



EU Risk Assessment -

provisional timing and outlook

- 31 January:** Deadline for release of second health draft risk assessment report if discussion scheduled for EU Technical Committee (TC NES) 8-10 March
- 9-10 March:** In-depth TC NES discussion on health draft risk assessment report (effects only) by EU Member State technical experts
- 1 May:** Deadline for new Environment (ENV) exposure data
- September:** Last visit discussion at TC NES for ENV dossier
- November:** Last visit discussion at TC NES for health dossier?
- Q2 2007** Finalised Risk Assessment Report approved by EU Competent Authorities?
- April 2007:** Planned cut-off date for start of REACH implementation and end of existing system of risk assessments

Need for emissions data from antimony trioxide users in pigments, paints, glass and flame retardants sectors (plastics-rubber-textiles)

Data gaps on environmental emissions from the above antimony oxide using sectors still remain. These data gaps have to be filled in **by May 1st, 2006**, a deadline imposed on IAOIA during the last TC NES discussions. Based on the positive experience with PET (see related article on the next page) this is well worth doing in order to avoid default data being used to demonstrate risks that do not exist in reality.

ATOS is contacting user industry groups such as Euratex, CIRFS, CEPI and EBFRIIP so as to ensure that individual users in the above sectors can generate the emissions data in time for the risk assessment deadline.

If you are a user in one of these sectors and are willing to contribute to the data filling process, please contact Mike Neal [petkonsept@ntlworld.com], the consultant leading this project for ATOS.

Swiss Government Study demonstrates safety of antimony levels in PET-bottled waters

In a study published in October 2005, the Swiss Federal Office of Public Health (SFOPH) has concluded that "the risk to health from the migration of antimony from PET bottles into mineral waters can be considered as negligible".

As part of an ongoing project started in 2003 studying the presence of trace elements in Swiss drinking water, the SFOPH examined the concentration of antimony (Sb) in bottled mineral water. Antimony oxide (Sb₂O₃) is used as a catalyst in the production of the plastic PET, which is used as a packaging material for mineral water.

The study found water bottled in PET to contain on average a concentration of 0.43 µg Sb per litre. The highest Sb concentration measured in water from a PET bottle was 1.14 µg/l. (The authors pointed out that the study's highest finding of 1.14 µg/l is sometimes matched by antimony concentrations naturally occurring in spring water.)

These findings are well within the regulatory limits set by the World Health Organization (WHO), which in 2003 increased the recommended maximum levels for drinking-water from 5 to 20 µg/l.

The study findings also indicate a high margin of safety. According to the WHO, the maximum tolerable daily intake of Sb for a 60-kg adult is 360 µg Sb. The Swiss study found that even if large volumes of mineral water containing Sb would be consumed (e.g. 3 litres of water with 1.2 µg Sb/l), it would only result in a level of 1% of the maximum tolerable daily intake.

Therefore the SFOPH study concluded that the risk towards consumers from a possible migration of antimony from a PET bottle is negligible.

Bundesamt für Gesundheit/Office fédéral de la santé publique, Bulletin 44/05, 31 Octobre 2005.

For full test see:

http://www.bag.admin.ch/dienste/publika/bulletin/d/BU44_05d.pdf - German language version;

http://www.bag.admin.ch/dienste/publika/bulletin/f/BU44_05f.pdf - French language version)

IAOIA Mission

The Mission of the International Antimony Oxide Industry Association is to serve the common interests of antimony producers, users and other stake holders world-wide concerning the environmental, health and safety regulatory affairs concerning antimony substances and their uses. The activities of the IAOIA are determined by its members, and may include the conducting studies, dissemination of information pertaining to the safety and benefits of antimony substances, and the development of scientific information for the submission to governmental agencies.

EU Risk Assessment – data confirm WHO and EFSA review

Over the past 5 years, the IAOIA group has invested time and effort in a wide range of studies focussed on providing data relating to the effect of DAT on both the environment and on human health. New scientific studies were sponsored in the framework of the Risk Assessment procedures (793/93/EC). The findings are in line with a toxicological review by the WHO ([World Health Organisation](#)) in 2003 in which, following an extensive review of the then available scientific data, a WHO guideline value was increased from 5 µg/l to 20 µg/l in drinking water, reflecting increased margins of consumer safety. In January 2004, the EFSA ([European Food Safety Authority](#)) agreed with WHO and doubled the specific migration limit value of DAT in food from 20 µg/kg to 40 µg/kg (making these less stringent). This limit has been implemented by Directive 2005/79/EC of 18 November 2005.

More information on the Risk Assessment process can be found at www.iaoia.org (click on Risk Assessment at the top of the page).

Progress on Environment Assessment – real data on industry emissions removes several risk scenarios

Joint cooperation between DAT producers and users in the Antimony Trioxide Stakeholders group (ATOS) has led to environmental studies being performed to ensure that real data are the basis for the EU assessment's calculation of potential risk to soil, sediment and waste water treatment. All PET resin production sites that use antimony oxide, responded to this questionnaire. Several sites performed measurements of Sb in their waste water. As a result, predictions of environmental Sb concentrations in surface water, sediments and soils could be based on reliable information with the following conclusions:

- a higher PNEC (predicted no effect concentration) for sediment
- no risks defined for waste water treatment plants
- no risks remaining for marine water
- no risks remaining for marine sediment

Progress on Human Health Assessment – new science indicates no restrictions on DAT use

Recently, IAOIA has filled data gaps regarding acute toxicity (sensitisation, irritation, and inhalation toxicity), occupational exposure (Particle Size Distribution- dermal exposure and absorption and dustiness) and finally mutagenicity studies (toxicokinetics and an *in vivo* clastogenicity study). These data provide conclusive evidence that DAT is neither a sensitizer, nor an eye or respiratory tract irritant. Human data confirm that DAT is irritating to human skin and should thus be labelled with the R phrase, R38.

Considering the results of a new toxicokinetics study and based on one new and one existing *in vivo* mutagenicity study, our scientists are convinced that DAT is not a mutagen (i.e. not a class 3 mutagen as Sweden has proposed in the past) and as a consequence is not a class 2 carcinogen and should remain class 3 (i.e. there is no data to justify classification as a possible carcinogen).

Updated List of IAOIA Members:

An updated list of IAOIA members is available at www.iaoia.org.

These are the responsible companies that are working very hard to ensure that antimony products are protected in the market place through proper response to appropriate government agencies and development and distribution of reliable data. These organizations share the costs, both financial and through employee time. By choosing to conduct your business with one of these companies you are supporting our industry.

If you are a producer, distributor or consumer of antimony products and would like to contribute to these efforts, contact an IAOIA, JMIA, CCCMC office or one of our member companies.

Organisation of IAOIA

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