CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

FINAL STATEMENT OF REASONS

TITLE 22 CALIFORNIA CODE OF REGULATIONS DIVISION 2
Safe Drinking Water and Toxic Enforcement Act of 1986
(Proposition 65)

January 1995

Amendment to: Sections 12301 Through 12306
(Science Advisory Board)

INTRODUCTION

On October 6 and December 12, 1994, two Public Hearings were held to receive public comment on the regulatory proposal designated OAL File Numbers 93-1021-01E, 94-0216-02ER, 94-0610-05E, 94-1018-13ER. At both hearings oral testimony was given, and a transcript of each proceeding was made part of the record. Also, received for the record were written comments submitted before 5:00 p.m. on August 15, 1994, December 12, 1994, and January 19, 1995, the closing dates for two 45 day comment periods and one 15 day comment period. The Office of Environmental Health Hazard Assessment (OEHHA) as lead agency has reviewed these written and oral comments as a part of the rulemaking process. Modifications to the proposed text have been based upon the objections and recommendations made in these comments. Among other things, this Final Statement of Reasons explains the lead agency's reasons for accepting some of the objections and recommendations, while declining to follow others.

Throughout the adoption process, the lead agency has considered the alternatives available to determine if any 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. The lead agency invited interested parties to present statements or arguments with respect to alternatives to the proposed amended regulations during the comment period or during the hearing. The lead agency has determined that no alternative considered would be more effective than or as effective and less burdensome to affected private persons than the adopted amendments to the regulations.

In accordance with Section 57005 of the Health and Safety Code, if the proposed regulations will have an economic impact exceeding 10 million dollars on the State's businesses, the lead agency must determine that no alternative it considers would be equally effective in achieving increments of environmental protection in a manner that ensures full compliance with statutory mandates within the same amount of time as the proposed amended regulatory requirements. Inasmuch as the proposed amended regulations impose no reporting, record keeping or other compliance requirements, the lead agency believes that the amendment of 22 CCR Sections 12301-12306 will have no adverse economic impact on the State's businesses. The lead agency invited interested parties to present statements or arguments with respect to adverse economic impact on individuals, businesses and small businesses during the comment period or during the hearing. The lead agency mailed the notice of proposed regulatory action to interested parties and to more than 700 individuals, businesses and representatives of businesses, large and small. No adverse economic impact statement or arguments were submitted or presented.

The next two parts of this document are divided into substantive and procedural issues. Part I is a substantive discussion associated with each particular section of the regulations. The comments and responses that pertain to each specific section of the regulations are provided after the "Determinations" for each section. Part II of this document is a series of comments and responses that concern procedural issues associated with the overall rulemaking.

PART I: SUBSTANTIVE ISSUES

SECTION 12301. "DEFINITIONS"

PUBLIC PROBLEM, ADMINISTRATIVE REQUIREMENT, OR OTHER CONDITION OR CIRCUMSTANCE THAT THE REGULATION IS INTENDED TO ADDRESS.

The Office of Environmental Health Hazard Assessment (OEHHA) filed emergency regulations, amending sections 12301 through 12305 in Title 22 of the California Code of Regulations (CCR), with the Office of Administrative Law (OAL) on October 21, 1993. OEHHA is now formally adopting these regulations in compliance with Government Code sections 11346.4 to 11346.8, inclusive, and amending 22 CCR section 12306 to merely conform with these regulations.

To this end, 22 CCR section 12301, as formally adopted, will, in pertinent part, change the name of the "Scientific Advisory Panel" to the "Carcinogen Identification Committee and the Developmental and Reproductive Toxicant (DART) Identification Committee of the Office of Environmental Health Hazard Assessment Science Advisory Board". 22 CCR Section 12301 will also change the designation of "lead agency" to OEHHA to reflect OEHHA's designation as lead agency for implementing the provisions of the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) by Governor Wilson in Executive Order W-15-91, dated July 17, 1991. Section 12301 will also shift the designation of "state's qualified experts" from the previous Scientific Advisory Panel (SAP) to two committees of the newly-established OEHHA Science Advisory Board (SAB).

SPECIFIC PURPOSE OF THE REGULATION

One of OEHHA's mandates is to provide leadership within the California Environmental Protection Agency (Cal/EPA) for sound risk assessment science in regulatory decision making. Risk assessment is a dynamic, evolving field at the interface of science and policy that is not without controversy. The best way to ensure that decisions are based on up-to-date science is to set up an open process for the development of scientific analyses which incorporates the elements of public participation, substantive and procedural due process, and external scientific peer review.

OEHHA is establishing the Office of Environmental Health Hazard Assessment Science Advisory Board (SAB) with the breadth and depth to deal with the varied scientific issues that OEHHA's risk assessment programs address. Members of the SAB will serve on one or more standing committees charged with advising OEHHA on specific scientific issues. One of OEHHA's programs that will utilize the SAB is the Proposition 65 Implementation Program. The Proposition 65 scientific functions will be subsumed within the larger activities of the OEHHA SAB, with two standing committees of the SAB replacing the former Proposition 65 Scientific Advisory Panel (SAP) as the "state's qualified experts." One committee will be dedicated to the identification of carcinogens and the other will be assigned to the identification of developmental and reproductive toxicants.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS, OR DOCUMENTS.

None

ALTERNATIVES TO THE PROPOSED REGULATORY ACTION THAT WOULD BE AS EFFECTIVE AND LESS BURDENSOME TO PRIVATE PERSONS OR BUSINESSES.

None

The proposed regulation will not affect any private person or business. It imposes no reporting, record keeping, or other compliance requirements. OEHHA finds that the amendment of 22 CCR sections 12301-12306 will have no adverse economic impact on individuals or the state's businesses. An alternative considered by OEHHA in the past was the continued maintenance of the Scientific Advisory Panel (SAP). However, the Scientific Advisory Panel, which in the past had been staffed by both private distinguished scientists as well as State of California (civil service) distinguished scientists, was not perceived by the public to be providing external scientific peer review as the "state's qualified experts." Two committees composed of external (to the State) distinguished scientists - with one dedicated to the identification of carcinogens and the other assigned to the identification of developmental and reproductive toxicants - will be better accepted and in fact more effective than the former SAP. OEHHA has determined that no alternative that it considered would be equally effective in achieving increments of environmental protection in a manner that ensures full compliance with statutory mandates within the same amount of time as the proposed amended regulations.

ALTERNATIVES TO THE PROPOSED REGULATORY ACTION THAT WOULD LESSEN ANY ADVERSE ECONOMIC IMPACT ON SMALL BUSINESSES.

None.

The proposed regulation will not affect any small businesses. It imposes no reporting, record keeping, or other compliance requirements. OEHHA finds that the amendment of 22 CCR sections 12301-12306 will have no adverse economic impact on small businesses.

DETERMINATIONS

The lead agency has determined that the adopted regulation would not impose a mandate on local agencies or

school districts, nor are there any costs for which reimbursement is required by Part 7 (commencing with Section 17500) of Division 4 of the Government Code.

The lead agency 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 adopted regulation. The adopted regulation will not affect any private person or business. It imposes no reporting, recordkeeping or other compliance requirements. The lead agency has determined that the adopted regulation will have no adverse economic impact on private persons.

The lead agency has determined that the regulations would not affect small business, because the regulations establish an external peer review panel of the "state's experts" who advise the Governor. The adopted regulations impose no reporting, recordkeeping, or other compliance requirements. The lead agency has determined there were no alternatives to the adopted regulations that would lessen any adverse economic impact on small businesses.

The lead agency has determined that the adopted regulations will not have a significant adverse economic impact on businesses, including the ability of California businesses to compete with businesses in other states.

The lead agency has determined that the regulations will not significantly affect the following:

(1) The creation or elimination of jobs within the State of California,

(2) The creation of new businesses or the elimination of existing businesses within the State of California,

(3) The expansion of businesses currently doing business within the State of California.

COMMENTS AND RESPONSES

1. One commentator (Kurtz, 8/11/94, p. 2) suggested that the proposed amendment would not only change reference from a "panel" to a "board", it would change the authority from the Safe Drinking Water and Toxic Enforcement Act of 1986 to the Office of Environmental Health Hazard Assessment. The commentator further suggested that it would be more appropriate to retain the language which refers to

the Safe Drinking Water and Toxic Enforcement Act Scientific Advisory Panel in the definition. The adopted regulation is a subset of Chapter 3, Safe Drinking Water and Toxic Enforcement Act of 1986 (Act), of Title 22 of the California Code of Regulations. The authority for the Science Advisory Board is still the Act. Nothing in this section leads the reader to believe that the authority for the panel is OEHHA and not the Act. Adoption of this recommendation does not appear to be necessary.

2. One commentator (Gibson, et al., 12/12/94, p. 21) recommended that subsection (a) be rewritten to reference the Science Advisory Board or Board to the OEHHA Science Advisory Board and to add the phrase "clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity" to clarify the basis on which the "state's qualified experts" render opinions. Under the Act, Health and Safety Code Section 25249.8 (b), a chemical is known to the State to cause cancer or reproductive toxicity if in the opinion of the state's qualified experts it has been clearly shown to do so through scientifically valid testing according to generally accepted principles. It is not the intention of the lead agency to eliminate a standard explicitly provided for in statute and that is why the standard has already been incorporated by reference into Health and Safety Code Section 25249.8. The standard is already incorporated in the Committees' duties, 22 CCR Section 12305 (a) 1 and (b) 1. Adoption of this recommendation would be duplicative.

SECTION 12302. "SCIENCE ADVISORY BOARD"

PUBLIC PROBLEM, ADMINISTRATIVE REQUIREMENT, OR OTHER CONDITION OR CIRCUMSTANCE THAT THE REGULATION IS INTENDED TO ADDRESS.

The Office of Environmental Health Hazard Assessment (OEHHA) filed emergency regulations, amending sections 12301 through 12305 in Title 22 of the California Code of Regulations (CCR), with the Office of Administrative Law (OAL) on October 21, 1993. OEHHA is now formally adopting these regulations in compliance with Government Code sections 11346.4 to 11346.8, inclusive, and amending 22 CCR section 12306 to merely conform with these regulations. The amendments, delineating procedures for implementation of Proposition 65, in particular the functions of the "state's qualified experts," had to be revised to allow for

greater public participation, increased visibility, and appropriate external peer review.

22 CCR section 12302, as formally adopted, will, in pertinent part, establish two committees, the Developmental and Reproductive Toxicant (DART) Identification Committee and the Carcinogen Identification Committee, which will meet separately and will each assume the responsibilities of the previous SAP for identification of reproductive toxicants and carcinogens, respectively. The size of the Committees, appointment authority for both Committees and Chairpersons and terms of office are defined. Also, definition of a quorum and related voting requirements are specified.

SPECIFIC PURPOSE OF THE REGULATION

The purpose of the amendments to section 12302 is to ensure greater public participation, increased visibility, and appropriate external scientific peer review by the "state's qualified experts," i.e., the Developmental and Reproductive Toxicant (DART) Identification Committee and the Carcinogen Identification Committee, who advise and assist the Governor in the implementation of section 25249.8 of the Health and Safety Code.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS, OR DOCUMENTS.

None.

ALTERNATIVES TO THE PROPOSED REGULATORY ACTION THAT WOULD BE AS EFFECTIVE AND LESS BURDENSOME TO PRIVATE PERSONS OR BUSINESSES.

None.

The proposed regulation will not affect any private person or business. It imposes no reporting, record keeping, or other compliance requirements. OEHHA finds that the amendment of 22 CCR sections 12301-12306 will have no adverse economic impact on individuals or businesses.

ALTERNATIVES TO THE PROPOSED REGULATORY ACTION THAT WOULD LESSEN ANY ADVERSE ECONOMIC IMPACT ON SMALL BUSINESSES.

None.

The proposed regulation will not affect any small business. It imposes no reporting, record keeping, or other

compliance requirements. OEHHA finds that the amendment of 22 CCR section 12301-12306 will have no adverse economic impact on small businesses.

DETERMINATIONS

The lead agency has determined that the adopted regulation would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by part 7 (commencing with section 17500) of Division 4 of the Government Code.

The lead agency 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 adopted regulation. The adopted regulation will not affect any private person or business. It imposes no reporting, recordkeeping or other compliance requirements. The lead agency has determined that the adopted regulation will have no adverse economic impact on private persons.

The lead agency has determined that the regulations would not affect small business, because the regulations establish an external peer review panel of the "state's experts" who advise the Governor. The adopted regulations imposed no reporting, recordkeeping, or other compliance requirements. The lead agency has determined there were no alternatives to the adopted regulations that would lessen any adverse economic impact on small businesses.

The lead agency has determined that the adopted regulations will not have a significant adverse economic impact on businesses, including the ability of California businesses to compete with businesses in other states.

The lead agency has determined that the regulations will not significantly affect the following:

(1) The creation or elimination of jobs within the State of California,

(2) The creation of new businesses or the elimination of existing businesses within the State of California,

(3) The expansion of businesses currently doing business within the State of California.

COMMENTS AND RESPONSES

1. One commentator (Brady, 8/11/94, p. 1) suggested that the two committee system is redundant and may be counterproductive if the two groups do not agree. The adopted regulations establish duties and responsibilities for each committee which are separate and distinct for each committee (see 22 CCR 12305 (a) 1-4 and (b) 4). The committees do not share the same responsibilities, so there is no opportunity for the committees to disagree over the same issue. This suggestion does not appear to be relevant.

2. One commentator (Kurtz, 8/11/94, p. 3) recommended that description of the Board be narrowed to describe the Board as consisting of two Committees, the Carcinogen Identification Committee and DART Committee as the proposed text leaves the Board open for later creation of additional advisory committees. This recommendation appears to assume the Governor intends to create additional committees under Title 22. However, the Act only refers to the "state's experts" review on chemicals known to cause cancer or reproductive toxicity. Under this section of the regulation the Committees as they appear in the adopted regulation are the only standing committees that can exist. The corresponding subcommittees are required to be composed of respective committee members. Therefore, while the number and process for the creation of additional advisory committees may be a subject for future regulatory action, it does not appear necessary to adopt this recommendation at this time.

3. Several commentators (Roberts, 8/15/94; p. 3; Hedrick, 1/5/94, p. 3; Kurtz, 8/11/94, p. 3) recommended that the size or the number of members that can be appointed to each committee should be specified. One of the commentators (Kurtz, 8/11/94, p. 3) recommended that each committee should consist of not less than 7 nor more than 9 members. Accordingly, adopted regulations 22 CCR Section 12302 (b)1 and (b)2 have been modified to allot each committee no less than 7 members and no more than 11 members. The modified language calls for a maximum of 11 members instead of the recommended 9 members because in some instances it is possible to have experts in more than 9 areas of specialization. The two additional authorized members therefore were added to accommodate appointments from other areas of specialization.

4. One commentator (Kurtz, 8/11/94, p. 3) recommended that committee membership should be limited to individuals

with proven records and credentials in the fields of oncology and reproductive and developmental toxicology and further that the adopted regulation should state that committee appointments are not limited to California residents. Under the adopted regulation, each person appointed to the Board must be an expert in one of the specified scientific disciplines pertinent to the identification of carcinogens or reproductive toxicants. Nothing in the adopted regulation prevents the Governor from appointing out-of-state individuals with proven records or credentials from the recommended areas of specialization. Moreover, considering the importance and consequence of the opinions rendered by the Committees, the Governor should preserve the option to have as many experts from among the widest range of appropriate and relevant areas of specialization. Therefore, this recommendation was not adopted.

5. Several commentators (Kronenberg, 7/29/94, p. 2; Roberts, 10/6/94, p. 32; Hedrick, 1/5/94, p. 1; Kurtz, 8/9/94, p. 4; Gibson et al, 10/6/94, p. 32; Vaughan, 10/6/94, p. 2; Guarino & Ziller, 10/6/94, p. 2) recommended that the appointment authority for the Committee should rest solely with the Governor and should not be shared or delegated to the lead agency Director. Further, two commentators (Roberts, 8/15/94, p. 1; Hedrick, 1/5/94, p. 1) recommended terms of office for Committee members. The adopted regulation has been modified to incorporate these recommendations. Accordingly, under the adopted regulation, Committee members are appointed by the Governor and serve staggered four year terms.

6. One commentator (Gibson, et al., 8/15/94, p. 3 and 10/6/94, p. 33) recommended that the lead agency clarify that the Executive Secretary is a non-voting position and not a member of the SAB. The Governor designates a state employee with expertise in more than one area of specialization (see 22 CCR 12302 (b) 1 and 2). It is the interpretation of the lead agency that the Executive Secretary is not a member of the Committee, as the adopted regulation provides for a selection by "designation" by the Governor, not "appointment" by the Governor. Moreover, all references to voting requirements (see adopted 22 CCR Sections 12302 and Section 12304) are related to Committee members. The Executive Secretary is an individual who provides staff support and meeting coordination to both Committees and, as a matter of practice, the Executive Secretary has been the Director of the lead agency. This explanation should satisfy the recommendation.

7. Two commentators (Vaughan, 12/12/94, p. 1; Guarino & Ziller, 12/12/94, p. 2) recommended that Cal/EPA employees should be barred from serving as voting members of the SAB. Since the stated purpose of the adopted regulation is to provide for appropriate external scientific peer review, the Governor's appointments by definition would be experts external to Cal/EPA and most likely external to state employee scientists. The present Committee members are distinguished scientists and physicians from academia and the private sector. No Cal/EPA or state employee scientist is a member of either Committee. Therefore, while this may be a subject for further regulatory action, it does not appear necessary in order to adopt this recommendation.

8. One commentator (Gibson, et al., 10/6/94, p. 33) recommended that the SAB meet not less than once a year. The adopted regulation has been modified to incorporate this recommendation.

9. Several commentators (Kronenberg, 7/29/94, p. 2; Gibson, et al., 8/15/94, p. 3; Roberts, 8/15/94, p. 2; Hedrick, 1/5/94, p. 2; Gibson, et al., 10/6/94, p. 33; Guarino & Ziller, 10/6/94, p. 2, and 12/12/94, p. 2; Vaughan, 10/6/94, p. 1 and 12/12/94, p. 1) recommended that the regulations specify what period of time constitutes "reasonable public notice" for SAB Committee and Subcommittee meetings and, that there be public access to materials on which Committees, SAB or Subcommittees rely. It is the policy of the lead agency to conduct SAB meetings in accordance with the Bagley-Keene Open Meeting Act (Government Code Section 11120 et seq.). Government Code Section 11125 (b) specifically requires that notice of a meeting shall include a specific agenda for the meeting, which shall include the items of business to be transacted or discussed. Accordingly, 22 CCR Section 12302 already incorporates that language. It is also the policy of the lead agency to treat materials presented for consideration or discussion as public records. Such materials are a public record at the time they are submitted to the Committees, and are being made available pursuant to the Public Records Act (see Government Code Section 6520, et seq.). The adopted regulation has been modified to provide that any correspondence to the Committees relating to materials presented for consideration or discussion are available as a public record.

10. One commentator (Gibson, et al., 12/12/94) recommended that more than 30 days notice be required when

the agenda for a Committee meeting schedules the review of more than one chemical. Under the open meeting law, however, only 30 days notice must be provided regardless of what is on the agenda. As a matter of general practice, the lead agency already provides thirty days notice through publication in the California Regulatory Notice Register. From the moment a chemical is identified as being of interest to the Committee through the opinion rendering meeting, the public has a minimum 60-90 days cumulative public notice through the California Regulatory Notice Register for most of the chemicals handled by the Committees. Therefore, this recommendation does not appear necessary.

11. Several commentators (Gibson, et al., 8/15/94, p. 3; Roberts, 8/15/94, p. 3; Hedrick, 1/5/94, p. 3; Kurtz, 8/9/94, p. 4; Gibson, et al., see manuscript 10/6/94, p. 35; Guarino & Ziller, 10/6/94, p. 2, and 12/12/94, p. 3; Vaughan, /10/6/94, p. 2 and 12/12/94, p. 2; California Rice Industry Association, 12/09/94, p. 1, Kelly, 12/9/94, p. 1; Gibson, et al., 12/12/94, p. 25) recommended that the voting requirement for committee decisions to list chemicals should be a "super majority" of three-fourths of those members voting, or the concurrence of no less than 4 to 5 members who are eligible to vote. This does not appear to be necessary. Under the adopted regulation, an affirmative vote of a majority of the appointed members appointed to the Committee is required. At a minimum 4 members constitute a quorum. Further, it has been the general practice of the agency to coordinate meetings times with members and publicly notice meetings at least 30 days in advance, which generally means that the meeting dates are arranged with members more than 30 days in advance. This has insured that almost all the Committee members have been able to attend each meeting. A review of past committees' activities shows that all of the listing decisions in the past two years were made based on the unanimous vote of each committee.

12. The commentators argue that the "clearly shown" statutory standard which is employed in the review of chemicals establishes a standard to be applied to the number of committee members required to make listing decisions. That is not the case. The "clearly shown" standard is a legal standard or threshold which must be met in order to render an affirmative listing opinion. The super majority voting requirement creates a hurdle not originally contemplated in the Act. The statute makes no reference to a minimum number of "state's experts." Secondly, the analogy to the Committee members being the equivalent of a

criminal/civil jury is inappropriate. Committees composed of expert scientists are more analogous to the judicial expert hearing evidence and rendering an opinion - the lone judge or at the appeal level, a panel of judges. In the judicial arena, the high courts do not require a super majority in order to make rulings. A simple majority of judges decide the life or death of citizens or in civil cases decide the liability of major corporations.

Based on past attendance and voting experience and for the reasons stated above, this recommendation does not appear to be necessary.

SECTION 12303. "COMPENSATION"

PUBLIC PROBLEM, ADMINISTRATIVE REQUIREMENT, OR OTHER CONDITION OR CIRCUMSTANCE THAT THE REGULATION IS INTENDED TO ADDRESS.

The Office of Environmental Health Hazard Assessment (OEHHA) filed emergency regulations, amending sections 12301 through 12305 in Title 22 of the California Code of Regulations (CCR), with the Office of Administrative Law (OAL) on October 21, 1993. OEHHA, is now permanently adopting those emergency regulations in compliance with Government Code sections 11346.4 to 11346.8, inclusive, and amending 22 CCR section 12306 to merely conform with these regulations.

22 CCR section 12303, as adopted, will, in pertinent part, clarify that members of the newly formed Carcinogen Identification Committee and the Developmental and Reproductive Toxicant (DART) Identification Committee, are entitled to reimbursement for their professional services to the State.

SPECIFIC PURPOSE OF THE REGULATION

The purpose of the amendment of section 12303 is to ensure that members of the newly formed Science Advisory Board (SAB) are reimbursed for their services as the "state's qualified experts" who advise and assist the Governor in the implementation of section 25249.8 of the Health and Safety Code.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS, OR DOCUMENTS.

None.

ALTERNATIVES TO THE PROPOSED REGULATORY ACTION THAT WOULD BE AS EFFECTIVE AND LESS BURDENSOME TO PRIVATE PERSONS OR BUSINESSES.

None.

The proposed regulation will not affect any private person or business. It imposes no reporting, record keeping, or other compliance requirements. OEHHA finds that the amendment of 22 CCR sections 12301-12306 will have no adverse economic impact on individuals or businesses.

ALTERNATIVES TO THE PROPOSED REGULATORY ACTION THAT WOULD LESSEN ANY ADVERSE ECONOMIC IMPACT ON SMALL BUSINESSES.

None.

The proposed regulation will not affect any small business. It imposes no reporting, record keeping, or other compliance requirements. OEHHA finds that the amendment of 22 CCR sections 12301-12306 will have no adverse economic impact on small businesses.

DETERMINATIONS

The lead agency has determined that the adopted regulation would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by Part 7 (commencing with Section 17500) of Division 4 of the Government Code.

The lead agency 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 adopted regulation. The adopted regulation will not affect any private person or business. It imposes no reporting, recordkeeping, or other compliance requirements. The lead agency has determined that the adopted regulation will have no adverse economic impact on private persons.

The lead agency has determined that the regulations would not affect small business, because the regulations establish an external peer review panel of the "state's experts" who advise the Governor. The adopted regulations impose no reporting, recordkeeping, or other compliance requirements. The lead agency has determined there were no

alternatives to the adopted regulations that would lessen any adverse economic impact on small businesses.

The lead agency has determined that the adopted regulation will not have a significant adverse economic on businesses, including the ability of California businesses to compete with businesses in other states.

The lead agency has determined that the regulations will not significantly affect the following:

(1) The creation or elimination of jobs within the State of California,

(2) The creation of new businesses or the elimination of existing businesses within the State of California,

(3) The expansion of businesses currently doing business within the State of California.

COMMENTS AND RESPONSES

No comments received

SECTION 12304. "FINANCIAL DISCLOSURE"

PUBLIC PROBLEM, ADMINISTRATIVE REQUIREMENT, OR OTHER CONDITION OR CIRCUMSTANCE THAT THE REGULATION IS INTENDED TO ADDRESS.

The Office of Environmental Health Hazard Assessment (OEHHA) filed emergency regulations, amending sections 12301 through 12305 in Title 22 of the California Code of Regulations (CCR), with the Office of Administrative Law (OAL) on October 21, 1993. OEHHA is now formally adopting these regulations in compliance with Government Code sections 11346.4 to 11346.8, inclusive, and amending 22 CCR section 12306 to merely conform with these regulations.

22 CCR section 12304, as adopted, will, in pertinent part, clarify that the financial disclosure requirements of Sections 81000 through 91015 of the Government Code and 2 CCR sections 18000 et seq. are fully applicable to members of the Carcinogen Identification Committee and the Developmental and Reproductive Toxicant (DART) Identification Committee. Also, it establishes that committee members must be in compliance with Government Code

Sections 81000 through 91015 and 2 CCR Sections 18000 et seq. in order to vote on an official action of a committee.

SPECIFIC PURPOSE OF THE REGULATION

The purpose of the amendment of section 12304 is to ensure that members of the newly formed SAB refrain from proscribed conflicts of interest, and that they comply with the financial disclosure requirements of the Sections 81000 through 91015 of the Government Code and 2 CCR sections 18000 et seq.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS, OR DOCUMENTS.

None.

ALTERNATIVES TO THE PROPOSED REGULATORY ACTION THAT WOULD BE AS EFFECTIVE AND LESS BURDENSOME TO PRIVATE PERSONS OR BUSINESSES.

None

The proposed regulation will not affect any private person or business. It imposes no reporting, record keeping, or other compliance requirements. OEHHA finds that the amendment of 22 CCR section 12301-12306 will have no adverse economic impact on individuals or businesses.

ALTERNATIVES TO THE PROPOSED REGULATORY ACTION THAT WOULD LESSEN ANY ADVERSE ECONOMIC IMPACT ON SMALL BUSINESSES.

None

The proposed regulation will not affect any small business. It imposes no reporting, record keeping, or other compliance requirements. OEHHA finds that the amendment of 22 CCR sections 12301-12306 will have no adverse economic impact on small businesses.

DETERMINATIONS

The lead agency has determined that the adopted regulation would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by Part 7 (commencing with Section 17500) of Division 4 of the Government Code.

The lead agency 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 adopted regulation. The adopted regulation will not affect any private person or business. It imposes no reporting, recordkeeping, or other compliance requirements. The lead agency has determined that the adopted regulation will have no adverse economic impact on private persons.

The lead agency has determined that the regulations would not affect small business, because the regulations establish an external peer review panel of the "state's experts" who advise the Governor. The adopted regulations impose no reporting, recordkeeping, or other compliance requirements. The lead agency has determined there were no alternatives to the adopted regulations that would lessen any adverse economic impact on small businesses.

The lead agency has determined that the adopted regulation will not have a significant adverse economic on businesses, including the ability of California businesses to compete with businesses in other states.

The lead agency has determined that the regulations will not significantly affect the following:

(1) The creation or elimination of jobs within the State of California,

(2) The creation of new businesses or the elimination of existing businesses within the State of California,

(3) The expansion of businesses currently doing business within the State of California.

COMMENTS AND RESPONSES

1. One commentator (Gibson, et al., 10/6/94, p. 23)recommended that only SAB members who met the financial disclosure requirements would be entitled to reimbursement and permitted to participate in committee activities or meetings. In order to ensure that the opinions of the Committee members are free of bias and undue influence, Committee members under the adopted regulation are subject to the Political Reform Act (see Government Code Sections 81000 through 91015) and corresponding regulations and additionally are required to annually report funding sources for all professional activities 12 months prior to

appointment and annually thereafter. The adopted regulation was modified to require committee members to be in compliance with the financial disclosure requirements in order to be eligible to vote. The lead agency believes this new voting eligibility provision helps to ensure that committee members must have met the financial disclosure requirements prior to engaging in the statutorily enumerated activity. Further modification of the adopted regulation is unnecessary.

2. Several commentators (Gibson, et al., 8/15/94, p. 4, 10/6/94, p.23, 12/12/94 pp. 43-45, transcript, 12/12/94, p. 9, transcript, 10/6/94, p. 8; Vaughan, 10/6/94, p. 1 and 12/12/94, p. 1; Kelly, 12/9/94, p. 1; Guarino & Ziller, 12/12/94, p. 2) recommended that the lead agency adopt criteria and procedures for identifying intellectual bias of SAB members and a recusal procedure similar to a process developed by federal advisory committees. Individuals are appointed to the committees as the "state's qualified experts" because they are recognized for their research, writings and lectures on carcinogens and reproductive toxicants. If committee members are to be eliminated from participation because of their expertise, then the core of individuals left to participate are people who are not qualified experts. Secondly, committee members have been made subject to the financial disclosure laws. Consequently, the required disclosure information is a public record and available for public inspection. There is nothing that prevents the disclosure information from becoming the catalyst for a member to recuse himself or herself, or for the public to request recusal of a Committee from participating on the review of a particular chemical. Finally, the procedures adopted by the federal agencies in some instances are guidelines, not regulations. Therefore, while this may be a subject for future regulatory action, it does not appear necessary or practicable to resolve it in these regulations.

SECTION 12305. "DUTIES"

PUBLIC PROBLEM, ADMINISTRATIVE REQUIREMENT, OR OTHER CONDITION OR CIRCUMSTANCE THAT THE REGULATION IS INTENDED TO ADDRESS.

The Office of Environmental Health Hazard Assessment (OEHHA) filed emergency regulations, amending sections 12301 through 12305 in Title 22 of the California Code of Regulations (CCR), with the Office of Administrative Law

(OAL) on October 21, 1993. OEHHA is now formally adopting these regulations in compliance with Government Code sections 11346.4 to 11346.8, inclusive.

22 CCR section 12305, as adopted, will, in pertinent part, delineate the activities and duties of the Carcinogen Identification Committee and the Developmental and Reproductive Toxicant (DART) Identification Committee.

SPECIFIC PURPOSE OF THE REGULATION

The purpose of the amendment of section 12305 is to clarify the activities and duties of the Carcinogen Identification Committee and the Developmental and Reproductive Toxicant (DART) Identification Committee as the "state's qualified experts" who advise and assist the Governor in the implementation of section 25249.8 of the Health and Safety Code.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS, OR DOCUMENTS.

None.

ALTERNATIVES TO THE PROPOSED REGULATORY ACTION THAT WOULD BE AS EFFECTIVE AND LESS BURDENSOME TO PRIVATE PERSONS OR BUSINESSES.

None.

The proposed regulation will not affect any private person or business. It imposes no reporting, record keeping, or other compliance requirements. OEHHA finds that the amendment of 22 CCR sections 12301-12306 will have no adverse economic impact on individuals or businesses.

ALTERNATIVES TO THE PROPOSED REGULATORY ACTION THAT WOULD LESSEN ANY ADVERSE ECONOMIC IMPACT ON SMALL BUSINESSES.

None.

The proposed regulation will not affect any small business. It imposes no reporting, record keeping, or other compliance requirements. OEHHA finds that the amendment of 22 CCR section 12301-12306 will have no adverse economic impact on small businesses.

DETERMINATIONS

The lead agency has determined that the adopted regulation would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by Part 7 (commencing with Section 17500) of Division 4 of the Government Code.

The lead agency 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 adopted regulation. The adopted regulation will not affect any private person or business. It imposes no reporting, recordkeeping, or other compliance requirements. The lead agency has determined that the adopted regulation will have no adverse economic impact on private persons.

The lead agency has determined that the regulations would not affect small business, because the regulations establish an external peer review panel of the "state's experts" who advise the Governor. The adopted regulations impose no reporting, recordkeeping, or other compliance requirements. The lead agency has determined there were no alternatives to the adopted regulations that would lessen any adverse economic impact on small businesses.

The lead agency has determined that the adopted regulation will not have a significant adverse economic on businesses, including the ability of California businesses to compete with businesses in other states.

The lead agency has determined that the regulations will not significantly affect the following:

(1) The creation or elimination of jobs within the State of California,

(2) The creation of new businesses or the elimination of existing businesses within the State of California,

(3) The expansion of businesses currently doing business within the State of California.

COMMENTS AND RESPONSES

1. One commentator(Roe, 7/31/94, p. 1) recommended that the DART Committee be given the same expansion of role in 22 CCR 12305 b as the Carcinogen Committee in (a) 5.

This was a California Regulatory Notice Register printing error corrected by letter(Shulock to Smith, / /94, p...). Several other commentators (Kronenberg, 7/29/94, p. 1; Roe, 7/31/94, p. 2; Roberts, 8/15/94, p. 4; Hedrick, 1/5/94, p. 4; Kurtz, 8/9/94, p. 5) suggested that the regulation restricts the role of the Committees to review or propose standards, procedures and definitions. The development or review of standards and procedures for determining chemical carcinogenicity or reproductive toxicity is basic to the Panel's ability to render expert opinions. The adopted regulation was modified to incorporate the recommendation by clarifying that the development or review occurs in support of its statutory duties specified in Health and Safety Code Section 25249.8.

2. Two commentators (Roberts, 8/15/94, p. 4 and Hedrick, 1/5/94, p. 6) recommended that a prioritization process be promulgated as regulations. This recommendation is outside the scope of this rulemaking process. It may be a subject for future regulatory action.

3. Several commentators (Kronenberg, 7/29/94, p. 2; Gibson, et al., 8/15/94, p. 4, 10/6/94, p. 36; Vaughan, 10/6/94, p. 2 and 12/12/94, p. 2) recommended that the regulations provide a reconsideration or delisting procedure for chemicals that are already listed. With regard to chemicals recommended for listing by the Committees pursuant to 22 CCR Section 12305 (a) and (b), such a procedure already exists, since nothing prevents the Committees from reconsidering such listed chemicals. The Act prevents any other administrative appeal since the Governor must list the chemicals which are known to the State to cause cancer.

SECTION 12306. "Chemicals Formally Identified by Authoritative Bodies"

PUBLIC PROBLEM, ADMINISTRATIVE REQUIREMENT, OR OTHER CONDITION OR CIRCUMSTANCE THAT THE REGULATION IS INTENDED TO ADDRESS.

The Office of Environmental Health Hazard Assessment (OEHHA) filed emergency regulations, amending sections 12301 through 12305 in Title 22 of the California Code of Regulations (CCR), with the Office of Administrative Law (OAL) on October 21, 1993. Now that OEHHA is formally adopting these regulations in compliance with Government Code sections 11346.4 to 11346.8, inclusive, and OEHHA is

amending 22 CCR section 12306 to merely conform with these regulations.

22 CCR section 12306, as amended, will, in pertinent part, delete all reference to the former Scientific Advisory Panel, i.e., the "Panel," and substitute the term "Carcinogen Identification Committee and the Developmental and Reproductive Toxicant (DART) Identification Committee," as appropriate, to make the section conform with sections 12301 through 12305. This will clarify that the Carcinogen Identification Committee or the Developmental and Reproductive Toxicant (DART) Identification Committee, as appropriate, is authorized to distinguish, pursuant to section 25249.8 of the Health and Safety Code, which chemicals have been formally identified by an authoritative body as causing cancer or reproductive toxicity.

SPECIFIC PURPOSE OF THE REGULATION

The purpose of the amendment of 22 CCR section 12306 is to clarify that the Carcinogen Identification Committee or the Developmental and Reproductive Toxicant (DART) Identification Committee, as appropriate, is authorized to distinguish which chemicals have been formally identified by an authoritative body as causing cancer or reproductive toxicity.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS, OR DOCUMENTS.

None.

ALTERNATIVES TO THE PROPOSED REGULATORY ACTION THAT WOULD BE AS EFFECTIVE AND LESS BURDENSOME TO PRIVATE PERSONS OR BUSINESSES.

None.

The proposed regulation will not affect any private person or business. It imposes no reporting, record keeping, or other compliance requirements. OEHHA finds that the amendment of 22 CCR sections 12301-12306 will have no adverse economic impact on individuals or businesses.

ALTERNATIVES TO THE PROPOSED REGULATORY ACTION THAT WOULD LESSEN ANY ADVERSE ECONOMIC IMPACT ON SMALL BUSINESSES.

None.

The proposed regulation will not affect any small business. It imposes no reporting, record keeping, or other compliance requirements. OEHHA finds that the amendment of 22 CCR sections 12301-12306 will have no adverse economic impact on small businesses.

DETERMINATIONS

The lead agency has determined that the adopted regulation would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by Part 7 (commencing with Section 17500) of Division 4 of the Government Code.

The lead agency 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 adopted regulation. The adopted regulation will not affect any private person or business. It imposes no reporting, recordkeeping, or other compliance requirements. The lead agency has determined that the adopted regulation will have no adverse economic impact on private persons.

The lead agency has determined that the regulations would not affect small business, because the regulations establish an external peer review panel of the "state's experts" who advise the Governor. The adopted regulations imposed no reporting, recordkeeping, or other compliance requirements. The lead agency has determined there were not alternatives to the adopted regulations that would lessen any adverse economic impact on small businesses.

The lead agency has determined that the adopted regulation will not have a significant adverse economic on businesses, including the ability of California businesses to compete with businesses in other states.

The lead agency has determined that the regulations will not significantly affect the following:

(1) The creation or elimination of jobs within the State of California,

(2) The creation of new businesses or the elimination of existing businesses within the State of California,

(3) The expansion of businesses currently doing business within the State of California.

COMMENTS AND RESPONSES

1. One commentator(Gibson, et al., 12/12/94, p. 35) recommended that this section be amended in this rulemaking process so that references could be altered to read "Boards" instead of "Panel." This recommendation was adopted following the close of the August 15, 1994 public comment period. 22 CCR Section 12306 was amended accordingly in the October 28, 1994 text.

2. One commentator (Gibson, et al., 12/12/94, p. 36) recommended that both the Carcinogen Committee and DART Committee have the authority to revoke or rescind any determination that a body is authoritative (see 22 CCR Section 12306 (b)). This recommendation was adopted following the close of the December 12, 1994 comment period.

Another commentator recommended a process whereby the Committees could reconsider chemicals which were initially listed by an authoritative body which the Committees later no longer consider to be authoritative. An equally effective process is already envisioned in 22 CCR Section 12306 j (1) and (2). Those subsections allow the lead agency, an interested party or a Committee member to initiate such a review. Nothing in existing or the adopted regulation prevents the Committees from reconsideration of chemicals under the circumstances suggested by the commentator. Therefore, these recommendations were not adopted.

PART II. PROCEDURAL ISSUES: COMMENTS AND RESPONSES

One commentator (Gibson, et al., 10/6/94, pp. 1-46 and 12/12/94, pp. 37-46) has raised procedural issues associated with this rulemaking. The commentator alleges that OEHHA has failed to properly initiate the rulemaking process necessary to formally amend the SAB regulations. Based on that allegation, the commentator argues that OEHHA is required to restart the rulemaking process. The issues raised by this commentator and OEHHA's responses are provided below.

1. The commentator states that OEHHA failed to notify the public until September 30, 1994 that it intended to undertake a formal rulemaking, and thus OEHHA must restart the formal rulemaking process. The commentator alleges that

the July 1, 1994 Notice: (i) pertained to emergency regulations; (ii) was inadequate notice of a formal rulemaking process; and (iii) did not satisfy the requirements of Government Code section 11346.5. (Gibson, et al., 10/6/94, pp. 1-12). The commentator also states that: (i) the alleged procedural inadequacy associated with the July 1 Notice caused a low number of comments; and (ii) OEHHA is estopped from adopting permanent regulations because an OEHHA employee indicated to Gibson et al. that the July 1 Notice pertained to emergency regulations (Gibson, et al., 10/6/94, pp.6 and 7).

OEHHA regrets that the commentator was confused by the July 1 Notice and conversations with OEHHA. However, the July 1 Notice substantially complied with the requirements of section 11346.5, and the purpose of such a notice is to notify the public of formal rulemaking. Additionally, the proposed permanent regulations were sufficiently related to the emergency regulations to justify use of the July 1 Notice to solicit comments on the proposed regulations. Nonetheless, even if, for the sake of argument, the July 1 Notice was flawed or the commentator's discussions with OEHHA were confusing, such problems were cured by the October 28, 1994 Notice of Proposed Rulemaking for the proposed regulations, which was followed by a 45 day comment period in compliance with Government Code sections 11346.4 and 11346.5. The effectiveness of the October 28 Notice and 45 day public comment period is evidenced by the 50 pages of comments submitted by Gibson, et al. on December 12, 1994 and the fact that 12 other commentators responded to the October 28 Notice. Subsequently, another Notice of 15 Day Availability appeared in the California Regulatory Notice Register on December 30, 1994. OEHHA has considered and responded to all timely comments.

Finally, according to Government Code section 11346.5 (c), any alleged inadequacy in the July 1 Notice or any other notice associated with this rulemaking is not grounds for invalidation of the regulations. Government Code section 11356.5(c) states:

> (c) This section shall not be construed in any manner that results in the invalidation of a regulation because of the alleged inadequacy of the notice content or the summary or cost estimates, or the alleged inadequacy or inaccuracy of the housing cost estimates, if there has been substantial compliance with those requirements.

2. The commentator also argues that OEHHA's Initial Statement of Reasons associated with the July 1 Notice was insufficient, thus requiring OEHHA to restart the formal rulemaking process (Gibson et al., 10/6/94 pp.9-10). In particular, the commentator argues that absence of the statement that "no alternatives considered by the agency would be more effective or..... less burdensome" in the Initial Statement of Reasons requires an agency to begin the rulemaking process all over again. To bolster its argument that absence of the statement regarding alternatives in the Initial Statement of Reasons is a fatal flaw, the commentator provides an incomplete quotation from OAL's decision in OAL File No. 93-0806-03S.

OEHHA responds that it made a good faith effort to comply with Government Code sections 11346.14, 11346.4, 11346.53, 11346.54 and 11346.6 in the Initial Statement of Reasons associated with the July 1 Notice. Furthermore, any flaws that might have existed were cured in the Final Statement of Reasons. For example, the Final Statement of Reasons contains a statement that "No alternative considered by the agency would be more effective or.. less burdensome.." When read in full, the decision in OAL File No. 93-0806-03S indicates that the alternatives statement can be provided in the Final Statement of Reasons to achieve compliance with Government Code sections 11346.14(b) and 11346.7(b)(4). The relevant complete quotation from the decision in OAL File No. 93-0806-03S is as follows:

> "Neither the initial statement of reasons nor the final statement of reasons contain a statement that no alternative considered by the agency would be more effective or ..."

93:41-Z Ca. Regulatory Notice Reg. 1274,1276. (Underlined text was omitted in the quotation provided by the commentator)

3. The commentator also states that no circumstances exist to justify another emergency amendment of the SAB regulations (Gibson, et al. 10/6/94 pp.11,12 and 12/12/94, pp.46-47). OEHHA is not seeking approval of emergency regulations at this time. Furthermore, the decision to approve the adoption of emergency regulations is made by OAL, not the affected state agency. In this case, OEHHA's successive requests for readoption of the emergency regulations were justified and approved by OAL.

4. The commentator also alleges that OEHHA must restart the rulemaking process because OEHHA has not described the alternatives it considered and has not stated its reasons for rejecting alternatives it has discarded (Gibson, et al. 12/12/94 pp. 37-43). The commentator alleges that OEHHA has not explained its reasons for adopting the proposed regulations instead of the alternatives suggested by the commentator on August 15 and October 6, 1994. The commentator also alleges that OEHHA has not complied with Government Code section 11346.14(b) (Gibson, et al. 12/12/94 p.42).

OEHHA disagrees with these comments. In its Final Statement of Reasons, OEHHA has in fact responded to all of the alternatives presented by all commentators during the public comment periods. In some instances, alternatives submitted by commentators were adopted and the proposed regulations were modified, while in some other situations OEHHA explained why it was not optimal to adopt commentators' alternatives (see, for example, the Final Statement of Reasons "Comments and Responses" regarding section 12302 of the regulations). Finally, OEHHA has complied with Government Code section 11346.14(b), because the "Determinations" sections of the Final Statement of Reasons contain the statement that "...no alternatives considered by the agency would be more effective in carrying out the purpose for which the regulation is proposed..." (Response No. 2 above is also incorporated into this response for further discussion of compliance with section 11346.14(b) and OAL Decision No.93-0806-03S).

5. The commentator also alleges that OEHHA must restart the rulemaking process because it did not comply with Government Code section 11346.5 and describe or cite to comparable federal law from which the SAB regulations substantially depart. The commentator argues that various federal scientific advisory bodies perform a role that is comparable to that of the Proposition 65 Committees of the Science Advisory Board (Gibson, et al. 12/12/94 pp.43-46).

The intent of section 11346.5 (a)(3) is to discuss federal laws, governing the same subject area as the state regulations, which overlap, affect or might be affected by the proposed state regulations. In this instance, no comparable federal law(s) exists. There is no body charged by statute to carry out, at the federal level, the missions of Proposition 65, the SAB or OEHHA. OEHHA has reviewed a majority of the federal laws, boards and panels cited by

commentators and finds that they are not comparable for purposes of Government Code section 11346.5(a)(3).

Although the referenced panels do provide various forms of scientific advice, their generalized roles are in no way comparable to the charge to the Proposition 65 committees. The role of the Proposition 65 committees is to serve as the "state's qualified experts" for purposes of determining if a chemical is known to the state to cause cancer or reproductive toxicity. Specifically, section 25249.8(b) of the Health and Safety Code states that "A chemical is known to the state to cause cancer or reproductive toxicity within the meaning of this chapter if in the opinion of the state's qualified experts it has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity."

The other panels referred to by Gibson, et al. provide various forms of generalized advice. The CERCLA panel advises on risks posed by waste sites; the various USEPA panels provide outside advice on a variety of USEPA programs; the FDA Public Board of Inquiry reviews disputes arising from FDA final regulatory actions; the Commission of Dietary Supplement Labels deal with subjects germane to that issue area. None of those panels have the role of identifying chemicals known to the State of California to cause cancer or reproductive toxicity.

OEHHA has also found that with regard to intellectual bias, some of the procedures adopted by the federal agencies are guidelines, not regulations. For additional discussion of comments on intellectual bias, please see Response No. 6 below and Response No. 2 for section 12304 above, both of which are incorporated herein by reference.

6. The commentator also alleges that OEHHA's proposed regulations are silent on intellectual bias and therefore depart significantly from comparable federal law. (Gibson et al., 12/12/94, p.45). As discussed in Response No.5 above, the federal laws cited by commentator are not comparable for purposes of Government Code section 11346.5(a)(3). For additional discussion of comments on intellectual bias, please see Response No. 2 for section 12304 above, which is incorporated herein by reference.

7. The commentator also states that OEHHA must issue a new informative digest which describes comparable federal

regulations and statutes (Gibson et al, 12/12/94, p. 45). As discussed in Response No. 5 above, the federal regulations and statutes cited by the commentator are not comparable for purposes of these regulations. Thus, the informative digest does not need to be revised. Even if, arguendo, the federal laws and regulations were comparable, failure to reissue the informative digest would not necessarily invalidate the regulations. Government Code section 11346.5(c) states that section 11346.5 shall not be construed in any manner that results in the invalidation of a regulation because of the alleged inadequacy of the notice content.

8. Commentators also state that the Initial Statement of Reasons incorrectly claims that OEHHA is permanently adopting the emergency regulations (Gibson et al., 12/12/94, p.46). The proposed regulations and the emergency regulations were sufficiently related so that the Initial Statement of Reasons is not invalid. The quantity and substance of comments received by OEHHA indicates that members of the public were not confused by the Initial Statement of Reasons.