Stakeholders' Response to Titanium Dioxide Manufacturers association**'s letter on Titanium dioxide**

Brussels, 17 September 2013

TO:

Paul Anselme, TDMA Manager
Myriam Goffin, CEFIC

COPY TO:
DG ENT: Ms Maila Puolaama and Mr Otto Linher (with request for sharing with CASG Nano MS expert group)
DG ENV: Mr Henrik Laursen
DG EMPL: Mr Jorge Costa-David
Mr Groote, Chairman: Europarl
Mr Liese, Co-coordinator of the EPP Group
Mr Seeber, Co-coordinator of the EPP Group Ms Korhola, EPP;
Ms McAvan, Coordinator of the S&D Group
Mr Davies, Coordinator of the ALDE Group
Ms Hassi, Coordinator of the Greens/EFA Group Ms Rosbach, Coordinator of the ECR Group
Ms Girling, ECR Group
Mr Rossi, Coordinator of the EFD Group
Ms Liotard, Coordinator of the GUE/NGL Group

Dear Mr Anselme,

On behalf of the undersigned public interest civil society organisations, we would like to thank you for your interest in our joint letter to the European Commission highlighting our concerns with the second

regulatory review on nanomaterials and provide the following comments on the letter the Titanium Dioxide Manufacturers association (TDMA) circulated in March 2013 (hereafter the TDMA letter).

We would in particular like to reiterate our concerns regarding the contradictory information disseminated by chemicals manufacturers in relation to titanium dioxide, some of them disregarding scientific studies used for the evaluation of associated risks enclosed to your letter and the obvious lack of independence of the science behind the studies TDMA have submitted which do not prove that the material is harmless.

The TDMA letter makes a number of incorrect statements (for more details on each of these point, see the in-depth review enclosed), including:

- Incorrectly stating that TiO_2 products on the market only contain a small fraction of nanoparticles.
- Incorrectly suggesting that all the studies it refers to are valid for the nanosize form.
- Confusing the use of protection measures with the idea that the material is inherently safe.
- Incorrectly assuming that all surfaces treatment forms have the same risk profile (with the apparent objective of limiting REACH registrations.

As a consequence, it the letter's conclusion that all nano forms of TiO_2 are safe does not appear to be substantiated and cannot be accepted.

It is an obligation under REACH for manufacturers of any chemical substance to prove that their substances are safe before they are placed in the market. In order to do so, manufacturers must assess their risks taking into account all available data, including particle toxicology and the most recent research results, as well as maximize efforts to agree on a common classification and labelling. Risk assessment processes must be comprehensive and regularly updated in order to provide quality and relevant information to consumers and workers so that they can make informed choices, and be adequately protected from the substances they are exposed to.

In that respect, it should be noted that six notifiers for the ECHA´s classification and labelling inventory have classified the TiO_2 in the ultrafine/nanoform as possible carcinogen (CLP´s category 2). We urge the TiO_2 manufacturers association to recognize the validity of information registered by these six notifiers.

France is currently doing a comprehensive evaluation of the risks posed by TiO_2 as a CoRAP substance. We express the hope that it will identify which additional measures may be needed to suppress any risks associated with the exposure to TiO_2. Finally, on the listing of TiO_2 as a possible carcinogen (Group 2B) by the International Agency for Research on Cancer (IARC), this classification applies to all forms of TiO_2, including the ultrafine particles and the nano form of the substance. The US National Institute for Occupational Safety and Health (NIOSH) classifies ultrafine/nano TiO_2 as potential occupational carcinogen. Given the international standing and recognition of these two institutions, it appears grossly inappropriate for TDMA to argue against the scientific integrity of IARC and NIOSH reports, in particular in light of the incorrect TDMA statement listed above.

Please find enclosed further information on the relevant and reliable sources we have used to identify strong evidence that ultrafine/nano TiO_2 is indeed carcinogen, cytotoxic, genotoxic, reprotoxic neurotoxic and can cause lung inflammation together with other adverse effects. We also invite you to review the enclosed Classification and Labelling notifications classifying ultrafine/nano TiO_2 as a possible carcinogen by TiO_2 producers.

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,
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European Environmental Citizens' Organisation for Standardisation – ECOS

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