

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 – and nano-scale materials have indeed been used to manufacture some diagnostic products. The products, which are used in hospital laboratories and by patients at home, do themselves 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.

We encourage further studies and promote an informed dialogue on nanotechnology among the different stakeholders. It is important to explore the opportunities of this technology cautiously but proactively. Given the valuable potential of nanotechnology, Roche takes a favorable position towards active, safety-aware research in the field and opposes any actions that would either block the development of potential benefits from nanotechnology. In all our present and future activities in nanotechnology – 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. Concerns relate to safety and possible long term effects on the environment. 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 this stage. 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.

In any case, as of today, final products do not contain 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. Although, proteins are not in scope of the regulatory definition of a nanomaterial and not subject to public concern related to nanomaterials, Roche not only fulfills all regulatory safety standards concerning this product, but has also carried out additional, voluntary tests, in order to exclude conceivable risks for the user and the environment.

Roche carefully follows ongoing developments of nanotechnology and is constantly monitoring any regulatory changes related to this subject.

Contact

Michaela Fuetsch, Expert Chemical Legislation, Chemical Legislation Unit, Group SHE
michaela.fuetsch@roche.com , +41 61 687 23 53, Basel / Switzerland.

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

*This position paper was proposed by the Corporate Sustainability Committee and adopted by the Corporate Executive Committee on January 16, 2014 and entered into force the same day.
It was reviewed in April 2020.*