# FINAL REPORT OF NANOKOMMISSION ISSUE GROUP 1

- PRINCIPLES PAPER

Second Dialogue Phase, 2009 - 2011



COMPLETED: 23 JULY 2010

## 1 REMIT

In the NanoKommission's first dialogue phase, a Working Group (WG 3) was set up to undertake the task of producing "Principles for responsible use of nanomaterials". These principles were intended to create a framework for action on the responsible use of nanomaterials and, in tandem with existing regulatory measures which cover nanomaterials in principle but may require amending, provide an umbrella under which science and industry could develop and apply the new technologies in a responsible fashion. The principles have a special role to play at a time when efforts are being made to close knowledge gaps and establish a scientific basis for updating current legislation. In its final report on the first dialogue phase, the NanoKommission recommended the development of a system for monitoring implementation, the publication of the names of firms/sectors which have committed to apply the principles, and a review of the principles after two years. Furthermore, it recommended that the Principles Paper should be extended to include other sectors in which nanotechnologies or nanomaterials are used.<sup>1</sup>

The remit assigned by the NanoKommission to Issue Group 1 (IG 1) in the second dialogue phase relates directly to these recommendations:

- To monitor implementation of the principles for responsible use of nanomaterials within the chemical industry (manufacturers of nanomaterials and of preparations containing nanomaterials), including evaluating "principles" as an instrument and assessing potential ways of optimising them.
- To expand the recommendations on practical guidelines for implementing the principles, especially relating to the possible integration of environmental and consumer protection issues.

To give concrete form to this basic remit and to implement other NanoKommission requirements, the Issue Group divided its work into the following four "packages":

- 1. To review the use of guidelines to specify the principles
- 2. To assess approaches for monitoring implementation of the principles
- To expand the recommendations in the areas of environmental and consumer protection
- To discuss options for extending the scope of the principles to cover other sectors.

<sup>&</sup>lt;sup>1</sup> Excerpts from "Responsible Use of Nanotechnologies: Report and recommendations of the German Federal Government's NanoKommission for 2008" (p.62ff.), concerning the first dialogue phase.

# 2 KEY DISCUSSIONS AND FINDINGS

### 2.1 General discussions

In the course of the Issue Group's work a number of general, cross-cutting issues emerged concerning the status and function of the NanoKommission Principles and the various ways in which they are implemented on the ground. Below we present the findings of the Group's discussions.

### 2.1.1 Status and function of the principles

In line with the recommendations from the NanoKommission's first dialogue phase,<sup>2</sup> the Issue Group thoroughly reviewed the Principles Paper, including its basic content.

Although debate within the group was intense and on occasions heated, fundamental agreement prevailed that the principles were (still) entirely fit for purpose and appropriate in their present form.

There were clear differences of opinion among group members, however, as regards status and function of the principles, and as regards how to assess the possible ways of implementing them. From the industry point of view the principles do not represent a voluntary commitment. Rather, they tend to be viewed as a sensible framework established on the basis of stakeholder consensus to foster responsible behaviour within industry.

Trade unions and environmental and consumer organisations, meanwhile, feel that the conditions necessary for "principles" to achieve broad acceptance as a policy instrument have not yet been established. These include most notably arrangements for external monitoring of implementation of the principles, and clarification of the commitment entered into by organisations when they adopt the principles, and of the consequences resulting from failure to adhere to them. It is difficult to arrive at any agreement in this area, especially as this would require more binding principles.

### 2.1.2 Commitment by companies to implement the NanoKommission Principles

Discussions within the Issue Group on the ways in which companies demonstrate their commitment to apply the principles revealed the need to differentiate between two distinct variants:

• "Explicit" commitment, where the company in question "publicly" declares its commitment to implementing the principles for the responsible use of nanomaterials.

<sup>&</sup>lt;sup>2</sup> cf. Report (2008), p.63

"Tacit" commitment, where the company implements the relevant sections of the principles for the responsible use of nanomaterials within the company divisions concerned. However, the company makes no clear, outwardly evident connection between this practice and the NanoKommission Principles. Instead, it implements them "implicitly", e.g. as part of general company governance.

No instances of explicit commitment by individual companies were identified by the Issue Group.

According to the interpretation of representatives of the German Chemical Industry Association (VCI), companies in the chemical industry are committed to implementing the NanoKommission Principles. Since these are already incorporated into existing governance structures and risk management systems, however, companies have not made any public declaration relating to the principles. In multinational corporations, moreover, it is difficult to achieve "explicit" commitment to principles that are connected with dialogue at national level. Small and medium enterprises (SME), meanwhile, generally face significant constraints in terms of the human resources required to meet the (additional) communication needs.

Within the Issue Group it was agreed that both approaches could, in principle, be equally appropriate in terms of the degree of established material protection they provide in the context of a company's operations. From an external perspective, i.e. for the purposes of dialogue with external stakeholders, there are, however, distinctions which need to be drawn:

Tacit commitment does not enable external stakeholders to

- identify "nanomanufacturers", and hence they have no starting point for contacting them directly or for pursuing dialogue at a more concrete level;
- ensure that a firm adheres to its commitment to the principles (e.g. concerning dialogue or information provision).

During the discussions, several of the participants in the Issue Group complained that tacit commitment runs counter to Principle 2, the transparency principle, as well as to the NanoKommission's recommendation with regard to the publication of the names of firms committed to applying the principles.

### 2.2 Inclusion of the principles in (sector) guidelines

In the first NanoDialogue phase, special emphasis was placed on implementing the principles by means of including and disseminating them in sector-specific guidelines.<sup>3</sup>

<sup>&</sup>lt;sup>3</sup> See e.g. discussion at the top of p.53 of the Report (2008).

NanoKommission Issue Group 1 was therefore given the task of developing criteria for assessing how (existing) sectoral guidelines translate the principles into specific contexts, conducting an initial stock-taking exercise and evaluating the benefits and limitations of sector guidelines as a tool.

A review of existing guidelines (see summary in Annex 2) produced the following results:

- In addition to individual company's codes of conduct, the chemical industry has produced guidelines for the sector as a whole that address the use of nanomaterials.
- At the level of the sectors using nanomaterials, so far only the German paint and printing ink industry association has produced sector guidelines.
- Only very few guidelines address the NanoKommission Principles directly. One reason for this is that the majority of existing guidelines (and company codes of conduct) were published before the principles were developed.

The Issue Group feels that there is still a need for nano-specific sector guidelines, particularly in the sectors using nanomaterials.

In order to assess the extent to which existing guidelines and company codes of conduct address and, where relevant, give concrete form to the NanoKommission Principles, a sub-group of the Issue Group devised an evaluation matrix.<sup>4</sup>

This matrix is intended to facilitate qualitative assessment of the extent to which the priorities underlying the Five Principles, set out in the Principles Paper, are covered. In addition, the matrix also assesses whether the document in question addresses one, two or all three of the protection targets (environment, occupational health and safety, consumers). The following table shows the matrix used:

Criteria	Evaluation	
	Principles addressed (Qualitative assessment -, 0, +)	Principles given concrete form (Qualitative assessment -, 0, +)
Equal consideration given to all protection targets (occupational health & safety / environment / consumers)		
1. Definition and disclosure of responsibility and management (good governance)		
Definition of responsibility in the management context		
Clarity of definition to outsiders		
Regular or continuous reporting		
Establishment of a clear and verifiable management system		
2. Transparency regarding nanotechnology-related information, data and processes		
Information on use of nanomaterials and products derived from them		
Information on relevant safety assessment issues		
Information on measures applied and recommended for safe use		
Information presented in appropriate way for target audience		

<sup>&</sup>lt;sup>4</sup> In addition to the Issue Group spokesperson, the sub-group included representatives of the German Chemical Industry Association (VCI) and environmental organisations.

3. Commitment to dialogue with stakeholders				
Conducting or fostering dialogue with interested stakeholders				
Evaluation of dialogue activities				
4. Establishment of risk management structures				
Appropriate application of the precautionary principle				
Indications of possible substitution testing				
Involvement of final consumers and partners in the supply chain				
Documentation of knowledge gaps				
Appropriate involvement in safety research				
5. Responsibility within the value chain				
Availability of central basic data for toxicological and ecotoxicological assessment				
Use of communication options				
Policy transparency				

Table 1: Matrix for evaluation of guidelines

Criteria were evaluated qualitatively using a three-level scoring system: (-) = criterion has not been addressed; (o) = criterion has been partially/inadequately addressed; (+) = criterion has been addressed in full/extensively.

At the time the evaluation was carried out (January 2010), none of the existing guidelines/codes of conduct made specific reference to the NanoKommission Principles. The authors of the documents were therefore asked whether they thought their own document (implicitly) applied the principles. Six of the guide-lines/codes of conduct whose authors claimed that this was the case were included in the evaluation.<sup>5</sup> At company level, any other codes of conduct the authors considered relevant were also included in the review to ensure that a proper overall picture was obtained.

The evaluation, carried out by the majority of the Issue Group members, produced highly heterogeneous results. This was due in part to differences in understanding of the purpose of the evaluation process (testing the usefulness of the evaluation matrix versus evaluating the guidelines/codes of conduct themselves). Another factor which had a clear impact on the results, however, was the overriding expectations of the group carrying out the evaluation. In addition, it proved tricky to evaluate the various types of guidelines/codes of conduct examined using a standard matrix.

In terms of implementation of the principles, however, a clear pattern emerged from the sample guidelines evaluation: Principle 4, "Establishment of risk management structures", is covered by most of the guidelines/codes of conduct. Next comes Principle 5, "Responsibility within the value chain". Principle 2, "Transparency" and Principle 3, "Commitment to dialogue", are referred to less often and also less clearly. Principle 1, "Good governance" is mentioned least often. In terms of content, occupational health and safety tends to be the primary focus of attention.

In the Issue Group discussions one comment made was that guidelines containing guidance for action or specifying how to apply the principles in particular areas of a given sector would be particularly useful in sectors where small and

<sup>&</sup>lt;sup>5</sup> Guidelines/codes of conduct from the following institutions: Federal Institute for Occupational Safety and Health (BAuA)/German Chemical Industry Association (VCI), Hessen NanoTech, the German Cosmetic, Toiletry, Perfumery and Detergent Industry Association (IKW), BASF SE, Bayer AG, and Evonik.

medium-sized enterprises (SMEs) predominate. In areas where larger companies predominate, other instruments might be more appropriate. Guidelines explicitly targeted at SMEs were being drawn up by the German paint and printing ink industry association (VdL) at the time the current NanoDialogue was taking place. These relate to occupational health and safety.

It was felt that if concrete suggestions for implementing the principles, e.g. in the form of checklists or similar tools, were included in sector guidelines, this would enable both the SMEs themselves and outside observers to assess properly whether nanomaterials are being used responsibly. It was also felt, however, that suitably qualified people are needed to ensure proper implementation of the principles within companies.

Some Issue Group members expressed the view that sector guidelines setting out adequately detailed instructions are valued by the courts of law in the absence of other regulations.

### 2.3 Implementation of the principles within companies

Representatives of Issue Group member firms BASF and Bayer gave examples of how the principles can be implemented within companies.

In general terms, responsibility within these firms is clearly defined within the framework provided by established management and communication routines and particularly by implementation of the voluntary "Responsible Care Initiative". This framework also covers the use of nanomaterials.

More specifically, the following instruments are used to implement the Five Principles:

Principle 1: Definition and disclosure of responsibility and management (good

<u>governance)</u>

In both of these major enterprises management systems are in place based on values, principles, codes of conduct and company regulations which are generally approved by the Board. These apply to all activities of the company worldwide and are also mandatory for the use of nanomaterials.

Principle 2: Transparency regarding nanotechnology-related information, data

and processes

The examples given for both of these companies demonstrate clearly how information is produced for specific target groups – from information on company websites to expert discussions or peer-reviewed scientific publications. Both enterprises use all available information channels while at the same time ensuring that confidential information (e.g. intellectual property) is protected.

Principle 3: Commitment to dialogue with stakeholders

The German chemical industry has long-standing experience of engaging in dialogue with stakeholders as a result of its obligations under the "Responsible Care" initiative. Corresponding structures and instruments are in place within the communications divisions of both enterprises. Extensive examples were provided – such as the principle "Commitment to Dialogue", which is implemented both within the enterprise and vis-à-vis third parties - which far exceed the legal requirement to produce Safety Data Sheets.

#### Principle 4: Establishment of risk management structures

Use of hazardous substances has long been a part of daily life for companies in the chemical industry, predating the debate on nanomaterials by many years. Both companies operate a multitude of policies and regulations laying down risk management systems for various fields – from product safety to occupational health and safety. Examples from both enterprises were given to demonstrate on the one hand that nanospecific codes of conduct are in place, particularly relating to occupational health and safety. In addition, general company guidelines cover the use of chemicals, and therefore also nanomaterials. The guidelines specifically pertaining to nanomaterials are available on the companies' web pages.

#### Principle 5: Responsibility within the value chain

Safe use of nanomaterials can only be ensured if all partners in the value chain work together responsibly. Successful cooperation in this regard requires basic data on toxicological assessment and information on the applications and handling of these materials. Information must therefore flow in both directions, from manufacturer to user and back. In addition to the Safety Data Sheet, there is a whole range of instruments that can be used for this purpose such as technical data sheets, websites, or conversations in person. The two companies in question decide for themselves which information instruments to use. The EU REACH Regulation will bring further improvements in communication along the value chain.

According to the chemical industry representatives and the Chemical Industry Association (VCI), as a rule the individual NanoKommission Principles are being implemented within the chemical industry by means of internal company guidelines. Risk management, according to the industry view, is fundamentally a task for companies, whatever the sector in which they operate. It is common practice for companies to have sound, working governance structures; differences in implementation of the principles may be a result of differing requirements for responsible use of nanomaterials in different industrial sectors of application or in different positions in the value chain.

From the chemical industry representatives' perspective, responsibility for the supply chain is a key area of action for companies. The chemical industry in Germany, they said, exercises its responsibility via the Safety Data Sheet, a communication instrument already firmly established and well known worldwide.

The other Issue Group members expressed clear understanding with regard to the differences in nature of the situation, particularly in larger enterprises. How-

ever, they are of the opinion that there is a lack of public transparency regarding application of the principles and the specific instruments used to implement them in each case. In addition, they noted that there is a need for external quality assurance, or at least for random testing of the particular evaluation and communication tools being used.

Enterprise representatives also pointed out that there remains considerable uncertainty as to which products fall within the scope of the principles and which do not. Another vital factor for ensuring broad implementation of the principles is to develop a common understanding of what constitutes grounds for concern. For this reason, BASF and Bayer have introduced preliminary working definitions for internal use. The issue of a "definition" was not discussed in any more depth within the working group because this is being debated in various national and European bodies, and it is not a question that the group can answer in any case.

### 2.4 Monitoring implementation

The issue of monitoring implementation of the NanoKommission "Principles for the Responsible Use of Nanomaterials" also played a major role in the first dialogue phase.<sup>6</sup>

In its Report the NanoKommission made very concrete recommendations in this regard:<sup>7</sup>

- that in 2010, within the remit of the NanoKommission, the state of implementation of the principles should be monitored on the basis of industry sector reports; this is in order to give the general public an idea of how far the principles have been implemented as part of company practice and to provide a quality assurance of the process;
- that the criteria for monitoring, the form of the report and issues of structure, quality assurance and control should be established at the start of the coming work phase in the context of the NanoKommission;
- that the names of those companies and business sectors that have committed to applying the principles should be published;

Issue Group 1 had access to the questions and aggregated results of a questionnaire survey carried out by the VCI among its member companies, a selfassessment exercise to verify implementation of VCI guidelines for the chemical industry on product stewardship for nanomaterials (*Selbsteinschätzung der Unternehmen im Rahmen der Verifizierung der Leitfäden des VCI zur Produktverantwortung bei Nanomaterialien*).

This survey fulfilled the offer made by the VCI at the end of the first dialogue phase to provide a progress report in late 2009/early 2010 on the status of im-

<sup>&</sup>lt;sup>6</sup> See e.g. discussion of Working Group 3 on this issue on p.53 of the Report (2008).

<sup>&</sup>lt;sup>7</sup> Report (2008), p.62ff.

plementation and areas for improvement. However, the Issue Group discussions highlighted the following shortcomings of the VCI survey:

- In its first round, the VCI survey was sent to only 40 companies closely involved in Chemical Industry Association bodies. Of these, seventeen companies responded.
- Lists of companies explicitly declaring their commitment to apply the NanoKommission Principles have not yet been compiled.
- The survey evaluation has been published in a highly aggregated form that gives outsiders no insight as regards implementation of the principles.

The VCI, too, views this questionnaire survey of member companies merely as a first step towards developing a system of self-survey/self-evaluation and raising awareness of the NanoKommission Principles among its membership. Involvement of other stakeholders in the design of future surveys is envisaged. Trade unions and environmental organisations have expressed their interest in being involved, especially in designing a transparent process for evaluating the results.

The Issue Group welcomes these activities undertaken by the VCI. The group agrees, however, that industry association surveys of this sort do not represent independent monitoring of implementation.

Evaluation of publicly accessible information<sup>8</sup> by representatives of trade unions and environmental organisations reveals the limited scope of the survey so far carried out. According to their evaluation, there are around 100 - 200 larger enterprises in Germany which manufacture or use nanomaterials. Of these, more than 60 are in the chemical sector.

Measured against the potential total of 100 – 200 large firms, the survey results account for only 10 to 15%. Out of a total of more than 60 firms in the chemical industry, the VCI survey response rate represents about 30%.

The limited survey coverage and low response rates led representatives of the trade unions and environmental and consumer organisations to conclude that implementation of the principles in industry is not widespread. This is contradicted by industry representatives, who assert that the number of firms actually using nanomaterials tends to be grossly overestimated in the public arena.

In support of their interpretation, representatives of trade unions and environmental and consumer organisations highlighted the following fact: even among the websites of major chemical enterprises that participated actively in the first NanoDialogue phase, only three could be found which allude to or take a stance on the issue of nanomaterials, albeit in varying degrees of depth and detail. In contrast, as of April 2010, the company websites of four other large manufactur-

<sup>&</sup>lt;sup>8</sup> The Association of German Engineers (VDI) Technologiezentrum website www.nano-map.de, and a VCI paper dated 8 March 2010.

ing and processing firms contained no mention of the company's position with regard to nanomaterials, despite their involvement in the NanoDialogue.

# 2.5 Additional recommendations for action in the areas of environmental and consumer protection

Implementing the principles for the responsible use of nanomaterials as specifically as possible in guidelines for companies and other actors was a key issue in the work of the NanoKommission's first dialogue phase. Lack of time, however, meant that it was not possible to formulate comprehensive recommendations for the actual design of guidelines. For this reason, although the Appendix to the Report for the first dialogue phase (see below) states clearly that guidelines should give equal consideration to occupational health and safety, environmental and consumer protection, it contains specific suggestions as regards possible content only in the case of occupational health and safety.

Recommendations for the other two protection targets were to be formulated during the second dialogue phase to redress this imbalance.

The Issue Group, however, was unable to agree on a formulation for these in the allotted time. A sub-group produced some initial contributions to the debate that could potentially offer a basis for establishing consensus among the various groups involved. It would be useful to pursue these efforts.

In the view of the Issue Group, the inclusion of specific recommendations for action should not be restricted to sector guidelines. It would be equally important to include such recommendations in other instruments aimed at implementing the principles.

### 2.6 Extending the principles to other sectors and institutions

In its first dialogue phase, the NanoKommission recommended extending the scope of the principles to cover other sectors so that the principles would not only apply to manufacturers of nanomaterials, but also inspire commitment in the companies and business sectors that use nanomaterials. Research carried out by the Issue Group on guidelines/codes of conduct for the responsible use of nanomaterials provided a very clear indication that companies and/or sectors other than the chemical industry have not yet in fact adopted the principles.

In view of this, the Issue Group spokesperson and other participants consulted users of nanomaterials outside the immediate reach of the chemical industry and chemical industry associations. Given the nature of the Issue Group's work it was not, of course, possible to carry out a broad or representative survey. The picture obtained from these consultations, however, was very clear.

Only a few of those questioned had even heard of the German Federal Government's NanoKommission. None of the SMEs questioned was aware of the principles for the responsible use of nanomaterials. One thing that became clear from this was that it is difficult to make straightforward reference to the principles, owing to the absence of a stand-alone document directly accessible via the Internet.

It seems difficult to communicate the significance and value of adopting these principles, let alone of making an explicit commitment to them. On the one hand this is a direct consequence of the principles' unclear status. At the same time, however, we do not as yet have any means of giving prominence to firms, sectors or, for that matter, public sector bodies and other institutions that have already committed to implementing the principles.

One measure of note has been adopted in the field of statutory accident insurance. In May 2010 the umbrella body German Statutory Accident Insurance (*Deutsche Gesetzliche Unfallversicherung* – DGUV) and accident insurance providers issued a position paper on the responsible use of nanomaterials in the workplace, which makes explicit reference to the NanoKommission Principles.<sup>9</sup>

The approach adopted by the DGUV includes partial implementation of Principle 5, "Responsibility within the value chain". It states *"The organisation's policy on nanomaterials, including the principles for the responsible use of nanomaterials, is made clear to the relevant partners with the aim of encouraging them to adopt a similar approach".* The Issue Group sees considerable potential for further dissemination of the NanoKommission Principles if other companies, industry associations and institutions involved in the NanoDialogue make this kind of explicit public commitment to the principles and take practical steps to implement them.

<sup>&</sup>lt;sup>9</sup> See also link to activities of the DGUV in Annex 3.

## 3 CONCLUSIONS AND RECOMMENDATIONS

#### (i) Basic evaluation of the principles

In terms of their content, the principles for the responsible use of nanomaterials continue to be supported by all of the dialogue partners.

Chemical industry representatives view the principles primarily as a framework based on consensus among stakeholder groups that serves as a guide for responsible self-regulation by firms.

From the perspective of trade unions and environmental and consumer organisations, meanwhile, the principles represent first and foremost no more than a declaration of intent; value only arises from them if there is mandatory implementation.

All in all, the Issue Group found that implementation of the principles in practice has so far fallen considerably short of stakeholders' expectations. This applies particularly to the adoption rate of the principles across industry and in other institutions, and to transparency concerning the details of how they are implemented.

In addition, some of the participants (trade unions and environmental and consumer organisations) also point out that although efforts have clearly been made by some companies and industry bodies, this is inadequate to achieve broad dissemination and implementation of the principles:

- across the chemical industry as a whole, and even in the case of many companies which actively participated in the NanoDialogue, explicit reference to the principles in communications with the general public is lacking;
- in other sectors of industry, operationalisation of the principles by way of sector guidelines to aid implementation remains embryonic;
- no enterprise or sector has so far declared its commitment to apply the principles in line with the NanoKommission recommendation in 2008;

Against this background, trade unions and environmental and consumer organisations have recently called into question the suitability of "principles" as an instrument for ensuring health and safety in the workplace and environmental and consumer protection in relation to "nanomaterials", whether as a precursor to or complementing government regulation.

These stakeholders perceive a widening gap between the spread of technologies and rules and principles governing their use as a result of the rapid progress made in the development and dissemination of nanotechnologies and their applications. They believe that the need for government regulation in these fields is therefore more urgent than it was as recently as two years ago. Consequently, they feel that significantly greater priority needs to be given to developing such regulation than to efforts to resolve difficulties relating to operationalising and implementing the NanoKommission Principles. Despite the shift in priorities which they believe is required, the stakeholders nevertheless consider it worthwhile to pursue efforts to implement the principles.

All in all, the Issue Group notes that the general consensus prevailing among the dialogue partners in 2008 regarding the status and function of the principles has not so far been given any more concrete form.

⇒ The Issue group recommends that the NanoKommission should (once again) clarify the status and function of the principles, and particularly the degree to which they are binding.

#### (ii) Commitment to the principles

A distinction needs to be drawn between two types of commitment to apply the principles on the part of businesses:

- "Explicit" commitment, where the company in question "publicly" declares its commitment to implementing the principles for the responsible use of nanomaterials.
- "Tacit" commitment, where the company "implicitly" implements the relevant sections of the principles for the responsible use of nanomaterials within the company divisions concerned. However, the company makes no clear, outwardly evident connection between this practice and the NanoKommission Principles. Instead, they are implemented e.g. as part of general company governance.

Company representatives share the view that explicit implementation, which presupposes a public statement of commitment on the company's website, has hitherto been inadequate. On the other hand, BASF and Bayer, both of which are participants in the dialogue, have shown how implicit implementation can take place in industry, largely by means of sound management and communication routines and especially through the Responsible Care initiative.

Although the other stakeholder groups also support proper implementation of the principles within industry, they call instead for "explicit" implementation, in other words, for companies to make a public declaration of commitment to the NanoKommission Principles and to implement the principles clearly and transparently. A problem that arose concerning evaluation was that it is difficult to measure implementation of the principles by companies, as this is often done within the framework of existing measures and mechanisms. From the perspective of the trade unions and environmental and consumer organisations, "implicit" implementation runs counter to the transparency principle.

- ⇒ The Issue Group reminds enterprises and industry associations of the NanoKommission recommendation that they should make a public commitment to apply the principles.
- ⇒ The Issue Group recommends that the Federal Environment Ministry should create a platform for publishing the names of enterprises, industry associations and institutions which implement or take account of the principles.<sup>10</sup>
- Some Issue Group members propose that the granting of public funding should be made conditional upon a binding commitment to apply the principles for the responsible use of nanomaterials. This proposal is not endorsed by the VCI.<sup>11</sup>

#### (ii) Disseminating/communicating the principles

Analysis of currently available guidelines on the responsible use of nanomaterials has shown that awareness of the NanoKommission Principles among users of nanomaterials, especially among downstream user industries, falls far short of the target levels set by the NanoKommission. The unsatisfactory rate of adoption and dissemination of the principles to date is also ascribed to poor levels of public awareness and failure of the dialogue partners to support the principles more actively.

In this context the Issue Group recalls that Principle 5, "Responsibility within the value chain," also includes making the principles transparent to customers in the supply chain to enable them to adopt a similar approach.

In addition, the Issue Group recommends that the NanoKommission should take a more vigorous approach to communicating the principles. Stakeholders are called upon to take corresponding steps to promote communication within their sphere of operation. To do so, stakeholders must have appropriate ways of making reference to the principles.

- In addition to industry, the other partners in the NanoDialogue (public authorities, trade unions, institutions, churches and environmental and consumer organisations) should publicly express their commitment to the principles for the responsible use of nanomaterials e.g. by including a specific declaration on their websites.
- A summary of the Principles Paper<sup>12</sup> should be published in a stand-alone brochure, and this should be made easily accessible to interested parties, including via the internet.

<sup>&</sup>lt;sup>10</sup> It remains to be decided whether companies, associations and institutions would enter the information themselves or if this would be done on request by a third party in accordance with criteria as yet to be determined.

<sup>&</sup>lt;sup>11</sup> All public funding agreements are based on adherence to codes of practice such as the "Code of Scientific Practice" of the Federal Ministry for Education and Research (BMBF), which also applies to research on nanotechnology. In the VCI's view, imposing additional requirements as a basis for allocating funding would impede and obstruct research in Germany in the longer term. <sup>12</sup> In other words, the general conditions and the Five Principles set out in Sections 3.1 and 3.2

<sup>&</sup>lt;sup>12</sup> In other words, the general conditions and the Five Principles set out in Sections 3.1 and 3.2 respectively of the Report and recommendations of the German Federal Government's NanoKommission for 2008.

- ➡ Efforts to include environmental and consumer protection aspects in recommendations for guidelines should be continued, taking into account the initial contributions from the Issue Group discussions.
- ⇒ The NanoKommission should actively communicate the approach to other companies, industry bodies and institutions not participating in the NanoDialogue.
- A public event to raise awareness of the principles should be organised by the Federal Environment Ministry.<sup>13</sup>

#### (iii) Guidelines and other implementation tools

As far as users in industry are concerned, the NanoKommission Principles need to be made more specific to business practice. This process has already begun in the form of industry association guidelines. Other sector-specific guidelines are currently being drafted. Differences in the ways guidelines are applied are due to differing requirements for responsible use of nanomaterials in different industrial sectors of application. Industry representatives did not feel it would be useful to establish a general format for guidelines with identical criteria for all sectors.

The way in which the principles are implemented in practice should relate to the specific conditions in industry structures, such as company size, position in the value chain, and the nature of a company's products. Implementation tools such as guidelines must allow for diversity of this sort.

In addition, it might be appropriate for such implementation tools to vary in terms of depth and specificity when elaborating on particular principles, depending on the management and risk communication structures already in place. This is something that should also be considered when applying the assessment or testing matrices devised by the Issue Group.

⇒ The Issue Group recommends that the NanoKommission should make the evaluation matrix available to authors of guidelines and codes of conduct to facilitate comparison and adjustment. It will only be worthwhile developing the "evaluation matrix" as an instrument, however, if the need arises as a result of new guidelines being produced on the basis of the principles.

In order to provide interested stakeholders in industry with tools that are fit for purpose, the Issue Group believes it would be desirable to produce examples of implementation tools agreed upon by the partners in the NanoDialogue. This would entail especially

⇔ elaborating a model set of guidelines for user industries, taking into account the predominance of SMEs in this sector (with guidance for

<sup>&</sup>lt;sup>13</sup> Working Group 3 first put forward this proposal during the first Dialogue Phase (see Report (2008) p.58)

action, checklist-style layout, and encompassing all areas of activity)

⇒ setting out examples of Good Practice showing how larger enterprises in the sector have integrated the NanoKommission Principles into their existing structures.

#### (iv) Monitoring implementation

As a possible means of monitoring implementation, the VCI suggested conducting a survey of its member companies. An initial survey was carried out in 2009.

The other dialogue participants welcomed this voluntary initiative. At the same time, however, they perceived this initial survey of the current situation regarding the use of nanomaterials in industry as inadequate, since it was limited to a small group of active VCI members. Some dialogue participants also pointed out that a survey does not equate to independent monitoring of implementation. For the kind of monitoring that delivers scientifically sound results and is accepted as independent by third parties, a fundamentally different approach would need to be employed. This would include not only a significantly broader basis for the survey, but also above all transparent evaluation methods and independent verification. In addition, for the kind of monitoring that meets these requirements, the Issue Group felt that financial support from external donors would be needed.

The VCI has offered to include questions on the principles in its general Responsible Care survey in future. This would also serve the purpose of spreading awareness of the principles and broadening the reach of the survey on the current situation regarding the use of nanomaterials within the chemical industry. Moreover, the data could be checked by auditors, thus ensuring independent third-party verification.

The VCI has also offered to include additional input from stakeholders in the design of the survey on implementation of the VCI guidelines. The environmental organisations have also expressed the desire to be involved particularly in the actual design of methods for transparent evaluation of the results.

#### (v) Conclusions

In this second dialogue phase the Issue Group debated issues relating to implementation of the principles from a critical perspective. The atmosphere in the Group was constructive.

Representatives of trade unions and environmental and consumer organisations noted that implementation of the principles by companies and industry associations has fallen short of their expectations.

Although some companies and industry associations have produced guidelines, these are thin on the ground compared to the number of companies and sectors working with nanomaterials. Explicit commitment to the principles, another of the goals of the first dialogue phase, has likewise not been achieved. For a variety of reasons, companies tend instead to implement the principles implicitly. Although implicit implementation may be just as good as explicit implementation in terms of the level of protection provided, it does not offer stake-holders the possibility of scrutinising the processes and instruments used and requesting dialogue.

Inadequate communication on the part of companies, policymakers and industry associations was identified as a major obstacle to dissemination of the principles over the past two years.

In general terms, however, the principles continue to enjoy the full backing of the dialogue partners.

Despite all the obstacles and hitherto unfulfilled expectations, the Group felt it would be useful to continue to monitor the implementation of the principles and to define them in more detail. This will allow the potential of this approach to be developed and exploited.

Improving the communication of the principles by the various parties and developing tools for monitoring their implementation were identified as useful initial steps in this direction. Aside from this, the group concluded that the NanoKommission needs to clarify the status and function of the principles, and the extent to which they are binding. This would help stakeholders to gain a sense of the importance of the principles and, where relevant, consider other – alternative or complementary – measures to implement their content.

# ANNEX 1 LIST OF ISSUE GROUP MEMBERS

A total of 20 individuals from public authorities, industry associations and companies participated with considerable continuity in the four working sessions of Issue Group 1 and in the interim working and consultation procedures.

Surname	First name	Institution	E-mail address
Becker	Dr. Heidi	Federal Environment Agency – UBA	heidi.becker@uba.de
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Glassl	Dr. Bernd	German Cosmetic, Toiletry, Perfumery and Detergent Industry Association (IKW)	bglassl@ikw.org
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Wriedt	Henning	Beratungs- und Informationsstelle Arbeit & Gesundheit (Occupational Health Advice and Information Centre)	wriedt@arbeitundgesundheit.de
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# ANNEX 2 ISSUE GROUP WORKING PROCEDURES

The Issue Group carried out its work in four sessions. The table below presents an overview of the key topics and outcomes of these sessions.

Table 1: Meetings of Issue Group 1

	Date	Key topics	Key outcomes
1	28.9.2009	Work programme and structures	<ul> <li>Detailed work programme set out</li> </ul>
		Sector guidelines	<ul> <li>Sub-group on methods for evaluating sector guidelines established</li> </ul>
2	16.12.2009	<ul> <li>Method of evaluating guidelines</li> <li>VCI survey on implementation of chemical industry guidelines</li> <li>Current state of debate on protection of the environment and of consumers</li> <li>Preliminary findings for the Dialogue Forum</li> </ul>	<ul> <li>Task of evaluating guidelines assigned to all IG members</li> <li>Procedure established for gathering additional suggestions on the VCI sur- vey</li> <li>Key discussion points set out for pres- entation to the Dialogue Forum</li> </ul>
3	25.3.2010	<ul> <li>Guidelines and other implementation measures (with relevance to company operations)</li> <li>Evaluation and additional comments concerning the VCI survey</li> <li>Current state of debate on additional recommendations for action concerning environmental and consumer protection</li> <li>Extension of the principles to other sectors</li> </ul>	<ul> <li>Fundamental support for the principles confirmed</li> <li>Basic agreement reached on the different ways the principles are implemented</li> <li>Additional comments/suggestions formulated concerning the VCI survey</li> <li>Pointers established for measures to extend the principles to other sectors</li> </ul>
4	1.6.2010	<ul> <li>Status of the principles in the food industry</li> <li>Presentation of new sector guide- lines for the German paint and print- ing ink industry</li> <li>DGUV activities on nano-related issues</li> <li>Discussion on the IG's draft final report</li> </ul>	<ul> <li>Comments and opinions gathered on passages requiring revision in the IG's draft final report</li> <li>Agreement reached on future working and consultation procedures</li> </ul>

# ANNEX 3

# RESOURCES RELATING TO THE USE OF NANOMATERIALS – GERMANY

(Last updated May 2010)

#### 1. Background:

Federal Environment Ministry (BMU): Responsible Use of Nanotechnologies: Report and recommendations of the German Federal Government's Nanokommission for 2008 (Section II.3.1: General conditions; II.3.2: Five basic principles for the responsible use of nanomaterials) http://www.bmu.de/files/english/pdf/application/pdf/nanokomm\_abschlussbericht

2008 en.pdf

#### 2. Existing guidelines for potential evaluation:

#### Federal/Länder authorities

Federal Institute for Occupational Safety and Health (BAuA) / German Chemical Industry Association (VCI):

Leitfaden für Tätigkeiten mit Nanomaterialien am Arbeitsplatz (*Guidelines for activities involving nanomaterials in the workplace*)

www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/Nanotechnologie/pdf/Leitfaden-Nanomaterialien.pdf

Hessen-Nanotech:

Sichere Verwendung von Nanomaterialien in der Lack- und Farbenbranche – Ein Betriebsleitfaden (*Safe use of nanomaterials in the paint and printing ink industry* – *guidelines for companies*) www.hessen-nanotech.de/mm/Betriebsleitfaden NanoFarbeLacke Vorab.pdf

LUBW, Landesanstalt für Umwelt, Messungen und Naturschutz Baden-Württemberg (Institute for the Environment, Measurements and Nature Conservation of the Land of Baden-Württemberg) :

Nanomaterialien – Arbeitsschutzaspekte (*Nanomaterials and occupational safety*)

www.lubw.baden-wuerttemberg.de/servlet/is/6644/?shop=true

#### Industry associations

German Chemical Industry Association (VCI): Responsible Production and Use of Nanomaterials http://www.vci.de/default~cmd~shd~docnr~122306~lastDokNr~-1.htm

German Cosmetic, Toiletry, Perfumery and Detergent Association (IKW): Sicherheitsbeurteilung für Pflege- und Reinigungsmittel, die Nanomaterialien enthalten und/oder Nanoschichten erzeugen (*Safety assessment of body care and cleaning products which contain nanomaterials and/or form nano-layers*) <u>http://www.ikw.org/pdf/broschueren/Nano\_d.pdf</u>

German Cosmetic, Toiletry, Perfumery and Detergent Association (IKW): Nanopartikel in kosmetischen Mitteln *(Nanoparticles in cosmetics)* <u>http://www.ikw.org/pdf/broschueren/Nano\_IKW231107.pdf</u>

German paint and printing ink industry association (VdL): Standpunkt zum Verantwortlichen Umgang mit Nanomaterialien in der Lackindustrie (*Position on the responsible use of nanomaterials in the paint industry*) <u>http://www.lackindustrie.de/default2.asp?cmd=shd&docnr=125998&rub=651&t</u> <u>ma=1&nd</u>=

German paint and printing ink industry association (VdL): "VdL-Leitfaden für den Umgang mit Nanoobjekten am Arbeitsplatz" (VdL guidelines for the use of nano-objects in the workplace) <u>http://www.lackindustrie.de/default2.asp?rub=676&tma=728&cmd=shd&docnr=</u> <u>127627&nd=&ond=tv</u>

#### Companies

BASF SE:

Guide to safe manufacture and for activities involving nanoparticles at workplaces at BASF AG <u>www.basf.com/group/corporate/de/content/sustainability/dialogue/in-dialogue-</u> <u>with-politics/nanotechnology/employees</u>

BASF AG:

Nanotechnology Code of Conduct http://www.basf.com/group/corporate/de/sustainability/dialogue/in-dialogue-withpolitics/nanotechnology/code-of-conduct

Evonik Degussa GmbH: Nanotechnologie – Sichere Produktion (*Nanotechnology* – *safe production*) www.degussa-nano.com/nano/de/nachhaltigkeit/sicherheit/ Bayer MaterialScience:

Nanomaterial Product Stewardship (registration required for access) <u>http://baycareonline.com/nano\_stewardship.asp</u>

Bayer Code of Good Practice for safe handling of nanomaterials in production and on-site use

http://baycareonline.com/nano\_stewardship.asp

#### 3. Other

IFA – Institute for Occupational Safety and Health of the German Social Accident Insurance:

Schutzmaßnahmen bei ultrafeinen Aerosolen und Nanopartikeln am Arbeitsplatz (*Protective measures relating to ultrafine aerosols and nanoparticles in the workplace*)

www.dguv.de/bgia/de/fac/nanopartikel/schutzmassnahmen/index.jsp

#### DGUV:

Positionspapier der Deutschen gesetzlichen Unfallversicherung zum verantwortungsvollen Umgang mit Nanomaterialien (*German Statutory Accident Insurance position paper on the responsible use of nanomaterials*) <u>http://www.dguv.de/inhalt/praevention/themen\_a\_z/nano/index.jsp</u>

#### Hessen-Nanotech:

Informationsplattform Nano-Sicherheit.de (web-based information platform on nano-safety)

www.infoplattform-nanorisiken.de/

#### Hessen-Nanotech:

Supplement "Innovationsfördernde Good-Practice-Ansätze zum verantwortlichen Umgang mit Nanomaterialien" (*Fostering innovation through goodpractice approaches to the responsible use of nanomaterials*) http://www.hessen-nanotech.de/mm/Suppl-NanoKomm\_final\_Web.pdf

TÜV SÜD:

CENARIOS® – first nanotechnology risk management and monitoring system www.tuev-sued.de/technische\_anlagen/risikomanagement/nanotechnologie