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Responsible Production and Use of Nanomaterials:

Implementing Responsible Care®

2nd Edition

Responsible Care®
OUR COMMITMENT TO SUSTAINABILITY

Background

The development of new nanomaterials and nanotechnologies is expected to play a major role in product innovation across a variety of sectors and applications. Nanotechnologies and nanomaterials can help meet growing global health, food, energy, water and environmental footprint needs - whilst contributing to sustained economic growth. However, nanomaterials have been produced and used since decades especially in products like mineral pigments used in paints and other every day products.

The management of potential risks related to nanomaterials - and what is needed to ensure their responsible development, use, distribution and disposal - is being discussed by stakeholders, policy makers and regulators at international and regional levels.

Cefic is committed to contribute to the sustainable and responsible development of nanomaterials applications in the European chemical industry. Responsible development implies a commitment to develop and use these materials to meet human and societal needs while making every possible effort to anticipate and avoid adverse effects and unintended consequences. It is industry's assurance that economic needs do not take priority over environmental and health considerations.

With the help of concrete examples, this document provides guidance on how companies can apply the Responsible Care principles to producing, using nanomaterials and placing them on the market.

Responsible Care®

Responsible Care is the global chemical industry's environmental, health, safety and security (EHSS) initiative to drive continuous improvement in performance across all its activities. It achieves this objective by meeting and going beyond legislative and regulatory compliance, and by adopting cooperative and voluntary initiatives with government and other stakeholders.

The Responsible Care Global Charter commits companies and national associations to work together to implement the principles of Responsible Care and turn them into a living and working reality in chemical companies throughout the world. The Charter focuses on new and important challenges facing the chemical industry and global society, including the growing public dialogue on sustainable development, public health issues related to the use of chemical products, the need for greater industry transparency, and the opportunity to achieve greater harmonisation and consistency among national Responsible Care programmes. One of the key pillars for the implementation of Responsible Care is Product Stewardship**.**

Product Stewardship Within the Chemical industry, the Product Stewardship programme represents the responsible and ethical management of the health, safety and environmental aspects of a product – including nanomaterials - throughout its total life cycle. Product Stewardship is Responsible Care applied to products: it is a shared responsibility between chemical producers, their suppliers and their customers. It provides the platform for companies to identify risks at an early stage and manage those risks along the value chain, thereby enabling adequate protection of human health and the environment.

What is nanotechnology?

Nanotechnology is engineering at the smallest scale – it describes a set of enabling technologies and processes that cross all industry sectors and scientific disciplines. These technologies are used to control materials in order to design, produce, characterize and use structures and systems at the nano-scale. The nano-scale is understood as a size between approximately 1 and 100 nanometers. Since the development of the electron microscope it has been possible to see those tiny structures. For over 100 years, scientists in the disciplines of chemistry, physics and biology have studied and worked with objects that have nanoscale dimensions.

Nanotechnologies will facilitate the development of novel applications for very different aspects of our daily lives from biomedical advances to applications in information technology. Nanotechnology has the potential to open up new perspectives to economic, environmental and social benefits and is an innovation driver offering significant opportunities for sustainable development, growth and employment in Europe.

Materials having such minute structures on the nanoscale may exhibit different properties compared to "traditional bulk materials" made from the same chemical composition. For example, nanomaterials may offer different mechanical, optical, chemical, magnetic or electronic properties compared to their bulk forms. The ability to selectively manage the size of nanoscale materials allows the chemical industry to develop materials with new properties that offer significant advantages in our macroscopic world.

What are nanomaterials?

The common thread between all nanomaterials is their tiny size: nanomaterials are measured on the nano-scale: 1 nanometer is one billionth of a meter.

The European Commission's recommendation for a definition of the term "nanomaterial", adopted in October 2011, states:

"Nanomaterial" means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm. (http://ec.europa.eu/environment/chemicals/nanotech/index.htm#definition)

Producing and Using Nanomaterials Responsibly

Companies and chemical associations actively participate in the debate around the safety of nanomaterials and the need to implement risk analysis and risk management according to the precautionary principle as developed by the European Commission [COM (2000) 1].

This document brings together best practice on the concrete application of Responsible Care to the development and use of nanomaterials. It focuses on the six Core Principles of the Responsible Care Global Charter – and, using concrete examples from our member companies and federations, describes ways in which each of these principles can be applied to nanomaterials.

Please share your own experiences with us so we can build upon this resource.

The 6 Core Principles of the Responsible Care Global Charter

1. Continuously improve the environmental, health and safety knowledge and performance of our technologies, processes and products over their life cycles so as to avoid harm to people and the environment
2. Use resources efficiently and minimise waste
3. Report openly on performance, achievements and shortcomings
4. Listen, engage and work with people to understand and address their concerns and expectations
5. Cooperate with governments and organisations in the development and implementation of effective regulations and standards, and to meet or go beyond them
6. Provide help and advice to foster the responsible management of chemicals by all those who manage and use them.

Sharing Best Practice

The following pages explain how Cefic, its members and national federations have implemented the 6 Principles of the Responsible Care Global Charter to the specific case of nanomaterials:

1. Continuously improve the environmental, health and safety knowledge and performance of our technologies, processes and products over their life cycles so as to avoid harm to people and the environment

The chemical industry is actively involved in improving and refining hazard testing and assessment methods for nanomaterials. Examples of chemical industry activities in this area include:

- **Long Range Research Initiative**[1]

  Through its Long Range Research Initiative (LRI), Cefic sponsors research into the safety of nanomaterials. These results are shared with regulatory bodies and academia in an effort to drive forward effective risk assessment and risk management. For example, the projects below are Cefic contributions (via BIAC[2]) to the Sponsorship Program of the OECD Working Party of Manufactured Nanomaterials (2008-2011):

  i. Assessing the suitability of OECD testing guidelines for nano zinc oxide and synthetic amorphous silica, and defining a tiered testing strategy for these nanoparticles. The results of this project should address the following questions: do the existing OECD reproductive toxicity test guidelines adequately assess a potential hazard posed by nanoparticles? Can the existing guidelines benefit from some revisions to better understand health risks posed by nanoparticles? Are there endpoints used to assess the potential hazard of industrial chemicals which may be inappropriate for testing nanoparticles?

  ii. Assessing the ecological risks that may be associated with nanoparticles. Currently accepted testing strategies will be evaluated, supplemented and improved where needed in order to address potential nano-specific effects on ecologically relevant exposures. The outcomes of this project will help determine the environmental impact of nanomaterials in aquatic systems

  iii. Analysing the suitability of current OECD guidelines to identify potential hazards associated with nanomaterials by testing and assessing the reproductive toxicity of nanomaterials using two of the OECD reference materials: silicon dioxide (e.g. synthetic amorphous silica) and zinc oxide. The three-year project started in Q1 2010.

An additional LRI research project run in 2009 entitled "Making Social and Natural Sciences Meet: Implications for the introduction of nanotechnology into society" aims to systematically review existing methodological approaches to understanding consumer/citizen responses to emerging technologies (for example, nanotechnology) and to identify gaps in knowledge/principles of best practice.

[1] http://www.cefic-lri.org/projects

[2] The Business and Industry Advisory Committee to the OECD. See Glossary

- **European Technology Platform – SusChem**

  SusChem[3] brings together a wide spectrum of organisations and individuals looking to boost sustainable chemistry, industrial biotechnology and chemical engineering research, development and innovation in Europe. One of its activities includes a cross-sectorial coordination programme called "NanoFuture" to optimise solutions to technology, safety and environmental challenges in the nanotechnology area. This brings together cross-sectorial, multi-disciplinary teams of experts across Europe to drive impactful EU research projects that address energy solutions, light weight materials for construction and transport and material design.

  Under the FP7 – NMP (2006/2007) programme, SusChem has enabled EU consortia and projects on nanotechnology, including safety research projects worth over Euro 120million in funding. These research projects include:

  i. Nanomaterials for energy management (batteries, printable electronics, charge transport, efficient lighting)

  ii. Design & safeguarding bio-nano-interactions (medical surfaces, biofouling, nanomembranes, nanocomposite life cycle, Environmental Health and Safety).

- **Companies conduct their own nano-safety research, for example:**

SOLVAY Solvay has established a cross-functional platform which pro-actively monitors our current and future product and application portfolio. To ensure worker safety, the company is actively involved in the assessment of exposure models and measurement devices specifically designed for nanoparticles. http://www.solvay.com/EN/Homepage.aspx
BASF The Chemical Company Company safety research such as "NanoTox" and "Aerosol Characterisation" www.basf.de/dialogue-nanotechnology/safety_research

[3] http://www.suschem.org/

Bayer product stewardship program for nanomaterials focuses on characterization, (eco)-toxicology as well as exposure measurement. Multi-Walled Carbon Nanotubes are of special interest and are subjected to in-depth investigation. More details can be found at: www.baycareonline.com

Since 2004 the company has joint collaboration with ISPRA joint research center for toxicological assessment on nanomaterials. Since 2006 it is a partner in European Project CellnanoTox.
Since 2006, the company is working on TiO2 anatase, AI2O3, Au, Ag, SiO2, ZrO2 nanospinels and nanoferrites.
www.cericol.com

Evonik has since 2000 joint measurements with University of Duisburg/IUTA.
Since 2006, the company is working on Carbon Black, Synthetic Amorphous Silica, Titania, Aluminia, Zinc Oxide, Ceria
http://nano.evonik.de/sites/nanotechnology/de/Pages/default.aspx

Exposure and Risk assessment of carbon nanotubes
http://www.nanocyl.com/en/HS-E/Introduction

Verband der deutschen Lack- und Druckfarbenindustrie e.V.

The German Paint Industry association sponsored research to assess particle release from coatings containing nanoparticles. The resulting Clean Room Aerosol Measurement Technique to quantify potential nanoparticle release has helped EU testing methodology and is currently under the process of standardisation in ISO/TC 24/SC4
http://www.cefic.org/Documents/PolicyCentre/Nanomaterials/CEFIC-PRESENTATION-Enabling%20Responsible%20Innovations%20of%20Nanotechnologies.pdf

- **Companies collaborate with multi-stakeholder nano-research projects such as:**
  - ACC Nanomaterials Voluntary Programme: http://www.americanchemistry.com/s_acc/sec_statistics.asp?CID=654&DID=2564
  - CarboSafe as part of the cluster Inno-CNT: http://www.inno-cnt.de/en/
  - CellNanoTox: http://www.fp6-cellnanotox.net/
  - HESI/ILSI Nanomaterials Programme: http://www.hesiglobal.org/
  - NanoCare: http://www.nanopartikel.info/cms
  - NanoSafe2: http://www.nanosafe.org/scripts/home/publigen/content/templates/show.asp?P=56&L=EN
  - Global-NanoMAPP: http://www.nanotechia.org/nia-activities/nia-projects/nia-projects-globalnanomappp
  - VVVF (VNCI): Exposure to nanomaterials in the paint industry: http:///www.vvvf.nl/verf-en-drukinktindustrie-gaat-blootstelling-nanodeeltjes-2011-onderzoeken
  - CarboTox: http://www.nanopartikel.info/cms/lang/en/Projekte/Carbotox
  - NanoGEM : http://www.nanogem.de/cms/nanogem/front_content.php

2. Use resources efficiently and minimise waste

Nanotechnologies increase the control on matter and enable an increased efficiency in producing materials.

Individual companies share their expertise to promote resource efficiency and waste minimisation.Methods used in this area include for example conducting chemical reactions in nanoreacters and using nanocatalysts to increase reaction efficiency whilst reducing amount of certain toxic chemicals, such as heavy metals, which would otherwise be needed in the reaction process – for example BASF's "NanoSelect" catalyst: www.catalysts.basf.com

Another example of best practice comes from Colorobbia: The production of all their nanomaterials is directly in suspension at low temperature (<200°C) – thereby saving energy whilst ensuring that no waste is generated in the process.
http://www.colorobbiaitalia.it/lang1/colorobbia_nanomaterials.html

Waste containing nanomaterials can be generated in the production or use of nanomaterials, for example during the production of substances, preparations or products, during the processing and repair of products, or during the disposal of products at the end of their lifecycle.

Industry is increasingly pooling best practice to provide guidance to its supply chain. For example, in 2009, the German Chemicals Industry Association developed "Guidance for the Safe Recovery and Disposal of Waste Containing Nanomaterials":
http://www.vci.de/template_downloads/tmp_VCIInternet/126414Handling_Nanomaterials_being%20Wastes_7_October_2009.pdf?DokNr=126414&p=101

3. Report openly on performance, achievements and shortcomings

In an increasing drive to further improve transparency, chemical companies are posting information on their websites, contributing to debates and stakeholder workshops on nano-related issues and openly sharing information about performance, achievements and shortcomings with their stakeholders.
http://www.cefic.org/Policy-Centre/Environment—health/Nanomaterials/

4. Listen, engage and work with people to understand and address their concerns and expectations

Openness and transparency are important. In addition to hosting its own stakeholder engagement activities, Cefic participates at EU and national level (through its national federations). For more information see: http://www.cefic.org/Policy-Centre/Environment--health/Nanomaterials/ In addition, our member companies are actively involved in engaging with stakeholders

5. Cooperate with governments and organisations in the development and implementation of effective regulations and standards, and to meet or go beyond them

Cefic strives for proportionate and efficient nano-regulatory framework that ensures safety whilst stimulating innovation and keeping Europe competitive. We agree with the European Commission that the current regulatory framework, including REACH, adequately covers nanomaterials.

We understand that, in line with the findings of the 2008 review of the regulatory aspects of nanomaterials, nano-specific guidance documents and implementation tools might need to be developed. Cefic is engaged in that process and is keeping its members informed and updated about new developments in this area. New guidance on food safety assessment has been issued by the European Food Safety Authority (EFSA), and the European Chemicals Agency (ECHA) is expected to update some of its guidance by mid-2012, based on recommendations prepared by a consortium of experts in which industry was represented.

EFSA guidance: http://www.efsa.europa.eu/en/efsajournal/pub/2140.htm

Experts recommendations - RIP-oNs (REACH Implementation project on Nanomaterials): http://ec.europa.eu/environment/chemicals/nanotech/index.htm#ripon

Industry contribution to ISO and CEN standards covering nanomaterials is also acknowledged.

Below is a sample of legislation Cefic member companies comply with all these pieces of legislation:

- General Products Safety Directive
- Classification, Labelling and packaging Regulation
- Toy Safety Directive
- Chemical Agents Directive (COSHH in UK)
- Carcinogens and Mutagens Directive
- Novel Foods and novel Food Ingredients Regulation
- RoHS for Electrical and Electronic Equipment
- Air, Water, Soil and Waste legislation
- Cosmetics regulations
- Biocidal Products Regulation
- Plant Protection Products Regulation

6. Provide help and advice to foster the responsible management of chemicals by all those who manage and use them

Responsible Care includes the responsible management of chemicals, including nanomaterials.

As well as this document, several of our national federations and member companies have produced codes of conduct for responsibly managing nanomaterials. These are often publicly available (see examples below). In addition, industry collaborates on external efforts such as the European Commission's Code of Conduct for responsible nanosciences and nanotechnologies research and the Responsible NanoCode.
http://europa.eu/rapid/pressReleasesAction.do?reference=IP/07/1140
http://www.nanotech.net/content/conference/themes/safety/regulatory-approaches/responsible-nano-code-%E2%80%93-a-timely-initiative-s

International collaboration with other organizations is also recognized like the US National Institute for Occupational Safety and HealthNIOSH document: Approaches to Safe Nanotechnology, DHHS (NIOSH) Publication Number 2009-125 - http://www.cdc.gov/niosh/docs/2009-125/

Workplace Safety

Ensuring workplace safety of our employees and those of our customers is at the heart of our industry's culture – this is true for handling all chemicals, including nanomaterials. To this end, we also work with external bodies such as trade unions, for example the European Mine, Chemical and Energy Workers Union (EMCEF), and the European Agency for Safety and Health at work (OSHA). An example of such cooperation is the Cefic-OSHA Partnership on workplace risk assessment (for all chemicals including nanomaterials):
http://www.cefic.org/Industry-support/Responsible-Care-tools-SMEs/2-Occupational-Health-Safety-Management/ .
http://www.emcef.org/news.asp

In addition, our companies and national federations also provide nano-specific guidelines for worker protection.

Codes of Conduct for the Responsible Production, Handling and Use of nanomaterials

Examples include:

- BASF code of conduct: http://www.basf.com/group/corporate/en/sustainability/dialogue/in-dialogue-with-politics/nanotechnology/code-of-conduct
- Bayer Code of Good Practice: http://www.baycareonline.com/NAFTA/handling_EN.asp?TID=1&PID=6&SID=13&LEVEL=4
- DuPont – Environmental Defence Nanoriskframework: http://www2.dupont.com/FirstChem/en_US/tech_info/environmental/resp_care.html
- Federchimica: Guidelines for the responsible management of nanomaterials (still in progress)
- Nanocyl HSE: http://www.nanocyl.com/en/HS-E/Introduction
- Producers Association of Carbon nanoTubes in Europe (PACTE) - Code of Conduct for the Production and Use of Carbon Nanotubes http://www.cefic.org/About-us/How-Are-We-Organised/Cefic-Headquarter/The-Industry-Sectors/Fine-Speciality-and-Consumer-Chemicals/Producer-Association-of-Carbon-Nanotubes-in-Europe-PACTE/?cat=Producer+Association+of+Carbon+Nanotubes+in+Europe
- UIC code of conduct : http://www.uic.fr/mediatheque.asp?card=12107
  Best Practices of nanomaterial / HSE (march 2009)
- Series of VCI documents on Responsible Production and Use of nanomaterials (all to be found at www.vci.de).
- VNCI – Guidance developed by Dutch employers organisation VNO-NCW in cooperation with two trade unions – “Guidance on how to work safely with nanoparticles”: http://www.ivam.uva.nl/index.php?id=356&L=1

Conclusion

This guidance is a tool to share best practice on how companies can apply Responsible Care principles to safely producing and using nanomaterials across their life cycle. It is intended to be an evolving tool, which will be updated as more companies use it, provide feedback and share experience.

Useful Information

The following website is the official European Union resource of information on nanomaterials and nanotechnologies:

http://ec.europa.eu/nanotechnology/index_en.html

Glossary

BIAC: The Business and Industry Advisory Committee to the OECD. BIAC is an independent international business association devoted to advising government policymakers at the OECD and other related forums on the many diversified issues of globalisation and the world economy. BIAC mission is to promote the interests of business by engaging, understanding and advising OECD policy makers on a board range of issues

OECD: Organisation for Economic Co-operation and Development

LRI Long-range Research Initiative is a global research initiative of the chemical industry, which funds independent research into the interaction between chemicals, human health and the environment

SUSCHEM European Technology Platform for Sustainable Chemistry