

**State of California
Office of Administrative Law**

**In re:
Office of Environmental Health Hazard
Assessment**

**Regulatory Action: Title 27
California Code of Regulations**

**Adopt sections: 25904
Amend sections:
Repeal sections:**

**DECISION OF DISAPPROVAL OF
REGULATORY ACTION**

Government Code Section 11349.3

OAL File No. 2014-1202-04S

SUMMARY OF REGULATORY ACTION

On December 2, 2014, the Office of Environmental Health Hazard Assessment (Office) submitted to the Office of Administrative Law (OAL) its proposed regulatory action to adopt section 25904 in title 27 of the California Code of Regulations. This regulatory provision sets out the procedures used to identify chemicals and substances that are to be added to the Proposition 65 list and the process used to remove them from that list.

On January 15, 2015, OAL notified the Office that OAL disapproved the proposed regulations because the regulations failed to comply with the clarity standard of Government Code section 11349.1 and the Office failed to follow procedural requirements of the California Administrative Procedure Act (APA). This Decision of Disapproval of Regulatory Action explains the reasons for OAL's action.

DECISION

OAL disapproved the above-referenced regulatory action for the following reasons:

- A. The proposed regulations failed to comply with the clarity standard of Government Code section 11349.1, subdivision (a)(3);
- B. The Office failed to comply with APA procedural requirements by omitting to:
 1. summarize and respond to all of the public comments made regarding the proposed action pursuant to Government Code section 11346.9, subdivision (a)(3);
 2. identify in a 15-day notice documents relied upon that were added to the record and state the place and business hours that the documents are available for

- public inspection, pursuant to Government Code section 11347.1, subdivision (b);
3. include authority and reference citations in the proposed regulation, pursuant to Government Code section 11343, subdivision (d), Government Code section 11346.2, subdivision (a)(2), and California Code of Regulations section 8, subdivision (a); and
 4. clearly indicate additions and deletions to the proposed regulatory text.

All APA issues must be resolved prior to OAL's approval of any resubmission.

DISCUSSION

The adoption, amendment, or repeal of regulations by the Department must satisfy requirements established by the part of the California Administrative Procedure Act that governs rulemaking by a state agency. Any regulation adopted, amended, or repealed by a state agency to implement, interpret, or make specific the law enforced or administered by it, or to govern its procedure, is subject to the APA unless a statute expressly exempts the regulation from APA coverage. (Gov. Code, sec. 11346.)

Before any regulation subject to the APA may become effective, the regulation is reviewed by OAL for compliance with the procedural requirements of the APA and for compliance with the standards for administrative regulations in Government Code section 11349.1. Generally, to satisfy the standards a regulation must be legally valid, supported by an adequate record, and easy to understand. In this review OAL is limited to the rulemaking record and may not substitute its judgment for that of the rulemaking agency with regard to the substantive content of the regulation. This review is an independent check on the exercise of rulemaking powers by executive branch agencies intended to improve the quality of regulations that implement, interpret, and make specific statutory law, and to ensure that the public is provided with a meaningful opportunity to comment on regulations before they become effective.

A. CLARITY STANDARD

In adopting the APA, the Legislature found that the language of many regulations was unclear and confusing to persons who must comply with the regulations. (Gov. Code, sec. 11340, subd. (b).) Government Code section 11349.1, subdivision (a)(3), requires that OAL review all regulations for compliance with the clarity standard. Government Code section 11349, subdivision (c), defines "clarity" to mean "written or displayed so that the meaning of the regulations will be easily understood by those persons directly affected by them."

The "clarity" standard is further defined in section 16, title 1, of the CCR, OAL's regulation on "clarity," which provides:

In examining a regulation for compliance with the “clarity” requirement of Government Code section 11349.1, OAL shall apply the following standards and presumptions:

- (a) A regulation shall be presumed not to comply with the “clarity” standard if any of the following conditions exists:
- (1) the regulation can, on its face, be reasonably and logically interpreted to have more than one meaning; or
 - (2) the language of the regulation conflicts with the agency’s description of the effect of the regulation; or...
 - (6) the regulation does not use citation styles which clearly identify published material cited in the regulation...

In this regulatory action, the Office failed to comply with the clarity standard of the APA.

1. Proposed section 25904, subdivision (a)(1)

The proposed regulation section 25904, subdivision (a)(1) states:

25904. (a) Pursuant to Section 25249.8(a) of the Act, a chemical shall be included on the list of chemicals known to the state to cause cancer or reproductive toxicity if it is a substance identified by reference in Labor Code Section 6382(b)(1) or by reference in Labor Code Section 6382(d) as causing cancer or reproductive toxicity.

(1) A substance shall be included on the list if it is identified by the International Agency for Research on Cancer in its IARC Monographs series on the Evaluation of Carcinogenic Risks to Humans (most recent edition) as:

- (A) Carcinogenic to humans (Group 1), or
- (B) Probably carcinogenic to humans (Group 2A) with sufficient animal evidence, or
- (C) Possibly carcinogenic to humans (Group 2B) with sufficient animal evidence.

The phrases “*probably* carcinogenic to humans with sufficient animal evidence” and “*possibly* carcinogenic to humans with sufficient animal evidence” are unclear because what the animal evidence is supposed to show is unspecified. A person directly affected by the regulation would not easily understand whether the animal evidence is required to show a potential carcinogenic effect on humans or a carcinogenic effect on animals. Also, the term “sufficient animal evidence” may have the same meaning for both phrases or it may have a different meaning. In other words, the threshold for what constitutes sufficient animal evidence may either be the same for both subdivisions (a)(1)(B) and (a)(1)(C) or it may be different.

The Initial Statement of Reasons (ISOR) provides information that supplements the regulatory language. It states that the chemicals in Group 2A, referenced in subdivision (a)(1)(B), added on the Proposition 65 list are those chemicals that have limited or inadequate evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals. It

further states that the chemicals in Group 2B, referenced in subdivision (a)(1)(C), added to the Proposition 65 list are those chemicals for which there is sufficient evidence of carcinogenicity in experimental animals. This must be made clear in the text of the regulation itself.

2. Proposed section 25904, subdivision (a)(2)

The proposed regulation section 25904, subdivision (a)(2) states:

25904. (a)(2) A chemical shall be included on the list if it is within the scope of the Federal Hazard Communication Standard and is identified in the most recent version of Title 29 of the Code of Federal Regulations, part 1910.1200, adopted by the federal Occupational Safety and Health Administration, as causing cancer or reproductive toxicity based on sufficient animal or human evidence.

The phrase “sufficient animal or human evidence” is unclear based on the same issues raised in regulation section 25904, subdivision (a)(1) above. Using consistent terminology within a regulatory text prevents the regulation from being interpreted to have more than one meaning.

In addition, the language of the regulation conflicts with the agency’s description of the effect of the regulation. The ISOR that was made available to the public for comment on September 12, 2014 states:

OEHHA is no longer proposing chemical listings based on the Threshold Limit Values, or [Code of Federal Regulations, title 29] part 1910, subpart Z, which have been the basis to date for the listing of reproductive toxicants under the Labor Code mechanism. Further, these changes to the OSHA regulations have resulted in elimination of the express provisions identifying the National Toxicology Program’s Report on Carcinogens and the IARC monographs as mandatory bases for classifying chemicals as carcinogens under the HSC.

Subsection (a)(2) of the proposed regulation simply tracks the existing California Labor Code provisions to clarify that chemicals will be listed as carcinogens or reproductive toxicants in the future if they are otherwise identified as “within the scope” of the HSC. For example, the HSC may be amended to add other bases for classifying chemicals as carcinogens or reproductive toxicants.

The language of the regulation proposes to include on the Proposition 65 list chemicals identified in the most recent version of Title 29 of the Code of Federal Regulations, part 1910.1200. However, the ISOR states that the Office excludes chemicals listed in part 1910, subpart Z. Here, the ISOR adds information and supplements the regulation which gives the regulatory language a different effect when it is read without the ISOR. Thus, the regulation is unclear because the language of the regulation conflicts with the agency’s description of the effect of the regulation.

The ISOR further cites provisions of the Code of Federal Regulations (CFR) that cannot be located: 29 C.F.R. 1910.1200(d)(4)(i), (ii), and (iii). This makes the regulation unclear because the description of the effect of the regulation is unclear.

3. Proposed section 25904, subdivision (b)

The proposed regulation section 25904, subdivision (b) states:

25904. (b) At least 45 days prior to adding a chemical that meets the criteria established in subsection (a) to the list, the lead agency shall publish a notice of intent to list the chemical and provide a 30 day public comment period on whether or not the chemical has been identified by reference in either Labor Code section 6382(b)(1) or 6382(d) or both.

The ISOR states that “[s]ince the listing procedure for this mechanism is ministerial and therefore essentially automatic, OEHHA restricts comment to the identification of a chemical as causing cancer or reproductive toxicity, not the underlying scientific determinations supporting the identification.”

The regulatory text in this provision does not expressly exclude comments related to the underlying scientific determination supporting the identification of a chemical as causing cancer or reproductive toxicity. This exclusion is only found in the ISOR. A person directly affected would not easily understand that the regulation explicitly excludes comments related to the underlying scientific determinations supporting the identification of a chemical as causing cancer or reproductive toxicity.

The clarity issues must be corrected and the modified text must be made available for a minimum 15-day comment period before the regulatory action can be resubmitted to OAL for review.

B. PROCEDURAL REQUIREMENTS

The Office failed to follow several required procedures. More specifically, the Office failed to summarize and respond to all of the public comments made regarding the proposed action, failed to identify in a 15-day notice documents relied upon that were added to the record and state the place and business hours that the documents are available for public inspection, failed to include authority and reference citations in the proposed regulation, and failed to clearly indicate additions and deletions to the proposed regulatory text.

1. Summary and Response to Comments

Government Code section 11346.9, subdivision (a), provides that an agency proposing regulations shall prepare and submit to OAL a final statement of reasons. One of the required

contents of the final statement of reasons (FSR) is a summary and response to public comments. Specifically, Government Code section 11346.9, subdivision (a)(3), requires that the final statement of reasons include:

(a)(3) A summary of each objection or recommendation made regarding the specific adoption, amendment, or repeal proposed, together with an explanation of how the proposed action has been changed to accommodate each objection or recommendation, or the reasons for making no change. This requirement applies only to objections or recommendations specifically directed at the agency's proposed action or to the procedures followed by the agency in proposing or adopting the action....

In this rulemaking action, the Office provided a 45-day public comment period for its originally proposed text. During that period, a number of written comments were received and the Office is required to include in the FSR a summary of the comments and an explanation of how the proposed action has been changed in response to the comment or the reasons for making no change. In its FSR, the Office did not summarize all comments and did not provide the required explanations.

1.1. Economic Impact Assessment and Major Regulation

One commenter states that the Office's economic impact analysis (EIA) is incorrect. The commenter claims that the proposed regulation could have an estimated economic impact exceeding \$50 million. Such an economic impact would require the Office to comply with the APA requirements related to major regulations, pursuant to Government Code section 11346.3. The Office did not summarize or respond to the comment in the FSR.

1.2. Other Comments

A number of other comments and recommendations were made that the Office rejected but the agency did not summarize or respond to those comments. The APA requires the agency to explain the reasons for making no changes to the regulation after objections or recommendations have been made. The Office may contact OAL for assistance in identifying the comments and recommendations that were not summarized or responded to.

Where the agency did change the regulation, the APA still requires a summary of the comment as well as an explanation of how the change accommodates the objection or recommendation. In this regulatory action, the Office did make some changes to the regulation and made the modifications available to the public for 15-day comment periods. However, the FSR does not provide the required explanations pursuant to the APA. Each objection or recommendation made by commenters must be summarized and responded to in the FSR.

2. Documents Relied Upon

Government Code section 11347.3, subdivision (b)(7), requires that the rulemaking file include:

(7) All data and other factual information, technical, theoretical, and empirical studies or reports, if any, on which the agency is relying in the adoption, amendment, or repeal of a regulation....

In this rulemaking file, the agency included a disk containing an electronic version of the documents relied on. However, these documents are not viewable. The Office must include in the file a viewable version of the documents relied on.

Further, Government Code section 11347.1, subdivision (a) states that when an “agency adds any... document to the rulemaking file after the publication of the notice of proposed action and relies on the documents in proposing the action shall make the documents available [to the public for a 15-day comment period].”

Although the documents could not be viewed, the disk’s content can be viewed. The content shows that two documents were not identified in the Initial Statement of Reasons: “side-by-side” and “Notice of Entry of Order Signed by Judge Freedman with POS attached (Sierra Club v. Brown).” If these documents were relied upon by the agency in drafting the regulation, they must be made available to the public pursuant to a 15-day notice for a minimum 15-day comment period prior to adoption.

3. Authority and Reference Citations

Government Code section 11343, subdivision (d), Government Code section 11346.2, subdivision (a)(2), and California Code of Regulations, title 1, section 8, subdivision (a)(1), requires regulations to include authority and reference citations. In this proposed regulation, the Office failed to include the required citations. These citations must be included in the regulation.

4. Underline/Strikeouts

The Office is required to use underline or italics to indicate additions to, and strikeout to indicate deletions from, the California Code of Regulations. (Gov. Code, sec. 11346.2, subd. (a)(3).) The California Code of Regulations further clarifies in section 8, subdivision (b), that:

(b) The final text of the regulation shall use underline or italics to accurately indicate additions to, and strikeout to accurately indicate deletions from, the California Code of Regulations. Underline or italics is not required for the adoption of a new regulation or set of regulations if the final text otherwise clearly indicates that all of the final text submitted to OAL for filing is added to the California Code of Regulations.

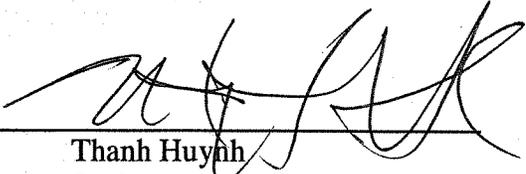
The final regulatory text simple underlined and struck out the modified text. However, because proposed section 25904 is an entirely newly proposed regulatory adoption, the final text must be either underlined entirely or it must otherwise clearly indicate that all of the final text submitted

to OAL for filing is added to the California Code of Regulations, pursuant to section 8 of the California Code of Regulations.

CONCLUSION

For the reasons stated above, OAL disapproved this regulatory action proposed by the Office. If you have any questions, please contact me at (916) 323-6824.

Date: January 22, 2015



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