Nanotechnological Medical Devices and Nanopharmaceuticals: The European Regulatory Framework and Research Needs

Abstract:
The current European regulatory framework is assessed in relation to nanotechnology based medical devices and medicinal products. Regulatory procedures are necessary for the approval and certification of products in order to guarantee their safety. This is especially important where there is significant public concern regarding the possible health and environmental impacts. Healthcare applications of nanotechnology will need to comply with the requirements for a high level of public health, safety, consumer and environmental protection. An assessment of the possible health or environmental risks associated with nanotechnology needs therefore to accompany the scientific and technological progress. The existing regulations appear adequate to deal with nanotechnology at its current stage of development. Reassessment of the current regulatory regime by the regulatory bodies will however be required to determine whether it is adequate to protect human health and the environment.

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