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Preliminary opinion

Guidance on the Determination of Potential Health Effects of Nanomaterials Used in Medical Devices

Fields marked with * are mandatory.

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If you have comments on different chapters/sections, please select the chapter, add your comment, and submit your comments separately. Please also upload the scientific papers you consider relevant for that section/chapter. Repeat this operation for each chapter you would like to comment on. After sending a comment, it will be indicated if it has been sent successfully and you will be able to enter your next comment.

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1. BACKGROUND

Please indicate the line numbers of the text on which you comment, if appropriate.

3,800 character(s) maximum

This Guidance should take note that the Medical Devices Regulation recast [1] has not been published and nano-specific provisions are not fixed. In this regard, the European Parliament's amended version significantly changes the scope of the regulation regarding nanomaterials as only devices where the nanomaterial is intended to be released are concerned by Rule 19 [2]:
Amendment 304 'All devices incorporating or consisting of nanomaterial deliberately intended to be released into the human body are in class III.'
[1] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009
[2] European Parliament legislative resolution of 2 April 2014 on the proposal for a regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 (COM(2012)0542 – C7-0318/2012 – 2012/0266(COD)) (Ordinary legislative procedure: first reading)

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ABSTRACT

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This guidance addresses nanomaterials used in medical devices on the basis that they 'pose a challenge for the safety evaluation and risk assessment of these medical devices'. Nanomaterials are nevertheless 'similar to normal chemicals/substances in that some may be toxic and some may not' [1]. Nanomaterials with no toxicological issues should be excluded from the scope of this guidance (e.g. liposomes).
In principle the described methodology is a realistic approach to determine adverse effects by a case-by-case and step-by-step approach.
Nanosilver particles are not used as free nanoparticles but embedded in the material; anti-microbial silver ions are released.
[1] European Commission, Communication on the Second Regulatory Review on Nanomaterials, COM/2012/0572 final

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3.1. Introduction

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Nanoparticles generated from wear-and-tear phenomena in devices where nanomaterials were not used originally should not be covered by this guidance as the title of the Guidance is directed to 'nanomaterials used in medical devices'.

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3.5. Exposure to nanomaterials from medical devices

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The complete absence of release is impossible to demonstrate scientifically. Also, the regulatory framework is, at the moment, unclear on the 'release' criteria: in the European Parliament's amended version, only devices in which nanomaterials are deliberately intended to be released are concerned by Class III classification [1].

[1] Amendment 304 European Parliament legislative resolution of 2 April 2014 on the proposal for a regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 (COM(2012)0542 – C7-0318/2012 – 2012/0266(COD)) (Ordinary legislative procedure: first reading)

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3.6.2. Methods to evaluate toxicokinetics of nanomaterials

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Nanosilver particles are not intended to be released into the body but they are embedded inside the material. Similarly to microsilver, silver salts or silver electrodes, nanosilver releases silver ions; the anti-microbial effect of nanosilver is ion-related and not nano specific.

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