



Department of Pesticide Regulation



Mary-Ann Warmerdam
Director

MEMORANDUM

Arnold Schwarzenegger
Governor

TO: Human Health Assessment Program Staff **HSM-05001**
(Rescinded on April 26, 2010 with approval from S. Edmiston)

FROM: Chuck Andrews, Chief (original signed by C. Andrews)
Worker Health and Safety Branch
(916) 445-4260

DATE: May 17, 2005

SUBJECT: FINALIZING, REVISING, AND RELEASING EXPOSURE ASSESSMENT DOCUMENTS AS HEALTH AND SAFETY REPORTS: **UPDATED TO INCLUDE ATTACHMENT OF EM06-04**

This memorandum supercedes all previous Branch procedures regarding reviews, revisions, and releases of exposure assessment documents (EAD). These procedures were revised to incorporate new responsibilities of the Program Technician (PT), and provide more flexibility to modify and release draft EADs. Memoranda dated December 21, 2001 (HSM-01018, C. Andrews to Worker Health and Safety [WHS] Staff) and December 22, 2000 (HSM-00006, C. Andrews to WHS Staff) are rescinded.

Health and Safety (HS) Reports are considered draft documents during the following processes:

- (1) scoping and drafting;
- (2) internal peer review within the WHS (i.e., WHS Branch Peer Review);
- (3) internal peer review by other branches (i.e., Department of Pesticide Regulation (DPR) Peer Review); and
- (4) external peer review by the Office of Environmental Health Hazard Assessment (OEHHA), U.S. Environmental Protection Agency (U.S. EPA), other government agencies and other stakeholders; and
- (5) final review of the EAD and risk characterization document.

Only the Branch Chief may approve sending draft documents outside the Branch. Staff will not release draft documents. Refer all requests for release of draft documents to the PRM or PT for Branch Chief approval and release. These procedures are not intended to impede communication between WHS scientists and other regulatory agencies (e.g., U.S. EPA). Staff shall consult with their supervisor if there are questions whether the exchange of information is covered by these procedures.

The following outlines WHS Branch procedures for finalizing EADs as HS reports. No deviations from this policy are allowed without Branch Chief approval. The Author must follow the WHS Branch Peer Review Process (see attached flow chart) to finalize the document. Keep in mind that you should allow approximately a three-month period for Branch and DPR peer review.

Finalizing EADs as HS Reports

- A. Staff obtains an HS report number for all EADs. The book for assigning HS numbers is kept by the Program Technician (PT; currently Olga Escobar).

- B. For all EADs, the lead author completes, at minimum, the Title (title of document), Subject (active ingredient), Author (always DPR; requirement of PDF documents posted online), and key words in the summary tab of the Properties dialog box in your Word document. This information is required for all PDF documents posted online and follows the Word document when it is converted into PDF format. It is DPR policy to put DPR as the author in this dialog box.

- C. The peer review and approval process includes:
 - 1. WHS Branch Peer Review**
 - a. The lead author submits the document to the PT for Branch peer review. The Author incorporates the term “Draft” on each page of the document.
 - b. The PT assigns two WHS reviewers to comment on the document. Reviewers provide written comments to the PT within three weeks. The PT submits all comments to the Peer Review Manager (PRM; currently Susan Edmiston) who reviews the document and compiles all WHS comments. The PRM forwards comments to the Author through the PT.
 - c. The author prepares written responses to the comments and sends the edited document (if any) and response via the Senior Toxicologist to the PT who forwards all documents to the PRM. The PRM reviews the Author’s responses to the comments and the edited document. At this point some negotiation may take place between the lead author, PRM, and supervisor.
 - d. When the document is ready for DPR Review, the PRM prepares a supplemental approval sheet. The PT obtains approvals to release the EAD for DPR review from the lead author, PRM, Senior Toxicologist, and Branch Chief.
 - e. The PT sends the lead author’s response to reviewers (if requested).

 - 2. DPR Peer Review:**
 - a. The lead author ensures the term “Draft” is typed on each page of the document. The PT sends the draft EAD and the signed supplemental tracking sheet to the Medical Toxicology Branch and the Environmental Monitoring Branch. DPR reviewers are given three weeks to provide comments. The PT collects all comments and forwards them to the lead author.
 - b. The lead author prepares written responses to the comments and sends the edited document (if changes are made) and response via the Senior Toxicologist to the PT who forwards to the PRM. The PRM reviews the Author’s responses to the comments and the modified document. At this point some negotiations may take place between the lead author, PRM, and supervisor.

- c. When the document is ready for External Review, the PRM prepares a supplemental tracking sheet. The PT obtains approvals to release for external review from the lead author, PRM, Senior Toxicologist, and Branch Chief. There may be some negotiation between the lead author and Branch Chief during this step.
- d. Upon approval from the Senior Toxicologist, PRM, and Branch Chief, the PT sends a copy of the lead author's written response to persons who commented.

3. External Peer Review (e.g., OEHHA, U. S. EPA, other agencies):

- a. The lead author incorporates the term "Final Draft" on each page of the document and submits the document to the PT for external review. The PT forwards the final draft document and signed supplemental tracking sheet to the Medical Toxicology (MT) Branch. (The MT Branch assembles the documents into a final draft Risk Characterization Document [RCD] and forwards it to the Registration Branch for external review distribution. The Registration Branch sends the final draft RCD [including final draft EAD] to OEHHA and U.S. EPA along with a cover letter. The Registration Branch sends a letter informing the registrant that the final draft RCD [including final draft EAD] is available for review.)
- b. OEHHA and U.S. EPA are requested to review the document and submit comments within 30 days. The lead author notifies the PT upon receipt of comments from external reviewers. The lead author considers the comments and prepares written responses (e.g., memorandum to the Senior Toxicologist) addressing the comments submitted by OEHHA, U.S. EPA, and registrants. If no comments were received, the lead author prepares a memorandum to the Senior Toxicologist for the RCD file indicating that no comments were received.
- c. Other institutions (including the Scientific Review Panel) and regulatory agencies may review a final draft RCD (including the exposure assessment) prior to finalizing the document. Final draft documents sent to the registrant must be made available to the public upon request; refer all requests to the PRM or PT. The lead author must consider all comments before the document is forwarded for final review and approval. The lead author must prepare a response to each commenter (e.g., memorandum to the Senior Toxicologist) addressing the comments submitted.
- d. Upon Senior Toxicologist approval, the lead author sends the comments, responses and the final document to the PT who forwards to the PRM. The PRM reviews responses to comments and the final document. At this point some negotiation may occur between the lead author, supervisor and PRM.
- e. Update the pesticide sales, pesticide use, label and illness data if greater than one year. The Branch Chief may approve a waiver of this requirement with adequate justification. The lead author should submit the request and justification to the PRM through the Senior Toxicologist.
- f. The lead author, PRM, and Senior Toxicologist will sign the tracking sheet indicating approval of the final draft and responses to external review comments.

4. Final Branch Document Approval

- a. The PRM (through the PT) forwards the signed tracking sheet and peer review package with the lead author's responses to external review comments to the Branch Chief for final review and Branch approval of the external review comments and the EAD. At this point there may be some negotiation between the Branch Chief and lead author.
- b. The Branch Chief, in coordination with the MT Branch Chief, writes a cover memorandum/letter to the external reviewers. All responses to external review comments will be included in the RCD file and made available to the public. The PT sends the documents to the external reviewers (except registrants) and includes a copy in the RCD and the Branch peer review folders. Each response to a pesticide registrant is forwarded to the Risk Assessment Coordinator in Registration (currently Ann Pritchard); the Risk Assessment coordinator will send the response to comments to the registrant.
- c. After the responses to comments are sent to the reviewers, the Branch Chief approves the EAD as final. However, until the Assistant Director approves the RCD for release, the EAD may not be released to the public without Branch Chief approval.

5. Assistant Director Approval

- a. The WHS and MT Branch Chiefs prepare a memorandum to the Assistant Director requesting RCD approval.
- b. After the Assistant Director approves the RCD (including EAD), it is completed and can be released to the public.

Release of Completed Exposure Assessment HS Reports

- A. Generally, only completed documents approved by the Assistant Director are made available to the public. Completed documents approved by the Assistant Director are in the HS report index (see WHS Home Page for access) and available via the WHS and DPR web site.
- B. If you are unsure of the document status, please contact the PT or PRM for guidance.
- C. The WHS Branch maintains, on the DPR web site for distribution to the public, only the most recent revision of an HS report. Electronic copies of earlier approved report versions will be maintained for historical purposes in the Branch archives. These versions will be available to the public only if specifically requested. Staff should check with the PT or PRM for electronic copies of earlier versions.

Revising Completed Exposure Assessment HS Reports

The following outlines WHS Branch procedures for revising Branch and Assistant Director approved exposure assessment documents as HS reports:

- A. An author may need to modify the EAD after it is approved by the Branch Chief, but prior to receiving RCD approval (RCD includes completed EAD) from the Assistant Director. The author receives approval in writing from the Senior Toxicologist. The Author briefly describes in the memorandum the reason(s) for the modification and the portion(s) of the document affected. The Senior Toxicologist provides a copy of the written approval to the PRM, through the PT.
1. Once approval is received, the lead author obtains an electronic copy of the document from the PRM or PT to modify a completed HS report. Before a modified HS report is finalized, the lead author and the PRM discuss the changes to determine whether WHS Branch peer review are necessary.
 2. If the most current pesticide sales, use, and illness data are greater than one year old, the lead author must update the information. The Branch Chief may waive this requirement with adequate justification; submit justification to the PRM through the Senior Toxicologist.
- B. After the Branch Chief and the Assistant Director sign off on an EAD as a HS report, **no** revisions will be made unless approved in writing by the Senior Toxicologist. HS report revisions that may be approved include any change in exposure values, data calculations, statistical analyses, new use report data, or the addition of other information or data. An author requesting a revision to make only editorial changes will generally not receive approval. The Senior Toxicologist must provide a copy of the written approval to the PRM and the PT.
1. Once approval is received, the lead author obtains an electronic copy of the document from the PRM or PT to revise the completed HS report. Do not use any other copy to initiate a revision. The lead author briefly describes in the report (usually in the abstract and introduction) the reason(s) for the revision and the portion(s) of the document affected.
 2. The lead author includes a revision number and a revised date on the document. The HS number will remain the same. Leave the original date and any previous revision dates on the document. The document should contain the following or substantially similar format:

TITLE
Author
HS-XXXX Date
Revision No X Revised Date.

3. Before a revised HS report is finalized, the lead author and the Peer Review Manager discuss the changes to determine whether WHS Branch peer review is necessary. The PRM and Branch Chief determine whether DPR and External peer review of the revised document is necessary. If DPR and external peer review is necessary, the PT immediately notifies other branches involved in the peer review process that a completed HS report will be revised.
4. The lead author and the PRM must follow the procedures in “Finalizing EADs as HS Reports.”
5. The previous HS report will be maintained for historical reference.

If you have any questions, please contact your supervisor.

Attachment

cc: Tobi L. Jones, Ph.D., Assistant Director, Division of Registration and Health Evaluation
Gary T. Patterson, Ph.D., Chief, Medical Toxicology Branch
Barry Cortez, Chief, Registration Branch
John Sanders, Ph.D., Chief, Environmental Monitoring Branch

WH&S BRANCH PEER REVIEW Exposure Assessment Documents

