Summary of External Peer Review and Public Comments and Disposition

This document summarizes the public and peer review comments that EPA's Office of Pollution Prevent and Toxics (OPPT) received on the external review draft *TSCA Work Plan Chemical Risk Assessment for ATO.* It also provides EPA/OPPT's response to the comments receive from the public and the peer review panel.

EPA/OPPT appreciates the valuable input provided by the public and peer review panel. The input resulted in substantial revisions to the risk assessment

Peer review charge questions[1] are used to categorize the peer review and public comments into specific issues related to four main themes.

- General Issues on the Risk Assessment Document
- Use of fate, transport and bioavailability information
- Environmental Exposure Assessment
- Hazard and Dose-Response Assessments
- Risk Characterization

[1]These are the questions that EPA/OPPT submitted to the panel to guide the peer review process.

1 Issue 1: Overall Clarity of the Assessment

The charge question under Issue 1 asked the peer review panel to comment on the following:

> *Please comment on the clarity, strengths and weaknesses of the risk assessment and provide specific suggestions for how it may be improved.*

1.1 Terminology

Comment: Peer reviewers stated that proper risk assessment terminology and organization were not used in the ATO risk assessment and suggested that it be restructured to follow EPA's Risk Framework Guidance.

Response: The revised ATO assessment has been revised extensively, including to better align basic terminology and structure with EPA's Guidelines for Ecological Risk Assessment.

Comment: Both public and peer review comments questioned the use of descriptive terms such as, "conservative", "sensitive", "robust" and "persistent" and requested that these terms be defined.

Response: Descriptive terms have been further clarified or removed from the assessment except where these descriptive terms are clearly defined.

Comment: Peer reviewers requested clarification for descriptive terms used to characterize persistence and bioaccumulation potential (*e.g.*, "low", "moderate", and "high").

Response: EPA/OPPT has removed to PBT predictions and descriptors used in draft assessment and included description of relevant data that informs persistence and bioaccumulation in the fate section.

Comment: The acronym "COC" can be interpreted as "chemical of concern" or "contaminant of concern" instead of the risk assessment's intended meaning of "concentration of concern".

Response: This acronym is clearly defined at the beginning of the document in the Glossary of Terms and Abbreviations section.

1.2 Scope

Comment: Public and peer review comments suggested that the report be referred to as a scoping or screening assessment, because it is based on conservative assumptions.

Response: EPA/OPPT acknowledges the conservative assumptions used in the ATO risk assessment. In response to this comment, additional clarifying language has been added in Chapter 1 and the risk characterization Chapter 3, which states that this evaluation is based on available data and modeling; models are described and referenced.

Comment: Public and peer review comments indicated that the risk assessment goals, objectives and scope were not adequately described in the report (*i.e.*, the assessment should be distinguished as either a nationwide, regional, or site specific assessment of past, current or future risks).

Response:
EPA/OPPT has made significant revisions to the ATO risk assessment to improve the clarity of the document. *Chapter 1* of the final risk assessment has been restructured to include additional sections describing Problem Formulation, Conceptual Model and the Analysis Plan for ATO; all of these address the issue of scope and scale of the assessment.

Comment: Peer reviewers identified the focus on aquatic ecosystems as a weakness of the ATO assessment (because most of the reported antimony releases are to terrestrial systems) and suggested that risks associated with land disposal be evaluated as part of the assessment.

Response: In response to this comment, the problem formulation section of Chapter 1 has been updated to provide further explanation for why risks to terrestrial and specifically, soil-dwelling organisms were not evaluated. During scoping, all potential exposure pathways were considered and risks to aquatic and benthic organisms were identified as a primary concern. The terrestrial compartment was not assessed due to limitations in the available monitoring data for soil which precluded a meaningful risk estimation. EPA/OPPT acknowledges that most of the reported antimony releases are to land; however, land disposal of antimony-containing materials is expected to represent a minor exposure pathway based on: 1) the limited bioaccessibility of antimony in soil and 2) existing land disposal regulations under other statues (CERLA and RCRA). Previous evaluations of the land disposal pathway (discussed in sections 3.1.2 and 4.1.3.4 of the European Union Risk Assessment Report support this conclusion.

1.3 Problem formulation

Comment: A lack of clarity was observed in the risk assessment's problem formulation, with some peer reviewers stating that this step was skipped.

Response: Problem formulation was conducted for the ATO assessment; however, in response to this comment, the description of this step has been expanded in Chapter 1.

Comment: Peer reviewers stated that a conceptual model which would have guided the analysis (and provided some justification for why certain environmental compartments were excluded) was absent from the assessment.

Response: To increase transparency, a conceptual model has been added in Chapter 1.

Comment: Public and peer review comments indicated that the assumptions about sources of ATO releases and potential contact with ecological receptors were not clearly communicated in the report.

Response: In response to this comment, the discussion of potential release sources has been expanded and a conceptual model has been added in Chapter 1 and in the analysis approach in Chapter 3. In addition, to increase transparency, further discussion of the primary assessment assumptions has been added to the exposure assessment.

Comment: Public and peer review comments indicated that use of a "worst-case scenario" was not well communicated in the risk assessment.

Response: In response to this comment, the risk characterization section has been updated to include additional clarifying language about assumptions used in the problem formulation and risk characterization that conveys this point. Furthermore, where conservative assumptions or data selections were made regarding exposure or hazard, they are noted.

Comment: Peer reviewers stated that more attention should be placed on assessment endpoints (*i.e*., hazard benchmarks) and data quality objectives.

Response: In response to this comment, Data evaluation criteria are stated and referenced in Chapter 3. Briefly, data adequacy criteria include, but are not limited to: test substance identification, number of organism in each dose/concentration group, dose/concentration level, route/type of exposure, duration of exposure, species, controls (for additional details, see EPA, 1999). Studies conducted according to established EPA or OECD Guidelines as well as studies using other protocols were included if they met data adequacy criteria. EPA/OPPT has also added additional detail to the tables to clarify the critical elements of each hazard benchmark including test type/guideline used, toxicity endpoint and effect.

1.4 Environmental Assessment

Comment: One peer reviewer stated that Chapter 3 of the report should be reorganized to include a discussion of all acute endpoints, followed by a discussion of all chronic endpoints.

Response: EPA/OPPT has revised the Ecological Hazard Assessment section to include separate sections acute and chronic toxicity to aquatic organisms. For sediment-and soil-dwelling organism, all available data were chronic data, so no acute discussion was included.

Comment: Public and peer review comments indicated that the following should be added to the ATO report: 1) the criteria for study selection, 2) a general summary of the hazard and exposure data, and 3) conclusions drawn from previous assessments.

Response: The draft ATO document referenced a general adherence to internationally accepted guidelines (*e.g.*, OECD, OPPTS, ASTM, etc) as the main criteria for study selection; however, EPA/OPPT agrees that further discussion of these topics may serve to strengthen the assessment. In response to this comment, a more transparent discussion of the available hazard information, including specific criteria used for study selection and conclusions drawn from previous assessments, has been added to the environmental hazards section including revised study summary tables.

Comment: Peer reviewers noted that a comprehensive discussion of antimony speciation and how it impacts environmental fate, transport, bioavailability, biotransformation, and bioaccumulation potential is absent from the report.

Response: EPA/OPPT has revised the Environmental Fate section. It includes discussion of fate of antimony in water, sediment, soil and air. In addition, a detailed discussion of environmental bioavailability, transformation and bioaccumulation of antimony has been included.

1.5 Environmental Risk Characterization

Comment: Peer reviewers requested further justification for the decision to use a deterministic approach based on single point estimates, rather than a probability distribution for the exposure concentration and response functions.

Response: Exposure and hazard data currently available for ATO are limited and largely inadequate for a probabilistic approach. However, a probabilistic approach was utilized for modeling releases from TRI facilities to estimate environmental water concentrations. EPA/OPPT maintains that a deterministic approach is most appropriate for evaluating the exposure concentration and response functions when data are limited, as is the case with the available hazard data.

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

The charge questions under Issue 2 asked the peer review panel to comment on the following:

> *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.*

2.1 Use of TRI data for Antimony compounds

Comment: Peer reviewers stated that Industry reported TRI data should not be the sole source of antimony release information due to the inherent limitations in this dataset (*e.g.*, inconsistent and/or incomplete release information, and the lack of verification).

Response: EPA/OPPT reviewed all data sources mentioned in the ATO peer review report; however, most of the reported information was not useful for a TSCA-related assessment because it was too generic with regard to the source of antimony. EPA/OPPT examined numerous reports and databases during the search for relevant release data, and concluded that TRI provided the best available release information because it is the only database that differentiates between the release of antimony compounds and that of elemental antimony, and allows for characterization of environmental releases across industry sectors. The caveats and limitations associated with use of TRI data are explicitly discussed in the ATO assessment.

Comment: One peer reviewer suggested that the assessment be revised to include a qualitative discussion of emissions from other release sources (*e.g.*, ammunition, brake linings) and waste disposal scenarios.

Response: In response to this comment, the problem formulation section in Chapter 1 has been further revised to clearly articulate the decision logic used to narrow the scope of the assessment to ATO use as a flame retardant synergist. This ATO assessment is not intended to present an extensive overview of antimony emissions from all sources across the US and was focused on the highest potential exposures/releases related to TSCA.

Comment: Peer reviewers requested that all TRI-related material be consolidated within the Exposure section of the ATO risk assessment.

Response: TRI information is now presented predominantly in the exposure with some mention of the modeled outputs in the risk characterization section.

Comment: Peer reviewers stated that sample collection details (*e.g.*, distance between sampling sites and TRI facilities) should be reported for the soil data set and an overview of antimony concentrations in biosolids should be included in the report within the context of potential application to agricultural or rangeland soils.

Response: As stated in the ATO risk characterization, EPA/OPPT evaluated the available hazard and exposure data for soil and determined that it was inadequate to support a quantitative risk evaluation. Due to data limitations this pathway was not assessed quantitatively in this assessment and therefore sample collection details were deemed unnecessary.

2.2 Modeling Approach and Assumptions

Comment: Peer reviewers requested that all model input data and assumptions be provided in the risk assessment.

Response: EPA/OPPT has provided modeling input data including the name of receiving stream, and stream flow, in Appendix B of the revised assessment.

Comment: One peer reviewer stated that use of TRI data in the model violated many conditions and assumptions of the model and represented an inappropriate use of the data. Specifically, E-FAST2 requires information on the total number of release days per year, which TRI data do not provide.

Response: EPA/OPPT disagrees with the assertion that TRI data are inappropriate for use in (or violate conditions of) the E-FAST2 model. While TRI data do not include the total number of release days per year, EPA/OPPT developed an approach, including two scenarios, for putting TRI release data into a release days per year context (see next comment). The limitations of the ATO exposure assessment are explicitly acknowledged in the data limitations and uncertainty section. These limitations which are predicated on conservative assumptions does not preclude use of the E-FAST2 model for estimating surface water concentrations at the identified points of release. All model assumptions are clearly articulated in the exposure section of the ATO assessment.

Comment: Peer reviewers requested further clarification for why the 250- and 24-day/yr release scenarios were selected, and whether the 24-day/yr release scenario reflects 24 consecutive days of release.

Response: EPA/OPPT has included more detailed explanation for the release scenarios in the Exposure Assessment section of the revised assessment. Briefly, because the TRI data do not include specific information on patterns of release, two hypothetical release

scenarios were developed to provide an upper and lower bound for the range of daily releases that could be used to estimate surface water concentrations. This allowed for comparisons between estimates based on higher daily release amounts incurred over a shorter time interval (*e.g.*, 24 consecutive days) and a less extreme situation in which lower daily release amounts are incurred over a longer time interval.

Comment: Peer reviewers requested further discussion of the exposure analysis and more information on how the Probabilistic Dilution Model and E-FAST2 model work.

Response: The exposure assessment has been revised to include additional discussion on the Probabilistic Dilution Model and E-FAST2. In addition, detailed information on these models is publicly available on EPA's website: http://www.epa.gov/oppt/exposure/pubs/efast.htm, a link to which is also provide in the revised document.

Comment: In order to help readers understand the geographic relationship between the monitoring data and TRI facilities, peer reviewers suggested that the report provide the HUC-12 code for watersheds impacted by selected TRI facilities, and specific locations for the water monitoring data used in the exposure assessment.

Response: As stated in the Exposure Assessment, none of the identified TRI facilities and environmental monitoring sites were located within the same watershed. As noted in the assessment, the monitoring data were collected for many reasons that are not linked to TRI facilities. It was clear based on the 8-digit scale (HUC-8) used in this report, that the selected TRI facilities were many miles away from the environmental monitoring sites. As such, additional refinement with more detailed information at the HUC 12-digit level would not significantly improve the assessment nor change the conclusions stated therein.

2.3 Alternative Data Sources

Comment: One peer reviewer suggested that data from TOXNET and CTD be used to identify point source discharge data gaps for air, water, and soil in order to improve the accuracy of the estimated environmental releases reported in the 2010 TRI.

Response: Unlike TRI, these databases do not contain point source discharge data. These sources are used primarily by Superfund cleanup programs and are not applicable to the TSCA-related use scenarios evaluated in this assessment. Therefore, these data sources were not included in the revised assessment.

2.4 Alternative Approaches

Comment: One peer reviewer stated that: 1) risk e**s**timation should be based on antimony trichloride rather than the total release of antimony compounds reported in

the 2010 TRI; 2) antimony trichloride can be presumed to be entirely trivalent antimony, whereas the TRI data for antimony compounds have an unknown composition of antimony ions; and 3) trivalent antimony is the more toxic form of dissolved antimony and will result in overestimates of the toxicity associated with TRI discharges.

Response: Given the available market and use information for antimony and related compounds, EPA/OPPT maintains that ATO is the most relevant substance for risk estimation. EPA/OPPT found no conclusive scientific to adequately support the assertion of increased toxicity to ecological organisms following exposure to trivalent versus pentavalent antimony. Because ATO is poorly soluble, antimony trichloride has been used as a surrogate to address data gaps for hazard characterization; however, antimony trichloride acidifies soil and water compartments, and therefore may be considered less reflective of conditions expected in the ambient environment. Only if experimental conditions are normalized (*e.g.*, ecologically relevant pH/ionic strength), can the reported effects be considered relevant for predicting what may occur under ambient conditions in the environment.

Comment: One peer reviewer stated that the risk assessment would benefit from a broader characterization that considers critical phases in the lifecycle of products rather than focusing solely on the largest manufacturing and use sector.

Response: The ATO assessment focused on use scenarios that could be addressed based on the information currently available. A life cycle analysis is unlikely to change the stated risk findings. A lifecycle assessment was beyond the scope of this assessment because of limitations in the database for all the relevant pathways and receptors required for lifecycle assessment.

3 Issue 3: Characterization of Environmental Exposures Based on Monitoring Data

The charge questions under Issue 3 asked the peer review panel to comment on the following:

> *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 use as a synergist in halogenated flame retardants.*

3.1 The Use of Large Monitoring Datasets

Comment: Peer reviewers stated that information presented in the ATO risk assessment was not representative of other locations in the US, and suggested that monitoring data obtained from other states (in addition to those initially selected) be included.

Response: EPA/OPPT acknowledges the data limitations and uncertainties associated with the exposure assessment used for the ATO assessment. The purpose of this effort was to refine the analysis so that it focused specifically on TSCA-related uses. EPA/OPPT did not intentionally limit the analysis to 10 states; however, areas with the highest reported environmental releases (i.e., from industries that potentially use or produce ATO as a synergist in halogenated flame retardants based on TRI reporting) were located in these areas. It was found that these TRI facility release sites were not located within watersheds where the available monitoring data were collected. Therefore, the monitoring data was not used for quantitative risk characterization, but only as a line of evidence support the risk conclusions.

Comment: Peer reviewers suggested that a query of hydrologic unit codes (HUCs) rather than states would allow EPA to better assess whether antimony discharges are causing environmental risk and requested that the HUC-12 code be included in Table 3-2.

Response: HUCs, unlike TRI data, do not allow for the identification of environmental releases that can be associated with TSCA-related uses. Therefore, extensive query of monitoring data that cannot be linked to TSCA-related antimony use is beyond the scope of this assessment.

Comment: Peer reviewers noted a discrepancy in the timeframe associated with the environmental monitoring information and industry reported release data used in the exposure assessment. Questions regarding the use of historical data for this risk assessment were also raised.

Response: Although the historical monitoring data may be useful for inclusion in a weight-of-evidence approach, it was not used for risk characterization in the revised

assessment. In response to this comment, the ATO document has been revised to explicitly state that the historical monitoring data were not use to evaluate current risks.

Comment: One peer reviewer noted that measured antimony concentrations were not considered within the context of background levels that occur naturally in the environment and suggested that a literature search be conducted to find published articles reporting antimony concentrations in the ambient environment.

Response: EPA/OPPT conducted additional literature searches on background antimony concentrations. Distribution patterns for antimony are largely dominated by natural variation, and a high sample density is required to establish a reliable baseline levels in the ambient environment. Because the available monitoring data are limited (in terms of the number of sites sampled over a given area), antimony levels reported in the USGS data set or other published literature may not accurately reflect natural background concentrations. In addition, regional differences in geochemistry and weather conditions, as well as variations in analytical and sampling techniques, make direct comparisons difficult. It is important to note however, that the measured and predicted antimony concentrations reported in the ATO risk assessment are low and do not indicate a concern for elevated background concentrations.

Comment: Peer reviewers suggested that the monitoring data collected for the ATO risk assessment should include waste disposal areas because they are the largest release sources by mass.

Response: Limited and rather uncertain data are available regarding the occurrence of ATO in waste materials and emissions that may be produced by various disposal methods. This exposure pathway is not expected to present the greatest potential for environmental exposure due the limited bioavailability of antimony in the soil and terrestrial compartment, as well as current regulatory, reclamation and recycling activities. In response to this comment, further explanation for the decision not to include the waste disposal exposure scenario in this assessment has been added to the problem formulation section of Chapter 1.

Comment: Peer reviewers noted that the monitoring sites for the STORET and USGS data do not correspond to any of the discharge locations reported to TRI and suggested that this information was used for purposes not originally intended.

Response: EPA/OPPT acknowledges the lack of spatial overlap between the TRI facilities and monitoring data, and the basic utility of the information gleaned from these datasets. Despite the conservative assumptions underpinning this assessment, the environmental monitoring data obtained from these databases showed very few instances where ambient antimony concentrations exceeded or even came near the identified hazard benchmarks that would otherwise indicate a concern for ecological organisms. While this

is informative and provided as a comparison to the findings linked to the TRI facilities, its use in quantitative risk estimation has been deemphasized in the risk characterization.

3.2 Data Set Limitations

Comment: Peer reviewers noted that STORET data do not undergo quality assurance review and require no standard methodology or levels of quantification. It was suggested that spatially and temporally unrelated data be used with caution in the risk assessment.

Response: EPA/OPPT agrees that spatially and temporally unrelated data should be used with caution. EPA/OPPT found that these TRI facility release sites were not located within watersheds where the available monitoring data were collected. Therefore, the monitoring data was not used for quantitative risk characterization, but only as a line of evidence support the risk conclusions.

Comment: One peer reviewer stated that the report lacked an exploratory data analysis (*i.e.*, distribution type, breaks in the information, spatial patterns in the regions).

Response: Given the stated data limitations in the spatial overlap between the TRI facilities and the monitoring data it is unclear how this would improve risk characterization.

4 Issue 4: Fate, Transport and Bioavailability

The charge questions under Issue 4 asked the peer review panel to comment on the following:

> *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 [of] Antimony compounds in [their] toxic forms for environmental receptors.*

4.1 Role of Environmental Factors on Antimony Bioavailability and Transformation

Comment: Peer reviewers noted that Environment Canada's recent review of environmental fate and bioavailability issues for antimony and the European Union Risk Assessment Report provide additional reference information that could inform the ATO assessment. It was suggested that the discussion regarding effects of environmental factors on antimony bioavailability and transformation be supplemented with a summary table indicating how bioavailability is affected by these factors.

Response: EPA/OPPT has revised the Environmental Fate section. It includes discussion of fate of antimony in water, sediment, soil and air. In addition, a detailed discussion of environmental bioavailability, transformation and bioaccumulation of antimony has been included.

Comment: One peer reviewer recommended that EPA use equations rather than single values to quantify antimony's BAF. Others noted that mining studies have measured antimony concentrations in soils and plants and that the principles for soil sequestration and uptake would be similar and could therefore provide general estimates for Antimony's BAF.

Response: EPA/OPPT could find no appropriate equations for calculating BAFs for metalloids and as a matter of principle this not recommended in EPA's metals assessment guidance. In response to this comment, EPA/OPPT has included monitoring information from areas near an antimony emitting smelter to provide additional insights regarding antimony uptake, and the potential for bioaccumulation in the food chain.

Comment: One peer reviewer stated that EPA should explore the literature for studies on antimony pertaining to storage and use facilities, previous mining operations, or accidents along transportation routes.

Response: EPA/OPPT's work plan assessments focus on its TSCA authority, which does not include evaluations of these types of scenarios; however, the monitoring information collected near an antimony emitting smelter has been included in the assessment for context. The revised assessment also speaks to these pathways and the respective regulatory authorities which already regulate them.

Comment: One peer reviewer stated that EPA could use information about antimony bioaccessibility and bioavailability in the peer-reviewed literature to adjust total antimony concentrations in the environment to bioaccessible concentrations.

Response: While site-specific parameters may provide some qualitative context, this information cannot be used quantitatively to determine the bioavailable fraction of antimony, because it is a function of many different environmental conditions (*e.g*., pH, temperature, geochemistry, matrix components, meteorological conditions), that can vary seasonally and temporally. Clarification of this myriad of contributing factors has been included in the revised assessment.

4.2 Environmental fate

Comment: One peer reviewer requested clarification for why antimony's behavior in air and marine waters is relevant to its behavior in fresh water.

Response: As stated in the EU RAR, deposition from combustion sources is expected to be a major source of antimony deposition in marine and freshwater systems. Combustion or incineration processes are likely to transform Antimony compounds to ATO regardless of the pre-incinerated form of antimony. This will release ATO into the air where it can undergo additional transformation and long range transport before being deposited to surface waters or soils through wet and dry deposition. This assessment did not focus specifically on this pathway. Evaluation of monitoring information would have taken into account deposition from air sources but there is no way to provide source attribution at the present time.

Comment: One peer reviewer stated that no obvious attempt was made to understand the fate, transport, and bioavailability of ATO at the sites considered.

Response: This is not a site specific risk assessment; however, a qualitative discussion of antimony fate, transport, and bioavailability can be found in the fate section.

Comment: One peer reviewer stated that fugacity modeling should be applicable to ATO and recommended that EPA identify two to three sites, characterize the routes of exposure, and conduct fugacity modeling.

Response: Fugacity modeling is not applicable to inorganic substances having a negligible vapor pressure, negligible Henry's Law constant and no octanol water partition coefficient. As noted in the Environment Canada Report on ATO: "…Typical mass balance fugacity modeling is also not applicable to Antimony trioxide or to the metal ions that are released from it on dissolution, because, as for other non-volatile chemicals, these substances exert zero partial pressure and fugacity in air…"

Comment: One peer reviewer stated that the partitioning of antimony between particles and water was not discussed in the fate section of the ATO risk assessment, and alluded to existing data which indicates that most antimony is present in the dissolved phase.

Response: Site-specific parameters can impact solubility; however, EPA/OPPT disagrees with the assertion that most antimony is present in the dissolved phase upon release into the environment. Based on reported sediment-water partition coefficients, antimony is expected to sorb to solid particles in aquatic media and precipitate out of solution. As reported in the EU RAR (section 3.1.3.1.3), the solubility of antimony in soil (and its bioaccessibility to soil-dwelling organisms) is limited due to the formation of a Ca-antimonate precipitate. In response to this comment, additional discussion of how the sediment water partition coefficient relates to solution chemistry has been added to the Fate section.

4.3 Bioaccumulation

Comment: One peer reviewer suggested that the Bioaccumulation section be organized into BCF and BAF for soil and water separately.

Response: EPA/OPPT revised the Fate section in the final assessment to incorporate this suggestion.

Comment: State that site-specific information on soil monitoring data can be used to investigate the transformation, bioavailability, and bioaccumulation of antimony in terrestrial systems.

Response: This is not a site-specific assessment, and there are no quantitative methods available at this time which can accurately determine the bioavailable or bioaccessible fraction of antimony based on total concentrations reported in soils or sediments. In response to this comment, EPA/OPPT has updated the Fate section to include a qualitative discussion of antimony transformation in the environment and how it can impact bioavailability to environmental receptors.

5 Issue 5: Environmental Hazard Assessment

Charge questions under Issue 5 asked the peer review panel to comment on the following:

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. 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 was 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.

Comment: One peer reviewer stated that toxicity data from studies using ATO are not similar to toxicity data derived using antimony trichloride (due to a difference in solubility which would require a greater amount of ATO to yield the same number of antimony ions as antimony trichloride), and requested a more in-depth discussion of these environmental chemistry issues.

Response: The data limitations and uncertainties associated with this approach are clearly stated in the environmental hazards and uncertainty sections. EPA/OPPT understands that antimony trichloride, being more soluble, will dissolve faster than ATO. As stated in the ATO assessment, the liberation of ions will be slower for ATO, therefore use of antimony trichloride as a surrogate for ATO represents a conservative approach for assessing aquatic hazards. In response to this comment, the environmental chemistry and hazard sections have been updated to include a more in-depth discussion of antimony dissolution chemistry.

Comment: One peer reviewer stated that the toxicity data do not account for degradation or transformation of antimony that may occur in environmental media or as a result of interactions with other compounds.

Response: Antimony cannot be degraded in the environment, but may be transformed between different chemical phases, forms and oxidation states. These types of transformations generally do not occur within the time frame of an acute or chronic toxicity test and therefore are not expected to impact test results. It is acknowledged however, that the test system should be allowed to reach equilibrium before testing, as the slow dissolution of ATO may create increasing pressure on organisms over time. If toxicity testing is conducted immediately after ATO has been added to the test media, the resulting hazard effects may not accurately reflect those that would be expected at

equilibrium. In response to this comment, clarifying text has been added to the hazard characterization and uncertainty sections to adequately convey this point.

Comment: One peer reviewer stated that the relative toxicities of pentavalent and trivalent antimony should be acknowledged in the report.

Response: As mentioned above, EPA/OPPT located no reliable scientific evidence to definitively support an increased relative toxicity following environmental exposure to trivalent versus pentavalent forms of antimony. As stated in the ATO assessment, antimony does not occur as a single oxidation state in the ambient environment. The equilibrium for redox transitioning between trivalent and pentavalent antimony varies with environmental conditions despite the theory that only one oxidation state should prevail (EU-RAR section 3.2.1). This precludes testing of a single oxidation state, and is one of the main reasons that the ATO assessment was based on the conservative assumption that all measured and monitored levels of antimony represent the total dissolved antimony concentration (even though this clearly is not the case).

Comment: Peer reviewers stated that a thorough review of the scientific literature should be conducted to supplement the toxicity data currently used in the report.

Response: EPA/OPPT reviewed the additional literature provided in the peer review report and found much of this information not to be relevant and/or not particularly useful for various reasons, including the following: 1) studies failed to adhere to the criteria used to establish data adequacy as outlined in the ATO document, 2) did not use a relevant test organism, as described in the OECD test guidelines, and/or 3) did not use ATO, antimony trichloride, or another relevant Antimony moiety for testing purposes.

5.1 Toxicity assessment

Comment: One peer reviewer requested further explanation of the calculations used to derive concern concentrations.

Response: The calculations used to derive concern concentrations are described in the Ecological Hazard Assessment and additional clarification shave been added to describe the use of assessment and uncertainty factors.

Comment: One peer reviewer stated that NOECs and LOECs are unreliable and should not be used in this risk assessment, and suggested it would be more appropriate to use an EC_x.

Response: It is clearly appropriate to estimate EC_x values where the data are sufficient ('fit-for-purpose') and the percent effect level to be estimated has a firm biological basis; however, most studies available to assess hazard for ATO do not fit this profile. Many of

these studies were not designed to quantify the precise concentration at which a specific size effect occurs, but to determine whether there is an effect that needs to be explored further. As such, regression models for these types of experiments (and the EC_x estimates derived from them) offer little value. The advantage associated with use of a NOEC/LOEC approach is that these values reflect actual tested concentrations obtained from toxicity studies which adhere to internationally accepted guidelines for data quality (designed to ensure that only reliable studies are included in hazard characterization). In short, the uncertainty associated with use of interpolation (or extrapolation) methods for derivation of EC_x values, and the questions surrounding data adequacy, and selection of the most appropriate effect level (*i.e.*, EC_{10} or EC_{50}), limit the utility of this approach.

Comment: Confidence intervals should accompany LC_{50} values.

Response: EPA/OPPT has added this information, where available, from the toxicity studies summarized in the hazard characterization section.

6 Issue 6: Environmental Risk Characterization

Charge questions under Issue 6 asked the peer review panel to comment on the following:

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. No exceedances of the hazard benchmarks for soil dwelling organisms were identified. The uncertainties/limitations of this approach are discussed in the ATO document.

6.1 Limitations of Data and Analysis

Comment: Peer reviewers stated that the ATO report should state upfront that the USGS and STORET data are not from the primary watersheds of the TRI facilities. It was further noted that an evaluation of data on a watershed basis instead of a state basis could focus the report on whether the TRI facilities are contributing to environmental risk, and decrease the relevance of other input pathways.

Response: The Environmental Exposure Assessment has been revised to include additional clarifying language which clearly states that the USGS and STORET data are not from the primary watersheds of the TRI facilities identified under the scope of this assessment.

Comment: One peer reviewer requested that the ATO document state up front that statistical analyses were not performed on the exposure data and that a comparison of all data points with hazard benchmarks was used to arrive at a percentage of exceedances.

Response: EPA/OPPT has acknowledged that the divisor used to calculate the percentage of exceedances was the total number of samples obtained from the USGS/STORET databases and that the exposure assessment was not a robust statistical analysis.

Comment: Peer reviewers noted that use of data older than 20 years is not recommended for use in the ATO risk assessment.

Response: In response to this comment, additional clarifying language which states that the ATO risk characterization was based on monitoring data collected over the last three years has been added to the exposure and risk characterizations, and has provided clarification on the data limitations and uncertainty in the risk characterization section.

6.2 Scope

Comment: One peer reviewer noted that a discussion of the effects of long-term antimony accumulation in sediments and soils is currently absent from the report.

Response: Land application of ATO is a complicated issue requiring material flow analysis and model estimates of long-term accumulation that would require considerable time and resources to generate. In response to this comment, additional language which clearly articulates that this issue was not addressed has been added in the Data Limitations and Uncertainty section.

6.3 Risk Characterization

Comment: One peer reviewer suggested that a weight-of-evidence approach be used to balance the input information and help identify which line of evidence is most likely contributing to an overestimate or underestimate of risk.

Response: In response to this comment, an expanded discussion of the available evidence, associated data limitations, expected impacts of the assumptions employed in thee analysis and implications for associated risk estimates have been added in the risk characterization section.

Comment: Peer reviewers stated that proper risk assessment terminology and organization were not used in the ATO risk assessment and suggested that it be restructured to follow EPA's Risk Framework Guidance.

Response: The revised ATO assessment has been revised extensively, including to better align basic terminology and structure with EPA's Guidelines for Ecological Risk Assessment.