European Union - Titanium dioxide: Regulation (EC) No 1272/2008   
(CLP Regulation), Annex VI, Part 2

statement by the united states to the committee on technical barriers to tradE  
6 and 7 march 2019

The following communication, dated 21 March 2019, is being circulated at the request of the delegation of the United States.

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We would like to discuss the proposed harmonized classifications, labeling, and formulation requirements, via the EU's CLP regulation, for the substances: titanium dioxide and cobalt, and the trade impacts these new requirements will on the substances and products that contain these substances.

The new proposed requirements as notified in G/TBT/N/EU/629, may be unnecessarily disruptive to billions of dollars in US-EU trade.

We are also concerned that the EU's process to reclassify and label these two substances have not been transparent in terms of when potential regulatory actions under CLP are notified to the WTO and providing time for meaningful consideration of WTO member comments.

Disappointingly, while the EU provided a sixty-day comment period via the WTO on the draft regulation ending on 10 February, the Commission met to vote on the draft regulation on 14 February, only four days after the WTO comment period closed, which raises questions about how comments were taken into account.

While the Commission's vote had to be delayed until 7 March, this rush to finalize the measure without meaningful consideration of WTO member comments, is surprising, as the notification received over 400 comments via the WTO and the EU's domestic Better Regulations consultation.

In the case of Titanium Dioxide, the US has submitted questions to the European Commission asking them to clarify how the draft regulation for TiO2 aligns with the UN Globally Harmonized System (GHS) for the labeling and classification of chemicals, and if not, why?

The US has asked for clarification, since if we understand the notified classification correctly, it may require a substance that the EU has in the ECHA scientific opinion labeled as "low toxicity" to be classified as a carcinogen.

We have also asked ECHA to clarify which products and articles in addition to chemicals will be impacted by the draft regulation notified to the WTO, as these were not included in the notification, despite there being many.

We are concerned that a number of products that contain Titanium Dioxide, including paints, cosmetics and plastics will have to reformulate or be labeled as containing a carcinogen.

Similarly, in the case of cobalt, we do not understand why the Commission is rushing towards a restriction on the presence of cobalt in metal compounds.

The EU, by its own admission in the text of notified draft regulation, notes that it has not yet completed its scientific assessment of cobalt in metal compounds, and yet instead of issuing an exemption for metal compounds until testing could be completed, the European Commission is moving forward.

If this restriction goes through for example, it will affect US exports of medical products and food processing equipment to the EU, since the stainless steel in these products contains two to three percentage cobalt, which cannot be removed. The EU restriction is based upon an arbitrary one percent generic limit set by CLP-rather than an actual scientific evaluation.

Given these concerns, we ask that the EU postpone its vote on the proposed classification and labeling proposals on these two substances, until it can:

* + Undertake a meaningful review of the other 400 comments provided via the draft regulation notification
  + Address in its response to WTO TBT Committee Members, if the EU is diverging from the GHS for TiO2 and why, given that there are far less trade disruptive alternatives
  + Consider delaying the inclusion of metal compounds in the CLP ATP listing for cobalt, until the necessary testing is completed
  + We also request that the EU in its response to comments, also consider how it might adapt the timing and use of WTO notifications in its regulatory processes for both the REACH and CLP regulations, so as to ensure that comments by interested parties can be taken into account.

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