Testimony of Frederick C. Klaessig, Degussa Corporation
Senate Foreign Relations Committee
European Affairs Sub-Committee
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Thank you, Senator Allen and Committee members and staff, for the opportunity to address Nanotechnology and Regulatory Issues from the standpoints of US and European firms. I am Dr. Frederick C. Klaessig, Technology Director for the Aerosil & Silanes Business Unit of Degussa Corporation. I am here representing Degussa plus several US and European member firms of the American Chemistry Council (ACC) that are actively involved with nanotechnology issues. Some of these firms are also active in the ACC's European and German counterparts, CEFIC and VCI, respectively.

If I am effective in my testimony today, I will be leaving you with three concepts:

1. The existing regulatory frameworks in Europe and the U.S. are robust enough to evaluate newer nanomaterials if on-going scientific advances are taken into consideration;..
2. Congressional support would be most effective in encouraging global coordination and harmonization of regulatory activities, so that newer materials do not face a patchwork of regulations; and,
3. Congressional support is also crucial in encouraging federal agencies to increase funds for environmental, health and safety (EHS) research.

Degussa Corporation is a wholly-owned subsidiary of Degussa AG, the third largest German chemical firm based in Duesseldorf, Germany. Degussa AG's roots go back to the mid-nineteenth century and we are presently the world's largest specialty chemical firm with

revenues of €13 billion, employing 45,000 people globally. In the United States, Degussa employs 6,000 workers at over 60 manufacturing sites, with major facilities in Alabama, Virginia, New Jersey, New York, Ohio, Georgia, and Texas.

Nanotechnology is regarded as one of the key technologies of the 21st century. Degussa regards this new technology as an opportunity to help develop new products and efficient scientific and technological solutions, and so make essential contributions towards environmental protection, health, and product quality. The company's responsible approach to nanotechnology is described in the policies recently approved by Degussa's Management Board; according to these policies, Degussa produces and markets nanomaterials only if, according to the latest available research, they can be manufactured and applied in a safe and environmentally compatible manner.

Degussa specializes in manufacturing fine scale powders. During these manufacturing processes, intermediates form that are nanoscale in part, which are smaller than one ten-thousandth of a millimeter and which immediately coalesce into much larger, micron-sized agglomerates. For special applications, formulations such as dispersions are selectively manufactured that contain these nanomaterials. In the research, production, and application of nanomaterials, Degussa is guided by informed prudent practices and the findings of scientific studies on hazard and risk assessment. These findings determine the measures necessary to protect employees, customers, and consumers when manufacturing and using nanoscale materials. Degussa works closely with leading European and U.S. research institutes for this purpose. Moreover, Degussa explicitly supports the establishment of new research methods, specially tailored to the specific effects of nanoscale materials, which permit refinement of risk assessment.

Unlike other "new" technologies, there is a long history of nanomaterials being safely used in commerce when following good industrial hygiene practice. As a manufacturer for more than 60 years of products that have nano-scaled features, we are in a position to bring an historical perspective to the current R&D initiatives taking place in the U.S., Europe, and Japan. We have actively participated in the general trend of utilizing finer and finer materials (smaller and smaller features) and narrower and narrower particle size distributions, which taken together are termed the top down avenue to nanotechnology. The decades long trend to smaller particles has led to a dramatic improvement in physical properties in such applications as reinforcement of silicone rubber, paint rheology control, fillers in general, glossy inkjet paper coatings and chemical mechanical planarization of semiconductor wafers.

From the broader historical perspective, we note the following tipping points when viewing the current nanotechnology initiative in the United States (expressed in the traditional *stasis* categories):

	Comment on current situation
Fact	Traditional concepts of surface and bulk chemistry are being confused when physical and life science disciplines participate in the dialog
Definition	There are a multitude of definitions for materials that have been in commerce safely for decades, while there is a lack of definition for newer materials and novel functionality
Quality	The safety of existing materials, as well as future innovative substances, is put into question when there are gaps in scientific knowledge and toxicity test methodology that are being actively pursued
Venue	The science and uses of nanotechnology are global in nature, but the research initiatives and regulatory schemes are potentially regional
Overall	The various branches of technology development are operating at different speeds, causing confusion regarding the science, safety, and utilization of nano-scaled materials

For those firms having existing nano-scaled products, like Degussa, there is a concern that new, naive definitions will undermine existing patents, trade secrets, and TSCA registrations. The same would be true for our customers who have relied on our technology in developing their own products. For those firms that are contemplating entering the field of nanomaterials with new "engineered" substances with novel functionality, there is uncertainty regarding evolving definitions that do not capture the essence of their innovative concepts in manufacturing, characterizing, and evaluating these materials. For some firms, especially those that are small, innovative and inexperienced, there is the greater likelihood that they are unaware of the regulatory issues they must address in order to achieve a finding of safety for their product(s). All categories of firms, no matter size or resources, will encounter the same regulatory issues during the commercialization process. However, it is not clear that regulatory agencies are viewing the development of nanotechnology with the same priority or coordinating with each other. Placing these concerns under the common heading of "regulatory risk", all categories of firms must now add an additional risk to the standard business risk of the marketplace.

Several member firms of the American Chemistry Council have established working groups with the purposes of coordinating a collective response to our concerns about both existing materials and those in the R&D pipeline.

It is our firm belief that the current regulatory frameworks in the U.S. and Europe are capable of addressing the development of new nanomaterials, if scientific results are taken into consideration as they arise. Certainly, emerging scientific results will need to be taken into consideration as they arise, but the regulatory framewoks are in place to deal with them. The firms participating in the ACC forums are committed to Responsible Care®

principles and are prepared to respond to new and on-going EHS studies. The same is true for industrial hygiene issues, where an industry consortium is already planning efficacy evaluations of face mask, gloves, and other materials when exposed to nanoparticles.

Governmental initiatives in both the U.S. and Europe are to be congratulated in fostering the development of applications in nanotechnology. As society has experienced in other emerging fields, meshing science, technology, funding, and patents does not guarantee success in the global marketplace with new products. We (Degussa and the like-minded firms at ACC, CEFIC, etc.) are most concerned with EHS issues, and we would ask the Senator and his colleagues to consider this issue in their future deliberations.

All new substances require EPA review before being introduced to the commercial market, yet to date, the global initiatives for nanotechnology have not emphasized EHS in their priority programs. Generating the body of knowledge needed to make findings of safety, the process inherent to being TSCA listed, are considered to be the domain of the commercial firm and not of the academic laboratory. Yet, too, the new nanomaterials can exhibit unique properties in both their physical performance as well as in their toxicological, environmental attributes. The novel materials are challenging to the field of toxicology as they are unique in their performance. A gap is forming where we as a society are generating nanotechnology more rapidly than we are creating the tools to measure the EHS impact of this same technology. We understand that public confidence in both the safety of the novel products of nanotechnology and in the methods and processes used to assess them are essential; both must be vigorously pursued. Existing materials may point the way to both health concerns and the Product Stewardship practices needed to eliminate those concerns.

The unknown, especially the unseen material with an uncertain toxicity, can lead to a sudden loss in public confidence about safety. Our concern, being global companies,

regarding the developing gap between generating nanotechnology and evaluating its EHS attributes, is that it may lead the different regions of the world to have separate and restrictive EHS regulations. If a competitive race between regions in generating nanotechnology should lead to a commensurate race in regulating these same materials, then our common desire for benefiting from nanotechnology will be undermined.

It is our firm belief at Degussa that nanotechnology is a global opportunity to be based on a global reservoir of scientific facts. We would urge the Congress to encourage the U.S. agencies to work cooperatively with their European and Japanese counterparts. For example, we commend the Environmental Protection Agency's staff for their active involvement with the upcoming OECD meeting on 7 June. The public meetings the EPA plans in the U.S. will parallel the public meetings to be held by the OECD in 2006. Efforts such as these should be encouraged.

It would help the research innovation cycle greatly if the Congress would encourage the funding agencies involved with the NNI to redirect money from the fundamental research of nanomaterials to the fundamental research for potential toxicity of nanomaterials, as well as their relevant exposure scenarios. It is currently assumed that industry should be responsible for generating the database needed to gain a TSCA listing, but the newer nanomaterials pose a challenge to existing testing methodology. However, test methodologies, structure activity relationships, and analytical techniques are not standardized in this field, and federal funding here would guide the regulatory agencies and responsible firms towards proper testing and evaluation of new materials. Industry and the EPA will look for some guidance to federally funded academic studies, which is preferable to case-by-case studies protected by trade secret status.

Many States have nanotechnology initiatives, which is true in Europe as well. These efforts are closely tied to job creation and often use local university and college resources in these efforts. Successful, state-funded firms will encounter EHS hurdles when commercializing their products at the point of regulatory review at the EPA level or when exporting to Europe or Asia. In fact, there is a range of trade-related issues, such as customs duties, that are similar to EHS concerns and are susceptible to confusing, isolated interpretations when viewed on the global perspective. Again, global coordination of Federal agency activities and research funding of EHS-related evaluation techniques are areas where Congressional encouragement would be most helpful.

I wish to join my other colleagues from industry in expressing our appreciation of the time you are giving to this topic.