U.S. Government Comments on EU Notification G/TBT/N/EU/629:

The United States appreciates the opportunity to comment on the Commission Regulation amending, for the purposes of its adaptation to technical and scientific progress (ATP), Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (CLP) and updating Commission Regulation (EU) 2018/669, notified to the World Trade Organization as G/TBT/N/EU/629 on December 12, 2018.

We recognize that a 60-day comment period was provided in the notification of the draft regulations and appreciate the Commission providing the United States an extension on that original comment period. U.S. stakeholders, including the American Chemistry Council, the Stainless Steel Industry Association, the American Coatings Association, and the Toy Association, submitted comments on this draft measure via the WTO inquiry point, in addition to U.S. stakeholders that responded to the EU Better Regulations consultation. We look forward to follow-up by the EU, as well as detailed responses to our comments and questions regarding the draft regulation.

Via these comments, we would like to discuss the proposed harmonized classifications, labeling and formulation requirements for the substances: titanium dioxide (TiO2) and cobalt, as well as products and articles that contain these substances.

The United States is highly concerned as to the potential—and it would seem unnecessary—trade impacts that will result from the EU's decision to harmonize classification for both titanium dioxide and cobalt as carcinogens under its CLP Regulation (Classification, Labelling and Packaging of Chemical Substances and Mixtures) (1272/2008/EU). Henceforth, products containing more than 1% of these substances may have to be labeled as potential carcinogens in the EU. Given the links between CLP and many downstream EU product regulations spanning from building materials, to stainless steel, to cosmetics, to medical devices. to food, the EU's CLP Regulation will mandate carcinogen labeling or restrictions on the use of these substances in many finished products, as well as additional waste disposal measures. These new requirements are not in line with chemical labeling, formulation requirements, and waste management measures in other WTO member countries for these substances. We understand that substantive concerns have been raised by other WTO members and industry—with over 400 comments received on the ATP.

We would therefore request that the EU consider delaying finalizing its regulations, while it reviews and seeks to address these comments. We would also ask that, as outlined in our comments, the EU consider for both substances if there are alternative, less trade disruptive means to manage the potential hazards identified that are more in line with international regulations and standards for chemical and metal classification and labeling.

Titanium dioxide

The Commission notes that the objective of the proposed regulatory reclassification of TiO2 is to define titanium dioxide *"in a powder form containing 1% or more of particles with diameter ≤ 10 μm"* as a carcinogen, category 2 by inhalation, so as to inform users, both workers and consumers, on "*the precautionary measures that need to be taken to minimize the hazard for human health".*[1]

[1] See page 6 of the full CLP ATP for the Annex IV entry:
https://members.wto.org/crnattachments/2018/TBT/EEC/18_6403_00_e.pdf
COMMISSION REGULATION (EU) …/… of XXX 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,

The Commission then qualifies the carcinogen classification, noting:

As titanium dioxide-induced lung carcinogenicity is associated with inhalation of respirable titanium dioxide particles, it is appropriate to define respirable titanium dioxide particles in the titanium dioxide entry.

The CLP ATP entry for TiO2 provides labeling guidance for all liquids and solid mixtures with more than one percent titanium dioxide by weight, with the specific guidance as follows:[2]

In Annex II to Regulation (EC) No 1272/2008, in Part 2, the following section 2.12 is inserted*:*

'2.12. Mixtures containing titanium dioxide.

The label on the packaging of liquid mixtures containing 1% or more of titanium dioxide particles with a diameter equal to or below 10 µm shall bear the following statement:

EUH211: 'Warning! Dangerous droplets may be formed when sprayed. See information supplied by the manufacturer. Comply with the safety instructions.'

The label on the packaging of solid mixtures containing 1% or more of titanium dioxide shall bear the following statement:

EUH212: 'Warning! Dangerous dust may be formed when used. See information supplied by the manufacturer. Comply with the safety instructions.'

The label on the packaging of liquid and solid mixtures not intended for the general public and not classified as hazardous which are labelled with EUH211 or EUH212, shall bear statement EUH210 in addition.

The following hazard statements are required:

ANNEX II

In Part 3 of Annex III to Regulation (EC) No 1272/2008, in Table 2.1, the following rows EUH 211 and EUH 212 are inserted:

'EUH211 Language Warning! Dangerous droplets may be formed when sprayed. See information supplied by the manufacturer. Comply with the safety instructions.

EUH212 Language Warning! Dangerous dust may be formed when used. See information supplied by the manufacturer. Comply with the safety instructions.'

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labelling and packaging of substances and mixtures and correcting Commission Regulation (EU) 2018/669. "(5) In its scientific opinion of 14 September 2017 on the substance titanium dioxide, RAC proposed to classify that substance as carcinogen category 2 by inhalation. As titanium dioxide induced-lung carcinogenicity is associated with inhalation of respirable titanium dioxide particles, it is appropriate to define respirable titanium dioxide particles in the titanium dioxide entry. In addition, as some dangerous dust or droplets could be formed during the use of mixtures containing titanium dioxide, it is necessary to inform the users on the precautionary measures that need to be taken to minimise the hazard for human health."

[2] https://members.wto.org/crnattachments/2018/TBT/EEC/18_6403_01_e.pdf. EU CLP Annexes 1 to 4.

The draft CLP ATP notes that the titanium dioxide classification and the labeling requirements, including for liquids and solid mixtures, are based upon the scientific opinion of European Chemical's Agency (ECHA) Risk Advisory Committee (RAC) on 14 September 2017.

The U.S. has consistently engaged with the EU on the proposed harmonized classification of titanium dioxide, since the European Chemical's Agency (ECHA) first published a draft dossier report by France proposing a harmonized carcinogen classification for TiO2 in 2016. A number of U.S. industry organizations submitted comments both to France's dossier and the subsequent draft RAC opinion on the dossier including the American Coatings Association, American Cleaning Institute, Huntsman Pigments and Additives, SPI: The Plastics Industry Trade Association, International Association of Color Manufacturers, Grocery Manufacturers Association (GMA), and Toy Association. The U.S. Government first raised the issue with the Commission in February 2017 at our bilateral discussions ahead of the WTO TBT Committee meeting. We have continued since to express our concerns on the proposed classification and labeling at each subsequent TBT Committee meeting, both bilaterally and on the floor.

We appreciate that the EU invited the U.S. Government and industry to participate in an April 2018 extraordinary workshop that it held on the substance classification, albeit as observers. We also recognize that the EU has provided written responses to some, but not all of the questions we have submitted on the classification via the TBT inquiry point. We also recognize that the EU provided 60 days for comments to the draft ATP subsequent to its WTO TBT notification.

The United States continues to have concerns regarding the transparency of the process and the potential trade impacts of the EU's decision to classify titanium dioxide under its CLP Regulation as a carcinogen by inhalation. The proposed labeling requirements may require products that contain TiO2 particles in liquid, or even embedded in a product such as a paint or plastic to be labeled as carcinogens for both consumers and workers. The U.S. questions whether this classification is unnecessarily disruptive to trade, as it has the potential to mandate carcinogen labeling or restrictions on use of the substance in many finished products, as well as additional waste management measures for products that contain one percent of more of TiO2.

By the EU's own admission in the September 2017 RAC opinion on TiO2, workers are the only group found to be at risk, and they would have to experience the same "lung overload" conditions as in the tests the EU cited with rats.[3] It is unclear on what basis the EU determined that exposures to TiO2 in liquids and solid mixtures are of concern.

Trade impacts of the proposed classification and labeling are significant. Trade in TiO2 is a $20 billion global industry, with the U.S. exporting $3 billion globally of the substance annually. In addition, an estimated $7 to $8 billion of U.S.-made products contained the substance in 2015, indicating a potential multiplier impact on EU-U.S. trade due to the number of products that contain more than 1% of the substance by weight. This trade may be disrupted, due to increased compliance costs associated with testing, labeling, and disposal of the substance and products containing it, as well as by companies that will choose to no longer use the substance given the increased regulatory demands. Over 70% of the TiO2 produced is used in paint, coatings, and cosmetics, with the remainder spanning across a wide variety of products, from food to medical products to toys.

[3] https://echa.europa.eu/documents/10162/682fac9f-5b01-86d3-2f70-3d40277a53c2 European Chemicals Agency. Risk Assessment Agency. Opinion: Proposing harmonised classification and labelling at EU level of Titanium dioxide. EC Number: 236-675-5 CAS Number: 13463-67-7.

Transparency in Notice and Comment on the TiO2 Harmonized Classification under the CLP Regulation

The U.S. requested, via its bilateral consultations and on the floor of the TBT Committee, that the Commission notify the intent of the European Chemicals Agency to prepare a harmonized classification for TiO2, at the time of the ECHA consultations. Earlier notification would help ensure that companies potentially impacted will be able to provide timely comments. The EU, however, did not notify these consultations, noting that the classification and potential labeling would only be notified to the WTO once a final recommendation had been made by ECHA to the Commission. As the EU notes in its draft ATP notified to the WTO (G/TBT/N/EU/629), it is "*appropriate and scientifically justified to follow [ECHA] RAC's opinions regarding the hazard classes proposed for the harmonised classification and labelling of certain substances"*. This indicates that the EU bases its classification and labeling decision on the RAC opinion. The RAC does not reconvene to consider comments solicited via the TBT notification and comment process, so these comments are not given the same weight as comments submitted via the scientific consultation. In contrast, the U.S. Government notifies the WTO of most federal-level proposed regulations, at a time when scientific consultations are still underway.

Another concern with the Commission's WTO notification is that it does not provide a list of the articles and products that will be impacted by the TiO2 harmonized classification. The notification states it applies to "*hazardous substances*," rather than including the list of HS codes for products that use TiO2, and the use of HS codes or CCCN codes is recommended by the TBT Committee. This information is available to the Commission, as it is provided domestically, after ATPs are finalized. Not including it in the WTO notification further hinders the ability of the United States and other stakeholders to comment, since without a list of HS codes, stakeholders may not be aware the notification impacts their products, including with regard to waste disposal.

U.S. stakeholders have also expressed concern to the U.S. Government that comments they have provided via ECHA's consultations on TiO2 have not been given due consideration. In their comments, U.S. stakeholders submitted a number of relevant scientific studies on TiO2, but they note that these studies are not referenced in the RAC opinion or subsequent consultative documents circulated by the Commission's CLP Committee on the classification, nor is an explanation given as to why these studies were not considered.

In addition, the U.S. is concerned that ECHA's process to harmonize not just the TiO2 classification, but all substance classifications via its CLP Regulation does not provide sufficient time for U.S. stakeholders to provide meaningful input into the scientific consultations used to inform the RAC opinions. This is particularly a concern when the RAC opinion on the potential hazard differs substantially from the original REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) registrations. For the CLP harmonized classifications, stakeholders are only given 60 days to provide input into RAC consultations, when months or even years may be needed to conduct scientific studies sufficient to evaluate the potential hazards identified in the RAC opinions. In the United States and other WTO member countries, stakeholders typically consult with their regulators to identify the potential hazards and risks in question in advance of a determination. They are then given a set period of time to conduct the necessary research—particularly when a new hazard or risk, previously not studied, is in question. The period provided for research typically spans six months to several years, depending on the concern identified. In the case of TiO2, it had, under REACH, been scheduled for a Community Rolling Action Plan (CoRAP) review in 2017; however, ECHA accelerated this review in 2015 when it accepted a dossier on the substance from France. This surprised industry, which had anticipated a multi-year process to review the current TiO2 REACH Substance Evaluation.

We are also concerned that now that the Commission is finalizing its harmonized classification of TiO2, foreign stakeholders will not be able to directly submit a new dossier requesting that the classification be reviewed, if they have new scientific information or other concerns. Instead, they have to rely upon an EU member state to submit such a request.

Alignment with UN Globally Harmonized System (GHS) for Chemical Classification and Labeling

We would also ask the EU to explain how the classification and labeling guidance for TiO2 aligns with the UN Globally Harmonized System (GHS) for the Labeling and Classification of Chemicals. The GHS notes that chemicals should be classified based upon "the intrinsic hazardous properties of substances or mixtures"[4]—i.e. if the substance is toxic or in the case of TiO2 if it is a carcinogen. In reviewing TiO2, both ECHA and the Member States imply that the substance is not intrinsically hazardous, as they describe it using the term "poorly soluble and low toxicity (PSLT)."[5] For substances such as TiO2 for which certain physical forms may be hazardous, the GHS provides labeling based on the physical hazard and the potential use cases as an alternative to classification. For TiO2, the U.S. and other countries have suggested exposure limits for nanoscale (untrafine) TiO2 that are generally lower than those for microscale (fine) TiO2. [6] In line with GHS guidance, National Institute for Occupational Safety and Health (NIOSH) suggested OELs for TiO2 that take into account the particle size and the higher potency of nanoscale (ultrafine) TiO2 compared to microscale (fine) TiO2 in experimental animal studies. [7] Based on the available evidence, NIOSH classified ultrafine (<100 nm) TiO2 as a potential occupational carcinogen but concluded that there were insufficient data to classify fine (100 nm or greater) TiO2 as a potential occupational carcinogen. For fine TiO2, the lung tumor rates in rats were elevated only at an exposure concentration of 250 mg per cubic meter of air (mg/m^3), but not at 50 or 10 mg/m^3 (Lee et al. 1985).[8] Since exposure concentrations greater than 100 mg/m^3 are not currently standard methodology in inhalation toxicity studies (Lewis et al. 1989), NIOSH questioned the relevance of the 250 mg/m3 dose for classifying exposure to TiO2 as a carcinogenic hazard to workers.[9] NIOSH notes that fine TiO2 has relatively low hazard potency in experimental animal studies with regard to both lung cancer and noncancer lung effects, including inflammation. Chronic pulmonary inflammation is considered to a key event in the biological mode of action for TiO2 in rodent lungs [NIOSH 2011].

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[4] UN Globally Harmonized System (GHS) for the Labeling and Classification of Chemical. Rev 7. Section 1.3.2.2.1 https://www.unece.org/fileadmin/DAM/trans/danger/publi/ghs/ghs_rev07/English/ST_SG_AC10_30_Rev7e.pdf

[5] Ibid. European Chemicals Agency. Risk Assessment Agency. Opinion. p. 40. "RAC acknowledges that the mode of action for the rat lung carcinogenicity in rats cannot be considered "intrinsic toxicity" in a classical sense: the deposited particles, but not solutes of TiO2 molecules can be assumed to be responsible for the observed toxicity. Nevertheless, this mode of action results in relevant toxicity and carcinogenicity which in principle merits consideration in classification and labelling. The CLP regulation does not exclude a health hazard classification triggered by physico-chemical characteristics of a chemical.
Generally, classification for carcinogenicity does not specify a route of exposure. However, the profile of lung carcinogenicity described for TiO2 is specifically linked to the inhalation route of application…The toxicity profile determined designates the titanium dioxide tested as a "poorly soluble low toxicity" particle."

[6] Occupational Exposure to Titanium Dioxide. DHHS (NIOSH) Publication No. 2011–160.
April 2011 https://www.cdc.gov/niosh/docs/2011-160/pdfs/2011-160.pdf. and Mihalache, R., Verbeek, J., Graczyk, H., Murashov, V., van Broekhuizen, P., 2017. Occupational exposure limits for manufactured nanomaterials: a systematic review. Nanotoxicology 11 (1), 7–19.

[7]Ibid. NIOSH.

[8] Lee KP, Trochimowicz HJ, Reinhardt CF. 1985. Pulmonary response of rats exposed to titanium dioxide (TiO2) by inhalation for two years. Toxicol Appl Pharmacol 79:179–192.

[9] Lewis TR, Morrow PE, McClellan RO, Raabe OG, Kennedy GL, Schwetz BA, Goehl TJ, Roycroft JH, Chhabra RS. 1989. Establishing aerosol exposure concentrations for inhalation toxicity studies. Toxicol Appl Pharmacol 99:377–383.

The U.S. would also would like to inquire what was the basis for the CLP TiO2 classification and labelling of particles between 100 nm and 10 µm, the same as the nanoscale (<100 nm) particles, as well as the requirements for liquid and solid mixtures, as this will impact a far greater number of products?

It is also a concern that in labeling such a low potency material as fine TiO2 particles as a carcinogen, that it will result in the substitution of TiO2 with less well tested and more toxic materials.

Duplication with Other EU Regulations, Resulting in More Trade Restrictive than Necessary Rules

The U.S. also questions why the EU required a review of TiO2 as a carcinogen by inhalation as it duplicated the regulatory role played by the EU's Chemical Agents Directive (98/24/EC) (CAD) to manage the physical hazard in question, inhalation by workers. Under CAD, EU member states set and can seek to harmonize OELs and safety equipment requirements to manage physical hazards. The EU, in discussions with the U.S., has noted that CAD is not sufficient to protect workers in non-traditional settings even though per CAD, the Directive applies to "any work activity involving chemical agents." The EU decision to pursue a classification and carcinogen label via CLP, instead of managing the risk via CAD, could place an undue burden on companies that use TiO2 in their products, since the carcinogen classification may result in the classification of products as hazardous waste.

Cobalt

The Commission notes that the objective of the proposed regulatory reclassification of cobalt is to propose a harmonized classification as carcinogen category 1B. Under this classification, all products containing ≥ 0,1% of cobalt will classify as containing carcinogens and likely require a label.

The EU ATP does not provide a clear justification for requiring all uses of cobalt to be classified and labeled. We question therefore if this universal classification is unnecessarily disruptive to trade.

Cobalt is widely available in the natural environment, and the minimum classification and reporting level of ≥ 0,1% proposed by the EU for the presence of cobalt in substances, articles, and products will have an adverse impact upon a number of materials and products in which cobalt is available as a residue. For example, ≥ 0,1% of cobalt is available in all types of stainless steel. Under downstream product regulations in the EU this carcinogen classification may result in a ban on the use of stainless steel in a number of products from medical devices to food utensils to water pipes—even though no immediate cause for concern was identified by the ECHA or EU regulators that oversee these products.

We understand from the draft ATP that the decision by ECHA to set a minimum concentration limit of ≥ 0,1% is arbitrary and proposed as a stopgap measure until additional information is available. The ATP notes that *the methodology used to determine a specific concentration limit required further assessment in particular of its applicability to metal compounds*.[10] U.S. industry, via comments submitted via the WTO, has proposed to collaborate with the EU on conducting these tests.

[10] https://members.wto.org/crnattachments/2018/TBT/EEC/18_6403_00_e.pdf
COMMISSION REGULATION (EU) …/… of XXX 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. "(4) In its scientific opinion of 22 September 2017 on the substance cobalt, RAC proposed to classify that substance as carcinogen category 1A with a specific concentration limit of ≥ 0,01 %. However, the methodology used to determine a specific concentration limit required further assessment in particular of its applicability to metal compounds. It is therefore appropriate not to introduce, for the time being, any specific concentration limit in Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008 for cobalt, in which case the general concentration limit of ≥ 0,1 % should apply, in accordance with Table 3.6.2 of Annex I to that Regulation."

Given this, we question why the EU is proposing a classification and required label before these tests are completed.

Conclusion

Given these concerns, both in terms of the EU's observance of its TBT obligations and the potential impacts upon U.S. exports to the EU, we request that the EU consider delaying its regulations on TiO2 and cobalt, while it reviews these comments and seeks to address the questions provided by the US government and industry via the WTO and EU Better Regulation consultation, including:

- Clarification as to what physical forms of the two substances and which specific products and articles will have to classify, potentially reformulate, and label, based upon the harmonized classifications.
- Clarification as to if substances, articles, and products containing more than 1% of these substances by weight will be classified as hazardous waste.
- How the classification and labeling guidance for TiO2 aligns with the UN Globally Harmonized System (GHS) for the Labeling and Classification of Chemicals, and if not, why not?
- What was the basis for the CLP TiO2 classification and labelling of particles between 100 nm and 10 μm the same as the nanoscale (<100 nm) particles?
- What was the basis for including liquid and solid mixtures in the classification and for requiring liquids and solid mixtures to be labeled, as this will impact a far greater number of products?
- Why ECHA is proposing a universal carcinogen classification for cobalt at ≥ 0,1%, including in metal compounds, when even by its own admission in the ATP, alternative tests are required to determine the potential hazards in metal compounds?

We would also ask that, as outlined in our comments, the EU consider for both substances if there are alternative, less trade disruptive means to manage the potential hazards identified that are more in line with international regulations and standards for chemical and metal classification and labeling.

In addition, as these two harmonized classifications have illustrated a number of challenges for U.S. stakeholders to meaningfully engage with the EU on CLP classifications that can impact trade, we ask that the EU consider the following actions in its future implementation of the CLP and REACH regulations, coinciding with its WTO TBT obligations:

- The Commission notifies the WTO of both the REACH CoRAP schedule and any harmonized classification consultations taking place under CLP for all chemicals, given the potential for regulatory action.

- The EU include HS (Harmonized Schedule) codes for potentially impacted articles/products in its notifications for REACH and CLP to the WTO, so that importers are aware in advance of how these chemical regulations may impact the manufacture, use, labeling, and disposal of their articles and products.

Thank you very much for your attention to these matters. Please let us know if you have any questions. We look forward to your response.