International Antimony Association

Dr. Ruth Lunn
Director, Office of RoC
National Institutes of Health
Department of Health and Human Services
Telephone (919) 316-4637
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Brussels, 11 October 2016

Dear Dr Lunn,

RE: Nominations to the National Toxicology Program for the Report on Carcinogens

The International Antimony Association (i2a) is a non-profit association whose mission is to gather, study and disseminate information on the safe use of antimony and antimony compounds, especially with regard to the relevant environmental, health and safety regulations.

In the specific context of hazard, exposure and risk assessment of antimony metal and antimony compounds, we act as Secretariat to support our Member companies in the US and worldwide to gather and collate the most current and accurate data on the use and related exposure to and applicable risk management of antimony and antimony compounds. In this role, we monitor and respond to information requests from the NTP or the European Chemicals Agency (ECHA), for instance.

We have been recently informed about the fact that Antimony Trioxide (ATO) has been nominated for possible review for future editions of the Report on Carcinogens (RoC). Our understanding is that we can provide by 11 October information on (1) current production, use patterns, and human exposure estimates for antimony trioxide; (2) recently published, ongoing, or planned studies related to evaluating adverse health outcomes (e.g., cancer, development); (3) scientific issues important for prioritizing and assessing adverse health outcomes; and (4) names of scientists with expertise or knowledge on ATO.

In response to this call for information, we are pleased to provide you with:

- A copy of the Chemical Safety Report which includes the hazard assessment, exposure assessment and risk assessment on ATO, as well as its annexes, including Exposure Scenarios which describe the conditions under which manufacture and use can take place safely. This reflects the data that our Member companies have generated and submitted to the European Chemicals Agency for the purpose of EU-REACH Registration, and which in our view is likely to represent very closely the US situation, and should be of use to the NTP. We had previously informed you about our work under EU Regulation in 2009 and 2014 (communication between Mary S. Wolfe, PhD and Karine Van De Velde) (cf. Annex 1)
- i2a's assessment of NTP's long-term carcinogenicity study on ATO, reported on http://ntp.niehs.nih.gov/results/pubs/longterm/reports/longterm/tr500580/listedreports/tr590/index.html, and which is currently being completed by our experts. (cf. Annex 2)
- The names of two US-based experts who can respond to further questions regarding the safe manufacture and use of ATO:

International Antimony Association

- **Dr Craig J. Boreiko, Ph.D.**
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- Dr John A. Biesemeier (available until 30 December 2016)
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As you may be aware, ATO is subject to a Substance Evaluation under EU-REACH which will start in 2018, preceded by a Compliance Check in 2017 of the joint Registration Dossier that was submitted collectively by all manufacturers and importers of ATO in the EU to ECHA.

In light of the similarity which exists between the two processes occurring in the US and in the EU, we wonder whether it would be possible for the NTP to consider postponing the assessment of ATO to the next RoC review, in order to align both US and EU regulatory processes, so that a more efficient, complete and internationally coherent deliverable can be achieved to the benefit of both programs.

Kind regards, and many thanks in advance for considering our information and suggestion,

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