Deriving a health-based guidance value for antimony to support development of UK Drinking Water Standards – further information

Introduction and Background

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This is a paper for discussion. This does not represent the views of the Committee and should not be cited.

Introduction

1. The UK Health Security Agency (UKHSA) advises the Drinking Water Inspectorate (DWI) on potential health risks from chemicals in drinking water. Post EU exit, the DWI is reviewing the regulatory standards for some chemicals in drinking water, including antimony. UKHSA is seeking advice from the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) with respect to an appropriate health-based guidance value (HBGV) for antimony.

2. In October 2024, the COT considered an initial discussion paper (TOX/2024/38) which outlined a study by (Poon et al. 1998) on antimony potassium tartrate and commentaries of this (Lynch et al. 1999, Valli et al. 2000).

The World Health Organization Drinking Water Guidelines (WHO, 2003), the US Agency for Toxic Substances and Disease Registry (ATSDR, 2019) and Health Canada Drinking water Guidelines (Health Canada, 2024) had all used the same study by Poon et al. (1998) to derive health-based guidance values but differed in interpretation of the study and choice of critical No Observed Adverse Effect Level (NOAEL). Health Canada and ATSDR selected a critical NOAEL of 60 micrograms Sb per kilogram bodyweight per day (µg Sb/kg bw/day) while the WHO selected a NOAEL of 6,000 µg Sb/kg bw/day. At the October 2024 meeting, the COT considered that the Poon et al. (1998) study showed a NOAEL of 6,000 µg Sb/kg bw/day, which is in agreement with the WHO and Lynch et al. (1999) interpretations of the study.

3. The previous discussion paper (TOX/2024/38) briefly summarised available oral toxicity studies and the COT noted that the Rossi et al. (1987) reproductive toxicity study identified a lower Point of Departure (POD) compared to NOAEL that COT selected for the Poon et al. (1998) study. To determine the appropriate POD for a HBGV, the Committee requested more details on the Rossi et al. (1987) study, additional information on other reproductive/developmental toxicity studies, and a table summarising the available oral and reproductive/developmental toxicity studies.

4. Therefore, this paper provides a detailed summary of toxicity studies reporting a NOAEL lower than 6,000 µg Sb/kg bw/day (the NOAEL identified by COT from the Poon et al. (1998) study). Studies with NOAEL above 6,000 µg Sb/kg bw/day are summarized in Annex A and Annex B contains a table presenting the details and findings of all studies (i.e., including those with NOAELs both below and above 6,000 µg Sb/kg bw/day).

5. In addition, this paper summarises the available information on solubility, absorption and bioavailability of different antimony compounds, as well as summarising the NTP intraperitoneal study on antimony, which the COT considered in October 2024 as potentially useful in a weight of evidence consideration with respect to toxicity of antimony.

6. The COT is asked to consider these additional studies and determine an appropriate point of departure, uncertainty factors and HBGV to support an update to the antimony drinking water standard in the UK.

Background

7. COT has previously reviewed the dietary exposure to antimony in infants and young children aged 4 to 18 months as part of the 2014 survey of metals and other elements in infant foods. COT has also reviewed dietary exposure to antimony in various population subgroups as part of the 2006 UK Total Diet study of metals and other elements. For these reviews, COT used the WHO tolerable daily intake (TDI) of 6 µg/kg bw/day for the evaluation. More recently Health Canada and ATSDR have considered antimony and derived lower HBGVs, these are described in detail in the previous discussion paper TOX/2024/38.