



Roche Position¹ on Nanotechnology

Roche's Position

As an innovation-driven global healthcare leader, Roche aims to improve the quality of human life by providing innovative products and services for prevention, diagnosis and treatment of diseases. Roche's goal is to help alleviate human suffering caused by diseases. Nanotechnology has the potential to play a role in that mission. Nano-scale materials have indeed been used to manufacture some diagnostic products. The products themselves, which are used in hospital laboratories and by patients at home, do not contain nanoparticles.

Roche is aware of the societal and ethical questions, concerns and expectations raised, in particular those related to potential human and environmental safety aspects of nanotechnology. Roche is fully committed to take these questions, concerns and requests seriously and to address them in a professional and socially responsible way.

In view of the current knowledge about nanotechnology, Roche encourages further studies and promotes an informed dialogue on nanotechnology among the various stakeholders. It is important to explore the opportunities of this technology cautiously and proactively. Given the valuable potential that nanotechnology could warrant, Roche takes a favorable position towards active, safety-aware research in the field and opposes any actions that would block the development of potential benefits from nanotechnology. In all our present and future activities in nanotechnology and in pursuit of our ultimate goal and responsibility to serve human health and well-being, we will conduct our activities by taking into account the public concerns and expectations as well as all applicable laws and regulations.

We actively support the advocacy of the industry associations to adequately and efficiently regulate nanomaterials, supporting innovation and avoiding unnecessary bureaucracy and duplication of regulation.

The global situation

Background: Nanotechnology deals with very small particles and structures in a size range between approximately 1 and 100 nanometers. Structures of that size may attain novel characteristics that have led to nanotechnology being viewed as one of the key technologies of the 21st century. Nanoscience is not seen as a branch of any specific scientific or technological discipline, but rather as inter-disciplinary science, encompassing and combining relevant areas of chemical, physical, biological, and information technologies. Nanotechnology is still a new and evolving field for scientists to explore. The risks and benefits of nanotechnology have to be carefully evaluated, especially if it is to be implemented in applied medicines or therapies.

In view of the wide range of applications of nanoscience and the highly different nature of nanomaterials, there are numerous approaches and proposals for broad and general definitions of nanomaterials, which are subject to on-going debate.

¹ Pertains to WHO Sustainable Development Goals 3



Stakeholder expectations and concerns: As in all new fields of science, there are expectations and concerns from various stakeholders in society relating to the research on and the impact of applying nanotechnology. Innovative companies are expected to explore emerging fields of science to find new opportunities and benefits for society. Stakeholder expectations regarding advantages of promising new technologies, however, are equally closely linked to the requirements for careful evaluation of potential health and safety risks e.g. possible long term effects on the environment. At this stage, neither all the properties of nanotechnology nor the possible long-term adverse effects of the use of nanotechnology based new materials, processes and therapies are known. At the same time, the use of nanotechnology offers important innovation and opportunities for scientific progress in the field of healthcare.

The situation at Roche

While applications of nanotechnology are expected in multiple areas, Roche's interest in nanotechnology is presently focused on:

- Starting materials to manufacture in-vitro diagnostics, and
- Materials and surface coatings for pharmaceutical products, sensors and test strips.

As of today, Roche does not have final products containing nanoparticles.

Roche has one special product using nanotechnology. This product involves a biological nanopore which is a protein pore embedded in a membrane and is used for DNA sequencing. Proteins, being out of the regulatory definition of a nanomaterial and are thus not subject to public concern related to nanomaterials, Roche has been voluntarily carrying out additional tests to exclude conceivable risks for the user and the environment besides fulfilling product regulatory safety standards as required.

Roche carefully follows the continual developments of nanotechnology and monitors emerging regulatory changes related to this subject.

Contact

Dr. Ya-Juin Chou, Expert Chemical Legislation, Chemical Legislation Unit, Group SHE
ya-juin.chou@roche.com , +41 61 682 12 67, Basel / Switzerland.

Dr. Jan Backmann, Head Chemical Legislation, Chemical Legislation Unit, Group SHE
jan.backmann@roche.com , +41 61 688 45 84, Basel / Switzerland.

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