individual operations and in companies not organized within VCI. Therefore, the question is critically discussed whether a Guidance can ensure a sufficiently binding implementation of requirements.

- Some participants voice concerns about SDSs frequently not reaching workers at production sites. Here, it should be considered whether there is a possibility of initiating stakeholder activities – in order to attract more attention and to help improve the information flow inside operations.

- It is noted that SDSs include information on substance properties which could change in the course of processing. Potential changes of safety-relevant parameters during the production process must be stated. In this context, it is also pointed to limitations in the usefulness of SDSs to consumers.

- Next, the question is critically discussed whether REACH ensures an adequate risk management for nanotechnologies. Some participants think that information requirements under REACH should be specified.

- At the end of the discussion, VCI offers to organize in 2008 a further dialog event on the regulation of nanotechnologies under REACH.

Focus on Safety Data Sheet

- Dr Eva Lechtenberg-Auffarth, German Federal Institute for Occupational Safety and Health (BAuA)

Dr Lechtenberg-Auffarth clarifies that the SDS is supplemented by new instruments under the REACH Regulation - such as chemical safety assessment, chemical safety report and exposure scenarios – which are included in the extended Safety Data Sheet (eSDS). She points out that compiling SDSs for non-classified substances is a voluntary step. However, all manufacturers are obliged by law to ensure the safe handling of their substances

- for different forms of uses and intended uses,
- in all phases of the life cycle,
- for the environment, workers and consumers.

In order to enable the concrete communication of information, one can resort to the standard phrases catalogue of the Federation of German Industries (BDI) and the information on safety data sheets and nanomaterials on the BAuA website. There is a choice of generally applicable standard phrases that can be completed with sector-specific standard phrases. Additionally, Dr Lechtenberg-Auffarth gives the following recommendations:

- Development of practice-oriented and sufficiently precise descriptions of uses, functions and fields of application.
- Examination of whether the descriptions and possibly necessary exposure scenarios concur with each other. Users must be able to see whether the described uses and exposure scenarios are applicable.
- Handling of (not yet) classified nanomaterials: Useful information about potential dangers must be worded clearly; the same holds true e.g. for not yet clarified properties (retention time in the atmosphere).
- Wherever possible, it should be pointed to relevant sector-specific rules.
- Where applicable, information should be given about substitute products of lower risk for certain uses.

Like Dr Klauk, Dr Lechtenberg-Auffarth holds the view that thresholds, suitable measuring methods and adequate recommendations for risk management need to be developed and standardized.

Workshop to discuss the VCI Guidance

Requirements to the industry supply chain from the viewpoint of users – Introductory statements:

In three short introductory statements, future users comment the VCI Guidance from their viewpoint and contribute additions. Next, further suggestions are taken up from the discussions in the table groups.

Thought provoker 1: Dr Michael Overs, Nanogate AG

Dr Overs points to the definition by the ISO TC 229, observing that contents of the Guidance mainly refer to powder and dusts. Because of this, other substance classes from the OECD definition might possibly receive too little attention. Substances with photocatalytic activity or radical formation potential are mentioned only once, but they do not necessarily need to be nanoscale substances. The VCI Guidance should consider this aspect, so that it should be included in a revision.

Working with the VCI Guidance for nanomaterials once more highlights the problem of drawing a borderline in terminology between "nanotechnology" and "conventional technology". Here, also changes from intermediates to end products should be taken into account. In this context, a concrete recommendation to users would be important.

As a matter of principle, the responsible handling and use of chemical products is necessary. This is particularly important against the backdrop of a technology for which it is extremely difficult to draw borderlines.

Furthermore, responsible handling and use must be communicated to consumers in a systematic manner. Companies should find out which contributions the safety data sheets can make in this context.

Thought provoker 2: Dr Winfried Kreis, BASF Coatings AG

Dr Kreis informs about the further processing of nanomaterials for coatings. BASF Coatings AG does not manufacture nanoparticles but obtains suspensions with nanoparticles from suppliers. After further processing, the produced pastes and coatings do not contain any free particles. Consequently, hazard analysis and hazard assessment are based on rules for coatings aerosols and abrasive dusts. According to Dr Kreis, it must be clarified whether the use of novel nanoparticles in coatings systems brings risk potentials that go beyond currently known risks. Therefore, possibly existing additional hazard potentials should be stated in safety data sheets from suppliers, where specific uses in the coatings sector are concerned.

Thought provoker 3: Henning Wriedt, Kooperationsstelle Hamburg, Projekt NanoCap

Mr Wriedt describes the requirements to the industry supply chain from the viewpoint of industrial health and safety in operations. In the development of communication instruments for the passing on of information, it would be recommendable to especially involve marketing/technical service departments – in order to ensure a better understanding of data. Mr Wriedt points to the need for a detailed substance characterization (in SDSs or in technical instruction sheets), for the purposes of technical specification and hazard assessment by users. Substance characterization also enables a comparability of data for products from other manufacturers and creates the necessary basis for exposure registers of exposed workers. Relevant parameters should be bindingly determined and standardized without delay. As a precaution, Mr Wriedt recommends assessing free nanomaterials as dangerous substances in SDSs (also where free nanomaterials are not classified as such) and to consequently subject them to a hazard assessment according to the German Dangerous Substances Ordinance (GefStoffV) (cp. § 3 (1) no. 4 GefStoffV). As a further extra measure, Mr Wriedt proposes to additionally incorporate exposure scenarios in SDSs, also where this is not obligatory under the REACH Regulation.

Results of the workshop to discuss the VCI Guidance:

Following the introductory statements, the participants develop – in table groups – proposals and additions to the VCI Guidance as well as further going accompanying measures. The outcomes are presented in the plenary, and some additions are made. The results are noted down in a simultaneous protocol by the anchor Dr Antje Grobe and her team, together with the participants.

Results:

General observations regarding the Introduction

- Additionally to the technical aspects (knowledge and information) of the Guidance, value attitudes should be conveyed for the handling of nanomaterials.
- The obligation to check the correctness of information given in SDSs should be communicated more clearly.
- The Guidance should emphasize more strongly that the entire life cycle of materials as such must be considered in SDSs - with information e.g. on further processing and disposal to be added, where necessary.
- It is recommended to emphasize with greater clarity what SDSs refer to, i.e.

(a) only to substances and preparations, not to products
(b) to the supply chain, not to private end consumers

Recommendations for extending the focus, in respect of contents:

- Contents of the VCI Guidance focus overly strongly on powder, while other forms of application and exposure routes are not given enough attention.
- Some workshop participants suggest the Guidance to give information on the handling of agglomerated substances, which might break down into nanoscale particles in their uses. Information in SDSs must correlate with the particle size distribution. Where special applications or uses are intended, these must be taken into account.
- Some participants discuss potential consequences of the handling of non-nanomaterials, from which free nanoparticles might form in their further processing.

Requested examples and wording aids:

- The participants request examples of ideally structured SDSs for frequently used materials – to be provided in the annex to the Guidance and on the VCI websites.
- Furthermore, the participants request wording aids for warnings.

- Suitable recommendations for the handling and storage of nanomaterials and adequate technical measures in risk management should be added to the SDS Guidance – compiled in the form of lists.
- Recommendations for voluntary exposure measuring should be given.
- The Guidance should include information on how companies can justify why certain items of information are not provided, taking into account relevant legal rules.

Terminology:

- In the Guidance the term "product" should be replaced by the term "substance/preparation".
- The wording of fields of application in the SDS should be reviewed: section 2 on page 3: fields with specific legislation (tobacco products etc) are not clearly worded.
- The distinction between nanoparticles and nanomaterials should be definitely clarified, with a uniform terminology to be agreed. The wording in section 3 should be supplemented with "Release in individual cases".

Closing panel: Response from politicians, public authorities, NGOs and industry

Anchor: Dr Antje Grobe, Stiftung Risiko-Dialog

Former state secretary Wolf-Michael Catenhusen (chairman of the nano-commission of the German federal government) highlights the important role of German companies in the international debate about the responsible handling and use of nanomaterials. He acknowledges and recognizes the activities of VCI. This association is leading the way, especially in the dialog with stakeholders when it comes to actively dealing with concrete questions of industrial health and safety and – in this event – with questions of information along the supply chain. He points out that the safety data sheet is designed as an important instrument for users in industry, but not as a communication instrument for end consumers. Here, an adequate form must be found, in order to ensure transparency for consumers and to build trust. Possibly, information from SDSs could be suitably prepared for this purpose. Mr Catenhusen sees the dialog about the responsible use of nanotechnologies as a joint learning process and as a special chance to constructively bring together the interests of different stakeholder groups – for a successful use of technological potentials of nanomaterials in Germany as a location of innovation.

Dr Anja Klauk (EU Commission, Directorate-General Enterprise) wants to contribute the results of this VCI event into the work of the Commission. In her view, closing the knowledge gaps regarding test and measuring methods counts among the most pressing goals, as this is decisive for concrete implementations. Furthermore, she endorses the demand to increasingly make information publicly available, in a way which is also understandable to end consumers. A relevant "stakeholder forum nano" will be held at European level. Dr Klauk once more stresses the importance of communicating more clearly the REACH requirements to the handling and use of nanomaterials. Once again, she draws the attention to a forthcoming overview by the European Commission.

Ministerialrat [rank in the German civil service] Dr Helmut Klein (German federal ministry of labour and social affairs) gives an expressly positive picture of the VCI's activities. At present, the decisive point for him is the communication between industry associations inside the European Union. It emerges in the European Chemical Industry Council (CEFIC) that the position of the German federal government is not always supported by all EU Member States. Furthermore, in his view the dialog between the associations of different industries needs to be intensified. He recommends incorporating standard examples in the Guidance, spreading both at international level. He is positive about the frankness of companies which gave presentations at this

workshop. Moreover, he advocates an orchestrated strategy of industry, in order to close the knowledge gaps addressed by Dr Klauk - on the basis of voluntary agreements.

Henning Wriedt (Kooperationsstelle Hamburg, Projekt NanoCap) describes the VCI's dialog as an exciting and transparent process. He highlights the positive development in the disclosure of relevant data by the companies. In particular, examples for the concrete design of SDSs are seen as an important step in this direction. He pleads to analyze in detail the REACH requirements to the handling and use of nanomaterials – enabling an identification of open questions and discussions with stakeholders about possibly necessary information. Furthermore, he believes in the usefulness of voluntary agreements, additionally to regulation. Finally, Mr Wriedt notes that the early involvement of trade unions in the approach to new technologies is a novelty – not for Germany, but for many other EU Member States -, so that trade unions still need to gather experiences in this respect.

Dr Gerd Romanowski (Verband der Chemischen Industrie e.V.) points out that SDSs for chemical substances are frequently available on the internet. This is highly recommendable for nanomaterials, against the backdrop of the public debate and the need for information. However, SDSs are not suitable as communication instruments for the dialog with consumers. Here, companies are called upon to develop adequate offers of information. All in all, Dr Romanowski sees the event in a very positive light. He thanks the participants for their manifold suggestions for the further development of the VCI Guidance. Some of the proposals from the working groups – such as e.g. the request for standard examples – will be taken up right away and implemented as soon as possible.

As the next step, VCI will publish further information on the safe handling and use of nanomaterials against the backdrop of the REACH Regulation. This information will be publicly discussed at an event. VCI is planning for 2009 a stakeholder dialog about "nano and the environment". US companies and the German chemical industry are driving forces in the OECD Working Party on Manufactured Nanomaterials. These events make major contributions in efforts to fulfil this international responsibility.

Dr Antje Grobe, Alexander Jäger, Viola Schetula
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