



BIAC Discussion Paper for the OECD Special Session on Nanomaterials

Paris, 7 June 2005

BIAC appreciates the opportunity to participate in and present its views to the OECD special session on nanotechnology, which is being organised as part of the 38th OECD Joint Meeting. BIAC wishes to emphasize the following five key concepts: ¹

- Nanomaterials are a significant commercial opportunity and promise societal and sustainable development benefits.
- There is an opportunity for all stakeholders to work together to implement these opportunities in a way that is socially responsible and economically viable within a practical regulatory framework.
- The existing regulatory frameworks in most OECD countries are robust enough to evaluate newer nanomaterials if on-going scientific advances are taken into consideration. These frameworks have also been adequate for the review of existing nanomaterials.
- Intergovernmental support will be critical in encouraging global coordination and harmonization of regulatory activities, so that newer materials do not face a patchwork of regulations, and
- Intergovernmental support is also crucial in encouraging agencies to facilitate and increase resources devoted to environmental, health and safety (EHS) research.

The potential for engineered nanomaterials to significantly improve our quality of life and our enjoyment is becoming increasingly recognized. In addition to engineered nanomaterials there are two other major groups: incidental and natural nanomaterials. Incidental nanomaterials include particulate from combustion processes, and many forms of attrition resulting from human activity such as vehicle traffic. Naturally occurring nanomaterials include volcanic ash, ocean spray, mineral composites and others.

It has not been established that all nanomaterials should be regulated and permitted as if they were new chemicals. A collateral issue of concern is whether at least some of the new nanomaterials² may be more toxic than their larger-sized counterparts. There are specific studies that indicate small size may accentuate toxicity in some cases, and others indicating small size does not accentuate toxicity. On balance, however, there are no integrated, peer-reviewed studies pointing to a broadly based increased hazard. However, there are also no studies demonstrating that broad classes of nanomaterials generally are not more toxic than their larger-sized counterparts although there are some nanomaterials that have been in commerce for a long time without the emergence of health or environmental problems.

We support an international effort that will create a broad understanding of nanomaterials, including standardisation of terminology, in a way that will be scientifically sound, publicly acceptable, and practical within a regulatory framework that is designed to ensure the safety of nanomaterial based systems. We support an international effort to define, conduct and assess the tests and procedures necessary to support the commercialization of “new” and existing

nanomaterials in a way that protects the worker, the public, and the environment while not needlessly impeding the development of valuable products in this important commercial area. Simultaneously we support establishing the grounds where appropriate, for not requiring new regulatory approval of “existing” nanomaterials. We support continued assessment of the existing regulatory mechanisms and adjustment as necessary to ensure worker, consumer and environmental safety. Based on our experience thus far, we believe the existing regulatory mechanisms among the developed nations provide an adequate framework for this task, albeit with some adjustments.³

Within the United States, there is already an American Chemistry Council CHEMSTAR Nanotechnology Panel, containing 17 members representing mostly international chemical companies. That Panel is working with the US EPA to advance the review of nanomaterials within the existing regulatory frameworks. In addition, a subset of these companies has formed the Global Coordination of Stewardship Nanotechnology Group (GCSNG) to foster a global and coordinated approach to stewardship. Elsewhere, a number of activities in the UK, Germany (VCI/DECHEMA) and in the International Council of Chemical Association (ICCA) also have already committed to contribute to this international effort. In parallel, there is an excellent opportunity for the OECD to play a major role in the harmonization of efforts such as this and to support the underlying research needed to advance the understanding of the potential health and environmental impacts of these materials.

To this end, we support the need for:

1. A multi-stakeholder effort comprised of academia, government agencies, industry and other non-government organizations representative of our larger societies.
2. The development of a broadly accepted mechanism to collect and share existing and future data on the human and environmental toxicology of nanomaterials, and on their fate and effect in the environment.⁴
3. The development of a broadly accepted mechanism to collect and share existing and future data on the tests and procedures for insuring worker safety and appropriate manufacturing containment.
4. The development of guidelines and procedures for tiered testing and review leading to determining the hazards, if any, associated with the uses of “new” nanomaterials and to setting appropriate guidelines for maintaining safety in the workplace.
5. The development of guidelines and procedures for establishing a record of safety for “existing” nanomaterials.
6. An on-going effort in the regulatory arena to identify best practices on protocols, hazard determination, and other testing and research issues, internationally.

Further, we advocate:

- The need for increased governmental funding on the environmental, health and safety issues of nanomaterials;
- The concept that government research should focus on ensuring approved testing methods are available while industrial firms focus on testing their products;
- The need for global coordination in research and regulation;
- Addressing the challenge of how to promote stewardship efforts to all firms along the value chain.

- (1) Taken in part from the testimony of Frederick C. Klaessig, Degussa Corporation Senate Foreign Relations Committee European Affairs Sub-Committee May 11, 2005
- (2) Materials where at least one dimension, that affects the function behavior of the product, is in the length range of < 100 nanometers
- (3) For example, in the USA, under the Toxic substances Control Act (TSCA), Section 8(e), what exists on the TSCA inventory should be tested if on-going scientific studies and their review indicate that there is a gap in the existing data. What does not exist on the TSCA inventory, must have its testing requirements established by the Agencies, and, if in the testing a new toxicity mechanism is uncovered, one may have to re-open "existing materials. A similar mechanism exists in other developed nations.
- (4) Our experience, thus far, suggests that such data is limited. However, that might be improved if we can successfully work with the pharmaceutical and pesticide industries.