

Nickel Institute Position Paper Proposed EU Regulation on medical devices

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Unintended consequences of European Parliament's amendment threaten use of metal alloys and stainless steel in Medical Devices

The issue

On 22 October 2013, the European Parliament voted on the [proposed EU Regulation on medical devices](#). The EP adopted, by a narrow margin, an amendment ([Amendment N°355](#)) which would require that: *“Medical devices or parts thereof that are invasive or come into contact with the body of patients, [...] shall not contain, in concentrations above 0.1% by weight in homogeneous materials, substances which are carcinogenic, mutagenic or toxic to reproduction [...]”*.

The Amendment also stipulates that the European Commission shall be empowered to adopt derogations to allow for the use of such substances for a period not exceeding four years, (but which could be renewed), provided that a number of very stringent conditions are fulfilled.

Possible unintended consequences for stainless steel and metal alloys

The current EU hazard classification of some metals used as alloying elements classified as suspected carcinogen and the EU rules on the classification of mixtures (which includes alloys) would prevent the use of these materials in “medical devices or parts thereof that are invasive or come into contact with the body of patients, [...]”, unless specific derogations are granted by the European Commission. For example, alloys, including stainless steels, containing above 0.1% of certain metals as alloying elements, could fall within the scope of the amendment. Thus, this provision could impact stainless steels and certain alloys (e.g. nitinol) used in medical implants (e.g. orthopedic implants, vascular stents, etc.), orthodontic devices and surgical instruments.

Furthermore, the proposed amendment is inconsistent with REACH, where the way in which the constituent substances are bonded in the chemical matrix has to be taken into account, and the metal/ substance release from (rather than the concentration of metals in) an alloy or special mixture needs to be considered for the assessment of health and environmental effects.

Who would be affected?

Companies producing in, or exporting such medical devices to, the EU market would be directly affected by this provision. In order to continue to use stainless steel and alloys containing specific alloying metals in these medical devices, manufacturers would have to apply for derogation(s) from the European Commission and submit detailed information,

including an analysis of possible alternative materials and proposed actions to develop possible alternatives. Businesses would hence be subject to additional administrative burdens and regulatory uncertainty.

The proposed amendment would impose a considerable burden on Competent Bodies in terms of derogation requests, particularly as there are many thousands stainless steel medical devices and the proposed amendment implies a case-by-case approach. A similar derogation process imposed by the EU Ecolabel Regulation has necessitated the setting-up of an Expert Group to assess Ecolabel derogation requests for a significantly smaller range of products.

Position of the Nickel Institute

Several metals find applications in a wide range of medical devices, some of which are important alloying constituents in stainless steel. The use of nickel as alloying constituent in stainless steel ensures corrosion resistance, durability, and the possibility to repeatedly disinfect and sterilize and ensure the integrity of implants.

Consequently, although we fully support the objective of the proposed Regulation (i.e. to reinforce patient safety), the Nickel Institute consider that the adoption of this amendment could lead to disproportionate and unintended adverse impacts, preventing the use of safe and valuable materials such as stainless steel, whose properties are indispensable for medical devices and the medical environment.

The Nickel Institute urges the EU policy makers to re-consider the amendment and its hazard-based approach in the light of potential unintended negative impacts that it could have on the use of safe materials such as stainless steel and other metal alloys in medical devices.

The Nickel Institute is the global association of the world's primary nickel producers who together account for approximately 85% of worldwide annual nickel production outside China. Our mission is to promote and support the use of nickel in appropriate applications. NI grows and supports markets for new and existing nickel applications including stainless steel; and promotes sound science, risk management, and socio-economic benefit as the basis for public policy and regulation. Through our science division NiPERA (www.nipera.org), we also undertake leading edge scientific research relevant to human health and the environment. NI is the centre of excellence for information on nickel and nickel-containing products and has offices in Asia, Europe and North America.