Report

Traceability of nanomaterials

Nano-databases and notification requirements

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Content

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1 Background

Nanomaterials have been on the EU market for a long time; even longer than the term “nanomaterial” exists. For example nanoscale gold particles were used as early as the medieval times to produce red glass. According to the predictions of different organizations the number and volumes of different nanomaterials as well as the number of different uses and products in which they are applied will significantly increase in the future, due to the (newly emerging) possibilities for their targeted manufacturing and design. Therefore, the likelihood of man and environment being exposed to nanomaterials will increase as well as the concentrations or doses of nanomaterials to which exposure may occur.

Hazards to human health and the environment have been identified through testing for some nanomaterials. Some may e.g. induce inflammation of the lungs after inhalation; others may inhibit algal growth. For a few, well tested nanomaterials adverse effects could be excluded based on testing. However, for many nanomaterials and their different modifications information on the hazardous properties is not available (yet).

Risk assessment of chemical substances and hence, also of nanomaterials, requires information on the likely exposures of humans and the environment, in addition to the data on the hazardous properties. Data on the use patterns of nanomaterials can be used to estimate emissions from industrial and professional processes and from products. From this, human and environmental exposure can be estimated. Consequently, the information on the real uses forms the basis for any exposure assessment and only the combination of this information with the hazard of a nanomaterial allows concluding whether or not there are risks connected to specific uses or if a use can be considered as safe.

In order to enable governments to fulfil their obligation for public and environmental welfare, they need to have information on how to protect against the current dangers and to identify potential future risks in order to efficiently prevent them. A separate report was published by the NanoCommission on the legal framework, the options to act on and the use of the precautionary principle in this regard.

Nano-databases and notification requirements for nanomaterials and nanoproducts can support the implementation of the governments’ obligation to provide for public welfare by supporting a sound knowledge base. The information in these databases can be used for the strategic development of policies and risk management measures to protect against dangers, e.g. by product recalls and for the provision of information for consumers.

This report aims to give an overview of different aspects in the context of goals and structures of databases with information on the manufacture and use of

nanomaterials as well as respective notification requirements. Activities at EU level and in the Member States (as of April 2012) are briefly presented. Aspects related to the labelling of and the risk communication on products containing nanomaterials are also shortly introduced.

The report is based on the discussions of the FachDialog 2 of the German Ministry of the Environment, Nature Protection and Nuclear Safety, which took place in April 2012 in Berlin. The FachDialog is part of the third dialogue phase of the NanoDialog of the German government.

2 Aims of nano-databases and information needs

In general, databases on (the uses of) nanomaterials can satisfy information needs of different actor groups, can serve different purposes and can be developed and maintained by different organizations. The discussions at the FachDialog and the following sections of the report focus on regulatory databases maintained by state authorities.

The purpose of a database determines to a high degree which information should be collected from which actors and at which level of detail. The purpose defines content and structure of the database and factually also the extent of the information input and thereby the notification requirements to the target groups. At the same time the purpose determines and describes the benefit of the database. A respective description and also the potential quantification of the benefits, such as the reduction of environmental damage or of the incidents of occupational disease, are among others helpful and necessary for regulatory impact assessments and the design of respective legislation.

For authority-run nano-databases three main purposes can be distinguished:

- **Support for risk assessments** by national authorities or at EU level by providing information on emissions and exposures from manufacture, use and disposal of nanomaterials and nanoproducts.
- **Enabling long-term traceability** of nanomaterials. In this context the term traceability means that information is available on product types containing a nanomaterial and the total amount used for this product type but not the concentration[1]. This information can help legislators to target risk management measures and ensure safe disposal of nanomaterial-containing wastes in the future.

[1] In this context, traceability does NOT mean that a specific substance can be identified and traced back from a specific article up the supply chain, such as it is implemented in the food sector.This type of article-specific traceability is addressed in the next bullet point ofthe list (market transparency).

- **Ensuring market transparency** e.g. to support an efficient and targeted market surveillance and to enable product recalls, in case safety concerns arise after they have been placed on the market. This purpose requires concrete information on the actors that place nanomaterials and nanoproducts on the market or use them.

These three main aims of nano-databases are discussed further in the following sections, including a characterization of the related information needs and a comparison with the currently available information on nanomaterials.

Another goal – the provision of information on nanomaterials in concrete products to consumers – should be regarded separately, as discussed in the second FachDialog. The central information instrument in this context is not the database but the product information or product labels. Nevertheless, a database connected to such product information could be helpful to provide background information.

2.1 Support for risk assessments

2.1.1 Explanation of aim and related information needs

Risk assessments of substances and hence, also of nanomaterials should lead to the identification of the uses and the subjects of protection (environment, workers, consumers) at risk, for which risk management is necessary. In this regard, risk assessment is an essential and integral part of precautionary policy making not only at the EU level and in the Member States, but also in the area of corporate responsibility and related actions.

Chemical risk assessments and related processes, which have been carried out for a long time are coordinated by the EU and conducted by the Member States[2].

Risk assessment (particularly the exposure assessment) requires information on use patterns. The more concrete the information on use patterns is, the more precise the risks can be identified and assigned to specific products or uses. With the term “use pattern” the following data are understood in relation to nanomaterials:

- product types (mixtures and articles) in which nanomaterials are contained,
- market amounts of these products and the average concentration / amounts of nanomaterials contained therein,

[2] The authorities of the Member States have assessed the risks of prioritized substances in the context of the Existing Substances Regulation (Regulation (EC) Nr. 793/93 of the Council of 23 March 1993 on the assessment and control of environmental risks from existing chemical substances). Under REACH this procedure is implemented as substance evaluation by the Member States. The European Chemicals Agency (ECHA) may also conduct substance evaluations. Proposals on marketing and use restrictions under REACH can also contain (parts of) risk assessments to justify the necessity and the type of restrictions. The REACH procedures are also applied to nanomaterials.

- industry sectors and conditions of use under which the products are actually applied,
- potentially also information on the disposal of the products and/or the waste types resulting from the product use.

This information is needed for the risk assessments not only by state authorities, but also by industry actors.

2.1.2 Existing information

The REACH registration dossiers should contain general information on the identified uses and the uses advised against for all substances, as well as the volumes and compositions of wastes from all life cycle stages (Annex VI, sections 3.5 to 3.7). For substances registered in amounts between 1 and 10 t/a only information according to Section 6 of REACH Annex VI is to be provided, specifying the type of users as industrial, professional and/or consumers.

If chemical safety reports are required in the registration dossier and if these contain exposure assessments[3], the uses have to be described in more detail by means of the use descriptor system[4]. A specification of the amounts of the substance supplied to the different uses is not necessary to date.

Manufactured nanomaterials are substances according to the substance definition of REACH and therefore they fall under the scope of REACH. After the end of the phase-in scheme, information on use patterns of nanomaterials should be available at the level of detail outlined above, if they are registered either as self-standing or as specific uses of substances.

Information from the registration dossiers are published in the ECHA database of registered substances. The competent authorities of the Member States in principle have access to all information in that database.

2.1.3 Gaps in the available data

Apart from the unclear issues related to the possibility of registering nanomaterials as a specific use or as self-standing substance as well as the questions on the definition of the substance identities of nanomaterials with a focus on potential functionalisation, it is already obvious now that the information from the REACH registration will not be sufficient to support a well-founded risk assessment at EU level, among others because:

[3] A chemical safety report is only required for substances, which are registered in amounts exceeding 10 t/a. The registrant is to carry out an exposure assessment and risk characterization for substances, which fulfill the criteria as dangerous according to the classification and labeling regulation (Regulation (EC) Nr. 1272/2008 OF THE EUROPEAN PARLIAMENT AND THE COUNCIL of December 16, 2008 on the classification, labeling and packaging of substances and mixtures) as well as for other hazardous substances, under certain conditions.

[4] The use descriptors are listed in the ECHA guidance document on information requirements and chemical safety reports, Chapter 12 (http://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf). They characterize the manufacturing and using industry sectors, the environmental relevance of processes, the types of mixtures as well as articles, in which chemicals are used.

- the use descriptors are too general and address only broad uses (the identification of specific consumer products and product types is not possible) and therefore can only be a starting point for emission estimations and exposure assessments,
- the amount of a substance/nanomaterial is not specified with regard to the different uses it is applied to.

Furthermore, no information will be available on nanomaterials which don't have to be registered, e.g. because they are manufactured or placed on the market in small amounts or because they are excluded from the scope.

An additional, more technical problem is that the chemical safety reports are provided as pdf-files with the registration dossiers. Due to this, the information on uses is not part of the database and up to now cannot be easily structured and analysed. This problem may be solved when the submission of chemical safety reports is changed to an IT-assessable format, which may be the case with the introduction and use of the ECHA-tool CHESAR.

2.2 Long-term traceability of nanomaterials

2.2.1 Explanation of the aim and information needs

Nanomaterials in long-lived products may remain in the technosphere for a long time. It is possible that in the future information on nanomaterials and their potential adverse effects becomes available, which is currently not known. In order to prevent or reduce future health and environmental risks from nanomaterials by regulatory action, it is necessary to know in which types of products nanomaterials are used.

In this context, the term "long-term traceability" means that information on product types and the total volumes of the nanomaterial used therein (not the concentrations) are available.[5] Establishing long-term traceability of nanomaterials requires the following types of information:

- specific product types that contain nanomaterials,
- specific amounts of nanomaterials in these product types,
- the manner of inclusion / function of the nanomaterials in these product types,
- quantified use patterns based on market information.

This information is particularly relevant for durable articles because they "store" nanomaterials. Information on mixtures used in the production of long-lived articles is also helpful. Information about concrete individual products and market actors is not necessary[6].

[5] In this context traceability does NOT mean that a specific substance can be identified up the supply chain in a specific product, as e.g. possible via the codification of meat or eggs in the food sector.

[6] This is an important difference to the third aim of creating market transparency.

2.2.2 Existing information

Information on product types containing nanomaterials in the area of cosmetics, biocides, food and food contact materials will be available in the near future. It will originate from obligatory authorization or notification procedures of the manufacturers of nanomaterials and/or nanoproducts. It is anticipated that the information will cover all marketed products.

2.2.3 Gaps in the available data

There is no systematic approach for data collection and provision on nanomaterials in long-lived articles. The majority of marketed articles don't have to be identified or notified.

In general, information on the possible uses of nanomaterials and the respective product types are available in the different use sectors and in sector publications. However, it is fragmented and cannot be structured and assessed centrally. Furthermore, this information does not give an overview of all realized uses, which would be necessary for efficient risk management of end-of-life products containing nanomaterials.

The information on nanomaterials in specifically regulated products, such as biocides or food contact materials are not connected to market volumes. Therefore, the relevance of a particular use of a nanomaterial can neither be evaluated short term nor in the long run. Furthermore, this information is available only for short-lived articles (food contact materials) or mixtures, for which a long-term traceability is not so relevant.

2.3 Creation of market transparency

2.3.1 Explanation of the aim and information needs

Providing protection to workers, consumers or the environment against dangers from nanomaterials, which may become evident from new scientific or technical information, may require for example a product recall. Recalling products from the market require knowledge of the concrete products and the specific actors who have placed them on the market. This type of information can also be used to develop market surveillance strategies or orientate the enforcement activities for installations (priority issues, enforcement campaigns). Furthermore, it may form the basis of consumer information on single products, if necessary.

Creating market transparency necessitates the following information:

- single actors that manufacture and/or use nanomaterials,
- specific, individual products (including trade name) containing nanomaterials as well as
- type, function and concentration of the nanomaterials in these products.

Information on the (total) market volumes is helpful but less relevant for this aim.

2.3.2 Existing information

Some nanomaterials in specific products may have to be authorised or notified, e.g. under legislation on biocides and cosmetics or food. The authorization and notification procedures deliver information on the (planned) uses of nanomaterials to the EU or national authorities. Information on the concrete individual products will become available only in some cases[7].

Different organisations have established databases with specific products and their content of nanomaterials[8]. Different products as well as the actors placing them on the market and the types of nanomaterials contained are named, including the trade name.

2.3.3 Gaps in the available data

A systematic overview of individual, specific products containing nanomaterials is not available up to now.

Databases are available or will be established soon for a few, specifically regulated mixtures. They will be populated with information from regulatory procedures which among others comprise of a scientific risk assessment.

The product registers in the Nordic countries, which are a comprehensive information source on recipes and uses of chemical products (mixtures) do not allow the identification of nanomaterials, because respective information on the characteristics (size) of the components is not separately collected.

The product databases on nanoproducts run by non-state organisations are mostly founded on public information by the producers. They are limited to this voluntary information and therefore neither complete nor have a quality assurance.

[7] For example, substances (nanomaterials) may only be used in food contact materials if they have been authorized respectively. However, the food contact material in which they are actually used in does not have to be authorized. Hence, only the intended but not the actual use of the materials is known. Also the actors placing the nanomaterial on the market as part of a food contact material are not known.

[8] See also the database on consumer products containing nanomaterials established by the „Project on Emerging Nanotechnologies“ at http://www.nanotechproject.org/inventories/consumer/ or in Germany the product register of Friends of the Earth at http://www.bund.net/nc/themen_und_projekte/nanotechnologie/nanoprodukt datenbank/produktsuche/.

3 Substance databases and product registers

In general two conceptual approaches of databases for chemicals can be distinguished.

- **Substance-based**: information is collected which focuses on the use of the substance in mixtures and articles and what these are used for.
- **Product-based**: specific (chemical) products (usually mixtures) including their ingredients (recipes) are included together with the product uses and other information related to the product.

These two approaches are structurally different. However, if the data and data structure have a high level of detail, it should be possible to generate reports of similar contents. For example, if a substance database contains detailed information on uses, the product types / categories containing nanomaterials can be extracted. The same information can be obtained from a product-based database by searching all recipes for the specific nanomaterial.

3.1 Substance-based approaches

A number of substance-based databases exist, among others with information on toxic/ecotoxic substance properties, such as the ECHA-run European inventory on classification and labelling. ECHA's database of registered substances contains, apart from information on hazards, also information on safe handling and generic uses. This information has been partially published.

For nanomaterials primarily the establishment of substance-based databases is discussed. They are expected to provide information on the nanomaterials' uses in form of types / categories of mixtures and potentially also of articles (with or without intended or likely release from the article). In contrast to the database of registered substances, this type of database would also contain the marketed amounts of nanomaterials.

3.2 Product-based approaches

The product registers of the Nordic countries which contain recipes and uses of chemical products (mixtures) are good examples of product-based approaches. Currently the particle size is not a property covered in them and therefore, no respective data evaluation is possible.

According to Article 45 of the Classification and Labelling Regulation[9]the EU Member States are required to establish national product registers[10] in order to support general prevention and emergency measures in case of potential damage to human health from mixtures. The registers should among others contain information on the composition of mixtures classified according to the regulation. The regulation does not require distinguishing the mixtures' components according to their size. An identification of nanomaterials is hence not principally foreseen, but could occur if specific classification rules or information on specific risks exist and/or are included.

The recipes of mixtures are confidential business information know-how and need to be protected as such. Therefore, product registers pose high data security requirements. In current discussions on nano-databases the concept of product registers is practically not mentioned. Additionally, the Nordic countries don't seem to consider the option of including information on nanomaterials in their product registers.

3.3 Design of nano-databases

The following sections provide background information on some core aspects on the design of nano-databases.

3.3.1 Possible level of detail of information and actors to be addressed with notification requirements

As described above and according to the current understanding, substance databases contain information on nanomaterials along their life-cycle and product registers contain information on chemical products (mixtures) and their (complete) composition[11].

The level of information detail may vary in substance databases and product registers. Which level of detail is desirable depends among others on the purpose of the database. Table 1 illustrates some levels of detail in a schematic way.

[9] Article 45(1) „Member States shall appoint a body or bodies responsible for receiving information relevant, in particular, for formulating preventative and curative measures, in particular in the event of emergency health response, from importers and downstream users placing mixtures on the market. This information shall include the chemical composition of mixtures placed on the market and classified as hazardous on the basis of their health or physical effects, including the chemical identity of substances in mixtures for which a request for use of an alternative chemical name has been accepted by the Agency, in accordance with Article 24."

[10] In the CLP-regulation the term only addresses mixtures.

[11] The existing product registers don't contain information on specific articles. This may however change in the future.

Table 1: Type and level of information detail on nanomaterials (NM) in substance databases and product registers

Substances		Products (mixtures)
Generic use patterns	Level of detail ⇩	
Quantified use information NM amount (per use)		Concentration ranges of NM in product types / categories Standard recipes
Market actors and NM amounts, which they place on the market or use		Individual products Specific recipes Concentrations of NM
Total amount of NM in all individual products		

The level of detail of the information contained in a (nano-) database naturally depends on the availability of information to the data providers and hence, the types of actors covered by a respective notification requirement.

Usually, nanomaterial manufactures can only generically describe the final uses of their products based on the functions and their knowledge of their markets and their customers' activities. Therefore, they may only describe generic use patterns and give rough estimates on the distribution of produced amounts between the different uses.

Nanoproduct producers (formulators) usually have information on the concentrations and amounts of nanomaterials in their products. As mixtures frequently have quite specific functions, which are considered in the development of respective recipes, they can normally describe their customers' use types specifically. Hence, databases covering information from formulators model the actual use of nanomaterials rather specifically and are based on actual market data. Through the aggregation of this data, the total amounts per use can be identified.[12]

Article producers could also be in the scope of potential notification requirements. They can specify the final articles and uses of nanomaterials and contribute information which may also be needed at a later point in time, e.g. for safe management of article wastes.

If formulators and article producers, which are not covered by the ECHA database, are included in a notification requirement for a nano-database, these actors and the nanomaterials and specific products they handle would be covered too, enabling long-term traceability and market transparency on actors and products (c.f. Section 2).

[12] If formulators are required to notify specific, individual products (trade names) it will enable product recalls, also.

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3.3.2 Product types in nano-databases

The range of products potentially contained in a nano-database can be distinguished according to the life-cycle stages substance, mixture and article.[13] Within these stages further differentiations are possible.

For nanomaterials among others the following distinctions are possible:

- All nanomaterials (substances) are covered or
- some nanomaterials are omitted, e.g. materials which have been proven to have hazardous properties, or
- only specific groups of nanomaterials are covered, e.g. a manageable set of specific nanomaterials could be included at the start or nanomaterials of which hazardous properties are known or expected, or which are used in certain applications.

In relation to mixtures, the coverage of nano-databases could be differentiated according to the following groups:

- mixtures for the general public or mixtures for professional use,
- specifically regulated mixtures (e.g. cosmetics, biocides) or non-regulated mixtures,
- mixtures from which nanomaterials may be released and mixtures, from which they may not be released.

In relation to articles the main differentiations are

- if a release of nanomaterials, as defined under REACH, is intended,
- if a release of nanomaterials is possible in principle,
- all articles are considered.

Which products are covered is an important determinant for the complexity of the information structure and therefore, also for the design and extent of notification requirements. The product coverage also determines the notification efforts of the market actors and the data processing efforts of the authorities.

3.3.3 Responsibilities

The share of responsibilities between market actors and authorities is more or less obvious with regard to nano-databases run by state authorities:

- The market actors fulfil the notification requirements and thereby provide the information to be stored and published in the database.
- The authorities build up the database and the technical infrastructure, the reporting system and ensure data security. They enforce compliance with the notification requirements.

It should be discussed how the quality of the notified data is ensured and how to balance the authorities' data interests and the notifiers' confidentiality concerns.

[13] There don't seem to be any considerations regarding an inclusion of information on the waste stage.

4 Activities on nano-databases (Spring 2012)

4.1 Activities of the EU Commission

The EU Parliament has asked the EU Commission to establish an inventory of the types of nanomaterials and their uses on the EU market[14]. In addition, the Environmental Council[15] has invited the Commission to "*evaluate the need for the development of specific measures for nanomaterials relating to risk assessment and management, information and monitoring, including the further development of a harmonized database for nanomaterials, while considering potential impacts*."

In the context of the EU regulatory review related to nanomaterial a Commission Communication will be published[16] which will among others contain information on how the EU intends to address nanomaterials in the future and which regulatory activities will be prioritized.

4.2 Activities of ECHA

ECHA operates two substance databases. The database on registered substances provides information on the hazardous properties and on the safe use of nanomaterials, if they have been registered either separately or as a use of a bulk substance. At present the database contains comparatively little information on nanomaterials. The data amount and quality is expected to increase over time among others because of the publication of guidance documents, which clarify how nanomaterials should be registered and which information should be submitted.

ECHA's classification and labelling inventory contains information on the classification of substances on the EU market, if they have been notified by their manufactures or importers separately or via the REACH registration dossier. As classification is to take the particle size into account, the information in that database should be specific for nanomaterials.

Both of ECHA's databases are still being developed.

4.3 Activities of the Member States –example France

The French government has adopted legislation implementing an obligatory notification requirement for nanomaterials. Information from the notifications will be included in a database.

[14] http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P6-TA-2009-0328&language=EN

[15] http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/envir/118646.pdf

[16] The Commission communication was not available at the time of writing this report.

The aim of the notification and the database is to improve the market transparency in the EU. It should be ensured that quick and appropriate action can be taken by the French authorities in case possible specific risks caused by nanomaterials are identified. In addition, more information on the identity and uses of nanomaterials should be made available to consumers and workers.

The manufacturers and importers into France[17] as well as the users of nanomaterials as such or in mixtures are obliged to notify information to the French authorities. Starting in 2013, the following data is to be reported annually if a threshold of 100 gram per year is exceeded[18]:

- identity of the nanomaterial,
- use of the nanomaterial,
- amount manufactured, imported or traded,
- identity of users.

Information on the identity and use of nanomaterials are intended to be published in an aggregated form as general report.

The French nano-database is substance-based and supports the traceability of nanomaterials, but it does not contain data on specific individual products.

4.4 Activities of the Member States – working group on the harmonization of nano-database approaches

The French initiative for a notification requirement is supported by Belgium, Italy and Denmark, who also want to establish a nano-database. Other Member States are following these processes and discussing similar national approaches. The German Minister of the Environment has also stated to consider options for the implementation of nano-databases. All Member States want to contribute to an improved regulatory framework at EU level.

The Member States considering the implementation of notification requirements have established a working group and agreed on several aspects to harmonize their processes.[19] This regards among others:

- use of the IUCLID data format to ensure compatibility of databases, e.g. with ECHA and international databases,
- collection of a core data set (e.g. product type),
- coverage of core product types (e.g. mixtures for professional use).

The working group also agreed that the participating Member States may collect additional data and/or include additional product groups into the notification and

[17] In this context and in contrast to the REACH definition, the term "importer" addresses actors who introduce products from a country outside of France into France, i.e. also actors in Germany of Greece.

[18] There are exemptions from the notification requirements, e.g. for uses in research and development.

[19] A document of the working group with information on their specific considerations is provided at http://www.oekopol.de/de/themen/chemie/nano/nanofachdialog/fd2/Material_fd2/Harmonization%20doc%20_17052011_last%20rev.pdf

database system (e.g. articles with intended or possible release of nanomaterials).

Under the condition that the establishment of a nano-database is regarded as necessary and helpful, most actors evaluate an implementation at EU level as most efficient and reasonable solution. The following aspects are the main arguments brought forward.

- A centralised notification and database instead of various, potentially differing national approaches simplify and harmonise data collection and data processing. The workload for all actors is expected to be lower if a central approach is implemented.
- The impacts of notification requirements cannot be limited to the national territories due to the international trade. “Importers” which have to notify the authorities need information from their suppliers. Hence, the suppliers are indirectly affected by the (national) requirements and, if “exporting” to companies in different countries might have to provide slightly different information to them.
- A nano-database at the EU level could be easily harmonized with the REACH registration of substances and could therefore be in analogy to the regulations for biocides, plant protection products, cosmetics and food etc. This would also avoid the need to have different meanings and understandings of “imports”, which would exist in the case of national notification requirements.

Arguments against an EU-wide nano-database include that there is currently no consensus about whether or not a nano-database is an appropriate, necessary and desirable instrument of a precautionary approach to environmental and health protection.

It should also be born in mind that the development of a regulatory basis and the needed EU-wide consultation processes, considering national priorities and approaches, would probably prolong the time period until a nano-database is operational to a period of 5 to 10 years.

5 Labelling of nanomaterials and products

Labels of nanomaterials and nanoproducts can be further important information instruments, in addition to or separately from nano-databases. Labels are directly linked to specific products and are the most important primary information source for consumers and workers.

The aim of the chemicals-related labelling is the communication of product hazards and advice on how to protect oneself against them (safety phrases).[20] In other regulatory areas further labelling systems exist with other information aims and purposes. Some examples are:

- CE labelling –conformity with EU norms and standards,
- Waste – labelling – advice on waste disposal,
- Eco-label – advantageous environment-relevant product quality,
- Product codes –quality and origin of products, such as eggs,
- Tables with nutritional values –nutritional value of foodstuff,
- List of ingredients – product composition (e.g. for cosmetics; here ingredients at nanoscale are to be labelled with “nano”).

Focusing on the large amount of information and labelling, which are complemented by an even larger number of voluntary labels of manufactures and quality certificates, current surveys and analyses show that most consumers are not able to distinguish and understand the information from these information instruments correctly[21].

A relationship between information on nanomaterials with the chemical labelling, but also separate information on the content of nanomaterials in products could be perceived by the general public as a potential risk.

A potential perception that nanomaterials may per sé be connected to risks should, also according to the opinion of the participants in the FachDialog 2, be prevented. It is important to establish a differentiated and trustworthy communication of the benefits and potential risks from nanomaterials and products containing these. In addition, it may be helpful to also communicate on the current information gaps. Whether or not the goal of providing sufficiently differentiated consumer information can be reached by means of product labels only or by means of labels in connection with a nano-database for background information is a subject that requires an in-depth analysis.

6 Summary

Nano-databases can be useful instruments for the risk management of nanomaterials. Information on the uses of nanomaterials in specific product groups / products and by certain actors can be provided to support risk assessment, market surveillance or prevention of dangers from products.

[20] Chemicals related labelling only regards mixtures and not articles; however, mixtures contained in articles are covered, such as pens and toner cartridges.

[21] C.f. the study by the BfR on product labels http://www.bfr.bund.de/cm/350/grenzen_und_moeglichkeiten_der_verbraucherinformation_durch_produktkennzeichnung.pdf or the current survey on the consumer knowledge on nanomaterials http://www.risiko-dialog.ch/images/RD-Media/PDF/Themen/Nanotechnologie/Consumerstudy_Nano_EN.pdf

The design of such databases and the information needed to populate them can however be very different. A general discussion of the instrument “nano-database” is therefore not helpful. It is necessary to first define the aims and purposes of these databases in order to start a fruitful discussion on the need for information and the related workload for the notifiers (among others which actors should be involved, which type of data should be reported how often and at which level of detail).

Several activities related to the establishment of nano-databases can be observed at the EU-level at the present time. It is currently not clear in which direction the activities of the EU Commission and the Member States will develop in the future.