

1.0 Introduction

The Occupational Alliance for Risk Science (OARS) is an initiative to facilitate sharing of information with workers and occupational health and safety professionals. OARS provides a forum for information exchange about exposure guidance for chemical stressors, methods for improving occupational risk assessments, and training opportunities. The OARS serves as the home of exposure guide values, including Workplace Environmental Exposure Levels (WEELs) and related guideline documents, for chemical stressors. These guide values and supporting documentation related to worker and community exposure levels for chemical stressors are published by OARS.

The OARS initiative is managed by the non-profit 501c3 organization, Toxicology Excellence for Risk Assessment (TERA). A standing board of science advisors, the Alliance Advisory Board (AAB) has been convened as one component to support the completion of the mission objectives of the initiative.

This Charter documents the roles of the AAB in support of the broader objectives of OARS; and the specific functional needs of TERA and the WEEL Committee functions.

2.0 Purpose and Roles of the Alliance Advisory Board

The Alliance Advisory Board (AAB) is established to provide recommendations and responses to requests for guidance directed from TERA and the WEEL Executive Committee. This advisory body is a critical resource for TERA and the WEEL Executive serving a science advisory function. The AAB is not established as a governing authority - the legal entity managing OARS is TERA and final decisions regarding technical and process matters reside with TERA in coordination with the WEEL Executive as appropriate. TERA will provide staff support to coordinate the operations of the AAB.

Input is sought from the AAB to assist in the achievement of the mission of the OARS initiative. In general, recommendations and input from the AAB can be viewed as supporting the needs of OARS management and science direction through TERA and in support the work of the WEEL Committee through the WEEL Executive.

2.1 Key Functions of the AAB in Support of OARS:

- Provide input on strategic furtherance of the mission
- Make statements on new risk assessment and OEL methods that work toward harmonization
- Serve in outreach and as a liaison with other entities involved in occupational risk assessment to facilitate the sharing of information, including identifying key organizations for Affiliate status.
- Provide input on collaboration agreements and proposed memorandum of understanding agreements

- Serve as a liaison with University training programs with the goal of developing formal mentoring opportunities and concepts for increasing training in occupational risk assessment
- Review financial audits and disclosures to increase transparency

2.2 Key Functions of the AAB in Support of the WEEL Committee:

- OEL request prioritization: Section 4 provides additional details regarding the operational aspects of this function
- Review and provide input on WEEL Committee AOPs
- Provide recommendations on COI issues (per COI volunteer policy) and recommend WEELs
- Provide input on disposition of external comments regarding WEEL Values
- Select representatives to attend WEEL Committee meetings to provide updates on AAB activities

3.0 Alliance Advisory Board Membership

The Alliance Advisory Board (AAB) is comprised of volunteer members who are professionals with specific expertise relevant to guide value development and principles of occupational risk assessment. The AAB is a group of leading scientists providing their own independent opinions – rather than as representatives of their host organizations. In this way, OARS stays informed of emerging issues in occupational risk assessment through the perspectives of key thought leaders, but is not viewed as representing any other organization. There is an envisioned role for organizational representatives to officially engage in the OARS initiative – via Affiliate status. Affiliates would have no legal obligations, just a commitment to the mission of OARS and a willingness to share information as deemed appropriate by both parties. In this way – any like-minded organization can be more or less interactive in OARS as it fits their needs.

The inclusion of the AAB in the overall OARS structure (See figure in Appendix D) is intended as an approach to engage many groups in the public health mission and to encourage information exchange and resource sharing. Thus, outreach to other professional societies and developing linkages with international associations is viewed as a goal of this effort. Outreach with such groups is an important role of the AAB as noted above.

3.1 AAB Nominations and Member Selection

Membership of the AAB is intended to include a balance of leaders with experience working with various stakeholder groups. A full AAB roster is expected to include 12 members. Ensuring a diversity of experience and prior affiliation among the AAB membership is a priority, including those with relationships in professional societies, industry, organized labor, and government, and is expected to enrich the knowledge base for OARS. The AAB will also include a position for the TERA

Program Manager (or designee) and WEEL Executive representative (Past-Chair or other designated officer).

At least annually, the current AAB members will review and analyze the membership roster for the AAB to confirm the continuing eligibility of current full members and to ensure that the members provide a balance of desired scientific expertise and perspectives from diverse organizational affiliations. External recommendations for members will be considered, but a formal nominating process is not planned. Members of the AAB will serve three year terms. Terms are renewable upon recommendation of the Nominating Committee of the AAB and acceptance by a majority of the current AAB members. The Nominating Committee will consist of three AAB members (Chair, TERA Program Manager, and WEEL Executive member). Executive positions on the AAB will include a Chair and Vice-Chair. These positions will be filled by current AAB members. Individuals for both positions will be selected by nomination from a current AAB member and approval of a majority of the current AAB membership.

3.2 AAB Executive Positions

The AAB will have two executive positions:

AAB Chair will:

- Organize and preside over group meetings
- Coordinate the participation of external organizations in the review process with TERA staff
- Prepare the budget, business plan and annual report for the group
- Serve as an ex-officio member of all AAB subcommittees, task forces, and teams
- The Chair shall serve a three-year term of office

AAB Vice-Chair will:

- The Vice-Chair shall automatically succeed the Chair upon completion of the Chair's term of office
- Organize and preside over AAB meetings in the absence of the Chair
- Perform any other duties as delegated by the Chair
- Ensure that the minutes of each AAB meeting are accurately recorded and that approved minutes are communicated to the members in a timely manner
- Work with the TERA staff liaison to ensure that minutes are posted on the TERA web site and retained as set forth by the applicable record retention policy
- The Vice-Chair shall serve a three-year term of office

4.0 Responsibilities of the Alliance Advisory Board (AAB) for WEEL Development Support

A primary function of the AAB is to support the AOPs [do we spell this out?](#) for WEEL Development. The AAB provides support in several areas as noted above. Additional details regarding the processes for (1) WEEL value development prioritization and (2) managing aspects of the WEEL Review and External Feedback processes are described in detail in the sections below.

4.1 Selecting Candidates for Guide Values: Candidate Hopping Process for New WEELs

THE AAB provides input at several key points in the substance hopping process. These include:

- Manage the movement of priority agents through the hopping process, using the initial filtering process to identify Bin 1 *Agents of Interest*
- Determine eligibility for promotion of Bin 1 agents to Bin 2, using the second filtering process
- Prioritize Bin 2 agents, request literature searches for agents of highest concern, and request review of pertinent literature by appropriate Volunteer Group members
- Review data and recommendation of the OARS representative (usually Past-Chair) to determine adequacy of an agent's data set for establishment of a guide value and promotion to Bin 3
- Determine the need for updates to existing guide values based on the submission by a stakeholder of significant new data.

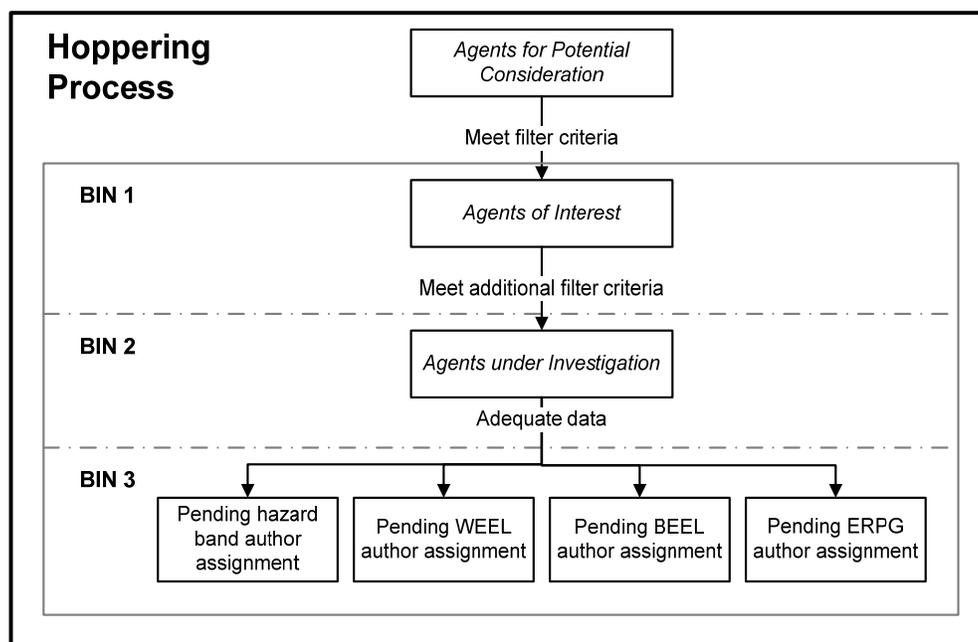
An updated list of agents for guide value assessment is developed and maintained through the hopping process. This process includes three bins to narrow the number of possible candidates to the priority candidates that have adequate data to support guide value establishment. The AAB manages the movement of priority agents through the Bin process. The list of substances considered for a guide value development and their position in the hopping process are to be published at least annually. This list will be available to stakeholders in the public domain.

TERA will go out annually to stakeholders with a call for nominations for chemicals for inclusion in the hopping process. The list of potential agents for inclusion in this hopping process is compiled from:

- ⌘ Lists of high production volume chemicals or agents
- ⌘ Other priority chemicals or agents identified by:
 - Non-government agencies
 - Government agencies, including military and international groups (e.g., European Union, Health Canada)

- Manufacturers and distributors
- Transportation entities, such as shippers and port authorities
- △ Requests from individuals or organizations

Through the nomination process, criteria must be submitted by requestors to substantiate the basis for the request (e.g. exposure, transport, and data availability) that will be considered to move various candidates through the hopping process.



Bin 1

The Bin 1 list, or *Agents of Interest*, includes priority agents for potential establishment of one or more guide values. Bin 1 agents are selected from the pre-bin hopper using a filtering process, managed by the AAB based on the following considerations, which are expected to be provided in the original nomination request for a guide value:

- △ Potential for the agent to be released and generate significant exposures (inhalation, oral, dermal) to workers, emergency response personnel, or the community
- △ Potential for significant adverse health effects (acute to chronic) from inhalation or dermal exposure (these agents can include, but are not limited, to potential carcinogens, genetic toxicants, reproductive toxicants or those that can cause significant and/or irreversible effects to organs or organ systems or significant irritation or discomfort)
- △ Chemical or biological warfare agents or agents of concern based on possible release from terrorism events

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- ⤴ Availability of a regulatory or guide value by a credible organization

Bin 2

Bin 2 agents, *Agents under Investigation*, are selected from the Bin 1 agents through a second filtering process using a ranking methodology resulting in a matrix of data to be used for prioritization. Specific filter considerations may vary for each type of guide value but can include:

- ⤴ Readily identifiable hazard information available from existing published hazard classifications, hazard information data bases, or structural or functional similarity to other chemicals with such data including human and animal data related to the systemic toxicity of the agent by a route of exposure (e.g., inhalation, ingestion, contact)
- ⤴ Readily identifiable information on exposure potential from existing exposure or chemical use databases or from modeling approaches
- ⤴ Anecdotal evidence of hazard potential or risk
- ⤴ Existence of stable chemical markers in biological media like urine, blood, and breath that are related to the internal dose of the agent or its adverse effects by any route of exposure, preferably in a workplace setting, along with sampling and analytical methods for those chemical markers

Bin 3

Agents with data sets adequate to establish a guide value are moved to the Bin 3 list, *Pending Author Assignment*, while the agents with marginally inadequate data sets remain on the Bin 2 *Agents under Investigation* list.

Agents with inadequate data sets are either maintained on the Bin 2 list or are moved back to the Bin 1, *Agents of Interest* list depending on the nature of the incomplete data set and the uncertainty in the guide value that will result.

Requesting stakeholders are informed if a guide value cannot be established due to a marginally or incomplete data set. The agent is re-prioritized for guide value development when additional data are available.

The Alliance Advisory Board (AAB):

- ⤴ Requests, or obtains from a sponsor, a literature search for those agents with the highest concern to determine both the need for a guide value and the availability of scientific data to establish the guide value, the Guide Rationale and/or the Technical Support Document
- ⤴ Works closely with the OARS WEEL members, requesting a review of the pertinent literature and a recommendation regarding the adequacy of the data
 - The weight-of-evidence approach is used to assess the adequacy of the data for any particular guide value

- ✦ Makes a decision regarding the adequacy of the data set for establishment of a guide value and promotion to Bin 3 (See Appendix B for additional information regarding data adequacy)

Prioritizing Agents in Bin 3

The Bin 3 list or *Pending Author Assignment* includes agents that appear to have sufficient data for establishing guide values. Agents with adequate data sets are prioritized for guide value establishment and assignment by the OARS-WEEL Executive following their procedures. Author availability, expertise and interest as well as potential conflicts of interest influences prioritization of Bin 3 agents for guide value development. The overall prioritization scheme is designed to reasonably apportion the work of the OARS between new recommendations and revisions to existing limits and agents of special interest. The Bin 3 list of agents *Pending Author Assignment* is published on the TERA website and is updated at least semi-annually.

Assignment to Author/Reviewer: The OARS-WEEL Chair is responsible to assign an agent to an Author and Reviewer(s).

Stakeholder Outreach

- ✦ A “Notice of Intent” is published on the TERA website, indicating that a guide value is in progress.
- ✦ Interested stakeholders will have at least three months from the time of publication of the “Notice of Intent” to indicate their intent to participate in the process and notify TERA that they plan to participate in the guide value development.

NOTE: An approximate timeline is established, based on urgency of guide value establishment and availability of Author. Since the establishment of guide values relies on the support of expert volunteers, strict timelines will not be established.

4.2 Balloting/Public comment on preliminary guide value

In order to expedite the process for providing guidance documents, OARS-WEEL balloting and AAB public reviews are completed concurrently. Balloting procedures are outlined in the WEEL AOPs.

4.2.1 Public Review

Preliminary guide value(s) are posted to www.tera.org and open 45 day public review period.

At the end of the public review period, comments are collated by the AAB, reviewed for relevance and forwarded to the WEEL Author and Reviewer(s) to determine whether modifications should be made to the Preliminary guide value and Technical Support Document. The Author responds to each comment. The comments and responses are archived by TERA staff liaison to the OARS website. After comments from the public review are addressed, and if modifications are significant and substantive (that is, they would change the proposed /preliminary guide values), the modified Preliminary guide value supporting documents are returned to the Volunteer Group for re-balloting. After re-balloting a second round of open public review following revisions.

4.2.2 Final Review

The Author and QA/QC Coordinator review the draft “final” document for editorial and typographical issues, and the Publication Coordinator ensures the full reference package is available. The QA/QC Coordinator will confirm that the complete reference package for each guide value is posted on the OARS web site, then collect all final Guide Rationales and Technical Support Documents, and forward to them to the AAB and/or the TERA Staff liaison.

4.2.3 Appeals

Persons who have directly and materially affected interests and who have been, or could reasonably be expected to be, adversely affected by a decision of the WEEL Committee shall have the right to appeal actions as per the procedures set out by TERA and the AAB.

4.2.4 Communicating guide values

- ⤴ Final guide values will be posted on the TERA web site.
- ⤴ Guide Rationales and Technical Support Documents will be available from TERA.

4.2.5 Follow up on post-publication comments

- ⤴ Comments on the final guide value are sent to the AAB Chair.
- ⤴ Chair categorizes comments as editorial or substantive
- ⤴ Comments are forwarded to the OARS WEEL Committee Chair to be discussed at the next meeting and documented in Minutes
- ⤴ OARS WEEL actions on substantive comments are addressed in writing to the AAB and archived through the TERA staff.

4.2.6 Periodic Review of Existing WEELs

Based on member availability, existing WEELs will be scheduled for automatic review at least every 10 years. More frequent reviews may be scheduled, based on compelling new toxicity data or information suggesting increased exposure potential.

4.2.7 Data Archival

All data, including literature search, individual scientific publications used in the final Guide Rationale and Technical Support Document, draft comments, suggestions for guide values, Guide Rationale and Technical Support Document drafts are archived electronically by TERA.

A. Appendix: Definitions

Workplace Environmental Exposure Levels (WEELs): Health-based values, expressed as either time-weighted average (TWA) concentrations (WEELs or Short-Term Exposure Levels, or STELs) or ceiling values believed to provide guidance for protection of most workers exposed as a result of their occupations.

WEEL: The TWA concentration, measured in the worker breathing zone, for a normal 8-hour workday, 40-hour workweek, for which it is believed that nearly all workers can be repeatedly exposed without adverse health effects. In general, periods of exposure should be followed by 16 hours of no exposure, can be repeated for 5 consecutive days provided the 5-day exposure period is followed by 2 days of no exposure before the cycle repeats. Application of the WEEL to alternative work schedules should consider the nature of the effects of concern and the toxicokinetic properties of the chemical or agent as described in the WEEL documentation.

WEEL STEL: A WEEL STEL is a 15 minute time weighted average concentration that should not be exceeded at any time during a work-day.

WEEL Ceiling: A WEEL Ceiling is the instantaneous concentration that should not be exceeded at any time during the workday to prevent acute adverse health effects or discomfort.

While it is intended that WEELs provide guidance for protection of most workers exposed to these chemicals or agents, adherence to these levels does not guarantee protection of all workers, particularly those with underlying health conditions, which make them unusually responsive to some chemicals or other agents.

Guide Rationale and Technical Support Document: The completed, reviewed and published document that summarizes and supports the ERPG values (ERPG-1, ERPG-2, ERPG-3), BEEL Method BEEL, Action BEEL, hygienic BEEL, and REMOVAL from Exposure BEEL) and WEEL (8-Hr Time Weighted Average (TWA), 15-min Short-Term Exposure Level TWA (STEL), and Ceiling Level) and associated health hazard bands. Guide Rationales and Technical Support Documents are published annually and updated every seven years (or more often if compelling data are discovered).

Health Hazard Band: A framework used to develop occupational hazard assessments in the face of uncertainties caused by limitations in the human health or toxicology data for a chemical or other agent. Health hazard banding presumes it is possible to group together chemicals or other agents into categories of similar toxicity or hazard characteristics. Such banding can guide risk communication and risk management strategies in the absence of robust dose-response information.

Stakeholders: "Stakeholders" are individuals or representatives from organizations or interest groups that have a strong interest in or are affected by guide values.

B. Considerations for Determining Adequacy of Dataset for Guide Values

Examples of data that are used in the derivation of a guide value include:

- ⤴ Acute toxicity
- ⤴ Irritation/corrosivity
- ⤴ Sensitization
- ⤴ Genotoxicity (mutagenicity and chromosomal damage)
- ⤴ Carcinogenicity
- ⤴ Reproductive and developmental effects
- ⤴ Toxicokinetics (routes of absorption, distribution, metabolism, and elimination)
- ⤴ Structural activity
- ⤴ Include studies of effects in humans at known airborne concentrations, if available
- ⤴ Known human experiences and epidemiology

The adequacy of the data for any particular guide value is assessed using the weight-of-evidence (WOE) approach. Specific data are emphasized differently depending on the type of guide value being established (see Table). WEELs would typically not be established based solely on acute data.

Guide Value Data Criteria Matrix			
Criterion	WOE Value for ERPG?	WOE Value for BEEL?	WOE Value for WEEL?
Acute toxicity (Rat inhalation LC50)	Highly Desired 0.5-, 1-, or 4-hr	Helpful	Helpful
Acute toxicity (Rat oral LD50)	Helpful	Helpful	Helpful
Sensory irritation (RD50)	Desired	Helpful	Helpful
Skin or eye irritation	Highly Desired	Helpful	Helpful
Irritation threshold (ppm)	Desired	Helpful	Desired
Target organ toxicity effect level (e.g., NOAEL, LOAEL, BMD)	Desired	Highly Desired	Highly Desired
Toxicity from repeated-exposure studies by inhalation route (qualitative evidence)	Helpful	Desired	Desired
Severity of target organ toxicity	Highly Desired	Desired	Helpful
Reproductive or Developmental Toxicity effect level	Helpful	Helpful	Highly Desired
Reproductive toxicity (qualitative evidence)	Helpful	Helpful	Desired
Developmental toxicity (qualitative evidence)	Helpful	Helpful	Desired
Genetic toxicity	Helpful	Helpful	Helpful
Cancer bioassay or tumor mode of action data (qualitative evidence)	Helpful	Desired	Desired
Carcinogenicity dose-response	Helpful	Highly Desired	Highly Desired
Other specialty studies (e.g., neurotoxicity or immunotoxicity) or mechanistic information	Helpful	Helpful	Helpful
Warning properties / odor	Highly Desired	Helpful	Helpful
Human Experience – epidemiology, clinical studies, or case studies	Highly Desired	Highly Desired	Highly Desired
Flammability and Reactivity	Desired	Limited value	Limited Value
Toxicokinetics/Toxicodynamics-Human and/or Animal	Desired	Required	Desired
Marker sampling and analytical chemical methods	Limited Value	Required	Limited Value

C. Communicating Draft Guide Values – Recommended Outreach

- ⤴ Proposed components of a “push” mechanism for making draft guide value manuscript and preliminary guide values available to stakeholders
- ⤴ Notification will drive interested parties/stakeholders to TERA web site where they can download/read information
- ⤴ List of current, pending and “under consideration” chemicals
- ⤴ List of “due for review” chemicals
- ⤴ Need to determine groups: do we include academia, government entities, consumers/general public or others as stakeholder groups we need to reach?
- ⤴ Develop list of stakeholders
- ⤴ Contact ANSI, ASTM and other SDO, accrediting bodies for assistance in developing stakeholder list
- ⤴ Always notified
 - Larger trade organizations like NAM, ACC, and SOCMA
 - Labor
 - ASTM, ASSE and other SDOs working on related standards
 - Related OEHS associations/professional membership organizations – ASSE, A&WMA, NEAM, etc.
 - Standard development coordinator or other identified individual within CESSE organizations (150+ engineering and scientific associations including IEEE, ASSE, ANSI, ASTM)
- ⤴ Notified when chemical of interest is under consideration
 - Manufacturers
 - Key distributors
 - Key end users
- ⤴ Identify person and/or mechanism to disseminate information
 - Staff to work to ID specific contact points – standards manager, publications calendar staff person, etc.
 - Post notice on TERA website
 - Make information available electronically at no charge
- ⤴ Longer-term: online “registration” and download to eliminate manual tracking by staff

- ⤴ Develop mechanism to allow persons or groups to “self-register” as a stakeholder
- ⤴ Track email notifications by AIHA to stakeholders, including bounce and read receipts to be able to monitor reach, gaps, and responses

D. Process Flow Diagrams

