Nanotechnology Industries Association
reply to the
SCENIR Call for Information on the Safety of Medical Devices Containing Nanomaterials

Introduction
In response to the Call for Information related to the request for a scientific opinion on the safety of medical devices containing nanomaterials by the European Commission’s Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), the Nanotechnology Industries Association (NIA) is submitting this reply to the call on behalf of its Members, ahead of the 10 October 2012 deadline.

The NIA welcomes the opportunity to provide information to SCENIHR related to the safety of medical devices containing nanomaterials, and anticipates that the provided comments and references will be considered by SCENIHR during its elaborations of the opinion. The NIA would further welcome a public consultation of a draft of the opinion to allow an opportunity to provide comments on the draft before its final adoption by SCENIHR.

This reply is submitted to SCENIHR via e-mail to Sanco-SCENIHR-Secretariat@ec.europa.eu specifying ‘Nano in MedDev – Call for Information’ in the subject line. In addition, an electronic compilation of the references will be provided to the SCENIHR Secretariat.

For any questions or clarifications, do not hesitate to contact David Carlander, NIA Director of Advocacy, david.carlander@nanotechia.org.

Comments
Nanomaterial Definition Recommendation
European commission published on October 19, 2011 a recommendation for a new definition of nanomaterials (Recommendation 2011/696/EU). Considering that the typical particle size distribution of naturally (e.g. sand) or industrially (e.g. fillers, pigments) milled solid particulates it can be seen that practically all of these fall under the definition containing a relative high number of particles in the nanorange. It can be calculated that for particulate solids with an average particle size by weight in the range of 1 – 100 µm (as often used) an amount of particles in the nanorange in the range of some ppb to some ppm by weight or volume is sufficient to fulfill this criteria.

Thus, based on the nanomaterial definition of the EU Commission most (if not even all) particulate solids become nanomaterials. Based on the definition there is no distinction between true nanomaterials (containing a high amount or all of particles in the nanorange) and other particulate solids used since hundreds of years or particulates to which the human beings are exposed since long (e.g. sand or other corrosion products from rocks e.g. iron oxides produced naturally by rusting). For Medical Devices, practically all solid particulates contained in medical devices (fillers, pigments, absorbents...) will be nanomaterials according to this definition. It should also be
considered that abrasion or other mechanical forces can generate particles in the nanoscale size range, be it from tissue like bones and teeth.


The term “unbound” is not specified in Rule 19, and thus, it is understood that every release of such a nanoparticle from the medical device would lead to the application of the rule. From a scientific standpoint the complete absence of release cannot be demonstrated. Even if with a certain method no release is found it cannot be assumed that with other, more efficient methods no released particles can be identified. Due to this scientific rational, the limitation to “unbound” nanoparticles is not helpful. Based on these considerations it must be expected that many medical devices and nearly all dental materials (excepting clear solutions) would fall under the new Rule 19.

The SCENIHR should consider providing a sound scientific basis aiming to reduce the uncertainties created in the EC proposal by the direct incorporation of the EC nanomaterial definition and of the wording of Rule 19, especially as regards the consequences of ‘unbound’ and ‘bound’ used in Article 2(16) and Rule 19 respectively.

The SCENIHR should also consider developing a sound scientific basis that help to differentiate between clearly hazardous products and products that contain only in small amount particles that fall under the definition of nanomaterials.

**SCENIHR call "Nanosilver**

Earlier in 2012 SCENIHR requested a scientific opinion on Nanosilver: safety, health and environmental effects and role in antimicrobial resistance. A submission with relevant information of the safety, health and environmental effects of nanosilver was provided that could also provide information to this call for medical devices containing nanomaterials.

**Nanotoxicology general**


**Usage of nanosilver as medicinal product in the last century**


Gastractin: a medicinal product, used in Germany: Enclosed label gastractin

**Toxicology of nanosilver for medical applications and (Nano-)Silver in medical devices**


**Review articles**

Consider also these review papers:


Review of 2007–09 literature on toxicological and health-effects relating to six nanomaterials (2009) Report prepared by Professor Brian G. Priestly, Director Australian Centre for Human Health Risk Assessment (ACHHRA) Monash University School of Medicine, Nursing and Health Sciences. (NICNAS)