Dr. Anne Fairbrother (Chair)

Issue 1. Overall Clarity of the Assessment.

Chapter 1 provides the scope of the assessment and a brief introduction. Supporting information on chemistry, fate, and uses are provided in Chapter 2 and the exposure, hazard, and risk characterizations are presented in Chapter 3. Additional supporting information is available in the appendices.

Question 1-1. Please comment on the clarity and strengths and weaknesses of the risk assessment and provide specific suggestions regarding how this may be improved.

The risk assessment was well laid out and described in the report. Most of the underlying assumptions were stated and acknowledged. However, the document should include a statement in the Introduction (Chapter 1) and Conclusions (Chapter 3C) that this is a screening assessment using very conservative assumptions to determine if it is necessary to move forward with a more detailed and realistic risk analysis. The document should use terminology and organization described in EPA’s Framework for Ecological Risk Assessment (http://www.epa.gov/raf/publications/framework-eco-risk-assessment.htm). Thus, the document would be reorganized as:

<table>
<thead>
<tr>
<th>Current Version</th>
<th>Risk Framework Version</th>
</tr>
</thead>
<tbody>
<tr>
<td>Background and Scope</td>
<td>Problem Formulation</td>
</tr>
<tr>
<td>Sources and Environmental Fate</td>
<td>Conceptual Model</td>
</tr>
<tr>
<td>Estimates of environmental releases of ATO during processing and use of flame retardants</td>
<td>Exposure Assessment</td>
</tr>
<tr>
<td>ATO Hazard characterization for ecological organisms</td>
<td>Effects Assessment</td>
</tr>
<tr>
<td>Environmental Risk Characterization</td>
<td>Risk Characterization</td>
</tr>
</tbody>
</table>

Furthermore, a justification should be included for why a deterministic assessment was conducted using single point estimates for exposure concentrations and response functions. A partial or complete probabilistic assessment based on probability distributions can be used in screening assessments as well as more in-depth analyses to provide the risk managers (i.e., decision officials) with an understanding of the amount of conservatism in the final risk estimate.

Finally, the document must be clear about whether the assessment is asking about risks from past and current operations or if it is looking into the future to determine risks. The time frame must be stated for both of these approaches. If the past is meant to inform the present (or future), then how far in the past is
reasonable? Were there any significant changes in discharge type, amount, or product that might change the historical baseline? And if risks are to be projected into the future, how far forward is the focus of the analysis?

A primary weakness of the assessment is its focus on aquatic ecosystems. Almost all (97%) of the antimony disposal is to terrestrial systems (landfills, etc.), yet there is little discussion about potential environmental exposure pathways from this disposal regime. If migration to ground- or surface-water is considered negligible and there is no indication that material is applied to agricultural or rangeland, then that should be clearly stated and a conclusion reached that terrestrial ecosystem risk is below levels of concern. The assessment mentions 32 soil samples with measured antimony concentrations but does not provide a summary of these data or other information about those samples (e.g., where and when were they collected). These data are part of the USGS NWIS dataset, but the Supplemental material provided in the EXCEL file had insufficient detail to identify the soil samples.

Furthermore, of the 2% of the antimony that is discharged from facilities into surface water, only 20% (0.4% of the total) goes directly to waterbodies while the remainder is released to publically owned treatment works or other similar facilities (the document does not state where this information came from although presumably it is contained in the TRI documentation). However, there is only a little further discussion about what might happen to the antimony in the POTWs; at least some portion (most?) likely settles into the sludge which then is disposed of in landfills or sold for fertilizer (this is mentioned on Page 15 but not followed up). This has the potential to transfer antimony to terrestrial systems, reinforcing the need to focus further on this potential exposure pathway. Information about antimony concentrations in sewage sludge are available for review (see, for example, http://water.epa.gov/scitech/wastetech/biosolids/tnsss-overview.cfm where antimony concentrations ranged from 0.45 to 26.6 mg/kg).

Specific comments about clarity of writing and terminology include:

1. The acronym “COC” was used throughout to refer to “concentrations of concern” when referring to various hazard benchmarks. In most risk assessments, “COC” refers to “chemicals of concern” (or sometimes, “chain of custody”). Therefore, my preference would be to continue to use the word “benchmarks” or some acronym related to that term. That said, since the term was defined for the purposes of this report, it technically is not incorrect to continue to use it.

2. The word “robust” is used frequently in the text. It is not clear what this means in the context of a dataset. A large amount of data (with “large” unquantified) may be referred to as “robust” or a smaller dataset of higher quality may also be “robust.” The term should either be defined or not used.

3. The acronym “NOEC” is used in the document, but should properly be “NOAEC.” The “A” is for “adverse” to specify that only adverse changes are used in this determination. The Europeans continue to use the older acronym “NOEC,” but the newer version has been adopted for use in the U.S.

4. The number of significant digits for all numbers in the text should be reviewed. Some are more precise than the data indicate. For example, on Page 31 the GMATC value is shown as 1,710.9 mg/kg. There really is no need to carry this value out to one decimal place – a value of 1,710 mg/kg would be more realistic.

5. Page 10 – suggest inserting a brief paragraph prior to the one that starts “EPA conducted an environmental exposure assessment…” to state the objectives of the report. This should include a
statement that this is a conservative, screening level ecological risk assessment meant to determine whether or not an in-depth detailed risk analysis is needed.

6. Page 11 – Here, and elsewhere, make it clear that the E-FAST2 models consecutive days; e.g., “over a period of 250 or 24 consecutive days/yr.” (italics added here for emphasis).

7. Page 12 – First paragraph of Section A. Suggest adding a brief statement that antimony can be methylated to trimethylstibine (or trimethylstiboxide) under anaerobic conditions.

8. Page 15 Section C Environmental Persistence – Suggest briefly discussing the methylation of antimony in this paragraph, noting that it is <10% of total amount in aquatic systems, but that it contributes to volatilization of the material. It is not known if methylated antimony is more or less toxic than the inorganic forms (e.g., like lead or like arsenic in regard to toxicity).

9. Page 16 – a reference is needed for the statement that background concentrations of antimony in unpolluted natural waters are usually less than 1 ppb. This should be qualified to be “waters of the U.S.”

10. Page 16 Fate in Water – this section could benefit from additional discussion of sorption (or lack thereof) of antimony to suspended particles and natural organic matter. Additional information on methylation should be included as well. This would naturally lead to a section on Fate in Sediments which should include binding to iron, manganese, and aluminum.

11. Page 16 Fate in Soil and Sediment – this discussion should be separated into sections for Sediment and Soil, not discussed together.

12. Page 17 Transformation – a discussion of methylation is missing from this paragraph

13. Page 18 Bioaccumulation – a discussion of methylation is missing from this section. Also, it has been noted that the antimony BCF/BAF is not a constant; i.e., it decreases with increasing concentration. This should be discussed here.

14. Page 24 – suggest rewriting last paragraph to state “Another large set of environmental monitoring data was obtained…”

15. Page 25 Exposure Assessment first paragraph – suggest deleting the sentence “A large amount of water and sediment data was available from these sources” as it’s not particularly informative.

16. Page 27 first paragraph – the statement that releases are the result of bi-monthly cleaning practices and therefore a release rate of 24 days/yr suggests that the releases occur only 2 days/month. However, the E-FAST2 model assumes 24 consecutive days. This should be explained clearly so the reader is not left with the assumption that the model is using some type of pulse-exposure metric. Note that a 24 consecutive day exposure is likely a more conservative estimate of potential risk than 2-days/month pulsed exposures, except for the months with very low flow.

17. Page 28, 32, and 34 -- Table 3-3, Table 3-4, and Table 3-5 should be expanded to include the test concentrations (and noted whether they are measured or nominal).

18. Page 33 – for the sediment invertebrate toxicity studies, each study reviewed should include a statement of how long after sediment spiking were the test organisms introduced (i.e., was the sediment aged or not?). Additionally, please indicate whether or not the growth (weight) endpoint
was based on ash-free dry weight, the age of the organisms at the start of the test, and whether the reported values are measured or nominal.

19. Page 35 second paragraph – using the EU approach plus a 10-fold assessment factor for determining a chronic benchmark for sediment will result in a very conservative value. This paragraph should firstly state what the “EU approach” is and acknowledge the conservatism of the derived value.

20. Page 36 – the top paragraph reports the number and percentage of sediment values that exceed the screening benchmark. In what years did these occur (were they all in the same year)? Why is the fact that none occurred in the last three years important? Was there something of importance relative to antimony discharge, production, or use that happened in 2009? These same questions apply to the summary of the water concentration exceedances. Perhaps Figure 3-1 could have the data locations in different symbols (or colors) depending upon the year so temporality will be evident as well as spatial distribution.

21. Page 45 last paragraph – the statement that “it is unknown whether the data are representative of other locations in the U.S.” is not necessary. As noted in my later comments, the objective of this risk assessment was to determine if antimony-related facilities were contaminating the environment. Therefore, the unknown is whether these data are properly representative of stream reaches below facility discharge locations. Characterizing all parts of the U.S. is not a study objective.

22. Page 46 – the last sentence again talks about being “representative of the U.S.” See comment immediately above. Moreover, for soils, it may be prudent to show where landfills are located that are likely recipients of antimony-contaminated waste as this would be locations most likely at risk. Distribution of biosolids from POTWs located near antimony facilities could be nationwide, and gathering such information would be difficult. Therefore, terrestrial risks from antimony discharge must rely more heavily on estimating soil concentrations from biosolids data and less on soil monitoring data.

23. Page 47 Conclusions – this paragraph should state that the purpose of the assessment was to conduct a screening-level risk assessment to determine if there is a need to proceed further with an in-depth analysis.

Page 47 second bullet – how do you know that the species tested in the cited studies are the most sensitive ecological species? If you truly believe this, then you would not need to use 10-fold assessment factors on benchmark calculations to protect possibly more sensitive

**Issue 2. Characterization of Environmental Exposures Based on Release Data.**

Characterization of Environmental Exposures Based on Release Data. During project scoping, OPPT identified ATO use as a synergist in halogenated flame retardants as the focus of this assessment. EPA’s 2010 Toxic Release Inventory (TRI) was used to obtain information on water releases associated with this end-use scenario. Data collection was refined using the North American Industry Classification System (NAICS) codes to identify a subset of TRI facilities (i.e., those indicating production, processing or use of ATO-containing flame retardants). Because ATO is not specifically listed on the TRI, data reported under the broader category of ‘antimony compounds’ were used as a surrogate for ATO in this assessment. ATO surface water concentrations were predicted using a screening level tool (E-FAST2), to model water releases reported by selected TRI facilities.
**Question 2-1:** TRI information reported for ‘antimony compounds’ was used to estimate ATO releases associated with its use as a synergist in halogenated flame retardants. Please comment on this approach.

Using the “antimony compounds” designation as a surrogate for determining the location of facilities that may release ATO into the environment is a reasonable approach. It must be kept in mind, however, that TRI release inventories are not particularly accurate and there is no requirement for verification. That said, the most striking feature of the inventory results is that the vast majority of material (97%) is released to “land/other” for disposal:

<table>
<thead>
<tr>
<th>Pounds of Antimony Released (TRI data)</th>
<th>Air</th>
<th>Water</th>
<th>Land/Other</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>11,235</td>
<td>15,691</td>
<td>966,617</td>
<td>993,543</td>
</tr>
<tr>
<td></td>
<td>1%</td>
<td>2%</td>
<td>97%</td>
<td></td>
</tr>
</tbody>
</table>

This fact gets lost in the remainder of the risk assessment which is heavily focused on assessing risks to surface water ecosystems. In fact, the Exposure Assessment section on pages 25 - 27 discusses ONLY how data for water concentrations were measured or calculated and makes no mention of land disposal issues. Soil concentration data are mentioned on Page 36 in the Risk Characterization section: “Only 32 soil samples were obtained from the USGS-NWIS database between 2005 and 2010.” This information needs to be provided in Section 3B Exposure Assessment – where were the samples located? When were they collected? What do we know about their soil characteristics? What were the antimony concentrations? As noted above in Question 1, information about antimony concentrations in sewage sludge (i.e., biosolids) should also be reviewed in the context of potential application to agricultural or rangeland soils.

Table 3-1 has some errors that should be corrected:

1. The Total for the category “Plastics material and resin, synthetic rubber, and fiber manufacturing should be 977 lbs for air (not 1,277).
2. The last category in the table had 3 facilities included, whereas the first of those (number 335931) is really in a separate category. The Totals for this category included only the 2 that belonged with “Textile product mills and apparel manufacturing” but there was no demarcation showing that the first is not included.
3. The table legend should also note that there were some rounding errors so the totals don’t always add up to exactly the amount within each category (several are off by a pound or two).

**Question 2-2:** Because TRI does not indicate the number of days associated with reported releases, two exposure scenarios were developed (assuming the total water releases reported in the 2010 TRI occurred over a period of 250 days or, a more conservative scenario of 24 days to provide a range of predicted water concentrations for comparison with hazard benchmarks (concentrations of concern) identified for aquatic organisms. Please comment on the assumptions used to develop modeling scenarios using EPA’s E-FAST2 model to assess aquatic exposures to ATO.
Not all of the input data / assumptions for running the model were provided. The water component of the model requires the following user-supplied inputs:

- Bioconcentration Factor (unitless)
- Wastewater treatment removal (percent)
- Adsorption to wastewater treatment sludge (percent)
- Drinking water treatment removal (percent)

The supplemental materials provided with the risk assessment report show the detailed output from the E-FAST2 model runs. This indicates that the BCF was set equal to zero as were the other 3 input parameters. However, it would be helpful if this were clearly stated in the assessment report itself.

Additionally, an “input” page for each of the types of model runs (1 year and 24-day) at the beginning of the supplemental materials would be very helpful.

Furthermore, it is my understanding that the model looks at consecutive days of exposure/discharge. That is, the “24 day” scenario is really 24 consecutive days, not 2 days per month for a year. If the latter is what EPA intends to model, then 12 runs need to be conducted for each facility, using monthly streamflow data. However, this is not possible with the E-FAST2 model that automatically retrieves streamflow data once the NPDES designation is entered; the model uses mean annual flow and 7Q10 flow values. Therefore, EPA should state that the “24 days” model is really 24 consecutive days and not 2 days per month for a year as is currently implied. EPA should also state in the document that they ran the “probability distribution module” (PDM) to predict the number of days per year the facility’s discharge will exceed a chemical concentration of concern (specified by the user).

Note that EPA found the NPDS designations for the facilities that were used in the E-FAST2 model using the NPDES Loading Tool which “highlights annual estimates of pollutant discharges that are potentially using data outliers” (http://sfpub.epa.gov/dmr/error_correction.dfm). NPDES codes for the Facilities that were found by using this tool are, therefore, those with at least one reported extreme high discharge level; this may be due to a reporting error but regardless, it provides a conservative exposure estimate which is compatible with a screening assessment. This tool also provides the HUC-12 code which identifies the watershed within which the facility is located (note that the HUC-12 code should be included in Table 3-2).

The E-FAST2 model also provides an option for generating a list of endangered species in the vicinity of a facility. EPA should consider including this information in the assessment for completeness.

Question 2-3: Please comment on the approach EPA used to estimate environmental releases resulting from uses of ATO as a synergist in flame-retardant chemicals. Are there other data sources or approaches that EPA should consider to estimate environmental releases of ATO in this end-use? If so, please provide citations or data for consideration in further revision of the draft assessment.

Limitation: none of the actual monitoring sites were located within the primary watershed of the TRI facilities. Therefore, the concentrations most likely have been significantly diluted from what they would be at the point of discharge. Providing the HUC-12 code for the facilities and locations of the water samples would help the reader understand the relationship between the monitoring data and the facilities locations. As noted above, using the HUC designation for retrieving water monitoring data would increase the representativeness of the monitoring data.
See above suggestions for using data from the sewage sludge (biosolids) survey conducted by EPA and noting the soil background concentrations recently released by the USGS (http://pubs.usgs.gov/ds/801/).

**Issue 3. Characterization of Environmental Exposures Based on Monitoring Data.**

*Characterization of Environmental Exposures Based on Monitoring Data.* OPPT used environmental monitoring information obtained from the U.S. Geological Survey- National Water Information System and EPA's STORET database to evaluate antimony levels in environmental media. Data collection was limited to states \( n=10 \) with TRI facilities \( n=14 \) having NAICS codes corresponding to ATO uses as a synergist in halogenated flame retardants.

**Question 3-1: Please comment on the use of these large monitoring data sets to characterize ecological exposures to ATO use as a synergist in flame retardants and their representativeness for other locations in the US.**

The primary shortcoming of both the USGS-NWIS and EPA’s STORET data is that the monitoring sites did not correspond to the discharge locations. This was recognized by EPA which is why the E-FAST2 model was used to estimate concentrations at end-of-pipe. This appears to be a reasonable solution for a screening level risk assessment of local effects from the manufacturing facilities. Unless the monitoring data are known to have been collected from a location directly downstream of the facility, they provide little information about the risk from that source.

If EPA wished to be “representative of other locations in the US” and, perhaps, conduct a regional or nation-wide risk assessment, then an analysis of a large set of these data sets would need to be conducted, perhaps using a stratified random design to collect representative samples from different ecoregions. Dates at which the monitoring stations were sampled would also need to be considered (in case there are significant temporal trends). However, this would be a different question than what is being addressed by the current assessment. The assessment is limited to asking whether antimony dischargers are causing environmental risk, whereas a review of data from across the US would address the question of whether antimony is exceeding risk benchmarks in some location(s), which might then necessitate a follow-up to determine why a particular location had exceeded the benchmark. The Agency should be careful to keep these two issues separate.

To better address the question stipulated in this assessment (whether antimony dischargers are causing environmental risk), it might be better to query the datasets by HUC (hydrologic unit code) and not by state. Displaying the data in this manner in Figures 3-1 and 3-2 would provide a better sense of the relationship between the facilities and the monitoring stations. Furthermore, when limiting the query to the state level, some nearby sites in adjacent states may be inappropriately ignored.

The monitoring data were for 1987 through 2011, although the TRI data were only for 2010. This is another mismatch between the monitoring data the reported release information. This is particularly apparent for sediments.

Note that the supplemental datafile for the USGS – NWIS data is not part of the report, although it was made available for review when requested.
Question 3-2: Are there other major sources of environmental monitoring data (or other pertinent information) that EPA should incorporate in the exposure assessment? If so, please provide the necessary citations and/or data for inclusion in the revised document.

Information about antimony concentrations in sewage sludge is available for review (see, for example, [http://water.epa.gov/scitech/wastetech/biosolids/tsnss-overview.cfm](http://water.epa.gov/scitech/wastetech/biosolids/tsnss-overview.cfm) where antimony concentrations ranged from 0.45 to 26.6 mg/kg). Parsing the data by location (i.e., in the vicinity of known facilities with the largest amount of landfill disposal) may be helpful. But it must be kept in mind that biosolids are sold and distributed widely so initial location may not be a reliable indicator of eventual environmental risks. A conservative risk screen can be conducted by comparing biosolid concentrations to benchmarks, followed by a more refined screen (if necessary) assuming that biosolids generally are tilled into soils (except when sprayed in forests or onto rangelands).

The USGS dataset of concentrations of elements in soils of the US ([http://pubs.usgs.gov/ds/801/](http://pubs.usgs.gov/ds/801/)) is not useful for the purposes of this risk assessment as the sampling locations were selected to be representative of background concentrations and not contaminated areas. However, they can provide context of areas where there may be naturally elevated background levels.

I am not aware of any other national datasets of antimony concentration in water, sediment or soils. States may have additional data on water quality that are not uploaded to STORET. It may be worth looking for such information in the states with the 15 TRI facilities.

Question 3-3: Are there concerns or limitations in these data sets that may impact their utility for risk assessment?

The primary concerns with all environmental data are 1) data quality and 2) consistency. In regard to data quality, there are no quality controls on the STORET data; i.e., states can upload data to the STORET database without any QA/QC data nor are the data disqualified if the QA/QC data show that they may be unreliable (e.g., standard recovery is too large a range). There is no requirement for the samples to all be analyzed by the same methods (e.g., GCMS, HPLC, or AA), nor are there standards for levels of quantification. Therefore, these data always need to be qualified as providing general indications of concentrations, and if a screening analysis suggests that concentrations are close to levels of concern, targeted monitoring with known QA/QC should be conducted.

The USGS-NWIS data are somewhat more reliable than STORET as they follow the same known protocols at all sites. However, differences occur across years, so the same caution in data use must be applied, particularly with targeted monitoring to follow up on any areas of concern.

These concerns were adequately stated in the Uncertainty section of the document (Page 45), except for noting that the time-frame of the data (1987-2011) is much longer than the TRI data (2010).

Issue 4. Fate, Transport and Bioavailability.

Information available in the published literature regarding the chemistry, fate and transport of ATO is used qualitatively to assess bioavailability to ecological organisms. There is a lack of site-specific data on geochemistry that would inform specification and availability antimony compounds in its toxic forms for environmental receptors.
**Question 4-1: Please comment on the use of this information in the ATO assessment. Are there other data sources that EPA should consider?**

Pages 17 – 18 provide a qualitative discussion about the influence of environmental factors on the bioavailability and transformation of antimony. While the general categories of factors (e.g., presence of other meals, pH, etc.) are listed, there is no indication of whether bioavailability is increased or decreased in the presence of increases/decreases of each of these factors. The one factor that is discussed (pH) is ambiguous in this regard: “...pH, which may increase the bioavailability of antimony to aquatic organisms at environmentally relevant pH.” Increase compared to what? Is bioavailability low at both very low and very high pHs and greatest at pH 7-8? This generally is not how elements behave in relation to pH and antimony generally is more bioavailable at higher pH. Inclusion of a table indicating how environmental factors affect bioavailability would be helpful, e.g.,

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Effect on Bioavailability</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>Increase with increasing pH</td>
</tr>
<tr>
<td>Fe, Mg, Al</td>
<td>Decrease with increasing concentration</td>
</tr>
</tbody>
</table>

Environment Canada recently addressed the issues of environmental fate and bioavailability for antimony: [http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=9889AB](http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=9889AB). This provides some reference information in addition to the EU RAR (2008). Both the Canadian and EU assessments stress the fact that the fate of antimony is determined, at least in part, by its partition coefficients, namely soil-water, suspended sediment-water and sediment–water partition coefficients (K_{sw}, K_{ssdw} and K_{sdw}). Antimony tend to bind to particles so the amount of suspended solids (possibly including natural organic matter) in the water can influence its concentration in the water column.

Environment Canada noted that “it was not possible to use the Windermere Humic Aqueous Model, version 6.0 (WHAM 2001; Tipping 2002), to obtain further information on the speciation of antimony in natural waters” because the thermodynamic stability constants are lacking.” This precludes the use of the biotic ligand model to standardize concentrations across sites with different bioavailability factors.

Bioaccumulation in terrestrial systems (soils) was not included in the discussion on Page 18. The following is from the Environment Canada assessment referenced above, some version of which should be included in this assessment:

Gá l et al. (2007) studied the mobility, bioavailability and soil-biota transfer of arsenic and antimony at a former antimony mining and smelting site. Average soil (0-10 cm) pH, Eh and organic matter content were 4.7, 84 mV and 23.2%, respectively. There were significant positive correlations between the antimony concentration in grass and earthworms on one hand, and total antimony concentration in soil on the other land. Biota-soil accumulation factors based on dry weight were low, with mean values reported by the authors of 0.009 for grass, 0.034 for *Lumbricus terrestris* and 0.063 for *Octlasion cyaneum*. These factors were expected to be higher for less antimony-contaminated soils. Indeed, log-log relationships between antimony in soil and biota samples had slopes less than unity which, according to Gá l and collaborators (2007), implied that biota–soil accumulation factors are greater when antimony levels in soils are lower.


Overall, there are no quantitative methods for adjusting total antimony concentrations in the environment to bioavailable concentrations nor are there quantitative models for adjusting the benchmark values to account for differences in the toxicity tests. Therefore, EPA is correct in including a qualitative
assessment of these bioavailability factors and including a discussion of such in the uncertainty section (currently missing from Pages 45–47).

**Issue 5. Environmental Hazard Assessment.**
The available hazard information was critically evaluated based on specific test guidelines, accepted endpoints used to assess ecotoxicity, and the amount of detail provided in each study report. Hazard benchmarks (i.e., concentrations of concern) were subsequently derived using the most robust ecotoxicity studies and conservative ecotoxicity values identified in the published literature. Acceptable toxicity data were not available for ATO for both chronic and acute exposures in all media. For this reason, toxicity data for antimony trichloride is used to characterize hazards to water, soil, and sediment dwelling organisms. This is not expected to significantly impact the findings of this assessment because (1) upon dissolution, antimony compounds release antimony ions, and it is the fate and toxicity associated with the total antimony ion concentration that is of most importance when assessing the toxicity of antimony in environmental media and (2) both the oxide and chloride salts of antimony produce comparable amounts of antimony ions upon dissolution in water.

**Question 5-1: What other factors should EPA consider in evaluating the potential risks of concern for ecological organisms from antimony species? Please comment on the use of toxicity data for antimony trichloride to characterize hazards to water, soil, and sediment dwelling organisms.**

The document states several times that use of toxicity data using either antimony trioxide or antimony chloride are similar as the organisms are reacting to the amount of dissolved ion present (in water or soil). However, the data are expressed in terms of the total amount of compound (or the added amount) in the system and not as the amount of antimony ion. Therefore, this conclusion is incorrect. This has been shown in soil studies where organisms are introduced shortly after chemical is mixed into the soil as compared to those where the soil is aged (and leached, to remove associated salts) for 30+ weeks prior to introducing the test organisms (see EU RAR, specifically work by Oorts et al. 2005). Therefore, the EU RAR elected to use soil data only from studies specifically designed to account for these differences when developing PNEC (benchmark) values.


Although it is correct to say that use of antimony trichloride is appropriate for toxicity tests due to the lengthy time it takes for antimony trioxide to dissolve (and as long as the salts are leached out from soil/sediments) the document would benefit from a somewhat lengthier discussion of these environmental chemistry issues. Most of this information can be found in the EU RAR report.

**Issue 6. Environmental Risk Characterization.**
The ATO assessment evaluates risks of concern posed to ecological organisms as a result of ATO use as a synergist in halogenated flame retardants. Generally speaking, risks are indicated when antimony levels in environmental media (as indicated by environmental monitoring and industrial release information) exceed the hazard benchmarks (i.e., concentrations of concern) identified for ecological organisms in water, soil and sediment. This approach resulted in very few instances where the concern concentrations for water or sediment dwelling organisms were exceeded (< 1%). No exceedances of the hazard benchmarks for soil dwelling organisms were identified. The uncertainties/limitations of this approach are discussed in the ATO document.
Question 6-1: Please comment on the implicit assumption that antimony concentrations measured in environmental media reflect many different inputs (i.e., from various end use applications and other types of antimony compounds in addition to ATO) and how this could impact the risk estimation.

The assumption that measured antimony concentrations in water and sediment reflect inputs from all potential sources is true. These data were taken from general monitoring databases (USGS NWIS and EPA STORET) and none of the stations were immediately downstream of a discharge location. However, there was some attempt to bias the samples towards those locations that were located within the same state (if not the same watershed) as production facilities. Reanalyzing the data on a watershed basis instead of a state basis will help focus the question on whether the facilities are contributing to environmental risk and may decrease the importance of other input pathways.

This question cannot be addressed for the soil data, as there is no information provided about the location of the monitoring sites or how they relate to use of biosolids from landfills associated with antimony disposal.

The fact that there were very few sites with concentrations in water, soil, or sediment that exceeded benchmark values provides a very strong line of evidence that environmental concentrations overall are not causing risk to organisms. However, it does not address the question about risk associated with specific TRI facilities as the samples are not collected adjacent to the facility. See my previous comment about needing to more clearly define the question of the assessment – local risk from discharge of antimony-flame retardant production facilities or regional (national) risk from all sources of antimony?.

Question 6-2: The findings reported in this assessment hinge on the assumption that a ‘conservative’ scenario has been presented (based on the assumption that all releases of various types of antimony compounds have been attributed to ATO use in flame retardants) and as such, reflect a conservative estimate of risk of exposure to ATO. Please comment on validity of this assumption and the likelihood that the actual risks of concern posed to ecological organisms have been over (or under) estimated.

It is likely that actual risks have been over estimated by assuming higher bioavailability than actually occurs in the environment since no quantitative adjustments could be made to account for this. However, it is likely that some risks have been under estimated because monitoring data were not associated with outfall locations. The incorporation of E-FAST2 model outputs as another line of evidence that is in concordance with the monitoring data strengthens the conclusion of lack of unacceptable risk. A weight-of-evidence approach could be used to balance all the input information and identify which line of evidence is most likely to over- or under estimate risk.

Question 6-3: Please comment on the data set used to evaluate exposures to soil-dwelling organisms and the limitations and/or uncertainties in estimating risk to soil-dwelling organisms. Please provide comment on additional data sources, surrogate/related chemicals, or approaches to estimate risks under data poor conditions?

As stated above, the lack of focus of this risk assessment on the soil ecosystem is a major weakness of the document. Data from biosolids concentrations can be used to estimate potential risks to soils; see http://water.epa.gov/scitech/wastetech/biosolids/tnsss-overview.cfm where antimony concentrations ranged from 0.45 to 26.6 mg/kg. The study by Oorts et al. 2005 cited above is the one study that should be used to set soil benchmarks.
Although this certainly would be considered a “data poor” condition, the Oorts et al. study goes a long way to fill the data gap. There are no ways to extrapolate information from other chemicals or organisms to predict soil toxicity of antimony trioxide.
Dr. Bruce Hope

Issue 1. Overall Clarity of the Assessment.

Chapter 1 provides the scope of the assessment and a brief introduction. Supporting information on chemistry, fate, and uses are provided in Chapter 2 and the exposure, hazard, and risk characterizations are presented in Chapter 3. Additional supporting information is available in the appendices.

Question 1-1. Please comment on the clarity and strengths and weaknesses of the risk assessment and provide specific suggestions regarding how this may be improved.

page 9, Chapter 1

The Introduction mixes both human health and ecological issues but the human health assessment is relegated to an appendix and the remainder of the document focuses on the ecological. It would be clearer if the document either (1) discussed only ecological issues or (2) brought the human health discussion forward as its own chapter. Since Appendix A is a compendium of exposures either unrelated to discharges to water or not quantified with respect to water (e.g., no comparison of surface water concentrations to drinking water standards or guidelines), perhaps option (1) would be the best choice?

page 11, 2nd paragraph

It doesn’t appear necessary to create a new term “concentrations of concern” when existing, more neutral, terminology, such as “toxicity reference value” is available. Whether something is a “concern” or not could be left to the hazard characterization section (i.e., Chapter 3C). “COC” can also be confused with “contaminant of concern.”

page 16, 1st - 2nd Paragraphs

This section needs to be reorganized to make a clearer statement about the fate of antimony trioxide (ATO) in water, with something said about whether the dominant species is more likely to be (III) than (V) and for how long. The work of Skeaff et al (2012) should also be incorporated to the extent possible. In the second paragraph, are “antimony concentrations” dissolved or total?

page 16, 4th Paragraph

Because of their differing characteristics and interactions with ATO, it would be better to have separate sections for soil and sediment. It would also be helpful to present a simple unit world model (as an adjunct to the necessary, but missing, conceptual model) summarizing the fate and transport of ATO between the soil, sediment, and water compartments.

page 19, “Conclusion…”

This section doesn’t actually reach a conclusion per se but simply “bullets” some points made previously. It is somewhat muddled and it is also not easy to trace the points summarized here to where in the preceding text they are supported with further explanation. As noted in a previous comment, a simple box diagram summarizing the fate and transport of ATO would also be helpful to show visually the linkages and mechanisms you are describing in the text.
page 20, Section A

This section is poorly organized and exactly how you performed the exposure assessment is hard to discern. This section should not be called “Introduction” but rather “Exposure Assessment” and divided into subsections for your three media.

page 27, Section B

This section should be re-organized so that discussions of all of the acute endpoints are together, followed by the chronic endpoints. The content of these sections is also uneven, with, for example, acute toxicity having one short paragraph on a fish study that was not even used while sediment toxicity has five paragraphs, many on the same study.

page 47, “Conclusions”

This wording more closely conveys the purpose and scope of this assessment: The purpose of this screening hazard assessment was to evaluate the potential ecological hazards that may be associated with ATO discharged from facilities producing ATO-containing flame retardants. Because it is not clear whether the measured concentrations (USGS, STORET) have any direct relevance to TRI facilities, estimates made with E-FAST2 and TRI data may be most representative of facility-related ATO concentrations in surface waters. This model should be modified to enable it to make similar estimates for the impact of discharges on sediment and soil, thus allowing you to rely solely on available TRI data. Since the PDM feature of E-FAST2 is closer to a true risk assessment than simply comparing concentration estimates to COCs (which is a hazard assessment at best), emphasis should be placed on using E-FAST2 and PDM to inform risk management decisions.

Overall

ATO is a relatively straight forward chemical and this assessment, despite its weaknesses, likely concludes correctly (but with considerable uncertainty) that ATO does not pose a hazard to human health or the environment. However, had an assessment of this quality been applied to a more contentious chemical - for example, a commercially important one for which there was a significant difference of opinion as to whether it posed a hazard – it would likely have withered under criticism from all quarters. This assessment, and the methods used to produce it, need substantial improvement before they will be ready for “prime time.”

This hazard assessment, particularly the toxicity assessment portion, relies heavily on EPA’s interpretive assistance document (EPA 2009, but updated in 2013). However, some of that document’s recommendations (e.g., those pertaining to toxicity) appear suspect and some (e.g., its definition of risk) are simply wrong. Has that document been peer-reviewed, either internally or externally? While it is outside the scope of our present charge to dig deeper into the problems with this interpretive document, these concerns will need to be addressed if workplan “risk” assessments based on it are to be scientifically credible. It is therefore suggested that the TSCA program (a) substantially revise this interpretive assistance document to be consistent with EPA’s current (and long established) human health and ecological risk assessment guidelines and frameworks (including allowing for problem formulation and a conceptual model) and (b) then subject the revised document to both internal and external peer-review. TSCA workplan risk assessment documents should also be organized to conform with the familiar, and well established, format of problem formulation, exposure analysis, toxicity (or exposure-response) analysis, and then risk characterization.
**Issue 2. Characterization of Environmental Exposures Based on Release Data.**

During project scoping, OPPT identified ATO use as a synergist in halogenated flame retardants as the focus of this assessment. EPA’s 2010 Toxic Release Inventory ( TRI) was used to obtain information on water releases associated with this end-use scenario. Data collection was refined using the North American Industry Classification System (NAICS) codes to identify a subset of TRI facilities (i.e., those indicating production, processing or use of ATO-containing flame retardants). Because ATO is not specifically listed on the TRI, data reported under the broader category of ‘antimony compounds’ were used as a surrogate for ATO in this assessment. ATO surface water concentrations were predicted using a screening level tool (E-FAST2), to model water releases reported by selected TRI facilities.

**Question 2-1:** TRI information reported for ‘antimony compounds’ was used to estimate ATO releases associated with its use as a synergist in halogenated flame retardants. Please comment on this approach.

**page 20, “TRI Data”**

- Are TRI data shown in Table 3-2 for total discharges in 2010 only? - if so, the table needs to note this.
- The “scaled annual release” in Table 3-2 looks like just a pounds to kg unit conversion or is there more to “scaled?”
- These TRI data and E-FAST2 were used to estimate ATO concentrations in surface water (as what (III), (V), total?).
- Presumably the loadings you put into E-FAST2 are those shown on Table 3-2 and the results from this model are shown on Table 3-7?
- Use of TRI data then skips over “Monitoring…” and appears again in the “Exposure Assessment” section on Page 25 and the top of page 27. The TRI modeling results - basically one of your exposure point concentrations (EPCs) for surface water - do not appear until Table 3-7 on page 43. Carrying over from Table 3-2, the concentrations shown in Table 3-7 would be the 7Q10 concentrations just for 2010? - if so, the table needs to note this.
- As noted in a prior comment, all of this TRI related material needs to be consolidated in one section within Exposure Assessment.
- The challenges (pros/cons) posed by use of TRI data for hazard estimation are not discussed until page 46 – that discussion could be moved to this section.

**page 20, 2nd Paragraph**

The totals for loadings from direct discharge and POTW discharge do not match any of the totals shown on Table s 3-1 or 3-2. It’s not clear that any of the loadings shown in Table 3-1 were actually used in this assessment. It’s unnecessarily confusing to present values that cannot be reconciled with one another and which are not even used. It is suggested that you remove these extraneous numbers from the document.

**page 24, 1st Paragraph**

Do releases to air really have a role in your exposure assessment? If so, how did you link these releases to Sb concentrations in the media of interest: soil, sediment, surface water? Or are you just saying that Sb
put into the air could eventually reach one or more of these three media but how isn’t important because you have measured values which likely include the contributions from air? Inclusion of a simple unit world model diagram would help clarify this issue.

**Question 2-2:** Because TRI does not indicate the number of days associated with reported releases, two exposure scenarios were developed (assuming the total water releases reported in the 2010 TRI occurred over a period of 250 days or, a more conservative scenario of 24 days to provide a range of predicted water concentrations for comparison with hazard benchmarks (concentrations of concern) identified for aquatic organisms. Please comment on the assumptions used to develop modeling scenarios using EPA’s E-FAST2 model to assess aquatic exposures to ATO.

**page 27, 1st Paragraph**

The difference between the 250 d/y and 24 d/y scenarios is the difference between acute (24 d/y) and chronic (250 d/y) exposures, since the 24 d scenario assumes episodic “flushing” of elevated ATO concentrations (as shown in Table 3-7). These less frequent exposures are “more conservative” only in the sense that they are at higher (acute) concentrations; they may not be conservative if longer exposures to lower concentrations could result in more significant (e.g., reproductive, developmental) adverse effects. And again, the results of these assumptions and calculations need to be in a fully annotated table in this section and not under “Risk Characterization” on page 43.

**Question 2-3:** Please comment on the approach EPA used to estimate environmental releases resulting from uses of ATO as a synergist in flame-retardant chemicals. Are there other data sources or approaches that EPA should consider to estimate environmental releases of ATO in this end-use? If so, please provide citations or data for consideration in further revision of the draft assessment.

**page 11, 1st paragraph**

The E-FAST2 model appears (based, for example, on Equation 3-1 of the 2007 E-FAST v2 documentation manual) to estimate surface water concentrations solely on the basis of total Sb loading, as reported in the TRI. Since the TRI does not distinguish between the different types and forms of Sb that may (or may not) be in any given discharge, the resulting estimate of surface water concentration can only be for “total Sb” of some unknown composition. Estimation of hazard on the basis of antimony trichloride (ATC) toxicity essentially means that this “total” is presumed to be entirely Sb(III), the seemingly more toxic form of dissolved Sb. The net result of this assumption is likely to be an over-estimate of the toxicity of TRI discharges.

**Issue 3. Characterization of Environmental Exposures Based on Monitoring Data.**

*OPPT used environmental monitoring information obtained from the U.S. Geological Survey-National Water Information System and EPA’s STORET database to evaluate antimony levels in environmental media. Data collection was limited to states (n=10) with TRI facilities (n=14) having NAICS codes corresponding to ATO uses as a synergist in halogenated flame retardants.*

**Question 3-1:** Please comment on the use of these large monitoring data sets to characterize ecological exposures to ATO use as a synergist in flame retardants and their representativeness for other locations in the US.
USGS data were split into two subsets: all (which, per page 35, is 1972 to 2012) and 2009-2010. Were both used in this analysis? Although USGS data are of high quality, changes in analytical methods, in sources and loadings of contaminants, in collection methods, etc., can make data from as far back as 1972 much less relevant, if not irrelevant, to a current issue. This makes the “all years” data set not particularly useful. Information like this apparently only appears in Table 3-6 on page 37 but it needs to be in this section.

It is also not clear until page 35, 1st paragraph that you are comparing toxicity values for bed sediment to measurements of suspended sediment. This mixing of exposure media seems highly problematic and thus deserves further discussion and justification.

What was the time frame for these data? You have water and sediment subsets but from what dates? Were these dates compatible with those for the TRI and USGS data sets? Information like this apparently only appears in Table 3-6 on page 37 but it needs to be in this section.

If the emphasis is on samples collected within the last three years (last bullet) why reach back as far as 1972 for data?

Question 3-2: Are there other major sources of environmental monitoring data (or other pertinent information) that EPA should incorporate in the exposure assessment? If so, please provide the necessary citations and/or data for inclusion in the revised document.

No attempt seems to have been made to obtain monitoring data from state environmental agencies, some of whom may have collected adequate data from within the same watersheds as the TRI facilities.

Question 3-3: Are there concerns or limitations in these data sets that may impact their utility for risk assessment?

If none of the actual monitoring sites were within the primary watersheds receiving discharges from the selected TRI facilities, what relevance do these data have to those facilities? If the TRI facility is discharging to Watershed A and you have samples from Watershed C, how can you say something about A based on C? You could decide A is different than C based on these data but any differences may or may not be due to the TRI facility. The USGS and STORET data sets are thus not “robust” with respect to statements about contributions specifically from TRI facilities. It would seem that the E-FAST2 model is really your only direct and best link between TRI facilities and surface water conditions.
Issue 4. Fate, Transport and Bioavailability.

Information available in the published literature regarding the chemistry, fate and transport of ATO is used qualitatively to assess bioavailability to ecological organisms. There is a lack of site-specific data on geochemistry that would inform specification and availability antimony compounds in its toxic forms for environmental receptors.

Question 4-1: Please comment on the use of this information in the ATO assessment. Are there other data sources that EPA should consider?

page 15, Section C, 2nd Paragraph

Fugacity models can be formulated to take availability into account through their definition of the fugacity capacities or Z values of the chemical in media such as water. The Z-value can contain terms for the dissolved and non-dissolved fractions. A corresponding procedure is adopted in the "equivalence" models which are used for non-volatile chemicals such as metal ions. There Z' is the equivalence capacity, which depends on the characteristics of the chemical, the medium, and temperature. The equivalence value of water (Z'W) is defined as 1.0 and the values for other media are obtained by multiplying Z'W by partition coefficients of particular medium. The 1992 literature cited is not the latest with respect to equivalence models.

page 16, 3rd Paragraph

It is not clear how the reference to Sb behavior in marine waters is relevant to its behavior in natural, fresh waters. Do some of the facilities in question discharge to marine waters? If so, it would be clearer to divide this section into the fate of Sb in fresh and marine waters. This issue also appears in Table 2-4 (which includes salt water values) on page 18 under “Bioaccumulation.”

page 17, “Fate in Air”

This section is probably included for completeness but it is not clear how it relates to ATO discharges to water, which are the main focus of this assessment. You show total releases to air in Table 3-1 but how (if at all) are those releases integrated with the direct discharges to surface water?

page 17, “Transformation” & “Bioavailability”

This issue was already addressed, in part, in the previous sections on fate and may not need to be repeated here. It would be better to be sure that the fate sections fully discuss these topics as they relate to how much and what form of Sb is actually available to aquatic life. Although you conclude that Sb is most likely present as hydroxides, there is no mention of how this affects its bioavailability or its toxicity (particularly if ATC is used as a toxicity surrogate).

page 18, “Bioaccumulation”

- This section mixes discussions of bioconcentration and bioaccumulation and of water and soil (e.g., the 1st sentence of the 3rd paragraph is about trout while the 2nd sentence of that same paragraph is about earthworms, etc.). It would be clearer to organize this section into BCF and BAF for soil and water separately.

- The accumulation reported by the Duran study (not shown in Table 2-4) may have been influenced by its proximity to Sb mining (forcing function) or by retention of Sb particles in clams that weren’t fully depurated. This needs further discussion in the text.
The opening sentence of this section, and the algae and Hyalella BCFs shown in Table 2-4, suggest some possibility for uptake but this is not fully discussed in the accompanying text. So what is your overall conclusion regarding the concentration or accumulation of Sb? You say low-to-moderate in the Conclusion but what does this mean - is the uptake pathway an issue or not?

**Issue 5. Environmental Hazard Assessment.**
The available hazard information was critically evaluated based on specific test guidelines, accepted endpoints used to assess ecotoxicity, and the amount of detail provided in each study report. Hazard benchmarks (i.e., concentrations of concern) were subsequently derived using the most robust ecotoxicity studies and conservative ecotoxicity values identified in the published literature. Acceptable toxicity data were not available for ATO for both chronic and acute exposures in all media. For this reason, toxicity data for antimony trichloride are used to characterize hazards to water, soil, and sediment dwelling organisms. This is not expected to significantly impact the findings of this assessment because (1) upon dissolution, antimony compounds release antimony ions, and it is the fate and toxicity associated with the total antimony ion concentration that is of most importance when assessing the toxicity of antimony in environmental media and (2) both the oxide and chloride salts of antimony produce comparable amounts of antimony ions upon dissolution in water.

**Question 5-1: What other factors should EPA consider in evaluating the potential risks of concern for ecological organisms from antimony species? Please comment on the use of toxicity data for antimony trichloride to characterize hazards to water, soil, and sediment dwelling organisms.**

**page 10, 4th paragraph**
This paragraph contains a number of statements that are either contradictory with respect to other published sources or do not fully convey seemingly important details of the behavior of ATO in water.

- The statement is made here (based on one made on page 206 of the 2008 EU risk assessment) that there is no evidence of a significant (undefined) difference in ecological hazards between the penta- and trivalent forms of Sb. However, Skeaff et al (2012) cites two references stating that the tri is more toxic than the penta. This contradiction needs to be reconciled.

- The use of ATC as a surrogate for ATO proceeds on the assumption that “total ion concentration” is what matters and that both compounds release similar amounts of ion upon dissolution. However, this statement fails to consider that, because of differences in solubility, a greater mass of ATO would be required to yield the same number of ions as the more soluble trichloride (a point made on pages 203 and 204 of the 2008 EU risk assessment). To assume equal solubility would seem to lead to an over-estimate of ATO-sourced ions in solution and hence to an overestimate of effect.

- Per Skeaff et al (2012), Sb dissolved from ATO is - and remains - mostly Sb(III), while that from the trichloride is quickly oxidized to Sb(V). This may not matter if the (III) and (V) forms are similarly toxic (as is asserted here) but would if (III) is the more toxic than (V) (as other literature suggests).

**page 13, Table 2-1**
Because ATC is being used as a toxicity surrogate, its properties should be shown in this table to facilitate comparisons in solubility, etc. Solubility data for ATO presented here are incomplete. The difference
between water solubilities in distilled water and in reconstituted standard water might be explained by a higher calcium concentration in reconstituted standard water and precipitation of calcium antimonite. The lower solubility is based on a loading of 100 mg/L, while the higher solubilities are from a loading of 100 g/L (not shown in this table). Additional tests (not shown in this table) have found the dissolution of ATO to be only 0.62 mg/L at pH 7 for a loading of 100 mg/L. Under environmentally relevant pH, temperature, and water conditions, ATO has a low solubility and a propensity to precipitate; however, its solubility can apparently increase with increases in loading. How does this relate to the actual environmental loadings? Since solubility is a major factor with respect to the number of Sb ions in solution it seems important to be as clear as possible about this particular physical-chemical parameter. This comment also applies to the last paragraph on page 46.

**page 27, Section B, 2nd Paragraph**

- What specifically was the nature and extent of the scientific literature that was reviewed and what were the criteria used to review it?
- Was any gray or technical literature considered?
- What about use of ECOTOX? A quick check there shows 42 results for ATO and 162 results for ATC - were any of these consulted?
- A clearer and more robust toxicity assessment would list all the potentially applicable studies examined and their disposition (adequate, inadequate) in an appendix and then focus in the main text on only those used to derive COCs. The reasons for choices between adequate studies could be included in the main text.
- Table 3-3, for example, mixes studies that were adequate and used to derive COCs, studies that were adequate and not used, and studies that were judged inadequate and not used. Rather than being a mix, Table 3-3 should be restricted to just the COCs and their supporting studies.
- Table s 3-3, 3-4, and 3-5 do not show the actual COCs - these (and there derivation) have to be teased out of the text. Table A (at end of comments) is an example of how to gather together the COCs scattered throughout the text – it would be helpful to have such a summary table in this risk assessment document.

**page 27, “Acute Toxicity...”, 2nd Paragraph**

It’s not clear why a marine species was even considered in the first place?

**page 29, “Chronic Toxicity...”, 1st Paragraph**

In the second sentence, it’s not clear what endpoint required use of acute studies? This paragraph also seems to conflict with what’s said in the paragraph following.

**page 31, “Terrestrial...”**

Three other studies are listed in Table 3-4 but, unlike previous sections, none of those are discussed in the text here (e.g., the sediment section discusses all of the studies listed in Table 3-5). As previously noted, this is an example of the unevenness of the toxicity sections.
page 33, “Sediment…”

- This section discusses several studies at length, while other sections don’t. As previously noted, this is an example of the unevenness of the toxicity sections.

- Isn’t there any provision in your procedure to take into consideration – if they exist – other regulatory guidelines (e.g., PEL, SQG, etc.) for bed sediment? It seems you should at least look for these and – again, if they exist – use them as a “check” on the COCs you have derived here.

- There is also the open question of the supposedly equivalency of suspended and bed sediment.

page 35, 1st and 2nd Paragraphs

In the first paragraph, an assessment factor of 10 is applied to a NOEC. The last sentence in the second paragraph seems to be the justification for this and should be moved to the first paragraph. It seems you’re trying to say that OPPT doesn’t have an approach for a case like this, but it does have a guidance (EPA 2009) that says use the EU approach in such cases? Please re-write for greater clarity.

page 35, Concerns About the Toxicity Assessment

- This toxicity assessment relies heavily on EPA’s interpretive assistance document (EPA 2009, but updated in 2013). Some of its methods (such as dividing a NOEC by 10) appear to have no justification other than “lower is better.”

- Table A (attached) also illustrates some peculiarities of the toxicity assessment that need explanation, namely:
  - A truly acute value (LC50) is divided by 5 to estimate an acute COC; however, in EPA 2009, a MATC (ChV) is divided by 4 to estimate an acute value for algae.
  - For surface water, the acute COC is only 2x the chronic COC – a spread that might be low if it were within a species but is hard to evaluate when two different species are involved.
  - A NOEC is used as an acute value, with NOEC/10 as a chronic value. This would very likely greatly over-estimate the likelihood of an acute effect.
  - A GMATC is used as an acute value, with GMATC/10 as a chronic value. This would very likely over-estimate the likelihood of an acute effect.
  - Is it coincidence or just reliance on a single study that makes it look as though midges and worms respond exactly the same (at least numerically) to antimony trioxide?
  - Calculating a GMATC (when separate NOECs and LOECs are available) and then dividing it by 10 appears to be because ECOSAR does not generate NOECs and LOECs - only MATCs (ChVs) - and EPA 2009 says to divide ChVs by 10. Wouldn’t a NOEC, if available, be preferred over these calculations?
  - Overall, there is the impression here that the toxicity values are simply being manipulated without much consideration as to their connection to underlying toxicological processes or mechanisms.
The ATO assessment evaluates risks of concern posed to ecological organisms as a result of ATO use as a synergist in halogenated flame retardants. Generally speaking, risks are indicated when antimony levels in environmental media (as indicated by environmental monitoring and industrial release information) exceed the hazard benchmarks (i.e., concentrations of concern) identified for ecological organisms in water, soil and sediment. This approach resulted in very few instances where the concern concentrations for water or sediment dwelling organisms were exceeded (< 1%). No exceedances of the hazard benchmarks for soil dwelling organisms were identified. The uncertainties/limitations of this approach are discussed in the ATO document.

Question 6-1: Please comment on the implicit assumption that antimony concentrations measured in environmental media reflect many different inputs (i.e., from various end use applications and other types of antimony compounds in addition to ATO) and how this could impact the risk estimation.

page 35, “Summary of Exceedances…”

- Harking back to page 25, second paragraph under “Exposure Assessment”, if none of the actual monitoring sites were within the primary watersheds receiving discharges from the selected TRI facilities, what relevance do these results have to those facilities? Looking at Figures 3-1 and 3-2, it’s obvious that you are trying to reach conclusions about TRI facilities in specific locations using data collected state-wide. This is an approach that is very likely to over-estimate contributions of Sb from TRI facilities to total Sb in the environment.

- And, as noted previously, using data that are 20+ years old to assess current conditions is highly problematic and not recommended. Much of this information on the dates and locations of the various samples should be in the Exposure Assessment section, not here.

page 35, Section C, 1st Paragraph

- It does not become clear until Table 3-6 that you did not perform any statistical analyses on your selected exposure data in order to derive an exposure point concentration but rather just compared all of the data points for a particular media against your COCs, to arrive at a percentage of points over the COC. Because you are dealing only with ratios, this portion of the assessment is a hazard, not a risk, assessment. Referring to COCs as “hazard benchmarks” is actually the more correct terminology.

- The Probability Distribution Model (PDM) is, however, a partial move toward a true risk assessment.

pages 37, Table 3-6

- Many of the USGS parameter codes are not described, so it is not clear that you always selected dissolved (filtered), and not total, surface water concentrations.

- In the 4th column, the value is above which COC – acute or chronic?

- Use of data 20+ years old is not recommended.

- Where are these stations relative to the TRI facilities? It’s evident from Figures 3-1 and 3-2 and a statement on page 25, that many (if not all?) of these stations are spatially isolated from TRI facilities.
• It is questionable whether suspended sediment can be used to assess bed sediment.

• On pages 38 and 39, under sediment, there are a number of typos in the sample dates.

• There are sediment stations in marine environments – do any TRI facilities discharge directly into such waters?

**Question 6-2: The findings reported in this assessment hinge on the assumption that a ‘conservative’ scenario has been presented (based on the assumption that all releases of various types of antimony compounds have been attributed to ATO use in flame retardants) and as such, reflect a conservative estimate of risk of exposure to ATO. Please comment on validity of this assumption and the likelihood that the actual risks of concern posed to ecological organisms have been over (or under) estimated.**

**pages 42-43, “Summary of TRI…”, 1st Paragraph, and Table 3-7**

• In a true risk assessment (i.e., one which assesses the probability of only an adverse outcome) you would arrive at a risk estimate by integrating an exposure distribution with an exposure-response function, taking into consideration the uncertainty (variability + incertitude) in both components. The PDM (EFAST2 manual, Appendix C) reports the “…probability that the downstream concentration will exceed the COC on any given day.” As such, it provides an estimate of the uncertainty in exposure (driven by variation in discharge rate, discharge concentration, and stream flow) but not in that of effect, since the COC is still taken as a single point. The probability of exceedance is defined by where a point, the COC, falls on a cumulative distribution function of exposure concentrations. This is a step toward a true risk assessment and it may be unreasonable to expect more given the difficulty in generating exposure-response functions (e.g., species sensitivity distributions) for many chemicals.

• Some of the exposure distribution parameters appear to be from documents created in the mid-1980s – aren’t more current references available?

• As noted previously, it would be more appropriate to compare 24 day releases to an acute COC and 250 day releases to a chronic COC, rather than both releases to a chronic COC.

**page 45, “Uncertainty…”, 2nd Paragraph**

Wouldn’t natural events include Sb in native soils? What is meant by the “…content of receiving waters…?”

**page 45, “Uncertainty…”, 3rd & 4th Paragraphs**

The statements here seem to skirt around the issue that all of the USGS and STORET data used here are seemingly not from the primary watersheds of the TRI facilities.

**page 46, “E-FAST2 Model...”**

Basing your conclusions on repeated over-estimation is appropriate for a screening assessment – which is what this assessment is – but much less so for an assessment intended to inform significant risk management decisions. Your approach is one that has very likely over-estimated TRI facility contributions of Sb to total Sb in the environment.
Question 6-3: Please comment on the data set used to evaluate exposures to soil-dwelling organisms and the limitations and/or uncertainties in estimating risk to soil-dwelling organisms. Please provide comment on additional data sources, surrogate/related chemicals, or approaches to estimate risks under data poor conditions?

page 31, “Terrestrial…”

Three other studies (all from the EcoSSL program) are listed in Table 3-4 but are not discussed in here. Why were these EPA studies excluded in favor on an unpublished industry study? Showing reproduction as less sensitive than survival seems unusual and should be discussed. It also appears questionable to apply assessment factors for aquatic organisms to terrestrial species.
Dr. David Ostrach

This assessment evaluated the environmental risks that may be associated with ATO use as a synergist in halogenated flame retardants. Human health risks were determined to be of low concern; the available hazard data are summarized in an appendix.

Issue 1. Overall Clarity of the Assessment.

Chapter 1 provides the scope of the assessment and a brief introduction. Supporting information on chemistry, fate, and uses are provided in Chapter 2 and the exposure, hazard, and risk characterizations are presented in Chapter 3. Additional supporting information is available in the appendices.

Question 1-1. Please comment on the clarity and strengths and weaknesses of the risk assessment and provide specific suggestions regarding how this may be improved.

I understand the need for agencies to respond to and assess potential risks to the environment. In doing so I always advocate that agencies use the best available science to aid them in their assessments and management decisions. In this case there is a lack of good science presented in this assessment and applicable to characterize the risk of ATO to the environment. The EPA has compiled a lot of disparate information to attempt to understand and access the potential risk of ATO to ecosystems. Characterizing this as a risk assessment is inappropriate. It should be categorized as a scoping assessment or perhaps a hazard assessment. In a risk assessment quantitative exposure data and real risk need to have been identified at lower assessment levels such as at scoping or screening levels. There is a lack of exposure data, both aquatic and terrestrial, to characterize the potential risks of ATO to EPA test organisms or more importantly to the native flora and fauna that may be exposed to this compound. In addition this assessment relies on acute and chronic toxicity to measure potential risks to ecosystems. However, we should learn from our experience with other flame retardant compounds such as PBDEs that in reality it’s not necessarily acute or chronic toxicity that causes significant damage to organisms or ecosystems. Contaminants in the environment can adversely affect organisms at various levels of biological organization. They can at levels well below those thought toxic by the metrics used in this assessment adversely affecting physiology, enzymatic systems, neurochemical pathways, biochemical processes as well as cause endocrine disruption. I believe that these endpoints need to be addressed and incorporated when appropriate in future scoping’s, screenings and risk assessments by EPA and other agencies. In addition, addressing the risk as a single compound, ATO versus the reality of it being found in a terrestrial or aquatic environment in a complex mixture as a part of a flame retardant or other product with other contaminants does not provide a realistic assessment of potential environmental concerns. ATO in combination with other compounds/contaminants in both aquatic and terrestrial environments may change the potential risk of ATO to the environment by acting act as a synergist, agonist or antagonist with other compounds. There are also potential indirect effects that ATO could have by affecting an organism’s food source or habitat. However, you need to begin as EPA has done with a single compound assessment but when doing so it’s necessary to have the appropriate related data and exposure information from which to make an appropriate risk assessment. If the initial monitoring data and exposure assessment indicates or reveals potential concerns then as suggested above you would move to a more rigorous assessment and try to incorporate additional endpoints to better characterize the risk. The minimal data presented in this assessment is qualitative and does not demonstrate risk/lack of risk by accepted standards. I consider this a scoping assessment for ATO as opposed to a risk assessment and would suggest changing the title to reflect this accordingly. This being said given the qualitative data and information provided in this document it appears that ATO will likely not be a significant risk to the environment. My recommendation is to gather more data at the scoping or screening level to determine if a full-blown risk
assessments for ATO is necessary. Comparable and consistent toxicity testing of ATO in both water and terrestrial systems should be performed and if the surrogate is used definitive data indicating the surrogate would have similar toxicity as ATO needs to be acquired and demonstrated. Samples need to be collected and monitored at the point source of the ATO discharges (as opposed to using monitoring data or data from STORET or TRI) as well as along the potential routes it would take as it enters and spreads through the environment. Construction of a clear statement of the problem and conceptual model is essential in any risk assessment and was not provided in this assessment. I recommend the authors provide a clear statement of the problem and conceptual model in the next draft of this assessment. It would’ve been helpful to start with as it would, as information became available, direct investigations/risk assessment in the areas that appeared to be of most concern. Given the data limitations and information available I feel the authors did a reasonable job in this document to characterize the potential hazard of ATO. I think with a little modification, additional data and re-characterizing it not as a risk assessment but as a scoping level assessment it will be useful to determine if pursuing a more detailed risk assessment of ATO is necessary.

**Issue 2. Characterization of Environmental Exposures Based on Release Data.**

*During project scoping, OPPT identified ATO use as a synergist in halogenated flame retardants as the focus of this assessment. EPA’s 2010 Toxic Release Inventory (TRI) was used to obtain information on water releases associated with this end-use scenario. Data collection was refined using the North American Industry Classification System (NAICS) codes to identify a subset of TRI facilities (i.e., those indicating production, processing or use of ATO-containing flame retardants). Because ATO is not specifically listed on the TRI, data reported under the broader category of ‘antimony compounds’ were used as a surrogate for ATO in this assessment. ATO surface water concentrations were predicted using a screening level tool (E-FAST2), to model water releases reported by selected TRI facilities.*

**Question 2-1: TRI information reported for ‘antimony compounds’ was used to estimate ATO releases associated with its use as a synergist in halogenated flame retardants. Please comment on this approach.**

I understand due to the apparent lack of point source monitoring and other data the decision to use TRI information for “antimony compounds” was determined to be an appropriate estimation of releases. However, this data has inherent problems. TRI data is self-reported by facilities and as such is questionable as to its reliability and quality. It’s unclear how the compound is being released at each site and if release data is even comparable between sites. It does not discuss if antimony compounds are being discharged as an aerosol, a particulate, a dissolved portion of an effluent nor does it define potential receptor zones. In addition, this risk assessment focuses heavily on surface water ecosystems where in fact the vast majority of ATO is being discharged into terrestrial systems. There is minimal data on soil concentration and again the data presented is vague. It is not clear where the samples were collected or located, when they were collected what kind of soil it is etc. Additional information needs to be provided in this assessment regarding concentrations and fate in the terrestrial ecosystems potentially affected. I believe this information is minimally useful (in a scoping assessment not risk assessment) and appropriate point source and environmental fate data collected or found within the current literature or from other sources.
Question 2-2: Because TRI does not indicate the number of days associated with reported releases, two exposure scenarios were developed (assuming the total water releases reported in the 2010 TRI occurred over a period of 250 days or, a more conservative scenario of 24 days to provide a range of predicted water concentrations for comparison with hazard benchmarks (concentrations of concern) identified for aquatic organisms. Please comment on the assumptions used to develop modeling scenarios using EPA’s E-FAST2 model to assess aquatic exposures to ATO.

What I see here is an attempt to use available data for a use that it was never intended for. The data set being used in the model violates several of the conditions and assumptions of the model (e.g. necessary to have the total number of release days per year, several critical input parameters in the model were set to zero with no mention or explanation) and the manner in which EPA is estimating the data to fit the model (24 day & 250 day scenarios) does not provide a clear picture of release or risk. The two scenarios developed to provide a reasonable range of estimated surface water concentrations for assessing potential risk to aquatic organisms are not really the appropriate way to use the data or the model. Stating that the less frequent exposures are more conservative is misleading. They are only more conservative in the sense that during periodic flushing they would be at potentially higher concentrations. However, it may not be more conservative if longer duration exposures to lower concentrations result in a more significant and adverse outcomes (e.g. developmental abnormalities, reproductive impairment, endocrine disruption etc.). It is unclear as to where the samples were taken in relation to the facilities and if as mentioned above site to site samples were comparable. I feel this exercise provided minimal useful information and that other sources of data need to be found or acquired to determine accurate releases from these facilities and their toxicity.

Question 2-3: Please comment on the approach EPA used to estimate environmental releases resulting from uses of ATO as a synergist in flame-retardant chemicals. Are there other data sources or approaches that EPA should consider to estimate environmental releases of ATO in this end-use? If so, please provide citations or data for consideration in further revision of the draft assessment. Page 2 of 3

I think the approach used by trying to determine the releases from the largest ATO users/potential dischargers was appropriate for a scoping level assessment. However, as mentioned above I believe the TRI data is insufficient to meet this goal. I reiterate that there is a need for point source discharge information for air water and soil to accurately estimate environmental releases. There may be other sources of information with some of this data available within other databases such as TOXNET and CTD and I recommend a more thorough exploration of databases as well as stakeholder, state and regulatory agency databases.


OPPT used environmental monitoring information obtained from the U.S. Geological Survey-National Water Information System and EPA’s STORET database to evaluate antimony levels in environmental media. Data collection was limited to states (n=10) with TRI facilities (n=14) having NAICS codes corresponding to ATO uses as a synergist in halogenated flame retardants.
Question 3-1: Please comment on the use of these large monitoring data sets to characterize ecological exposures to ATO use as a synergist in flame retardants and their representativeness for other locations in the US.

Using these large monitoring data sets for a purpose they were never intended provides for minimal information at best. It seems the intent was to attempt to link the monitoring data to the TRI facilities but I can see no rational way to do this. The EPA’s STORET and USGS-NWIS monitoring data sites do not correspond to any of the discharge locations. This is one of the rationales as stated as to why the E-FAST2 model was used to estimate final concentrations. There are few if any sites that cover all potential routes of exposure via air, water or terrestrial near any of the facilities. There is separation between where different types of samples were taken and the samples were not collected in a manner to assess the potential risk of ATO or the facilities in general. These monitoring samples were taken for different purposes and I don’t believe can be used in a meaningful way to interpret transport or fate of ATO. As mentioned above to appropriately evaluate ATO levels in the environment point source data must be found within the literature or collected as well as transport data. I don’t believe the data presented can be used to represent potential ATO risk in other states or geographic locations. The assessment document states this as well “Because site-specific environmental parameters that can impact bioavailability vary significantly, it is difficult to extrapolate to other sites or geographic regions within the US.” Each location has different geological, biotic and environmental factors that can affect potential risk or fate of ATO.

Question 3-2: Are there other major sources of environmental monitoring data (or other pertinent information) that EPA should incorporate in the exposure assessment? If so, please provide the necessary citations and/or data for inclusion in the revised document.

Although I’m not specifically aware of other sources of environmental ATO data I think using only monitoring data that was not intended for this purpose was a mistake. Since a significant portion of this material seems to be taken for disposal to waste disposal locations or treatment plants there may be local municipalities, state or academic monitoring data available for those sites. In California both the state and regional water control boards collect significant information and perhaps some of the 10 states listed have similar programs or agencies that might have additional data. Expanding the data search beyond the 10 states would likely be productive.

Question 3-3: Are there concerns or limitations in these data sets that may impact their utility for risk assessment?

I think there are significant limitations in using these data sets for risk assessment in this case. A lot of the data is inconsistent from the source (different collection methods, different analytical methods used etc.) so the quality and comparability of the data is in question. In addition, as mentioned the samples have no spatial or temporal relationship to the facilities in question so I don’t believe they are appropriate or relevant to use in a risk assessment. Perhaps they would be useful to provide inferential information for a scoping assessment and a thus would provide a means to design monitoring studies to collect appropriate samples. They are also very limited terrestrial samples available and the vast majority of ATO ends up in terrestrial environments/facilities.
Issue 4. Fate, Transport and Bioavailability.
Information available in the published literature regarding the chemistry, fate and transport of ATO is used qualitatively to assess bioavailability to ecological organisms. There is a lack of site-specific data on geochemistry that would inform specification and availability antimony compounds in its toxic forms for environmental receptors.

Question 4-1: Please comment on the use of this information in the ATO assessment. Are there other data sources that EPA should consider?

This information was provided but it’s not clear to me how it was used in this risk assessment? The lack of site-specific data, not only geochemical but in general, is troubling as the purpose is to try and understand what happens to ATO when it’s released from these sites, where does it go and what is its environmental fate. In addition, the section on environmental transformation, bioavailability, and bioaccumulation section is focused heavily on aquatic systems whereas previously stated over 90% of this material ends up in terrestrial systems. There is a lack of terrestrial ATO data used in this risk assessment and that is of great concern. Although I don’t have specific sources of information it seems that there’s a significant amount of environmental data on water and soil collected in most states by local agencies, state agencies as well as stakeholders that could be pursued and used in this assessment.

Issue 5. Environmental Hazard Assessment.
The available hazard information was critically evaluated based on specific test guidelines, accepted endpoints used to assess ecotoxicity, and the amount of detail provided in each study report. Hazard benchmarks (i.e., concentrations of concern) were subsequently derived using the most robust ecotoxicity studies and conservative ecotoxicity values identified in the published literature. Acceptable toxicity data were not available for ATO for both chronic and acute exposures in all media. For this reason, toxicity data for antimony trichloride is used to characterize hazards to water, soil, and sediment dwelling organisms. This is not expected to significantly impact the findings of this assessment because (1) upon dissolution, antimony compounds release antimony ions, and it is the fate and toxicity associated with the total antimony ion concentration that is of most importance when assessing the toxicity of antimony in environmental media and (2) both the oxide and chloride salts of antimony produce comparable amounts of antimony ions upon dissolution in water.

Question 5-1: What other factors should EPA consider in evaluating the potential risks of concern for ecological organisms from antimony species? Please comment on the use of toxicity data for antimony trichloride to characterize hazards to water, soil, and sediment dwelling organisms. Page 3 of 3

The toxicity information provided was not raw or graphical data but was interpreted data such as LC50s, LOECs & NOECs. Without significant background information and not having the raw data it’s difficult to interpret this information in a reliable or useful manner. The authors state many times that toxicity data using either antimony trioxide or antimony chloride are similar and that the toxicity is related to ion concentration. However, data provided is in terms of the compound added to the toxicity’s test or found in the environment and is not represented as ionic concentration. Therefore, it’s difficult to interpret the data provided in any meaningful manner. This type of information does not take into account degradation or transformation that may take place in the environmental media as well as interactions with other compounds/contaminants found at sites were ATO will end up. As fellow panelists have indicated this risk assessment is based on data from a very few studies while significant other information is available.
A search of EPA’s own ECOTOX database and Web of Science will indicate an additional ~100 publications on ATO in the aquatic and terrestrial environment that was not provided in this assessment. Why was this information not used and if it was evaluated and not used why was this not explained in the document or to the panel? Dr. Sepulveda provided a summary of these references with her draft comments so I will not repeat the list here please refer to her list of additional available references. I have not seen any conclusive evidence that the toxicity of the 2 compounds is directly comparable and as such I would strongly recommend using the compound in question, ATO in future toxicity evaluations. The use of terms such as “ecologically sensitive” species are misleading and should not be used especially given the lack of toxicity data on ATO presented. The data presented shows differences in sensitivity to ATO for the species selected in these few studies but to say that they are ecologically sensitive or sensitive to ATO is incorrect and misleading. Terms like this should be removed from this document.

**Issue 6. Environmental Risk Characterization.**

The ATO assessment evaluates risks of concern posed to ecological organisms as a result of ATO use as a synergist in halogenated flame retardants. Generally speaking, risks are indicated when antimony levels in environmental media (as indicated by environmental monitoring and industrial release information) exceed the hazard benchmarks (i.e., concentrations of concern) identified for ecological organisms in water, soil and sediment. This approach resulted in very few instances where the concern concentrations for water or sediment dwelling organisms were exceeded (< 1%). No exceedances of the hazard benchmarks for soil dwelling organisms were identified. The uncertainties/limitations of this approach are discussed in the ATO document.

**Question 6-1:** Please comment on the implicit assumption that antimony concentrations measured in environmental media reflect many different inputs (i.e., from various end use applications and other types of antimony compounds in addition to ATO) and how this could impact the risk estimation.

In the data set provided in this document that assumption is correct but essentially irrelevant. The data set provided was not associated or linked in any meaningful way with the facilities potentially discharging ATO into the environment or to where solid waste containing ATO is disposed of. So of course the samples reflect inputs from various anthropogenic and natural sources. You could perhaps get some inferences as to if facilities are impacting the ecosystem in question if the data analysis was analyzed on a finer scale (e.g. watershed vs by state). As stated previously this data set and the manner in which it is being represented is inappropriate for use in a risk assessment scenario for ATO for the facilities chosen.

**Question 6-2:** The findings reported in this assessment hinge on the assumption that a ‘conservative’ scenario has been presented (based on the assumption that all releases of various types of antimony compounds have been attributed to ATO use in flame retardants) and as such, reflect a conservative estimate of risk of exposure to ATO. Please comment on validity of this assumption and the likelihood that the actual risks of concern posed to ecological organisms have been over (or under) estimated.

Based on the information and rationale provided in this document it could be stated that this is a “conservative” scenario. However, I really don’t like the word conservative and with the lack of data at the release sites I can’t really determine if this is a conservative scenario or not. It should be reworded to reflect a potential range of impact/risk given the available data and not be described as conservative which is misleading. With the paucity and sources of data provided that are not associated in any meaningful way with the facilities, it is likely that some risks are underestimated in this assessment as well. I agree from the qualitative information provided ATO is likely not a significant risk to the environment and that a somewhat conservative scenario has been provided. However, without data
relevant to the ATO manufacturing facilities and their release and transport it is difficult to say that this is a conservative estimate of risk exposure to ATO from these facilities. I think a better term such as “protective” would be more useful in describing what the authors are attempting to do with this assessment.

**Question 6-3:** Please comment on the data set used to evaluate exposures to soil-dwelling organisms and the limitations and/or uncertainties in estimating risk to soil-dwelling organisms. Please provide comment on additional data sources, surrogate/related chemicals, or approaches to estimate risks under data poor conditions?

The data set provided to evaluate soil dwelling exposures was minimal compared to aquatic toxicity information. Since the vast majority of ATO ends up in a terrestrial environment this is a major problem with this assessment. It does not adequately address the risk. I believe there are other sources of information on terrestrial toxicity of ATO to soil dwelling organisms available but I have no specific sources at this time the site. As mentioned previously a conceptual model needs to be conceived which would help identify and manage data gaps and uncertainty.

General Comments:

1) Generate a clear conceptual model and problem statement in the next revision of this document.

2) Rename as a Scoping or Hazard Assessment as this is not a Risk Assessment.

3) Use ATO toxicity data not data on surrogate compounds.

4) More data is needed for terrestrial ecosystems as this is lacking and a major weakness in this assessment.

5) Do not limit data sets to these 10 states and primary production facilities. Investigate product users and distributors as well to determine other sources of ATO being released into the environment.

6) Using Kimball (1978) a 35-year-old study as the basis for all the aquatic COC’s is inappropriate. Additional data should be found or generated before determining COC’s.

7) Remove and do not use incorrect or misleading terms such as “sensitive” as it refers to test species, conservative (replace with protective or something similar), robust, overestimate effects (when there is little or no data to back this term up) or acceptable effects.

8) Present detailed toxicity data not interpreted data in the form of LC-50s, NOEC’s etc.

9) How were “safe factors” determined and they don’t really seem necessary.

10) Given the data and information presented the purpose of this assessment as stated in the conclusion, “The purpose of this assessment was to evaluate the potential ecological risks of concern that may be associated with ATO use as a synergist in halogenated flame retardants.”, can’t be met. Additional data and information is necessary to evaluate any potential risk. I’m not stating that ATO is a problem but rather that simply we just don’t know or have enough information or data at this point given what was provided in this assessment.

Several of my fellow panelists have provided additional references and databases so I will not repeat the information here. I suggest a thorough search of TOXNET as well as local agencies and stakeholder
databases will uncover significant additional information. Following please find additional references and database information that may be helpful.


Anan, Y., Kunito, T., Watanabe, I., Sakai, H. and Tanabe, S. (2001), Trace element accumulation in hawksbill turtles (Eretmochelys imbricata) and green turtles (Chelonia mydas) from Yaeyama Islands, Japan. Environmental Toxicology and Chemistry, 20: 2802–2814. doi: 10.1002/etc.5620201220


A.Murciego Murciegoa, A. Garcia Sánchezb (2007), Antimony distribution and mobility in topsoils and plants (Cytisus striatus, Cistus ladanifer and Dittrichia viscosa) from polluted Sb-mining areas in Extremadura (Spain) Environmental Pollution, Volume 145, Issue 1, January 2007, Pages 15–21


Helen C Flynn, Andy A, Phillipa K Bowyer, Graeme I Paton ,Antimony bioavailability in mine soils, Environmental Pollution, Volume 124, Issue 1, July 2003, Pages 93–100

**Database sites for more information:**

For human risks for antimony/ATO:


For listings of Antimony in Children’s Products:


For other data including specific TRI site data:

Table A. Summary of COC Values

<table>
<thead>
<tr>
<th>Media</th>
<th>COC Type</th>
<th>Test Compound</th>
<th>Test Species</th>
<th>Test Duration</th>
<th>Endpoint</th>
<th>Endpoint Value (Type)</th>
<th>Assessment Factor</th>
<th>COC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquatic (surface water)</td>
<td>Acute</td>
<td>SbCl₃</td>
<td>Hydra</td>
<td>96 h</td>
<td>Mortality</td>
<td>1.77 mg Sb/L (LC₅₀)</td>
<td>5</td>
<td>0.35 mg Sb/L</td>
</tr>
<tr>
<td></td>
<td>Chronic</td>
<td>SbCl₃</td>
<td>Fish</td>
<td>30 d</td>
<td>Growth</td>
<td>1.62 mg Sb/L (GMATC) §</td>
<td>10</td>
<td>0.16 mg Sb/L</td>
</tr>
<tr>
<td>Aquatic (sediment)</td>
<td>Acute</td>
<td>SbCl₃</td>
<td>Worm, midge</td>
<td>28 d</td>
<td>Growth</td>
<td>112 mg Sb/kg dw (NOEC)</td>
<td>1</td>
<td>112 mg Sb/kg dw</td>
</tr>
<tr>
<td></td>
<td>Chronic</td>
<td>SbCl₃</td>
<td>Worm, midge</td>
<td>28 d</td>
<td>Growth</td>
<td>112 mg Sb/kg dw (NOEC)</td>
<td>10</td>
<td>11.2 mg Sb/kg dw</td>
</tr>
<tr>
<td>Terrestrial (soil)</td>
<td>Acute</td>
<td>Sb₂O₃</td>
<td>Springtail</td>
<td>28 d</td>
<td>Reproduction</td>
<td>1,711 mg Sb/kg dw (GMATC) §</td>
<td>1</td>
<td>1,711 mg Sb/kg dw</td>
</tr>
<tr>
<td></td>
<td>Chronic</td>
<td>Sb₂O₃</td>
<td>Springtail</td>
<td>28 d</td>
<td>Reproduction</td>
<td>1,711 mg Sb/kg dw (GMATC) §</td>
<td>10</td>
<td>171 mg Sb/kg dw</td>
</tr>
</tbody>
</table>

§ GMATC calculated from available NOEC and LOEC values.
Dr. Larry Kapustka

Issue 1. Overall Clarity of the Assessment.

Chapter 1 provides the scope of the assessment and a brief introduction. Supporting information on chemistry, fate, and uses are provided in Chapter 2 and the exposure, hazard, and risk characterizations are presented in Chapter 3. Additional supporting information is available in the appendices.

Question 1-1. Please comment on the clarity and strengths and weaknesses of the risk assessment and provide specific suggestions regarding how this may be improved.

I recognize that there are many forms of risk assessments ranging from informal qualitative impressions to sophisticated quantitative descriptions, but generally within the regulatory environment consensus has emerged around the concept of tiered assessments that incorporate increased quantitative rigor as one moves from scoping to screening to definitive assessments. Several colleagues have argued for many years that to have a risk assessment, one must report the probability of a certain magnitude of effect occurring under the scenario that was evaluated. In this context, any use of a ratio as the regulatory determinant does not qualify as a risk assessment; rather it should rightfully be called a scoping or a screening assessment. The subject document in this case should be renamed to reflect the content of the report – it is at best a scoping assessment.

To begin, what is the purpose of a scoping assessment? Basically, it is to make a determination whether there is sufficient information available to make an informed environmental management decision? In the information points to dire consequences, that might be sufficient to move directly to an aggressive action (e.g., removal in the case of a large release, banning production or use of a substance). Alternatively, if the information consistently indicates that the substance or action is essentially benign, that there is no reason to anticipate adverse effects either because there is very low hazard or virtually no plausible exposure scenarios. In either of these cases, a screening assessment would suffice. In the middle are the situations in which one cannot demonstrate a need for immediate restrictive action and cannot rule out the plausibility of adverse effects occurring – this would trigger a more intensive assessment that zeroes in on aspects of hazards and exposure scenarios that replaces broad protective assumptions with more realistic bounded assumptions.

Now there is nothing wrong or inappropriate with scoping assessments. Performing a scoping assessment for a substance such as Sb03 was the prudent thing to do, especially given the conclusions of Environment Canada/Health Canada, the European Union, OECD, and WHO. So I rephrase the charge – “comment on the clarity, strengths, and weaknesses of this scoping assessment.

Several structural deficiencies within the context of the risk assessment framework exist within the ATO report. Regardless of the tier (scoping, screening, and definitive), the Framework details three phases to an assessment: Problem Formulation, Analysis, and Characterization. In the report, Problem Formulation was largely skipped. In particular, there was no presentation of a conceptual model around which the work would be organized, (though a simple pictogram was shown during our kick-off WebEx meeting). No attention was given to stating assessment endpoints, measurement endpoints, or data quality objectives. Each of these components of Problem Formulation are detailed in EPA Guidance, yet for some reason none was addressed adequately in this report. Consequently, both clarity and strength of the report suffer. Perhaps because inadequate attention was given to these crucial features of Problem Formulation, the assembly and evaluation of data sets led to the use of unrelated and un-relatable fragments of information from air, water, and sediment monitoring stations (discussed elsewhere).
Clarity was not achieved in the report in that it was not possible to determine whether the focus of the assessment was nationwide, regional, or site specific. Aspects of the data assembled for the assessment point in multiple directions and the reader is not provided with explanations of which aspects were being emphasized.

A good conceptual model (or a series of nested models) would have helped the authors sort through the different parts of their analysis or at least lead them to explain why certain areas of the investigation received more emphasis than did others. One such curiosity is that even though the majority of Sb is described as going to industrial or municipal treatment facilities and then being disposed on land, the bulk of the Report is focused on aquatic systems. Perhaps that is what the majority of reports that were examined emphasized, but there is a large body of literature dealing with soil amendments (sludge) and site assessments around mines and smelters that could have been used to provide balance to the evaluation.

Considerable emphasis was given to a select number of facilities that reported antimony releases under the voluntary Toxics Release Inventory program. These seemed to be the drivers for selection the States that were considered. Yet, there does not appear to have been any attempt to identify data that would characterize conditions near these facilities or compare up-gradient (water and air sheds) to down-gradient concentrations of antimony. Here again, conceptual models would have been useful to guide the study design so that areas suspected of having the highest concentrations of antimony could have been evaluated.

In its present form, the assessment fails to document the ranges of expected concentrations of antimony in air, sediments, soils, water or biota. There was no effort made to relate the releases and projected future concentrations (such as might occur after ten years of antimony-sludge onto land) in various media. These gaps constitute major weaknesses in the assessment. One might rightly suggest that the findings of Environment Canada/Health Canada, the European Union, OECD, and WHO establish that SbO3 does not pose substantive risks to ecological receptors. However, in this Report, the case is not documented sufficiently well to reach that conclusion independently.

Fortunately, the document could be revised relatively easily (notwithstanding the gaps on terrestrial systems) to make it compatible with the Framework by adding a few sections (noted above) and clearly identifying that this is a scoping assessment, not a risk assessment – the purpose being to determine if there is reason to pursue a more detailed formal risk assessment or if there is sufficient information to conclude that adverse effects are unlikely. The Report need not restate all of the underlying information that was used in the previous reports mentioned above, but should summarize the types of data used, the scenarios evaluated, and the conclusions drawn. If from these summaries, one can reasonably conclude that concentrations of antimony near receiving, handling, processing, distribution, and disposal facilities are likely to remain below threshold (benchmark concentrations, then perhaps the conclusions currently presented in the report will stand. If not, then a study plan to gather the necessary data to close the data gaps should be added to the last section of the Report.

Issue 2. Characterization of Environmental Exposures Based on Release Data.

During project scoping, OPPT identified ATO use as a synergist in halogenated flame retardants as the focus of this assessment. EPA’s 2010 Toxic Release Inventory (TRI) was used to obtain information on water releases associated with this end-use scenario. Data collection was refined using the North American Industry Classification System (NAICS) codes to identify a subset of TRI facilities (i.e., those indicating production, processing or use of ATO-containing flame retardants). Because ATO is not specifically listed on the TRI, data reported under the broader category of ‘antimony compounds’ were
used as a surrogate for ATO in this assessment. ATO surface water concentrations were predicted using a screening level tool (E-FAST2), to model water releases reported by selected TRI facilities.

**Question 2-1:** TRI information reported for ‘antimony compounds’ was used to estimate ATO releases associated with its use as a synergist in halogenated flame retardants. Please comment on this approach.

Several limitations arise with the use of these sources of information (many were acknowledged in the report). For the scoping assessment, there is some usefulness to looking at these releases, but the vagueness with respect to form (particulate, dissolved, etc.), airshed/watershed conformation, receptor zones, and such suggest that minimal inferences can be drawn from the information.

The TRI information could be used to identify facilities that use and release antimony. But it should not be the only source of information as to where antimony might be released. The standards for reporting releases are minimal and lack consistency from one facility to the next. Values reported are typically estimates derived from crude mass balance inventories (what was received minus what left the facility as product equals release). The information does not indicate the rate of release over time and typically is not corroborated in monitoring data. Because the information lacks temporal and spatial relationships, it provides minimal value toward estimating environmental concentrations, flux rates, or form needed to perform a proper fate and transport modelling analysis. The quality of such data is insufficient to stand as credible in a true risk assessment.

**Question 2-2:** Because TRI does not indicate the number of days associated with reported releases, two exposure scenarios were developed (assuming the total water releases reported in the 2010 TRI occurred over a period of 250 days or, a more conservative scenario of 24 days to provide a range of predicted water concentrations for comparison with hazard benchmarks (concentrations of concern) identified for aquatic organisms. Please comment on the assumptions used to develop modeling scenarios using EPA’s E-FAST2 model to assess aquatic exposures to ATO.

There probably isn’t too much value in parsing these data too finely, but if one is looking for a worst-case in a scoping level, why not consider quarterly, semi-annual, or once-a year release of the total mass? There was only the vaguest justification provided for using either the 250- or the 24-day release period. Moreover, the constraints of the model used in this exercise does not provide realistic projections for pulse releases, cumulative releases, seasonality, or other critical consideration for evaluating effects on receptors resulting under acute and chronic exposure scenarios.

**Question 2-3:** Please comment on the approach EPA used to estimate environmental releases resulting from uses of ATO as a synergist in flame-retardant chemicals. Are there other data sources or approaches that EPA should consider to estimate environmental releases of ATO in this end-use? If so, please provide citations or data for consideration in further revision of the draft assessment.

The case for using the largest industrial use sector seems appropriate for this scoping assessment. If unacceptably high risks were indicated, then further refinement could have been considered. What is missing, however, is a broader characterization that considers critical phases in the lifecycle of the products. One might be able to demonstrate that other points along the lifecycle chain pose lower exposure concentrations to receptors, but this was not documented in the report.
Issue 3. Characterization of Environmental Exposures Based on Monitoring Data. OPPT used environmental monitoring information obtained from the U.S. Geological Survey – National Water Information System and EPA’s STORET database to evaluate antimony levels in environmental media. Data collection was limited to states (n=10) with TRI facilities (n=14) having NAICS codes corresponding to ATO uses as a synergist in halogenated flame retardants.

Question 3-1: Please comment on the use of these large monitoring data sets to characterize ecological exposures to ATO use as a synergist in flame retardants and their representativeness for other locations in the US.

These monitoring datasets appear to be entirely irrelevant if the intent was to link back to the TRI sites (note the large spatial separations for facilities and monitoring stations; Figure 3-1 on page 40-41). There is even separation between water and sediment sampling stations such that no inferences are warranted regarding transport of Sb. This is another instance where a good conceptual model and data quality objectives would have helped the authors to see the disconnects among the TRI information and these monitoring data sets.

There does not appear to be a good reason for limiting the assessment to the ten States that were considered. There was no attempt to related measured antimony concentrations to background concentrations. And there was no effort undertaken to post-classify the data sets so that legitimate comparisons of data could be performed. Even a cursory look at the distribution of monitoring stations reveals that data are being pooled from different ecoregions, different watersheds, different airsheds, and the like thereby violating assumptions about statistical populations. Simple scatterplots would likely reveal skewed distributions that could be informative in designing appropriate analyses.

Question 3-2: Are there other major sources of environmental monitoring data (or other pertinent information) that EPA should incorporate in the exposure assessment? If so, please provide the necessary citations and/or data for inclusion in the revised document.

Are there any studies around the storage and use facilities, previous mining operations, or accidents along transportation routes? The mistake seems to be in limiting the assessment to monitoring data, especially if there are site studies that could be used.

Question 3-3: Are there concerns or limitations in these data sets that may impact their utility for risk assessment?

The concerns may be less severe for a scoping assessment such as this one. However, the use of these spatially and temporally unrelated across wildly different ecotypes introduces a high probability of committing both the Fallacy of Averages and the Ecological Fallacy. Scale matters.

Issue 4. Fate, Transport and Bioavailability.
Information available in the published literature regarding the chemistry, fate and transport of ATO is used qualitatively to assess bioavailability to ecological organisms. There is a lack of site-specific data on geochemistry that would inform specification and availability antimony compounds in its toxic forms for environmental receptors.
Question 4-1: Please comment on the use of this information in the ATO assessment. Are there other data sources that EPA should consider?

See my response to Question 3-2.

Issue 5. Environmental Hazard Assessment.
The available hazard information was critically evaluated based on specific test guidelines, accepted endpoints used to assess ecotoxicity, and the amount of detail provided in each study report. Hazard benchmarks (i.e., concentrations of concern) were subsequently derived using the most robust ecotoxicity studies and conservative ecotoxicity values identified in the published literature. Acceptable toxicity data were not available for ATO for both chronic and acute exposures in all media. For this reason, toxicity data for antimony trichloride is used to characterize hazards to water, soil, and sediment dwelling organisms. This is not expected to significantly impact the findings of this assessment because (1) upon dissolution, antimony compounds release antimony ions, and it is the fate and toxicity associated with the total antimony ion concentration that is of most importance when assessing the toxicity of antimony in environmental media and (2) both the oxide and chloride salts of antimony produce comparable amounts of antimony ions upon dissolution in water.

Question 5-1: What other factors should EPA consider in evaluating the potential risks of concern for ecological organisms from antimony species? Please comment on the use of toxicity data for antimony trichloride to characterize hazards to water, soil, and sediment dwelling organisms.

The authors of the report revealed a bias for use of NOECs and LOECs, which as many have pointed out for decades are unreliable and should not be used. If a point estimate must be used, then use an ECx. Better yet, report the concentration-response relationship so that if at a later time a quantitative risk assessment is warranted, the information has value. It is troubling that some portions of the US EPA continue to go its own way using NOECs and LOECs – US EPA Eco-SSL, Environment Canada, OECD, and others have moved away from them.

The use of “Safety Factors” is also an unnecessary step to include in the technical portion of an assessment. In doing so, the policy in effect transfers a managerial responsibility onto the science-based analysis in a most unscientific manner.

PS: “Potential Risk” used in this charge question and in many places throughout the Report is a nonsensical and redundant couplet. Risk is a probability of some adverse event occurring. When linked together it translates to a “potential probability.” Once can talk about potential effects or potential exposures, but should not invoke potential risks.

The ATO assessment evaluates risks of concern posed to ecological organisms as a result of ATO use as a synergist in halogenated flame retardants. Generally speaking, risks are indicated when antimony levels in environmental media (as indicated by environmental monitoring and industrial release information) exceed the hazard benchmarks (i.e., concentrations of concern) identified for ecological organisms in water, soil and sediment. This approach resulted in very few instances where the concern concentrations for water or sediment dwelling organisms were exceeded (< 1%). No exceedances of the hazard benchmarks for soil dwelling organisms were identified. The uncertainties/limitations of this approach are discussed in the ATO document.
**Question 6-1:** Please comment on the implicit assumption that antimony concentrations measured in environmental media reflect many different inputs (i.e., from various end use applications and other types of antimony compounds in addition to ATO) and how this could impact the risk estimation.

As noted above, the monitoring and TRI datasets used are not relatable. The datasets, despite the attempts to characterize the data as robust, are especially limited in scope and breadth. No attempt appears to have been made to anchor the data with actual site data in which higher concentrations of Sb were reported; if none exist, then so be it, but at least make the effort to demonstrate the range. The conclusions would be strengthened if minimal or no adverse effects were observed at sites with substantially higher Sb concentrations (and the sites need not be within the US borders).

**Question 6-2:** The findings reported in this assessment hinge on the assumption that a ‘conservative’ scenario has been presented (based on the assumption that all releases of various types of antimony compounds have been attributed to ATO use in flame retardants) and as such, reflect a conservative estimate of risk of exposure to ATO. Please comment on validity of this assumption and the likelihood that the actual risks of concern posed to ecological organisms have been over (or under) estimated.

The generalized scenario may be fine for normal operations, but to be truly protective, it would seem necessary to consider upset scenarios.

**Question 6-3:** Please comment on the data set used to evaluate exposures to soil-dwelling organisms and the limitations and/or uncertainties in estimating risk to soil-dwelling organisms. Please provide comment on additional data sources, surrogate/related chemicals, or approaches to estimate risks under data poor conditions?

Though individual studies from the Sb Eco-SSL document were cited, the report itself was not. The SSL for invertebrates and mammals certainly seems relevant. General references such as Alloway Heavy Metals in Soils, 2nd Edition and Kabata-Pendias and Pendias Trace Elements in Soils and Plants, 2nd Edition provide useful references that could bolster the information contained in the report.
Dr. Wayne Landis

Charge Question Review

As a preface, I think that screening or preliminary risk assessments have an important contribution to make to a decision making process. They should point out to deficiencies in the dataset, characterize what is known about fate, transport, toxicity, disposal and other features regarding risk. A preliminary risk assessment can also help determine the priority of performing a more definitive study. This study has certainly pointed to issues with the current understanding of ATO in the environment. Most of my comments regard how to make straightforward improvements to the process and to better characterize the uncertainties in the assessment.

EPA has produced classic risk assessment documents that represent a framework (EPA 1992) and guidance (EPA 1998). This document does not seem to follow the suggestions in those reports. Where is the problem formulation, conceptual model, the interaction between fate and transport and the organisms? The risk calculation appears simplistic and there is not a quantitative assessment of uncertainty. This report could be reorganized to reflect those EPA standards.

The lack of a cause-effect conceptual model is a issue that makes the construction of a coherent risk assessment extremely difficult. A conceptual model would assist in the organization of the exposure and assessment data and allow an organized discussion of the related uncertainties. A strong conceptual model would point out the importance of including terrestrial data for exposure and terrestrial endpoints for the hazard assessment.

Issue 1. Overall Clarity of the Assessment.

Chapter 1 provides the scope of the assessment and a brief introduction. Supporting information on chemistry, fate, and uses are provided in Chapter 2 and the exposure, hazard, and risk characterizations are presented in Chapter 3. Additional supporting information is available in the appendices.

Question 1-1. Please comment on the clarity and strengths and weaknesses of the risk assessment and provide specific suggestions regarding how this may be improved.

1) It is important that time be take and that editing take place to ensure that EPA produces documents that correctly reflects the scientific state of the art written in an accessible fashion. In studies such as this where the exposure data were not originally collected to estimate ATO concentration and the toxicity data have multiple issues. It is better to acknowledge the issues with the uncertainty.

2) The emphasis on the aquatic exposure and risk reads as a misdirection away from the waste disposal and terrestrial sectors. I understand that much of the toxicity data are for aquatic organisms but does not justify such a dramatic emphasis. The disconnect between the available information and the actual route of exposure to the environment.

3) I do not understand the word “conservative” except to mean bias in the face of uncertainty. The amount of bias seems inconsistent. Why not accurately describe the uncertainty and then describe the distribution that should incorporate the tail.

4) Word choice is important. The summary has a number of issues with word choice in the conclusions section-bottom of page 8. These word choices indicate that the assessment is stronger than indicated from a careful reading. When I read conclusions such as these I wonder if there is non-scientific influence.
“Use of the generic category, ‘antimony compounds’ and conservative assumptions regarding modeled releases likely overestimate exposure potential. “

Given that the measurements taken are not downwind or downstream of the manufacturing or the waste disposal sites how can it be said that they overestimate exposure potential. Given the uncertainty of the measurements and the issues with measurement I cannot concur with this statement.

“Use of highly sensitive ecological species to delineate conservative hazard benchmarks showed very few exceedences of the COCs. “

What does highly sensitive mean? They are at best the most sensitive of the organisms that have been tested; you have no idea if there is something more sensitive to ATO.

“Environmental monitoring data obtained during the last three years showed no exceedences of COCs.”

Given the location of the sampling sites I would not expect exceedences even with high concentrations being released from the manufacturing sites or waste disposal facilities.

“This assessment provides important insights regarding the potential risks of concern to ecological organisms associated with ATO’s use in halogenated flame retardants. Measured and modeled concentrations of ATO are assumed to represent reasonable estimates of environmental exposures.”

Please explain to me what are the “important insights”. The insight may be that away from potential sources of ATO that the environmental concentrations (in water) are often below levels that produce toxicity in the test organisms. However terrestrial organisms are under-represented and concentrations near sites of manufacture and disposal have not been measured.

What constitutes a reasonable estimate of environmental exposure? What would be an unreasonable estimate?

5) General comment on the evaluation of toxicity in this report.

5a) There does not appear to be any set of a priori requirements or specifications for what constitutes an adequate toxicological study design for this report. Studies are included or exclude for what seems to be ad hoc reasoning. Since this reader has no idea of what constitutes an adequate design (by the authors) how can I evaluate their judgments.

5b) Have the authors of this report had any access to the actual data from any of the toxicity tests? Almost all of the toxicity data are reported as NOEC, LOEC or some other endpoint from a hypothesis test approach. Moore and Caux (1997) and my experience have generally found that a NOEC is actually a 8-20 percent effect on the exposure-response curve. LOECs have a greater variability in the effect level. So what degree of toxicity is actually acceptable in this study? I do see an occasional EC50 value but it is unlikely that this is an acceptable effect. Depending on the slope of the exposure-response curve and EC10 or EC20 can be much less than the EC50.

Issue 2. Characterization of Environmental Exposures Based on Release Data.

During project scoping, OPPT identified ATO use as a synergist in halogenated flame-retardants as the focus of this assessment. EPA’s 2010 Toxic Release Inventory (TRI) was used to obtain information on water releases associated with this end-use scenario. Data collection was refined using the North American Industry Classification System (NAICS) codes to identify a subset of TRI facilities (i.e., those
indicating production, processing or use of ATO-containing flame-retardants). Because ATO is not specifically listed on the TRI, data reported under the broader category of ‘antimony compounds’ were used as a surrogate for ATO in this assessment. ATO surface water concentrations were predicted using a screening level tool (E-FAST2), to model water releases reported by selected TRI facilities.

**Question 2-1:** TRI information reported for ‘antimony compounds’ was used to estimate ATO releases associated with its use as a synergist in halogenated flame-retardants. Please comment on this approach.

Other reviewers have already commented on the issues related to antimony compounds. The numerous issues related to using TRI data for estimating releases to the receiving environment are well documented.

**Question 2-2:** Because TRI does not indicate the number of days associated with reported releases, two exposure scenarios were developed (assuming the total water releases reported in the 2010 TRI occurred over a period of 250 days or, a more conservative scenario of 24 days to provide a range of predicted water concentrations for comparison with hazard benchmarks (concentrations of concern) identified for aquatic organisms. Please comment on the assumptions used to develop modeling scenarios using EPA’s E-FAST2 model to assess aquatic exposures to ATO.

The issues with the E-Fast2 model are well documented in other reviews.

**Question 2-3:** Please comment on the approach EPA used to estimate environmental releases resulting from uses of ATO as a synergist in flame-retardant chemicals. Are there other data sources or approaches that EPA should consider to estimate environmental releases of ATO in this end-use? If so, please provide citations or data for consideration in further revision of the draft assessment.

EPA used the information for those sites that reported releasing ATO as part of the TRI reporting process. Apparently there are 23 sites that deal with fabric manufacture and treatment. In Figure 3-1 I count only 13 sites with TRI information. There seem to be a number of manufactures that use halogenated flame-retardants and given that ATO is in the retardants there should be ATO there as well.

Halogenated flame-retardants are found in soil, sediment and biota. Again given that ATO can be found in the product it should be assumed that if there are flame-retardants present then there must have been some exposure to ATO to that environment as well.

I also noted that there are especially large amounts of materials reported to be disposed of in land and other disposal sites. Where are these sites? Although not manufacturing plants they clearly store the majority of ATO materials. Many landfills are sources of contaminants to the aquatic and terrestrial environments.

A vast majority of the material released to the environment is to the terrestrial component. So where is this going, what kind of facility, and does transport occur to the aquatic and terrestrial systems in the area? The current information does not address those issues.

Do these manufacturing sites that do not have NPDES permits discharge into a local municipal system? What are the permit requirements and do they measure ATO concentrations?

More importantly, where are their point discharges for both air and water? If you have the point discharge for the water then it would be possible to search for studies directly applicable to that receiving water. For stacks there may be other studies specific to that region.
If I am looking for sites of environmental releases I would use the STORET and USGS data to find levels of high concentration and then work to determine the source. I would also include any of the flame-retardants where ATO is used in the manufacturing process. I would not limit the analysis of these data to the 10 states of this program. You have assumed that these are the sources and there may be others.

A Google search for flame resistant cloth manufacturers included Ames Rubber Manufacturing in Los Angeles CA, Cascade Coil Drapery in Tualatin OR, and Consolidated Cordage in Boca Raton FL. There notices claim to be manufacturers of the fire resistant cloth. I do not see these States included in the analysis or these kinds of processes.

**Issue 3. Characterization of Environmental Exposures Based on Monitoring Data.**

*OPPT used environmental monitoring information obtained from the U.S. Geological Survey-National Water Information System and EPA's STORET database to evaluate antimony levels in environmental media. Data collection was limited to states (n=10) with TRI facilities (n=14) having NAICS codes corresponding to ATO uses as a synergist in halogenated flame-retardants.*

**Question 3-1: Please comment on the use of these large monitoring data sets to characterize ecological exposures to ATO use as a synergist in flame-retardants and their representativeness for other locations in the US.**

I certainly understand that the authors are doing the best they can with a dataset not generated to answer the specific question they are addressing. The weaknesses of the approach should be pointed out and the uncertainties clearly listed.

If the purpose of this study was to estimate risk due to materials released from a pulp and paper mill, a refinery, or a contaminated site the data set would be considered inadequate. In those kinds of assessments there is specific attention paid to the receiving water and the surrounding terrestrial environment. The stream adjacent to the receiving water typically has very low concentrations of the effluent, the measurements are taken downstream and usually a gradient of decreasing concentration is observed.

In my examination of the monitoring data I do not see any that are likely to correspond to either the receiving water or the terrestrial environment. In the case of ATO the largest sources my mass should be the waste disposal areas and those are not considered in this assessment. That information should be available.

Large databases such as that collected for STORET and the USGS monitoring program usually have specific criteria for the selection of the sampling sites. Is there any reason to expect that these criteria would facilitate the detection of ATO in the environment?

The lack of a systematic sampling for ATO release has consequences for the risk assessment. The risk to the environment in areas with known discharges is not represented in this data set. Looks like a lot of data but it does not answer the question of risk to the environment.
Question 3-2: Are there other major sources of environmental monitoring data (or other pertinent information) that EPA should incorporate in the exposure assessment? If so, please provide the necessary citations and/or data for inclusion in the revised document.

Many states and local jurisdictions have sampling programs of their own for a variety of reasons. Sampling of watersheds and terrestrial systems is often done as part of RCRA, CERCLA or state versions of these laws. Was there an attempt to examine what specific environmental information was available for the sites under consideration? Similarly was the waste-disposal areas examined for potential datasets?

Why limit the review to states with TRI data? It was very easy to locate other companies and end product manufactures using flame-retardant materials in states outside of the original 10.

Question 3-3: Are there concerns or limitations in these data sets that may impact their utility for risk assessment?

If I assume that the goal is to include the entire exposure range to ATO, then yes there are severe limitations

1) The largest loading of ATO is to the terrestrial environment but there are very few samples and it is not clear how they relate to the manufacturing site or the disposal area.

2) The aquatic dataset does not correspond to the site of manufacture or use. So if the question is what is the distribution of the concentration of ATO in the aquatic environment when no source of ATO is present the dataset may be suitable. That is a different question that what this report seems to be addressing.

3) In reviewing the data analysis in this report there does not appear to be any exploratory data analysis. Are the data better described by a Poisson or other non-normal distribution? Are there particular breaks in the information? Any spatial patterns in the bioregions or watersheds? How were non-detects used in the assessment of the concentrations?

Issue 4. Fate, Transport and Bioavailability.

Information available in the published literature regarding the chemistry, fate and transport of ATO is used qualitatively to assess bioavailability to ecological organisms. There is a lack of site-specific data on geochemistry that would inform specification and availability antimony compounds in its toxic forms for environmental receptors.

Question 4-1: Please comment on the use of this information in the ATO assessment. Are there other data sources that EPA should consider?

1) It is not clear to me that this information was used in the risk assessment. No attempt seems to have been made to understand the fate, transport and bioavailability of ATO at any of the sites being considered for examination. I understand that sufficient data may not be available for some of the sites but it does not appear that an understanding of these processes was accomplished for any of the sites.

Fugacity modeling has been successfully used for a variety of chemicals and environments and should be applicable here. Why not take two or three of the sites, characterize the site and especially the routes of ATO to the air, terrestrial and aquatic environments and do some simple modeling. Some of the studies cited may be able to provide the necessary information to get estimates with some bounds for the uncertainty involved.
2) It is not clear what is meant by a lack of site-specific data. Are you stating that for none of the sites under consideration there is not the information necessary to conduct the necessary modeling? I find that difficult to understand given the amount of data available from various State and Federal agencies regarding soils, water, and other characteristics of the receiving environment.

**Issue 5. Environmental Hazard Assessment.**

The available hazard information was critically evaluated based on specific test guidelines, accepted endpoints used to assess ecotoxicity, and the amount of detail provided in each study report. Hazard benchmarks (i.e., concentrations of concern) were subsequently derived using the most robust ecotoxicity studies and conservative ecotoxicity values identified in the published literature. Acceptable toxicity data were not available for ATO for both chronic and acute exposures in all media. For this reason, toxicity data for antimony trichloride are used to characterize hazards to water, soil, and sediment dwelling organisms. This is not expected to significantly impact the findings of this assessment because (1) upon dissolution, antimony compounds release antimony ions, and it is the fate and toxicity associated with the total antimony ion concentration that is of most importance when assessing the toxicity of antimony in environmental media and (2) both the oxide and chloride salts of antimony produce comparable amounts of antimony ions upon dissolution in water.

**Question 5-1: What other factors should EPA consider in evaluating the potential risks of concern for ecological organisms from antimony species? Please comment on the use of toxicity data for antimony trichloride to characterize hazards to water, soil, and sediment dwelling organisms.**

1) As stated in my comments to section 1 it is not clear how I should consider the evaluation process for the studies and the subsequent dataset. When doing QSAR research and evaluating hundreds of studies the team evaluating published literature had specific criteria that delineated that the properties that a study had to have in order for the results to be included into the database. Page 27 “on the most robust ecotoxicity information” without these criteria for the studies I do not know how robust was defined.

It seems that whether or not a study was included in the derivation of a benchmark concentration (COC is chemical of concern and is widely used in other EPA documents) was arbitrary.

2) Let’s be clear, there are only results of the data analysis for the studies reported in this document, not data. It is not clear that the authors have access to the data on which to base their conclusions. Remember that NOECs, MATCs, LOECs and EC values are the summary of the exposure-response relationship. For the NOECs, MATCs, and LOECs there cannot be confidence intervals produced and other indications of the uncertainty in the analysis are not reported in this document. EC values should have the confidence intervals reported and almost all programs that do the calculation also calculate the confidence intervals.

For the NOECs and other endpoints derived from hypothesis testing there are no indications of the statistical power of the analysis.

2) It is not clear from this analysis what an acceptable effect would be for ATO. Should it be a 20 percent reduction in growth, reproduction or survivorship? Then studies that provide information at those effects levels should be a point of focus.

3) The use of assessment factors whether by the EU or EPA (page 30) especially by 10 is arbitrary in almost every instance. I understand if the uncertainty in the estimate of toxicity is so large that the tail of the effect distribution requires such a factor. However we have almost no information on the uncertainty of the toxicity estimates. Similarly examining the difference between the benchmark and the
environmental concentration without an estimate of the uncertainty is similarly uninformed. Without an
indication of the uncertainty to use either approach is a policy decision not a scientific one.

4) Given the exposure to the terrestrial environment there is a dramatic lack of information available on
the effects to the organisms living there. Given the lack of studies and the breadth of organisms exposed
the uncertainty surrounding any benchmark is large. I consider the benchmark suggested on page 31 to be
unreliable.

**Issue 6. Environmental Risk Characterization.**
The ATO assessment evaluates risks of concern posed to ecological organisms as a result of ATO use as a
synergist in halogenated flame-retardants. Generally speaking, risks are indicated when antimony levels
in environmental media (as indicated by environmental monitoring and industrial release information)
exceed the hazard benchmarks (i.e., concentrations of concern) identified for ecological organisms in
water, soil and sediment. This approach resulted in very few instances where the concern concentrations
for water or sediment dwelling organisms were exceeded (< 1%). No exceedences of the hazard
benchmarks for soil dwelling organisms were identified. The uncertainties/limitations of this approach
are discussed in the ATO document.

Editorial comment: What organisms are not ecological organisms? Would we use the data for laboratory
rats and mice, dogs, whatever? Of course we would since they are closely related to the mammals in
North America.

I wish the charge questions demonstrated a better understanding of the current practice of risk assessment.
Assuming conservatism in exposure and effects means that you have very little certainty in the accuracy
of either variable. There are better ways of dealing with such issues that divide by 10 and then compare.
Essentially there are no terrestrial data for concentration of ATO. The effects are poorly characterized for
aquatic, sediment, soil and terrestrial organisms.

**Question 6-1:** Please comment on the implicit assumption that antimony concentrations measured in
environmental media reflect many different inputs (i.e., from various end use applications and other
types of antimony compounds in addition to ATO) and how this could impact the risk estimation.

Your risk estimation is not based on concentrations from expected sources so I doubt that ATO from the
production of flame-retardants is an appreciable amount. So it is not clear to me that this is a reasonable
question.

**Question 6-2:** The findings reported in this assessment hinge on the assumption that a ‘conservative’
scenario has been presented (based on the assumption that all releases of various types of antimony
compounds have been attributed to ATO use in flame retardants) and as such, reflect a conservative
estimate of risk of exposure to ATO. Please comment on validity of this assumption and the likelihood
that the actual risks of concern posed to ecological organisms have been over (or under) estimated.

1) I assume that by conservative you mean that you have overestimated the exposure and overestimated
the sensitivity of the organism. Since there seems to have been little effort to sample expected sources of
flame-retardant ATO concentration it is not clear how it can be said that your results are accurate. There
is such a large amount of uncertainty that the best that can be done is to give a low and high boundary and
assume an even distribution.
2) Given the uncertainties in the exposure and effects datasets this is my take on the risk (of concern???). I expect aquatic exposures to ATO from flame-retardants to be higher near site of manufacture and of waste disposal. So I expect any of the field data seen in this analysis to be at a lower concentration that would be expected from an outfall. Exposures to the terrestrial environment are so poorly documented that an expert solicitation may be a better estimator of probable exposure than the dataset in this report.

**Question 6-3**: Please comment on the data set used to evaluate exposures to soil-dwelling organisms and the limitations and/or uncertainties in estimating risk to soil-dwelling organisms. Please provide comment on additional data sources, surrogate/related chemicals, or approaches to estimate risks under data poor conditions?

There are a number of techniques for dealing with situations without suitable data. P-bounds tools are used when upper and lower limits can be estimated but when the distributions are unknown. Bayesian expert elicitation techniques can be used and then put into a Bayesian belief network. However both of these tools are beyond the tools used here.

The first step I would take is to generate a clear conceptual model just as suggested in the 1998 EPA guidance document. A clear cause-effect conceptual model helps to categorize the missing data and to identify unmanageable uncertainty.
Dr. David Ostrach

Page 1 of 3

OPPT Proposed Draft Charge to External Peer Reviewers for the review of the TSCA Workplan

Chemical Risk Assessment of ATO

December 2012

This assessment evaluated the environmental risks that may be associated with ATO use as a synergist in halogenated flame retardants. Human health risks were determined to be of low concern; the available hazard data are summarized in an appendix.

Issue 1. Overall Clarity of the Assessment.

Chapter 1 provides the scope of the assessment and a brief introduction. Supporting information on chemistry, fate, and uses are provided in Chapter 2 and the exposure, hazard, and risk characterizations are presented in Chapter 3. Additional supporting information is available in the appendices.

Question 1-1. Please comment on the clarity and strengths and weaknesses of the risk assessment and provide specific suggestions regarding how this may be improved.

I understand the need for agencies to respond to and assess potential risks to the environment. In doing so I always advocate that agencies use the best available science to aid them in their assessments and management decisions. In this case there is a lack of good science presented in this assessment and applicable to characterize the risk of ATO to the environment. The EPA has compiled a lot of disparate information to attempt to understand and access the potential risk of ATO to ecosystems. Characterizing this as a risk assessment is inappropriate. It should be categorized as a scoping assessment or perhaps a hazard assessment. In a risk assessment quantitative exposure data and real risk need to have been identified at lower assessment levels such as at scoping or screening levels. There is a lack of exposure data, both aquatic and terrestrial, to characterize the potential risks of ATO to EPA test organisms or more importantly to the native flora and fauna that may be exposed to this compound. In addition this assessment relies on acute and chronic toxicity to measure potential risks to ecosystems. However, we should learn from our experience with other flame retardant compounds such as PBDEs that in reality it’s not necessarily acute or chronic toxicity that causes significant damage to organisms or ecosystems. Contaminants in the environment can adversely affect organisms at various levels of biological organization. They can at levels well below those thought toxic by the metrics used in this assessment adversely affecting physiology, enzymatic systems, neurochemical pathways, biochemical processes as well as cause endocrine disruption. I believe that these endpoints need to be addressed and incorporated when appropriate in future scoping’s, screenings and risk assessments by EPA and other agencies. In addition, addressing the risk as a single compound, ATO versus the reality of it being found in a terrestrial or aquatic environment in a complex mixture as a part of a flame retardant or other product with other contaminants does not provide a realistic assessment of potential environmental concerns. ATO in combination with other compounds/contaminants in both aquatic and terrestrial environments may change the potential risk of ATO to the environment by acting act as a synergist, agonist or antagonist with other compounds. There are also potential indirect effects that ATO could have by affecting an organism’s food source or habitat. However, you need to begin as EPA has done with a single compound assessment but when doing so it’s necessary to have the appropriate related data and exposure information from which to make an appropriate risk assessment. If the initial monitoring data and exposure assessment indicates or reveals potential concerns then as suggested above you would move to a more rigorous assessment and try to incorporate additional endpoints to better characterize the risk. The minimal data presented in this assessment is qualitative and does not demonstrate risk/lack of risk by accepted standards. I consider this
a scoping assessment for ATO as opposed to a risk assessment and would suggest changing the title to reflect this accordingly. This being said given the qualitative data and information provided in this document it appears that ATO will likely not be a significant risk to the environment. My recommendation is to gather more data at the scoping or screening level to determine if a full-blown risk assessment for ATO is necessary. Comparable and consistent toxicity testing of ATO in both water and terrestrial systems should be performed and if the surrogate is used definitive data indicating the surrogate would have similar toxicity as ATO needs to be acquired and demonstrated. Samples need to be collected and monitored at the point source of the ATO discharges (as opposed to using monitoring data or data from STORET or TRI) as well as along the potential routes it would take as it enters and spreads through the environment. Construction of a clear statement of the problem and conceptual model is essential in any risk assessment and was not provided in this assessment. I recommend the authors provide a clear statement of the problem and conceptual model in the next draft of this assessment. It would’ve been helpful to start with as it would, as information became available, direct investigations/risk assessment in the areas that appeared to be of most concern. Given the data limitations and information available I feel the authors did a reasonable job in this document to characterize the potential hazard of ATO. I think with a little modification, additional data and re-characterizing it not as a risk assessment but as a scoping level assessment it will be useful to determine if pursuing a more detailed risk assessment of ATO is necessary.

**Issue 2. Characterization of Environmental Exposures Based on Release Data.**

*During project scoping, OPPT identified ATO use as a synergist in halogenated flame retardants as the focus of this assessment. EPA’s 2010 Toxic Release Inventory (TRI) was used to obtain information on water releases associated with this end-use scenario. Data collection was refined using the North American Industry Classification System (NAICS) codes to identify a subset of TRI facilities (i.e., those indicating production, processing or use of ATO-containing flame retardants). Because ATO is not specifically listed on the TRI, data reported under the broader category of ‘antimony compounds’ were used as a surrogate for ATO in this assessment. ATO surface water concentrations were predicted using a screening level tool (E-FAST2), to model water releases reported by selected TRI facilities.*

**Question 2-1: TRI information reported for ‘antimony compounds’ was used to estimate ATO releases associated with its use as a synergist in halogenated flame retardants. Please comment on this approach.**

I understand due to the apparent lack of point source monitoring and other data the decision to use TRI information for “antimony compounds” was determined to be an appropriate estimation of releases. However, this data has inherent problems. TRI data is self-reported by facilities and as such is questionable as to its reliability and quality. It’s unclear how the compound is being released at each site and if release data is even comparable between sites. It does not discuss if antimony compounds are being discharged as an aerosol, a particulate, a dissolved portion of an effluent nor does it define potential receptor zones. In addition, this risk assessment focuses heavily on surface water ecosystems where in fact the vast majority of ATO is being discharged into terrestrial systems. There is minimal data on soil concentration and again the data presented is vague. It is not clear where the samples were collected or located, when they were collected what kind of soil it is etc. Additional information needs to be provided in this assessment regarding concentrations and fate in the terrestrial ecosystems potentially affected. I believe this information is minimally useful (in a scoping assessment not risk assessment) and appropriate point source and environmental fate data collected or found within the current literature or from other sources.
Question 2-2: Because TRI does not indicate the number of days associated with reported releases, two exposure scenarios were developed (assuming the total water releases reported in the 2010 TRI occurred over a period of 250 days or, a more conservative scenario of 24 days to provide a range of predicted water concentrations for comparison with hazard benchmarks (concentrations of concern) identified for aquatic organisms. Please comment on the assumptions used to develop modeling scenarios using EPA’s E-FAST2 model to assess aquatic exposures to ATO.

What I see here is an attempt to use available data for a use that it was never intended for. The data set being used in the model violates several of the conditions and assumptions of the model (e.g. necessary to have the total number of release days per year, several critical input parameters in the model were set to zero with no mention or explanation) and the manner in which EPA is estimating the data to fit the model (24 day & 250 day scenarios) does not provide a clear picture of release or risk. The two scenarios developed to provide a reasonable range of estimated surface water concentrations for assessing potential risk to aquatic organisms are not really the appropriate way to use the data or the model. Stating that the less frequent exposures are more conservative is misleading. They are only more conservative in the sense that during periodic flushing they would be at potentially higher concentrations. However, it may not be more conservative if longer duration exposures to lower concentrations result in a more significant and adverse outcomes (e.g. developmental abnormalities, reproductive impairment, endocrine disruption etc.). It is unclear as to where the samples were taken in relation to the facilities and if as mentioned above site to site samples were comparable. I feel this exercise provided minimal useful information and that other sources of data need to be found or acquired to determine accurate releases from these facilities and their toxicity.

Question 2-3: Please comment on the approach EPA used to estimate environmental releases resulting from uses of ATO as a synergist in flame-retardant chemicals. Are there other data sources or approaches that EPA should consider to estimate environmental releases of ATO in this end-use? If so, please provide citations or data for consideration in further revision of the draft assessment. Page 2 of 3

I think the approach used by trying to determine the releases from the largest ATO users/potential dischargers was appropriate for a scoping level assessment. However, as mentioned above I believe the TRI data is insufficient to meet this goal. I reiterate that there is a need for point source discharge information for air water and soil to accurately estimate environmental releases. There may be other sources of information with some of this data available within other databases such as TOXNET and CTD and I recommend a more thorough exploration of databases as well as stakeholder, state and regulatory agency databases.

OPPT used environmental monitoring information obtained from the U.S. Geological Survey-National Water Information System and EPA’s STORET database to evaluate antimony levels in environmental media. Data collection was limited to states (n=10) with TRI facilities (n=14) having NAICS codes corresponding to ATO uses as a synergist in halogenated flame retardants.
Question 3-1: Please comment on the use of these large monitoring data sets to characterize ecological exposures to ATO use as a synergist in flame retardants and their representativeness for other locations in the US.

Using these large monitoring data sets for a purpose they were never intended provides for minimal information at best. It seems the intent was to attempt to link the monitoring data to the TRI facilities but I can see no rational way to do this. The EPA’s STORET and USGS-NWIS monitoring data sites do not correspond to any of the discharge locations. This is one of the rationales as stated as to why the E-FAST2 model was used to estimate final concentrations. There are few if any sites that cover all potential routes of exposure via air, water or terrestrial near any of the facilities. There is separation between where different types of samples were taken and the samples were not collected in a manner to assess the potential risk of ATO or the facilities in general. These monitoring samples were taken for different purposes and I don’t believe can be used in a meaningful way to interpret transport or fate of ATO. As mentioned above to appropriately evaluate ATO levels in the environment point source data must be found within the literature or collected as well as transport data. I don’t believe the data presented can be used to represent potential ATO risk in other states or geographic locations. The assessment document states this as well “Because site-specific environmental parameters that can impact bioavailability vary significantly, it is difficult to extrapolate to other sites or geographic regions within the US.” Each location has different geological, biotic and environmental factors that can affect potential risk or fate of ATO.

Question 3-2: Are there other major sources of environmental monitoring data (or other pertinent information) that EPA should incorporate in the exposure assessment? If so, please provide the necessary citations and/or data for inclusion in the revised document.

Although I’m not specifically aware of other sources of environmental ATO data I think using only monitoring data that was not intended for this purpose was a mistake. Since a significant portion of this material seems to be taken for disposal to waste disposal locations or treatment plants there may be local municipalities, state or academic monitoring data available for those sites. In California both the state and regional water control boards collect significant information and perhaps some of the 10 states listed have similar programs or agencies that might have additional data. Expanding the data search beyond the 10 states would likely be productive.

Question 3-3: Are there concerns or limitations in these data sets that may impact their utility for risk assessment?

I think there are significant limitations in using these data sets for risk assessment in this case. A lot of the data is inconsistent from the source (different collection methods, different analytical methods used etc.) so the quality and comparability of the data is in question. In addition, as mentioned the samples have no spatial or temporal relationship to the facilities in question so I don’t believe they are appropriate or relevant to use in a risk assessment. Perhaps they would be useful to provide inferential information for a scoping assessment and a thus would provide a means to design monitoring studies to collect appropriate samples. They are also very limited terrestrial samples available and the vast majority of ATO ends up in terrestrial environments/facilities.


**Issue 4. Fate, Transport and Bioavailability.**

Information available in the published literature regarding the chemistry, fate and transport of ATO is used qualitatively to assess bioavailability to ecological organisms. There is a lack of site-specific data on geochemistry that would inform specification and availability antimony compounds in its toxic forms for environmental receptors.

**Question 4-1: Please comment on the use of this information in the ATO assessment. Are there other data sources that EPA should consider?**

This information was provided but it’s not clear to me how it was used in this risk assessment? The lack of site-specific data, not only geochemical but in general, is troubling as the purpose is to try and understand what happens to ATO when it’s released from these sites, where does it go and what is its environmental fate. In addition, the section on environmental transformation, bioavailability, and bioaccumulation section is focused heavily on aquatic systems whereas previously stated over 90% of this material ends up in terrestrial systems. There is a lack of terrestrial ATO data used in this risk assessment and that is of great concern. Although I don’t have specific sources of information it seems that there’s a significant amount of environmental data on water and soil collected in most states by local agencies, state agencies as well as stakeholders that could be pursued and used in this assessment.

**Issue 5. Environmental Hazard Assessment.**

The available hazard information was critically evaluated based on specific test guidelines, accepted endpoints used to assess ecotoxicity, and the amount of detail provided in each study report. Hazard benchmarks (i.e., concentrations of concern) were subsequently derived using the most robust ecotoxicity studies and conservative ecotoxicity values identified in the published literature. Acceptable toxicity data were not available for ATO for both chronic and acute exposures in all media. For this reason, toxicity data for antimony trichloride is used to characterize hazards to water, soil, and sediment dwelling organisms. This is not expected to significantly impact the findings of this assessment because (1) upon dissolution, antimony compounds release antimony ions, and it is the fate and toxicity associated with the total antimony ion concentration that is of most importance when assessing the toxicity of antimony in environmental media and (2) both the oxide and chloride salts of antimony produce comparable amounts of antimony ions upon dissolution in water.

**Question 5-1: What other factors should EPA consider in evaluating the potential risks of concern for ecological organisms from antimony species? Please comment on the use of toxicity data for antimony trichloride to characterize hazards to water, soil, and sediment dwelling organisms. Page 3 of 3**

The toxicity information provided was not raw or graphical data but was interpreted data such as LC50s, LOECs & NOECs. Without significant background information and not having the raw data it’s difficult to interpret this information in a reliable or useful manner. The authors state many times that toxicity data using either antimony trioxide or antimony chloride are similar and that the toxicity is related to ion concentration. However, data provided is in terms of the compound added to the toxicity’s test or found in the environment and is not represented as ionic concentration. Therefore, it’s difficult to interpret the data provided in any meaningful manner. This type of information does not take into account degradation or transformation that may take place in the environmental media as well as interactions with other compounds/contaminants found at sites were ATO will end up. As fellow panelists have indicated this risk assessment is based on data from a very few studies while significant other information is available. A search of EPA’s own ECOTOX database and Web of Science will indicate an additional ~100
ons, a number of publications on ATO in the aquatic and terrestrial environment that was not provided in this assessment. Why was this information not used and if it was evaluated and not used why was this not explained in the document or to the panel? Dr. Sepulveda provided a summary of these references with her draft comments so I will not repeat the list here please refer to her list of additional available references. I have not seen any conclusive evidence that the toxicity of the 2 compounds is directly comparable and as such I would strongly recommend using the compound in question, ATO in future toxicity evaluations. The use of terms such as “ecologically sensitive” species are misleading and should not be used especially given the lack of toxicity data on ATO presented. The data presented shows differences in sensitivity to ATO for the species selected in these few studies but to say that they are ecologically sensitive or sensitive to ATO is incorrect and misleading. Terms like this should be removed from this document.

The ATO assessment evaluates risks of concern posed to ecological organisms as a result of ATO use as a synergist in halogenated flame retardants. Generally speaking, risks are indicated when antimony levels in environmental media (as indicated by environmental monitoring and industrial release information) exceed the hazard benchmarks (i.e., concentrations of concern) identified for ecological organisms in water, soil and sediment. This approach resulted in very few instances where the concern concentrations for water or sediment dwelling organisms were exceeded (< 1%). No exceedances of the hazard benchmarks for soil dwelling organisms were identified. The uncertainties/limitations of this approach are discussed in the ATO document.

Question 6-1: Please comment on the implicit assumption that antimony concentrations measured in environmental media reflect many different inputs (i.e., from various end use applications and other types of antimony compounds in addition to ATO) and how this could impact the risk estimation.

In the data set provided in this document that assumption is correct but essentially irrelevant. The data set provided was not associated or linked in any meaningful way with the facilities potentially discharging ATO into the environment or to where solid waste containing ATO is disposed of. So of course the samples reflect inputs from various anthropogenic and natural sources. You could perhaps get some inferences as to if facilities are impacting the ecosystem in question if the data analysis was analyzed on a finer scale (e.g. watershed vs by state). As stated previously this data set and the manner in which it is being represented is inappropriate for use in a risk assessment scenario for ATO for the facilities chosen.

Question 6-2: The findings reported in this assessment hinge on the assumption that a ‘conservative’ scenario has been presented (based on the assumption that all releases of various types of antimony compounds have been attributed to ATO use in flame retardants) and as such, reflect a conservative estimate of risk of exposure to ATO. Please comment on validity of this assumption and the likelihood that the actual risks of concern posed to ecological organisms have been over (or under) estimated.

Based on the information and rationale provided in this document it could be stated that this is a “conservative” scenario. However, I really don’t like the word conservative and with the lack of data at the release sites I can’t really determine if this is a conservative scenario or not. It should be reworded to reflect a potential range of impact/risk given the available data and not be described as conservative which is misleading. With the paucity and sources of data provided that are not associated in any meaningful way with the facilities, it is likely that some risks are underestimated in this assessment as well. I agree from the qualitative information provided ATO is likely not a significant risk to the environment and that a somewhat conservative scenario has been provided. However, without data relevant to the ATO manufacturing facilities and their release and transport it is difficult to say that this is
a conservative estimate of risk exposure to ATO from these facilities. I think a better term such as “protective” would be more useful in describing what the authors are attempting to do with this assessment.

**Question 6-3:** Please comment on the data set used to evaluate exposures to soil-dwelling organisms and the limitations and/or uncertainties in estimating risk to soil-dwelling organisms. Please provide comment on additional data sources, surrogate/related chemicals, or approaches to estimate risks under data poor conditions?

The data set provided to evaluate soil dwelling exposures was minimal compared to aquatic toxicity information. Since the vast majority of ATO ends up in a terrestrial environment this is a major problem with this assessment. It does not adequately address the risk. I believe there are other sources of information on terrestrial toxicity of ATO to soil dwelling organisms available but I have no specific sources at this time the site. As mentioned previously a conceptual model needs to be conceived which would help identify and manage data gaps and uncertainty.

**General Comments:**

1) Generate a clear conceptual model and problem statement in the next revision of this document.

2) Rename as a Scoping or Hazard Assessment as this is not a Risk Assessment.

3) Use ATO toxicity data not data on surrogate compounds.

4) More data is needed for terrestrial ecosystems as this is lacking and a major weakness in this assessment.

5) Do not limit data sets to these 10 states and primary production facilities. Investigate product users and distributors as well to determine other sources of ATO being released into the environment.

6) Using Kimball (1978) a 35-year-old study as the basis for all the aquatic COC’s is inappropriate. Additional data should be found or generated before determining COC’s.

7) Remove and do not use incorrect or misleading terms such as “sensitive” as it refers to test species, conservative (replace with protective or something similar), robust, overestimate effects (when there is little or no data to back this term up) or acceptable effects.

8) Present detailed toxicity data not interpreted data in the form of LC-50s, NOEC’s etc.

9) How were “safe factors” determined and they don’t really seem necessary.

10) Given the data and information presented the purpose of this assessment as stated in the conclusion, “The purpose of this assessment was to evaluate the potential ecological risks of concern that may be associated with ATO use as a synergist in halogenated flame retardants.”, can’t be met. Additional data and information is necessary to evaluate any potential risk. I’m not stating that ATO is a problem but rather that simply we just don’t know or have enough information or data at this point given what was provided in this assessment.

Several of my fellow panelists have provided additional references and databases so I will not repeat the information here. I suggest a thorough search of TOXNET as well as local agencies and stakeholder databases will uncover significant additional information. Following please find additional references and database information that may be helpful.


1. †Presented at the Symposium on Risk Assessment of Metals in Soils, 14th Annual Meeting, SETAC Europe Meeting, Prague, Czech Republic, April 18–22, 2004.


Anan, Y., Kunito, T., Watanabe, I., Sakai, H. and Tanabe, S. (2001), Trace element accumulation in hawksbill turtles (Eretmochelys imbricata) and green turtles (Chelonia mydas) from Yaeyama Islands, Japan. Environmental Toxicology and Chemistry, 20: 2802–2814. doi: 10.1002/etc.5620201220


A.Murciego Murciegoa, A. García Sánchezb (2007), Antimony distribution and mobility in topsoils and plants (Cytisus striatus, Cistus ladanifer and Dittrichia viscosa) from polluted Sb-mining areas in Extremadura (Spain) Environmental Pollution, Volume 145, Issue 1, January 2007, Pages 15–21


Helen C Flynn, Andy A, Phillipa K Bowyer, Graeme I Paton ,Antimony bioavailability in mine soils, Environmental Pollution, Volume 124, Issue 1, July 2003, Pages 93–100

Database sites for more information:

For human risks for antimony/ATO:


For listings of Antimony in Children’s Products:


For other data including specific TRI site data:

Dr. Erik Smolders

Comments are structured according to the 6 charge questions

Question 1: On the on the clarity and strengths and weaknesses of the risk assessment

The section on fate and transport needs to be elaborated to explain the assumption made in the exposure assessment, in the selection of the effects data and, hence, in the outcome of the risk assessment. Let me explain:

This document has basically ignored Sb speciation in water and that all Sb released in an inventory to water becomes readily dissolved and equitoxic as Sb in the tests with SbCl₃. I consider it acceptable as the speciation would not change the conclusion (exposure and effect concentrations are well apart) but the document is too brief in the argumentation and too brief in explaining that they conservatively assumed ATO to completely dissolve.

The ATO is dissolved to Sb(OH)₃ in water, followed by oxidation to Sb(V):

\[
\begin{align*}
    \text{Sb}_2\text{O}_3 & \rightarrow \text{Sb(OH)}_3 \rightarrow \text{Sb(OH)}_6^- \\
    k_{\text{diss}} & \quad k_{\text{oxid}}
\end{align*}
\]

The dissolution rate \(k_{\text{diss}}\) is likely slow and this is well reviewed in the EU risk assessment report (EU RAR, reference in the EPA document). For example, a transformation–dissolution test in water shows that only 14% of the ATO is dissolved after 28 days (described in EU). This slow dissolution rate is one of the reasons why no reliable toxicity data can be generally established with ATO: it takes a longer time to dissolve than the duration of a toxicity test, see also the toxicity data here. The Sb(III) salts (chlorides, sulphates) do dissolve much faster than ATO and are used as a surrogate. The toxicity of an Sb(III) salt in water is the combination of toxicity of Sb(OH)₃ and that of Sb(OH)₆⁻ that gradually forms by oxidation during the toxicity test, the former is more toxic than the latter (see below). The environmental effects due to Sb from Sb₂O₃ is likely lower than that of Sb(III) salts at equal dissolved Sb since the oxidation rate \(k_{\text{oxid}}\) is faster than the dissolution rate \(k_{\text{diss}}\), hence the transient Sb(OH)₃ form is only present in minor fractions during the exposure to ATO, as confirmed by analyses of environmental waters.

The kinetics of oxidation (part 2 of reaction above) are only very briefly discussed on page 16 with the reference to Cutter 1992, this reference is not very relevant for surface water. In that paper, the \(k_{\text{oxid}}\) is 0.008 day⁻¹ i.e. reactions times for oxidation >100 days. The kinetics are derived from data in the Black Sea (transition zone of suboxic-oxic), not for surface water. If applicable for the general waters, that would mean that ATO would be mainly present as Sb(III) in most rivers, because their residence times are less than 100 days (Sb would be in the sea before it is oxidized). More importantly, that would also mean that the assessment should be based on Sb(III) toxicity data. The Sb(III) is more toxic than Sb(V) (Oorts&Smolders, Env. Chem, 2009,6,116). The oxidation kinetics of Cutter are unlikely applicable to aerated surface water. The authors have not used the excellent review of Filella et al (Earth-Science Reviews 59 (2002) 265) that shows that, first, Sb is mainly present as Sb(V) in surface waters and, second, that oxidation in the presences of Fe(III) minerals have a \(k_{\text{oxid}}\) of about 0.6 day⁻¹, i.e. the oxidation occurs within hours to days and can be assumed almost instantaneously. We have found that as well in soil solution (Oorts et al. Environ. Sci. Technol. 2008, 42, 4378).

The document needs to clarify the above reasoning to show that the risk assessment in waters is based on effect of readily soluble Sb(III) salts as a likely worst case for toxicity of ATO in water. In addition, the exposure assessment (modeling) has used the worst case assumption that all ATO is readily dissolved in water, it is worst case since the dissolution rate of ATO is slow. In contrast, for soils, the document has
used the long-term ATO toxicity data for very good reasons but did not justify why they rejected these Sb(III) salt data and only kept the ATO data with “aged soils” (i.e. most ATO transformed). Reasons to reject the Sb(III) salt data are the confounding factors of salt stress and acidification in Sb(III) salt amended soils that are no model for an ATO contaminated soils. The entire reasoning is set-out in the EU RAR (and in Oorts&Smolders, Env. Chem, 2009,6,116) but needs to be added here for justifying the choices.

Additional points

- p. 8, bullet 2: it is not justified to state that the COC was derived from highly sensitive species. One cannot call the species with the lowest NOEC among 3-4 species a “highly sensitive one”.
- p. 47, conclusion bullet point one needs to be deleted or clarified: “the use of ‘antimony compounds’ as a surrogate for ATO …are likely to overestimate exposure potential’: what do you mean with this?. Perhaps that Sb compounds (not ATO) in the release inventory are assumed to have the same fate (release rate?) as ATO? In fact, the transformation of ‘Sb compound’ was not discussed here and that should either be discussed before or simply avoided. Strictly speaking, the worst case assumption is used, i.e. complete and instantaneous dissolution of all Sb forms that are released and that are assumed to have the same effect as Sb(III) salts.

Question 2: On the local exposure assessment using the TRI data and EFast-2 model

- The assessment of ATO from the TRI does not include the releases from use of Sb in ammunition, from application with diffuse environmental emissions (braking lines) and from end-of-life facilities (incineration and landfill). These sources should at least qualitatively be added.
- It must be clarified why ‘local’ sediment and soil data are not evaluated, i.e. near sites with high Sb emission.
- p. 25, on the modeled releases. The sites are selected where -7Q10 values were available. How widely available are these data, i.e. what is the risk that a high emission site is located at a river with no such flow data? This must be clarified.
- p. 25&p42: on the Probabilistic Dilution Model (PDM) and E-FAST2 modeled, please clarify how that works and why you find, to me, an unexpected result in Table 3.7: number of exceedance days is smaller in the second site with higher 7Q10 values than with the site 6.
- The geological background in water is not added to the added Sb in the E-Fast2 model, that is not likely to change the conclusion but it needs to be discussed at least.

Question 3: On the monitoring data

- The water/soil/sediment data should cover all states, not only the states with selected TRI facilities.

Question 4: On fate and transport and bioavailability

- Site specific information is unlikely to change the conclusions of the document since the exposure estimates has used the worst case assumption that the ATO becomes fully dissolved instantaneously and that there are no abiotic constituents that reduce the bioavailability of Sb. However, these assumptions are not clarified or justified with existing literature as explained
above. I suggest that sections on fate (page 16 and p. 46, bottom) are elaborated and that the executive summary clarifies this as well.

- The document section on fate has not discussed the partitioning of Sb between particles and water, i.e. the fraction dissolved in water. In the Filella et al. 2002 paper and in the EU RAR there is plenty of data to justify that, in general, most Sb is present in the dissolved phase. This logically follows because the anionic Sb(OH)₆⁻ has only weak affinity for particulates (logKp<4 in most cases). This should be mentioned to justify that the issue about water filtration (and selection of monitoring data: dissolved or total Sb in water) is not critical for the conclusions here.

**Question 5: Effects assessment**

- Clarification needed on the choice for Sb(III) salt toxicity data in water and not for soils. For water this given above. For soils, on p. 30 it is written ‘these tests were not used for COC derivation due to deficiencies (or discrepancies) in study design and uncertainties associated with inadequate or missing information are summarized in Table 3-4.’, however Table 3.4 does not explain the uncertainties.
- Information on relative toxicity of Sb(III) to Sb(V), see above for details, must be included in the document, e.g. on p. 10.
- p. 30: I’m surprised that there are no plant data mentioned as there are such available, see the EU RAR.

**Question 6: On the risk assessment**

- The risk of long term accumulation of Sb in soils and sediment is not included in this assessment, probably it is not mandatory in the EPA framework. This assessment relates to the actual, not the future risks in soils and sediments and I leave it to the authors to decide if that needs to be added in the summary. Antimony is persistent and can accumulate on the long term in soils and sediments. The risk of this needs modeling to forecast this accumulation and a regulatory choice of the timeframe for modeling (10 years, 100 years, steady state?)

**Details**

1. p. 18, bottom, to rephrase “In aquatic systems, the bioavailability of antimony compounds may be impacted by solubility.” This is incorrectly phrased, the abiotic factors indeed change the solubility but in this section only reference is made to dissolution and bioavailability refers to differences in uptake and toxicity at equal total concentration of a dissolved compound. It is correct that abiotic factors change speciation of Sb and this, in turn, may affect bioavailability.
2. p. 18: “increased adsorption and decreased mobility occur in the presence of oxidized…” replace by higher concentrations of oxidized … (as oxidized Al is the common form in contrast with Fe and Mn that have both oxidize and reduced forms).
3. The document often mentions “ions” whereas it should refer to dissolved Sb. The dissolved forms of Sb(III), for example, is a neutral species. Please replace accordingly.
4. I would avoid the term ‘comparable amounts of ions’ for justifying why other compounds than ATO are used. Be precise in what is meant (e.g. it might be even incorrect: SbCl₃ releases only half of the moles Sb than Sb₂O₃ upon dissolution of the same mole of the substance…)
5. The document incorrectly notes the oxidation state as an ion, e.g. Sb\(^{3+}\) is mentioned whereas it should read Sb(III). The trivalent ion is not known to occur in water, instead mainly the hydrolysis products occur.

6. p. 28/29 on the toxicity data, the argumentation must be improved why the ATO NOEC value for the algae is not used. The EU RAR discusses this at length and explains that the highest concentration tested only yielded 3% inhibition, hence the NOEC is rather meaningless. The phrase “ErC50 value could not be determined due to uncertainties regarding the concentration response “ is, hence, an understatement. The phrase below mentions the “limit concentration”, replace by “highest concentration”.

7. p. 28, just out of curiosity, is a 72h test with algae considered acute in US-EPA, the Table 3.3 does not mention anything but the text suggest acute. The time for cell division is less than 12h for this species, so they do reproduce in 72h.

8. p. 30 ‘For hazard assessment purposes’, should read ‘risk assessment purposes’.

9. Throughout: avoid ppb and replace by µg Sb/L. The ppb term is not scientific and can be confused as µg ATO/L, that is not the same as µg Sb/L.
Dr. Maria Sepulveda

Issue 1. Overall Clarity of the Assessment.

Chapter 1 provides the scope of the assessment and a brief introduction. Supporting information on chemistry, fate, and uses are provided in Chapter 2 and the exposure, hazard, and risk characterizations are presented in Chapter 3. Additional supporting information is available in the appendices.

Question 1-1. Please comment on the clarity and strengths and weaknesses of the risk assessment and provide specific suggestions regarding how this may be improved.

The document states that the “available evidence” suggests that Sb\textsuperscript{5+} is less toxic than Sb\textsuperscript{3+} and that the dissolution and release of Sb ions is “of most importance when assessing the persistence, bioaccumulation and toxicity of Sb” (page 10). However, there is little information presented on how different environmental conditions can impact the presence of penta or trivalent forms, especially in terrestrial systems with no BCF given for plants on Table 2-4. Further, bioavailability of Sb in barely discussed (page 17) and no mention of some important abiotic factors such as presence of organic matter on bioavailability are discussed. It is not clear why bioaccumulation data on marine organisms is presented in this document.

Because of the lack of data for ATO, EPA uses other forms (e.g. SbCl\textsubscript{3}) and assumes no significant impact to the risk findings as both compounds release comparable amounts of Sb upon dissolution (page 10). However, no references are provided that support this assumption.

The document states “publications were critically evaluated based on adherence to specific test guidelines” and …”COCs were calculated using conservative ecotoxicity values derived from the most robust studies available in the published literature” (page 10). This statement is vague and needs clarification. It is obvious that almost all of the toxicity literature reported (except for a handful of citations) did not come from peer-reviewed literature, but from reports that would be considered “gray” literature. Is this acceptable?

A quick literature search covering the last 5 years using the keyword “antimony”, identified several additional studies on Sb toxicity and environmental fate and transport that are quite relevant to this risk assessment but were not included in this document, and over 60 citations from EPA’s ECOTOX datable that are absent from the document (see more on this below under point 5).

In the document it is stated that “it is expected that a significant portion of these (i.e. Sb) releases are associated with the combustion of fossil fuels as opposed to the use of ATO-containing flame-retardants…” (page 24). This means Sb is ubiquitous in the environment, and both aquatic and terrestrial systems likely being contaminated with this metal. So it is puzzling why so much more emphasis was given to aquatic systems and so little emphasis placed on terrestrial systems.

At the end of Chapter 2 it is concluded that “ATO is an environmentally persistent metalloid that exhibits high persistence and low-to-moderate bioaccumulation potential”. “High persistence” and “low-to moderate” are vague and need clarification.
Issue 2. Characterization of Environmental Exposures Based on Release Data.

During project scoping, OPPT identified ATO use as a synergist in halogenated flame retardants as the focus of this assessment. EPA’s 2010 Toxic Release Inventory (TRI) was used to obtain information on water releases associated with this end-use scenario. Data collection was refined using the North American Industry Classification System (NAICS) codes to identify a subset of TRI facilities (i.e., those indicating production, processing or use of ATO-containing flame retardants). Because ATO is not specifically listed on the TRI, data reported under the broader category of ‘antimony compounds’ were used as a surrogate for ATO in this assessment. ATO surface water concentrations were predicted using a screening level tool (E-FAST2), to model water releases reported by selected TRI facilities.

Question 2-1: TRI information reported for ‘antimony compounds’ was used to estimate ATO releases associated with its use as a synergist in halogenated flame retardants. Please comment on this approach.

The document states that “These release scenarios were developed to provide a reasonable range of estimated surface water concentrations for assessing potential risks to aquatic organisms” (page 27). However, it is not clear whether this release data directly relates to surface water pollution. In other words, are the effluents from these TRI companies being released directly to streams and rivers, or are these effluents treated in some way?

Question 2-2: Because TRI does not indicate the number of days associated with reported releases, two exposure scenarios were developed (assuming the total water releases reported in the 2010 TRI occurred over a period of 250 days or, a more conservative scenario of 24 days to provide a range of predicted water concentrations for comparison with hazard benchmarks (concentrations of concern) identified for aquatic organisms. Please comment on the assumptions used to develop modeling scenarios using EPA’s E-FAST2 model to assess aquatic exposures to ATO.

A major requirement for data input into the E-FAST2 model is information on total number of release days per year. Because this data is not provided by TRI facilities, the EPA evaluated two scenarios: a 250 and a 24 release day/yr. For the latter, the document states: “The more conservative scenario was selected because some facilities may only incur releases as a result of bi-monthly cleaning practices” (page 27). This statement is not clear and needs further clarification.

What was the distance of the sampling sites to the TRI faculties? Where these sites always “downstream” from the facilities?

Question 2-3: Please comment on the approach EPA used to estimate environmental releases resulting from uses of ATO as a synergist in flame-retardant chemicals. Are there other data sources or approaches that EPA should consider to estimate environmental releases of ATO in this end-use? If so, please provide citations or data for consideration in further revision of the draft assessment.

The only additional database I am familiar with that could provide further information on ATO releases is Toxnet (http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB).

OPPT used environmental monitoring information obtained from the U.S. Geological Survey-National Water Information System and EPA's STORET database to evaluate antimony levels in environmental media. Data collection was limited to states (n=10) with TRI facilities (n=14) having NAICS codes corresponding to ATO uses as a synergist in halogenated flame retardants.

Question 3-1: Please comment on the use of these large monitoring data sets to characterize ecological exposures to ATO use as a synergist in flame retardants and their representativeness for other locations in the US.

A total of 8,500 water, sediment and soil samples were selected from STORET and USGS-NWIS and used for the exposure assessment (page 24). It is not clear what criteria were used to select these samples. These data set also included samples collected from 1987-2011, but the TRI data used was only from 2010. Why was this done?

It would have been useful to present a probabilistic assessment of ATO concentrations in different environmental media for the whole U.S. Presumably, this analysis could also incorporate important biotic factors (such as pH, etc.) so as to better assess bioavailability and exposure risks across sites.

Question 3-2: Are there other major sources of environmental monitoring data (or other pertinent information) that EPA should incorporate in the exposure assessment? If so, please provide the necessary citations and/or data for inclusion in the revised document.

A literature search for the last 5 years identified several published articles reporting environmental concentrations (including biota concentrations) of Sb. These are not listed in this review, but can be provided if needed.

Question 3-3: Are there concerns or limitations in these data sets that may impact their utility for risk assessment?

Why was data collected over 20 years ago (1987) included? What was the rationale behind this?

The document presents little information on how different environmental conditions can impact the presence of penta or trivalent forms, especially in terrestrial systems with no BCF given for plants on Table 2-4. This is a major weakness and should be addressed. Just as an example, a recent study (not cited in the document) found that neutral pH increases Sb mobility and thus its translocation to plants (Sh et al. 2012). Therefore, it is not clear why so much emphasis was placed on bioaccumulation and toxicity of aquatic organisms, with little data presented on terrestrial systems.

Issue 4. Fate, Transport and Bioavailability.

Information available in the published literature regarding the chemistry, fate and transport of ATO is used qualitatively to assess bioavailability to ecological organisms. There is a lack of site-specific data on geochemistry that would inform specification and availability antimony compounds in its toxic forms for environmental receptors.
Question 4-1: Please comment on the use of this information in the ATO assessment. Are there other data sources that EPA should consider?

This question needs clarification since it is not clear what “lack of site-specific data on geochemistry” means. I would suspect that basic parameters such as pH, temperature and dissolved oxygen levels are available for a large number of sites across the U.S. for which Sb concentrations are also available.

The “Environmental Transformation, Bioavailability and Bioaccumulation” section is almost exclusively focused on aquatic systems (pages 17-18). However, and as already stated, the lack of terrestrial Sb data used in the present risk assessment is troublesome, considering that terrestrial ecosystems are just as likely to be polluted by this metal than aquatic systems.

Issue 5. Environmental Hazard Assessment.

The available hazard information was critically evaluated based on specific test guidelines, accepted endpoints used to assess ecotoxicity, and the amount of detail provided in each study report. Hazard benchmarks (i.e., concentrations of concern) were subsequently derived using the most robust ecotoxicity studies and conservative ecotoxicity values identified in the published literature. Acceptable toxicity data were not available for ATO for both chronic and acute exposures in all media. For this reason, toxicity data for antimony trichloride is used to characterize hazards to water, soil, and sediment dwelling organisms. This is not expected to significantly impact the findings of this assessment because (1) upon dissolution, antimony compounds release antimony ions, and it is the fate and toxicity associated with the total antimony ion concentration that is of most importance when assessing the toxicity of antimony in environmental media and (2) both the oxide and chloride salts of antimony produce comparable amounts of antimony ions upon dissolution in water.

Question 5-1: What other factors should EPA consider in evaluating the potential risks of concern for ecological organisms from antimony species? Please comment on the use of toxicity data for antimony trichloride to characterize hazards to water, soil, and sediment dwelling organisms.

The document states that “The most reliable hazard data were obtained for ATO (Sb2O3) and antimony trichloride (SbCl3)” (page 27). This needs further justification. If what really matters in terms of toxicity are the Sb ions released, why only focus on SbCl3? It is also not clear why for the terrestrial data, Sb2(SO4)3 was also included.

Overall, this risk assessment is based on a very small number of toxicity data. The document states that “Publications were critically evaluated based on the endpoints used to assess toxicity, the amount of detail provided in each study, and adherence to specific test guidelines. Ultimately, the COCs identified for ecological organisms in water, soil, and sediment were based on the most robust ecotoxicity information available in the published literature (Summarized in Table 3-3) (page 27)”. A quick search spanning the last 5 years using Web of Science revealed a total of 25 peer-reviewed articles that present information on exposure and effects of Sb to different ecological receptors that are absent from this table. Furthermore, a quick search using EPA’s ECOTOX database revealed a total of 62 citations (50 for aquatic data and 12 for terrestrial data) related to Sb papers covering the period of 1959-present. These are listed at the end of this document. Why were so many references omitted? Thus overall, is not clear how papers were selected for the current risk assessment.

It is not appropriate to just show LC50 values without also presenting 95% CI. Thus, the data summarized in Table 3-3 is incomplete and even misleading and confidence intervals need to be shown.
It is concluded at the end of the document that the “Use of sensitive ecological species to identify the most conservative COCs showed very few instances where measured or predicted values exceed the COCs for water-, sediment-, or soil-dwelling organisms” (page 47). What does “ecological sensitive” species mean? This document used a scarce number of toxicity data and what was selected was just what was available and not necessarily what was “most sensitive”.

Finally, the main focus of this risk assessment is ATO used as a synergist in halogenated flame retardants since this end-use application represents the largest global market for Sb because it enhances the effectiveness of flame retardants. As a toxicologist, it is difficult to focus on the sole toxicity of Sb when the product formulation that is being evaluated also contains some sort of halogenated (likely brominated) compound. However, this issue is not discussed in the document. If EPA’s risk assessments are by principle only focused on a single compound, then this should be stated in the document.

**Issue 6. Environmental Risk Characterization.**

The ATO assessment evaluates risks of concern posed to ecological organisms as a result of ATO use as a synergist in halogenated flame retardants. Generally speaking, risks are indicated when antimony levels in environmental media (as indicated by environmental monitoring and industrial release information) exceed the hazard benchmarks (i.e., concentrations of concern) identified for ecological organisms in water, soil and sediment. This approach resulted in very few instances where the concern concentrations for water or sediment dwelling organisms were exceeded (< 1%). No exceedances of the hazard benchmarks for soil dwelling organisms were identified. The uncertainties/limitations of this approach are discussed in the ATO document.

**Question 6-1:** Please comment on the implicit assumption that antimony concentrations measured in environmental media reflect many different inputs (i.e., from various end use applications and other types of antimony compounds in addition to ATO) and how this could impact the risk estimation.

As already stated, the major source of Sb ions to the environment is not from end-use of halogenated flame retardants but from fossil fuel combustion. However, since this data is difficult to estimate at this point it is ignored. Also, if what determines toxicity are Sb ions, why just focus on ATO?

**Question 6-2:** The findings reported in this assessment hinge on the assumption that a ‘conservative’ scenario has been presented (based on the assumption that all releases of various types of antimony compounds have been attributed to ATO use in flame retardants) and as such, reflect a conservative estimate of risk of exposure to ATO. Please comment on validity of this assumption and the likelihood that the actual risks of concern posed to ecological organisms have been over (or under) estimated.

**Question 6-3:** Please comment on the data set used to evaluate exposures to soil-dwelling organisms and the limitations and/or uncertainties in estimating risk to soil-dwelling organisms. Please provide comment on additional data sources, surrogate/related chemicals, or approaches to estimate risks under data poor conditions?

These two points have already been addressed. Similarly to sediments, soils may also be major sinks for metals. In summary, based on the scarce data presented on Sb bioavailability, in particular for terrestrial organisms, this risk assessment suffers from considerable uncertainty and so I am not sure it can be determined whether risk of Sb to ecological receptors has been over or under estimated. Additional data
on exposure and effects due to Sb was identified from a literature search and from EPA’s ECOTOX database and are included at the end of this review.
References for Antimony From EPA’s ECOTOX Database That Are absent From the ATO Risk Assessment Document

I. Aquatic Data

Author(s): Goettl, J.P., Jr., J.R. Sinley, and P.H. Davies
Publication Year: 1974
Title: Water Pollution Studies

Reference Number: 638
Author(s): Applegate, V.C., J.H. Howell, A.E., Jr. Hall, and M.A. Smith
Publication Year: 1957
Title: Toxicity of 4,346 Chemicals to Larval Lampreys and Fishes

Reference Number: 720
Author(s): Bringmann, G., and R. Kuhn
Publication Year: 1981
Title: Comparison of the Effect of Toxic Substances on the Flagellate Organisms Such as Ciliates and the Holozoic Bacteria-Devouring Organisms Such as Saprozoic Protozoans (Vergleich der Wirkung von Schadstoffen auf Flagellate
Source: Gas Wasserfach Wasser Abwasser 122(7): 308-313

Reference Number: 2042
Author(s): Tarzwell, C.M., and C. Henderson
Publication Year: 1960
Title: Toxicity of Less Common Metals to Fishes
Source: Ind. Wastes 5:12-

Reference Number: 2054
Author(s): Anderson, B.G.
Publication Year: 1948
Title: The Apparent Thresholds of Toxicity to Daphnia magna for Chlorides of Various Metals when Added to Lake Erie Water
Source: Trans. Am. Fish. Soc. 78:96-113

Reference Number: 2394
Author(s): Bringmann, G., and R. Kuhn
Publication Year: 1959
Title: Water Toxicological Studies with Protozoa as Test Organisms

Reference Number: 2849
Author(s): De Jong, L.E.D.
Publication Year: 1965
Title: Tolerance of Chlorella vulgaris for Metallic and Non-Metallic Ions
Source: Antonie van Leeuwenhoek (Gedrukt) 31:301-313

Reference Number: 2918
Author(s): Khangarot, B.S.
Publication Year: 1991
Title: Toxicity of Metals to a Freshwater Tubificid Worm, *Tubifex tubifex* (Muller)
Source: Bull. Environ. Contam. Toxicol.46:906-912

Reference Number: 2965
Author(s): Curtis, M.W., and C.H. Ward
Publication Year: 1981
Title: Aquatic Toxicity of Forty Industrial Chemicals: Testing in Support of Hazardous Substance Spill Prevention Regulation
Source: J. Hydrol.51:359-367

Reference Number: 3437
Author(s): Williams, P.L., and D.B. Dusenbery
Publication Year: 1990
Title: Aquatic Toxicity Testing Using the Nematode, *Caenorhabditis elegans*
Source: Environ. Toxicol. Chem.9(10): 1285-1290

Reference Number: 3731
Author(s): Dorfman, D.
Publication Year: 1977
Title: Tolerance of *Fundulus heteroclitus* to Different Metals in Salt Waters

Reference Number: 4943
Author(s): Birge, W.J., J.A. Black, and A.G. Westerman
Publication Year: 1979
Title: Evaluation of Aquatic Pollutants Using Fish and Amphibian Eggs as Bioassay Organisms

Reference Number: 5282
Author(s): Hollibaugh, J.T., D.L.R. Seibert, and W.H. Thomas
Publication Year: 1980
Title: A Comparison of the Acute Toxicities of Ten Heavy Metals to Phytoplankton from Saanich Inlet, B.C., Canada

Reference Number: 5303
Author(s): Bringmann, G., and R. Kuhn
Publication Year: 1980
Title: Comparison of the Toxicity Thresholds of Water Pollutants to Bacteria, Algae, and Protozoa in the Cell Multiplication Inhibition Test

Reference Number: 5305
Author(s): Birge, W.J.
Publication Year: 1978
Title: Aquatic Toxicology of Trace Elements of Coal and Fly Ash

67
Reference Number: 5459
Author(s): Kitamura,H.
Publication Year: 1990
Title: Relation Between the Toxicity of Some Toxicants to the Aquatic Animals (Tanichthys albonubes and Neocaridina denticulata) and the Hardness of the Test Solution

Reference Number: 5590
Author(s): Buccafusco,R.J., S.J. Ells, and G.A. LeBlanc
Publication Year: 1981
Title: Acute Toxicity of Priority Pollutants to Bluegill (Lepomis macrochirus)
Source: Bull. Environ. Contam. Toxicol.26(4): 446-452

Reference Number: 5718
Author(s): Bringmann,G., and R. Kuhn
Publication Year: 1977
Title: Results of the Damaging Effect of Water Pollutants on Daphnia magna (Befunde der Schadwirkung Wassergefahrdender Stoffe Gegen Daphnia magna)
Source: Z. Wasser-Abwasser-Forsch.10(5): 161-166

Reference Number: 5719
Author(s): Bringmann,G., R. Kuhn, and A. Winter
Publication Year: 1980
Title: Determination of the Biological Effect of Water Pollutants in Protozoa. III. Saprozoic Flagellates (Bestimmung der Biologischen Schadwirkung Wassergefahrdender Stoffe Gegen Protozoen III. Saprozoische Flagellen)

Reference Number: 6097
Author(s): Amiard,J.C.
Publication Year: 1976
Title: Experimental Study on the Acute Toxicity of Cobalt, Antimony, Strontium and Silver Salts in Some Crustacea and Their Larvae and Some Teleostei
Source: Rev. Int. Oceanoogr. Med.43:79-95

Reference Number: 6533
Author(s): Amiard,J.C.
Publication Year: 1973
Title: Accumulation of Antimony-125 by some Groups of Marine Organism

Reference Number: 6601
Author(s): Bringmann,G.
Publication Year: 1978
Title: Investigation of Biological Harmful Effects of Chemical Substances Which are Classified as Dangerous for Water on Protozoa

Reference Number: 6631
Author(s): Khangarot,B.S., and P.K. Ray
Publication Year: 1989
Title: Investigation of Correlation Between Physicochemical Properties of Metals and Their Toxicity to the Water Flea *Daphnia magna* Straus
Source: Ecotoxicol. Environ. Saf. 18(2): 109-120

Reference Number: 6791
Author(s): Bringmann, G., and R. Kuhn
Publication Year: 1980
Title: Determination of the Biological Effect of Water Pollutants in Protozoa. II. Bacteriovorous Ciliates (Bestimmung der Biologischen Schadwirkung Wassergefahrdender Stoffe Gegen Protozoen. II. Bakterienfressende Ciliaten)

Reference Number: 7136
Author(s): Umezu, T.
Publication Year: 1991
Title: Saponins and Surfactants Increase Water Flux in Fish Gills
Source: Nippon Suisan Gakkaishi 57(10): 1891-1896

Reference Number: 7453
Author(s): Bringmann, G., and R. Kuhn
Publication Year: 1977
Title: Toxicity Threshold for Water Pollutants in the Cell Multiplication Test with Respect to Bacteria (*Pseudomonas putida*) and Green Algae (*Scenedesmus quadricauda*)

Reference Number: 9607
Author(s): U.S. Environmental Protection Agency
Publication Year: 1978
Title: In-Depth Studies on Health and Environmental Impacts of Selected Water Pollutants

Reference Number: 9908
Author(s): Thomas, W.H., J.T. Hollibaugh, and D.L.R. Seibert
Publication Year: 1980
Title: Effects of Heavy Metals on the Morphology of Some Marine Phytoplankton
Source: Phycologia 19(3): 202-209

Reference Number: 10366
Author(s): Heitmuller, P.T., T.A. Hollister, and P.R. Parrish
Publication Year: 1981
Title: Acute Toxicity of 54 Industrial Chemicals to Sheepshead Minnows (*Cyprinodon variegatus*)
Source: Bull. Environ. Contam. Toxicol. 27(5): 596-604

Reference Number: 11838
Author(s): Birge, W.J., J.A. Black, A.G. Westerman, and J.E. Hudson
Publication Year: 1980
Title: Aquatic Toxicity Tests on Inorganic Elements Occurring in Oil Shale
Reference Number: 12284
Author(s): Kimura, K.
Publication Year: 1986
Title: Accumulation and Retention of Antimony-125 in the Short-Necked Clam
Source: Nippon Suisan Gakkaishi 52(3): 531-537

Reference Number: 13580
Author(s): Doe, K.G., W.R. Parker, S.J. Ponsford, and J.D.A. Vaughan
Publication Year: 1987
Title: The Acute and Chronic Toxicity of Antimony to Daphnia magna and Rainbow Trout

Reference Number: 14980
Author(s): Sauvant, M.P., D. Pepin, C.A. Groliere, and J. Bohatier
Publication Year: 1995
Title: Effects of Organic and Inorganic Substances on the Cell Proliferation of L-929 Fibroblasts and Tetrahymena pyriformis GL Protozoa Used for Toxicological Bioassays

Reference Number: 15134
Author(s): Bringmann, G., and R. Kuhn
Publication Year: 1978
Title: Testing of Substances for Their Toxicity Threshold: Model Organisms Microcystis (Diplocystis) aeruginosa and Scenedesmus quadricauda

Reference Number: 15148
Author(s): MacPhee, C., and R. Ruelle
Publication Year: 1969
Title: Lethal Effects of 1888 Chemicals upon Four Species of Fish from Western North America

Reference Number: 16049
Author(s): Tojo, J.L., M.T. Santamaria, J. Leiro, F.M. Ubeira, and M.L. Sanmartin
Publication Year: 1994
Title: Pharmacological Treatments Against Ichthyobodo necator (Henneguy, 1883) in Rainbow Trout, Oncorhynchus mykiss (Walbaum)
Source: J. Fish Dis. 17(2): 135-143

Reference Number: 16050
Author(s): Tojo, J., M.T. Santamaria, F.M. Ubeira, J. Leiro, and M.L. Sanmartin
Publication Year: 1993
Title: Efficacy of Antiprotozoal Drugs Against Gyrodactilosis in Rainbow Trout (Oncorhynchus mykiss)

Reference Number: 16142
Author(s): Sauvant, M.P., D. Pepin, J. Bohatier, and C.A. Groliere
Publication Year: 1995
Title: Microplate Technique for Screening and Assessing Cytotoxicity of Xenobiotics with Tetrahymena pyriformis
Source: Ecotoxicol. Environ. Saf. 32(2): 159-165
Reference Number: 19121
Author(s): Bringmann, G., and R. Kuhn
Publication Year: 1978
Title: Limiting Values for the Noxious Effects of Water Pollutant Material to Blue Algae (Microcystis aeruginosa) and Green Algae (Scenedesmus quadricauda) in Cell Propagation Inhibition Tests
Source: Vom Wasser 50:45-60

Reference Number: 19302
Author(s): Lin, H.C., and P.P. Hwang
Publication Year: 1998
Title: Acute and Chronic Effects of Antimony Chloride (SbCl3) on Tilapia (Oreochromis mossambicus) Larvae
Source: Bull. Environ. Contam. Toxicol. 61(1): 129-134

Reference Number: 61178
Publication Year: 1986
Title: Acute Toxicity of Antimony III to Several Species of Freshwater Organisms
Source: Center for Lake Superior Environmental Studies, University of Wisconsin-Superior, Superior, WI: 12 p.

Reference Number: 61194
Author(s): Bringmann, G., and R. Kuhn
Publication Year: 1959
Title: Comparative Water-Toxicological Investigations on Bacteria, Algae, and Daphnia

Reference Number: 80935
Author(s): Borgmann, U., Y. Couillard, P. Doyle, and D.G. Dixon
Publication Year: 2005
Title: Toxicity of Sixty-Three Metals and Metalloids to Hyalella azteca at Two Levels of Water Hardness

Reference Number: 83925
Author(s): Syracuse Research Corp.
Publication Year: 2000
Title: Results of Continuous Exposure of Fathead Minnow Embryo to 21 Priority Pollutants

Reference Number: 116888
Author(s): Nam, S.H., C.Y. Yang, and Y.J. An
Publication Year: 2009
Title: Effects of Antimony on Aquatic Organisms (Larva and Embryo of Oryzias latipes, Moina macrocopa, Simocephalus mixtus, and Pseudokirchneriella subcapitata)
Source: Chemosphere 75(7): 889-893

Reference Number: 120960
Author(s): Stephan, C.E.
Publication Year: 1978
Title: Chronic Screening Toxicity Test with Daphnia magna
II. Terrestrial Data

Reference Number: 35119
Author(s): Damron, B.L., and H.R. Wilson
Publication Year: 1975
Title: Lead Toxicity of Bobwhite Quail

Reference Number: 44484
Author(s): He, M., and J. Yang
Publication Year: 1999
Title: Effects of Different Forms of Antimony on Rice During the Period of Germination and Growth and Antimony Concentration in Rice Tissue
Source: Sci. Total Environ. 243-244: 149-155

Reference Number: 46846
Author(s): Ainsworth, N., J.A. Cooke, and M.S. Johnson
Publication Year: 1991
Title: Biological Significance of Antimony in Contaminated Grassland
Source: Water Air Soil Pollut. 57-58: 193-200
Reference Number: 56183
Author(s): Rossi,F., R. Acampora, C. Vacca, S. Maione, M.G. Matera, R. Servodio, and E. Marmo
Publication Year: 1987
Title: Prenatal and Postnatal Antimony Exposure in Rats: Effect on Vasomotor Reactivity Development of Pups
Source: Teratog. Carcinog. Mutagen.7(5): 491-496

Reference Number: 56446
Author(s): Poon,R., I. Chu, P. Lecavalier, V.E. Valli, W. Foster, S. Gupta, and B. Thomas
Publication Year: 1998
Title: Effects of Antimony on Rats Following 90-Day Exposure via Drinking Water
Source: Food Chem. Toxicol.36:21-35

Reference Number: 60589
Publication Year: 1991
Title: Comparative Toxicity and Tissue Distribution of Antimony Potassium Tartrate in Rats and Mice Dosed by Drinking Water or Intraperitoneal Injection

Reference Number: 60649
Author(s): Ainsworth,N., J.A. Cooke, and M.S. Johnson
Publication Year: 1991
Title: Behavior and Toxicity of Antimony in the Short-Tailed Field Vole (Microtus agrestis)
Source: Ecotoxicol. Environ. Saf.21:165-170

Reference Number: 61372
Author(s): Kanisawa,M., and H.A. Schroeder
Publication Year: 1969
Title: Life Term Studies on the Effect of Trace Elements on Spontaneous Tumors in Mice and Rats
Source: Cancer Res.29:892-895

Reference Number: 62865
Author(s): Schroeder,H.A.
Publication Year: 1970
Title: Metallic Micronutrients and Intermediary Metabolism: Final Progress Report No. 3

Reference Number: 62929
Author(s): Dieter,M.P.
Publication Year: 1992
Title: Report on the Toxicity Studies of Antimony Potassium Tartrate in F344/N Rats and B6C3F1 Mice (Drinking Water and Intraperitoneal Injection Studies)

Reference Number: 65512
Author(s): Schroeder,H.A.
Publication Year: 1968
Title: Serum Cholesterol Levels in Rats Fed Thirteen Trace Elements
Source: J. Nutr.94(4): 475-480
Reference Number: 65797
Author(s): Schroeder, H.A., M. Mitchener, J.J. Balassa, M. Kanisawa, and A.P. Nason
Publication Year: 1968
Title: Zirconium, Niobium, Antimony and Fluorine in Mice: Effects on Growth, Survival and Tissue Levels
Source: J. Nutr. 95: 95-101