Health Care Without Harm
the campaign for environmentally responsible healthcare

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HCWH Europe's Comments on the Impact Assessment on Possible Measures to Increase Transparency on Nanomaterials on the Market

Health Care Without Harm (HCWH) is an international coalition of hospitals, healthcare systems, medical professionals, community groups and academic and research institutions. HCWH's mission is to transform the healthcare sector so that it becomes ecologically sustainable and a leading advocate for environmental health and justice. To that end, we are working to implement ecologically sound and healthy alternatives to health care practices that pollute the environment and contribute to disease.

On 5 August 2015, the European Commission concluded its public consultation on the impact assessment on possible measures to increase transparency on nanomaterials on the market. The assessment was meant to identify and develop the most adequate means to increase transparency and ensure regulatory oversight on nanomaterials, as part of the Communication of the Second Regulatory Review on Nanomaterials (1). Below is a selection of HCWH Europe's responses to the impact assessment.

Due to nanomaterials' potential risk to human health and the environment, HCWH Europe supports the creation of a European-level nanomaterials registry, with registration by use for all actors along the supply chain. A comprehensive registry will best enable decision makers to create appropriate, effective, and efficient responses to the health and environmental risks posed by nanomaterials.

On the current legislative framework:

The current legislative framework does not provide decision makers and consumers with adequate information on nanomaterials. For example, REACH does not specifically address nanomaterials, and nanomaterials are often not distinguished from chemically identical bulk substances in REACH registration dossiers. (Though nonbinding ECHA guidance recommends separate registration, REACH does not require it). Many products that contain nanomaterials are not registered under REACH as they fall below the 1 tonne/year/manufacturer or importer threshold.

While some sector specific legislation provides for labelling of products containing nanomaterials, such as the biocidal products regulation and the cosmetics regulation, there are no systematic labelling requirements upon which consumers can rely. Inconsistency between regulatory frameworks creates confusion. Consumers cannot know whether the products they buy contain nanomaterials, and may become suspicious to discover on their own that such products contain nanomaterials. A registry would create transparency and ensure consumer trust in the products they buy, enabling them to make informed decisions and decide for themselves whether to be exposed to the potential health and environmental risks.

Although some data on nanomaterials is available through the sectorial legislation, a consumer is unlikely to know how to find it, or to know that only some products containing nanomaterials are labelled. Information on nanomaterials that is available under the current legislative framework is not presented in a way that consumers can understand.

On the health hazards of nanomaterials:

In vitro and *in vivo* toxicological studies have shown that some nanomaterials (carbon based nanomaterials, metal based nanomaterials and dendrimers) have cytotoxic, genotoxic, carcinogenic and reprotoxic behaviour and can therefore pose potential risks to human health. The purposed mechanism is cellular damage through oxidative stress and induction of inflammation (2). Due to the special properties of nanomaterials (chemical reactivity and biological mobility) their toxicity can manifest locally at the site of exposure (skin, lungs or gastrointestinal tract) or systemically in distal sites (liver, cardiac tissue, heart, kidneys).

Pulmonary toxicity – Studies prove that nanomaterials can easily reach the lungs due to their small size and can inflict pulmonary damage due to pro-inflammatory effect. A study in mice showed that after inhalation, carbon nanotubes induced an inflammatory effect with a decline in pulmonary function and enhanced susceptibility towards infection (3). Another study on mice showed that single wall carbon tubes have more pulmonary toxicity than carbon black and quartz, which are already considered serious occupational health hazards (4). Nanotubes introduced into the abdominal cavity of mice provoked inflammation and formation of granulomas similar to those caused by exposure to asbestos (5), a substance that has been regulated in worker safety programs for many years. Rats exposed to titanium dioxide have also presented inflammation and epithelial damage (6).

Other organ toxicity – Nanomaterials can cause cytotoxic effects due to oxidative stress and accumulation. A study on cell cultures showed cell death after treatment with carbon fullerenes (7). Metal oxides caused liver damage after accumulation in mice (8). Dendrimers have known toxic effects on cells due to their surface capacities and have been functionalized to reduce this effect (9). Quantum dots that contain cadmium selenium and zinc were found to accumulate in the liver, spleen and kidney of monkeys (10). A study of quantum dots done on a liver model proved the reactive substances making up the inorganic core of quantum dots present acute toxicity to hepatocytes, the main tissue of the liver (11).

Antimicrobial resistance – Bacteria can develop resistance to the antimicrobial effects of nanosilver. A study in a hospital environment shows that *Bacillus sp* can develop resistance to nanosilver (12). This is particularly concerning as nanosilver is used extensively in the medical environment today, and the Bacillus species include *Bacillus anthracis* that causes anthrax and *Bacillus cereus* that causes food poisoning.

On the environmental hazards of nanomaterials:

An unknown quantity of nanomaterials is emitted into the environment and numerous studies show they can inflict toxic behaviour on plants and animals.

Beneficial soil microbe toxicity – Studies show that nanogold can decrease colony formation of microbial communities in soil that are essential to plant growth (13).

Growth inhibition in plants – Silicon dioxide and nanosilver have been found to decrease the growth rate of fresh algae (14), (15). Carbon nanotubes have been shown to inhibit the root elongation of different vegetables (including tomato, lettuce, onion, cabbage, carrots) depending on functionalization (16). Silver nanoparticles have been proven to inhibit the seedling growth rate of common grass (17). Nano iron oxides have showed accumulation in hydroponically grown pumpkin plants (18).

Aquatic and soil organism toxicity – A study on fathead minnow embryos demonstrated that nanosilver could lead to a reduction of the number of embryos (19). Several metal oxides showed acute toxicity in experimental test organisms and cells (20). Carbon nanoparticles studies on earthworms showed that in they were responsible for slowing population growth, increasing mortality and damaging tissue (21).

On why a nanomaterials registry would significantly contribute to reducing the health and/or environmental risks related to the use of nanomaterials:

The registry would contribute to reducing the health and/or environmental risks related to the use of nanomaterials, as it would provide an overview of exposure and emissions of nanomaterials across all sectors, and inform future policy making. A registry would allow for the prioritization of regulatory action and research funding based on data that raise concerns, such as wide dispersive use, high tonnages, overuse of substances that contribute to antimicrobial resistance and other information that the current regulatory framework does not provide. Furthermore, the availability of registry information to companies would help improve risk management and hence reduce health and environmental risks related to the use of nanomaterials. A registry would also allow for traceability of products containing nanomaterials should urgent health or environmental problems arise, and hence can serve as a guarantee for the products already on the market.

On why a registry requiring notification per use would be most useful for public authorities, downstream user companies, workers and consumers:

A registry requiring notification per use would have the most added value and would be most useful for public authorities, downstream users, workers and consumers. Complementing the registry with labelling obligations for products containing nanomaterials and a tracking number would make the system even more effective for traceability purposes.

Public authorities – A registry requiring notification per use could reveal the total number and range of products containing nanomaterials on the market. Public authorities would then be able to better understand the exposure and emissions and create risk management methods to mitigate health and environmental effects. Public authorities could also use the registry information for enforcement purposes, such as crosschecking environmental permits, product controls, or marketing claims. A registry requiring notification per use would allow for

traceability in the event of a public health or environmental emergency or product recall, and would inform decision makers on risk assessments and risk management.

Downstream user companies – A registry requiring notification per use would force downstream user companies to inquire about the substances in their products and would improve supply chain communication, especially where products are not regulated under REACH. Knowing that products contain nanomaterials and understanding potential exposure pathways allows companies to better manage associated risks.

Workers – A registry requiring notification per use would allow workers to know that products they work with contain nanomaterials, and better understand where exposure may occur. Depending upon the level of detail required in the registry, a notification by use would allow for a better understanding of risk assessment and management, and hence could improve proper use and handling. Trade unions will have better information to create and support demands for safer work environments.

Consumers – A registry requiring notification per use would allow consumers to look up whether specific products contain nanomaterials, how the nanomaterials are incorporated and what their purpose is. Consumers can learn where and how nanotechnology is improving products and make more informed purchasing decisions.

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