

## **GSK Public Policy Position Statement on Nanomaterials**

### **The Issue:**

Nanotechnology is the application of engineered, aggregated poly-atomic and -molecular materials. As a platform nanotechnology has diverse applications ranging from electronics, structural materials and biomedical products which may lead to improved treatments for patients. Hence, nanotechnology offers many potential benefits, but there are emerging concerns about possible hazards to human health, safety and the environment arising from the novel properties of some materials engineered at the nano-scale(1). Information is accumulating on the potential hazards of nanomaterials (2) with significant research efforts underway in many countries to investigate their hazards and risks. There is also discussion regarding the need for new regulations to control the development and use of this technology so that the benefits to patients and consumers can be delivered safely and responsibly.

GSK currently has no products on the market that contain deliberately engineered nanomaterials. However, they may be important constituents of future products as the technology may enable new approaches to treating disease, particularly in drug delivery. GSK is actively investigating a number of opportunities that utilize nanomaterials in our Research & Development programmes. This paper sets out what GSK believes to be a responsible approach to assess and manage potential nanomaterial risks. It is anticipated that this position statement will evolve with the increased knowledge gained during the discovery and development process and as new products emerge from that work.

### **The GSK Position:**

- 1. GSK believes that risk assessment of nanomaterials should be built into the existing Regulatory framework:**
  - The existing regulatory framework for pharmaceuticals and consumer products ensures that we produce extensive scientific evidence to support the claims we make regarding safety and efficacy of our products.
  - GSK believe that this framework is robust and should sufficiently provide for future risk assessment of products using nanomaterials (4). However, GSK would be pleased to contribute to any future revision of regulations governing the development and marketing of such products.
- 2. GSK will conduct risk assessments to minimise any potential public and environmental risks relating to products containing nanomaterials.**
  - During the discovery and development process GSK gains an in depth understanding of its future products and the technologies used to create them. During the development and marketing of any new product, GSK has procedures that assess its hazards and risks. It is recognized that nanomaterials may exhibit different hazard properties than those of the same substance in larger particle sizes.
  - The processes for product development and risk assessment for health, safety and the environment approach described in our existing policies, which are used for non-nanomaterials, are generally consistent with best practice for nanomaterials (5, 6).

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3. **GSK is committed to ensuring that we control the risks to employees developing and manufacturing products that employ nanomaterials.**
  - We acknowledge that there are concerns about the health risks presented by nanomaterials. If hazard data is insufficient to quantify risk GSK adopts a precautionary approach during the development of new products.
  - Until risks are quantified, strict exposure controls are used so that substances are rigorously contained by physical means while in GSK control.
  - Only properly trained and authorised personnel will handle the substance using detailed procedural controls.
  - GSK's EHS testing strategy provides a high level of protection for those working in the development, manufacture, transportation and disposal of our proprietary materials. This will be revised as necessary to allow identification of unusual risks for environment, health or safety related to nanomaterials.
  - All of our operations are required to conduct EHS risk assessments to identify appropriate controls and protect against risk of exposure to any hazardous substances.
  - Our R&D and manufacturing sites are routinely audited against GSK global standards for their performance in controlling risks for environment, health and safety. These standards often go beyond the requirements of local regulations.
  - We intend to share best practice used to monitor and minimise the risk of employee and environmental exposure to nanomaterials throughout the organisation.
4. **GSK is committed to the control of environmental, health and safety risks throughout our manufacturing supply chain:**
  - GSK considers this principle central to product stewardship. We expect our suppliers to meet equivalent standards for quality and EHS to those expected from our own factories and audit contract manufacturers against them.
  - We will communicate information and guidance for customers, contract manufacturing partners and onward users on the safe processing, usage, transportation and disposal of any nanomaterial intermediates or products derived from nanomaterials.
5. **GSK is committed to openness and transparency about how we manage risks associated with use of nanomaterials and will continue to engage with stakeholders on the issue.**
  - We meet with groups of external stakeholders on a regular basis to review our EHS performance and issues. We will address developments with nanomaterials as part of these discussions.
  - As internal experience with the control the EHS hazards and risks of nanomaterials develops, we intend to share this at relevant public meetings and so that others benefit from this knowledge.

## **BACKGROUND**

### **Definitions**

Much of the focus of current nanotechnology research, and the area that triggers most concern for human, environmental and process safety is that of nanoparticles. There is no generally agreed definition of a nanoparticle. However many organisations define a nanoparticle as a material with a mean particle diameter of less than 100 nanometers, as measured by a defined particle sizing method. Materials vary but at this approximate size the physical properties of materials often are different to those of the same material at larger particle sizes.

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Biomedical applications of nanotechnology include diagnostics, quantitative analysis, drug delivery and enhanced therapeutic index by cell and tissue targeting and improved absorption of drugs, for example. An emerging field using nanomaterials is regenerative medicine, examples of which are non-biological scaffolds that provide a matrix which tissues can regenerate. A number of nanomaterials are already marketed for biomedical applications. Many of these are diagnostic agents, using nano-based materials to significantly improve the detection of the diseased state. Others are aimed at better delivery of existing anti-cancer drugs to reduce their toxicity, which is of huge benefit to patients (7).

### **Growing investment in Nanotechnology**

Nanotechnology is rapidly developing and is expected to result in transformations in many biomedical areas (7).

Research and Development investment in this area is significant as governments and industry see opportunities to advance old technologies create new ones from the use of engineered nanomaterials. The United States alone is investing 1.5 billion dollars in 2008, up from 464 million in 2001 (8). Considerable investment is also being made throughout the world into research towards new methods for assessing the EH&S hazards and risks of nanomaterials.

The EU has established a European Technology platform for investment in nanomedicine with several initiatives under way to ensure that European countries remain competitive in this area and also to address related issues such as consumer safety and concerns for environment, health and safety (7)

### **The Regulatory Framework for Nanotechnology**

Hundreds of consumer products are already on the market, which claim enhanced performance from the use of nanomaterials, including sunscreens and toothpastes. As current projects mature it is anticipated that there will be a massive growth in production of these materials through the coming years (9).

It is against this background that several groups have called for caution, or even a moratorium on future development of nanotechnology until the risks are better understood. Companies developing nanotechnology-based products recognise that new research is required to characterise the hazards of novel materials. If the science is to flourish so that the benefit of these materials can be assessed and then realized, then companies need to be open and transparent about uncertainties, and committed to working to address them.

Industry, including GSK, has therefore actively participated in various consortia in several parts of the world with a view to producing Codes of Practice for developing nanomaterials (10). These codes are also supported, or sponsored by governments, recognising potential risks to health and the environment and some have developed initiatives such as the UK voluntary scheme for reporting risk assessments of nanomaterials.

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## Further Background Information:

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- 4) Nanotechnology: A Report of the U.S. Food and Drug Administration Nanotechnology Task Force, July 25, 2007; (<http://www.fda.gov/nanotechnology/taskforce/report2007.pdf>)
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