International Antimony Association

To : American Conference of Governmental Industrial Hygienists (*ACGIH*)

Concerning: comments on Tier1 listing of '*Antimony and compounds, as Sb*' and '*Antimony trioxide, production*' on ACGIH *Under Study* list

Brussels, 10 July 2012

Dear Madam, Sir,

Following the response letter ACGIH sent to the i2a (*International Antimony Association*) on 20th July 2011, we would herewith like to submit comments on the Tier 1 listing of 'Antimony and compounds, as Sb' and 'Antimony trioxide, production' on the *Under Study* list.

The i2a has been performing and gathering scientific data for antimony and antimony compounds for more than 10 years now. Data have been used for the EU Risk Assessment Report for antimony trioxide (EU-RAR, May 2008) under the EU Existing Substances Regulation (EEC n° 793/93), and for the EU REACH registration process (Regulation (EC) n° 1907/2006) of 8 antimony substances since 2010 (cfr i2a website).The EU RAR was reviewed and accepted by OECD under the SIAP process (October 2008), and later also by the Canadian (2010) and Dutch (2011) governments.

Based on these internationally peer reviewed, high quality scientific hazard data, the i2a has derived DNELs (Derived No Effect Levels) for tri- and pentavalent Sb substances. The background information, methodologies and values are explained in detail in Annex to this letter. The results of lung capacity testing in an antimony trioxide production plant from 2000-2011 strongly suggest that this theoretically derived DNEL (corresponding to the current OEL) is protective for workers' health on the long-term. An official letter from the company doctor is attached to this email.

We hope that ACGIH, when reviewing the TLV values for antimony and antimony compounds of 1993-1994, will realize that the Notion of Intended Change (NIC) is not needed for antimony based on i) the above mentioned recent scientific data and ii) the results of the >10 years biomonitoring campaign. The current TLV value of 0.5 mg/m³ is still accurate and protecting the health of the workers exposed to antimony at the workplace.

Please don't hesitate to contact us further if you have further concerns or questions regarding antimony and antimony compounds.

Best regards,

Dr. Jelle Mertens
i2a Regulatory Scientist

International Antimony Association (VZW)
Avenue de Broqueville 12, 1150 Brussels, Belgium
Phone : +32 (0) 32 97 60 92 / Fax : +32 (2) 762 82 29

Annex: Comments on Tier1 listing of 'Antimony trioxide,production' and 'Antimony and compounds, as Sb' on ACGIH *Under Study* list

Executive Summary

According to the EU REACH Regulation, DN(M)ELs have to be derived for substances manufactured or imported in the EU in quantities >10t/y for the purpose of human risk assessment. DN(M)ELs are derived for acute and long-term exposure, local and systemic effects, different exposure routes (inhalation-dermal-oral) and different target groups (eg workers/general population) if appropriate. If national OELs exist, the scientific basis behind has to be considered as well. The general approach used: i) selection of relevant dose-descriptor, ii) modification to correct starting point if required and iii) application of assessment factors.

The i2a derived DNELs for 7 antimony substances. Herefore, Sb substances were grouped as trivalent substances, with antimony trioxide (ATO, CAS 1309-64-4) as 'reference' substance, and pentavalent substances, with sodium hexahydroxoantimonate (SHHA, CAS 33908-66-6) as 'reference' substance. Within each group, full read-across to the reference substance was allowed based on water solubility, bio-elution (solubility in artificial human body fluids) and speciation characteristics.

Based on hazard information, a $DNEL_{inhalation,local}$ and $DNEL_{dermal,systemic}$ was derived for ATO (resp. 0.5 mg/m³ and 281 mg/kg/d) and a $DNEL_{inhalation,systemic}$ for SHHA (365 mg/kg/d). Within each group, the DNELs of the reference substance were extrapolated to the other substances based on molecular weight and number of Sb atoms in the molecule. Following this, the lowest DNELs for Sb(III) substances was $DNEL_{inhalation,local}$=0.5 mg/m³ and $DNEL_{dermal,systemic}$=235 mg/kg/d and for Sb(V) substances $DNEL_{inhalation,systemic}$=260 mg/kg/d.

Latter values have been derived by the i2a using high quality internationally peer-reviewed scientific literature, and proposed TLVs are:

- 'antimony trioxide, production': **TLV(inhalation)=0.5 mg/m³**
  TLV(dermal)=281 mg/kg/d

- 'antimony&compounds, as Sb': **TLV(inhalation)=0.5 mg/m³**
  TLV(dermal)=235 mg/kg/d

Results of lung capacity testing at an antimony production plant (2000-2011) strongly suggest that the proposed TLV(inhalation) is sufficiently protective to ensure long-term workers' health.

International Antimony Association (VZW)
Avenue de Broqueville 12, 1150 Brussels, Belgium
Phone : +32 (0) 32 97 60 92 / Fax : +32 (2) 762 82 29

List of Recommendations/Actions

-grouping of Sb substances for the purpose of TLV derivation based on the valence of the Sb atom (trivalent and pentavalent Sb substances) as verified by scientifically sound read-across criteria (solubility, bio-elution and speciation data of individual Sb compounds)

-use of internationally accepted hazard data of antimony trioxide (CAS 1309-64-4; OECD, 2008) as worst-case scenario for trivalent antimony substances

-use of the EU REACH data of sodium hexahydroxoantimonate (CAS 33908-66-6; ECHA, 2010) as most data rich and representative pentavalent Sb substance

-selection of appropriate exposure and effect criteria to derive TLVs: '*inhalation exposure/local effects*' and '*dermal exposure/systemic effects*' for trivalent Sb substances and '*inhalation exposure/systemic effects*' for pentavalent Sb substances

- modification of the hazard data to the correct starting point if appropriate

-application of scientifically sound ECETOC (2003) assessment factors

-TLV for 'antimony trioxide, production': **TLV(inhalation) = 0.5 mg/m³**
TLV(dermal) = 281 mg/kg/d

-TLV for 'antimony and compounds, as Sb': **TLV(inhalation) = 0.5 mg/m³,**
TLV(dermal) = 235 mg/kg/d

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Rationale

Introduction

According to the EU REACH Regulation (EC 1907/2006), DN(M)ELs (Derived No(Minimal) Effect Level) have to be derived for substances manufactured or imported in the EU in quantities > 10 ton/year to do human risk assessments (DNELs for threshold effects, DMELs for non-threshold effects). DN(M)ELs have to be derived for acute and long-term exposure, for local and systemic effect in the human body, for different exposure routes (inhalation-dermal-oral) and for different target groups (eg workers vs general population). If national OELs for a certain substance are established, REACH explicitly requires that the scientific basis for setting the OEL is examined and evaluated if relevant.

Following this requirement, the *International Antimony Association* (i2a) derived DNELs for 7 antimony substances that have been REACH registered in 2010 or will be registered by the 2013 REACH registration deadline. These substances are:
Trivalent Sb substances: antimony metal (**Sb**: CAS n° 7440-36-0); diantimony trioxide (**ATO**; CAS n° 1309-64-4); diantimony trisulfide (**ATS**; CAS n° 1345-04-6); diantimony tris(ethylene glycolate) (**ATEG**; CAS n° 29736-75-2)
Pentavalent Sb substances: sodium hexahydroxoantimonate (**SHHA**; CAS n° 33908-66-6); sodium antimonate (A) (**SAA**; CAS n° 15432-85-6); diantimony pentoxide (**APO**; CAS n° 1314-60-9)

There was a stepwise approach followed to derive DNELs:

- selection of the relevant dose-descriptor for the endpoint based on the appropriate hazard assessment
- modification, when necessary, of the relevant dose descriptor to the correct starting point
- application, when necessary, of assessment factors to the correct starting point to obtain an endpoint-specific DNEL for the relevant exposure pattern (exposed human population, route, duration and frequency)

Hazard assessment Sb substances

For ATO (and via read-across also for Sb, ATS and ATEG; see later), data are based on the Risk Assessment Report of ATO (EU RAR; finalized in May 2008), created under the EU Existing Substances Regulation (EEC No 793/93) with Sweden as rapporteur member state and accepted by OECD under the SIAP process in October 2008. Revision of the data of the EU RAR for use under the EU REACH Regulation end 2011 confirmed that the conclusions are still valid.

For SHHA (and via read-across also for SAA and APO; see later), data are based on the EU REACH dossier, submitted to the European Chemicals Agency (ECHA) in 2010. An update of the dossier end 2011 showed that the data are still valid.

The threshold concentrations for human endpoints, derived for ATO and SHHA, are based on a critical review of existing peer reviewed literature (Klimish-scoring considering use of internationally agreed study protocols, GLP compliance, level of detail provided etc) and additional studies performed by the i2a using internationally recognized ISO/OECD study protocols (cfr EU RAR and EU REACH dossiers as mentioned above). Threshold concentrations are based on criteria stated in the EU REACH Regulation and CLP Regulation (EC) 1272/2008, and summarized in Table 1.

Table 1: Summary of hazard assessment data for antimony trioxide and sodium hexahydroxoantimonate

Human health hazards		Toxic threshold ATO	Toxic threshold SHHA
Toxicokinetics	Oral	1%	<1%
	Dermal	0.26%	1%
	Inhalation	6.82%	0.7%
Acute toxicity (oral)		$LD50_{rat}$ >20000 mg/kg/day	$LD50_{rat}$ >2000 mg/kg/day
Acute toxicity (dermal)		$LD50_{rabbit}$ >8300 mg/kg	Not determined (inhalation major exposure route, low dermal absorption)
Acute toxicity (inhalation)		$LC50_{rat}$ >5200 mg/m³	$LC50_{rat}$ >5400 mg/m³
Skin corrosion / irritation		Not irritating/corrosive	Not irritating/corrosive
Serious eye damage / eye irritation		Not irritating	Not irritating
Respiratory sensitization		Not respiratory sensitizing	Not respiratory sensitizing
Skin sensitization		Not skin sensitizing	Not skin sensitizing
Germ Cell mutagenicity		No germ cell mutagen	No germ cell mutagen
Carcinogenicity		$NOAEC_{inhalation}$ 0.51 mg/m³	No data indicating any concern for carcinogenicity
Reproductive toxicology		Not reprotox	Data lacking – testing proposal in the REACH registration dossier, testing currently ongoing
Target organ toxicity (single exposure)		Not STOT (single exposure)	Not STOT (single exposure)
Target organ toxicity (repeated exposure)		$NOAEL_{oral}$ = 1686 mg/kg/d $NOAEC_{inhalation}$ 0.51 mg/m³	Data lacking (cfr testing for *reproductive toxicology*)
Aspiration toxicity		No aspiration tox	No aspiration tox

Based on the outcome of above hazard assessments, the approporiate DNELs for workers were derived per substance (cfr below). The i2a antimony substances were grouped for this purpose; all trivalent Sb substances were considered one group, and all pentavalent Sb substances were considered another goup. The reasoning behind this 'grouping' is explained in the respective paragraphs below.

Eight different DNELs were considered for relevant workers. For local effects, the oral uptake route is not relevant (systemic distribution of ingested substance). Also, for systemic acute effects, the dermal and oral route is not considered relevant for antimony subtances because of the low uptake (cfr above). As such, the total number of DNELs to be considered for workers is the theoretical number of DNELs (2 x 2 x 3) minus the 4 excluded ones (cfr reasoning above) giving a total number of 8.

Based on the information of the hazard assessment, summarized in Table 1, only 3 DNELs were considered relevant/appropiate for effectively deriving a value for tri- or pentavalent Sb substances (Table 2).

Table 2: overview of DNELs for tri- and pentavalent antimony substances and short verification if not possible or applicable to derive a DNEL

DNEL				Sb(III) substances[1]				Sb(V) substances[2]		
Exposure duration	Route of exposure	Effects	*Unit*	ATO	Sb	ATS	ATEG	SHHA	SAA	APO
Acute	Inhalation	Local	*[mg/m³]*	*ND (lack of acute local toxicity)*				*ND (lack of acute local effects)*		
Acute	Inhalation	Systemic	*[mg/m³]*	*ND (lack of acute systemic toxicity)*				*ND (no toxicity observed in acute inhalation study and no high short-term peak exposure expected)*		
Acute	Dermal	Local	*[mg/kg(bw)/d]*	*Qualitative approach**				*ND (no acute local effects)*		
Long-term	Inhalation	Local	*[mg/m³]*	**0.5**	**0.5**	**0.70**	**0.87**	*ND (no long-term local effect expected)*		
Long-term	Inhalation	Systemic	*[mg/m³]*	*ND (lack of systemic toxicity after repeated inhalation exposure in a 12-month toxicity study in rats)*				**364.9**	**263.1**	**260.9**
Long-term	Dermal	Local	*[mg/kg(bw)/d]*	*Qualitative approach**				*ND (no long-term local effect expected)*		
Long-term	Dermal	Systemic	*[mg/kg(bw)/d]*	**281**	**234.7**	**327.4**	**408.4**	*ND (dermal absorption is negligible and no data available indicating systemic toxicity)*		
Long-term	Oral	Systemic	*[mg/kg(bw)/d]*	*Not relevant*				*Not relevant*		

ND: Not determined

[1] Sb = antimony metal (CAS n° 7440-36-0); ATO = diantimony trioxide (CAS n° 1309-64-4); ATS = diantimony trisulfide (CAS n° 1345-04-6); ATEG = diantimony tris(ethylene glycolate) (CAS n° 29736-75-2)

[2] SHHA = sodium hexahydroxoantimonate (CAS n° 33908-66-6); SAA = sodium antimonate (A) (CAS n° 15432-85-6); APO = diantimony pentoxide (CAS n° 1314-60-9)

* The Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA) concluded that a harmonised classification of irritating to skin was not supported, since special conditions, namely, substantial heat and sweat, were required in addition to high chemical dermal exposure, in all the cases where skin effects had been described in workplace observations. Furthermore, it was unclear whether diantimony trioxide was the only chemical substance to which these workers had been exposed (ECHA/PR/09/09, Helsinki, 06 July 2009). Based on this, no $DNEL_{dermal,local}$ has been derived for workers, since standard occupational hygiene practices provide a sufficient level of protection.

Trivalent Sb substances

°DNEL$_{inhalation,local}$ for ATO and Sb metal:

The EU RAR concluded on repeated dose toxicity: *'Repeated inhalation exposure to ATO gives local toxic effects in the lung and a NOAEC of 0.51 mg/m³ is derived from a 12 month inhalation exposure study in rat (Newton et al., 1994), supported by observations of acute pneumonia in a 19 days inhalation developmental toxicity study (Schroeder, 2003). No systemic toxicity is observed after repeated exposure, therefore no quantitative risk characterization is performed for systemic repeated dose toxicity.*
ATO is considered to be a carcinogenic substance and is classified for carcinogenicity. Although the mechanism for pulmonary tumor formation is still unclear it may be assumed that particle deposition followed by macrophage infiltration, pulmonary inflammation and impaired clearance are pivotal initial steps in the process. Consequently, diantimony trioxide can be regarded as a threshold carcinogen and as a starting point for a quantitative risk characterization the NOAEC of 0.51 mg/m³ derived for local repeated dose toxicity is also used for carcinogenicity.'

As ATO is considered a threshold carcinogen, a DNEL (and no DMEL) has to be derived.
A NOEC of 0.51 mg/m³ from a chronic inhalation toxicity study with rats was used as starting point. The two other available inhalation bioassay studies (Watt, 1983 and Groth et al., 1986) lack decisive information relevant for risk characterisation. It has to be mentioned that all three studies have severe shortcomings, and NTP decided to perform a new chronic inhalation bioassay. The experiments were finalized in 2010, but results are still not published. At the TC NES (Technical Committee on New and Existing Substances) meetings in 2008, it was decided to base all risk characterisations on the Newton et al. (1994) study for the time being, and eventually re-evaluating this endpoint after publication of the NTP study results.

The starting point has to be corrected for workers:
-activity driven differences of respiratory volumes for workers: 6.7/10 = 0.67
-for differences in deposition rate between rats and workers: mean value of 4

giving a NOAEC$_{corrected}$ of 0.51 x 0.67 x 4 = 1.4 mg/m³.

The detailed reasoning behind these corrections is available within the i2a.

This DNEL is derived for a local effect, i.e. an effect observed at the site of first contact and caused irrespective of whether the substance is systemically available. Thresholds for local effects are generally driven by the concentration at the target organ rather than by a cumulative/systemic dose. In this case, where the target organ is the lung, the constantly operating clearance mechanisms are not overwhelmed up to a certain local concentration, rather independently of the duration of exposure. Whereas the severity of the effects may increase with increased exposure duration, the minimum threshold concentration (NOAEL) from which the effect starts to occur does not decrease with increasing exposure duration. Thus, a modification of the starting point with regard to different duration of exposure in the laboratory animals relative to humans via the factors 6h/8h for workers can be neglected for this local DNEL.

To derive a DNEL, assessment factors (AF) have been applied to the NOAEC$_{corrected}$. The following aspects were taken into account: inter-species variability (extrapolation from animal data to humans), intra-species variability (variability in chemical sensitivity within humans), differences in duration of exposure, issues related to dose-response, and quality of the whole database. For all AFs, a value of 1 applies (AF for inter-species variability is 1, as it is assumed that rats are more sensitive and humans respond to the insult less or, under a conservative assumption, in the same way), except for intra-species variability for which a value of 3 is taken (ECETOC, 2003).

Following the science-based derivation, **a DNEL of 0.47 mg/m³ for ATO was obtained, which is in good agreement with the current OEL of 0.5 mg/m³ for Sb substances.**

Antimony as a semi-metal is subject **at its surface to a passivation by the formation of a layer of antimony trioxide**. In particular for antimony metal powder (because of its large surface area), the oxide layer will form a quantitatively relevant portion of the entire particle. Furthermore, in vitro bioaccessibility testing in various artificial body fluids has shown that antimony metal compared to ATO has a similar release rate of Sb ions (Hedberg et al., 2010). In view of this, and since transformation/dissolution testing (Skeaff et al., 2012) has shown that Sb may be expected to release trivalent Sb cations upon dissolution, it may be assumed that human exposure towards Sb is secondary to that of ATO. Thus, unlimited read-across for repeated dose toxicity from ATO to Sb is considered justified, and levels of protection designed for ATO will also be adequate for Sb, by **applying the same DNEL (inhalation, local).**

°$DNEL_{inhalation,local}$ for ATS and ATEG:

Upon dissolution in aqueous media at physiologically relevant concentrations and pH conditions, the only aqueous antimony species emerging from all considered trivalent antimony substances is the trivalent antimony cation. In vitro bioaccessibility testing in various artificial body fluids (Hedberg et al., 2010) has shown that ATS and ATEG compared to ATO has a similar release rate of antimony ions. Thus, read-across from ATO towards ATS and ATEG is justified without restriction, and levels of protection designed for ATO will also be adequate for ATS and ATEG.

Considering the conservative nature of the DNEL derivation procedure for ATO, in a sense that it is based on a mechanism (particle overload of poorly soluble particles) that is of questionable relevance for humans, and that a conversion of the OEL for all antimony substances (expressed as Sb) for ATO would yield a value of 0.6 mg/m³, it was **decided to adopt the current OEL of 0.5 mg/m³ as a DNEL (expressed as 'Sb') for all trivalent Sb substances, except for ATO (because of data specific for ATO, a value of 0.5 mg/m³ is adopted as DNEL).**

Because the DNEL has been derived for antimony, the DNEL for ATS and ATEG has to be calculated according to their molecular weight (ATS 339.68 g/mol and ATEG 423.68 g/mol) and number of Sb atoms:

$DNEL_{inhalation,local}$ for ATS = 0.70 mg/m³
$DNEL_{inhalation,local}$ for ATEG = 0.87 mg/m³

°$DNEL_{dermal,systemic}$ for ATO:

The EU RAR on ATO concluded on the repeated dose toxicity: "*Two repeated dose oral studies suggest that ATO may be toxic to the liver based on a 10% increase in liver weight, supported by significantly elevated ALP and ASAT levels (Sunagawa, 1981; Hext et al., 1999). However, in the absence of histological changes or any clinical signs of antimony intoxication to support that the liver findings are adverse, the findings are regarded as adaptive or incidental to treatment with ATO and a NOAEL of 1686 mg/kg(bw)/d for repeated dose toxicity is derived from these studies.*"

A NOAEL of 1686 mg/kg(bw)/d from a subchronic oral toxicity study in rats is used as starting point. Because the route of exposure is not identical in animals and humans, a correction needs to be made theoretically. However, the only necessary correction refers to the differences in absorption by the oral route in animals and dermal route in humans. Based on the EU-RAR, absorption via the oral route is low (1%). There is no adequate dermal absorption data in humans available, but a guideline conform in vitro percutaneous absorption study with human skin showed a dermal absorption value of 0.24%. For simplification, a value of 1% is assumed for both routes. This approach also implies an additional safety margin.
Assessment factors are applied to the NOAEL to derive a DNEL. The AF for intra-species variability is 3 (ECETOC, 2003), and the AF for exposure duration (subchronic to chronic) is 2 giving a total AF of 2 x 3 = 6
Based on this, the **$DNEL_{oral,systemic}$ for ATO = 281 mg/kg(bw)/d**

°$DNEL_{dermal,systemic}$ for Sb, ATS, ATEG:

Upon dissolution in aqueous media at physiologically relevant concentrations and pH conditions, the only aqueous antimony species emerging from all considered trivalent antimony substances is the trivalent antimony cation. In vitro bioaccessibility testing in various artificial body fluids (Hedberg et al., 2010) has shown that Sb, ATS and ATEG compared to ATO has a similar release rate of antimony ions. Thus, read-across from ATO towards Sb, ATS and ATEG is justified without restriction, and levels of protection designed for ATO will also be adequate for Sb, ATS and ATEG.

As the $DNEL_{dermal,systemic}$ above is derived for ATO, the according DNEL for Sb, ATS and ATEG have to be calculated according to their molecular weight and number of atoms. This results in:

$DNEL_{dermal,systemic}$ for Sb = 234.7 mg/kg(bw)/d
$DNEL_{dermal,systemic}$ for ATS = 327.4 mg/kg(bw)/d
$DNEL_{dermal,systemic}$ for ATEG = 408.4 mg/kg(bw)/d

Pentavalent Sb substances

°$DNEL_{inhalation,systemic}$ for SHHA:

This DNEL is derived by route-to-route extrapolation, based on human clinical trials conducted for the treatment of leishmaniasis, usually involving in vitro or intramusccular administration.
Out of the 7 key human studies (Aronson et al, 1998; Ballou et al, 1987; Lawn et al, 2006; Navin et al, 1992; Thakur et al, 1988; Thakur et al, 1990; Thakur et al 1998), 5 were conducted with the standard dosing regimen (20 mg/kg bw/d Sb(V)) and 2 studies with dose regimens in the range 10 to 20 mg/kg bw/d Sb(V). In human trials regarded as supportive, 10 were conducted with the standard regimen and 6 studies with varying dose regimens in the range 5 to 60 mg/kg bw/d Sb(V). Based on the evaluation of side effects described in these studies, a dose level of 10 mg/kg bw/d Sb(V) was identified as LOAEL (lowest observed adverse effect level).
Correction from human i.v. LOAEL in mg/kg(bw)/d to a corresponding inhalation LAEC in mg/m³ for a worker of 70 kg is performed by using:

- -100% absorption by i.v. route
- -difference in inhalation-absorption rates for antimony compounds as given in Appendix 2
- -10 m³/person standard respiratory volume for workers (wRV) considering light activity and 8 h of exposure

LOAEL of 10 mg/kg bw/d corresponding to 700 mg/person (70 kg), corrected for inhalation rates resulted in of LAEL of 97222.2 mg/person/d for SHHA
Conversion to mg/m³ by using the wRV: dividing LAELs (mg/person/d) by 10 (m³/person) resulting in LAECs (lowest adverse effect concentration) for workers (8h) of 9722.2 mg/m³ for SHHA
Assessment factors were applied as follows: 3 for intra-species variability (ECETOC, 2003), 6 for exposure duration (subacute to chronic; 40 d vs lifetime) and 3 for dose response (LOAEL instead of NOAEL) giving a total AF of 3 x 6 x 3 = 54

The corresponding DNEL is 180.04 mg/m³. As the DNEL was derived for the Sb(V) cation, the DNEL for SHHA had to be calculated according to their molecular weight and number of Sb(V) atoms in the molecule giving a final

$DNEL_{inhalation,systemic}$ for SHHA = 364.89 mg/m³

°$DNEL_{inhalation,systemic}$ for SAA and APO

Upon dissolution in aqueous media at physiologically relevant concentrations and pH conditions, the only aqueous antimony species emerging from all considered pentavalent antimony substances is the pentavalent antimony cation. The water solubility of all pentavalent shows similar values. Thus, with respect to systemic toxicity, read-across between all pentavalent antimony substances is justified without restriction (Hedberg et al., 2010).
Based on this, a similar reasoning was applied for SAA and APO:

LOAEL of 10 mg/kg bw/d corresponding to 700 mg/person (70 kg), corrected for inhalation rates resulted in of LAEL of 89743.6 mg/person/d for SAA and 106060.6 mg/person/d for APO.
Conversion to mg/m^3 gives 8974.4 mg/m^3 for SAA and 10606.1 mg/m^3 for APO.
After applying the appropriate AFs and conversion for molecular weight and number of Sb(V) atoms, the final DNELs are

$DNEL_{inhalation,systemic}$ for SAA = 263.09 mg/m^3
$DNEL_{inhalation,systemic}$ for APO = 260.91 mg/m^3

Biomonitoring campaign at antimony production plant

The results of lung capacity tests of workers in an antimony production plant at Campine NV strongly suggest that there are no effects on workers' health when complying with the current OEL value of 0.5 mg/m^3. This confirms that the theoretically derived value above is effectively protecting workers' health on the long-term.
Due to the relatively low amount of data, it is impossible to draw any statistically conclusions from the data. However, considering the relatively long duration of this monitoring campaign (2000-2011), and the absence of any visual evolution of the tests during this period, we believe the data strongly suggest that the current OEL is sufficiently protective, and that no change is required.

Citable Material *(all studies are available at the International Antimony Association)*

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