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SUBMISSION BY THE AFRICAN, CARIBBEAN AND PACIFIC GROUP OF STATES (ACP) TO THE TBT COMMITTEE ON NOTIFICATION G/TBT/N/EEC/212 ON NICKEL CLASSIFICATIONS IN THE 31ST ATP TO DANGEROUS SUBSTANCES DIRECTIVE 18-19 MARCH 2009

Communication from Mauritius on behalf of the ACP Group

The following communication, dated 16 March 2009, is being circulated at the request of the delegation of Mauritius.

A. INTRODUCTION

1. The ACP Group would like to thank the EC for its Reply to comments from the ACP Group and other WTO countries regarding the EC's decision to classify as hazardous over 100 nickel compounds in the 31st ATP directive.[1] However, the issues raised in our comments were not satisfactorily addressed by the EC Reply.

2. The ACP Group is extremely disappointed by the EC's decision to push ahead and adopt the 31st ATP in January, despite the unprecedented level of concern raised at the TBT Meeting in November. The ACP Group remains concerned that the decision to classify the nickel substances in the 31st ATP will have significant market impacts, and was taken without the requisite and appropriate levels of transparency and scientific rigor.

3. This document summarises the central issues that have not been satisfactorily addressed by the EC Reply. It is not necessary to repeat here the detailed technical comments that we and other WTO Members, as well as industry stakeholders, have provided the EC and which we incorporate by reference. We continue to advance and support those comments.

4. At the outset, we note that the EC Reply states that, upon adoption, the 31st ATP will have immediate legal effect across a wide range of existing EU laws, including requirements relating to cosmetics (Directive 76/768/EEC), biocidal products (Directive 98/8/EC) and plant protection products (91/414/EEC). This contradicts previous EC representations to WTO Members who expressed concerns about the impact of the 31st ATP, in which the EC stated that the 31st ATP only

[1] Commission Directive 2009/2/EC of 15 January 2009 amending, for the purpose of its adaptation to technical progress, for the 31st time, Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ [2009] L11/6.

related to 'labelling' and would not result in bans or restrictions on the use of these substances in consumer products.[2]

5. The EC also concedes that its actions will have an impact on the market for nickel compounds, noting that one of its goals was to classify as many nickel compounds as possible in order to reduce 'market distortions'. The reference to 'market distortion' confirms the serious trade impact that these classifications will have. Further, the avoidance of market distortions clearly is not a reason to classify without the necessary evidence on the properties of the substances.

6. The ACP Group believes that the severe classification of nickel substances will have a significant negative economic and commercial impact on all nickel producing and exporting countries. These adverse effects would be particularly severe for developing countries which, given their low levels of development and industrialisation, tend to rely on a few basic exports for employment and revenue. For example:

7. Botswana, Cuba and the Dominican Republic are small and vulnerable economies that are highly dependent on mineral exports. In 2007, in each of these countries, nickel contributed to about 50 per cent of its total exports of goods;

8. The nickel market is worth about US$ 4 billion per annum to South Africa. South Africa fears that the implementation of the 31st ATP would seriously affect the future investment by the industry itself and impact negatively on trade and growth.

9. The classification of the nickel compounds in the 31st ATP also takes place in the context of a global financial crisis that is severely affecting developing countries, and which has led to a global contraction of credit, investment and demand. The 31st ATP is likely to further aggravate conditions in this industry, and cause increased production, transport and insurance costs.

10. The 31st ATP is of concern not only for nickel producers but also for those countries that manufacture goods using nickel compounds in diverse industrial chemical processes. The nickel compounds listed in the 31st ATP are used in a broad range of industries and processes, including in important 'green' technologies, such as nickel-hydride batteries.

11. The EC market accounts for about 40 per cent of total world nickel usage. The classification of such a wide and diverse range of nickel compounds on such an important world market will affect access not merely to that market, but also potentially to other major markets. The ACP Group fears that it will not be long before a domino effect will be seen in other major markets, as has been the case previously with other standards and classifications. We also remain concerned that a read-across method based solely on water solubility could be used as a precedent for taking regulatory decisions about other substances (be it about organic or inorganic chemicals) and concentrates produced in the ACP or in other jurisdictions, particularly given the EC's recent implementation of REACH and of the UN's globally harmonised system (GHS) of classification and labelling.

12. Given the significant commercial implications, it is essential that any classification of nickel compounds takes into account the special development, financial and trade needs of developing countries, as is required by WTO provisions.

[2] See, e.g., *Minutes of the Meeting of 1 – 2 July, 2008*, Committee on Technical Barriers to Trade, G/TBT/M/45, 9 September 2008.

B. SERIOUS CONCERNS ABOUT SCIENTIFIC BASIS FOR NICKEL CLASSIFICATIONS

13. The ACP Group naturally recognises the importance of ensuring a high standard of protection for human health and environment and supports the development of regulatory strategies to achieve such protection. However, we maintain that the EC has not proved that the nickel classifications in the 31st ATP are based on a sound or transparent scientific method. The EC's Reply has not answered our concerns and either others presented by other WTO Members in the last TBT Committee.

14. We continue to disagree that the EC's 'grouping' and 'read-across' methodology used in the 31st ATP for nickel compounds conformed to the criteria established by the OECD or the U.S. EPA guidance referred to by the EC. The EC skipped 3 of the 8 essential steps set forth in OECD's guidance, steps that are critical to verifying, with objective data, the assumptions made in the read-across. The EC has not presented a scientific basis for omitting those essential steps, other than, in its judgment and without justification, these steps simply were not necessary.

15. Further, the EC's continued reliance on a single data point, water solubility, as the initial and primary basis for categorising nickel compounds is not supported by the facts and is contrary to the OECD and U.S. EPA guidance on which the EC claims to rely. At the outset, the EC's claimed reliance on water solubility is not supported by the facts, since it did not obtain water solubility data for most of the nickel compounds classified. Most of the water solubility information relied on by the EC was based on estimates contained in an unpublished draft document that was not peer reviewed.

16. Both OECD and U.S. EPA guidelines are clear that establishing categories of chemicals for purposes of read-across is a complex process that involves reviewing a number of inputs to determine if a group or category of chemicals whose physicochemical (e.g., molecular weight, water solubility, particle size and structure, partition coefficient and vapour pressure), toxicokinetic and human health and/or environmental properties are likely to be similar or follow a regular pattern as a result of structural similarity. The EC did not do this, failing to take into account the full range of inputs described by the OECD and U.S. EPA.

17. Perhaps most importantly, the EC has yet to affirmatively demonstrate the scientific basis for its assertion that water solubility is an 'approximation' of the 'systemic bioavailability of the nickel ion'. The few studies referred to by the EC do not support its claim that "the division into groups across the spectrum of water solubility follows the approach already widely used for nickel compounds" The EC simply asserts, without scientific evidence, that "nickel substances having similar water solubility will induce similar bioavailabilty" and that "water solubility is thereby an acceptable measure of similarity between nickel compounds" (EC Reply at p. 4). Such groupings of convenience do not scientifically establish a causal relationship between water solubility and toxicity, and ignore the data in the EC's possession that positively demonstrates the opposite: that water solubility is not a good indicator of the bioavailability of the nickel ion.

18. The EC has essentially been promoting an unproven theory, postulating a causal relationship between water solubility and toxicity to support an important regulatory decision with significant economic consequences, and then claiming that it must be proven wrong: "Industry has had the opportunity to put forward data disproving this classification" (EC Reply at p. 7). However, the EC did not make a request to Industry to provide these data within a reasonable time and the EC has failed to meet its responsibility to demonstrate the validity of this classification in the first instance. In any event, when industry submitted data, in the narrow timeline conceded, on specific substances that called into question the EC's hypothesis, the EC's typical response was to simply exclude those substances from the classification.[3] Inconsistent with the scientific method and good public policy,

[3] This approach is reflected in the following statement: "The essential refinement of the approach [i.e., classification based on water solubility] was to remove from each group compounds that would not be expected

the EC did not use these submissions to critically review its unproven postulate that water solubility is a predictor of toxicity and bioavailability.[4]

19. The EC also incorrectly claims nickel carbonate, which was classified in the 30th ATP, was not used as a reference substance for the category of slightly soluble nickel compounds in the 31st ATP. The original classification proposal by the Danish EPA was clear that "[f]or sparingly soluble nickel (II) compounds the hazards are based on the classification agreed for the nickel carbonates."[5] Further, the EC incorrectly claims that the classification of nickel carbonate in the 30th ATP was not based on a derogation, or deviation, from the otherwise applicable science and data based criteria. The European Chemicals Bureau, part of the Commission, explicitly informed the Technical Committee on Classification and Labelling that "due to the derogation statement" nickel carbonate should be classified as a mutagen despite advice to the contrary from the Specialised Experts.[6]

C. TBT NOTIFICATION OF 31ST ATP WAS SERIOUSLY FLAWED

20. The scientific and commercial issues raised by the nickel classifications in the 31st ATP are highly technical and complex. Yet, the legislative timetable of the 31st ATP failed to provide sufficient time for meaningful consultation with other WTO Members, as is required by Article 2.9 of the TBT Agreement.

21. The EC notified the 31st ATP to the WTO Committee on Technical Barriers to Trade on 18 September 2008, announcing a 60-day comment period scheduled to conclude on 18 November 2008. The EC's Technical Progress Committee (TPC) met and decided to approve the 31st ATP on 19 November, not even 24 hours after the close of the comment period. Therefore, the ACP Group disagrees with the EC that EU Member States had a full opportunity to consider the comments that have been made by WTO Members on the 31st ATP.[7] Further, the full list of over 600 substances subject to the 31st ATP was distributed to the EU Member States several weeks in advance of the November 19 meeting, with the instruction that Member States could only accept or reject the entire list, and could not object to or revise specific proposed classifications, such as those relating to nickel compounds.[8] There was obviously insufficient time or meaningful opportunity for full consideration of any concerns the TPC Members wished to raise, or for the TPC Members to communicate with WTO Member States regarding the comments.[9]

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to behave similarly to the nickel compound used for comparison" (EC Reply at p. 8). In other words, the default approach was to categorise and classify based on the hypothesis that there was a causal connection between water solubility and toxicity, unless the actual data demonstrated otherwise.

[4] The EC's dismissal of contrary data was sometimes simply conclusory, a non-scientific approach illustrated by this passage: "However, the nickel industry has as yet not submitted any information or experimental results on the basis of which members of the TC C&L were ready to change their original opinion on the hazardous properties of the Nickel compounds at stake" (EC Reply at p. 7). A simple unwillingness to 'change opinions' is not a scientific rebuttal to, for example, the data submitted to the EC demonstrating that the solubility of nickel compounds in water was not a predictor of their solubility in biological fluids.

[5] Danish proposal for classification of the nickel compounds in the 31st ATP (ECBI/96/04 Add. 2).

[6] Summary record of the TC C&L meeting of 21-24 September 2004 (ECBI/139/04 Rev. 2).

[7] "[T]he EC confirms that written comments from WTO Members are fully and properly taken into account during the ongoing legislative process," and the "Committee vote of 19 November 2008 took therefore place in full knowledge of the third countries' comments" (EC Reply at p. 18).

[8] At least one EU Member State was refused permission to vote on the 31st ATP list without the nickel compounds.

[9] The EC attempts to gloss over this shortcoming by claiming that the WTO Members' comments were 'carefully examined' by EC staff, and that EC staff summarised the results of TBT meetings for EU Member States (EC Reply at p. 18). Communications with and among EC staff is not a substitute for timely, full and direct communications among WTO Members.

D. NOTIFICATION OF THE 1ST ATP TO THE CLP REGULATION

22. The ACP Group understands that the EC intends to reintroduce the 30th and 31st ATP nickel classifications in the 1st ATP to the EC's new classification legislation, the CLP Regulation,[10] and that this legislative process has already begun. We trust that, as is required by Article 2.9 of the TBT Agreement, the EC will notify any such proposal to the TBT Committee at an early stage and will fully engage with WTO Members to address any concerns that we may have.

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[10] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ [2008] L353/1.