CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

FINAL STATEMENT OF REASONS

TITLE 22 CALIFORNIA CODE OF REGULATIONS DIVISION 2

Amendment to: **Section 12701 (General)**
Repeal of: **Section 12713 (Exposure to Foods, Drugs, Cosmetics, and Medical Devices)**

The Safe Drinking Water and Toxic Enforcement Act of 1986 (Health and Safety Code, Section 25249.5, *et seq.*) (hereinafter referred to as the "Act" or "Proposition 65") was adopted as an initiative statute by a margin of two to one at a general election on November 4, 1986. The Act prohibits any person in the course of doing business from knowingly and intentionally exposing any individual to a chemical known to the state to cause cancer or reproductive toxicity "without first giving clear and reasonable warning to such individual." Chemicals which are known to the state to cause cancer or reproductive toxicity are placed upon a list, which now includes more than 500 substances.

Section 25249.12 of the Act authorizes the Governor to designate a lead agency to implement the Act, and empowers the lead agency to adopt and modify regulations as necessary to conform with and implement the provisions of the Act, and to further its purposes. By Executive Order D-61-87, Governor Deukmejian designated the Health and Welfare Agency to be the lead agency for the implementation of the Act.

On February 16, 1988, the Health and Welfare Agency adopted emergency regulations in Article 7 of Chapter 3 of Division 2 of Title 22 of the California Code of Regulations. (Unless otherwise indicated, all section references are to Title 22, California Code of Regulations, hereinafter 22 CCR.) These regulations included an interim measure to make specific the phrase "no significant risk" as it pertains to food, drug, cosmetic and medical device products (22 CCR, Section 12713). The emergency regulation was resubmitted on June 27, 1988, October 17, 1988, and February 21, 1989. On June 9, 1989, the Health and Welfare Agency submitted a certificate of compliance with the Administrative Procedure Act (Government Code, Section 11342, *et seq.*) adopting Section 12713. The interim regulation was filed with the Secretary of State on July 10, 1989.

The Office of Environmental Health Hazard Assessment (OEHHA) is now the designated lead agency for the implementation of the Act (Executive Order W-15-91, July 17, 1991). OEHHA is repealing Section 12713 and amending Section 12701 to delete references to Section 12713.

Procedural Background

On May 7, 1993, OEHHA issued a notice of proposed rulemaking advising that the agency intends to repeal Title 22, California Code of Regulations, Section 12713, and to amend Section 12701 to make conforming changes.

Pursuant to such notice, on June 24, 1993, a public hearing was held to receive public comments on the proposed action. Eight exhibits were entered into the record during the hearing, six of which contained comments on the proposed action (Exhibits C to H). Six commentors presented oral testimony (PH-1 to PH-6). Twelve pieces of correspondence were received (C-1 to C-12). (See "Index to Exhibits, Public Hearing Speakers and Correspondence".)

Purpose of Final Statement of Reasons

This final statement of reasons sets forth the reasons for the repeal of Section 12713 and the amendment to Section 12701, and responds to the objections and recommendations submitted regarding these actions. Government Code Section 11346.7, subsection (b)(3), requires that the final statement of reasons submitted with an amended, adopted or repealed regulation contain a summary of each objection or recommendation made regarding the action 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. It specifically provides that this requirement applies only to objections or recommendations specifically directed at the proposed action or to the procedures followed in proposing or adopting the action.

Some parties included in their written or oral comments remarks and observations which do not constitute an objection or recommendation directed at the proposed action or the procedures followed. Accordingly, OEHHA is not obligated under Government Code Section 11346.7 to respond to such remarks in this final statement of reasons. The absence of a response in this final statement of reasons to such remarks should not be construed to mean that OEHHA agrees with them.

Specific Findings

A. Mandate on Local Agencies or School Districts

OEHHA has determined that the regulation imposes no mandate on local agencies or school districts.

B. Alternatives Considered

OEHHA has identified no alternatives to the proposed repeal which, if adopted, would be more effective in carrying out the purpose for which the repeal of section 12713 is

proposed, or would be as effective and less burdensome to affected private persons than the proposed repeal.

Comments: One commentor (PH-1, public hearing transcript, page 13, line 17 to page 16, line 12 [hereinafter 13:17-16:12]) stated that OEHHA's action would violate Government Code Section 11346.7 because the agency has failed to consider reasonable, less restrictive and less onerous alternatives to outright repeal of the regulation that would have less of an impact and still achieve the objective -- e.g., expediting the development of no significant risk levels for the remaining chemicals for which no levels have been established, and delaying repeal until that has been accomplished. Commentor C-9 (pages 3 and 5) stated that OEHHA has failed to present evidence in the record that adoption of levels or any other alternatives to repeal had been considered. The commentor suggested that the establishment of regulatory levels is more consistent with the initial explanation for adopting Section 12713 than is the repeal of the regulation.

Response: Upon evaluation of the history of Section 12713, of the State's experience with the regulation in particular and with the implementation of Proposition 65 in general over the past five years, and of the provisions of existing regulations (see "Reasons for Repeal of Section 12713", beginning on page 20), OEHHA was unable to identify alternatives to the repeal of the regulation which, if adopted, would be more effective, or as effective and less burdensome to affected parties than the repeal. The available evidence did not provide OEHHA with justification for further retaining a regulation dealing specifically with foods, drugs, cosmetics and medical devices. It was determined that, given the circumstances which exist at this time, repeal of the regulation is necessary in order to make clear that these products are subject to the Act in the same manner as other products. Further, it is OEHHA's view that Section 12713 provides no protection in many instances anyway (see "Reasons for Repeal of Section 12713," Reason 7, pages 30-33), and that neither the regulated community nor the public are served by the continued existence of a regulation that is often misunderstood to be a categorical exemption. No other alternatives would have achieved this purpose. Leaving the regulation in place would be contrary to the statutory mandate that regulations further the purposes of the Act.

OEHHA has rejected the commentors' recommended alternative to the repeal of Section 12713, since the establishment of regulatory levels alone would not mitigate the problems presented by the existence of Section 12713. Moreover, delaying the repeal until more regulatory levels are established would be inconsistent with the original intent of Section 12713 -- i.e., the regulation was intended to provide an "interim" standard pending the establishment of no significant risk levels for 50 chemicals (see "Background: History of Section 12713," pages 12-20, and "Reasons for Repeal of Section 12713," Reason 4, pages 24-27).

OEHHA has established, in Section 12705, a procedure for adopting no significant risk levels in regulation using conventional risk assessments and "expedited" risk

assessments. This regulation includes a provision (subsection (d)), which authorizes the adoption of levels based on risk assessments conducted following default assumptions, allowing OEHHA to develop levels in an expedited manner. No chemicals have been identified which cannot be addressed through this process. In addition, OEHHA has recently established a priority list of carcinogens for dose-response assessments, which includes provisions for interested parties to request the assignment of a higher priority to a particular chemical -- upon providing OEHHA with supporting documentation indicating that the chemical is of legitimate concern. (Even prior to the establishment of the priority list, OEHHA has requested and encouraged the regulated community -- particularly the food, drug, cosmetic and medical device industries -- to identify chemicals for which levels are necessary to assist in compliance with the Act.) Accordingly, if the commentors are concerned about the need for a specific level for a particular substance, existing administrative and regulatory mechanisms are already available to them. It is unnecessary to provide additional alternatives in this regulatory action.

C. Economic Impact

Under the Administrative Procedure Act (Government Code, Section 11346.53), OEHHA is not required to assess the potential for adverse economic impact on business from the repeal of a regulation. Nevertheless, OEHHA has concluded that repeal of the regulation will not have a significant impact on business, because: (1) it does not apply to the majority of carcinogens listed under the Act, and at this time has little, if any, regulatory impact; (2) it does not provide a categorical exemption from the Act for foods, drugs, cosmetics and medical devices, and it provides little protection from liability under the Act; (3) other regulatory provisions unaffected by the repeal make this regulation unnecessary; (4) the inapplicability of the regulation to chemicals for which "no significant risk" levels have been developed has not resulted in significant adverse economic impacts; (5) the lead agency has prioritized those chemicals for which there is currently no adopted "no significant risk" level, and has an ongoing process which allows the lead agency to quickly develop such levels as necessary to avoid uncertainty among the regulated and enforcement communities; and (6) the absence of a similar regulation for chemicals listed as causing reproductive toxicity has not resulted in significant adverse economic impacts.

Comments: A number of commentors (PH-1, 13:25-16:12; PH-4, 27:6-27:9; PH-5, 28:23-29:5; Ex-E, page 1; C-1, page 2; C-5, page 1; C-8, page 1; C-12, pages 3-4) disagreed with OEHHA's assessment of the economic impact of the repeal of Section 12713 . They identified consequences of the repeal which they claim will have a significant economic impact on business, as follows:

(a) The repeal will result in a waste of resources, time and effort due to duplication by thousands of businesses of chemical risk assessments, without increasing food safety (Ex-E, page 1/PH-2, 22:12-22-25).

(b) The repeal will create a substantial impact on business, "...as it has the obligation, if the safe harbor is not present, of evaluating the level of risk of all substances which are the subject of the priority lists in a vacuum...without guidance from the agency purporting to regulate these substances" (PH-5, 28:23-29:5).

(c) The repeal will result in members expending resources to assess whether warning is required, or make a decision to provide prophylactic warnings until a no significant risk level is established; such efforts do not add to product value, nor allow the business to recoup expenditures (C-1, page 2).

(d) The repeal will eliminate an exemption, thereby adding to the cost of products, promoting confusion and creating conflict with current regulations. The repeal will increase regulatory burden by adding redundant regulations (C-5, pages 1-2).

(e) The repeal will create a need for industry to conduct their own risk assessments, a very costly undertaking, and when state risk assessments are completed, they will supersede those of industry's (C-8, page 1).

Response: Each of the consequences identified above appears to be predicated on the assumption that the repealed regulation provides categorical exemptions for the Proposition 65 warning requirement. As described later in this document (see "Background: History of Section 12713," pages 12-20, and "Reasons for Repeal," Reasons 5 and 6, pages 27-30), the regulation provides no exemption, and was not intended to provide an exemption. The consequences identified by the commentors, to the extent that they are valid, are more accurately described as being caused by the statutory requirements created by the Act itself, and have existed since before the regulation was adopted. They are not the consequence of this regulatory action.

For example, the need for a business to assess whether a warning is required (see paragraph (c) above) is the result of the Act's requirement for a business that is knowingly and intentionally exposing individuals to regulated chemicals to provide a clear and reasonable warning prior to exposure (Health and Safety Code Section 25249.6). Whether or not Section 12713 is in place, this obligation exists.

Commentor C-5 (see paragraph (d) above) misconstrues the regulation as an "exemption". This common mischaracterization of Section 12713 is further addressed later in this final statement of reasons (see "Reasons for Repeal of Section 12713," Reason 6, pages 28-30). OEHHA does not believe the repeal of Section 12713 adds a redundant regulation, given that the obligation to provide a warning for an exposure that cannot be demonstrated as posing no significant risk exists, as discussed above, as a result of the statute. The only purpose served by this regulation is a means by which "no significant risk" can be demonstrated for specified products, under certain conditions. Its repeal eliminates one means by which a determination of no significant risk can be made, but does not result in a requirement that duplicates existing regulations.

To the extent that businesses have not been assessing whether or not a warning is required on account of Section 12713, it merely underscores the confusion caused by Section 12713, and amplifies the need for its repeal. In short, Commentor C-5's remarks provide a good illustration why this regulation should be eliminated to erase an misconception that certain product categories may be exempt from Proposition 65.

With regard to the points raised in paragraphs (a), (b) and (e) above, OEHHA notes that assessing the cancer risks posed by exposures caused by a business is an option available to businesses wishing to utilize the statutory exemption from the warning requirement for exposures that pose no significant risk. A business unable to make a showing of no significant risk may forego such assessments and simply provide warnings about the exposures, or reformulate their product to avoid exposure to carcinogens altogether. Making a determination of no significant risk invariably requires a business to conduct an exposure assessment to quantify the level of exposure to the average consumer of the product. In the absence of a regulatory level for the carcinogen in question, the business would, in addition to the exposure assessment, need to conduct a dose-response assessment to determine the cancer potency of the chemical.

No evidence has been submitted or is otherwise available to OEHHA to establish that the repeal will create a need for a large number of cancer potency derivations by affected businesses to avail themselves of the exemption for exposures posing no significant risk. Most of the chemicals that are of concern to the food, drug, cosmetic and medical industries already have regulatory levels in place (i.e., levels for 216 chemicals are set forth in Section 12705). Further, OEHHA has identified levels for 55 other chemicals, including levels for 33 chemicals that were determined to be high priority substances based on their occurrence in foods, drugs, cosmetics and medical devices. While the levels for the latter group of 55 chemicals have not been promulgated into regulation at this time, they provide a considerable degree of protection, as it is highly unlikely that an enforcement action would be taken against businesses that rely on State-identified no significant risk levels. The evidence available to OEHHA indicates that very few, if any, of the listed chemicals for which levels have not been derived are of significance to the food, drug, cosmetic and medical device industries.

OEHHA also notes that, in situations where a level is not available for a chemical which is widely used in a particular industry, it is not uncommon for a trade association or an industry-wide group to take the lead in deriving a cancer potency estimate for the chemical, thereby precluding the need for individual businesses to each conduct their own assessment. There is no reason to believe that this industry practice will change.

In response to Commentor C-8 (see paragraph (e), page 5), it should be noted that a no significant risk level derived or identified by OEHHA does not "supersede" assessments conducted by industry. Levels derived or identified by OEHHA are intended to provide "safe harbors" to businesses that utilize them, without precluding the use of alternative levels that can be demonstrated by their users as being scientifically valid. (Section 12701

provides: "Nothing in this article shall preclude a person from using evidence, standards, risk assessment methodologies, principles, assumptions or levels not described in this article to establish that a level of exposure to a listed chemical poses no significant risk.") Hence, if a business is confident in the scientific validity of an alternative number, it may rely on such number despite the existence of a number developed by the lead agency.

Rulemaking File

The rulemaking file submitted with the final regulation and this final statement of reasons is the complete rulemaking file for the repeal of Section 12713 and amendment to Section 12701.

Necessity for Repeal

OEHHA has determined, following an evaluation of the history of Section 12713, of the State's experience with the regulation in particular and with the implementation of Proposition 65 in general over the past five years, and of the provisions of existing regulations, that a number of reasons exist which make repeal of the regulation necessary in order to further the purposes of Proposition 65. In addition, the repeal would ensure that all products are subject to the same standards, and therefore that the public is not denied its rights to be informed about exposures to carcinogens from a select group of products.

A list of reasons justifying the repeal of Section 12713 appears elsewhere in this document ("Reasons for Repeal of Section 12713," pages 20-37). A number of commentors questioned the adequacy and/or validity of these reasons; their comments are addressed under the discussion for the reason in question.

Background

A. The Provisions of the Act

Health and Safety Code Section 25249.6 sets forth the warning requirement under the Act. That section provides:

> "No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in Section 25249.10."

This language is broad enough to encompass exposures to chemicals subject to the Act from virtually every media. The warning requirement was specifically intended to apply to foods. Health and Safety Code Section 25249.11 (f) states that "[i]n order to minimize the burden on retail sellers of consumer products **including foods**, regulations

implementing Section 25249.6 shall to the extent practicable place the obligation to provide warning materials such as labels on the producer or packager rather than on the retail seller, . . ." (Emphasis added.).

Section 25249.8 requires that the Governor cause to be published at least annually a list of chemicals known to the state to cause cancer or reproductive toxicity. The initial list was published on February 27, 1987, and contained 26 carcinogens and 3 reproductive toxicants. By February 27, 1988, the first effective date of Section 12713, the list contained 171 carcinogens and 14 reproductive toxicants. As of April 1, 1993, the list contains 391 carcinogens and 150 reproductive toxicants.

Section 25249.10 provides an exemption from the warning requirement for exposures to carcinogens which pose "no significant risk" of cancer. That section provides in pertinent part:

"Section 25249.6 shall not apply to any of the following:

"(c) An exposure for which the person responsible can show that the exposure poses no significant risk assuming lifetime exposure at the level in question for substances known to the state to cause cancer, and that the exposure will have no observable effect assuming exposure at one thousand (1000) times the level in question for substances known to the state to cause reproductive toxicity, based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of such chemical pursuant to subdivision (a) of Section 25249.8. In any action brought to enforce Section 25249.6, the burden of showing that an exposure meets the criteria of this subdivision shall be on the defendant." (Emphasis added.)

The Act itself does not otherwise define what constitutes "no significant risk".

Persons in the course of doing business which violate the warning requirement, however, may be enjoined from violating the requirement and are liable for a civil penalty of up to twenty-five hundred dollars ($2500) per day for each violation in addition to any other penalty provided by law. (Health and Safety Code Section 25249.7, subd. (a).) The civil penalties are recoverable in a civil action brought in the courts. (Health and Safety Code Section 25249.7, subd. (b).)

Actions to enforce the warning requirement may be brought by the state Attorney General in the name of the people, any district attorney, city attorneys in cities with populations of more than 750,000, or full-time city prosecutors with the consent of the district attorney. (Health and Safety Code Section 25249.7, subd. (c).) Actions may also be brought by any person in the public interest following 60 days' notice to each of the public prosecutors with jurisdiction over an alleged violation and to the business involved. If within sixty days none of the public prosecutors has commenced and is diligently

prosecuting an action against the violation, the private prosecutor may proceed. (Health and Safety Code Section 25249.7, subd. (d).) Under Health and Safety Code Section 25192, the public prosecutor or person who brings the action receives twenty-five (25) percent of the civil penalties collected. (Health and Safety Code Section 25192, subd. (a)(2).) This provides an economic incentive to bring actions.

Thus, the Act creates a self-executing enforcement mechanism for chemical exposures under which civil liability may be imposed by the courts where exposure to a chemical listed as causing cancer occurs without warning and the business causing exposure cannot show that the exposure poses "no significant risk".

B. The Regulations

Several of the current regulations are pertinent to the discussion herein. First, Section 12501 excludes exposure to naturally-occurring chemicals in food from the meaning of the term "expose" as that term is used in Health and Safety Code Section 25249.6. The validity of this regulation was upheld in Nicolle-Wagner v. Deukmejian, et al. (1991) (230 Cal.App.3d 652). To the extent that a business can show that a chemical in food is naturally-occurring, the Act does not apply to exposures to it. That regulation is unaffected by the repeal of Section 12713. (See Exhibit 1, 22 CCR, Section 12000, *et seq.*)

Section 12503 excludes exposure to chemicals contributed to any product through the use of drinking water from specified sources, such as public water systems, from the meaning of the term "expose" as that term is used in Health and Safety Code Section 25249.6. To the extent that a business can show that an exposure results from use of drinking water, the Act does not apply to it. That regulation is unaffected by the repeal of Section 12713.

Section 12601 provides specific "safe harbor" warning methods and messages for foods in certain circumstances, and for consumer products in general. The use of these warnings is deemed to be "clear and reasonable". That section also provides that warnings for prescription drugs provided through the labeling approved or otherwise provided under federal law and the prescribing physician's accepted practice of obtaining a patient's informed consent are deemed to be clear and reasonable. That regulation is unaffected by the repeal of Section 12713.

Section 12701 establishes the minimum standard for the determination whether an exposure to a carcinogen poses "no significant risk". It further describes the relative priority of the various "no significant risk" provisions adopted in Article 7. In particular, Section 12701 permits the determination of "no significant risk" through a risk assessment conforming to prescribed criteria, or through a regulatory level established for the chemical and set forth in Section 12705. If no level is set forth in Section 12705, then "no significant risk" may be determined, among others means, by application of Section 12713,

the provision which is now repealed. Under this proposal, Section 12701 is amended to delete references to Section 12713.

Section 12705, as originally adopted, provided in subsection (a) that exposure to a chemical at a level which does not exceed the level set forth in subsection (b) for such chemical poses no significant risk. In other words, compliance with the levels set forth in subsection (b) provided a "safe harbor" from liability under the Act. At the time Section 12705 was first adopted, there were no levels set forth in subsection (b). That subsection was simply reserved for the later addition of chemical levels. (Exhibit 2, , 22 CCR Section 12705, adopted as an emergency regulation, February 16, 1988.)

In October, 1992, Section 12705 (which contained levels for approximately 30 chemicals) was amended (effective November 9, 1992) to contain three categories of numeric levels. The first category included the levels previously contained in Section 12705. The second category included levels derived from risk assessments performed by other state or federal agencies and transferred from Section 12711. The third category consisted of levels derived from risk assessments using default assumptions, following the procedures set forth in Section 12703. In this last category, 140 levels were added by the amendments. This brought the total number of "no significant risk" levels in Section 12705 providing a "safe harbor" to 216.

The amendment also provided a regulatory locus for numeric levels quickly developed by OEHHA to respond to the needs of the regulatory and enforcement communities (Section 12705(d)). As a practical matter, levels developed by the lead agency, even prior to their regulatory adoption into Section 12705, become de facto "no significant risk" levels because the enforcement community is unlikely to take enforcement action against exposures in compliance with such levels. OEHHA has established a process to prioritize substances for the development of these levels. (Exhibit 3, "Priority List for the Development of Carcinogen Dose-Response Assessment for Proposition 65", January, 1993.) Chemicals of significant commercial interest are assigned high priority. Businesses which have a particular interest in a listed chemical and need a numeric level to assist them in complying with the Act should immediately advise OEHHA.

Section 12713, subsection (a) provides:

"The Health and Welfare Agency has determined, **based on the recommendation of the Scientific Advisory Panel**, that exposure to a listed chemical in a food, drug, cosmetic or medical device regulated under state and federal food safety laws poses no significant risk as described in this section. **This section is an interim standard.** As quantitative risk assessments are performed or identified for listed chemicals and specific regulatory levels are adopted under section 12705, **those levels will supersede the provisions of this section**." (Emphasis added.)

Subsection (b) provides definitions for the terms "food", "cosmetic", "drug", "medical device", and "administrative standards". Subsection (c) provides that, unless there is a level for a listed chemical in Section 12705, exposure to a listed chemical in a food, drug, medical device, or cosmetic (including constituents and contaminants):

> "shall be deemed to pose no significant risk within the meaning of Health and Safety Code section 25249.10(c), provided that: . . ."

the chemical falls within specified categories subject to specific regulatory levels, "...and is in compliance with **all** applicable standards." (Emphasis added.)

Subsection (d) provides that, where a listed chemical does not fall into the categories in subsection (c) and there is no level set forth in Section 12705 for the chemical, "an exposure to such chemical shall be deemed to pose no significant risk within the meaning of Health and Safety Code section 25249.10(c), provided that the exposure is in compliance with all applicable administrative standards."

The historical note to Section 12713 submitted by the Health and Welfare Agency and published in the California Code of Regulations provides:

> "This section provides interim standards pursuant to the policy of the Health and Welfare Agency and the recommendations of the Scientific Advisory Panel."

Section 12713, like all the other provisions in Article 7, applies only to chemicals listed by the state as carcinogens. It does not apply to chemicals listed as reproductive toxicants, unless the chemical is also listed as a carcinogen. There are currently 150 chemicals listed as reproductive toxicants. Some of these chemicals are relevant to foods, drugs, cosmetics or medical devices.

There is no provision for reproductive toxicants similar to Section 12713 authorizing reliance upon federal safety standards. Moreover, the standard for exemption from the warning requirement for reproductive toxicants is generally more restrictive than the standard for carcinogens; an exposure is exempt only if it would not exceed 1/1000th of the no observed adverse effect level (Health & Saf. Code, Section 25249.10(c).), and no provision is made in regulation which allows exposure to reproductive toxicants to be averaged over the lifetime of the exposed individual (see discussion below of Section 12721(d)).

Nevertheless, the lack of a provision for listed reproductive toxicants similar to Section 12713 does not appear to have promoted unrestrained litigation against manufacturers of food, drug, cosmetic and medical device products. Enforcement activities have proceeded against exposures to lead leachate from the glazes on ceramicware, lead exposures in wine caused by decorative lead-foil caps used on wine

bottles, and mercury in some over-the-counter drug formulations. (Exhibit 4, "Proposition 65 Litigation", State Department of Justice, January 15, 1993.)

Finally, Section 12721 establishes definitions for the phrases "lifetime exposure" and "level in question", and assumptions for calculating exposures to chemicals through specific media, including consumer products. Specifically for consumer products, Section 12721 provides:

> ". . . lifetime exposure shall be calculated using the average rate of intake or exposure for average users of the consumer product, and not on a per capita basis for the general population. The average rate of intake or exposure shall be based on data for use of a general category or categories of consumer products, such as the United States Department of Agriculture Home Economic Research Report, Foods Commonly Eaten by Individuals: Amount Per Day and Per Eating Occasion, where such data are available."

In effect, this provision allows the manufacturer of a consumer product to base its "no significant risk" analysis upon exposure to the average consumer, and to average exposures where the reasonably anticipated rate of consumption of products in the same category is less than daily. Thus, "[i]f it is reasonably anticipated that the product category containing chemical will be ingested only once per week, once per month, or once per year, the resulting intake of the chemical averaged over a daily basis would be 1/7, 1/30, and 1/365 of the value determined when the food is eaten once each day." (Exhibit 10, Final Statement of Reasons, article 7, June 9, 1989, page 30-31.) There is no provision for such averaging in Section 12821, which relates to exposure to listed reproductive toxicants.

C. History of Section 12713

On April 30, 1987, the Grocery Manufacturers of America and eleven other industry trade associations submitted to the Health and Welfare Agency under Government Code Section 11347.1 a petition for regulation entitled "Petition Requesting That The California Health and Welfare Agency Promulgate A Regulation Establishing Standards For Food Products To Exempt From the Public Warning Requirement of The California Safe Drinking Water and Toxic Enforcement Act Of 1986 Natural Food Substances and Other Food Substances That Are In Compliance With The Food Safety Requirements Of The Federal Food, Drug, and Cosmetic Act of 1938, The Federal Meat Inspection Act, The Poultry Products Inspection Act, The Egg Products Inspection Act, The Animal Virus, Serum, and Toxin Act, The California Sherman Food, Drug and Cosmetic Law, and The California Food and Agricultural Code." The petition contained a proposed regulation and supporting text.

The proposed regulation began with the following paragraph:

"A food does not pose a significant risk and therefore is exempt from the warning requirement under Section 25249.6 of the Health and Safety Code if the food contains a chemical included on the list of chemicals known to the State to cause cancer or reproductive toxicity caused to be published by the Governor under Section 25249.8 and is in compliance with the following requirements, as applicable, under Federal and California food safety laws."

It then contained several provisions (subsections (a)-(h)) which made reference to specific standards set forth in federal law, such as tolerances for food additives, or chemicals attributable to specified sources, such as water supplies, cooking and naturally-occurring substances. It concluded with subsection (i), which read:

"(i) The chemical is otherwise regulated under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 301, *et seq.*), the Federal Meat Inspection Act (21 U.S.C. Section 601, *et seq.*), the Poultry Products Inspection Act (21 U.S.C. Section 451, *et seq.*), the Egg Products Inspection Act (21 U.S.C. Section 1031, *et seq.*), the Sherman Food, Drug, and Cosmetic Law (California Health & Safety Code Section 26000 *et seq.*), or the California Food & Agricultural Code, and the amount of the chemical complies with the safety standards established under the applicable provisions of those statutes and all applicable limitations established in any formal or informal action levels or other regulatory announcements."

Similar petitions were filed by the Cosmetics, Toiletries and Fragrances Association, the Independent Cosmetic Manufacturers and Distributors, the Proprietary Association, and the Pharmaceutical Manufacturers Association. In response to these petitions, the Health and Welfare Agency conducted hearings on the petitions in Sacramento and Los Angeles on June 15 and 16, and July 17, 1987. Many industry representatives appeared and testified about the safety of their products, the extent of existing regulation, and the damage which warnings would cause to their industries.

The Health and Welfare Agency, however, did not adopt the proposed regulations. Subsequently, the United States Commissioner of Food and Drugs wrote the Governor on August 28, 1987, requesting that the Governor take into consideration the regulatory scheme Congress enacted in the Federal Food, Drug, and Cosmetic Act and urging the Governor to consider recognizing that the products regulated by the Food and Drug Administration under that act "present no significant risk".

Because of the widespread interest in this matter, the Agency wrote the Chairman of the Scientific Advisory Panel on November 20, 1987, requesting the Panel's opinion on whether existing state and federal standards for food, drugs, medical devices and cosmetics constitute assurance that chemicals in these products pose no significant risk within the meaning of section 25249.10(c).

In accordance with this request, the Panel considered this matter on December 11, 1987 at its scheduled public meeting. The current Commissioner of Food and Drugs, a former Commissioner of Food and Drugs, a former director of the Food and Drug Administration's Bureau of Foods, a representative of the United States Department of Agriculture, the Chief of the Food and Drug Branch of the State Department of Health Services, and a large number of interested individuals and organizations presented testimony. At the conclusion of this testimony, the Panel issued the following statement:

> "The Panel has heard substantial testimony regarding the level of protection provided by existing State and local standards regarding chemicals in foods, as well as implementation. Implementation of these standards has led to a high level of protection for the American people.
>
> "However, there is still an insufficient scientific data base to ensure that these standards fully protect against any significant risk within the meaning of Prop 65."
>
> "The Panel feels that the current State and Federal regulations do provide considerable protection of our foods, drugs, cosmetic and medical device supplies from containing excess amounts of carcinogens. Thus, on an interim basis, we recommend that levels of no significant risk for all carcinogens classified by this Panel be established according to current State and Federal regulations.
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> "However, in the spirit of Proposition 65, these regulations should only be followed until such time that risk assessments have been made for each substance by the State, [if] available, or have been obtained from some Federal agency [and made available by any organization].
>
> "If the risk assessment suggests a need for regulatory changes, then these changes should be reviewed and approved by the Scientific Advisory Panel before any further regulatory action is taken.
>
> "Further, the Panel encourages the State to establish a realistic timetable to adequately define `significant risk' and to immediately develop a priority list of approximately 50 carcinogens from the established list that we have established for risk assessments. The carcinogens on this list could be selected on the basis of the probability of exposure by humans." (Exhibit 5, Transcript, Scientific Advisory Panel meeting, December 11, 1987, pages 178-180.)

At the time of this meeting, there were 71 carcinogens on the list. Dr. Wendell Kilgore, Chairman of the Panel, who drafted all but the first two paragraphs of this statement, explained the reference to fifty chemicals:

> "I came to the conclusion that 50 was a respectable number because I expect that there will probably be approximately 300 compounds eventually on our list, and I suspect

maybe 15 to 20 percent of these could be a problem." (Exhibit 5, Transcript, Scientific Advisory Panel meeting, December 11, 1987, page 164.)

Following this meeting of the Scientific Advisory Panel, the Health and Welfare Agency issued a notice to interested parties setting forth all but the first two paragraphs of the Panel's statement. (Exhibit 6, Notice to Interested Parties, December 15, 1987.)

On February 16, 1988, the Health and Welfare Agency adopted Article 7 of Chapter 3 of Division 2 of Title 22 of the California Code of Regulations as emergency regulations to make specific the phrase "no significant risk". (22 CCR Sections 12701 - 12721.) Subsequently, the Health and Welfare Agency issued several notices to interested parties, one undated, one dated October 26, 1988, and the last dated January 1, 1989. The undated notice advises that on March 16, 1988, the Health and Welfare Agency had requested the Department of Health Services to provide or review risk assessments for 45 substances, and set forth a schedule for the completion of those activities. The subsequent dated notices set forth similar schedules for a diminishing number of substances. Each of these notices anticipated that section 12713 would be repealed by, at the latest, July 1, 1989. (Exhibit 7, Notices to Interested Parties, one undated, and others dated October 26, 1988, and January 1, 1989.)

On March 31, 1988, a coalition of labor and environmental groups filed suit seeking declaratory and injunctive relief on the ground that Section 12713 unlawfully provided an automatic or categorical exemption from Health and Safety Code Section 25249.6 for foods, drugs, cosmetics and medical devices. (Exhibit 8, "Complaint for Declaratory and Injunctive Relief", AFL-CIO, et al. v. Deukmejian, et al.* (Super. Ct. Sacramento County, 1988, No. 502541)) Several of the trade associations which originally submitted petitions for exemption from Proposition 65 based upon existing regulation intervened in the case. Throughout this case (which proceeded through the trial court to the court of appeal before settling on December 23, 1992), the state steadfastly maintained that Section 12713 does not, nor was it intended to, provide a categorical exemption from the warning requirement of Proposition 65 for food, drug, cosmetic or medical device products. It was intended to permit businesses to rely upon existing state or federal standards to the extent that these standards sustained the safety of products from carcinogenic risk. As stated in its first explanation to the trial court on the merits of the regulation:

"In fact, nothing in the regulation adopting the federal food, drug, cosmetic and medical device safety standards would exempt the proposed intervenors from Proposition 65. Section 12713 simply provides that an exposure poses no significant risk " ... provided that ... [the exposure] ... is in compliance with all applicable administrative standards" established pursuant to federal and state safety laws.

"Plaintiffs declare:

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* Commonly referred to as the "Duke II" lawsuit.

> `[T]he precise purpose of [Proposition 65] was to alter the previous scheme of exclusive but ineffective governmental enforcement by sharing enforcement power with the citizenry.' (Cite)

"Defendants agree. That is why section 12713 does not accept the fact of regulation and enforcement by federal or state agencies as proof that exposures caused by the regulated businesses pose no significant risk. It merely adopts on an interim basis existing and familiar safety standards. Persons doing business with food, drugs, cosmetics and medical devices who expose individuals to listed chemicals are still subject to enforcement actions under the Act by 27 million Californians, in addition to state and federal regulators. These businesses must prove that their exposure is in compliance with all applicable state and federal safety standards. It does not provide businesses regulated by federal or state agencies are posing no significant risk as a matter of law. Whether the exposure poses no significant risk remains a question of fact which the defendant businesses must prove." (Exhibit 9, "Defendants' Reply to Plaintiffs' Memorandum of Points and Authorities in Opposition to Motions to Intervene", August 11, 1988, pages 3-4, AFL-CIO, et al. v. Deukmejian, et al. (Super. Ct. Sacramento County, 1988, No. 502541))

The emergency regulations were resubmitted on June 27, 1988, October 17, 1988, and February 21, 1989. On June 9, 1989, the Health and Welfare Agency submitted a certificate of compliance with the Administrative Procedure Act (Government Code, Section 11342, *et seq.*) adopting Sections 12701 through section 12721. These regulations were filed with the Secretary of State on July 10, 1989. Among these regulations was Section 12713.

The Final Statement of Reasons submitted in support of these regulations contained an extensive discussion of Section 12713. It stated in part:

"This regulation is based upon the recommendation of the Panel. The Agency finds that existing state and federal food, drug, cosmetic and medical device safety standards, if complied with, are sufficient to protect consumers from substances in such products that pose any significant risk of cancer within the meaning of section 25249.10(c), pending the establishment of specific `no significant risk' levels. The Agency's conclusion is based on the broad applicability of state and federal safety standards, as reflected in the numerous regulatory decisions prohibiting or restricting the presence of carcinogens in such products . . . pending the establishment of specific levels for the chemical constituents and contaminants of foremost concern in such products." (Exhibit 10, Final Statement of Reasons, Article 7, June 9, 1989, page 45-45.)

In response to objections to the approach, and some comments of support, the Health and Welfare Agency observed:

"Implicit in some of the supporting comments and most of the objections is the belief that, under this regulation, the mere fact that a product is regulated under certain federal or state laws means that the product poses no significant risk. This is incorrect. This section refers to standards only. Each of these product categories is subject to some kind of administrative standard. In every case there are non-specific qualitative standards. In many cases there are specific quantitative standards. In order for a product to be deemed to pose no significant risk, it must be in compliance with all applicable administrative standards.

"The fact that an administrative agency, such as the federal Food and Drug Administration (FDA), has not taken action against persons causing exposure to a product which may not be in compliance with the applicable administrative standards does not mean that the product poses no significant risk. The absence of administrative action may simply mean that the FDA has, for administrative reasons, decided not to take action. It cannot be taken as conclusive proof that the applicable standards have been met.

"It is the intention of the Agency that an action under the Act be available to make certain that these standards are satisfied. Accordingly, the `safe harbor' afforded by this section is available only where all applicable administrative standards have been complied with. Public prosecutors or persons in the public interest may bring actions where such products result in exposures to listed chemicals. The defendant in such an action may prove compliance with all applicable administrative standards and avoid liability. If the defendant cannot show such compliance, then the `safe harbor' is not available, but the defendant may still attempt to prove that there is no significant risk within the meaning of the Act by some other means not reflected in the regulations." (Exhibit 10, Final Statement of Reasons, Article 7, June 9, 1989, pages 45-46.)

With regard to the provision of subsection (a) of Section 12713 that the section is "interim", the Final Statement of Reasons observed:

"Since the adoption of this standard, the Agency has published a timetable for the conduct of risk assessments for the purpose of adopting permanent standards for specific chemicals of concern in food, drug, cosmetic and medical device products. Once adopted, these permanent standards would supersede any standard referred to by this section. The Agency has also advised repeatedly that it intends to repeal the non-specific standards referred to in this section one year following the scheduled completion of the risk assessments. The Agency intends to follow this schedule, but does not believe that it is necessary to adopt it as part of the regulation." (Exhibit 10, Final Statement of Reasons, article 7, June 9, 1989, pages 47-48.)

On August 1, 1989, the Health and Welfare Agency filed with the Office of Administrative Law a notice of proposed rulemaking to repeal subsection (d) of

Section 12713. A hearing was held and a final regulation was submitted to the Office of Administrative Law. (Exhibit 11, Notice of Regulations Submission, dated July 23, 1990.) In the Final Statement of Reasons submitted with the final regulation, it was observed that, notwithstanding the Health and Welfare Agency's declared purpose in adopting Section 12713, many commentors to the proposed repeal of subsection (d) continued to believe that Section 12713 provided them with an exemption from Proposition 65.

> "Thus, the Agency has repeatedly explained that the reference to standards in section 12713, including subsection (d), was intended to define, not lessen the burden of persons in the food, drug, cosmetic and medical device industries. Nevertheless, in light of some of the comments received regarding the proposed repeal of subsection (d) of section 12713, it is apparent that many interested parties believe the opposite. Section 12713 and the effect of the proposed repeal of subsection (d) were characterized in the following ways:
>
> > "'The food and drug exemption (section 12713 (a)-(d), as it presently exists, coordinates the federal and State regulatory systems by, in effect, linking the 'no significant risk' status under Proposition 65 of a chemical exposure in a food, drug, cosmetic or medical device to the Food and Drug Administration (FDA) status of the exposure." (C-4, p.2; C-6, p.5.)
> >
> > "'The Health and Welfare Agency's proposed revocation of the administrative standards exemption would interfere with the comprehensive Federal regulatory scheme outlined above and call into question the reliability of the FDA's determinations that regulated substances do not pose a significant risk to consumers. (C-11, p.6.)'
>
> "As a result, many commentors predict dire consequences if section 12713(d) is repealed, including confusion among consumers and industry, loss of product availability, undue and unnecessary burdens on commerce, needless conflict with the federal regulatory scheme, and spurious cancer warnings. In other words, the prevailing view among commentors, most of which represent the food, drug, cosmetic and medical device industries, is that, so long as subsection (d) is in effect, products regulated by the FDA require no warnings. Once subsection (d) is repealed, these commentors believe, warnings will need to be given." (Exhibit 12, Final Statement of Reasons, Section 12713(d) Repeal, July 23, 1990, pages 4-5.)

The Final Statement of Reasons also reemphasized the interim status of Section 12713:

> "Subsection (a) of section 12713 plainly states that the section is interim. In other words, the regulation was not intended to permanently define 'no significant risk' for purposes of exposures to chemicals in foods, drugs, cosmetics and medical devices. Rather, it was designed as a bridge to provide standards for proving 'no significant

risk' until the state and industry had an opportunity to develop specific, quantitative standards for certain chemicals of concern.

. . .

"Section 12713 also provided that the administrative standards recognized in that section would be applicable only in the absence of a standard for the chemical in question in section 12705. On March 16, 1988, the Agency requested the Department of Health Services (DHS) to conduct risk assessments on approximately 50 carcinogens expressly for this purpose. The Agency published a timetable for the conduct of risk assessments anticipating completion by July, 1989. Thirty of the levels resulting from these assessments have been adopted in section 12705. The Agency also advised repeatedly that it intended to repeal section 12713 one year following the scheduled completion of the risk assessments. (See Updated and Revised Schedule of Risk Assessment for Proposition 65, dated September 1988, October 26, 1988, and December 1, 1988.) The Agency also encouraged persons to determine whether their products comply with available specific standards, and to develop their own specific standards for the chemicals which may be found in their products." (Exhibit 12, Final Statement of Reasons, Section 12713(d) Repeal, July 23, 1990, pages 6-7.)

A final regulation to amend Section 12713 to repeal subsection (d) was submitted to the Office of Administrative Law. The proposal was withdrawn from the Office of Administrative Law on August 14, 1990, following representations by the cosmetics industry that it would identify for the Health and Welfare Agency those chemicals on the carcinogen list which were of concern in cosmetic products to enable OEHHA to develop numeric levels. (Exhibit 13, letter from Rodney J. Blonien to Clifford L. Allenby, Secretary for Health and Welfare, dated August 14, 1990.) Under Section 12701 and Section 12713, those levels would supersede Section 12713. Eventually, the cosmetics industry identified several listed chemical carcinogens potentially present in their products, and furnished risk assessments for approximately 12 of these substances. (Exhibit 14, letter plus attachments from G. N. McEwen, Jr., Ph.D., J.D., to Steven A. Book, Ph.D., Science Advisor to the Secretary, dated September 12, 1990.)

The Final Statement of Reasons to the repeal of Section 12713(d), in addition, was available to the public and continues to be available as an expression of the lead agency's long-standing construction of the regulation and intent to repeal Section 12713. It also demonstrates that some businesses and interested parties have erroneously construed Section 12713, since its adoption, to provide a categorical exemption for FDA regulated products from Proposition 65. Thus, by its very existence, Section 12713 appears to have lulled members of the regulated community into the belief that Proposition 65 did not apply to them, and that they could not be subjected to liability for failure to warn.

Later, in its opening brief to the court of appeal in AFL-CIO, et al. v. Deukmejian, et al. (Super. Ct. Sacramento County, 1988, No. 502541; Third District Ct. of Appeal, Case

No. 3 Civil C 008697), the state defendants explained how Section 12713 was intended to operate:

> "Under section 12713, the defendant would have to prove that the exposure did not violate any applicable safety standards, which includes general safety standards and any specific standards applicable to the commodity. If there is a specific standard, e.g., one which sets a quantitative tolerance level for the chemical in the product, the defendant would need to prove that the levels of chemical does not exceed the tolerance and that the product complies with the applicable general safety standard.
>
> "If there is no specific standard, the defendant would need to prove compliance with the applicable general safety standard. The applicable general safety standard varies depending upon the nature of the chemical and its presence in the food. For example, if the chemical is a food additive, the general safety standard is that the additive may not render the food injurious to health. It would remain the defendant's burden to prove that the exposure to the listed chemical added to the food does not render the food injurious to health. The court hearing the enforcement action would decide whether in fact the defendant had met its burden." (Exhibit 15, Appellant's Opening Brief, November 15, 1990, page 13.)(Emphasis in the original.)

In July, 1992, the Ninth Circuit Court of Appeal held in Les v. Reilly (9th Cir.1992)968 F.2d 985, that the Delaney clause of the Federal Food, Drug, and Cosmetic Act prohibits approval of a food additive shown to induce cancer in animals, even if the risk to humans is de minimis or negligible. Inasmuch as Proposition 65 permits exposure without warning where the exposure poses "no significant risk", equating the standard under the Act with the standard in federal law would no longer afford any benefit. In effect, after the Les decision, Section 12713 became irrelevant to any food additive considered a carcinogen by the federal Food and Drug Administration, because federal law arguably provided no standard for these chemicals.

Some businesses continue to erroneously construe Section 12713 to provide a categorical "'safe harbor' for FDA-regulated products" (see Exhibit 16, letter to Governor Pete Wilson from J.E. Nethercutt of Merle Norman Cosmetics dated January 15, 1993; emphasis added.)

Reasons for Repeal of Section 12713

In light of the background information presented, the lead agency bases its repeal of Section 12713 on the following reasons:

1. The warning requirement of Health and Safety Code Section 25249.6 was expressly intended to apply to foods and food products. (Health & Saf. Code, Section 25249.11.)

2. The warning requirement of Health and Safety Code Section 25249.6 was intended by its drafters to apply to drugs, cosmetics, and medical devices.

Comment: One commentor (Ex-C, pages 15-16) contended that, since Section 12713 was not premised on the argument that foods, drugs, cosmetics and medical devices are exempt from warning requirement, Reasons 1 and 2 are irrelevant, and were rejected by the State when the regulation was originally adopted and defended against in litigation.

Response: OEHHA agrees with this commentor that the regulation was not premised on an argument that the products in question are exempt from the warning requirement. However, in light of the interpretations of Section 12713 (i.e., that it does provide an exemption), Reasons 1 and 2 are highly relevant. These reasons simply argue that the statute intended the products in question to be subject to the warning requirement. This provides a valid justification for eliminating any regulation which suggests otherwise. It should be further noted that nothing in the administrative record appears to support the commentor's claim that the State had rejected the applicability of the warning requirement to the products in question in its decision to adopt Section 12713 or in subsequent litigation.

3. The scope of the applicability of Section 12713 has substantially diminished since its adoption in 1988. By its own terms and the provisions of Section 12701, Section 12713 is superseded and is no longer applicable whenever a numeric value has been established for a chemical in Section 12705. There are currently numeric values in Section 12705 for 216 listed carcinogens. Levels were adopted for these substances on the basis of their priority to the regulated community. Thus, Section 12713 should be repealed because it does not apply to the majority of carcinogens listed under the Act, and at this time has little, if any, regulatory impact.

Comments: Several commentors (Ex-F, page 1; C-3, page 2; C-4, pages 10-11; C-12, page 2) disagreed that this is a valid reason for repealing the regulation, most of them contending that there is, and will continue to be, a need for the regulation until the establishment of levels for more chemicals.

One commentor (Ex-C, pages 16-17) pointed out that there are still approximately 185 carcinogens without levels -- including the 29 priority chemicals identified in the Duke II settlement agreement, for which no action has been taken. This commentor asserted that the 216 chemicals for which levels have been set were not chosen on the basis of priority to the food, drug, cosmetic and medical device industries, and many chemicals of importance to these industries remain without levels. In his oral testimony, the same commentor (PH-1, 15:10-16:4) claimed that of the initial list of 50 priority chemicals, only 30 presently have no significant risk levels, and that of the 29 chemicals identified as priority carcinogens in the settlement agreement, none have been the subject of a proposed or final no significant risk level.

Another commentor (Ex-F, page 1) stated that the conditions that gave rise to the need for the regulation have not been satisfied: i.e. no significant risk levels have not been established for the 50 chemicals designated in 1988; moreover, no levels have been set for the 29 in the settlement or the remaining 148 on the list.

Response: OEHHA acknowledges that there still are 175 listed carcinogens for which no significant risk levels have not been adopted into regulation. However, very few of these 175 chemicals occur in foods, drugs, cosmetics and medical devices. Most of the chemicals that are of concern to the food, drug, cosmetic and medical device industries (including 47 of the 50 priority substances designated in 1988) already have regulatory levels in place (a total of 216 chemicals). Further, OEHHA has identified levels for 55 other chemicals, including levels for 33 chemicals that were designated as high priority substances in the Duke II settlement agreement or otherwise determined by OEHHA as being of significance to the food, drug, cosmetic or medical device industries. While the levels for the latter group of 55 chemicals have not been promulgated into regulation at this time, they nevertheless provide a considerable degree of protection, as it is highly unlikely that an enforcement action would be taken against businesses that rely on State-identified no significant risk levels. The evidence available to OEHHA indicates that very few, if any, of the listed chemicals for which levels have yet to be derived are of significance to the food, drug, cosmetic and medical device industries.

Unfortunately, none of the commentors identified those chemicals which continue to concern the food, drug, cosmetic or medical device industries. Had they done so and demonstrated the need for a specific level, OEHHA could have assigned an appropriate level of priority to establish a level to provide certainty to businesses, including manufacturers of foods, drugs, cosmetics and medical devices. In the course of selecting chemicals for levels development, the State repeatedly but unsuccessfully solicited nominations from industry. Absent any information regarding the significance of other substances, OEHHA must assume that the remaining substances are of little concern, and finds no further need for the continued existence of Section 12713. Unsubstantiated claims about the value of Section 12713 in providing possible protection (i.e., exemption) in the event that, at some future time, a chemical widely used or commonly present in these products may be listed do not support retention of that section, particularly when one considers that these claims are predicated upon a misinterpretation of Section 12713.

In addition, with the establishment of a priority list of carcinogens for dose-response assessments, a mechanism is now in place whereby a business may request OEHHA to assign a higher priority to a given chemical upon providing information indicating a need for a level for such a chemical. This, along with the regulation allowing the establishment of regulatory no significant risk levels derived from risk assessments using default assumptions (Section 12705(d)) -- which enables the development of levels within a fraction of the time required for conventional risk assessments -- make the retention of Section 12713 until levels for all the remaining carcinogens are established unjustifiable.

Comments: Three commentors (Ex-C, page 17; C-3, page 2; C-4, page 9) recommended the retention of Section 12713 because it represents an important mechanism which provides regulatory certainty, particularly for newly listed chemicals. Commentor Ex-C (page 17) stated that the fact that the regulation has functioned effectively provides justification for keeping it in place, instead of a reason for repealing it. Commentor C-4 (pages 10-11) claimed that repeal will lead to difficulty in establishing compliance and defending that determination, especially in light of the burden being on the defendant to provide that exposure is safe.

Response: Section 12713 may have served as a valuable interim mechanism for providing regulatory certainty to the affected industries. However, the regulation has outlived its usefulness, its value having been diminished by the adoption of regulatory levels for most of the chemicals that are of significance to the food, drug, cosmetics and medical device industries -- as well as the availability of levels for more than 50 additional chemicals. In light of the fact that certainty is already afforded to the regulated community by the existence of regulatory levels for majority of the chemicals of concern, further retention of the regulation is no longer necessary at this time.

As was stated in OEHHA's response to the previous comments (page 22), the lack of nominations from the food, drug, cosmetic or medical device industries for chemicals for which dose-response assessments should be conducted has led OEHHA to assume that the remaining substances are of little importance to these industries. Additionally, in the absence of a no significant risk level either promulgated in regulation or otherwise identified by OEHHA, the mechanism for prioritizing carcinogens for dose-response assessments and for conducting "expedited" risk assessments should address the need for the development of levels for newly listed chemicals that create legitimate concern.

Comments: Two commentors (Ex-C, pages 16-17; C-4, page 11) observed that the development of levels by the State has progressed at a slow pace, and implied that Section 12713 is especially necessary in light of this. Commentor Ex-C (page 17) stated that the only reason why over 50% of the carcinogens currently have levels is due to the "incorporation wholesale of some 140 risk assessments from other sources," and that the number of chemicals for which levels will be required will grow in the future as more chemicals are listed. Commentor C-4 (page 11) stated that there is typically a lengthy gap between chemical listing and the adoption of a no significant risk level.

Response: These commentors may not be familiar with the rate at which regulatory levels have been established under other state and federal laws. No other regulatory agency has been able to adopt close to the number of levels adopted in the Proposition 65 regulations over as brief a period of time (i.e., five years since assessments were first conducted), despite the fact that adoption of chemical-specific levels is not a mandate imposed upon the State by the statute. The availability of no significant risk levels for most of the chemicals that are of significance to the regulated community reflects OEHHA's (and previously, the Health and Welfare Agency's) recognition of the value of the certainty

provided by such levels, and the State's commitment in assisting businesses in complying with the Act. It is OEHHA's intent to continue to be responsive to requests from the regulated community for the development of risk assessments on chemicals with clearly identifiable significance.

Commentor Ex-C mischaracterizes the manner by which 140 regulatory levels were recently promulgated into regulation. Such levels were, pursuant to Section 12705(d), derived by OEHHA from published animal data using an "expedited" method consistent with default risk assessment principles, rather than a "wholesale" incorporation of risk assessments "from other sources". The "expedited" method was adopted following endorsement of the approach by the Scientific Advisory Panel, and the determination by OEHHA that cancer potency values derived via this method were concordant with those derived via conventional, time-consuming, and resource-intensive risk assessments.

Comment: One commentor (C-6, pages 3-4) concurred with Reason 3 for repeal, stating that repeal of Section 12713 is justified by the fact that numerical standards are now in place, and there is no evidence and no claim by any affected industry or group that any identified carcinogen covered by statute which is present in the products in question lacks a firm numeric standard. The commentor further stated that any ambiguity regarding whether numeric standards have been fixed for all relevant chemicals is caused solely by affected industries' own actions. Despite repeated requests from State officials for industry to identify specific chemicals, no such chemicals have been named. The commentor concluded that either (1) every listed carcinogen that occurs in the products already have numbers; or (2) affected industries have consistently refused to disclose the identity of such chemicals requiring no significant risk levels. The commentor stated that, in either case, there was no rationale for continuing special treatment for these industries.

Response: None necessary.

4. Section 12713 should be repealed because it is an interim provision designed to provide guidance only until specified conditions had been satisfied. Those conditions have been satisfied. Section 12713 was based upon the recommendation of the Scientific Advisory Panel (SAP), which contemplated that reliance upon existing state and federal standards would continue only until the state had established numeric levels for approximately 50 listed carcinogens. The state has consistently taken the position that Section 12713 should be repealed once approximately 50 numeric "no significant risk" levels had been established. There are now 216 numeric levels in Section 12705.

Comments: Two commentors disagreed with OEHHA's characterization of the "interim" nature of the regulation (PH-1, 10:22-12:10, 19:9-19:20/Ex-C, pages 17-19; C-4, pages 11-12).

Commentor PH-1 (19:9-19:20)/Ex-C (page 19) argued that OEHHA's interpretation is a "misreading of what the SAP and the FDA Commissioner said," which was that the regulation is interim on a chemical-by-chemical basis. According this commentor, the SAP recommendation to establish no significant risk levels referred to all listed carcinogens. This commentor further argued that repeal of the regulation cannot be justified on the basis of expectations (i.e., the SAP statement quoted in the initial statement of reasons referring to 50 priority chemicals and the administrative notices regarding plans to repeal the regulation) of the drafters of the regulation that are not expressed in the text of regulation, and that the description of regulation as "interim" makes no difference for purposes of applying rules of administrative law. The commentor also noted that the SAP's expectations have not been fulfilled, as only 30 of 50 priority chemicals have levels at this time.

Commentor C-4 (pages 11-12) claimed that the SAP recommendation was to follow the safe harbor "until such time as risk assessments have been made for each substance," and for the Panel to be given the opportunity to review and approve risk assessments before any regulatory action is taken. The commentor stated that, while the SAP's views are relevant, they should not be treated as dispositive of the intent or scope of a regulation promulgated by an administrative agency, and greater weight should be accorded to the language of the regulation and the statement of reasons/Finding of Emergency: nothing in these documents call for repeal upon adoption of levels for a specific number of chemicals; instead, they indicate that Section 12713 was intended to remain as long as there were listed carcinogens potentially in products regulated by the U.S. Food and Drug Administration (FDA) for which no permanent no significant risk level has been set. The commentor further pointed out that there was nothing in rulemaking reflecting the SAP's intent to repeal the regulation upon establishment of 50 no significant risk levels, and that the SAP statement merely indicated a desire to establish risk assessments for a group of 50 chemicals which could be a problem.

Response: While OEHHA recognizes the value of recommendations made by external advisory bodies such as the Scientific Advisory Panel, it should be noted that the authority to adopt regulations rests with OEHHA, as lead agency for the implementation of the Act, rather than the Panel or any other entity. The repeal of Section 12713 is based on OEHHA's conclusion that sufficient reasons, one of which is the intended interim nature of the regulation, exist to warrant this action.

Nevertheless, the repeal of Section 12713 is not inconsistent with the recommendations of the SAP. The commentors' claims about the intent of the SAP and the lead agency in recommending and adopting this regulation and about the "interim" nature of the regulations are not supported by the administrative record. The SAP's recommendations have been previously discussed in the previous section of this final statement of reasons ("Background: History of Section 12713," pages 12-20). The SAP statement issued at the December 11, 1987 read as follows:

"The Panel has heard substantial testimony regarding the level of protection provided by existing State and local standards regarding chemicals in foods, as well as implementation. Implementation of these standards has led to a high level of protection for the American people.

"However, there is still an insufficient scientific data base to ensure that these standards fully protect against any significant risk within the meaning of Prop 65."

"The Panel feels that the current State and Federal regulations do provide considerable protection of our foods, drugs, cosmetic and medical device supplies from containing excess amounts of carcinogens. Thus, on an interim basis, we recommend that levels of no significant risk for all carcinogens classified by this Panel be established according to current State and Federal regulations.

"However, in the spirit of Proposition 65, these regulations should only be followed until such time that risk assessments have been made for each substance by the State, [if] available, or have been obtained from some Federal agency [and made available by any organization].

"If the risk assessment suggests a need for regulatory changes, then these changes should be reviewed and approved by the Scientific Advisory Panel before any further regulatory action is taken.

"Further, the Panel encourages the State to establish a realistic timetable to adequately define `significant risk' and to immediately develop a priority list of approximately 50 carcinogens from the established list that we have established for risk assessments. The carcinogens on this list could be selected on the basis of the probability of exposure by humans." (Exhibit 5, transcript, Scientific Advisory Panel meeting, December 11, 1987, pages 178-180.)

It was clearly not the intent of the Panel to require the establishment of levels for all listed carcinogens, as indicated by the following comment on the above statement, made during the same meeting by Dr. Warner North, a member of the Panel:

"I am still concerned about the wording, because I would not want our statement to imply that a risk assessment is needed on every listed carcinogen." (Exhibit 5, Transcript, Scientific Advisory Panel meeting, December 11, 1987, page 181)

At the time of this meeting, there were 71 carcinogens on the list. Dr. Wendell Kilgore, Chairman of the Panel, who drafted all but the first two paragraphs of the Panel statement, explained the reference to fifty chemicals:

"I came to the conclusion that 50 was a respectable number because I expect that there will probably be approximately 300 compounds eventually on our list, and I

suspect maybe 15 to 20 percent of these could be a problem." (Exhibit 5, Transcript, Scientific Advisory Panel meeting, December 11, 1987, page 164.)

In addition, the final statement of reasons for the initial adoption of Section 12713 states:

"Since the adoption of this standard, the Agency has published a timetable for the conduct of risk assessments for the purpose of adopting permanent standards for specific chemicals of concern in food, drug, cosmetic and medical device products. Once adopted, these permanent standards would supersede any standard referred to by this section. The Agency has also advised repeatedly that it intends to repeal the non-specific standards referred to in this section one year following the scheduled completion of the risk assessments. The Agency intends to follow this schedule, but does not believe that it is necessary to adopt it as part of the regulation." (Exhibit 10, Final Statement of Reasons, article 7, June 9, 1989, pages 47-48.)

Commentor PH-1/Ex-C is incorrect in stating that only 30 of the 50 initial priority chemicals have no significant risk levels. Section 12705 presently includes levels for 47 of the 50 initial priority chemicals. The chemicals for which levels have not been established are: aflatoxins (for which a risk assessment document has been completed); sodium saccharin (for which a draft risk assessment document was recently completed); and acetaldehyde (for which a level for inhalation is in place, and a risk assessment on oral exposures is in progress).

The lack of a need to establish levels for all listed chemicals has been addressed previously in OEHHA's responses to comments on Reason 3 (pages 21-24).

Comments: One commentor (C-6, page 2) agreed with OEHHA's characterization of the regulation as interim, stating that the regulation was always intended to be interim, and its expiration is long overdue. Further, it is explicitly styled as interim in its text and statement of reasons and, during rulemaking, state officials consistently and repeatedly offered assurances that regulation would soon be replaced by levels.

Response: None necessary.

5. Section 12713 should be repealed because it is confusing to the regulated and enforcement communities. It is often interpreted as creating a categorical exemption for food, drug, cosmetic and medical device products. Such a categorical exemption would be inconsistent with the Act, which the lead agency finds was intended to apply to foods, drugs, cosmetics and medical devices. As a consequence of this confusion, many businesses which are subject to the Act may have neglected to take steps necessary to defend themselves from potential liability under the Act, including steps to avoid exposure to listed chemicals in their products, to evaluate whether exposures

to listed chemicals in their products in fact pose "no significant risk", or to devise and disseminate clear and reasonable warning where exposures are significant.

6. Section 12713 should be repealed because it is often construed as creating a categorical exemption from the Act for foods, drugs, cosmetics and medical devices, but there is no historical basis for such a construction. The language of Section 12713 is ambiguous. The lead agency has consistently denied that Section 12713 provides any exemption for FDA regulated products. The lead agency has consistently construed Section 12713 to require that businesses causing exposure to listed carcinogens in FDA regulated products prove the safety of such exposures.

Comments: Four commentors (PH-1, 17:18-18:13/Ex-C, pages 20-21; C-4, pages 12-13; C-12, page 2; Ex-F, page 1) disagreed with OEHHA's assertions in Reasons 5 and 6. One commentor (PH-1, 18:5-18:13) noted that neither represents a reason to repeal the regulation, but rather to explain and make people understand it. Commentors Ex-C (pages 20-21) and C-12 (page 2) observed that no evidence was provided by OEHHA of industry consistently misunderstanding the limited nature of regulation or that the regulation has resulted in confusion.

Commentors Ex-C (page 21), C-12 (page 2), and C-4 (page 13) asserted that misuse of the regulation would have presumably led to enforcement actions, yet no evidence of such actions was presented.

One commentor (Ex-F, page 1) disagreed that the regulation is confusing to the "vast majority" of the regulated community, and indicated that if it is, the initial statement of reasons has clearly restated the agency's position and will serve to remove uncertainty. Commentor C-4 (page 13) claimed that the regulation is not unduly ambiguous or confusing, and that it, instead, reduces confusion by relieving businesses from making safety evaluations duplicative of FDA requirements.

Response: Evidence of industry's confusion over Section 12713 was provided by Exhibit 16 (letter to Governor Pete Wilson from J.E. Nethercutt of Merle Norman Cosmetics dated January 15, 1993), which represents a typical perspective of the regulation from the regulated community. OEHHA has, over the past five years that the regulation is in place, repeatedly explained the provisions of the regulation to affected businesses. However, it is evident that, despite all efforts to correct mistaken beliefs that the regulation provides an exemption, businesses have continued to view Section 12713 as an exemption from Proposition 65. Since the announcement of the settlement of the Duke II lawsuit, OEHHA has received a large number of phone inquiries from representatives of the food, drug, cosmetic and medical device industries, expressing concern about the "removal of the exemption" and inquiring about the steps they need to take to comply with Proposition 65. Interestingly, when asked by OEHHA staff to identify the chemical of concern to the caller, the caller would often identify a carcinogen for which a level already exists in Section 12705 (e.g., formaldehyde, ethylene oxide, diethylhexyl phthalate), or a

reproductive toxicant, in which case Section 12713 would not have applied in the first place.

OEHHA finds that this continued confusion over the regulation is a valid reason for repeal. The continued existence of a regulation that is widely viewed by the regulated community as providing an exemption does not further the purposes of the Act, as it lulls certain industries into a false sense of security based on the belief that they need not take any steps to determine compliance with the Act.

This confusion may run both ways. The lack of enforcement actions against businesses that may have misunderstood the regulation to provide a categorical exemption, could more likely be attributable to uncertainty whether an exemption exists than to acquiescence in any exemption. Public officials and private enforcers have limited resources available to permit such actions, in light of other priorities, and particularly in the face of legal uncertainties. Moreover, it is unclear whether the enforcement community is even aware of exposures which would justify an enforcement action. Therefore, the commentors' contentions based upon the lack of enforcement action may assume too much.

Comment: Commentor Ex-C (page 20) complained that OEHHA has impermissibly limited the otherwise clear terms of the regulation, and stated that, to the extent that there has been any difficulty, it is due to State delays in adopting levels -- i.e., if the State would move promptly to promulgate levels for all chemicals, disputes regarding the meaning of the regulation will lose any significance.

Response: This commentor is directed to the interpretation of Section 12713 provided in the final statement of reasons at the time of its adoption and to the transcripts of the Scientific Advisory Panel meeting. The interpretation of the regulation provided in the initial statement of reasons for its proposed repeal is consistent with the final statement of reasons for the original adoption and with the expressed intent of the Scientific Advisory Panel. The interpretation of the regulation has also been discussed under "Background: History of Section 12713," pages 12-20. This commentor is also directed to the recent addition to Section 12705 of 140 chemical levels. In fact, the remedy which this commentor seeks has already occurred.

Comment: Another commentor (Ex-G, page 1) noted that an active outreach program on the correct interpretation of Section 12713 is needed to educate and allow for identification of chemicals for the priority list.

Response: As mentioned earlier (previous page), the State has repeatedly explained the regulation to affected businesses. Parties seeking information about the correct interpretation OEHHA have never had difficulty obtaining this information from the lead agency for Proposition 65 implementation. In addition, as pointed out earlier, the final statement of reasons for the adoption of the regulation is available to all interested parties.

In light of the other reasons to repeal Section 12713, an active outreach program would not mitigate the need to repeal that section.

More recently, OEHHA has published and distributed copies of the Priority List for the Development of Carcinogen Dose-Response Assessment for Proposition 65, which includes an invitation for any interested party who wishes to have a higher priority assigned to a particular chemical to submit information on the chemical in support of the recommended priority.

7. Section 12713 should be repealed because it provides little protection in the absence of a federal numeric regulatory level firmly based upon scientific data. Section 12713 requires businesses to prove that an exposure complies with all applicable administrative standards to obtain an exemption from the Act. Proving such compliance is substantially similar to proving that the exposure poses "no significant risk". Thus, the regulation does not facilitate compliance with the Act. In addition, following the decision in Les v. Reilly, Section 12713 may be irrelevant to any food additive considered a carcinogen by the federal Food and Drug Administration, because federal law provided no standard for these chemicals.

Comment: One commentor (Ex-C, pages 21-22) disagreed with the validity of this reason for justifying repeal of Section 12713, stating that disputes regarding the manner of proving compliance with existing safety standards and interpretive questions are not grounds for repeal. According to this commentor, OEHHA's interpretation of the regulation is too narrow, and OEHHA's assertion that, in the absence of numeric levels, the burden of demonstrating compliance is substantially similar to proving that the exposure poses no significant risk is wrong, because Section 12713 gives industry "far greater certainty to rely on these well-established and well-understood safety standards than it would to rely on a vague standard with no consistent history of interpretation".

Response: As to this commentor's first point that OEHHA's interpretation is too narrow, it is the duty of courts and administering agencies to interpret ambiguous provisions of law in a manner consistent with the intent of the drafters. OEHHA's interpretation of the regulation is supported by the administrative record:

> "...This section refers to standards only. Each of these product categories is subject to some kind of administrative standard. In every case there are non-specific qualitative standards. In many cases there are specific quantitative standards. In order for a product to be deemed to pose no significant risk, it must be in compliance with all applicable administrative standards." (Exhibit 10, Final Statement of Reasons, Article 7, June 9, 1989, page 46.)

OEHHA's interpretation is consistent with the original intent and is not, therefore, too narrow.

As was discussed under the section entitled "History of Section 12713," in the opening brief to the court of appeal in AFL-CIO, et al. v. Deukmejian, et al., the state defendants stated:

> "If there is no specific standard, the defendant would need to prove compliance with the applicable general safety standard. The applicable general safety standard varies depending upon the nature of the chemical and its presence in the food. For example, if the chemical is a food additive, the general safety standard is that the additive may not render the food injurious to health. It would remain the defendant's burden to prove that the exposure to the listed chemical added to the food does not render the food injurious to health...." (Exhibit 15, Appellant's Opening Brief, November 15, 1990, page 13.) (Emphasis in the original.)

The burden of proving compliance with non-specific quality standards may often not provide any more certainty to the business than would a showing of "no significant risk" pursuant to other provisions of the Proposition 65 regulations. For example, a demonstration of compliance with the general safety standard for a food additive that the additive does not render the food injurious to health may pose a heavier burden of proof than would a showing that the level of exposure to the additive is calculated to result in a lifetime cancer risk not exceeding one in 100,000, the definition of no significant risk in Section 12703.

Comments: Another commentor (C-4, pages 13-14) stated that, even if the regulation applied only where federal levels exist, it would still be justified; when no levels exist, the regulation would still be useful since administrative standards used by Food and Drug Administration have been long established and are well understood by regulated industries and interested parties, unlike Proposition 65 standards which are subject to differing interpretations, some of which have led to enforcement actions.

Response: Nothing in this repeal is intended to preclude businesses from using federal standards as evidence of safety, thus, even without this regulation, those standards may be useful. However, OEHHA is not aware that federal numeric levels apply for many more chemicals listed under Proposition 65 for which no significant risk levels have not been adopted, hence limiting the applicability of Section 12713. Commentor C-4's description of Proposition 65 standards as being "subject to differing interpretations," is inaccurate, in light of the fact that regulations in Article 7 (Section 12701 to 12721) clearly define no significant risk and provide specific guidance on no significant risk determinations. OEHHA is unclear as to what this commentor means by FDA administrative standards being long-established and well-understood. As was discussed in OEHHA's response to the preceding comment, in instances where only non-specific quality standards apply under federal (or state) law, the burden of showing no significant risk may represent a heavier burden of proof than would making a showing that the level of exposure in question is calculated to resulted in a lifetime cancer risk not exceeding one in 100,000.

Comment: Commentor PH-1 presented oral testimony severely criticizing OEHHA for its inaccurate characterization of the Delaney Clause as requiring "that all carcinogens be taken out of the regulated products."

Response: This commentor is directed to the initial statement of reasons, pages 18 and 20, in which OEHHA describes the decision as prohibiting approval of a carcinogenic food additive:

> "In July, 1992, the Ninth Circuit Court of Appeal held in Les v. Reilly (968 F.2d 985) that the Delaney clause of the Federal Food, Drug, and Cosmetic Act prohibits approval of a food additive shown to induce cancer in animals, even if the risk to humans is de minimis or negligible. Inasmuch as Proposition 65 permits exposure without warning where the exposure poses "no significant risk", equating the standard under the Act with the standard in federal law would no longer afford any benefit. In effect, after the Les decision, section 12713 became irrelevant to any food additive considered a carcinogen by the federal Food and Drug Administration, because federal law provided no standard for these chemicals." (page 18)
>
> "In addition, following the decision in Les v. Reilly, section 12713 is irrelevant to any food additive considered a carcinogen by the federal Food and Drug Administration, because federal law provided no standard for these chemicals." (page 20)

It is unclear to OEHHA how Commentor PH-1 could have misconstrued these statements as referring to "all carcinogens" in "regulated products".

Comments: Three commentors (PH-1, 16:23-17:17/Ex-C, pages 22-23; C-3, pages 2-3; C-4, page 14) disagreed with OEHHA's assessment of the impact of the Les v. Reilly decision on Section 12713.

Commentors PH-1 (16:23-17:17)/Ex-C (pages 22-23) and C-3 (pages 2-3) pointed out that since the provision in question applies only to food additives and excludes many substances, including pesticide residues, generally recognized as safe substances, and prior-sanctioned substances, Section 12713 still has broad application to FDA-regulated products and continues to provide flexibility and an important regulatory mechanism.

Commentor C-4 (page 14) contended that the Les decision has little bearing on Section 12713, as it merely reaffirms the meaning of the Delaney Clause with respect to a pesticide that concentrates in processed food.

Response: While OEHHA recognizes that the Les v. Reilly decision only impacts food additives and is, therefore, of limited scope, OEHHA nevertheless maintains that, as a result of the decision, the range of available standards referred to in Section 12713 is certainly narrowed, and may be further confined if the Les decision is judicially expanded.

When combined with the other reasons for repeal, the limited protection provided by Section 12713 makes it unnecessary.

8. Section 12713 should be repealed because there is no historical basis to conclude that it avoids unnecessary warnings on food, drug, cosmetic or medical device products. By its own terms and the provisions of Section 12701, Section 12713 does not apply to exposures to a chemical listed because the chemical is known to the state to cause reproductive toxicity. There are currently 150 chemicals listed as known to the state to cause reproductive toxicity. The statutory criteria set forth in Health and Safety Code Section 25249.10(c) and the regulatory criteria set forth in Section 12801 through Section 12821 to exempt exposures to chemicals known to the state to cause reproductive toxicity are often more stringent than the criteria for chemicals known to the state to cause cancer. There is no provision similar to Section 12713 for chemicals known to the state to cause reproductive toxicity. The lead agency is unaware that significant numbers of food, drug, cosmetic or medical device products carry warnings solely for purposes of the Act, or that any use of any such product will expose the consumer to a chemical known to cause birth defects or other reproductive harm. Nevertheless, since February 27, 1988, the date on which the warning requirement first took effect, there have been relatively few enforcement actions under the Act for exposure to listed reproductive toxicants in foods, drugs, cosmetics and medical devices.

Comments: Two commentors (Ex-C, pages 23-24; C-4, pages 14-15) argued that the historical experience with reproductive toxicants is irrelevant to carcinogens. Commentor Ex-C (pages 23-24) stated that the two classes of listed chemicals present different concerns, and since many reproductive toxicants are only recently listed, it is premature to anticipate the number of lawsuits involving these chemicals (although there are already a number of suits involving toluene where a private enforcer has a different view of Proposition 65 than the State).

Commentor C-4 (page 15) argued that fewer reproductive toxicants are listed, and they are less likely to be found in consumer products. This commentor predicted that repeal of the regulation will result in a large number of unnecessary warnings and further stated that "where there have been enforcement actions for reproductive toxins, e.g., lead, more thorough product assessments have been undertaken, and the number of products for which warnings are being provided has increased even though the level of exposure is completely trivial."

Response: The fact that there are fewer reproductive toxicants than there are carcinogens does not mean that the historical experience with reproductive toxicants is totally irrelevant to carcinogens. A number of reproductive toxicants that have been listed for at least three years are clearly chemicals that have the potential to be used, or be present as contaminants in foods, drugs, cosmetics and medical devices. Examples include lead, ethylene oxide, methyl mercury, phenyl mercuric nitrate (a mercury compound), and some

pesticides. Lead alone may potentially be found as a contaminant in a large number of products. Ethylene oxide is a widely used sterilant for medical devices and spices. Yet, warnings for either lead or ethylene oxide, particularly in foods, are highly uncommon, despite the absence of a provision similar to Section 12713.

The small number of unnecessary warnings given for reproductive toxicants may be explained, in part, by conscientious efforts made by affected businesses to either eliminate or reduce the levels of these chemicals from products, or to carefully assess the need to issue warnings that could result in potentially adverse financial consequences. As a result of such efforts, the absence of a regulation similar to Section 12713 for reproductive toxicants has not led to an avalanche of unnecessary warnings. There is no reason to believe that the regulated community will not act as responsibly in the case of carcinogens following the repeal of Section 12713, even in the few situations where the chemical involved does not have a no significant risk level. Hence, the commentors' predictions of unnecessary warnings being issued are highly unlikely.

Comment: One commentor (C-6, page 6) agreed with OEHHA's analysis, stating that the experience with reproductive toxicants is highly corroborative that repeal will have no disruptive effect, or that Proposition 65 will have no disproportionate effect on these products compared to others. No consumer warnings have been observed during the last five years for these chemicals in foods, drugs, cosmetics and medical devices. A possible explanation is that products are more likely to contain carcinogens than reproductive toxicants, but there is no evidence to this effect; an industry petition for the regulation identified six Proposition 65 chemicals present in trace amounts in a large number of foods, two of which are reproductive toxicants. Industry's fears ought to have long been realized based on their data, but experience has disproven them.

Response: None necessary.

9. Section 12713 should be repealed because there is no historical basis to conclude that the establishment of numeric "no significant risk" levels in the alternative will result in unnecessary warnings on food, drug, cosmetic or medical device products. No warnings are being provided on food or cosmetic products for exposure to chemicals subject to the levels which have been established, and no enforcement actions have been taken against food, drug, cosmetic or medical device products.

Comments: One commentor (PH-1/Ex-C, C-3, C-4) questioned the logic behind this reason for repeal, stating that it "turns Section 12713 on its head." The commentor contends that the regulation gives certainty to avoid unnecessary warnings prior to the establishment of levels for all chemicals of concern. The commentor stated that because carcinogens are ubiquitous in foods and other FDA-regulated products, a requirement for warnings about insubstantial risks is inappropriate. Continuance of Section 12713, according to this commentor, is justified because it prevents "dilution" (i.e., consumers ignoring product labels as a result of the large number of warnings) and "overreaction"

(i.e., consumers being alarmed by warnings). Another commentor (C-3, page 4) echoed these views, stating that Section 12713 protects against unnecessary warnings for chemicals without no significant risk levels.

Response: Commentor Ex-C misses the thrust of this stated reason for repeal, which simply states that there is no basis to conclude that the existing standards referenced by Section 12713 provide any greater degree of protection than standards set forth in Section 12705, or that reliance upon Section 12705 will not result in warnings where none were needed under Section 12713. There is simply no substantial factual basis for such conclusions.

Based on the State's historical experience, OEHHA does not expect the issuance of unnecessary warnings to be an outcome of the repeal. Levels are already in place for majority of the chemicals of concern, and based on representations made by industry representatives in other forums, very few (if any) chemicals found in these products do not currently have no significant risk levels.

Comment: Commentor C-12 (page 2) suggested that the lack of historical basis for concluding that the regulation avoids unnecessary warnings is due to the fact that the regulation has been functioning effectively.

Response: If the absence of warnings is the standard by which functional effectiveness is measured, one could conclude that the regulation had been functioning effectively. From OEHHA's perspective, there are additional measures, e.g., the degree to which businesses are encouraged to determine compliance, or to take steps to avoid exposure. To the extent that businesses believe they have no such incentive, the regulation is not functioning effectively. The fact that unnecessary warnings for products have not been issued following the adoption of no significant risk levels for chemicals appears to indicate that measures can be -- and have been taken -- by business to preclude the need to issue warnings for their products. Such measures may include eliminating listed chemicals from products, reducing the levels of such chemicals, or conducting careful assessments to determine the need to issue warnings for a product.

10. Section 12713 should be repealed because other regulatory provisions make it unnecessary, specifically: (1) the provision enabling manufacturers to develop their own "safe harbor" numeric level (Section 12703); (2) the numeric levels set forth in Section 12705; (3) the regulation to exclude exposure to naturally-occurring chemicals in food from the meaning of the term "expose" as that term is used in Health and Safety Code Section 25249.6 (Section 12501); (4) the regulation to exclude exposure to chemicals contributed to any product through the use of drinking water from specified sources, such as public water systems, from the meaning of the term "expose" as that term is used in Health and Safety Code Section 25249.6 (Section 12503); (5) the regulation to implement the "clear and reasonable warning" requirement (Section 12601), particularly for prescription drugs; and, (6) the

regulation which permits exposure to chemicals through consumer products to be calculated based upon average use by the average user (Section 12721).

Comments: Commentor Ex-C (page 26) argued that the other regulations cited only partly address the difficulties avoided by Section 12713.

Response: There are three difficulties with this objection. First, it appears to assume that Section 12713 provides a global exemption, which it does not. Second, it fails to identify situations in which the regulations referred provide less coverage than existing law, which cannot be remedied by the adoption of levels. These other regulations provide sufficient guidance for businesses to make decisions, with a reasonable degree of certainty, regarding the need to provide warnings. For example, regardless of the provisions of Section 12713, a business faced with making a decision regarding whether to warn about a chemical in food, after making a determination that the chemical is not naturally occurring (Section 12501) or that the presence of the chemical is not a result of the use of drinking water from specified sources (Section 12503), may choose to either provide a warning following the guidance provided by Section 12601, or make a determination of no significant risk by application of the level established for the chemical in question under Section 12705; in the absence of a level in Section 12705, the business may derive its own no significant risk level through a risk assessment conducted in accordance with Section 12703. In addition, Section 12711 allows a determination of no significant risk to be based upon a State or federal standard which represents a cancer risk not exceeding one in 100,000. Finally, compliance with federal standards may continue to be used as evidence of compliance with Proposition 65.

Comment: Commentor C-4 (page 16) asserted that the other regulations were adopted at the same time as Section 12713, and at that time were viewed by the State as complementing, not displacing, Section 12713; no reason was offered by OEHHA for this change in conclusion.

Response: The commentor is reminded that the adoption of Section 12713 follows the recommendation of the Scientific Advisory Panel for an "interim standard" allowing reliance on compliance with all existing state and federal standards, pending the adoption of no significant risk levels for 50 chemicals. At the time of adoption of Section 12713, no levels had been adopted in Section 12705. In directing the State to develop risk assessments for 50 chemicals of concern, it was the Scientific Advisory Panel's intent that these assessments be used as the basis for determining what regulatory changes may be necessary. Now that 216 levels have been adopted, in addition to these other regulations, the fact that these other regulations were adopted at the same time as Section 12713 is irrelevant.

11. Section 12713 should be repealed because, to the extent that numeric values have not yet been developed for listed carcinogens, the lead agency has prioritized those chemicals for which there is currently no adopted "no significant risk" level, and has an

ongoing process which allows the lead agency to quickly develop such levels as necessary to avoid uncertainty among the regulated and enforcement communities. As a practical matter, levels which have been developed by the lead agency but not yet adopted as regulations are available to prove compliance with the Act.

Comments: One commentor (PH-1, 15:6-16:4/Ex-C, pages 26-27) stated that there was no reason to repeal Section 12713 until risk assessments for all listed carcinogens are completed, and observed that the State has not proposed levels for any of the 29 chemicals identified as priorities in the Duke II settlement agreement. This commentor stated further that the slowness and unresponsiveness to industry concerns of the process of establishing no significant risk levels support the need for Section 12713, as does the need to address additions to the chemical list.

Commentor C-4 (page 16) noted that no assurance is provided that risk assessments will be undertaken in a timely manner, and that the priority schedule does not cover additions to the list.

Response: Not all of the carcinogens listed under Proposition 65 are found in foods, drugs, cosmetics and medical devices. Levels are now in regulation for 216 chemicals, and are available for 55 others, including 19 of the 29 chemicals identified as priorities in the Duke II settlement agreement. Very few, if any, of the chemicals for which no levels have been identified are of significance to the food, drug, cosmetic and medical device industries. None of the commentors identified chemicals relevant to the food, drug, cosmetic and medical device industries which cannot be addressed by this process. Hence, risk assessments for all listed carcinogens are unnecessary for these industries, and the argument that all chemicals should have no significant risk levels prior to the repeal of Section 12713 is unreasonable. OEHHA intends to continue to prepare risk assessments for the remaining priority chemicals, and to develop additional numbers on an ongoing basis. The mechanism established by OEHHA by which carcinogen risk assessments are prioritized is designed to incorporate additions to the chemical list, and to accommodate recommendations from affected businesses to assign a different (presumably higher) priority to a particular chemical based upon appropriate documentation indicating the necessity for a level for the chemical in question. If these commentors are concerned about a particular chemical, they should communicate their concerns to OEHHA.

Comments: Commentor Ex-G (page 1) suggested that the priority list be held open for a sufficient period of time for businesses to identify chemicals of concern.

Response: This commentor is advised that the procedure established by OEHHA to prioritize carcinogens for dose-response assessments is not a close-ended process. Priority designations are subject to change, depending upon identified needs for levels to be established for certain chemicals before others.

General Comments on the Repeal of Section 12713

Several parties objected to the repeal of the regulation on procedural grounds and on grounds that OEHHA has failed to meet specified statutory standards and principles in its rulemaking, as follows:

1. *The proceedings are unlawful because the outcome has been predetermined by a settlement agreement entered into by the State (PH-1, 5:5-5:14; 6:16-9:24/Ex-C, pages 2-11; PH-5, 30:24-31:3; C-1, page 1; C-2, page 1; C-4, pages 2-3, 5-6; C-10, page 1; C-12, pages 1-2).*

A number of commentors (C-1, page 1; C-2, page 1; C-4, pages 2-3; C-10, page 1; C-12, pages 1-2) complained that the Initial Statement of Reasons failed to mention the settlement agreement to AFL-CIO, et al. v. Deukmejian, et al. (commonly referred to as "Duke II") as the actual reason for the repeal of Section 12713. Commentors C-4 (page 6) and Ex-C (page 4) assert that, since the settlement obligates the State to repeal the regulation, the outcome of the rulemaking has been predetermined, and will not be changed regardless of the information obtained by the State in the rulemaking process. One commentor (Ex-C, pages 4-11) claimed that by entering into a binding contract with a private party which excludes all exercise of judgment, OEHHA has violated the right of interested persons to comment; moreover, external pressures (such as the provisions of the settlement) should not distort the agency decisions on the merits of the proposed rule. Another commentor (C-4, pages 5-6) contended that, by virtue of the decision to repeal being made as a result of the settlement outside of the rulemaking process, OEHHA has denied the public meaningful opportunity to participate in the rulemaking process, thereby disregarding the purpose behind well-established notice and comment requirements for due process. Commentor C-10 (page 1) noted that the public was not allowed to participate in the settlement discussions.

Response: The commentors are correct in stating that the Duke II settlement agreement did provide for the repeal of Section 12713. However, the State's decision to agree to the repeal of the regulation as part of the settlement is a consequence of its determination that a number of reasons -- as described in the previous section -- clearly make repeal of the regulation necessary. OEHHA was not precluded from exercising its judgment in agreeing to repeal Section 12713 as one of the terms of the settlement agreement. It had been OEHHA's intent, in light of the reasons described earlier, to propose the repeal of the regulation. The settlement merely provided the agency an opportunity, in the context of litigation surrounding the regulation, to minimize the amount of attorney's fees to be paid to the plaintiffs and to make predictable the timing of the repeal in the face of a potential and, perhaps, immediate appellate defeat.

This rulemaking process has provided the opportunity for industry to submit information concerning chemicals of particular concern for which "safe harbor" numerical no significant risk levels should be developed, prior to any repeal of the regulation.

Moreover, it has provided the opportunity for industry to propose any additional regulatory measures related to the proposed repeal that would be appropriate. If the Court of Appeal were to have issued a decision on the Duke II lawsuit affirming the trial court, there would have been no opportunity to consider such issues prior to the loss of any legal effect of the regulation.

OEHHA does not agree that the public had been denied a meaningful opportunity to participate in the rulemaking process to repeal Section 12713, or that the settlement agreement "distorted" OEHHA's decisions on the merits of the proposed rule. OEHHA has, in good faith, carefully considered all objections and recommendations to the proposed repeal of Section 12713 received as part of these rulemaking proceedings, and determined that none of the objections and recommendations received would justify reversal of its decision to repeal the regulation. After considering all information obtained from the rulemaking, OEHHA remains convinced that repeal is necessary to further the purposes of Proposition 65.

Without addressing the legal effect of the courts' orders in the Duke II case, OEHHA's review of the rulemaking record in this case has persuaded it that there are independently sufficient reasons to proceed with the repeal of Section 12713. Thus, any suggestion that there is a "conflict" between the legal requirements of the settlement and the appropriate result of the rulemaking process is incorrect. The issue of OEHHA's legal duties in the instance of such a conflict is therefore purely a hypothetical one.

Moreover, it is worth noting that the trial court in the Duke II case has found Section 12713 contrary to Proposition 65, which would require its repeal. OEHHA is aware of no legal requirement that it pursue all possible appeals to that decision, nor of any bar to the withdrawal of an appeal, whether undertaken unilaterally or as part of a settlement. Finally, we note that some of the commentors who have opposed this repeal were intervenors in the Duke II litigation, and after the settlement of that case filed a statement in the court of Appeal stating that they did not oppose the dismissal of the appeal.

Persons who are not parties to a lawsuit are not usually invited to participate in settlement discussions. OEHHA did involve the industry representatives who were intervenors to the Duke II suit in settlement discussions.

Comment: One commentor (C-1, page 1) stated that the settlement does not remove the need for an "interim safe harbor" such as that which is provided by Section 12713.

Response: OEHHA directs this commentor to the reasons outlined in the previous section, which illustrate that Section 12713 is no longer necessary, not because of the settlement, but because of a number of reasons independent of the settlement.

Comment: Another commentor (PH-6, 32:22-33:13) claimed that the ramifications of the repeal have not been fully considered by OEHHA, and are not fully apparent at this time.

The commentor urged OEHHA to follow "all proper procedures" in reviewing the proposal.

Response: OEHHA assures this commentor that it has considered the ramifications of the repeal, along with the evidence indicating the need for the repeal, and concluded that repeal of the regulation is necessary and appropriate. OEHHA has complied with all the requirements of Administrative Procedure Act in this rulemaking.

Comment: Commentor PH-1 (9:3-9:24) claimed that, for the rulemaking proceeding to be lawful, OEHHA must repudiate the settlement, and reinstitute the rulemaking proceeding from the beginning, with the statement of reasons "rewritten by an untainted group of individuals who were not involved in the original document," and hold a new hearing at which arguments can be presented to "an unbiased individual".

Response: As discussed earlier, OEHHA is convinced that, notwithstanding the settlement, there are many valid reasons to repeal the regulation, and it has carefully considered all information presented to it. Repudiating the settlement agreement would ignore these reasons, would be in conflict with OEHHA's determination that repeal is necessary to further the purposes of Proposition 65, and would not be in the State's best interest as it would give rise to further litigation involving an issue that has already been carefully studied by OEHHA. Reinstituting the rulemaking proceeding will be a waste of valuable staff time and resources and is unwarranted.

2. *The reasons for repeal are deficient, and do not constitute substantial evidence to meet the "necessity" standard of Government Code Section 11346.7(a)(2) (Ex-C, pages 12-28; C-9, pages 2-6; C-12, pages 1-2).*

Comment: One commentor (Ex-C, page 3) claimed that the repeal of Section 12713 is unnecessary due to the built-in sunset mechanism in the regulation.

Response: The "built-in sunset mechanism" in Section 12713 is as much a reason to repeal Section 12713 as to retain it. Retaining the regulation despite the reasons identified by OEHHA -- particularly the existence of no significant risk levels for a majority of the chemicals found in foods, drugs, cosmetics and medical devices -- serves no identifiable purpose for the consumer or for the regulated community.

Comment: Commentor Ex-C (page 28) also contended that the reasons cited by OEHHA for the repeal are unconvincing, refer to inconsequential points about limited scope, application and impact, and instead prove that the regulation should be retained. Commentor C-12 (page 1) observed that the reasons given by OEHHA do not justify repeal of the regulation. Another commentor (C-9, page 1) claimed that Section 12713 is necessary and that the proposed repeal is contrary to the rational implementation of Proposition 65.

One commentor (C-9, page 3) contended that OEHHA is obligated to supply a reasoned analysis beyond that which may be required when no action is taken in the first instance, that it needs to make a showing of changed circumstances, but "...there is not more reason to presume that changing circumstances require the recission of prior action instead of a revision in or even the extension of current regulation". According to this commentor, OEHHA must establish that repeal is reasonably necessary to implement Proposition 65, and that circumstances giving rise to the initial adoption have changed so that repeal instead of revision or extension is reasonably necessary.

Response: Section 12713 has been in place for five years, despite the fact that it was clearly intended to be "interim" at the time of its adoption, and repealed by 1990. OEHHA is unable to justify -- given the reasons discussed in the previous section -- retaining the regulation. Specific rebuttals made by commentors PH-1/Ex-C and C-12 to the reasons for repeal are addressed in the discussion of comments received on each reason in the previous section. The repeal is consistent with, rather than contrary to, the rational implementation of Proposition 65 because it ensures that all products are subject to the same standards, thereby providing for more equitable implementation of the requirements of the Act and ensuring that consumers are not denied their right to be provided with information about significant carcinogens exposures, regardless of the source. Further, repeal would ensure that the food, drug, cosmetic and medical device industries would act to evaluate their products and determine what action is necessary to comply with Proposition 65, instead of passively relying upon an "exemption".

Comment: One commentor (C-6, pages 1, 6, 7) supported the repeal, stating that Section 12713 is completely unnecessary for a number of reasons, and that not repealing the regulation would violate the "necessity" standard. This commentor pointed out that key industry representatives had testified that, to their knowledge, there is not a single product for sale in California covered by Section 12713 that will require additional warning or face additional data-gathering burdens when the regulation is repealed, and that the undisputed evidence from the intervenors in the Duke II lawsuit is that no products sold in California would be adversely affected by the repeal (although they held open the possibility that this may change due to some future chemical listing). The commentor further asserted that there is no need for the food, drug, cosmetic and medical device industries to receive special regulatory treatment, a fact corroborated by the benign experience over the past five years with products in situations not "sheltered" by Section 12713. The commentor stated that the Duke II settlement requires repeal, in addition to the fact that the Court has found the regulation to be illegal.

Response: None necessary.

3. *The reasons for the original adoption of Section 12713 are still valid; no evidence has been presented by OEHHA to dispute the relevance of these reasons.*

Comments: A number of commentors (PH-1, 10:14-13:16/Ex-C, pages 13-14; PH-5, 28:3-28:13; Ex-E, page 1; Ex-F, page 1; Ex-G, page 2; C-3, page 3; C-4, pages 4, 7-10; C-8, page 1; C-9, pages 4-5; C-10, page 1; C-12, page 2) made reference to reasons cited in the final statement of reasons for the original adoption of the regulation, and argued that, because these reasons are still valid, Section 12713 should not be repealed.

Response: Clearly there are changed circumstances which justify repeal of Section 12713, such as the adoption of 216 levels which render Section 12713 inapplicable, and five years of enforcement and compliance history which did not previously exist. These changed circumstances outweigh any general reasons cited to support the original adoption of Section 12713. To argue that the reasons for the initial adoption of Section 12713, some of which were little more than historical points, must no longer be true for the repeal of the regulation to be justified would make too much of these reasons. In short, OEHHA has determined, based on the reasons listed in the preceding section, that repeal of the regulation is necessary, regardless of whether or not some of the reasons used to support its original adoption may still be valid.

The reasons for the original adoption cited by commentors, and specific points raised by commentors are discussed below:

(a) Section 12713 was based on the Scientific Advisory Panel's recommendation.

Comment: Commentor (C-9, page 4) pointed out that no action has been taken by the Panel to remove this recommendation.

Response: Panel action is not a prerequisite to repeal of the regulation. Decisions to adopt, amend or repeal administrative regulations are made, pursuant to authority provided by Health and Safety Code Section 25249.12, by the lead agency for the implementation of Proposition 65, not by the Panel.

Comment: Commentor PH-1 (11:4-12:3)/Ex-C (page 19) contended that the Panel's recommendation referred to all listed carcinogens, not just to 50; thus, the regulation should not be repealed until all chemical risk assessments are completed.

Response: This comment is not supported by the administrative record of the regulation and has been previously addressed in OEHHA's responses to comments on Reason 4 (pages 24-27). The Scientific Advisory Panel's recommendations upon which Section 12713 was based have been previously discussed under "Background: History of Section 12713," pages 12-20.

Not only would postponing repeal of the regulation until levels are established for every listed carcinogen be inconsistent with the administrative record, it would also be an imprudent and impractical use of limited State resources to have to establish levels for those listed chemicals that are clearly not relevant to the food, drug, cosmetic and medical

device industries. Levels are now in regulation for 216 chemicals, and are available for 55 others. Very few, if any, of the chemicals for which no levels have been identified are of significance to the food, drug, cosmetic and medical device industries.

Comments: A number of commentors (Ex-E, page 1; Ex-G, page 1; C-1, pages 1-2; and C-10, pages 1-2) expressed concern over the consequences of repealing the regulation where no significant risk levels are not yet available for all of the listed carcinogens. Commentor Ex-E (page 1) pointed out that there are no assurances or guarantees from the State about the establishment of exposure levels for the remaining chemicals or additional chemicals. Commentor C-1 (pages 1-2) complained that there is no guarantee that levels will be adopted within twelve months after chemical listing, that the agency does not have good track record in establishing levels, that its ability to do so is impacted by the availability of resources, and that there is no assurance that no new chemicals will be listed until levels are in place for all previously listed chemicals. Commentor Ex-F (page 1) observed that no significant risk levels for "all of the chemicals delineated in 1988 when the regulations were developed" have yet to be completed by OEHHA; otherwise, repeal will leave entities that relied on the development of standards at risk of litigation. Commentor Ex-F (pages 1-2) contended that the regulation will become "even more important in the future" with addition of chemicals, as it will assure a rational approach in the absence of no significant risk levels. Commentor PH-6 (33:3-33:6) complained about the lack of due process in chemical listing and the establishment of no significant risk levels and no observable effect levels.

Response: Not all of the carcinogens listed under Proposition 65 are found in foods, drugs, cosmetics and medical devices. Levels are now in regulation for 216 chemicals, and are available for 55 others. Very few, if any, of the chemicals for which no levels have been identified are of significance to the food, drug, cosmetic and medical device industries. Hence, risk assessments for all listed carcinogens are unnecessary, and the argument that all chemicals should have no significant risk levels prior to the repeal of Section 12713 is unreasonable. OEHHA intends to continue to prepare risk assessments for the remaining priority chemicals, and to develop additional numbers on an ongoing basis. The mechanism established by OEHHA by which carcinogen risk assessments are prioritized is designed to incorporate additions to the chemical list, and to accommodate recommendations from affected businesses to assign a different (presumably higher) priority to a particular chemical based upon appropriate documentation indicating the necessity for a level for the chemical in question.

(b) Federal and State safety standards have been adequately protective for over 80 years.

Comments: Commentors C-9 (page 4), Ex-E (page 1) and Ex-F (page 2) pointed out that this finding has remained unchanged. Commentor PH-1 (12:11-13:16) noted that OEHHA is unable to take issue with this finding, or point to a single chemical which has been identified by the State, the Panel or any witness where FDA or state standards are inadequate to prevent significant risk. Commentors C-3 (page 3) and C-12 (pages 2-3)

also noted that no evidence was presented to question this finding. Commentor C-12 (page 3) further contended that there is no defensible rationale to change a system that has worked successfully.

Response: A finding of inadequacy of federal and State standards is not necessary in order to justify repeal of Section 12713, particularly since the repeal is not intended to deprive businesses of the opportunity to rely upon federal standards as evidence of the safety of chemical exposures. OEHHA need only demonstrate that the repeal of Section 12713 is necessary. Thus, the issue is whether the regulation continues to be necessary to provide a safe harbor based upon federal standards for foods, drugs, cosmetics and medical devices alone, when the state has adopted specific, numeric safe harbor levels for the substantial majority of listed carcinogens, and has established a mechanism for quickly establishing such levels.

Comment: One commentor (C-2, page 1) stated that "current regulations allow the state to reference the Federal Insecticide, Fungicide, and Rodenticide Act tolerances" which are the result of exhaustive science-based risk assessment procedures. The commentor stated that the Proposition 65 standard of one one-thousandth of the no observable effect level is frequently totally different from federal tolerance numbers, and unrelated to dietary risk assessment science.

Response: OEHHA is unclear about what the commentor is referring to. The one one-thousandth of the no observable effect level (NOEL/1000) is the threshold below which exposures to reproductive toxicants are exempt from the warning requirement. Section 12713 is not applicable to reproductive toxicants. It would not be surprising that tolerances established under federal law for pesticides are higher than the NOEL/1000 because such tolerances usually are not derived by application of a 1,000-fold uncertainty factor to the NOEL, as required by Proposition 65. For exposures to carcinogens, the commentor is directed to Section 12711, which allows businesses to use existing state and federal standards provided that such standards are based on the carcinogenicity of the chemical and are set at a cancer risk level not exceeding one in 100,000. Thus, in making a determination of no significant risk, a business may continue to rely on a federal tolerance that satisfies these criteria.

(c) Section 12713 applies the policy of preserving existing statutory and administrative standards.

Comment: Commentor C-9 (page 4) observed that no explanation is given by OEHHA for why this policy is no longer being applied.

Response: Nothing in this repeal is intended to prohibit the availability or use of existing statutory or administrative standards as evidence that exposures to carcinogens pose no significant risk. A business may continue to introduce evidence derived from actions undertaken to comply with federal law as evidence of compliance with Proposition 65.

Accordingly, the repeal does not undermine any policy of preserving existing statutory and administrative standards.

(d) Section 12713 applies the general principle of comity among administrative agencies.

Comments: Commentor C-9 (page 4) noted that no explanation is given by OEHHA for why it now has concluded that it has the exclusive ability to regulate these products and "...that no deference should be given to FDA, Department of Health Services and Food and Agriculture." Commentor PH-1 (19:23-20:8) stated that Section 12713 reflects the principle of national comity.

Response: The repeal of Section 12713 simply deletes one mechanism specifically authorized in regulation by which a demonstration of no significant risk may be made for specific products. Nothing in this repeal is intended to deprive businesses of the opportunity to utilize state standards to prove the safety of chemical exposures.

Neither does this action interfere with how the agencies identified by the commentor regulate these products. Commentor C-9's statements about OEHHA asserting "exclusive authority" to regulate the products in question is clearly not implied by, or a direct result of the rulemaking action. While there is no question that the statute applies to foods, drugs, cosmetics and medical devices, the scope of the Act's regulation of these products is limited to a requirement for warnings to be provided prior to knowing and intentional exposures at significant levels.

(e) Section 12713 applies the policy of uniformity in regulation of food, drugs, cosmetics and medical devices (Health and Safety Code Section 26204).

Comments: Commentor C-9 (page 5) observed that no explanation is given by OEHHA for why this policy has been abandoned, and why OEHHA feels that uniformity of nationally produced and marketed products is no longer of value. Commentor PH-1 (20:9-20:18) stated that Section 12713 reflects the policy of national uniformity of building on what exists at the federal and State government.

Response: The repeal of Section 12713 will not be disruptive of the uniformity of existing state and federal regulation of these products. Nothing in this repeal is intended to deprive businesses of the opportunity to utilize otherwise relevant information concerning safety that were derived from actions undertaken to satisfy federal standards as evidence of the safety of chemical exposures. The commentors should note that where both federal and state standards govern a food, drug, cosmetic and medical device, the state standard is often more stringent than the federal, unless otherwise provided, so there is not complete uniformity to begin with. Further, this comment appears to assume that the levels adopted under Section 12705 are more stringent than the levels referred to by Section 12713. However, in light of the averaging permitted for exposures to carcinogens in consumer

products by Section 12721, it is highly unlikely that the standards under Proposition 65 as applied to particular products will be more stringent than under federal law.

Proposition 65 is not intended to "alter or diminish any legal obligation otherwise required in common law or by statute or regulation," or to "create or enlarge any defense in any action to enforce such legal obligation," as provided by Health and Safety Code Section 25249.13. The repeal of Section 12713 does not violate this provision.

(f) Section 12713 follows the policy of furthering meaningful warnings regarding chemical hazards.

Comments: Commentor C-9 (page 5) pointed out that the absence of unnecessary warnings in foods, drugs, cosmetics and medical devices does not constitute a reason for repealing the regulation, but instead is evidence that Section 12713 has fulfilled its purpose and furthered the purposes of Proposition 65. Commentor Ex-E (page 1) contended that repeal of the regulation is contrary to the State's policy of furthering meaningful warnings.

A number of commentors (Ex-C, pages 14, 24-26; Ex-G, page 1; C-3, page 4; C-4, pages 9-10; C-5, page 1; and C-10, page 2) claimed that repeal of Section 12713 will lead to overwarning or excessive, unnecessary warnings to avoid liability. Several commentors (Ex-C, page 14; Ex-E, page 1; Ex-F, page 1; Ex-G, pages 1-2/PH-4, 27:1-27:5; PH-6, 33:7-10; C-1, page 2; C-3, page 4; C-4, pages 3-4, 9-10; C-8, page 1; and C-10, page 2) argued for retaining Section 12713 due to the uncertainty that will result from repeal. According to these commentors, uncertainty would result from the lack of guidance or the difficulty in determining no significant risk.

Response: OEHHA continues to recognize the value of preventing the issuance of unnecessary warnings. As was discussed in the preceding section (see discussions under Reasons 8 and 9), the small number of warnings associated with foods, drugs, cosmetics and medical devices containing reproductive toxicants, or containing carcinogens for which no significant risk levels have been established provide historical basis to conclude that unnecessary warnings will not result from the repeal of Section 12713.

The small number of warnings given for foods, drugs, cosmetics and medical devices may be explained, in part, by conscientious efforts made by affected businesses to either eliminate or reduce the levels of these chemicals from products, or to carefully assess the need to issue warnings. There is no reason to believe that the regulated community will not act as responsibly in the case for carcinogens following the repeal of Section 12713. In addition, there will be only few situations where the chemical involved does not have a no significant risk level. Hence, the commentors' predictions of unnecessary warnings being issued are highly unlikely.

Comment: According to one commentor (C-5, pages 1-2), the repeal will require additional warning labels for diagnostic products with small quantities of radionuclides; these products are already subject to requirements by the Food and Drug Administration, the Department of Health Services and the Nuclear Regulatory Commission which require labelling with appropriate radiation warning labels, as well as specific warnings and precautions in package inserts.

Response: The commentor should note that, where a business responsible for such diagnostic products is able to make a showing of no significant risk, no warnings are required under Proposition 65. A no significant risk determination may be based upon State and federal standards established for other regulatory purposes, provided that the standards represent a cancer risk not exceeding one in 100,000 (Section 12711). In addition, where the labels required under other laws already clearly communicate the fact that a cancer hazard exists, such labels may constitute a "clear and reasonable" warning and no additional warnings may be necessary.

(g) Section 12713 is based upon the conclusion that compliance with all applicable standards will pose no significant risk.

Comment: One commentor (C-9, page 5) noted that no evidence was presented by OEHHA to contradict this statement, which is as true today as it was in 1988, and OEHHA needs to present substantial evidence that the opposite is true to avoid acting in a arbitrary and capricious manner.

Response: This commentor is reminded that this conclusion goes on to say "...pending the establishment of specific `no significant risk' levels" (Exhibit 10, Final Statement of Reasons, Article 7, June 9, 1989, p. 45). As discussed elsewhere in this final statement of reasons for the repeal of Section 12713 , levels are now in place for 216 carcinogens and, in view of this and several other reasons, OEHHA has concluded that Section 12713 is no longer necessary. Moreover, if there is nothing to indicate that these products pose a significant risk, then there is no use for a special regulation to that effect.

4. *The repeal of Section 12713 violates two principles set forth in Proposition 65 itself (PH-1, 19:21-20:18; C-9, page 4).*

Comments: According to Commentor PH-1 (19:21-20:18), the repeal would be inconsistent with Health and Safety Code Section 25249.10(a), which reflects the principle of national comity and national uniformity, and Section 25249.13, which states that regulations implementing Proposition 65 must preserve existing state and federal administrative standards. Commentor C-9 (page 4) states that Section 12713 is an application of the policy of preserving existing statutory and administrative standards, and some explanation must be provided for why OEHHA is no longer choosing to apply this policy to the administrative standards for foods, drugs, cosmetics and medical devices.

Response: Section 25249.10(a) provides that the warning requirement of Proposition 65 shall not apply to "an exposure for which federal law governs warning in a manner that preempts state authority". To the extent that a federal law preempts the requirements of Proposition 65, that preemptive effect would apply regardless of whether or not Section 12713 exists. Further, nothing in this repeal is intended to deprive businesses of the opportunity to utilize federal standards as evidence of the safety of chemical exposures.

Section 25249.13 states, in part: "Nothing in this chapter shall alter or diminish any legal obligation otherwise required in common law or by statute or regulation, and nothing in this chapter shall create or enlarge any defense in any action to enforce such legal obligation." Nothing in this repeal is intended to prohibit the availability or use of existing statutory or administrative standards as evidence that exposures to carcinogens pose no significant risk. A business may continue to introduce evidence of compliance with federal law as evidence of compliance with Proposition 65. Accordingly, the repeal does not undermine any policy of preserving existing statutory and administrative standards.

In its efforts to implement Proposition 65, OEHHA needs to balance the application of these valuable principles with the need for implementation actions to further the purposes of the Act. In this instance, OEHHA has concluded that the purposes of the Act are furthered by the repeal rather than the retention of Section 12713.

5. The repeal of Section 12713 is preempted by the Food, Drug and Cosmetic Act (Ex-D, pages 2-4).

Comment: Commentor Ex-D (pages 2-4) stated that the repeal of Section 12713 is preempted by the Food, Drug and Cosmetic Act (Section 521), which prohibits state requirements different from or in addition to the Act's, where such requirements are related to the safety or effectiveness of a medical device.

Response: OEHHA does not agree that Proposition 65 is preempted by the Food, Drug and Cosmetic Act. However, assuming that the commentor is correct in asserting that it is preempted with respect to medical devices, that preemptive effect would apply whether or not Section 12713 is in place.