FINAL STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS

TITLE 22, CALIFORNIA CODE OF REGULATIONS

AMENDMENT TO SECTION 12104 (RENUMBERED TO SECTION 12204)
SAFE USE DETERMINATION
SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986

BACKGROUND

On May 17, 2002, OEHHA issued a Notice of Proposed Rulemaking (hereafter referred to as Notice) announcing that OEHHA was proposing changes to the Proposition 65 regulations, namely; Title 22, California Code of Regulations, Division 2, Chapter 3, Section 12104. A public hearing was held on July 1, 2002 to receive comments on the proposed changes. Comments were received orally at the public hearing and in writing during the 45-day public comment period. Summaries and responses to the comments received are provided later in this document. Since the issuance of the Notice, another OEHHA regulatory filing has been approved by the Office of Administrative Law (OAL), filed with the Secretary of State, and became effective during the intervening time. The final regulatory text of this package reflects these recent amendments to conform with the current text of the regulations. Most notably, the section number was amended from Section 12104 to Section 12204 and several grammatical changes were made. These latest changes are all made without regulatory effect.

Regulatory Action File # 02-1121-02S adopted amendments in Title 22, California Code of Regulations, Division 2, Chapter 3, Sections 12102 – 12302, 12304 – 12504,12601, 12701, 12705, 12709, 12711, 12721 – 14000. The amendments included: changes to outdated terminology, consistency of references, consolidation and alphabetization of definitions into one section coupled with the repeal of other definition sections, relocation and renumbering of sections for regulatory continuity, and grammatical corrections. OAL approved the package on January 7, 2003, and the changes were effective on February 6, 2003.

<u>Section 12204 (b) (formerly Section 12104(b))</u>

The proposed amendments to the regulation are revised to clarify that issuance of a SUD may proceed even after a 60-day notice of violation has been served or civil complaint filed as long as the SUD request is ultimately determined to be complete as originally submitted. It is logical to continue review, and acceptance, of the request if the request would have been accepted as submitted if not for the lapse of time between submittal of the request and determination of completeness by OEHHA. OEHHA's inability to determine completeness and issue an acceptance of a request before a notice was served or a complaint was filed should not be grounds for termination of the request. Accordingly, under the circumstances in which a SUD would not be issued, the regulation is amended to state, "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 a complaint, whichever is applicable."

Section 12204(d)(2) (formerly Section 12104(d)(2))

Section 12204(c) as proposed deems the SUD request to be official information pursuant to Evidence Code Section 1040 and not subject to public disclosure. Paragraph (2) of subsection (d) clarifies that a request for SUD and its supporting information would not be publicly disclosed until written acceptance of the request is issued. It is intended that once a written acceptance has been issued that the SUD and its supporting information would cease being official information and could be subject to public disclosure. An amendment to paragraph (2) of this subsection is made to make clear this intention. Public disclosure of the SUD request would be subject to the limitations and exceptions specified in the Public Records Act (Government Code Section 6250 et seq.).

SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE INITIAL NOTICE PERIOD OF MAY 17, 2002 THROUGH JULY 1, 2002

COMMENT 1a: Consumer Healthcare Products Association (CHPA) (See Comment 1, pp. 4 and 5) stated that "the proposal expands the items that can trigger termination beyond pending litigation in a court that involves the identical subject matter to also include 60-day notices on that issue as well." CHPA further stated that, "(t)he proposed regulation still precludes consideration of an (sic) SUD request if the 60-day notice or civil action commences prior to either the filing of the SUD request or to the acceptance of the request by OEHHA." The commenter believes the proposed changes are too modest to give businesses confidence in the SUD process so that they will actually use these proceedings for voluntary compliance as envisioned.

RESPONSE: The amendments as proposed are to deter submission of ill-prepared or "placeholder" SUD requests. Although technically a SUD could be terminated if a 60-day notice of violation was served after a SUD request had been filed but not yet accepted by OEHHA, in practice it is not likely that a SUD could be completed before a suit could be filed anyway. This concern is addressed by the exception added to the regulation, that if the SUD is subsequently determined to be complete as submitted and thus accepted, OEHHA would still proceed with the review of the SUD even if a 60-day notice of violation had been served upon the business seeking the SUD.

COMMENT 1b: Consumer Healthcare Products Association (CHPA) (See Comment 1, pp. 5 and 6) proposed that the regulation be further revised to permit a SUD request to proceed regardless of the status of any litigation on the same subject matter. The commenter questioned what policy was served by automatically terminating a SUD between the time the request is received by the agency and the time the agency acknowledges that it received all the appropriate materials it needs for its determination. The commenter argued that the service of a 60-day notice of violation and a pending civil matter are not the same. Many 60-day notices are served that never lead to a filing of a formal complaint. Accordingly, the commenter requests that the regulations be revised to permit OEHHA to consider a SUD at any time, regardless of whether litigation has been instituted on the subject matter of the request or at least retract the portion of the proposed regulation that would terminate a SUD because a 60-day notice of violation is initiated even while OEHHA reviews the completeness of the request.

RESPONSE: OEHHA acknowledges that service of a 60-day notice of violation is not the same thing as pending litigation. To address this concern in part, as stated in the previous response, the regulations are further amended to allow for the processing of a SUD even after a 60-day notice of violation has been served upon the business if the SUD is ultimately determined to be complete as submitted. It is not OEHHA's intention to process a SUD request in all situations because the SUD process should not be used as a means of providing expert assistance once a business has knowledge that it may be a litigant in a Proposition 65 enforcement action. It is not OEHHA's role to provide assistance to businesses in preparing for litigation or other enforcement actions.

COMMENT 1c: Consumer Healthcare Products Association (CHPA) (See Comment 1, pp. 7 and 8) stated that, "(t)here are several strong reasons for the agency to maintain the confidentiality of the SUD request: more complete information on which to base its decisions, the interest of justice, fairness to the requestor and the encouragement of voluntary compliance through the SUD process." CHPA further stated that OEHHA "has provided no compelling reason why the information should be made public," nor explained "why the interest of justice is diminished because of an artificial demarcation created in the proposed rulemaking at the time the request is 'accepted' by the agency." Accordingly, the commenter requests that the regulation be revised to permit complete confidentiality of both the existence of a SUD request and all supporting pacts, documents and other materials submitted, and that once a final determination is released by OEHHA, OEHHA's opinion, but not the supporting materials, could be made public. Alternatively, OEHHA "might place conditions on the public disclosure of the SUD by the requestor that would compel release of the supporting materials along with any announcement of agency's determination."

RESPONSE: Continuing to proceed with review of the SUD under specified circumstances will dispel some of the concern of businesses about identifying themselves as "targets" by submitting SUD requests with supporting information under confidence only to have the same information released and used against them by private parties anxious to sue them for causing exposures to listed chemicals without providing proper warning. Most likely businesses would apply for a SUD only if they believed that the data supported their determination that their product use was "safe", i.e., did not pose a significant risk to those individuals exposed. The cost of receiving a SUD can be significant, and would not be pursued without fair assurance on the part of the business that the outcome would be favorable. That being said, it would also seem less likely that private parties would seek to file suit against businesses that have assessed the exposures for which they are responsible and assembled information and data to support their position. OEHHA does not believe that extending the conditions of confidentiality is authorized or necessary in furtherance of the Proposition. OEHHA believes there is a need for meaningful public input and that the access to public records should be upheld to make such input possible. It should be noted though that businesses will still be provided the full privileges from disclosure provided under the Public Records Act. OEHHA has addressed this concern in part by adopting exceptions to the circumstances that would terminate review of a SUD. (Also, see Response to Comments 1a and 1b as to this aspect of OEHHA's approach.)

COMMENT 2: Cosmetic, Toiletry and Fragrance Association (See Comment 2, pp.3, 6, and 7) requested additional regulatory changes: "(1) to maintain the complete confidentiality of the request for a safe use determination, the supporting data, and OEHHA's determination; the information would be released only at the initiation of the business requesting the safe use determination and

only to the extent that it chooses to release the information; (2) OEHHA should, as the regulations currently permit, accept and consider requests for a safe use determination and issue a determination even if the request was submitted after the business requesting the safe use determination is served with a 60- day letter raising an issue that is the subject matter of the request." The commenter suggested the following regulatory amendments to Section 12204(c) and Section 12204(d)(2):

> "(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:
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> ~~(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.~~
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> ~~(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.~~
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> ~~(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.~~
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> …
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> (d)(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)~~. 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."

The commenter also proposed regulatory changes to Section 12204(b)(1) and (2):

"(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 12903(c) for actions subject to Section 25249.7(d) of the Act; or~~

~~(B)~~ filing of a complaint for actions subject to Section 25249.7(c) of the Act. 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 12903(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~~ service 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. No refund of fees imposed or costs incurred by the lead agency prior to such termination will be made."

RESPONSE: See Response to Comments 1a, 1b and 1c.

COMMENT 3: Peter Rooney, The Rooney Group, through oral testimony at the public hearing on July 1, 2002 (See Transcript, pp. 16 - 18) commended OEHHA for the progress made in addressing the issue of confidentiality, but stated that OEHHA should revise the regulation to be able to proceed with a SUD request even if a 60-day notice of violation has been served.

RESPONSE: See Response to Comments 1a and 1b.

COMMENTS RECEIVED DURING THE PERIOD THE MODIFIED TEXT WAS AVAILABLE TO THE PUBLIC

The modified text was made available to the public from January 27, 2003 through February 11, 2003. No comments were received on the modifications to regulatory text.

ALTERNATIVES DETERMINATION

OEHHA has determined that no alternative would be more effective in carrying out the purpose for which the regulation is proposed or would be as effective and less burdensome to affected private persons than the proposed regulation.

LOCAL MANDATE DETERMINATION

Pursuant to Health and Safety Code Section 25249.11(b), the provisions of Proposition 65 do not apply to local, state or federal agencies. The proposed regulations do not impose any mandate on local agencies or school districts.