Stakeholders' Response to the Communication on the Second Regulatory Review on Nanomaterials

Brussels, 23 October 2012

To:

Mr Maroš Šefčovič, European Commissioner responsible for Health and Consumer Protection.
Mr Philippe Martin, Risk Assessment Unit, DG SANCO, European Commission.
Mr Malcom Harbour, Chair of the European Parliament IMCO Committee.

Dear Commissioners,

Our organisations are writing to express our extreme disappointment and deep concerns with the Commission's Second Regulatory Review on Nanomaterials, published on 3 October 2012 (the 2nd Regulatory Review).

As highlighted below in more detail, the European Commission's approach is inconsistent with its own analysis, presented in the Staff Working Paper (SWP). Furthermore, the Staff Working Paper itself neglects to consider all available scientific information and its conclusions appear inconsistent with the reported studies.

The SWP acknowledges the existence of possible risks due to exposure to nanomaterials, and considers that REACH does not currently deliver adequate or reliable information to enable the concerns to be assessed or addressed. It further takes note of the failure of any existing tool to address, in a reliable manner, the current knowledge gap, meaning that citizens are prevented from exercising their right to know about the hazards, risks and uses of nanomaterials.

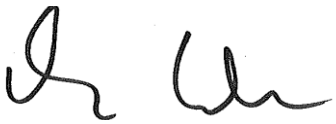
In contradiction with these conclusions, the Commission only considers a limited amendment to the REACH annexes, which is insufficient to close existing loopholes, and manifestly insufficient to overcome the current lack of information on nanomaterials in products. When information is lacking

on the toxicity of a substance, rather than assuming that no data means no harm, the Commission should enforce a precautionary approach and regulate the production and collection of data, and adequately restrict, ban, or tightly regulate the marketing of the substance concerned.

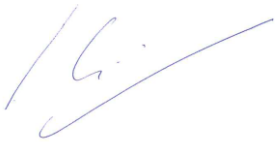
As environmental NGOs, workers and consumer organisations representing concerned citizens at European level, we disagree with the content and conclusions of the Commission's documents and hereby question and challenge the unbalanced approach chosen. In refusing to implement a precautionary approach and by putting the interests of industry ahead of the wellbeing of society, the Commission will only cause further delay in the collection of comprehensive data on the hazards and risks associated with nanomaterials, and will similarly delay the design and adoption of risk management measures where necessary.

We call upon the Commission to correct its analysis according to the inconsistencies mentioned above, and to consider efficient ways to close the loopholes in the legal framework for the regulation and safe management of nanomaterials. Amendments to the Commission's documents are detailed in the annex of this letter.

Yours sincerely,



Jeremy Wates,
Secretary General
European Environmental Bureau - EEB



Bernadette Ségol,
Secretary General
European Trade Union Confederation - ETUC

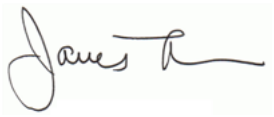
Monique Goyens,
Director General
The European Consumers' Organisation - BEUC

Laura Degallaix,
Secretary General
European Environmental Citizens' Organisation for Standardisation – ECOS

Stephen Russell
Secretary General
The European Consumer Voice in Standardisation –
ANEC

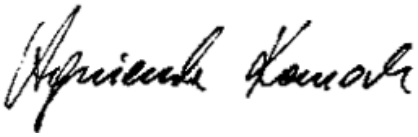
Sascha Gabizon
Executive Director
Women in Europe for a Common Future- WECF

David Azoulay
Managing attorney
The Centre for International Environmental Law- CIEL



James Thornton
CEO
ClientEarth

Olaf Bandt
Director Policy and Communications
BUND e.V. (Friends of the Earth Germany)



Agnieszka Komoch
Head of Operations & Acting Director
Friends of the Earth Europe

CC:

Mr László Andor, European Commissioner responsible for Employment, Social Affairs and Inclusion

Mrs Maire Geoghehan-Quinn, European Commissioner responsible for Research, Innovation and Science

Mr Janez Potočnik, European Commissioner for the Environment

Mr Antonio Tajani, Vice-President of the European Commission, European Commissioner responsible for Industry and Entrepreneurship

Members of the Competent Authorities for REACH and CLP (CARACAL).
Mr Björn HANSEN, Deputy Head of Unit, Chemicals, Biocides and Nanomaterials, DG Environment, European Commission.
Mr Matthias Groote, Chair of the European Parliament ENVI Committee.
Mrs Amalia Sartori, Chair of the European Parliament ITTRE Committee.

ANNEX 1

1. Nanomaterials have distinct properties and all available scientific evidence needs to be taken into account by the Commission

The main conclusion in the 2nd Regulatory Review states that *nanomaterials are similar to normal chemicals/substances*. This is not consistent with the Staff Working Paper, which recognises that *physical and chemical properties of materials may change with size* and *potential toxicity could be primarily due not to the chemical elements but rather to factors associated with size and shape.* Moreover, the SWP ignores the majority of existing scientific evidence which indicates that nano-scale range particles may have different properties, including (eco)toxicity properties, than larger-sized particles of similar chemical composition.[1] A series of animal experiments predicts that particles at nano scale are more toxic, showing more biological activity and greater uptake than their larger counterparts, due to their greater surface area per mass.[2]

For example, the SWP states that *some manufactured nanomaterials (carbon black, TiO_2) show low toxicity.* However, the document acknowledges that the International Agency for Research on Cancer (IARC) found sufficient evidence for the carcinogenicity of carbon black and of TiO_2 (titanium dioxide) in experimental animals. Moreover, carbon black nanoparticle instillation has been shown to induce sustained inflammation and genotoxicity in mouse lung and liver,[3] it has shown to be more genotoxic in human lymphocytes at lower than at higher doses, unlike its non-nano form.[4]

The analogy with ultrafine particles is rightly highlighted in the Commission's document; however, the conclusions drawn from this analogy to the effect that the current approach is sufficient to guarantee the protection of human health and the environment appears grossly incorrect, given that ultrafine particles are already responsible for causing serious health and environmental problems, especially in cities and around airports. The potential toxicity of airborne nano-scale particles is currently considered to be even higher.[5,6,7]

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[1] These differences include a high rate of pulmonary deposition, the ability to travel from the lung to systemic sites, and a high inflammatory potential.
FAO (2012) State of the art on the initiatives and activities relevant to risk assessment and risk management of nanotechnologies in the food and agriculture sectors.
http://www.fao.org/fileadmin/templates/agns/pdf/topics/FAO_WHO_Nano_Paper_Public_Review_20120608.pdf

[2] Yokel, RA et al. (2011) Engineered Nanomaterials: exposures, hazards and risk prevention. *Journal of Occupational Medicine and Toxicology* 2011, 6:7 doi:10.1186/1745-6673-6-7.

[3] Bourdon, JA (2012) et al. Carbon black nanoparticle instillation induces sustained inflammation and genotoxicity in mouse lung and liver. http://www.particleandfibretoxicology.com/content/9/1/5

[4] Ghosh et al. (2010) Genotoxicity of Titanium Dioxide (TiO_2) nanoparticles at two trophic levels: Plant and human lymphocytes.

[5] Nano-scale particles have been implicated in higher mortality in the general population at higher pollution rates, and in aggravation of asthma and lung cancer, cardiovascular effects, fume fever and more severe irreversible respiratory illness. Carcinogenicity of inhaled nanoparticles has been also acknowledged, in Roller, M (2009) Carcinogenicity of inhaled nanoparticles.

[6] BAuA (2007) Nanotechnology: Health and environmental risks of nanomaterials. Research strategy.
http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/Nanotechnology/pdf/research-strategy.pdf;jsessionid=CDCF19DB15C9C04EFCB9937F12021152.1_cid246?__blob=publicationFile&v=2

According to the SWP, the EC concludes that *existing risk assessment methods are adequate for nanomaterials* and that *notwithstanding a number of uncertainties, there is no reason for alarm about nanomaterials*. In contrast, it is our view that there is sufficient scientific information available to warrant a precautionary approach to protect humans and the environment from potential harmful effects of nanomaterials.

2. <u>It is critical to focus on reliable information sources and information generation</u>

The 2nd Regulatory Review points out that the applicable legislation must ensure a high level of health, safety and environmental protection and mentions that in this context, transparency of information on nanomaterials and products containing nanomaterials is essential. After reviewing existing databases containing information on nanomaterials and nano-containing products, the Regulatory Review points out that none of these are reliable because they are not based on systematic data collection over a wide range of products, nor is it certain that the products mentioned do indeed contain nanomaterials. The Commission also takes note of the complete failure of any voluntary reporting schemes put in place so far.

Despite these clear conclusions, the only action foreseen by the Commission is the creation of a web platform with references to all relevant information sources. This solution, which implies no generation of reliable information on nanomaterials, is at odds with the SWP conclusions above.

It is unacceptable that, despite the acknowledged failure to ensure citizens' right to know about the uses, hazards, and risks of nanomaterials, the Commission is trying to maintain the status quo, favouring industry's refusal of transparency over the interests of citizens and their right to know about what chemicals they are exposed to and how.

3. <u>Questions raised on health and safety at work</u>

The 2nd Regulatory Review mentions that direct employment associated with nanotechnologies is estimated at 300,000 to 400,000 jobs in the EU. The original source that the Commission refers to does not disclose the methodological approach used to reach these estimates, and does not seem to include structural changes in the job market, which raises questions over both the estimates and the intention behind the use of these undocumented figures.

[7] The identified hazards indicate potential toxic effects of certain nanomaterials as well as chronic lung toxicity (inflammation, fibrosis) and the formation of tumours through nanoparticles and "microparticles" (fine dust) have already been observed in animal experiments under specific exposure conditions. BauA (2006) http://www.baua.de/cae/servlet/contentblob/717964/publicationFile/48609/draft-research-strategy.pdf

Furthermore, the SWP claims that the paucity of data on exposure to nanomaterials and available exposure models, as well as the absence of nano-specific information in Safety Data Sheets, is *making it often difficult for employers and workers at the use stage to assess specific exposure to nanomaterials and to implement adequate prevention measures*. It is unacceptable that the 2nd Regulatory Review then shifts the burden of proof to the employers and workers to assess the risks of nanomaterials used at the workplace. This is especially troublesome when it is even unknown to them if they are present in the products.

4. <u>The REACH adaptation proposals are grossly insufficient</u>

The SWP notes that *Exposure to consumers and the environment at the use stage, and to an extent also in the waste stage is more difficult and often impossible to control through risk management measures at the place of exposure*. This reinforces the statement that REACH is the cornerstone legislation to collect adequate information for the safe management of nanomaterials.

There is, however, a stark contrast between the recognition that registrations of nanomaterials to date are extremely rare, as well as being incomplete, unclear and containing only very limited information addressing safe use, and the proposals supposed to remedy this situation. The 2nd Regulatory Review feigns to discover the dearth of available information, choosing to blame the absence of detailed guidance for the registrant and the general wording of the annexes. This situation has in fact been foreseen and denounced by all stakeholders alike, except industry, since the first regulatory review over three years ago. The causes of such a situation have furthermore been thoroughly traced back to the inadequacy of the REACH provisions (absence of a definition in the REACH text, inadequacy of tonnage thresholds, inadequate implementation of phase-in rules for the vast majority of nanomaterials, etc.) and to the industry's systematic refusal to adopt and implement transparency mechanisms.

By ignoring the views of most stakeholders and strictly adopting the views of industry in contradiction with available scientific and legal analysis and experience of these past three years, the 2nd Regulatory Review risks further postponing the collection of necessary information, and automatically allowing the production and marketing of nanomaterials, without appropriate data being available, for several more years. The Commission is going directly against the '*no data no market principle*' of REACH, as well as against the precautionary principle embedded in the treaty texts.