Ministerie van Infrastructuur en Milieu

Conference
"Building Blocks for Completing
EU Regulation of Nanomaterials"
The Hague, 11-12 April 2013

Chairman's Report

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Date
29 april 2013

Chairman's Report

Pragmatic steps towards a more effective EU nano policy

Conference agrees that
additional regulations on nanomaterials
should ensure availability of information and safety,
while at the same time do not need to impede innovation

Pragmatism and transparency are pivotal in creating a more comprehensive and effective nanotechnology policy in the European Union. Most participants at the second European Conference on Nanomaterials in The Hague agreed that immediate parallel steps need to be taken to address the need for information and public concern on nanomaterials. The conference also supported the view that additional safety regulations should not impede innovation within the nanomaterials industry and that innovation and innovative products should not pose hazards to health or the environment.

The conference agreed that the current information on safety and whereabouts of nanomaterials is either incomplete or lacking. There is still a lot of discussion on the definition and characteristics of nanomaterials, which may partly explain the lack of information and transparancy. More data need to be generated or released by manufacturers concerning substance identity, physical-chemical and hazardous properties of nanomaterials as well as on exposures throughout the life-cycle.

Many nanomaterials in products are currently untraceable due to the lack of standardised measurement methods and missing data on production supply chains. The participants agreed that a single definition is needed taking into account some specific requirements in existing legislation. Also, the information requirements need to be made more explicit for industry. Workers and consumers will benefit from better information.

During the two-day meeting, many considered that databases or registries will be indispensable for gathering the necessary information on (products with) nanomaterials. France already has a national 'nanoregister' and in some other member states, such as Denmark and Belgium, steps are being taken towards national 'nanoregisters'. The participants, however, agreed that a EU-registration on nanomaterials is preferred over a series of varying national databases. The latter possibly creates more problems than solutions in improving a harmonised European policy on nanomaterials.

A European Commission official pointed out at the conference that the main problem on the table is to define the level of information on nanomaterials that is required. A justification in terms of actual risks is necessary. On the other hand it was argued that you need information to identify potential risks and that in a number of cases, risks have actually been identified. Whereas steps like the preparation of an impact assessment have been taken, the current European Commission (which will be in office until the second half of 2014) is unlikely to take a decision on setting up a community-wide EU-database for (products with) nanomaterials.

Several member states and other participants at the conference called for the Commission to set up a 'nanoregister' soon. They indicated that as long as the information flow on nanomaterials remains patchy and obscure, as it is now, more websites and databases are expected to appear that are too critical about nanomaterials. It is in the interest of both industry and policy makers to prevent uncertainties about nanomaterials and products containing nanomaterials to increase any further.

The representatives of industry acknowledged that public confidence can grow by a centralised EU 'nanoregister', but they also fear that this process can lead to the stigmatisation of nanoproducts. As for now, in their opinion there is no proof that unacceptable risks are connected to products containing nanomaterials. Manufacturers also fear that more complex 'nanoregistrations' will lead to too high costs for industry, especially small and medium businesses, who will then reduce their budgets for innovation. Some participants highlighted however that new regulations have also the potential to encourage innovations.

Through REACH, the responsibility on the safety of chemicals, and thus also of nanomaterials, is in the hands of industry. The conference agreed that the current REACH legislation provides a good and practical basis for developing a more comprehensive EU-'nanopolicy'. At the same time, participants indicated that the current REACH-annexes on nanomaterials need to be revised for addressing the safety assessment of nanomaterials as soon as possible. Furthermore, the conference chair indicated that any amended legislation for nanomaterials, including REACH, would need a legally binding definition. According to the chair, without legal obligation, registrants may still ignore the nano-specific information requirements REACH regulation can offer through its annexes.

Others, including the Commission, considered that there are many terms in the REACH annexes which are not defined in Article 3 of REACH and that this did not affect their legal applicability. To them, a co-decision proposal only to introduce the nanomaterial definition seems disproportionate and may end up in opening many other issues.

The current or amended REACH Regulation provides ways to gather information on materials and production. REACH may trigger industry to show it takes its responsibilities, not only in the REACH registration dossiers and in the communication within the supply chain, but also in informing the public on how to use and work safely with products with nanomaterials and in providing more transparency on their products and their evaluation methods.

The Commission invited Member States to intensify their efforts on substance evaluation. Other participants argued substance evaluation is time-consuming and resource intensive for authorities, is only possible in a limited number of cases, and should not be regarded as taking over the primary responsibilities of industry.

Consumers' organisations and representatives of workers in the industry expressed that a lot more needs to be done. Consumers' organisations stated that additional and more specific 'nano'-labelling on products is needed. "We need to know more than just the ingredients that are in the products: we need to know how much," one representative said. The participants agreed that the European public should be able to make informed decisions about buying cosmetics, food or other products that contain nanomaterials. At the moment this is not yet possible as only some data on nanomaterials are known, and most are still lacking.

The information on health and safety hazards for the 300,000 workers in the European nanomaterials industry needs to be improved considerably. The directive on Safety and Health at Work and the Chemical Agents Directive apply in principle, but improved implementation will help, accompanied by more information on safety as generated by REACH or by other means. It was felt that DG Employment should take the lead in implementing existing regulation and apply a precautionary approach for the protection of workers handling nanomaterials, if necessary by proposing adaptations or new legislation.