

Roche Position¹ on Nanotechnology

1. Roche's Position

At Roche, we take a favourable position towards active, safety-aware research and development in nanotechnology. We oppose actions that would block the development of potential benefits from nanotechnology.

As an innovation-driven global healthcare leader, Roche strives to improve the quality of human life by providing innovative products and services for prevention, diagnosis and treatment of diseases.

Through research, development and innovation, Roche recognizes that nanotechnology with valuable potential will help Roche to achieve this goal.

In view of the current knowledge available, Roche explores nanotechnology proactively and with caution.

Roche takes actions to address the questions, concerns and requests raised by stakeholders in a professional and socially responsible way i.e. the possible impact on human and environmental safety while developing, manufacturing or using the products associated with nanotechnology:

- Roche complies with all regulatory requirements and carefully considers the public concerns and expectations while conducting all activities associated with nanotechnology
- Roche supports scientific studies required to verify the potential concerns
- Roche promotes dialogue on nanotechnology among stakeholders in the society
- Roche advocates for adequately and efficiently regulating nanomaterials without unnecessary bureaucracy and duplication to support innovation

2. Current global situation

2.1 Background

Nanotechnology is the application of phenomena and materials at atomic, molecular and macromolecular scales, where properties differ significantly from those at a larger scale eg. novo nano-based materials.

Under the European Commission, nanomaterials are being defined as particles and structures in a size range between 1 and 100 nanometers.

¹ Pertains to WHO Sustainable Development Goals 3

Currently, many products for medical applications are being developed using nanotechnologies which offer important innovation and opportunities for scientific progress in the field of healthcare.

Nanotechnology is an evolving and new interdisciplinary technology combining areas of chemical, physical, biological, and information technologies with a wide range of applications. Given The highly different nature of nanomaterials, all properties and possible long-term effects of nanotechnology are yet to be verified pending on the new materials, processes and therapies.

Therefore, regulations are currently emerging globally to scrutinise nanotechnology use for product development or manufacturing.

2.2 Stakeholder expectations and concerns

Various stakeholders in society show both expectations and concerns towards Nanotechnology.

Expectations

- Innovative companies are expected to explore emerging fields of nano-science to find new opportunities and benefits for society.

Concerns

- In the meantime, besides the advantages that promising new technologies will bring, expectations are also to carefully evaluate the potential human health and environmental risks in association with nanotechnology.

3. Nanotechnology at Roche

Striving for innovative products for medical applications to benefit human health, Roche exploits nanotechnology and complies with all rules and regulations in place.

To verify the possible risks of human health and environment, Roche takes actions to address these concerns i.e. conduct scientific studies, avoid exposure while substance handling, follow nanotechnology developments, and monitor emerging regulatory requirements.

Roche's current focus in the area of nanotechnology is on:

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

3.1 Biological nanopore in medical device

For the purpose of DNA sequencing, this device comprises a protein nanopore embedded in a membrane. Proteins as biological materials are out of the EC chemical regulatory scope (e.g. REACH regulation) of nanomaterial.

3.2 Excipients in solid oral dosage forms

For Roche medicinal products containing excipients with nanoparticle-associated concerns, e.g. titanium dioxide (TiO₂), Roche is closely following the regulatory developments and requirements to ensure continual compliance and safe use.

While the EU authorities plan to further assess in the year 2025 if TiO₂-use in medicinal products is to be continued, Roche's efforts to find alternatives are on-going.

3.3 Innovation in progress

To support innovation, Roche is continually looking into promising therapeutic uses of nanotechnology, e.g. mRNA-liposome vaccines in oncology.

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Reference

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[1] Pertains to WHO Sustainable Development Goals 3