International ANTIMONY OXIDE Industry Association

IAOIA News

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EU Risk Assessment - timing and outlook

April 26:	ATO on the agenda of the C&L meeting on ENV
April 28:	Bilateral meeting with the Swedish Rapporteur to discuss the industry comments COM415_HH_IND5 to the second draft Risk Assessment Report
1 May:	Deadline for new Environment (ENV) exposure data
18-19 May:	IAOIA meeting for members in Barcelona
16 May:	Deadline for release of 3rd revised HH RAR.
14-16 June:	TC NES II**:** In-depth discussion of revised HH RAR? Will depend on outcome of bilateral meeting.
12-15 Sept:	Last visit discussion at TC NES III for ENV dossier? Will most likely become December.
6 Nov.:	Deadline for new ENV and HH report
4-7 Dec.:	Last visit discussion at TC NES IV for health and ENV dossier?
12-14 Dec:	PET 2006 conference in Amsterdam
Q2 2007	Finalised Risk Assessment Report approved by EU Competent Authorities?
April 2007:	Planned cut-off date for start of REACH implementation

Exposure and emissions data gathering from our downstream users ongoing

Data gaps on environmental emissions and exposure at the workplace from the antimony oxide using sectors still remain. These data gaps have to be filled in the coming months for the purpose of the EU's Risk Assessment. Based on the positive experience with PET this is well worth doing in order to avoid default data being used to demonstrate risks that do not exist in reality. One example to demonstrate this: in the current risk assessment report, workers in the following sectors: production of flame retardants back-coating formulations, pigment in paint and ceramics and compounding of engineering plastics are supposedly in theory exposed to 25-50 mg Sb/m³. That is up to 100 times the OEL (occupational exposure limit)!

If you are a user of antimony trioxide and willing to contribute to the data filling process, please contact the IAOIA Secretary-General (kvdv@iaoia.be).

Reaction of IAOIA/ATOS to newspaper articles regarding safety of antimony levels in PET-bottled waters

In recent months, some media articles have made questionable and misleading statements about antimony leaching into PET bottled water. The statements are supposedly based on the outcome of a study of Prof Shotyk, a Canadian scientist from Heidelberg University in Germany.

ATO is the major catalyst for the production of PET plastic used in the packaging of mineral water. It should be emphasised that PET continues to prove itself as an excellent material for mineral water bottles, with a history of safe use by millions of consumers every day.

Prof Shotyk published a scientific article in the Royal Society of Chemistry's journal. Prof Shotyk studied the very low antimony concentrations in for example ground water and soil. With his analytical equipment, he is able to measure extremely low concentrations and the low migration from antimony into PET bottled waters influences his measurements. Such findings have nothing to do with the safety of drinking water out of a PET bottle, as his highest concentrations of antimony are all 60 times below the allowed World Health Organisation (WHO) limit in drinking water. Drinking water out of a PET bottle is SAFE. This only goes to prove that we should not always believe what we read in the popular press.

For more detailed information, please check www.iaoia.org under 'publications'.

EU Risk Assessment – outcome of the first in-depth discussion of the second draft HH report

On March 9, the human health (HH) report of the ATO risk assessment (RA) was discussed at the EU's Technical Committee for New and Existing Substances (TC NES) meeting in Arona, Italy. The second draft of this RA report only contains the exposure scenarios (occupational exposure, consumer exposure and exposure via the environment), toxicokinetics and the mutagenicity effects. All other acute and chronic effects data had been deleted from the report again by KemI, including the risk characterisation.

Based on the comments from industry and several member states, the exposure scenarios will need to be revised by the rapporteur. As industry is gathering new data on ENV and HH exposure, the ECB made it clear that a new discussion at TC NES is only possible when all new data are available, which makes it unlikely that the exposure will be discussed in June or perhaps even September.

The main remaining issue is the potential mutagenic effects of ATO and the mechanism behind the carcinogen effects seen in female rats. Industry released 4 position papers (available at request to the IAOIA secretary general) on the potential mutagen and carcinogen effects. The position papers can be summarised as follows:

The occurrence of carcinogen effects only in female rats, the lack of genotoxicity *in-vivo* and the doubtful relevance for man render the extrapolation from the existing rat carcinogenicity studies to humans inapplicable. Industry therefore proposes:

1) To retain the current carcinogenicity classification of Diantimonytrioxide (class 3) and no mutagen classification for the meantime,
2) To incorporate the threshold-mediated lung overload phenomenon observed in rats as a possible mechanistic explanation of the tumours seen in the Watt and Groth studies,
3) To use the current OEL as a benchmark for the protection of humans from the chronic active inflammation risk to humans.

The last bilateral meeting with the Rapporteur dates from November 2004. The discussion at the TC NES in March showed clearly that there is a need for more regular bilateral meetings to achieve a good communication and cooperation between industry and the Rapporteur. A bilateral meeting is now planned for April 28th. The outcome of this discussion will be reported at TC NES II in June.

IND hopes that a turning point has now been reached in the Risk Assessment process. Industry is looking forward to a constructive cooperation with the Rapporteur and a detailed, purely scientific evaluation of all available data.

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

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.

Organization of IAOIA

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