Bayer Code of Good Practice
on the Production and On-Site-Use of Nanomaterials

Bayer is an inventor company which operates globally with core competencies in the fields of health care, crop science and high-tech materials. We see nanotechnology as a key technology of 21st century. For Bayer it is as an enabling science, which, through interdisciplinary research, can help us provide new and better product solutions in each of our business areas - from materials engineering and electronics to medical devices and drug delivery systems.
The safe and environmentally sound handling is essential for every new technology. We share the opinion that existing chemicals legislation offers a sufficient framework for the evaluation of nanomaterials. This "Code of Good Practice" describes how we at Bayer intend to fulfill our commitment to promoting human health and environmental safety while realizing nanotechnology's benefits.

- **Scope**

The scope of this "Code of Good Practice" is targeted at the production and use of nanomaterials including ongoing maintenance and disposal activities. Nanoparticles unintentionally generated in other chemical processes, which fall into the nanoparticle size distribution, are already covered by existing work and protection practices.

Currently, the potential hazardous properties of nanomaterials are a matter of ongoing research activities. Therefore the best practice for handling and disposing of nanomaterials is minimizing worker exposure. Additionally, regularly scheduled review of best practice control measures is necessary.

- **Potential for Exposure**

In general, processes using or producing nanomaterials as powders are likely to pose greater exposure potential than suspensions in liquid or other media. Nanostructures, such as integrated circuits or large-scale composites where nanoparticles are embedded in the polymer matrix, will most likely not present significant exposure potential. Thus, whenever possible, nanomaterials should be used in the form of suspensions, pastes, granular materials, or composites.

- **Protection and Prevention Measures**

When the nature of an activity does not allow for effective exposure control through particle encapsulation, the risk mitigation measures must be observed based on the following:

- Technical Protection Measures

Appropriate engineering controls and adequate equipment must be used to prevent or minimize the release of nanomaterials. The production of nano-particles in closed systems can be regarded as having low probability for airborne emissions. If an activity cannot be conducted in a closed system (e.g., sampling or specific maintenance), an effective local exhaust ventilation system must be used. To further reduce exposure to nanomaterials, work areas must be cleaned using a suitable HEPA (high efficiency particulate air) filtration system and wet wiping methods, instead of dry sweeping or compressed air methods.

- Organizational Protection Measures

Before working with nanomaterials, all workers must receive specific information and instruction on the materials and processes, including any potential associated hazards, proper use of personal protective equipment, and the type of engineering control systems in place. In addition, work processes must be carefully documented and approved before putting them into practice. Compliance with instructions, particularly with required protective measures, must be routinely monitored.

- Personal Protection Measures

In cases where exposure cannot be eliminated by technical and organizational protection measures, adequate personal protection measures must be used. Choice of respiratory protection must be risk based depending on each specific operation. In most cases, adequate protection from airborne nanomaterials can be obtained by using a filtering facepiece respirator type (e.g. FFP2/FFP3 or N95/N100 or equivalent). As the potential health effects associated with skin contact with nanomaterials is not yet fully determined, the current best practice is to minimize dermal exposure using suitable protective clothing. In addition, a high standard of personal hygiene after handling and during disposal of nanomaterials must be implemented.

- **Monitoring Workplace Exposure**

Traditional workplace exposure monitoring is performed according to established occupational hygiene practices using gravimetric techniques (guidance is available from professional organizations such as the Berufgenossenschaft in Germany and the Occupational Safety and Health Administration (OSHA) in the United States). In addition, new methods based on particle size (e.g., Scanning Mobility Particle Sizer) possibly in combination with characterization/identification methods (e.g., Transmission Electron Microscopy) need to be considered.

Currently, since there are no established occupational exposure limits for airborne nanomaterials, exposure levels must be maintained at background levels. As natural and man-made nanomaterials such as combustion engine exhaust are ubiquitous, measurements need to be performed to obtain background data before production or processing of a nanomaterial occurs. Measurements made during production or processing can then be specifically evaluated to determine any changes in airborne levels and the appropriateness of the level of controls applied.

One has to take into consideration that methods currently are not standardized, so comparing data across methods is subject to interpretation. Bayer is significantly involved in research and standardization projects, which focus on nanomaterials characterization and development of measuring methods for their exposure assessments.

- **Worker Health Surveillance**

Worker exposure can be adequately controlled by carefully assessing the potential exposures and applying current best practice control measures. As an added precaution, workers handling nanomaterials can participate in routine health surveillance programs to ensure that any work related change in health status is quickly determined and steps taken to identify and address the causes.

The frequency and extent of these examinations will be defined by the employer on a case-by-case basis. As the field of nanotechnology is still developing, occupational health professionals should be involved in the definition of needed technical or laboratory examinations.