

27 CALIFORNIA CODE OF REGULATIONS
STATE OF CALIFORNIA
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

ARTICLE 2. GUIDELINE AND SAFE USE DETERMINATION PROCEDURES

25204. Safe Use Determination

(a) As a part of this overall responsibility to provide guidance to persons or organizations that are or may be affected by the Act, the lead agency will consider the applicability of the Act or the exemptions specified in the Act to business activities or prospective business activities. A safe use determination issued by the lead agency represents the state's best judgment concerning the application of the Act to the particular facts presented in the request.

(b) Safe use determinations will not be issued under the following circumstances:
(1) Where the subject matter of a request for safe use determination is at issue in a civil or criminal case pending in any court except when a request has been received and accepted in writing by the lead agency before:

(A) service of a notice pursuant to Section 25903(c) for actions subject to Section 25249.7(d) of the Act unless the safe use determination request is ultimately accepted and determined to be complete as submitted prior to the service of the notice; or

(B) filing of a complaint for actions subject to Section 25249.7(c) of the Act unless the safe use determination request is ultimately accepted and determined to be complete as submitted prior to the filing of the complaint. For purposes of this section, a case is not pending after entry of judgment even though the court retains jurisdiction over the matter for purposes of injunctive relief, supervision of compliance with the court's orders or any other purpose. Nor is a case pending simply because a settlement entered as a final judgment is subject to modification or other "reopeners."

(2) If the individual or organization requesting the safe use determination receives a notice pursuant to Section 25903(c) or a complaint is filed pursuant to Section 25249.7(c) of the Act before receiving a written acceptance from the lead agency of its request, the individual or organization shall notify the lead agency's Deputy Director for Scientific Affairs in writing within 5 business days of receiving the notice or filing of the complaint. Upon notification, the lead agency shall terminate the safe use determination process and return all data and information submitted by the requester observing full confidentiality unless the safe use determination request is ultimately accepted and determined to be complete as submitted prior to the service of the notice or filing of the complaint, whichever is applicable. No refund of fees imposed or costs incurred by the lead agency prior to such termination will be made.

(3) Where the individual or organization requesting the safe use determination is not directly required to enforce or comply with the provisions of the Act, provided, however, where two or more businesses which are members of the same trade association share a business practice which may be the subject matter of a request for a safe use

determination, the request may be made by the trade association on behalf of such members.

(4) Where the request for determination concerns compliance with laws other than the Act, or with regulations, permits, requirements or orders of any federal, state or local agency. For example, questions concerning whether chemical discharges comply with the Water Code, state regulations and waste discharge requirements should be addressed to the appropriate Regional Water Quality Control Board.

(5) Where the request for determination does not involve a current or planned activity of the requester. Safe use determination will not be issued concerning hypothetical situations or on each of several alternative plans in a proposed activity.

(6) Where, in the discretion of the lead agency, issuance of a safe use determination will not further the public interest, or is otherwise inappropriate under the circumstances presented in or related to a particular request for safe use determination. For example, where the subject matter of the request is at issue in an administrative proceeding before a government agency that began before the request for a safe use determination was received and accepted in writing by the lead agency or does not concern a chemical listed pursuant to Section 25249.8 of the Act.

(c) A request for a safe use determination shall be clearly marked "Official Information Pursuant to Evidence Code Section 1040" and submitted in writing to the lead agency's Deputy Director for Scientific Affairs. Except as provided in paragraph (2) of subsection (d), the request for safe use determination is deemed official information pursuant to Evidence Code Section 1040. The request shall contain all of the following:

(1) A complete statement of all relevant facts related to the activity for which the safe use determination is requested. Such facts include the names and addresses of all interested parties, a description of the business reason for the activity and a carefully detailed description of the activity.

(2) True copies of any contracts, agreements, instruments, reports, analyses or other documents directly related to the activity for which the safe use determination is requested and to the applicability of the Act to the activity.

(3) A clear statement of the issue or issues on which a safe use determination is sought.

(4) If the determination request includes references to a specific chemical, the request should include the chemical name and the Chemical Abstract Services (CAS) Registry Number, if applicable.

(5) If the activity for which the safe use determination is sought is only one step of a larger integrated process, the description of the activity shall include a description of the entire process.

(6) If the requester is contending for a particular result in the determination, the request shall include an explanation of the grounds for the contention together with an identification of any relevant authorities which support such view.

(7) If a request for safe use determination contains any information which the requester claims should not be available for public inspection under the Public Records Act (Government Code Section 6250 et seq.), the request shall specifically identify the information and the basis for the claim.

(A) If the request for determination contains information which the requester claims should not be available for public inspection, it shall be accompanied by a copy of the request and any supporting documents on which shall be indicated, by the use of brackets, the material which the requester contends should be deleted.

(B) All requests for safe use determination shall be open for public inspection except as otherwise specifically identified by the requester under this section. If the lead agency determines that information which the requester claims should not be available for public inspection must be released to the public under the Public Records Act (Government Code Section 6250 et seq.), it will promptly notify the requester by telephone or in writing of this determination and provide a reasonable opportunity for the requester to submit additional justification for the claim or to contest the determination in an appropriate proceeding.

(8) If the requester claims that fees or other charges for safe use determination should be waived, the request shall include an explanation of the basis for the claim.

(9) A statement concerning whether to the best of the requester's knowledge the subject matter of the request is:

(A) An issue in a civil or criminal case pending in any court.

(B) An issue in any administrative proceeding pending before a federal, state or local agency.

(C) The subject of a notice of violation to the Attorney General, a district attorney or a city attorney as described in Section 25249.7(d) of the Act.

(10) The signature of the person making the request for determination. Where the request is made by an authorized representative for an individual or organization, the request shall indicate the source of the authority to make the request.

(d) (1) Each request for a safe use determination shall be accompanied by a nonrefundable processing fee of \$1,000. In addition, the requester shall be assessed a charge in the amount of any costs to the lead agency or other state agency which are necessarily incurred in considering the request and which exceed \$1,000. Such additional assessment shall be made only after the requester has been provided an estimate of the amount, has elected to proceed with the request for safe use determination and has agreed to pay the additional assessment. All or part of the processing fee or other charges assessed pursuant to this section may be waived if the lead agency determines that payment of the fee would present a hardship to the requester or that it is otherwise in the public interest to proceed with the request without payment of such fees or charges.

(2) The lead agency will not publicly disclose the existence, data, or information in a request for a safe use determination until a written acceptance of the request is issued as specified in subsection (f). Upon issuance of a written acceptance by the lead agency, the request shall no longer be regarded as "official information" and shall be subject to disclosure upon request. If a request is withdrawn prior to the issuance of written acceptance of the request, all data and information submitted by the requester will be returned to the requester observing full confidentiality. No refund of fees imposed or costs incurred by the lead agency for a withdrawn request will be made.

(e) If during the initial review of the request for safe use determination, the lead agency requests essential information and it is not received within 30 days, the request shall be closed and all data and information submitted by the requester thus far will be returned to the requester observing full confidentiality. No refund of fees imposed or costs incurred by the lead agency for a closed request will be made. If the information requested by the lead agency is received after the request is closed, the request will be reopened and treated as a new request as of the date of receipt.

(f) In the case of a request for safe use determination that appears to comply with these procedures, the lead agency shall issue a written acceptance of the request. At the same time, a public notice of the acceptance of the request will be submitted for publication in the California Regulatory Notice Register and sent to interested persons. The public notice will include the text or a summary of the request as appropriate. It will advise interested persons that they may comment on the request in writing or in person at a public hearing which shall be held on a date not less than 30 days after the notice is published.

(g) At any time while an accepted request for a safe use determination is pending, the lead agency or any other state agency that is considering the request may ask for any additional information or explanation from the requester as necessary to complete a consideration of the request. The information requested must be received within sixty (60) days, unless the lead agency agrees to an extension in writing.

(h) After considering the request, any comments of the public received in writing or at the public hearing, and the comments of any other state agencies that have considered the request, the lead agency shall in response to the request:

- (1) Issue a safe use determination.
- (2) Decline to issue a safe use determination because the facts are insufficient to clearly establish the basis for the requested determination or for any other reason.
- (3) Issue an information letter to the requester.
- (4) Issue an interpretive guideline.

(i) The lead agency's response to the request shall be sent to the requester and the text or a summary of the response shall be published in the California Regulatory Notice Register and sent to interested persons, including any person who submitted comments on the request.

(j) Safe use determinations issued by the lead agency are limited to the particular facts on which they are based and they reflect the lead agency's view of the best interpretation of the Act and the state of scientific knowledge at the time they are issued. Whenever the issuance of a safe use determination requires the performance by a state agency of a risk assessment of the carcinogenicity or reproductive toxicity of a chemical, such assessment shall be performed pursuant to the methodologies adopted by the lead agency. A safe use determination found to be in error or not in accord with the best interpretation of the Act or the current state of scientific knowledge may be modified or revoked. Modification or revocation of a safe use determination may be effected by a

notice to the individual or organization that requested the ruling along with notice in the California Regulatory Notice Register or by the issuance of an interpretive guideline.

(k) A safe use determination shall be issued to a particular individual or organization with respect to the application of particular provisions of the act to particular facts. Determinations are not intended to affect other individuals or organizations, or other activities of the requester.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.5 - 25249.13, Health and Safety Code.