FINAL
STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS DIVISION 2

Amendment to Section 12601. Clear and Reasonable Warning

The Safe Drinking Water and Toxic Enforcement Act of 1986 (Act) was adopted as an initiative measure (Proposition 65) by California voters on November 4, 1986. The Act imposed new restrictions on the use and disposal of chemicals which are known to the State to cause cancer or reproductive toxicity.

Part of the Act provides that, "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 . . . ." (Health & Saf. Code, § 25249.6.) (Unless otherwise specified, all statutory section references are from the Health and Safety Code.)

Violations of this prohibition can result in civil penalties of up to $2,500 per violation per day (§ 25249.7). Legal action to impose these penalties can be brought by the Attorney General, a district attorney, certain city attorneys, or, under specified circumstances, any person "in the public interest" (§ 25249.7).

Section 25249.12 authorizes agencies designated to implement the Act to adopt regulations as necessary to conform with and implement the provisions of the Act and to further its purpose. The Health and Welfare Agency ("Agency") has been designated the lead agency for the implementation of the Act.

Procedural Background

Effective February 27, 1988, the Agency adopted section 12601 of the California Code of Regulations to implement the clear and reasonable warning portion of the Act. This original adoption was done on an emergency basis. A permanent version of the regulation, and the version which this amendment changes, was adopted effective December 15, 1988.

On May 30, 1989 the Agency issued a notice of emergency rulemaking advising that the Agency intended to adopt permanently this amendment to section 12601 of Title 22 of the California Code of Regulations. Two other regulations were noticed for that same hearing. Pursuant to such notice a public hearing was held on July 25, 1989, to receive public comments on the proposed amendment to section 12601 and the adoption of the other regulations. Out of 18 pieces of correspondence received commenting on the regulations and 1 additional document submitted at the hearing, 8 contained comments regarding the proposed amendment to section 12601.

Purpose of Final Statement of Reasons

This final statement of reasons sets forth the reasons for the final language adopted by the Agency for this amendment to section 12601. Government Code section 11346.7, subsection (b)(3) requires that the final statement of reasons submitted with an amended or adopted regulation contain a summary of each objection or recommendation made regarding the adoption or amendment, 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 Agency's proposed action or to the procedures followed by the Agency in proposing or adopting the action.

Some parties included in their written or oral comments remarks or observations about this regulation which do not constitute an objection or recommendation directed at the proposed action or the procedures followed. Also, some parties offered their interpretation of the intent or meaning of the proposed regulation. Again, this does not constitute an objection or recommendation directed at the proposed action or the procedures followed. Accordingly, the Agency is not obligated under Government Code section 11346.7 to respond to such remarks in this final statement of reasons. Since the Agency is constrained by limitations upon its time and resources, and is not obligated by law to respond to such remarks, the Agency has not responded to these remarks in this final statement of reasons. The absence of response in this final statement of reasons to such remarks should not be construed to mean that the lead agency agrees with them.

Specific Findings

Throughout the adoption process of this regulation, the Agency has considered the alternatives available to determine which would be more effective in carrying out the purpose for which the regulations were proposed, or would be as effective and less burdensome to affected private persons than the proposed regulations. The Agency has determined that no alternative considered would be more effective, or as effective and less burdensome to affected persons, than the adopted regulation.

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

Rulemaking File

The rulemaking file submitted with the final regulation and this final statement of reasons is the complete rulemaking file for section 12601. However, because regulations other than section 12601 were also the topic of the public hearing on July 25, 1989, the rulemaking file contains some material not relevant to section 12601. This final statement of reasons cites only the relevant material. Comments regarding the regulations

other than section 12601 discussed at the July 25, 1989 hearing have been or will be discussed in separate final statements of reason.

Necessity for Amendment to Regulation

The Agency has determined that this amendment to section 12601 is necessary for the following reasons:

Chemicals subject to the Act's exposure provision (and the related warning requirement) are set forth on a list which was first issued on February 27, 1987, and which is periodically revised (§ 25249.8). Since the exposure provision takes effect 12 months after the chemical involved first appears on the list, the initial list of chemicals became subject to this prohibition on February 27, 1988 (§ 25249.9).

Ethyl alcohol in alcoholic beverages was added to this list as a reproductive toxicant on October 1, 1987 and thus became subject to the Act's warning requirement on October 1, 1988.

Title 22, California Code of Regulations section 12601, which first became effective on February 27, 1988, provides guidance on how businesses can give the required clear and reasonable warning.

Subsection (a) of this regulation sets forth the general rule about such warnings. Any person in the course of doing business who needs to provide a warning under the Act may choose to proceed pursuant to the general rule in subsection (a). However, the Agency believes that many such persons would prefer more certainty and would instead choose to follow more specific requirements, if to do so would constitute compliance with the Act's requirement of giving a clear and reasonable warning. As a result, this regulation also contains provisions which are detailed in their application to certain products. A person who follows these detailed requirements will be deemed under the Act to be giving a clear and reasonable warning. These detailed requirements provide what is commonly referred to as a "safe harbor."

Alcoholic beverages are one of the items covered by the detailed product-specific provisions of the regulation. (See subsections (b)(1)(D) and (b)(4)(E)). Included in these product-specific provisions is a sample warning message for alcoholic beverages. Use of this warning message in the manner specified in the regulation is deemed to be in compliance with the warning requirements of the Act.

However, this sample warning, which is used by approximately 100,000 California businesses, became incomplete on July 1, 1989. This is because under law prior to that date, alcoholic beverages were subject to the Act's warning requirement only as a reproductive toxicant. However, on July 1, 1988, alcoholic beverages when associated with alcohol abuse were also added to the list as a known carcinogen and, as a result, became

subject to the cancer warning requirements of the Act on July 1, 1989.

In light of the extensive use of this warning method, the Agency decided that it was necessary to provide for the new warning message in this regulation prior to July 1, 1989, the day the cancer warning requirement went into effect. The amendment to section 12601 which is the subject of this final statement of reasons was thus adopted on an emergency basis effective that date.

This amendment also contains more detail about how the alcoholic beverage warning message can be conveyed. These changes are prompted by what the Agency has learned from actual experience during the time since alcoholic beverages were first subject to the Act's warning requirements. It is necessary to incorporate these other changes into section 12601 so that the new alcoholic beverage warning messages can be installed in accordance with the more detailed requirements.

Failure to adopt this amendment would create the very uncertainty which this regulation was in part designed to prevent. Without an approved new warning message, the affected businesses would have to guess as to what message might comply with the Act. Persons seeking to enforce the Act would likewise lack any certainty about what would or would not meet the requirements of the Act. The possibility of widely differing warning messages concerning the same product could confuse the public and thus severely diminish the effectiveness of the Proposition 65 warning requirement.

Changes to the Wording and Format of the Warning Message

Subsection (b)(4)(E) of the amendment sets forth the new "safe harbor" warning message for alcoholic beverages. The wording used in the new warning message to convey the strength of the causal connection between the exposure and the health risk involved is different for cancer than for reproductive toxicity. The cancer warning portion states that consumption of alcoholic beverages ". . . May Increase Cancer Risk . . .", whereas the reproductive toxicity portion states that such consumption "During Pregnancy Can Cause Birth Defects" (emphasis added). The word "can" used in the birth defects warning portion signifies a higher degree of scientific knowledge about the risk of fetal harm even under what is normally considered (absent pregnancy) to be light consumption of alcohol. However, the available scientific data about the cancer risk of alcoholic beverage consumption indicates that its carcinogenicity is related to abusive levels of consumption over a long period of time.

Three commentors felt that the new proposed message was too long and difficult to read when compared with the previous warning message. These commentors suggested that the warning messages on the current sign should be split into separate signs (C-10 page 1; C-17 page 1; C-18 page 2). The Agency disagrees. The current sign is quite clear in its present form and has the

distinct advantage of being together on a single sign which communicates both risks.

If, for example, this "safe harbor" provision called for separate signs for the two risks involved, then two very similar looking messages would appear where currently there is just one. Those persons who are to receive these warnings might read one sign and stop reading the second sign because it would appear so similar that it was thought to be the same message. It is also possible that a person would not look for another warning message after reading one sign about the risk of consuming alcoholic beverages. As a result, a single sign referring to both risks is far more likely to convey the warning than would be separate signs, due to the chance that the second warning sign could be mistakenly ignored.

Three commentors suggested that the sign should be rewritten or rearranged in various ways for the purpose of increasing its effectiveness. One of these commentors stated that the use of the words "can" (for the risk of birth defects) and "may" (for the risk of cancer) was too weak and that minors, who are skeptical about messages from authority figures, might ignore the warning message as being merely a scare tactic (C-18 page 2). No alternative wording was suggested. The suggestion that stronger words should be used has not been followed by the Agency because it is crucial that "safe harbor" warning signs be accurate. Making a warning sign stronger than the actual risk cannot be justified; asking the state to intentionally overstate a danger is no way to promote greater trust of authority figures.

The second commentor in this group suggested that the warning message would be improved by more clearly separating the two warnings in order to make them more accessible from a visual perception standpoint (C-3 pages 1 and 2). The study cited by this commentor in support of the recommended change did not involve the warning message and format which are the subject of this regulation. Therefore, it is speculative whether or not the cited study would have come to the same conclusion as did the commentor. In light of the time, effort, and cost which would be expended in changing warning signs at this time, the Agency believes that the potential increase, if any, in warning sign comprehension is not justifiable.

This same commentor was joined by the third commentor in this group in suggesting that the stronger warning, that relating to birth defects, should be placed ahead of the warning about cancer (C-3 page 2; C-13 page 5). No explanation is offered as to why such a change is beneficial. Putting the birth defect warning message ahead of the cancer message may be preferable if the primary intent of the sign was to warn of the risk of birth defects. However, the Agency did not intend to promote one danger over another. As stated above, in light of the time, effort, and cost which would be expended in changing warning signs at this time, the Agency believes that the potential increase, if any, in warning sign comprehension is not justifiable.

One commentor stated that the cancer warning message is weak because use of the word "may" understates the strong link between alcoholic beverage consumption and liver cancer (C-18 page 2). The reason the Agency chose the use of the word "may" instead of something more definite is because the known link between alcoholic beverage consumption and cancer causation reflects chronic alcohol abuse, but not moderate levels of consumption. This is vastly different than the risk of birth defects which is of concern even with light consumption. As a result, the Agency believes that the current choice of wording is appropriate.

In order to accommodate the size of the new warning message, which is longer than the previous version, the specifications of the ten and five-inch signs have been modified. While type size has been decreased, the top and side margins have been narrowed so that more of the sign is taken up with text, with the result that the changes do not significantly affect readability.

The amendment provides for a wider choice of sign formats than were previously available under the "safe harbor" provisions for alcoholic beverages. Previously, the only general use sign was a ten-inch square sign bearing the warning message specified in the regulation. A smaller five-inch square sign (bearing the same proportions as the larger sign) was allowed for use only at tables where alcoholic beverages were served. The third format previously allowed involved the placement of the warning message on a menu or list of alcoholic beverages served at the premises.

The ten-inch square sign is described in great detail as to format, type size and type style. The five-inch square sign is to be done in proportion to the larger sign.

The menu/list option is intentionally not subject to any specific format or style so that it can be compatible with the design of the menu/list involved provided that the resulting warning is clear and likely to be read and understood prior to the exposure (consumption of alcoholic beverages).

Additional Warning Message Formats

The amendment recognizes that there should be more options available to those desiring to use a "safe harbor" warning. With the wide variety of environments through which alcoholic beverages are sold, a sign format that may be workable in one situation may be less desirable in another. As a result, one new sign format is being added, a ten and one-half by one and one-quarter inch "strip," and the five-inch sign is being authorized for broader use. The allowable use of the menu/list notice format is being expanded in order to provide for menus or lists which are posted only rather than provided on hand-held versions.

The new "strip" format is to be used on shelves where alcoholic beverages are displayed. As with the ten and five-inch signs, a uniform format, type size and style is specified. This will aid

in identification and recognition of the strip as a Proposition 65 warning.

Placement of Warning Messages

The five-inch sign will now be usable not only on tables as discussed earlier, but at the location(s) where customer purchases are made. The amendment provides that this sign must be conspicuously placed at each cash register, check-out counter, etc., in a manner so that it is likely to be read during the transaction. Furthermore, the amendment requires that the five-inch sign must be set in white type on a contrasting red background. This color combination will help ensure visibility.

The Agency believes it is necessary for warning signs to be not only posted but readable at all times when the business is open. Since readability and conspicuousness are essential parts of a clear and reasonable warning, the Agency has decided to add a specific provision clarifying that posted warnings shall be readable in all lighting conditions normally encountered during business hours.

Since alcoholic beverages are acquired, sold, or consumed through a wide variety of environments, the Agency has decided to expand the specific "safe harbor" provisions of this regulation in order to account for a greater number of situations through which exposure may be experienced. By covering more situations with a "safe harbor" warning system, the Agency believes that such warnings will be more frequently used and thus increase the chances that these warnings will be given in a manner that the Agency has, by this regulation, deemed to be a clear and reasonable warning under the Act.

The amendment specifically addresses facilities which offer both on-sale and off-sale purchases. Persons going to such a facility may visit the on-sale area such as a tasting room, but not enter the off-sale portion of the premises. The reverse situation may also occur. While some individuals may visit both portions of the premises, there is no guarantee of this occurring. As a result, the Agency has decided that the only way to ensure that all visitors receive a warning prior to consumption is to require that each portion of such "mixed" facility adhere to the applicable standard found elsewhere in the regulation. Thus, the off-sale portion of this type of "mixed" facility would adhere to the off-sale provision of the regulation and the "tasting room" portion must adhere to those provisions of the regulation applicable to businesses providing liquor for consumption on the premises.

The amendment alters the pre-existing "safe harbor" provision relating to businesses which distribute alcoholic beverages either in whole or in part by way of counter service (subsection (b)(1)(D)(2)). The prior version of this provision allowed such businesses to satisfy this "safe harbor" by posting the ten-inch square sign described in this regulation in a manner so that it was readable and likely to be read from all counter

locations available to the public. The amendment requires that posting be done at both the entrance(s) as well as behind the counter. The amendment also expressly states that the definition of counter service includes portable bars. In making this change, the Agency felt that the environments in which counter service is available can vary so widely that more protection to the consumer should be afforded before allowing "safe harbor" protection to the business involved.

One commentor objected to the counter service amendment on the basis that there was no value in giving repeat warnings and that it was unreasonable to single out counter service for extra warnings (C-5 pages 2-4, 6). The Agency believes that the wide variety of counter service situations was not adequately covered by the prior provision and more should be required to gain the protection of a "safe harbor." As a result, the Agency retained the language of the amendment as originally proposed.

This commentor also felt that where portable bars, (such as those used in hotel lobbies and conference/reception facilities) are involved, the ten-inch square sign is too large and the five-inch square sign should be allowed for use (C-5 page 6). The Agency disagrees. In order to grant "safe harbor" protection to the wide variety of situations in which portable bars might be found, there needs to be more assurances of visibility than the smaller sign is designed to provide.

This same commentor also objected to the lack of any "safe harbor" provision for "mini bars" such as those found in hotel rooms (C-5 page 5). This commentor suggests that for mini bars, a sign smaller than the five-inch square sign be authorized for use. It is also suggested that the regulation specifically state whether or not a "safe harbor" warning can be given for situations such as mini bars by way of the menu or price list which is usually the way by which room occupants are informed of the available selections and their prices. With regard to the request for a smaller sign, the Agency believes that the five-inch sign is small enough for such use. Also, the Agency believes that the "safe harbor" provision for menus and price lists clearly includes the type of menus or lists to which the commentor refers and there is no need to make the regulation any more clear in this regard.

The amendment sets forth standards for alcoholic beverages acquired by delivery or through mail order. Since the person receiving the delivery package or mail order container is not necessarily the person who placed the order, it is required that the warning message be placed on or in the package or container in such a format and manner so that it is likely to be read and understood prior to consumption. As with menu warnings, the precise type size, type style, and format is not specified so that the message may be more easily incorporated into the document. However, the warning message must be likely to be read and understood prior to the consumption of an alcoholic beverage.