



February 7, 2019

European Commission
EU-TBT Enquiry Point
Via E-mail: grow-eu-tbt@ec.europa.eu

Re: European Union WTO Notification (G/TBT/N/EU/629): Draft Commission Regulation amending, for the purposes of the adaptation to technical and scientific progress, Regulation (EC) no 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting Commission Regulation EU 2018/669

To Whom It May Concern:

On behalf of the Specialty Steel Industry of North America (SSINA), I am pleased to submit the following comments regarding the above captioned Draft Commission Regulation Amending Regulation (EC) no. 1272/2008 and Correcting Regulation (EU) 2018/669, notified to the WTO as G/TBT/N/EU/629.

Background: Notification – EU Classification Proposal

In their draft Regulation for the 14th adaptation to technical progress of Regulation (EC) 1272/2008 on classification, labelling and packaging of substances and mixtures (the CLP Regulation),¹ the European Commission proposes to classify Cobalt metal as:

- Carcinogen category 1B for all routes of exposure, with an interim Generic Concentration Limit (GCL) of 0.1% (mixtures, including alloys, above the GCL are classified similarly)
- Reprotoxic category 1B
- Mutagen category 2.

The recital refers to further assessment on the applicability of the methodology used to determine potency and specific concentration limits for metal compounds.

Justification for this draft regulation is the protection of human health or safety and protection of the environment.

¹ *Draft Commission Regulation amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting Commission Regulation (EU) 2018/669.*

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The WTO consultation on this notification in view of Technical Barriers to Trade (TBT) is open until **February 10, 2019**.

Impact on Imports of Stainless Steel and Stainless Articles into EU

The EU proposal will lead to the classification of stainless and other specialty steels, as well as articles containing these materials, as carcinogens *for all routes of exposure* (including ingestion and dermal contact, as well as inhalation) as cobalt is present in all types of stainless steel above the 0.1% concentration limit.

The classification would impact the import into the EU of stainless and other specialty steels, particularly for uses involving *oral and dermal contact*, such as for food industry and medical applications where stainless steel is considered as the material of choice enabling clean and sterile conditions. The implication that all contact with stainless steel should be considered carcinogenic is deeply troubling, particularly in light of the long history of safe use of these materials. Given the widespread use of stainless and specialty steel – including for public transport, water pipes, surgical instruments, medical devices and implants, hospitals, schools, kitchens, food processing, cookware, cutlery, aerospace, pharmaceutical production, jewelry and so on – the scale of the impact could be significant, creating public concern and a climate of anxiety and confusion. This would lead to unnecessary obstacles in trade in stainless and specialty steels and impact the global stainless steel market.

The main regulatory problem posed by the proposal, especially in Europe, is expected to be the impacts under downstream legislation that ban or restrict “hazardous substances.” Approximately 19 pieces of legislation in the EU potentially will have downstream impacts on stainless steel as a result of the proposed classification. These rules contain hazard-based provisions that do not take exposure and risk issues into account,² which are crucial factors for assessing the safety of metals and their alloys. This type of hazard-based approach may lead to the potential ban or restriction of products that generate significant economic or social benefits, where no threat may exist in reality.

In addition, SSINA is concerned about the inappropriate stigmatization of stainless steel and other specialty alloys, leading to public concern, and unwarranted restrictions or “material deselection” resulting from other well-intentioned, but hazard-based, initiatives such as “green procurement” and “green buildings.”

Importantly, it is technically and economically impossible to produce “cobalt-free” stainless steel. The vast majority of stainless steel grades do not have cobalt metal as a deliberate alloying addition. However, cobalt metal is present as an impurity in all stainless alloys at levels in excess

² See, e.g., the Toys Directive (2009/48/EC); the ECOLABEL / GPP regulation (2010/66/EC); the End of Life Directive for Vehicles (ELV) 2000/73/EC; the Eco-Design Directive 2009/125/EC; the Medical Devices Directive 2001/83/EC; and various EU regulations addressing food contact materials.

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of the proposed GCL of 0.1%, and can be present in concentrations up to 1 or 2% (this is particularly true for the more scrap-intensive stainless production, such as that most common in the United States). The residual presence of cobalt in alloys is unavoidable, as it is a ubiquitous naturally-occurring element present as an impurity in raw materials.

Scientific considerations: Carcinogenicity

SSINA accepts that cobalt metal should be classified as carcinogen 1B for the inhalation route of exposure only, based on evidence from animal studies. Accordingly, industry currently self-classifies cobalt metal as such. SSINA also agrees with the proposal to include an interim GCL of 0.1% while evaluating potential revision of the EU methodology for assessing concentration limits for metals.

However, SSINA is deeply concerned that the classification proposal for “*all routes of exposure*” is overly conservative, based on a very rigid interpretation of the EU regulations in this area. Extensive high-quality human data indicating that there is no risk of carcinogenicity by the inhalation route, let alone the oral and dermal routes, was not considered by the regulators because workers’ exposures are lower than those in the animal studies. Specifically, the “all routes” designation was assigned as a default based on the alleged lack of “conclusive” data showing lack of hazard from other exposure routes (*i.e.*, the human data were dismissed because they did not involve exposure at the same high levels to which animals were subjected, despite the fact that the available epidemiological data show no hazard present via ingestion or dermal contact).

SSINA also supports efforts to develop an alternative methodology for the classification of alloys, such as stainless steel, as studies and research have shown that the concentration of a metal in an alloy is not the determining factor for toxicity. Hence, the mechanism for classifying metals and alloys should be revisited to take this into account and ensure a more accurate determination of the potential hazard of the alloy, which in turn will allow for appropriate protection of human health and the environment.

Incompatibility with GHS/TBT

As noted above, the proposed classification for “all routes” of exposure (and not inhalation-only as would be appropriate) is overly conservative, based on a very strict interpretation of the EU regulations governing the classification, labelling and packaging of substances and mixtures (the “CLP Regulation”). Specifically, paragraph 3.6.2.1 of Annex 1 of the EU CLP regulation (2018) states “For the purpose of classification for carcinogenicity, substances are allocated to one of two categories based on strength of evidence and additional considerations (weight of evidence). In certain instances, route-specific classification may be warranted, **if it can be conclusively proved that no other route of exposure exhibits the hazard.**”

The CLP Regulation reflects the EU’s adoption of the United Nation’s Globally Harmonized System for classification and labelling of chemicals (“GHS”). In contrast to CLP, the UN GHS

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text (rev.7, 2017), as well as the U.S. implementation of GHS under OSHA's Hazard Communication System, do not include the provision in bold text above requiring a default "all routes" designation unless there is "conclusive" proof that other routes of exposure do not have the same hazard. In the case of cobalt, this provision was used to justify the "default" "all routes" designation and the dismissal of existing high quality human epidemiological data showing no association with increased cancer risk from workplace exposures to cobalt. This approach ignores the "weight of evidence" standard of the GHS and turns it on its head. Accordingly, the EU CLP regulation is more restrictive than necessary to fulfil a legitimate objective and therefore in breach of Article 2.2 of the WTO TBT Agreement.

To be consistent with the GHS (and TBT requirements), we recommend that the EU amend CLP guidance or regulatory text to reconsider the use of all relevant data, such as human epidemiological data, to enable proper classification based on the weight of evidence for all relevant routes of exposure.

Proposal for Consultation Input from WTO members

- Request a formal notification to the TBT Committee, including proper consultation, sufficient time for review, response and comments to be taken into account, in view of the potentially severe consequences on important markets.
- Urge the European Commission to consider all data, including human epidemiological data, to come to a balanced classification proposal which reflects the appropriate toxicity and relevant routes of exposure for cobalt metal.
- Request the EU to remove the cobalt metal classification entry from this draft Regulation while the further review is ongoing.
- Urge the European Commission to proceed swiftly with the adoption of the alternative (bioelution-based) methodology for the human health classification of alloys to ensure an appropriate reflection of their toxicity.

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