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MEMORANDUM

TO: Paul H. Gosselin, Assistant Director
Division of Registration and Health Evaluation
HSM-99001

FROM: John Sanders, Branch Chief
Worker Health and Safety Branch

DATE: March 24, 1999

SUBJECT: EXPOSURE SCENARIO SCOPING PROCESS AND MITIGATION DOCUMENT DEVELOPMENT PROCESS

Attached is a description of the Exposure Scenario Scoping Process. This is the process that the Worker Health and Safety Branch (WH&S) uses to identify all relevant exposure scenarios for the exposure assessment of each active ingredient.

The document also contains a description of Mitigation Document Development Process. This process follows the completion of the Risk Characterization Document which identifies occupational and non-occupational use practices with unacceptable exposure scenarios. The Mitigation Document identifies the mitigation measures that will reduce exposure to an acceptable level.



The Exposure Scenario Scoping Process
and
The Mitigation Document Development Process

March 24, 1999

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Background

In 1995, the Risk Mitigation Coordination Quality Improvement Team recommended improvements in the Department of Pesticide Regulation's (DPR) risk mitigation process. Although the Team's Charter was limited to risk mitigation, they concluded that improvements in the preceding risk assessment process, specifically in exposure assessment, would strengthen the risk mitigation process. The Team recognized that the content of the exposure assessment impacted both the subsequent risk mitigation proposal and the efficiency of the inter-branch risk mitigation review process. The Team's recommendations included: inter-branch exposure scenario scoping meetings to identify and select the most important exposure scenarios, commitment of Branch Chiefs to consistent staffing representation throughout the process, development of a document library available to all participating staff, and better information sharing. To improve both the exposure assessment and risk mitigation processes, the Worker Health and Safety Branch (WH&S) developed the "Exposure Scenario Scoping Process".

An "exposure scenario" refers to any situation where people may contact pesticides or pesticide residues, regardless whether the contact is passive or active, occupational or non-occupational, incidental or constant, and expected or unanticipated. A pesticide exposure assessment identifies the most important exposure scenarios and then estimates, for each situation, the amount of pesticide a person may inhale, ingest, or absorb through the skin. The identification and selection of appropriate exposure scenarios allows the author to produce a comprehensive and concise exposure assessment document.

The "Exposure Scenario Scoping Process", based on the Team's recommendations, provides for objective identification, evaluation, and selection of exposure scenarios; promotes consistency between different authors; and invites Branch staff input in the exposure assessment process. To facilitate inter-branch review, the author prepares an exposure scenario scoping proposal that summarizes important background information, documents how the author used this information in the selection process, and identifies the exposure scenarios the author wishes to include in the exposure assessment. Depending on the proposal's complexity or length, the author may choose between an individual review with written comments or an inter-branch scoping meeting. Since the expanded proposal contains data summaries, background information will be kept in a document chronology and made available to the reviewers upon request.

Steps in the Exposure Scenario Process

<u>Step</u>	
1	The WH&S Branch Chief assigns an author to an exposure assessment for each active ingredient (a.i.) entering risk.
2	<p>The author creates and maintains a complete document file for each exposure assessment, including but not limited to:</p> <ul style="list-style-type: none"> • correspondence • written comments • background information (Pesticide Use Report, Pesticide Illness Information, Mill Assessment information, pesticide labels) • Any other information used by the author to develop an exposure assessment.
3	<p>For the Exposure Scenario Scoping Proposal, the author or assigned designee obtains the following information from:</p> <p><u>Information Technology Office</u></p> <ul style="list-style-type: none"> • The most recent 3-5 years of pesticide sales data, including registration number, product name, pounds of product sold, and pounds of a.i. sold. • The pesticide sales database tends to be more current than the pesticide use report database. When comparing pesticide sales and use report information, try to use the same time period for each type of data. <p><u>Environmental Monitoring and Pest Management Branch</u></p> <ul style="list-style-type: none"> • The most recent 3-5 years of pesticide use report information. To assure productive query results, the pesticide use report information request must use the data fields identified in Information System's data dictionary. <p><u>Worker Health & Safety</u></p> <ul style="list-style-type: none"> • Request at least 5 years of illness and injury data associated with exposure. For a short narrative description of each case, request a detailed report for definite, probable, and possible categories. For a numeric description, request the report Summarized by Activity and Type of Illness/Injury. • Activity patterns of residents (from sources such as: the California Air Resources Report, U.S. EPA Exposure Factors Handbook). <p><u>Pesticide Registration Branch:</u></p> <ul style="list-style-type: none"> • The author requests a review of the labeled pesticide uses

from the WH&S label reviewer, allowing at least one month to complete the review.

- The reviewer will provide a list of currently registered pesticides and copies of the pesticide labels to the author.
 - * If there are 20 registered pesticide products or less, the reviewer should review and copy all labels.
 - * If there are more than 20 registered pesticide products, the reviewer should examine as many labels as feasible and make copies of those that represent the range of use sites registered for the a.i. The reviewer has the discretion to determine the number of pesticide product labels reviewed and copied.
- The reviewer will examine Special Local Need (24c) and Emergency Exemption (18) labels and obtain copies only when the use patterns create exposure scenarios not already included in the regular labeling.
- If the reviewer discovers registered agricultural pesticide product labels that do not comply with the federal Worker Protection Standard (WPS), the reviewer will send written notification to the registration specialist and registration supervisor. The reviewer should avoid selecting non-compliant agricultural labels unless the number of registered products is very limited. The author may opt to include the use sites shown on non-compliant agricultural labeling after discussing the situation with the reviewer.
- As part of the label review, the reviewer tabulates the following information from selected labels:
 - * formulations
 - * registered trade names
 - * percent active ingredient
 - * use sites
 - * label required PPE
 - * engineering exemptions
 - * reentry intervals
 - * other information deemed necessary by the author

Pesticide Enforcement Branch

- Since some regulatory requirements and departmental policies affect pesticide handling and reentry activities, the author should review pertinent state laws, regulations, and policies (Enforcement Letters, B Section of the Enforcement

	<p>Manual, Information Requests and Label Interpretations). Consult the Pesticide Enforcement Branch for help with this review.</p> <p><u>Other Information</u></p> <ul style="list-style-type: none"> • California crop information concerning area specific planting and harvesting periods (such as: California Agricultural Resource Directory). • Available data regarding frequency and duration of exposure (from sources such as: County Agricultural Commissioner, pesticide registrants, pest control advisors or operators).
4	<p>Exposure Scenario Scoping Proposal Process.</p> <p>The exposure assessment author or assigned designee prepares the exposure scenario scoping proposal according to the approved format. The proposal includes a detailed description and summaries of the background information; identifies all relevant exposure scenarios.</p>
5	<p>Exposure Scenario Scoping Proposal Review Process.</p> <p><u>Peer Review</u></p> <ul style="list-style-type: none"> • The author provides the exposure scenario scoping proposal to the Senior Toxicologist and Branch Chief for review. If there is a large volume of background information, the author may provide only the proposal and make this information available for review. <p><u>Inter-Branch Review</u></p> <ul style="list-style-type: none"> • The author provides the exposure scenario scoping proposal to the WH&S Branch Chief for inter-branch review. The proposal is sent to Information Systems, Pesticide Enforcement, Pesticide Registration, Environmental Monitoring, and Medical Toxicology requesting comments. The WH&S Branch management prefers written comments because they provide an accurate record of the review results. • A meeting with Branch representatives to discuss the exposure scenario scoping proposals may be scheduled if deemed necessary by WH&S Branch Chief. <ul style="list-style-type: none"> * The Branch Chief determines the due date for the comments and should follow-up late assignments with

	<p>the Branch Representative or Branch Chief. If comments are not received within a reasonable amount of time past the due date, the Branch Chief will conclude that the lack of submission suggests concurrence with the proposal.</p> <ul style="list-style-type: none"> • If the author amends the proposal based on Branch Representative input, the author may ask the Branch Representative to review the changes, or continue the process without additional review. • As a courtesy to Branch Representatives, the author should acknowledge their participation by either responding to their comments in a memo or sending the amended proposal highlighting changes attributable to that member's participation.
6	<p>Beginning the Exposure Assessment.</p> <ul style="list-style-type: none"> • The author should review and update the information identified in Step 3 whenever necessary to assure that the exposure assessment accurately reflects the most current background information available. At a minimum, periodic updates should occur when more than one year elapses between the final exposure scenario scoping proposal and beginning the exposure assessment and before releasing the final draft of the exposure assessment for peer review. If the review results in the need to amend the exposure scenario scoping proposal, the author may ask for additional branch review or incorporate the changes with no additional review. • The excluded exposure scenarios and reasons for the exclusion will appear in the exposure assessment document. This section should also state that if new uses with significant exposure are discovered during the mitigation phase, they will be covered in the risk mitigation document, the EAD will not be amended.

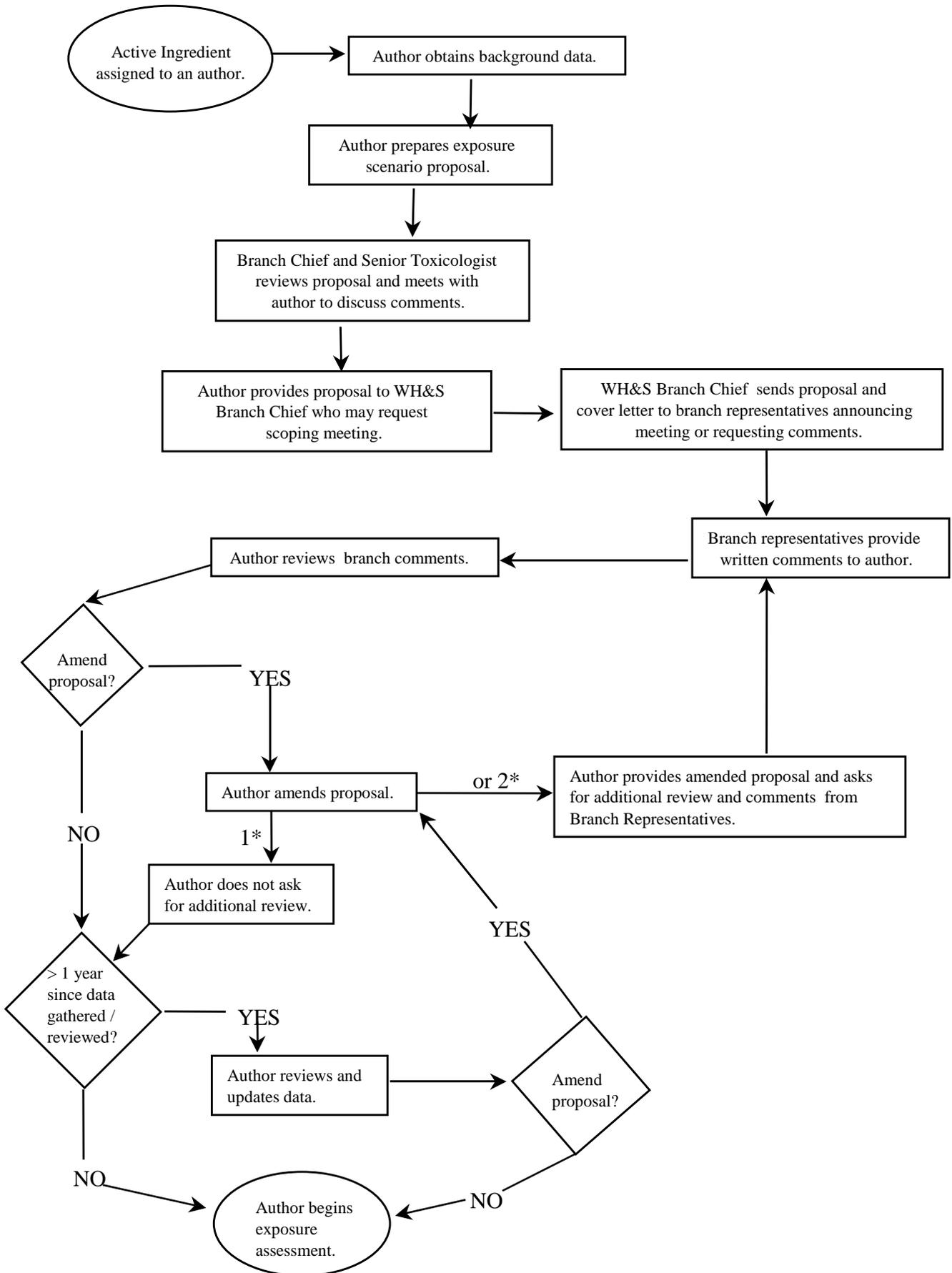
Risk Mitigation Document (RMD) Development Process

Step	
1	<p>DPR provides Risk Characterization Documents (RCD) requiring risk mitigation measures to registrants.</p> <ul style="list-style-type: none"> • When the final RCD indicates the need for risk mitigation, the Assistant Director notifies all registrants, data generators, and consultants and gives them 90 days to comment and propose mitigation measures. • After receiving the registrants' risk mitigation proposals, the Directorate provides a risk management directive to WHS indicating the use scenarios requiring mitigation. <ul style="list-style-type: none"> * If the Directorate has not provided a risk management directive or if the registrants did not provide any risk mitigation proposals, the RMD author should prepare risk mitigation proposals using the exposure scenarios in the RCD that have Margins of Exposure (MOE) below those generally regarded as health protective.
2	<p>The WH&S Branch Chief appoints an RMD author. The WH&S Branch Chief will facilitate the risk mitigation meetings. The author of the EAD should author the RMD.</p> <ul style="list-style-type: none"> • The author continues the document chronology developed during the preceding exposure assessment.
3	<p>Prior to the first draft of the RMD, the author obtains updated background information.</p> <ul style="list-style-type: none"> • Request current federal registration status from the Pesticide Registration Branch. Request status of federal risk assessment (e.g., special reviews, Reregistration Eligibility Documents) from the Medical Toxicology Branch. • Request a list of current pesticide registrations from the Pesticide Registration Branch and copies of all pesticide labels that were registered or amended after the Exposure Assessment Document was finalized (if greater than 20, choose a representative portion). <ul style="list-style-type: none"> * If the new or amended pesticide label does not appear to meet the current registration standards (i.e., the Worker Protection Standard), notify the registration specialist

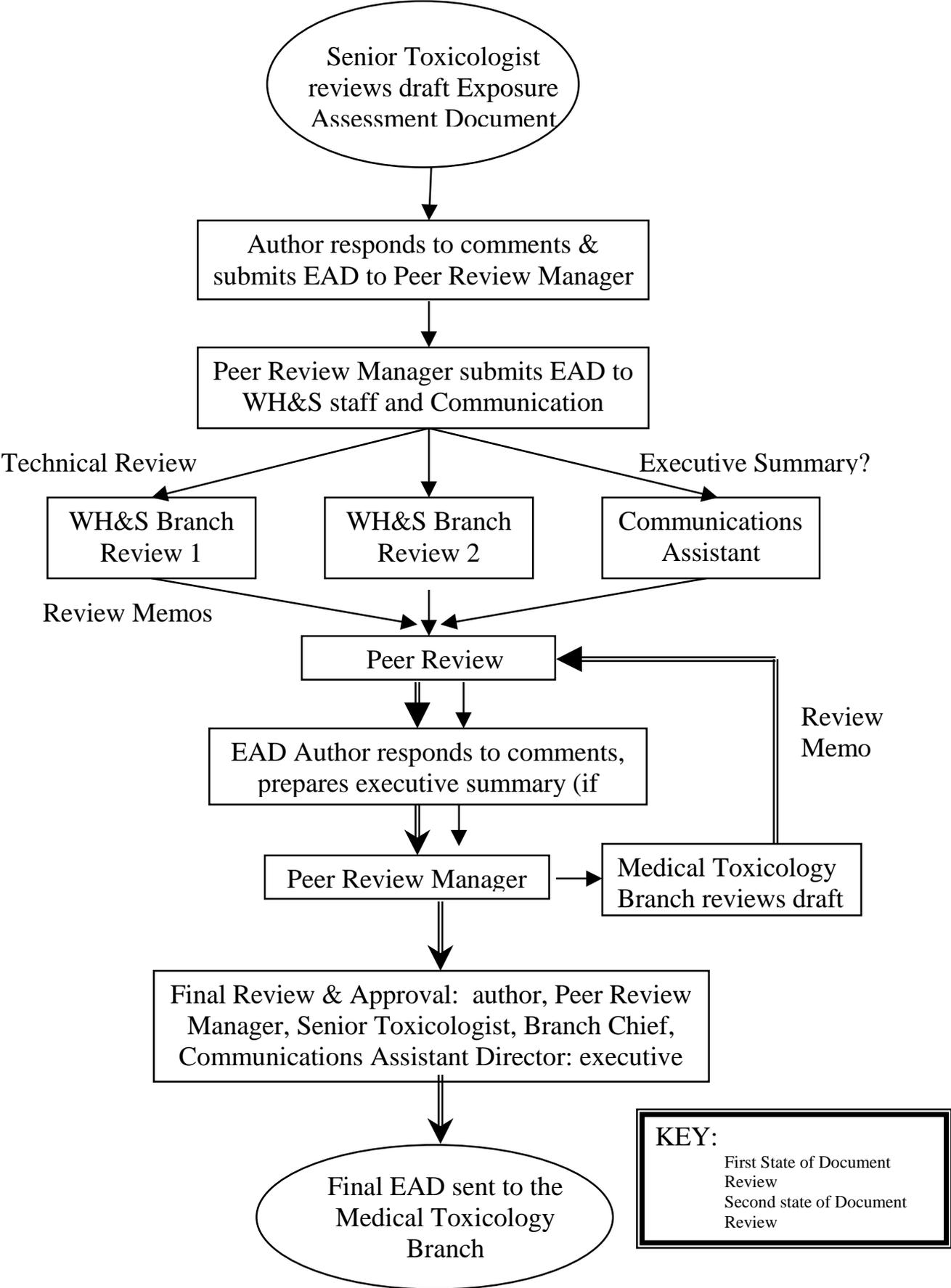
	<p>and registration supervisor and document the use of nonstandard labels in the RMD.</p> <ul style="list-style-type: none"> • Request Pesticide sales and use report data from the Information Systems Branch. Use query parameters that are the same as those used in the EAD scoping. • Request pesticide illness information from Pesticide Illness Surveillance Program. Since this information is available in chronological order, the request only needs to cover the time between the last request made for the EAD and the present RMD.
4	<p>The RMD author develops a table of exposures requiring mitigation, the corresponding MOEs from the RCD, and proposed mitigation measures.</p> <ul style="list-style-type: none"> • The proposal is reviewed by the Senior Toxicologist and WH&S Branch Chief.
5	<p>RMD “Re-scoping” meeting.</p> <ul style="list-style-type: none"> • The reviewed mitigation proposal is sent to the other Branches and a meeting is scheduled to discuss the proposal with them. • During the meeting, the RMD team discusses the author’s proposal; identifies changes (pesticide label, laws and regulations, federal status, use or sales) to the exposure scenarios identified in the EAD; and evaluates the proposed mitigation measures. • The RMD team may determine that further meetings are necessary to gain consensus concerning the risk mitigation options. • The RMD team must notify the WH&S Branch Chief if risk mitigation measures cannot be implemented and cancellation or suspension of the product registration appears to be the only adequate solution.
6	<p>Draft RMD (Refer to attached flowchart: “Risk Mitigation Document Peer Review Process”).</p> <ul style="list-style-type: none"> • Once all issues raised during re-scoping are addressed, the revised RMD is reviewed by the Senior Toxicologist and Branch Chief.

	<ul style="list-style-type: none"> • Further meetings may be scheduled with the RMD team as necessary.
7	<p>Final draft RMD.</p> <ul style="list-style-type: none"> • The final review and approval is conducted by the WH&S Branch Chief, the author, and the Senior Toxicologist. The WH&S Branch Chief (or Assistant Director) sends the final draft of the RMD to Branch Chiefs for approval.
8	<p>Final draft RMD forwarded to Directorate.</p> <ul style="list-style-type: none"> • WH&S attends Directorate briefing on RMD. • WH&S responds to verbal risk mitigation directives resulting from briefing.
9	<p>Implementation of risk mitigation measures.</p> <ul style="list-style-type: none"> • Assistant Director takes the lead to implement mitigation measures.

Exposure Scenario Scoping Process



Exposure Assessment Document Peer Review Process



KEY:
 First State of Document Review
 Second state of Document Review