DERIVING WEELS AND PREPARING SUPPORTING DOCUMENTATION

A. Introduction

An author and a review subcommittee of two members are assigned candidate chemicals for OEL development. Generally, this is done on a voluntary basis.

For WEEL revisions, a task group of three to four individuals will be appointed on an annual basis to manage the WEEL updates for the year, as described below.

The following describes the procedures to be followed when preparing WEELs.

B. General guides for references

If a stakeholder provides data packages (literature searches and / or retrievals), professional judgment must be exercised in determining the amount of effort to be expended in conducting a supplementary literature search or obtaining additional references including original papers. The more important the reference in determining the WEEL value, the more important it is to obtain the original reference.

The author identifies major producers and users of the material through Internet sources, polling the Committee or TERA staff if assistance as required. Additional information sources may include industry organizations such as the American Chemical Council (ACC), Synthetic Organic Manufacturers Association (SOCMA), American Petroleum Institute (API), etc.

Where additional data is likely to be available, the author requests information on unpublished toxicology, medical or industrial hygiene information from producers and users through the TERA administrative liaison.

C. WEEL Revisions

Revisions are conducted on existing WEELs generally on a ten-year cycle, unless OARS is made aware of significant new data which may impact the OEL. A subcommittee composed of a minimum of three members shall obtain from TERA existing WEEL documentation and a current comprehensive search (including abstracts) of literature published in peer-reviewed journals since the last revision
The subcommittee shall review the literature search results and make a determination of the significance of any new data.

If it is determined that no new relevant or significant data exist which will impact the WEEL level, the WEEL document shall be revised if necessary including the new data, and a note added to the Rationale indicating that no significant new data were found.

If it is determined that data exist which impact the WEEL value, the subcommittee shall obtain copies of the relevant literature and the original reference package for the WEEL and submit the package to the Committee for assignment to an author for revision.

If the assigned author determines that the data packages are incomplete , the author will contact TERA to retrieve the missing literature. If the reference(s) supporting data cited in the previous WEEL Documentation cannot be retrieved, then such data must be deleted in the revision.

Where abstracts were used in previous documentation, the author will determine whether to obtain the primary reference. It is particularly important to verify any references that were used in the Rationale. If the primary reference or authoritative secondary reference cannot be obtained, that reference must not be used as the primary rationale to justify a WEEL but may be used as supporting evidence..

D. New WEELs

New WEELs shall be assigned by the Advisory Board based on their prioritization for review. Full data packages including a full literature search and all published, and if applicable unpublished, literature on the chemical shall be provided to the Committee Secretaryfor author assignment.

If the author determines that inadequate data exist to form the basis for a WEEL, the Committee may consider placing the substance on the list of "substances considered but determined to have an inadequate minimum dataset."

Document Preparation

Where the data set appears sufficient to proceed, the draft WEEL Document will use the format shown in Appendix A using the following guidelines:

Documents will be written and presented in MS WORD 97 ".doc" format (not ".docx").

Line numbers will be added to the entire draft document.

The document will be marked "DRAFT".

Physical properties will be given at at 760 mmHg and 20-25 ^{o}C whenever possible.

Consistent units of measure will be used throughout including mg/kg for LD_{50}s, ppm (gases and vapors) and mg/m^3 (particulates, aerosols).

When no information is available, "No data found" is used.

Negative findings will also be included when summarizing toxicology studies.

The meaning of any abbreviations will be included on first occurrence.

Default conversions for extrapolation from animal data to human exposures should use a 55-kg person, breathing 8 m^3 of air per 8-hour work day. If other body weight or inhalation volumes are used, the conversions used must be stated in the WEEL documentation along with the reasons for deviation from the default values.

Where analogy to another substance is used in setting a WEEL, or in providing additional assurance that a WEEL is protective, the rationale will NOT cite the Occupational Exposure Limit for the other substance. Instead, the rationale should cite the results of the critical study for the comparable material and use that as the basis for deriving or supporting the recommended WEEL.

WEELS are generally based on a weight-of-evidence approach. Safety and/or uncertainty factors are usually not included in the rationale unless justified.

Document Review, Balloting, and Publication

After the author has completed the first draft, the production schedule in Appendix B is followed. Subcommittee members are expected to discuss and review information from key references to the extent necessary to assure themselves that the data are being accurately interpreted.

After incorporation of subcommittee comments, the author posts a copy of the draft and a summary sheet of the proposed document on the Committee Group website, as described in Appendix B, and notifies the Secretary that the document is ready for review.

The summary sheet should include a brief description of the toxicity, identification of key studies, primary basis for WEEL, and any particular issues for Committee discussion.

The Secretary schedules a review of the WEEL draft at the next Committee meeting.

Committee members are expected to have reviewed all such drafts prior to the meeting.

If no major changes are necessary, the attending Committee membership may, by a simple majority, approve the WEEL for balloting. If a quorum is not present, a simple majority of those present may elect to have the secretary conduct an electronic poll of the entire Committee to determine whether to send the draft to ballot. Alternatively, the Committee may direct the author to revise the WEEL and present it for further discussion at a future meeting. The author then reviews additional references, if appropriate, makes the necessary changes and posts the revised draft in the next meeting folder on the Committee Group website.

At the same time that a draft is sent for ballot by the Committee, a copy of the WEEL value, rationale, and reference list will be provided to TERA for use in any applicable stakeholder consultative processes.

If a ballot is not approved by a two-thirds majority of non-abstaining Committee members, it is discussed at the next Committee meeting to determine the appropriate course of action.

Once the WEEL is approved by a two-thirds majority of non-abstaining Committee members, copies of ballot comments are forwarded by the Secretary to the author. All substantive comments must be addressed in the final draft.

Copies of the comments received will be forwarded by the Secretary to the Scientific Content Quality Coordinator.

For all substantive (non-editorial) comments, the author must create a document showing the comment, Committee member name and the manner in which the comment was resolved. Where necessary, the author will consult with the commenter to ensure resolution.

Where negative ballots are cast, the author will contact the commenter and make a record of efforts to resolve the comments resulting in the negative vote. Note that resolution is not always possible. Comments from external sources will be addressed, following the AOP for Resolution of External Comments.

If resolution of a substantive comment results in a change to the WEEL value or a change in the basis for the value, the draft must be re-balloted.

Once a draft has been successfully balloted, the Vice-Chair will provide a notice of the accepted value to TERA.

Once all comments have been addressed on a successfully balloted draft, a copy of the revised draft and the record of resolution of substantive comments will be forwarded by the author to the Scientific Content Quality Coordinator, who will:

Review the draft versus the comments and record of resolution of substantive comments to determine that all comments were adequately addressed.

Review the draft in comparison to the balloted draft to ensure that changes were not substantive (requiring a new ballot).

If no concerns are found, forward the draft and record of resolution of comments to the Publications Coordinator.

Upon receipt of the approved draft and record of resolution of comments, the Publications Coordinator will notify the author to provide all supporting documentation, including reference articles, literature searches, and correspondence with manufacturers and users. The Publications Coordinator then:

Performs a final editorial review.

Ensures the reference package is complete, properly copied into electronic format, and posted to the AIHA server for retention.

Completes the production matrix and keeps the Secretary informed of changes in status of WEELs.

Sends the WEEL Document and all supporting material to TERA for publication.

Monitors publication status, including checking status of WEELs 30 days prior to each meeting and preparing a WEEL Status update for the Committee.

Reviews the galley proofs from TERA with the author, ensuring that no substantive changes occurred in preparation for publication.

APPENDIX A: WEEL FORMAT

WORKING DRAFT: DO NOT CITE OR QUOTE

OCCUPATIONAL ALLIANCE FOR RISK SCIENCE
WORKPLACE ENVIRONMENTAL EXPOSURE LEVEL (WEEL)

(CHEMICAL NAME)

AUTHOR:
SUBCOMMITTEE MEMBERS:
DRAFT NUMBER:
DATES:
REVISION # ___:

I. IDENTIFICATION

Chemical Name: [IUPAC name should be first priority, ACS name second]
Synonyms: [include trade names and common names, where appropriate]
CAS Number:
Molecular Formula:
Structural Formula:

II. CHEMICAL AND PHYSICAL PROPERTIES

Physical State and Appearance: (at room temperature)
Odor Description:
Odor Threshold: [100% recognition should be cited, when possible, for odor thresholds]
Molecular Weight:
Conversion Factors: ____ ppm = ____ mg/m^3 ____ mg/ m^3 = ____ ppm
Melting Point:__ ^oC (___ ^oF)
Boiling Point: ___ ^oC (___ ^oF) at 760 mm Hg
Vapor Pressure: ___mm Hg at ___ ^oC (___^oF) {25 ^oC preferred}
Saturated Vapor Concentration: ___ at ___ ^oC (___oF) {25 ^oC preferred}
Flammability Limits: LEL: ____% in air; UEL: ____% in air
Flash Point: (closed cup) ___ ^oC (___^oF) (cite open cup if closed cup is not available)
Autoignition Temperature: ___ ^oC (___^oF)
Specific Gravity: ___ at ___ ^oC (___^oF)
Solubility in Water: ___% by weight at ___ ^oC (___^oF)
Stability:
Reactivity and Incompatibilities:
Cite Partition Coefficient (Ko/w) if available
Cite Ionization Constant(s) (pKa) if applicable and available

III. USES (volume information should not be cited in the document).

IV. ANIMAL TOXICITY DATA

A. Acute Toxicity and Irritancy [1-5 days]

1. Oral Toxicity
2. Eye Irritation
3. Skin Absorption
4. Skin Irritation
5. Skin Sensitization
6. Inhalation Toxicity [state exposure method, concentration, duration.]
7. Other Toxicity [include subcutaneous, intraperitoneal, intravenous, etc., if useful in understanding the nature of the toxicity for purposes of the WEEL] Delete this heading if no data is reported.

B. Subacute Toxicity [6-28 days typically]

C. Subchronic Toxicity [29 days to 6 months typically. List each study separately in order of duration rather than route. Give duration, route, species, all doses tested and the effects observed at each dose.]

D. Chronic Toxicity/Carcinogenicity [>6 months; present in same manner as subchronic studies.]

E. Reproductive/Developmental Toxicity

F. Genotoxicity/Mutagenicity: Where such studies have been performed by multiple techniques, the order in which such studies are to be presented is bacteriological screening tests (such as Ames test); then other *in vitro* tests, followed by *in vivo* tests.

G. Metabolism/Pharmacokinetics

H. Other [Include results of studies on immunotoxicity, neurotoxicity, and other data that do not fit into previous headings. Delete this heading if such data are not cited.]

V. HUMAN USE AND EXPERIENCE
Include industrial hygiene, epidemiological and medical information such as exposure levels, subjective response data and medical observations.

VI. RATIONALE
Give basis for recommended WEEL. Describe the data, critical endpoints, and judgments used in selecting the number. Do not introduce any new data in the Rationale which does not appear in the appropriate section of the document. References are not normally cited in the Rationale. Do not generally include safety or uncertainty factors in the rationale unless justified.

VII. RECOMMENDED WEEL

Give in both ppm and mg/m^3 with unit time, if appropriate based on physicochemical characteristics. If the material will be predominantly an aerosol (whether liquid or solid) at ambient temperature, the WEEL need only be expressed as mg/m^3. Unless otherwise stated, WEELs are expressed as 8-hour TWAs.

Include a short-term exposure limit, if appropriate. Note that in the absence of a STEL, the Committee presumes that excursions in worker exposure level may exceed 3 times the TWA for no more than a total of 30 minutes during a workday, and under no circumstances should they exceed 5 times the TWA, provided that the TWA is not exceeded. Thus, a STEL is appropriate if adverse effects are reasonably anticipated even for excursions not exceeding these limitations.
When the health effect to be prevented occurs immediately upon exposure, a Ceiling limit will be established instead of a STEL or TWA.

When compliance with a STEL limit alone obviates the need for a TWA, no TWA limit will be established.

Consider a "Skin" notation if the material may be absorbed in toxicologically significant amounts (e.g. Dermal LD_{50} <1,000 mg/kg).

Include DSEN and/or RSEN notations if criteria are met; see AOP on DSEN/RSEN notation.
Generally, a WEEL will not be set higher than 1,000 ppm for vapors or gases or
5 mg/m^3 (respirable dust) and/or 10 mg/m^3 (total dust) for aerosols.

VIII. REFERENCES

Include a statement listing the literature databases searched.

Always cite primary references when possible; e.g., avoid use of NIOSH RTECS as a reference citation. Secondary references may be used if authoritative but attempts should always be made to retrieve the primary reference if it is the pivotal study used to establish a WEEL.

TERA technical staff will revise the citations in the text and the bibliography to conform to approved format before publication.

Note that personal communications without supporting data are not acceptable.

Companies may provide proprietary data supplied under an agreement of confidentiality. The title of the study report shall be listed as a reference, however in order to be included as part of the WEEL document the company shall agree to made the study available to WEEL Committee members for examination in consultation with TERA.

APPENDIX B. WEEL PRODUCTION TIMETABLE

ACTIVITY	PERFORMANCE GOAL	USUAL DRAFT NO.
Author submits draft to subcommittee and notifies Committee Secretary.		1
Subcommittee comments to author and notifies the Committee Secretary	30 days to provide comments to author	
Author posts revised draft on the website and notifies the Committee Secretary	30 days to revise draft and post	1
Once a sufficient number of draft documents are ready for consideration, the Committee Secretary establishes meeting date and location in consultation with membership	60 days prior to meeting	
The full Committee reviews and determines if draft is ready to ballot. A simple majority of those members present is required.	Committee meeting	1
If document is not adequate, the author shall solicit comments, revise the draft and submit to the subcommittee for review.	Within 45 days	2
If document is forwarded for balloting, Author revises WEEL and sends to the Committee Secretary for balloting.	Within 45 days of receiving comments	
The Committee Secretary forwards the proposed WEEL, rationale and references list to TERA to coordinate public review and comment.	Post by date of issue of ballot	
All members return ballots to secretary	30 days from ballot issue	
Deadline for receipt of public comments to be considered in drafting	45 days from posting to TERA web site	
Substantive comments (if received during balloting) are discussed as necessary	Second meeting	2
Author incorporates comments and sends final document to Scientific Content Quality Coordinator	30 days after receiving ballot comments	FINAL