REVISED FINAL
STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS DIVISION 2

Section 12601. Clear and Reasonable Warning

The Safe Drinking Water and Toxic Enforcement Act of 1986 (Health and Saf. Code, § 25249.5, et seq.)(hereinafter the "Act") was adopted as an initiative statute 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 providing a "clear and reasonable warning."

Health and Safety Code 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.

On October 16, 1987, the Agency issued a notice of proposed rulemaking advising that the Agency intended to adopt a regulation implementing the terms "clear and reasonable warning" (R-87-87), along with two other regulations related to the Act. (R-85-87 and R-86-87.) Pursuant to such notice, on December 3, 1987, a public hearing was held to receive public comments on the proposed regulation (R-87-87)(hereinafter the "December 3 proposal"), and two other proposed regulations. Out of sixty-eight pieces of correspondence received commenting on the regulations and twenty-one additional documents submitted during the hearing, forty-eight contained comments regarding the December 3 proposal.

On February 16, 1988, the Agency issued a notice of emergency rulemaking adopting an amended version of the December 3 proposal effective February 27, 1988. On June 15, 1988, the Agency issued Notice of Public Availability of Changes to Proposed Regulations Regarding the Safe Drinking Water and Toxic Enforcement Act of 1986 for R-85-87 and R-87-87 ("June 15 proposal"). The notices afforded interested parties the opportunity to provide to the Agency their post-hearing comments on proposed modifications to the December 3 proposal and another regulatory proposal. The comment period closed July 5, 1988. Twenty-six pieces of post-hearing correspondence were received, thirteen of which contained comments regarding the June 15 proposal.

This revised final statement of reasons sets forth the reasons for the final language adopted by the Agency for section 12601, and responds to the objections and recommendations submitted regarding that section as originally proposed and modified. The rulemaking file submitted with the final regulation and this revised final statement of reasons is the complete rulemaking

file for R-85-87, R-86-87, and R-87-87. Therefore, the rulemaking file contains material not relevant to this regulation. This revised final statement of reasons cites only the relevant material. Comments regarding R-85-87, dealing with "discharge or release" under the Act, will be addressed in a separate final statement of reasons. R-86-87, which would have addressed issues of exposure, will not be adopted by the Agency. That proposal has been superseded by a new proposal issued May 20, 1988.

Health and Safety Code Section 25249.6 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. The terms "clear and reasonable" are not further defined. Section 25249.11, subdivision (d) provides some general guidance as to how the warnings are to be accomplished. It provides that general methods of warning, such as labels on consumer products, mailed notices to water customers, posted and media notices, and the like, may be acceptable, provided that the warning accomplished is clear and reasonable.

There are two elements to any warning: the manner in which the warning is presented, and the message by which the warning is communicated. The term "reasonable" appears to have been intended to apply to the first element. The manner of transmission must be reasonable. The term "clear", on the other hand, appears to have been intended to refer to the message which the warning must convey. Therefore, in order for a warning to be clear and reasonable, the manner of transmission must be reasonable, and the message employed must be sufficiently clear to communicate the warning.

Whether a particular manner of transmission is reasonable may depend upon the circumstances. Similarly, a message which is clear in a particular setting may not be in another. The purpose of this proposed regulation is to establish minimum standards for clear and reasonable warnings, and to provide "safe harbor" warnings for three types of exposures which, if complied with, are deemed to provide a warning which is clear or reasonable, or both.

Subsection (a)

The December 3 proposal would have established the following minimum criteria for clear and reasonable warnings:

1. The method employed to transmit the warning must be reasonably calculated, considering the alternative methods available under the circumstances, to make the warning message available to the individual exposed.

2. The message must clearly communicate to such individual that the individual is being exposed to a listed chemical.

One commentator objected to the first criterion because it requires that the alternative methods available under the circumstances be considered on the ground that this suggests that certain methods of warning are more reasonable than others. (C-65, p. 16.) The commentator contends that Health and Safety Code section 25249.11 (f), which permits warnings to be provided by "general methods such as labels on consumer products, inclusion of notices in mailings to water customers, posting of notices, placing notices in public news media, and the like," grants equal dignity to all manner of warning.

The first sentence of Health and Safety Code section 25249.11 (f) does not grant equal dignity and status to all warning methods. The obvious and sole purpose of that provision is to relieve businesses of the need to warn each exposed individual separately. It points out different general warning methods by way of example only, not to establish a principle that a warning provided by any method is reasonable.

Under the Act, warnings must be clear and reasonable. By definition, "reasonable" means "not excessive or extreme, fair." (American Heritage Dict. (2nd college ed. 1985) p. 1031.) Thus, by definition, all methods cannot be reasonable. In order to determine whether a particular warning method is fair and not extreme, it stands to reason that the method needs examination in light of the other available methods. The regulation simply provides for such consideration, and requires that the warning method chosen must be reasonable. The Agency concludes that this is consistent with the Act, and the language complained of remains unchanged.

Two commentators objected that the warning method must make the message available to the individual exposed, because it suggests that each individual exposed must be warned. (Exh. 21, p. 8; C-65, p. 17.) Under Health and Safety Code section 25249.11 (f), warnings "need not be provided separately to each exposed individual." To avoid this suggestion, the June 15 proposal deleted the word "exposed" from the first criterion above, and further eliminated the requirement that the message clearly communicate "to such individual that the individual is being exposed." This amendment also served to correct another problem in the original language. The requirement that the warning advise that the individual "is being exposed" was not consistent with the requirement under the Act that exposed individuals receive prior warning. If a person "is being exposed" at the time of the warning, it is not a prior warning.

In place of the deleted language, the June 15 proposal required that the message clearly communicate that the chemical in question is known to the state to cause cancer. One commentator objected to the deletion of the original language, contending that the message should alert individuals that they are being

exposed to a listed chemical. (P-22, p. 2.) However, by communicating that a listed chemical is present, i.e., that the chemical in question is listed, the fact of potential exposure would normally be implied. It does not appear necessary in every case to specifically state that an exposure will take place. Also, it is unclear how such a specific statement would be made. If made in the present tense ("you are being exposed"), the message would be inconsistent with the requirement that warnings precede exposure. If made in the future tense ("you will be exposed"), it would also be necessary to state the condition which will result in the exposure, e.g. "entering this area" or "using this product." Stating the condition would make the warning longer and more cumbersome, both to the business giving it and the reader.

Two commentators objected to the revised language on the ground that the phrase "chemical in question" could be construed to require the warning to specify each chemical involved by name. (P-18, p. 7; P-23, p. 3.) The Agency believes that such a construction would be unreasonable. The regulation does not require specific chemical references. Further, such a construction would be contrary to the Agency's intention in adopting this regulation. It was intended that, at a minimum, warning messages would advise of the presence of a listed chemical, regardless which one. If the exposed individual desires information about the chemical, it appears preferable that the information be obtained from the party responsible for the exposure after the warning, rather than through the warning. Otherwise the warnings may become visually too congested and cumbersome to read and understand.

One commentator would have had the statement read "you <u>may</u> be exposed" to a listed chemical. (C-29, p. 2.) However, where there is an exposure to a listed chemical, such a warning would be untrue, since in fact the individual <u>will be</u> exposed. Only where there is no exposure, but the business is uncertain of the fact, would such a warning be accurate. Situations may exist in which a business cannot know whether in fact there is an exposure from each item sold, as in the case of bulk produce. Those situations may warrant special treatment under these regulations. As a general rule, advising that a person "may be exposed" appears inaccurate and unclear.

One commentator recommended clarification that section 12601 is intended to permit any clear and reasonable warning, while providing "safe harbors" which may, but are not required to be used. (C-29, p. 2.) This is the Agency's intent. Subsection (a) specifically prevents the "safe harbor provisions of subsections (b), (c) and (d) from being construed as the only clear and reasonable warnings available. The only requirements for warnings are contained in the first two sentences of subdivision (a). Businesses may provide whatever warning they choose, provided that it complies with these minimum requirements. Thus, if a business decides to provide a warning through a combination of product marking and in-store compendia, it may do so if it

complies with subsection (a), even though warnings through such a method are not mentioned in the "safe harbor" provisions. Whether such a warning is clear and reasonable would be a question of fact.

The approach employed in these regulations is intended to provide the maximum flexibility, while assuring that warnings satisfy the intent of the voters who adopted the Act to receive warnings which will enable them to make informed choices. One commentator recommended allowing businesses to include additional information along with the basic statements set out in the "safe harbor" provisions. (Exh. 1, p. 2.) This is allowed under subsection (a). A business may utilize the appropriate "safe harbor" language and include other truthful and accurate information. While it would not comply with the "safe harbor" and, therefore, be deemed clear and reasonable, it may still satisfy the requirements of the Act.

One commentator recommended that the regulation apply only to exposures by the "relevant" route of exposure and media. (C-29, p. 2.) The issue whether exposure by a particular route or through a particular media poses a significant risk, and therefore, requires a warning under the Act, is addressed in article 7 of title 22 of the California Code of Regulations. The commentator is directed to this regulation and supporting materials.

Similarly, other commentators objected that the warning provision provides no guidance when warnings will be required. (Exh. 7, p. 2; Exh. 14, p. 5.) Under the Act, warnings are required whenever there is an exposure to a listed chemical. (Health & Saf. Code § 25249.6.) Liability will not attach whenever the party or parties responsible for the exposure can show that the exposure poses no significant risk. (Health & Saf. Code § 25249.10 (c).) Thus, as a practical matter, warnings are required only where it cannot be shown that the exposure poses no significant risk assuming lifetime exposure at the reasonably anticipated rate of exposure, or that the exposure would produce no observable effect assuming exposure at 1000 times the level in question, and liability may attach. The purpose of this regulation is to describe how warnings may be provided, not to establish when warnings are required, or how it can be shown that an exposure poses no significant risk or would produce no observable effect. Those issues are addressed in articles 7 and 8 of the regulations.

Another commentator recommended that the regulation be revised to exclude foods, drugs, cosmetics and packaging materials from the warning requirement of the Act. (C-31, p. 2.) Similar requests have been made to the Agency by petition pursuant to Government Code sections 11347 and 11347.1. However, there appears to be no basis for such an exemption. The Act was plainly intended to apply to foods, since Health and Safety Code section 25249.11 (f) specifically mentions food in the definition of "warning." Further , the Act applies to all "persons in the course of doing

business," which would include persons doing business involving cosmetics or drugs.

The Agency is aware of the concern of marketers of such products that the need for such warnings may be widespread. It has adopted on an interim basis "no significant risk" standards based upon familiar product safety law in order to afford these industries some guidance pending the establishment of "no significant risk" levels specific to the Act. However, these products cannot categorically be exempted from the Act as recommended.

Exemption Where Federal Law Governs Warning

Two commentators recommended that the regulation should exempt certain exposures from the Act on the ground that the Act is preempted by federal law. (C-35; C-36, p. 4.) The Act does exempt exposures "for which federal law governs warning in a manner that preempts state authority." The term "warning," for purposes of the Act, is defined to include general methods of warning such as labels, mailed notices, posted notices, news media notices and the like. (Health & Saf. § 25249.11 (f).) Thus, it appears that the term "warning" is intended to include all available methods of providing warnings.

As one commentator points out, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) may preempt state or local laws requiring the labeling of the products it covers. (C-36, p. 4.) However, even assuming this to be the case, labels represent only one method of warning. Where the federal law preempts the use of certain methods, leaving other methods available, then it cannot be said that the federal law "governs warning", since "warning" includes all methods. Since the exemption from the Act applies only where federal law governs warning, it appears that the exemption may not apply in the case of FIFRA.

The Agency is authorized to adopt regulations necessary to conform with and implement the provisions of the Act. (Health & Saf. Code § 25249.12.) The Act authorizes an exemption only where federal law governs "warning." The federal law regarding such products governs only labels and labeling, not warning altogether. Accordingly, the Agency appears to lack the authority to exempt such products from the Act by regulation. Similarly, one commentator contended that the federal Meat Inspection Act preempts the marking, labeling, packaging and ingredients of meat products. (C-56, p. 2.) This contention is made on the ground that labeling under the Act would irreconcilably conflict with the federal scheme. The Act, however, does not require labeling or packaging warnings, nor do these regulations. Therefore, it does not appear that the Act authorizes the exemption of such products from the Act. Such products would still be subject to the Act. Although warnings through methods expressly preempted by federal law could not be required, warnings through other methods could be required where federal law does not provide a clear and reasonable warning under

the Act about the carcinogenicity or reproductive toxicity of the chemical.

It is also possible that a federal scheme could be so comprehensive in its scope that it evinces a congressional intent to preempt all state authority. However, until the courts have passed upon the issue, the Agency cannot definitively conclude that federal law is preemptive. The Agency believes that, in any event, this would not be an appropriate subject for regulation. If a federal law clearly preempts the Act, then no regulation is necessary to interpret the Act. If the resolution of the preemption question is less clear, then the question is more properly one for the judiciary to decide on a case-by-case basis, rather than by this Agency in the abstract. Should the issue arise in an enforcement action, the courts may appropriately determine whether the application of the Act violates the supremacy clause of the federal constitution. Accordingly, the Agency does not in these regulations intend to acknowledge any preemption arising out of this federal law. Rather, those issues are left for judicial determination.

One commentator requested that medications which are either ingested or topically applied to the skin be exempted from the Act, because the physician already provides information to the patient under his obligation to obtain the patient's informed consent. (C-68, p. 1.) The special problems raised by the patient-physician relationship are addressed in subsection (b)(2). These products are not exempted from the Act, but a specific "safe harbor" warning provision is set forth.

Four commentators recommended the exemption of textile products from the Act on the ground that they pose no significant cancer risk. (C-37, p. 1; C-41, p. 1; C-42, p. 1; C-43.) If this is in fact the case, then these products are already exempt under the terms of Health and Safety Code section 25249.10. Therefore, this recommendation was not adopted.

Subsection (b)

The purpose of subsection (b) is to provide a "safe harbor" where warnings for consumer product exposures include the methods of transmission and the warning messages specified therein. Warnings which comply with these provisions are deemed to be clear or reasonable as required by the Act.

Normally, whether a warning is clear and reasonable will be a question of fact to be determined on a case by case basis. However, reasonable men can differ on what is clear, and what is reasonable. Even with the minimum requirements set forth in subsection (a), a business may not be certain that its warning, as a matter of fact, will protect it from liability. Since the Act imposes civil liability where a warning is found not to be clear and reasonable, the Agency has concluded that it is necessary to provide businesses with an opportunity to be certain that the warning which they give is reasonable or clear, or both,

and that providing general "safe harbor" warning methods and messages which are deemed sufficient without further proof is a reasonable means to accomplish this result.

As explained earlier, businesses are not required to give the "safe harbor" warnings. Subsection (a) specifically prevents the "safe harbor" provisions of subsections (b), (c) and (d) from being construed as the only clear and reasonable warnings available. Businesses may provide whatever warnings they choose provided that they comply with the minimum requirements set forth in subsection (a). The "safe harbor" is offered simply to provide the businesses choosing to use them reasonable certainty that they will not be subjected to an enforcement action over the warning they provide. It is not intended to be a warning straight-jacket.

The regulation sets forth several "safe harbor" methods, often with a corresponding "safe harbor" message. Subsection (b) provides that both the message and the method must be used in order for the warning to be deemed clear and reasonable.

Consumer Products Exposures Defined

Subsection (b) defines "consumer products exposure" as "an exposure which results from a person's acquisition, purchase, storage, consumption, or other reasonably foreseeable use of a consumer good, or any exposure that results from receiving a consumer service." Originally, the term "consumer good" was qualified by the phrase "including, but not limited to, any food." Upon further consideration, the Agency determined that this qualifying phrase was unnecessary. The term "consumer good" is generally defined as "goods, such as food and clothing, that satisfy human wants through their consumption." (American Heritage Dict. (2nd college ed. 1976) p. 315.) Since the term "consumer goods" refers to food products anyway, it appears unnecessary and duplicative to specifically mention food. Therefore, the phrase referring to food was deleted.

One commentator recommended that the safe harbor warnings apply to industrial and commercial products as well as consumer goods. (Exh. 21, p. 14.) The term "consumer product exposure" is intended to have broad application. Not only is it intended to apply to exposures to products normally regarded as consumer items, such as food, clothing, automobiles, appliances and dwellings, which are acquired by individuals, it applies to exposures resulting from any "person's" acquisition, purchase, storage, consumption or use of a consumer good. The Act defines "person" to include business entities as well as individuals. Accordingly, if a products is intended for acquisition, purchase, storage, consumption or other reasonably foreseeable use by a person, then the "safe harbor" of this subsection may be used, though it is not required to be.

Not all persons acquire the materials which they use in the same manner as the retail purchaser, and some of the "safe harbor"

methods of giving warning may apply only in the retail setting. Thus, in some situations, warnings of the consumer product type may not be desirable or workable. Where, for example, one business sells and ships directly to another business a component or ingredient to be incorporated into a final product for sale to the public, sales personnel may choose to communicate the presence of a listed chemical to the purchasing officer of the receiving company. The regulation does not prohibit the transmittal of information in this manner. The receiving business would then have the information to pass along, if necessary, to its customers and employees.

One commentator recommended that this "safe harbor" also apply to exposures resulting from any person's transportation of a consumer good. (Exh. 20, p. 7.) The Agency does not envision that trucking companies or other common carriers would be providing their own warnings for the goods which they transport. Rather, it is contemplated that carriers will pass along warning information received from the shipper along with the goods to the consignee. Therefore, the Agency determined that the reference to transportation might create unnecessary confusion and did not include it.

One commentator recommended deletion of the definition of "consumer products exposure" on the ground that it is unnecessary, that it is a human exposure to a listed chemical in a consumer product. (C-36, p. 4.) In light of the questions raised about the applicability of this "safe harbor" to industrial or commercial products (above), it appears that some definition is necessary.

One commentator recommended that the regulation define "reasonably foreseeable", or substitute the phrase "reasonably intended." (C-31, p. 7.) However, "reasonably" does not appear to be susceptible of definition. "Reasonably" is simply the adverbial form of "reasonable," which is an elastic term . . . of uncertain value in a definition." (Ballentine's Law Dict. (3rd ed. 1969) p. 1060.) "Foreseeable" plainly refers to something which can be anticipated. It does not have the same meaning as "intended," since something which may be anticipated may not be intended. It was not the Agency's intention that this provision apply only to reasonably intended exposures. Accordingly, this recommendation was not adopted.

Three commentators recommended that the regulation define what is a "consumer good." (C-20, p. 3; C-27, p. 3; C-31, p. 4.) One of these commentators recommended a lengthy definition which would exclude component parts of products, arguing that only the end-product manufacturers should be required to provide the necessary warning. (C-31, p. 4.) Similarly, two other commentators recommended that the regulation exclude aerospace parts and components from the meaning of "consumer good" and "consumer products". These commentators misunderstand the purpose of this subsection. It is not designed to include or exclude businesses from the warning requirement of the Act. It is intended to

provide "safe harbor" warnings which businesses may use for certain kinds of exposures. Limiting the scope of this section would simply reduce the availability of the "safe harbor" warning. It is the Agency's intention that the "safe harbors" have broad availability. Accordingly, these recommendations were not adopted.

One commentator objected that consumer exposures are triggered by the purchase of a product, rather than by consumption. (C-65, p. 23.) The definition of "consumer products exposure", however, is not intended to establish when an exposure occurs. It is intended to address the availability of the "safe harbor" warning. The term "expose" is defined elsewhere as meaning "to cause to ingest, inhale, contact via body surfaces or otherwise come into contact with a chemical." (22 C.C.R. § 12201 (f).) This could include the purchase by an individual of a product, not just the consumption of that product.

Subsection (b)(1)

This portion of the regulation would provide the methods by which "safe harbor" warnings for consumer products exposures may be given. The methods may be used either singly or in combination. Failure to use one of the methods described does not mean that the method used is unreasonable. It simply means that the reasonableness of the method used is a question of fact which must be proven. In other words, in order to be reasonable without further proof, the method used must be one set forth under subsection (b)(1).

Originally, subsection (b)(1) provided: "The method employed to transmit the warning must include one of the following alternative methods:. . . " Several commentators recommended that the provision be amended to provide that the specified methods "may" be used in order to be consistent with subsection (a). (C-1, p. 1; Exh. 21, p. 8; C-25, p. 4; C-27, p. 3; C-36, p. 4.) This recommendation was adopted in the June 15 proposal, which rewrote subsection (b)(1) to its present form. This amendment should not be construed to mean that any method of warning is deemed reasonable. It was intended to allay concerns that the "safe harbor" warning methods are the only methods available under the Act. Some of the commentators were apparently under the impression that subsection (b)(1) imposed requirements for consumer products warnings under the Act. As indicated in the discussion under subsection (a) and subsection (b), this is not the case.

The rewrite of subsection (b)(1) was also prompted by the objections of one commentator to the reference to alternative methods. This commentator construed this to mean that all methods must be used, i.e., that the placement of signs might not be enough. (Exh. 15, p. 21.) The revised version plainly refers to the use of methods "singly or in combination," which the Agency believes adequately addresses this concern.

Three commentators recommended the deletion of subsection (a), and further recommended that the regulation should establish a hierarchy of warning methods which are practical in different circumstances, with apparent emphasis on the practice of labeling. (C-45, p. 2; C-47, p. 1; C-54, p. 2.) This recommendation was not adopted. The purpose of this provision is not to establish a hierarchy of required warnings, just "safe harbors." Further, a hierarchy would imply that the warning method used must under the Act be more than reasonable; that it must be the best method. This is not the case. Warnings must simply be clear and reasonable. It would impart a rigidity to the selection of warning methodologies which, given the enormous variety of products subject to the Act, the Agency believes should be avoided. A regulation requiring certain kinds of warnings, particularly labels, might raise constitutional questions as well.

"Safe Harbor" Methods for Consumer Products

1. Labels and Labeling

Subsection (b) provides several methods of transmission which, either singly or in combination, may be deemed reasonable. One method is the placement of the warning on the product's label or labeling. The term "label" refers a display of written, printed or graphic matter upon the product on its immediate container. "Labeling" refers to any label or other written, printed or graphic matter affixed to or accompanying a product or its container or wrapper.

One commentator objected to the statement in the Notice of Rulemaking that the regulation would result in cost savings, because a labeling requirement will cost money. (C-61, p. 11.) Another commentator objected to the reference to graphics or printed matter as part of the product label, because it would place large businesses at a competitive disadvantage. (C-16, p. 1.) Similarly, another commentator objected to subsection (b) on the ground that federal food safety laws already protect the consumer and labels would unfairly impact the larger, more sanitary food processing operations. (C-44, p. 2.) Again, this section is not intended to require labels. It simply deems labels to be reasonable when used in a warning complying with the subsection. The choice whether to employ the "safe harbor" warnings or some other warning continues to reside with the businesses covered by the Act. As for the protections of federal food safety law, that issue is addressed in regulations regarding the term "no significant risk" (22 C.C.R. § 12701, et seq.).

One commentator recommended clarification regarding the term "immediate container," since a product may have several containers during its passage through the distribution chain. (C-67, p. 2.) The Agency believes that the term is clear on its face. The warning for the consumer product exposures should be provided for those exposures which are "reasonably foreseeable." The container or containers on which the warning is placed should

be selected in light of the reasonably foreseeable exposures. The term "immediate" in this context simply means close at hand, and this is consistent with the Agency's intent that labeling be closely associated with the consumer product for which the warning is given. No clarification in the regulation appears to be necessary.

One commentator pointed out a typographical error in the definition of "label." It defined "label" as matter "upon a product on its immediate container. This commentator recommended that the word "on" be changed to "or" to give effect to the term "immediate container." (C-25, p. 3.) This definition was derived in part from the Sherman Food and Drug Law, which defines "label" as matter "upon a food, . . . or upon its immediate container." (Health & Saf. Code, § 26016.) Use of the word "on" instead of "or" was not intended. This typographical error has been corrected.

2. Retail Outlet Warnings

Another method described in subsection (b)(1) which may be deemed reasonable is the identification of the product at the retail outlet in a manner which provides a warning, such as shelf labeling, signs, menus, or a combination thereof.

Three commentators objected to this provision on the ground that it shifts the burden of warning onto the retailer, and that the Act requires that the manufacturer give the warnings which the Act mandates. (Exh. 11, p. 4; C-11, p. 2; Exh. 12, p. 2.) This contention is apparently based upon that portion of Health and Safety Code section 25249.11 (f) which directs that regulations implementing the warning requirement of the Act, to the extent practicable, place the obligation of providing warning materials such as labels on the producer or packager rather than on the retail seller.

This provision does not require retailers to provide warnings. It simply describes certain warnings at the retail outlet as a method of providing warnings which are deemed to be clear and reasonable. Moreover, it does not appear that the Act places the burden of providing warnings exclusively upon manufacturers, producers or packagers. The Act provides that no person in the course of doing business shall knowingly and intentionally expose any individual to a listed chemical without first giving a clear and reasonable warning. (Health & Saf. Code, § 25249.6.) It does not provide that only manufacturers are so prohibited.

Similarly, section 25249.11 (f) does not require that warnings be given by manufacturers. It simply requires that under the regulations, to the extent practicable, warning materials should be provided by the producer or packager. Providing warning materials is not the same as providing warnings. A manufacturer could provide warning materials to a retailer without ever warning the individuals exposed. Since section 25249.5 does not provide "without first giving clear and reasonable warning

materials," the Agency has concluded that section 25249.11 (f) does not absolve retailers of the need to participate in the warning process.

Two other commentators recommended that labels be required for products purchased in a container, citing page three of the Initial Statement of Reasons as expressing the Agency's own preference for warnings by this method. (C-45, p. 3; C-49, p. 5.) These commentators also recommend that posters and shelf labeling should be required where labels are not practical, and should be placed as near to the price listing for the item as possible. (C-45, p. 3; C-49, p. 5.) As indicated above, the purpose of this regulation is not to require any particular type or hierarchy of warnings. It is the intention of the Agency that the regulation be flexible to accommodate the wide range of warning situations which may arise under the Act. A hierarchy of "safe harbors" may not satisfy this intent.

As for the initial statement of reasons, these commentators read too much into the Agency's narrative. The passage which they cited reads:

> "In some circumstances, warnings on the the label or labeling may not be practicable or possible. In such cases, warnings to the consumer would likely be conveyed by the retail outlet."

This was not intended to express a preference for anything. It was simply an observation that in some circumstances labels may not work well. It could just as easily have said that in some circumstances shelf labeling, or menu warnings, may not work well. Where one method of warning is not as suitable as others to the party giving the warning, it is assumed that more suitable methods will be employed. However, no particular method of warning is required. The "safe harbor" provisions afford equal dignity to the limited range of methods of warning described.

As for the placement of shelf labeling, subsection (b)(3) already provides for the placement of warnings so that they will be conspicuous.

As originally proposed, subsection (b)(1) included cash register receipts as a method by which a "safe harbor" warning could be provided. Two commentators recommended that this provision be deleted. (C-45, p. 3; C-49.) This recommendation was adopted. However, this does not mean that cash register receipts cannot be used as a method of transmitting warnings. It is conceivable that warnings at the cash register or check-out stand could be effective, and subsection (a) permits any warning which may be clear and reasonable. Whether such a warning is clear and reasonable would remain a question of fact.

The methods of warning described in subsection (b)(1)(B) were carefully chosen to avoid methods which might, without additional restrictions, impose unreasonable burdens upon retail consumers.

Several commentators objected that the regulation did not include in-store compendia and mass-media warnings among the list of methods which may be deemed reasonable. (C-5; C-11, p. 2; C-32, p. 4; C-53, p. 7; C-61, pp. 4-5; C-65, p. 17; Exh. 16, p. 6; Exh. 10, p. 6; Exh. 17, p. 3; C-9, p. 10; Exh. 14, p. 5; Exh. 7, p. 2.)

The recommendation about the compendia had been made prior to the original proposal. It had been proposed that the retailer would maintain at some location in the store a compendia of all products carried by the retailer which contain levels of listed chemicals in a significant amount. However, given the enormous size of many of today's stores, the likelihood that many people will be shopping in such stores at a given time, often in the company of children, and the further likelihood that a shopper's basket may contain dozens of items, to require a shopper to journey to a remote corner of the store to compete with other shoppers for the opportunity to consult textual material on a large number of items cannot be deemed reasonable without some factual showing. Placement of the compendia in each aisle, or at each of the check-out stands might mitigate some of these burdens, but not others, and may create congestion affecting its reasonableness. Accordingly, the use of "compendia" was not described as a method which may be deemed reasonable. The reasonableness of employing compendia to convey warnings would remain a question of fact in the event an enforcement action is brought under the Act.

Media warnings had also been recommended prior to the original proposal. The warnings would be published once every three months in newspapers of general circulation. Presumably these media warnings would resemble warnings for environmental exposures set forth in subsection (d) of this regulation. Although Health and Safety Code Section 25249.11 (f) does mention the placement of notices in public news media, it does not appear that such notices are always reasonable for warning consumers about products which they purchase. It could make receipt of the warning a matter of chance and, if received, might have little apparent relationship to the product itself.

The concept of clear and reasonable warnings implies that the selection of the method employed will consider the suitability of the method under the circumstances and the availability of more suitable alternatives. Hence, subsection (a) requires that the methods of warning must be reasonably calculated, considering the available alternatives, to transmit the warnings to those who will foreseeably be exposed. In the case of consumer products, the consumer receives goods the physical presence of which provides a medium for warning, often from a retailer or distributor who is further capable of providing a warning. Thus, there is an array of methods available to provide warnings directly to consumers purchasing a particular product. Likewise, in the case of consumer services, the person rendering the service is generally available to provide a warning directly to the consumer.

Published notice, on the other hand, would have no apparent relationship to the product or service, other than the fact that the product may be mentioned in the notice. The consumer may never see the notice. Even if the consumer sees the notice, the likelihood that it would be read and associated with the consumers own purchasing activities appears to be remote.

Accordingly, in the case of consumer products and services, the Agency has concluded that published notice of the variety described in subsection (d) for environmental exposures would seldom be appropriate for lack of a more suitable alternative, and cannot be deemed reasonable without further proof. This does not mean that the public media cannot be used to provide consumer products warnings. Many products are advertised in the media, and warnings could be associated with these advertisements. The frequency and visibility of advertisements containing such warnings could render the warnings reasonable. However, due to the number of variables involved, the regulation does not describe such warnings in the media as a method which may be deemed reasonable. Whether they would be reasonable is a question of fact.

Some commentators recommended that all warning methods expressed in the statute be deemed clear and reasonable. (Exh. 10, p. 5; C-61, p. 5.) The statute refers to labels, mailed notices, posted notices and media notices. In fact, all these methods are deemed clear and reasonable for one kind of exposure or another in subsections (b), (c) or (d). They are not, however, deemed to be clear and reasonable for all purposes, particularly for consumer products exposures, for the reasons expressed above. Mailed notices, posted notices, and media notices may be used to convey a consumer products warning, but the reasonableness of such use would be a question of fact.

One commentator recommended the use of symbols in combination with media campaigns and in-store signs, and suggested some possible symbols. (C-11, p. 3.) While there may be considerable merit to such an approach, the Agency believes that the details of such a system must be worked out by the regulated community before the Agency can accept one particular system as a "safe harbor" in these regulations. Certainly, subsection (a) permits the regulated community to utilize such an approach even in the absence of recognition in subsection (b).

One commentator recommended that restaurants be able to put all of its warnings in one place, as on the menu. (T. pp. 60:16-61:4.) This comment appears to have arisen out of the mistaken impression that in order to provide a "safe harbor" warning under subsection (b)(1)(B), it is necessary to provide warnings by all the methods described. Subsection (b)(1) has been amended to provide that the methods may be used "singly or in combination." The Agency believes that the amendment addresses the concern expressed in this comment.

3. Warning Information Systems

As originally proposed, subsection (b) made no reference to warning systems which provide information through toll-free telephone services. At the December 3 hearing, a commentator proposed and a number of other commentators endorsed a system which would combine news media notices, in-store information signs, and a toll-free telephone information service. (Exh. 10, p. 7; Exh. 17; C-5; C-11.) No detailed proposal was made.

At the time of this proposal, many businesses already operated toll-free telephone information services about their products as a customer service. The Agency believes that, because the mechanism for providing these services already exists, businesses should be permitted to utilize them for purposes of the Act to the extent that the services in fact provide a warning that is clear and reasonable. To recognize this potential, the Agency moved the "safe harbor" warning for alcoholic beverages to subsection (d) and proposed a new subsection (c) which incudes as a warning method:

> "A system of signs, public advertising identifying the system and toll-free telephone information services that provides clear and reasonable warnings."

This amendment was endorsed by several post-hearing commentators. (P-12, p. 1; P-7, p. 3; P-8, p. 1; P-20, p. 1; P-21, p. 8.) One commentator objected to it on the ground that it embraces the "800" number system. (P-2.) This is an apparent reference to a service set up for grocery and other consumer items which establishes an "800 hot-line" which consumers may call to obtain a warning. Similarly, another commentator attached to its post-hearing comment a copy of an informal opinion from the Office of the Attorney General regarding the legal sufficiency of a system "if there is no identification of specific products at the point of sale in a manner which would enable consumers to make informed choices among competing products on the basis of point-of-sale information." The commentator stated that, absent a response from the Agency, it will conclude that the Agency concurs in the opinion rendered. (P-22, p. 4.)

The purpose of the Agency in adopting this provision is simply to acknowledge the possibility that a legally sufficient warning system could be developed. That is why the reference to such systems is qualified by the language ". . . that provides clear and reasonable warnings." The Agency does not believe that such systems are clear and reasonable per se by virtue of their mere existence, and the Agency takes no position on the legal sufficiency of any particular system.

One commentator recommended that a general warning, instead of signs, labels and printed material, which would alert the customers to the availability of other information be deemed sufficient. (C-52, p. 3.) It is unclear what form this general warning would take, or how this other information would be made

available. Presumably, the general warning would have no relationship to the products in the retail setting. For the reasons already discussed, the Agency did not adopt such an approach as a "safe harbor" in these regulations.

4. Alcoholic Beverage Warnings

For alcoholic beverages, which include, without limitation, beer, wine, malt beverages, and distilled spirits, subsection (b)(1)(D) provides specific methods of warning by signs or notices at the point of sale or of consumption which may be deemed reasonable. This is because such beverages are regulated as a whole, have an easily recognizable common ingredient, are often sold in facilities dedicated to the sale of such beverages, and frequently in the supermarket setting have a point of sale different from that of food items.

Two commentators recommended that warnings given by businesses pursuant to local ordinance about the health risks associated with the consumption of alcoholic beverages be deemed both clear and reasonable for purposes of the Act. (Exh. 9, pp. 9-10; T. pp. 62:12-24.) However, the purpose of the Act is to warn about exposures to chemicals known to cause cancer, or birth defects or other reproductive harm. Alcohol in alcoholic beverages has been listed as a chemical known to the state to cause cancer and reproductive toxicity. Under this recommendation, warnings pursuant to local ordinance would be deemed clear and reasonable for purposes of the Act, even if they made no reference to the risks of cancer or reproductive harm and referred only to other health risks. This appears to be inconsistent with the Act and, therefore, unauthorized.

Further, the purpose of this regulation is to identify methods of warning and warning messages which the state deems to be clear and reasonable. Only a few local jurisdictions in the state, according to the testimony, have ordinances requiring warnings about the health risks of alcoholic beverages. Thus, many jurisdictions have yet to adopt any particular warning methodology. Under this recommendation, or any proposal accepting locally required warnings, the regulation would deem clear and reasonable warnings under local ordinances, whether or not they currently exist. The Agency believes that, to deem a warning clear and reasonable, it must have some assurance that the warning will be sufficient.

Those local ordinances which have been brought to the Agency's attention appear to be criminal in nature, i.e. violation of the ordinance will result in criminal penalties, rather than civil. The ordinances require a specific message to be delivered in a specified manner. The Act simply requires a warning which is clear and reasonable. Where a warning required by local ordinance addresses the cancer or reproductive risks of consuming alcoholic beverages, compliance with that ordinance will avoid the imposition of criminal sanctions and likely will be sufficient to avoid enforcement actions under the Act unless the

locally required warning is clearly unreasonable or unclear. Thus, as a practical matter, businesses would probably not be placed in the position of providing separate state and local warnings, and recognition of the local ordinances in these regulations appears unnecessary.

Several commentators objected that warnings for alcoholic beverages through signs or menus may be deemed reasonable without further proof. One suggested that the signs would not be seen by minor women because they do not personally enter the retail establishments to purchase the beverages. Rather, they have adults make the purchase. (T. pp. 88:5-14.) However, the Agency believes that minor women will be aware of these warnings and will receive considerable exposure to the warning message. Under the regulation it is anticipated that the warning message will be boldly displayed in supermarkets, convenience stores and on restaurant menus, among other places. Minor women visiting these establishments will have ample opportunity on each occasion to see the warning message and comprehend its significance so as to influence their later decisions. Further, these signs will likely be seen prior to the time the alcoholic beverage is purchased. If only labels were required, once an adult has purchased an alcoholic beverage on behalf of a minor woman, it is unlikely that upon seeing the label warning the minor woman will avoid consuming the beverage, since it has been paid for and she would be unable to return it.

Two commentators contended that if signs are allowed it will be too difficult to monitor compliance. (C-48, p. 2; C-45, p. 5.) However, since every individual is authorized under the Act to bring enforcement actions and can "monitor" compliance, the Agency believes that this regulation will not result in a lower level of compliance with the Act.

One of these commentators observed that there are 27 types of licenses to allow the retail sale of alcohol, and that alcohol will be sold in a variety of settings, such as airplanes, hotel rooms, catered events, nudist colonies, limousines and clubs. C-48, p. 2.) The Agency does not believe that this requires 27 different kinds of warning methodologies. The "safe harbors" provided by the regulation are designed to cover the majority of settings in which exposures to alcoholic beverages occur. They are intended to be flexible enough to be adapted to most of the situations referred to by this commentator. In the event this subsection does not apply, it simply means that, for that situation, there is no "safe harbor" warning, and the reasonableness of whatever warning is given would be a question of fact. It does not mean that no warning would be necessary.

One commentator expressed its concern that only one sign near the hard liquor in a retail setting would be insufficient, particularly since displays of alcoholic beverages are often spread around the store. (T. pp. 134:14-135:8.) It was the Agency's intention under the original language that warnings be visible at each point of display of alcoholic beverages. To make

certain that this intention is understood, the June 15 proposal inserted the word "each" before "point of display" in the second to the last sentence of subsection (b)(1)(D)1.

Each of these commentators, and others expressed a preference for labels, and recommended that labels be required. (C-26, p. 1; C-45, p. 5; C-48, p. 1; T. pp. 132:9-22.) As the Agency has repeatedly indicated, the purpose of this subsection is to establish "safe harbors," not to impose requirements or limit the range of available warning methods.

Warnings under the Act do not need to be by the best method. They simply need to be clear and reasonable. The Agency believes that signs are reasonably calculated, even when considering labels or labeling as alternatives, to make the warning message available to the people who may be exposed. They would be seen by purchasers and non-purchasers alike, and thus serve as a form of public education.

The reasons argued to support a labeling requirement are not persuasive. It is contended that they will be seen by everyone. However, many people who consume alcoholic beverages may never see the label. The beverage may be decanted, or served in a glass which may have no warning. It is contended that labels would apply to all types of beverages. A comprehensive warning on a sign could accomplish the same result. It is contended that compliance with and enforcement of a labeling requirement would be relatively easy. However, producers and distributors do not support this contention with regard to compliance. As for enforcement, it appears no more difficult to determine whether a sign warning is present at the time of sale than it is to observe whether a product is labeled.

It is finally contended that labels are more effective. However, according to data provided in support of a petition requesting labels filed with the Agency, a copy of which was submitted as a comment to the regulations, point of sale displays regarding the nutritional value of food are effective in changing consumer awareness, knowledge and attitudes. (Review of the Research Literature on Effects of Health Warning Labels, A Report to the United States Congress, June, 1987, p. 4.) One study reviewed noted that point of sale displays on negative nutrients in food had a significant impact. (Russo, et al. (1986) 13 Journal of Consumer Research 48.) The report also concluded that the studies on the effectiveness of labeling "cannot be regarded as conclusive evidence that health warning labels are necessarily effective in all situations." (Review of the Research Literature on Effects of Health Warning Labels, A Report to the United States Congress, June, 1987, p. 5.) Also, it should be observed that the consumption of cigarettes among minor women increased during a period in which labels warning of potential health hazards were offered. (Id. at Appendix B, p. 12.)

One commentator recommended that signs be placed no more than five feet from any display of any alcoholic beverage. (C-7, p. 1.) As originally proposed, the regulation required signs to be no more than ten feet from any display, and no less than 10 inches by 10 inches in size. Thus, the sign should be no more than ten feet from any bottle or container. The Agency believes that this is sufficient to ensure that the signs will be effective.

One commentator recommended that the "safe harbor" for restaurants serving alcoholic beverages specify that menu warnings be printed in such a manner as to assure its effective dissemination. (C-7, p. 2.) This commentator is apparently concerned that the restaurant may be too dimly lit, or the wine list may be too extensive to make the warning easy to read. It is the intention of the Agency that menu warnings be presented in such a fashion that the warning is likely to seen, read and understood by an ordinary individual under customary conditions of purchase or use. This is the requirement imposed upon menu warnings under subsection (b)(1)(B), and there is no reason why menu or wine list warnings for alcoholic beverages should have any less of a presentation. The Agency does not believe it is necessary to again repeat this requirement.

One commentator representing three alcoholic beverage trade associations objected that signs are not approved for restaurants. (C-64.) A "safe harbor" warning may be given by signs placed at each table where alcoholic beverages are served at tables, and a special sign dimension has been provided. One commentator objected that the sign dimension provided could be construed to mean that menus must contain warnings of the same dimensions. (P-26, p. 2.) This was not the Agency's intention. The Agency recognizes that menus employ a variety of formats, and therefore, did not specify dimensions for menu warnings. Each restaurant has the discretion to adapt the warning message to its menu format so that it is likely to be read and understood by an ordinary individual under customary conditions of purchase or use. Warnings five inches by five inches in dimension are required only if table top signs or notices are used. This appears to be well-expressed by the regulation, and no clarification appears to be necessary.

Subsection (b)(2)

Subsection (b)(2) provides that, to the extent practicable, warning materials such as labels shall be provided by the manufacturer, producer or packager of the consumer product. This provision is intended to implement the requirement of Health and Safety Code Section 25249.11 (f), which provides in part:

> "In 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 any warning materials such as labels on the producer or packager

rather than on the retail seller, except where the retail seller itself is responsible for introducing a chemical known to the state to cause cancer or reproductive toxicity."

The apparent purpose of section 25249.11(f) is to encourage the origination of warning materials such as labels with the persons in the chain of distribution most likely to know the chemical properties of products intended for retail sale to consumers. This does not mean that these persons must provide the warning, but simply the warning materials. Accordingly, the proposed regulation states that warning materials should be given by the manufacturer, producer or packager. The warning materials need not be included as part of the product package, but should be made available along with the product to the retailer for transmission to the consumer.

Two commentators recommended that the regulation clarify what party in the chain of distribution must provide warnings. (C-25, p. 4; C-67, p. 2.) However, the purpose of this provision is not to determine who actually provides warnings to consumers, but to allocate the burden of providing warning materials. One of these commentators recommended deletion of the phrase "to the extent practicable," so that the burden of providing warning materials would fall on the manufacturer absolutely. (C-67, p. 2.) The Agency believes that this requirement should not apply where it is impracticable, since to do otherwise might produce absurd results.

Similarly, for alcoholic beverages, the responsibility for providing the warning materials is specifically placed upon the manufacturer or distributor. In addition, the placement and maintenance of such warnings are made the responsibility of the manufacturer or distributor at no cost to the retailer. If the manufacturer or producer fails to provide, place and maintain such warnings, liability under the Act falls solely upon the manufacturer or distributor.

One commentator objected that the regulation places the burden of placing and maintaining the warning signs on the distributor, arguing that it is impossible to determine liability at a location which deals with many manufacturers and distributors. (C-58.) The intention of this regulation is to make every distributor or manufacturer of products for which an adequate warning is not provided liable for that failure, unless the retailer interferes with attempts by the manufacturer or distributor to provide such warning. Where warnings are not present, the prosecutor may proceed against each manufacturer and distributor of alcoholic beverage products sold at that establishment, as well as the retailer. The Agency believes that this will provide ample incentive for the manufacturers and distributors to make certain that the warnings are present, and for the retailer to leave the warnings in place.

Two commentators objected to this same provision contending that it is contrary to the Act. (Exh. 20, p. 8; T. pp. 118:6-12.) The Act authorizes designated agencies to adopt regulations to further the purposes of the Act, and further directs that in adopting those regulations the obligation to provide warning materials shall be placed upon the packager or producer of the product. The regulations concerning alcoholic beverages implement this directive. The Agency can see no basis for imposing liability upon retailers where the responsibility for providing, placing and maintaining warning signs falls upon another party. Where the retailer interferes with the manufacturer's or distributor's attempts to place and maintain warnings, the retailer would assume the liability for continuing to sell the alcoholic beverage products without warning.

One commentator objected to this provision contending that it is ambiguous. (T. pp. 75:24-76:4.) However, no specific recommendation was made. Most other commentators appear to have had no difficulty understanding this provision. Thus, the Agency has concluded that it is clear.

Subsection (b)(2) further provides that, for exposures to prescription drugs, the labeling approved or otherwise provided under federal law and the prescriber's accepted practice of obtaining the patient's informed consent shall be deemed to be a clear and reasonable warning. As originally proposed, subsection (b)(2) provided that warnings would be the sole responsibility of the prescribing physician. Physicians prescribing drugs already have an obligation to inform patients about adverse side effects, and this reasonably should include any warning as to the carcinogenicity or reproductive toxicity of the drug. The regulation attempted to take advantage of this existing warning mechanism. However, in some cases federal law may provide labeling about the carcinogenic or reproductive effects of the drug which the prescribing physician may rely upon. In such cases the failure of the physician to provide his own warning should not give rise to liability.

The amended language is consistent with recommendation offered by several commentators. (C-22; C-28, p. 3; C-57.) Two commentators objected to the amendments on the ground that it offers no assurance that the warning will be received, that the tort standard of informed consent should not be used to prevent injury, and that accepted practice often does warn about relevant risks, citing the failures to warn about the drug Accutane as an example. (P-2; P-22, p. 5.) However, the informed consent standard does appear to be appropriate, since one purpose of the doctrine is to impose liability where the patient has not been adequately informed to enable the patient to make an informed choice. This is similar to one purpose of the Act, which is to enable individuals to make informed choices about being exposed to listed chemicals. Further, the drug Accutane is required under federal law to be accompanied by numerous warnings, so it may make no difference whether the physician provides additional warnings to the patient.

One commentator recommended that non-prescription drugs receive similar treatment, and that no additional warning is required where the non-prescription drug complies with the requirements of the federal Food & Drug Administration. (C-61, p. 3.) However, a key element permitting the treatment afforded prescription drugs is that such drugs are prescribed. The prescription process affords an opportunity for the prescribing physician to provide information where federally required labeling does not. Of course, in the case of non-prescription drugs there is no prescribing physician. The Agency does not believe that it can deem warnings to be clear and reasonable where no warning may exist.

Another commentator made a similar recommendation for the labeling which accompanies medical devices. (T. pp. 53:15-54:8.) Again, for many devices there is no prescribing physician. The Agency cannot conclude that the warnings provided will always satisfy the requirements of the Act.

Subsection (b)(3)

Subsection (b)(3) requires that warnings provided pursuant to subsections (b)(1)(A) and (b)(1)(B) be sufficiently conspicuous that they are likely to be read and understood by an ordinary individual under customary conditions of purchase or use.

One commentator objected to the requirement that warnings be conspicuous, on the ground that this may detract from other more important warnings. (C-61, P. 67.) Under the Act, no warning is required where the exposure poses no significant risk of cancer, or would produce no observable reproductive effect if magnified 1000 times. The Agency assumes that consumer products warnings will be provided only for exposures which exceed these amounts. Since the risks involved are considered significant, the Agency cannot conclude that the warnings should not be conspicuous when compared with other warnings and literature accompanying the product.

One commentator objected to the requirement that the warning be "likely" to be read, arguing that it is too vague and recommending highly detailed regulations. (C-31, p. 8.) No detailed regulation was proposed. The word "likely" connotes more than a mere possibility but less than a certainty. It is intended to be a flexible term which would apply to a broad spectrum of exposure and warning situations. No more suitable alternative has been offered.

Two commentators objected to the requirement that the warnings be likely to be "read and understood," contending that this could be construed to require each individual to be separately warned, and may require warnings in foreign languages. (Exh. 21, p. 11; C-32, p. 4.) The Agency does not agree that this provision could be construed to require separate warnings to each individual. The provision clearly states that warnings are likely to be read and

"understood by an ordinary individual." Thus, it is not required that the warning be understood by exceptional or extraordinary individuals in a given situation.

As originally proposed, subsection (b)(3) required that warnings be likely to be read and understood "under customary conditions of purchase and use." One commentator objected to the use of the conjunctive "and" between the words "purchase" and "use," on the ground that it implies labels are the only acceptable method of warning. (C-65, p. 23.) To avoid this implication, the word "and" was deleted and replaced with the disjunctive "or."

Subsection (b)(4) - "Safe Harbor" Warning Messages

1. In General

Subsection (b)(4) provides specific messages which must be used in order to provide a warning deemed clear without further proof. Messages are provided for consumer products in general, for exposures to carcinogens and reproductive toxicants. Special messages for use in restaurants and in connection with bulk produce, and for alcoholic beverages are also provided.

For consumer products in general containing a listed carcinogen, the warning message is as follows:

> WARNING: This product contains a chemical known to the State of California to cause cancer.

For consumer products in general containing a listed reproductive toxicant, the warning message is as follows:

> WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

For food served in restaurants or other similar facilities, the warning message is as follows:

> WARNING: Chemicals known to the State of California to cause cancer, birth defects or other reproductive harm may be present in the foods or beverages sold or served here.

For fresh fruits, nuts and vegetables, the warning message is as follows:

> WARNING: This product may contain a chemical known to the State of California to cause cancer, or birth defects or other reproductive harm.

For alcoholic beverages, the warning message is as follows:

WARNING: Drinking Distilled Spirits, Beer, Coolers, Wine and Other Alcoholic Beverages During Pregnancy Can Cause Birth Defects.

One commentator recommended the deletion of the reference to the "State of California," on the ground that such language would be inappropriate where labeled products are shipped out of the state. (Exh. 21.) The reference to the "State of California" is intended to lend authority to the warning message and is an important part of it. Further, the warning messages are not intended at this time to address particular warning methods, such as labels. Rather, the same message is available for a number of warning methods other than labels.

One commentator recommended that the warning specify the chemicals involved by name. (C-67, p. 4.) The Agency believes that this would provide little benefit to consumers and might greatly complicate the warning process. Chemical names would probably hold little meaning for the ordinary individual. Placing the name in the warning would mean that separate warning placards might need to be obtained for each product. The goal of the prescribed warnings is to effectively place persons on notice that a risk of cancer or reproductive toxicity is associated with the use of the product. Once on notice, if the person desires additional information, he or she can direct further inquiries to the party giving the warning.

Several commentators objected that the warnings are too strong, and recommended that different warnings be provided where chemicals are listed on the basis of animal bioassay data, rather than human evidence. (Exh. 16, p. 6; Exh. 19, p. 2; C-3, p. 1; C-11, p. 3; C-27, p. 4; C-35, p. 2.) Whether listed on the basis of animal or human data, listed chemicals are known to the state to cause cancer or reproductive toxicity. Health and Safety Code section 25249.8, which provides for the listing of chemicals, does not appear to authorize that the list distinguish between chemicals on the basis of the type of data available. Therefore, the authority of the Agency to fashion warnings creating such a distinction is doubtful. Further, the Agency believes that making such a distinction in the warning may create the incorrect impression that chemicals for which only animal data exists pose less of a risk than chemicals for which there is human data.

Similarly, one commentator recommended that warnings also specify the route of exposure which produced positive test results. (C-38, p. 3.) Again, this may create a misleading impression that exposure by other routes poses no risk. As a general rule, it is assumed that a chemical which produces an adverse effect by one route will produce adverse effects by other routes as well. (See 22 C.C.R. §§ 12703(a)(4) and 12803(a)(5).) Accordingly, the Agency did not include such information in the warnings which may be deemed clear. The clarity of warnings which convey such information will be a question of fact in the event of an enforcement action.

One commentator recommended that the regulation clarify that warnings need not identify the brand name of the product or the manufacturer. (Exh. 16, pp. 6-7.) No such clarification appears to be necessary. Neither the prescribed "safe harbor" warnings nor subsection (a) make such a requirement. It is assumed that warnings associated with a product will already bear implied reference to the brand name and manufacturer. Expressed reference in such a warning would simply make the warning more difficult to read and to deliver.

Several commentators objected to the regulation's insistence on specific language, and recommended that more general language be used or that the specific language be treated as illustrative only. (Exh. 10, p. 8; Exh. 16; Exh. 21, p. 13; C-9, p. 10; C-11, p. 2; C-61, p. 7; C-65, p. 20; T. p. 100:9-16.)

The "safe harbor" provisions create generic warnings which are deemed to be clear and reasonable. Since all warnings cannot be clear and reasonable, it is essential for the regulation to describe with some specificity the warning methods and messages. Nor can the prescribed messages simply be illustrative. Otherwise, <u>any</u> method might be deemed reasonable and <u>any</u> message might be deemed clear. Obviously this cannot be the case. Therefore, specific methods or messages appear necessary so long as "safe harbors" are provided.

As for the use of general warnings, such as "this product <u>may</u> contain" a listed chemical, providing a "safe harbor" for the use of such a warning might discourage businesses from taking the steps necessary to determine whether chemicals listed are in fact present. They might simply provide the warning to avoid liability, and the public would be little better informed as a result. The Agency provided such a general "safe harbor" only for the limited situations, such as where fresh fruits, nuts and vegetables in bulk are sold, due to the likelihood that shipments from different sources will be mixed, and the potential for spoilage necessitates rapid turnover of the inventory. These similar reasons do not apply to other products. Therefore, this recommendation was not adopted.

The use of the term "birth defects or other reproductive harm" for exposure to listed reproductive toxicants is consistent with the language of the Act. Section 1, subdivision (b) of the Act specifically provides: "The people therefore declare their rights:. . . [Par.](b) To be informed about exposures to chemicals that cause cancer, <u>birth defects, or other reproductive harm</u>."

Two commentators objected to the references to "birth defects or other reproductive harm," and recommended that the warning messages refer instead to "reproductive toxicity." (Exh. 16, p. 6; C-36, p. 4.) While that term may be comprehensive, its use would be unlikely to carry much significance with the intended recipients of the warning. The concept of birth defects, on the other hand, is widely recognized by the public and was obviously

a strong motivating force in the passage of the Act. Although it is conceivable that the reference to birth defects in a warning for a product posing only a significant risk of some other form of reproductive harm (e.g., reduced sperm count) may incorrectly lead some members of the public to conclude that the product could cause teratogenesis, this potential misconception is outweighed by the fact that the term "birth defects" does plainly communicate that the product may pose some reproductive consequences. Also, the warning expressly refers to "other reproductive harm" in the disjunctive. Further, the proposed language does not foreclose a business from providing a more specific warning for such products, provided that it too is clear.

The proposed warning language is based upon the assumption that warnings will be provided only for consumer products which pose a significant risk of cancer or reproductive harm. It was not anticipated that businesses would provide warnings where not otherwise required to. Plainly, neither the Act nor the proposed regulations require warnings for all exposures to listed carcinogens or reproductive toxins in consumer products. Had the people intended that warnings be provided for every exposure, the Act would not have exempted exposures posing no significant risk or producing no observable effect.

Other regulations exclude from the meaning of the terms "expose" and "exposure" those amounts of a chemical in a food product which are naturally occurring. This relieves businesses of the need to warn about the presence of chemicals over which they have no control, many of which industry representatives have insisted are ubiquitous in their natural form. The purpose of this exemption was to avoid the indiscriminate use of warnings on every food product, and the consequent dilution of the significance of warnings as a whole.

Further, the Agency has provided specific no significant risk levels to assist businesses in determining whether to provide a warning. Accordingly, the Agency anticipates that warnings will be necessary in relatively few cases, and that the warning language set forth in subsections (b)(1)(A) and (b)(1)(B) will be associated only with consumer products which contain, or which the businesses connected with the exposure reasonably believe to contain, significant levels of listed chemicals in excess of those levels which are naturally occurring. The overuse of such warnings, or the categorical or generic use of similar language by retailers, may cause the Agency to reconsider its regulatory approach.

2. Restaurants

A special "safe harbor" warning is provided for restaurants and other food service establishments or facilities. Due to the difficulties associated with determining whether particular foods received from diverse sources and prepared or cooked in such an establishment contain listed chemicals, the Agency believes that

it is reasonable for such establishments to warn generally that the foods or beverages sold or served in the establishment may contain listed chemicals.

One commentator objected that the warning message specified for restaurants is too strong, and recommended that the word "warning" be replaced with something less alarming, such as "notice" or "attention." (Exh. 9, p. 11.) This recommendation was not adopted because the warning specified for restaurants is already more dilute than the warnings specified for consumer products. Softening the word "warning" in the manner suggested might make the warning ineffectual.

Two commentators objected that the restaurant warning is more dilute than the warning for consumer product exposures, and recommended that the warning instead provide that "some of the products" served "contain" listed chemicals. (Exh. 20, p. 10; C-45, p. 5.) A similar objection was made to the message specified for fresh fruits, nuts and vegetables. (Exh. 20, p. 10; C-45, p. 5.) The Agency believes that, in these narrow circumstances, stating that chemicals may be present implies that some foods sold contain listed chemicals, and is sufficient to stimulate inquiry by the persons receiving the warning. Accordingly, no amendment appears to be necessary.

One commentator recommended that the regulation permit the business to provide additional language to the effect that the food and beverages served comply with all state and federal standards, however, the Act requires that the following notice be given: . . ." (Exh. 9, p. 12.) This suggested preamble could be construed as a disclaimer of the warning which follows. Thus, the Agency did not adopt this recommendation. If a restaurant chooses to include such a preamble, the clarity of the warning will be a question of fact.

3. Fresh Fruits, Nuts and Vegetables

Similar to the warning provided for restaurants, vendors of fresh fruits, nuts, and vegetables may provide a general "safe harbor" warning that a particular product may contain chemicals known to the state to cause cancer, birth defects or reproductive harm. This is made necessary by the fact that cases of produce from different, wide-ranging and even international sources, some of which may require a warning and others not, are frequently mixed at the point of sale. The warning must be directly associated with the produce for which it is given.

One commentator objected that any warning would be required for these products, on the ground that the sale of such products is prohibited if they pose a significant risk. (Exh. 1, p. 3.) Similarly, another commentator reasoned that, since a general warning is the only possible warning which can be given, but is of little value to consumers, no warning should be required if food safety laws have been complied with. (Exh. 14, p. 5.) However, this regulation does not require warnings. Rather, it

is the Act which requires warnings. This regulation simply describes how such warning must or may be given. Regardless whether this regulation provides "safe harbors," the Act requires a clear and reasonable warning prior to exposure to a listed chemical. Objections to the Act are not relevant for purposes of these regulations. Further, the arguments are internally contradictory, for if the product poses no significant risk, then no warning is required even under the Act.

One commentator recommended that the regulation deem clear a generic warning for fresh fruits, nuts, and vegetables similar to the warnings described for restaurants. (C-53.) This would mean that a single sign could be hung in a retail outlet stating that listed chemicals may be present in produce sold there. This does not appear provide a sufficient nexus between the warning and the products for which it is given. Further, unlike restaurants, the display of the bulk produce, such as a bin of apples, affords a venue for a warning about the produce in the display. No practical reason requires that the warning be removed from the product for which it is given. Thus, this recommendation was not adopted.

One commentator recommended that dairy products be included in the fresh fruits, nuts and vegetables provision. (C-50, p. 2.) Unlike milk, much produce is imported into the United States, and retailers cannot be certain what chemical differences will exist between one batch and another. The chemical content of milk, on the other hand, appears to be more susceptible of local control, and some degree of certainty about the chemical content of milk appears to be attainable. A generic warning might be a disincentive to achieving this certainty. Thus, this recommendation was not adopted.

4. Alcoholic Beverages

One commentator recommended the addition of a provision which would require warnings in languages additional to English where a substantial number of the public patronizing a premises offering alcoholic beverages for sale use a language other than English as their primary language. (C-58.) In adopting the "safe harbor" warning messages, it was not the intent of the Agency that in every event the message would be conveyed in the language set forth in the regulation. However, where the warning for alcoholic beverages is provided in English, such warning is deemed sufficiently clear, and need not also be provided in other languages.

One commentator suggested that article 3, section 6 of the California Constitution, adopted at the same election as the Act, requires that the regulations insure that the role of the English language is preserved and enhanced and, therefore, precludes any requirement that warnings be in a foreign language. (Exh. 21, p. 11.) However, it is the Act which requires that warnings be clear, not the regulations. One purpose of the Act is to ensure that people are informed about exposures to chemicals that cause

cancer, birth defects, or other reproductive harm. (Section 1 of the Act.) Health and Safety Code section 25249.11 (f) permits warning by general methods, "provided that the warning accomplished is clear and reasonable." Thus, it is the Act, an initiative statute adopted by the voters of California, not these regulations which imposes a requirement that warnings accomplish a clear warning, and article 3, section 6(c) of the Constitution does not appear to apply.

As originally proposed, the required "safe harbor" message for alcoholic beverages read:

> WARNING: Beer, Wine, and other alcoholic beverages are known to the State of California to cause birth defects.

Two commentators recommended that the warning for alcoholic beverages specify that "drinking" alcoholic beverages during pregnancy causes birth defects. (C-17, p. 1; C-58.) Another commentator similarly recommended that the warning be directed at pregnant women, and that it refer to all beverages. (C-64, p. 13.)

In response the June 15 proposal contained the following language:

> WARNING: Drinking Distilled Spirits, Beer, Coolers, Wine and Other Alcoholic Beverages During Pregnancy Can Cause Birth Defects.

One commentator recommended deletion of this warning on the ground that the Safe Drinking Water and Toxic Enforcement Act Scientific Advisory Panel (Panel) recommended listing ethanol, not ethanol in alcoholic beverages. (C-36, p. 4.) Regardless what the Panel recommended, alcoholic beverages are a primary source of human exposure to ethanol, and a special warning is justified by the severity of the consequences which can arise from such exposure.

Subsection (b)(5)

Subsection (b)(5) provides that persons in the chain of distribution of consumer products who know that a product contains a listed chemical in an amount which requires a warning under the Act must provide a warning to any person to whom the product is sold or transferred, unless the product is packaged or labeled with a warning. In this way it is ensured that the person who finally distributes the product to the consuming public will have knowledge of the need to warn, and will do so.

One commentator recommended clarification about the chain of responsibility, i.e., which party or parties in the chain of distribution are responsible for providing warnings to consumers. (Exh. 20, p. 7.) That issue is beyond the scope of this provision, which merely attempts to ensure that goods passing through a distribution chain are accompanied by warning materials or information. It does not assign the responsibility for

passing that information or generating the warning finally received by consumers. The Agency is currently considering that issue.

One commentator recommended that the regulation provide that parties in the distribution chain may rely on warning information received from the transferor, and may rely upon the transferee to pass on the warning. (Exh. 7, p. 2.) This would mean that a retailer could rely on the fact that no information was received from a supplier, and so pass no information on to the consumer, even though the retailer has knowledge about the presence of significant amounts of listed chemicals in the product. That would be contrary to the purpose of this provision, which is to make certain that retailers and suppliers who have knowledge pass that knowledge along with the product. Further, there may be many reasons why information is not received from the transferor of a product. For example, the transferor may be a business exempt from the Act due to its small size. This does not appear to provide a basis for breaking the information chain altogether. Therefore, this recommendation was not adopted.

As for relying upon the transferee to pass the warning on, other commentators offered a similar recommendation that the regulation require the cooperation of retailers in assuring that a warning is transmitted. (Exh. 16, p. 7; C-11, p. 2.) The Agency takes the view that, where labels or labeling are not provided, once warning material or information clearly communicating the presence of a listed chemical has been passed on to the transferee, the transferor may have done all that it can to ensure that the warning will reach those who are subsequently exposed. In such cases the Agency believes that liability of the transferor could appropriately be limited. The Agency will consider future regulatory action on this issue, taking into account the difficulties it potentially may impose upon retailers.

One commentator objected that no business can know what amount "requires a warning," and thus cannot know whether it must pass a warning along. (C-67, p. 4.) Under the Act, warning is required for any amount of a listed chemical unless it can be shown that the amount poses no significant risk or would produce no observable effect assuming exposure at 1000 times the level in question. Thus, if a person in the course of doing business knows that a listed chemical is present in a product or part of a product, and there is no means of proving that the amount poses no significant risk, then some kind of warning or information is required. Since the time that this comment was offered, the Agency has adopted regulations setting the concentration levels which pose no significant risk. (See 22 C.C.R. § 12701, et seq.) Thus, many businesses may be able to determine from these levels that they need or do not need to warn. Where no level is available for a chemical, businesses that know of the presence of listed chemicals in their product would also know that warning information or materials need to be transmitted with the transfer of the product.

Two commentators recommended that businesses only be required to warn of listed chemicals found on the material safety data sheets (MSDS), or where the threshold level under the federal Hazard Communication Standard is exceeded. (C-1, p.2; C-9.) As indicated above, a supplier who knows of the presence of a listed chemical in its material which cannot be proved to pose no significant risk or to produce no observable effect assuming exposure at 1000 times the level in question must communicate that information to its customers. Nothing limits the supplier's obligation to warn to the information contained in the material safety data sheets (MSDS). Although the MSDS may provide a means for transmitting information to the transferee, it is simply one method to fulfill an obligation arising under the Act.

On the other hand, one party objected that the regulation would force small businesses to test materials received from out-of-state suppliers, since the material safety data sheets apply only to limited carcinogens and address concentrations above those found in the Act. (C-52, p. 2.) The Act, however, requires warnings only where there is a knowing and intentional exposure to a listed chemical. Nothing requires that each business conduct a scientific analysis of all its products. Unless a business has reason to know that the product contains a listed chemical, no testing is needed, and no warning is necessary.

One commentator recommended that, if under normal conditions of use an exposure would not occur, then no warning should be required. (C-1, P. 2.) If under normal conditions of business operation it is not reasonably foreseeable that anyone at the business will be exposed, then no occupational warning needs to be given. (See discussion under subsection (c).) However, if under normal conditions of use of a product it is reasonably foreseeable that an exposure will occur to a transferee or the ultimate consumer, then information must be passed to the next transferee in the distribution chain. Thus, a distributor to retailers of a product which contains a listed chemical to which consumers foreseeably will be exposed must advise the retailers of that fact. The distributor does not need to actually warn the consumers, but warning information or materials should be made available to the retailer. If the retailer is small and exempt from the Act, then such warning information may never be transferred to the consumer. Nevertheless, the information should be made available in the event the small retailer elects to inform its customers.

One commentator recommended that the regulation clarify that, where food is sold for consumption off the premises where the sale occurred, warning need only be given to the purchaser, and not to all those persons to whom the purchaser may transport the food. (Exh. 9, p. 13.) Such clarification does not appear to be necessary. The Act provides that warnings need not be given to each exposed individual, but may be given by general methods. (Health & Saf. Code, § 25249.11 (f).) The regulation has already been amended to clarify that warnings need not be given to each

individual. The Agency is unaware of any method which is certain to provide a warning to every exposed individual where consumption occurs off the premises. Most warnings are directed at the purchaser, who often represents the last person to receive the product in a commercial setting. Therefore, it appears to be implied from the entire statutory and regulatory scheme that warnings need not be given to all persons who come into contact with a product subsequent to purchase.

Subsection (c)

The purpose of subsection (c) is to provide "safe harbor" warnings for occupational exposures including the methods of transmission and the specified warning messages. Warnings which comply with these provisions are deemed to be clear and reasonable. Normally, whether a warning is clear and reasonable will be a question of fact to be determined on a case by case basis. However, reasonable men can differ on what is clear, and what is reasonable. Even with the minimum requirements set forth in subsection (a), a business may not be certain that its warning, as a matter of fact, will protect it from liability. Since the Act imposes civil liability where a warning is found not to be clear and reasonable, the Agency has concluded that it is necessary to provide businesses with an opportunity to be certain that the warning which they provide is reasonable or clear, or both, and that providing general "safe harbor" warning methods and messages which are deemed sufficient is a reasonable means to accomplish this result.

As explained earlier, businesses are not required to give the "safe harbor" warnings. Subsection (a) specifically prevents the "safe harbor" provisions of subsections (b), (c) and (d) from being construed as the only clear and reasonable warnings available. Businesses may provide whatever warnings they choose provided that they comply with the minimum requirements set forth in subsection (a). The "safe harbor" is offered simply to provide the businesses choosing to use them reasonable certainty that they will not be subjected to an enforcement action over the warning they provide. It is not intended to be a warning straight-jacket.

The regulation sets forth several "safe harbor" methods, sometimes with a corresponding "safe harbor" message. Where both a method and a message are provided, both the message and the method must be used in order for the warning to be deemed clear and reasonable. Where only a "safe harbor" method, but not a corresponding message, is provided, then the method is deemed reasonable, but the clarity of the message will be a question of fact.

Occupational Exposures Defined

Subsection (c) defines an occupational exposure as any exposure in the workplace of an employer causing an exposure to any employee. This would include exposures by one employer to the employees of another employer visiting the first employer's workplace.

Several commentators recommended that the provision related to occupational warnings be deleted, on the ground that the Act is preempted by the federal Hazard Communication Standard (HCS), or that the regulation recognize such preemption. (Exh. 6, p. 1; Exh. 21, p. 15; C-14, p. 14; C-27, p. 4; C-30, p. 4.) However, deletion of this provision would mean that, if occupational warnings are not preempted, there would be no "safe harbor" warning for occupational exposures, even though a clear and reasonable warning would still be required under the Act. Even assuming that the HCS does preempt warnings where it applies, since the application of the HCS to the construction industry is in doubt due to pending litigation, that industry and any other uncovered industry may be subject to the warning requirement under the Act.

Further, the HCS expressly does not preempt hazard communication to certain classes of employees. Subdivision (a)(2) of the HCS (29 C.F.R. § 1910.1200) provides:

> "This occupational safety and health standard is intended to address comprehensively the issue of evaluating the potential hazards of chemicals, and communicating information concerning hazards and appropriate protective measures to employees, and to preempt any legal requirements of a state, or political subdivision of a state, pertaining to the subject."

This provision applies only to state legal requirements pertaining to the subject of communicating information to "employees."

The term "employee" is defined to mean "a worker who may be exposed to hazardous chemicals under normal operating conditions or in foreseeable emergencies. Workers such as office workers or bank tellers who encounter hazardous chemicals only in non-routine, isolated instances are not covered." (29 C.F.R. § 1910.1200 (c).) Thus, the term "employee" does not apply to all workers.

Since the HCS preemption provision addresses only state law pertaining to communicating information to "employees" and the term "employee" does not cover all workers, it follows that HCS preemption does not apply to all state laws communicating information to workers. The Act requires that clear and reasonable warning be given prior to exposing "any individual" to a listed chemical. Therefore, the Act appears to apply to exposures to workers who are not "employees" under the HCS, and

even if the HCS does preempt the Act in part, it may not preempt with regard to such workers. Accordingly, the Agency cannot conclude that the "safe harbor" provisions for occupational warnings should be deleted.

As for recognizing that the HCS preempts the Act, the Agency believes that this would not be an appropriate subject for regulation. If the HCS clearly preempts the Act, then no regulation is necessary to interpret the Act. If the resolution of the preemption question is less clear, then the question is more properly one for the judiciary to decide on a case-by-case basis, rather than by the Agency in the abstract. Should the issue arise in an enforcement action, the courts may appropriately determine whether the application of the Act violates the supremacy clause of the United States Constitution. Accordingly, the Agency does not in these regulations intend to acknowledge any preemption arising out of this federal law. Rather, those issues are left for judicial determination.

Subsection (c)(1) provides that the method employed to transmit occupational warnings must include one of the specified alternative methods. One commentator recommended that subsection (c)(1) refer to methods which "may" be used, rather than methods which "must" be used. (C-1, p. 2.) The "safe harbor" provisions create generic warnings which are deemed to be clear and reasonable. This makes it necessary for the regulation specifically describe the warning methods for which "safe harbor" is given. Use of the word "may" could imply that any method is reasonable. Obviously, that cannot be the case. Therefore, the Agency did not adopt this recommendation.

Occupational Exposure "Safe Harbor" Warning Methods

1. Labels

Three methods of transmission are referred to as methods which may be deemed to be reasonable. The first is a label or labeling similar to that provided for consumer products. The second, which is in the nature of an environmental warning, is the placement of a sign in the workplace advising that the area contains a listed chemical. The third is warning which complies with all information, training and labeling requirements of the federal or state HCS, or, for pesticides, the Pesticide and Worker Safety requirements of the California Food and Agriculture Code.

Labels may be particularly useful where the chemical to which employees are exposed is stored in a container, such as a drum or carton, or where the source of exposure to the employees is a product emitting the chemical. In some circumstances a chemical, or a product emitting the chemical will be distributed to or handled by employees after it has been removed from its original drum or carton, or transferred to a different container. In such cases the label or labeling could be displayed upon the substituted container, or on the product. Whenever a "safe

harbor" is sought through the use of labels or labeling in the occupational setting, the labels or labeling must be prominently displayed in a manner likely to be read and understood by employees or persons likely to be exposed in the course of their employment.

2. Sign

As an alternative to labels or labeling, a sign in the affected area or near the work stations of those employees exposed may provide a warning. Where warning signs are utilized, they too must be posted in a conspicuous place, and under conditions making them likely to be read and understood by the employees or other persons likely to be exposed. Accordingly, the sign or signs must be placed in a location and be of of suitable size to attract attention, and must have print of sufficient size and clarity to be understood by those who will foreseeably be exposed.

One commentator recommended that the term "conspicuous" be defined as in the regulations promulgated by the federal Consumer Products Safety Commission (16 C.F.R. § 1500.1). (C-31, p. 8.) However, the regulation simply requires that signs be posted in a "conspicuous place." In this context, the word "conspicuous" plainly means "easy to notice." Since the term is clear as used, no further definition appears to be necessary.

3. Federal Hazard Communication Standard

A warning about the carcinogenicity or reproductive toxicity of a chemical which uses the methods set forth in the federal and state HCS is also deemed reasonable. This permits employers to utilize an established method of hazard communication as an alternative to creating new methods of warning.

As originally proposed, subsection (c)(1)(C) would have provided that a material safety data sheet (MSDS) which includes a statement concerning the carcinogenicity or reproductive toxicity of a chemical may be deemed to be a reasonable method of warning.

One commentator objected to reliance upon the MSDS, contending that it would be inadequate for purposes of the Act and should be used in only limited circumstances as a last resort, if at all. (C-54, p. 2.) Several commentators also urged varying degrees of reliance upon the federal Hazard Communication Standard (HCS) as a clear and reasonable warning. Two commentators recommended that the Agency find employers in compliance with the HCS in compliance with the Act as well. (C-19, p. 1; C-20, p. 3.) Several commentators recommended that warnings under the HCS be deemed both clear and reasonable. (C-5, p. 4; C-21, p. 3; C-29, p. 2; C-38, p. 3; C-52, p. 2; C-55, p. 2; T. p. 49:2-23.) One recommended that subsection (c)(1) refer to employee information and training under the HCS as a method which may be deemed reasonable. (Exh. 17, p. 3.) Another recommended that the regulation expressly provide that for those not subject to the

HCS compliance with HCS would satisfy the requirements of the Act. (Exh. 21, p. 16.)

The Agency concluded that compliance with the HCS could not be treated as compliance with the Act because, as expressed above, the HCS does not cover all employees even where it does apply to a particular industry. Although the Agency believes that the majority of exposures to employees not covered by the HCS would be exempt from the Act under Health and Safety Code section 25249.10 (c), because there is the potential of exposures not exempt from the Act, and because the Act prohibits exposing any individual without first providing a warning, it would be inaccurate to conclude that compliance with a warning scheme which excludes warnings to exposed individuals provides a clear and reasonable warning under the Act in every case.

The Agency further concluded that it would be inappropriate to deem warnings given under the HCS clear and reasonable in every case. The purpose of subsection (c)(1)(C) is simply to identify methods which may be deemed reasonable, not the clarity of the message communicated. Further, there is no message prescribed under the HCS. It would be difficult to deem clear a message which does not even exist.

The HCS does specify methods of providing information, and the Agency could perceive no reason why these methods, which are well-established as a part of business operations, could not be deemed reasonable where followed. The original proposal relied upon this concept in part by recognizing one of the HCS methods, the MSDS, as a reasonable means to transmit warnings. However, due to concerns over the adequacy of the MSDS alone, the Agency believes that other HCS methods, such as training and labels, should also be included in the "safe harbor." The availability of the HCS methods as a "safe harbor" also appears to address the concern that businesses not subject to HCS be able to use these methods.

Similarly, the Pesticide and Worker Safety regulations (C.C.R., tit. 3, § 6700, et seq.) provide for training and the posting of signs to warn employees. Again, these methods are well-established in the agricultural industry, and the Agency believes that providing a "safe harbor" where these methods are used in connection with a clear warning will encourage their use and further the purpose of the Act. Accordingly, these methods were included pursuant to the recommendation of two commentators. (Exh. 13, p. 4; C-25, p. 4.)

Due to the deletion of the reference to MSDS as a method, subsection (c)(4) was deleted. Several commentators recommended clarification whether the warnings under the HCS are deemed clear. (P-4, p.4; P-5; P-10, p. 10; P-18, p. 13; P-21, p. 9.) As indicated above, the HCS does not prescribe warnings. There is nothing which the Agency may deem reasonable. Therefore, warnings given under the methods of the HCS need to be clear, and the issue of their clarity is a question of fact.

Occupational Exposure "Safe Harbor" Warning Messages

The proposed regulation provides specific language for use on warning signs which will be deemed clear. For chemicals known to the state to cause cancer, the warning reads:

> WARNING: This area contains a chemical known to the State of California to cause cancer.

For chemicals known to the state to cause reproductive toxicity, the warning reads:

> WARNING: This area contains a chemical known to the State of California to cause birth defects or other reproductive harm.

As explained under the discussion of consumer products warnings, the use of the words "birth defects or other reproductive harm" is more appropriate than the term "reproductive toxicity", and is supported by the language of the Act.

One commentator recommended that the regulation set forth permissive, rather than mandatory, messages for signs. (Exh. 21, p. 16.) A similar recommendation was made regarding the "safe harbor" methods. As indicated in the response to that recommendation, the "safe harbor" provisions create generic warnings which are deemed to be clear and reasonable. This makes it necessary for the regulation specifically describe the warning methods and messages for which "safe harbor" is given. Use of the word "may" could imply that any method or message is reasonable. Obviously, that cannot be the case. Therefore, this recommendation was not adopted.

Two commentators objected that the regulation does not require identification of the source of the exposure. (Exh. 20, p. 10; C-54, p. 4.) However, unlike environmental exposures, it is anticipated that occupational exposures will occur within confined areas, and that the warning signs will be placed so that the employee will receive the warning prior to entering those areas. The source of the exposure should be implied from the placement of the signs, and so it appears unnecessary to specify the source in the warning. Further, such a requirement may make it more difficult to utilize signs, and to read and understand the warning message. Therefore, no amendment was made.

Subsection (d)

The purpose of subsection (d) is to provide a "safe harbor" where warnings for environmental exposures include the methods of transmission and the warning messages specified therein. Warnings which comply with these provisions are deemed to be clear and reasonable as required by the Act.

Normally, whether a warning is clear and reasonable will be a question of fact to be determined on a case-by-case basis. However, reasonable men can differ on what is clear, and what is reasonable. Even with the minimum requirements set forth in subsection (a), a business may not be certain that its warning, as a matter of fact, will protect it from liability. Since the Act imposes civil liability where a warning is found not to be clear and reasonable, the Agency has concluded that it is necessary to provide businesses with an opportunity to be certain that the warning which they provide is reasonable or clear, or both, and that providing general "safe harbor" warning methods and messages which are deemed sufficient without further proof is a reasonable means to accomplish this result.

As explained earlier, businesses are not required to give the "safe harbor" warnings. Subsection (a) specifically prevents the "safe harbor" provisions of subsections (b), (c) and (d) from being construed as the only clear and reasonable warnings available. Businesses may provide whatever warnings they choose provided that they comply with the minimum requirements set forth in subsection (a). The "safe harbor" is offered simply to provide the businesses choosing to use it with reasonable certainty that they will not be subjected to an enforcement action over the warning which they provide. It is not intended to be a warning straight-jacket.

The regulation sets forth several "safe harbor" methods, often with a corresponding "safe harbor" message. Where both a method and a message are provided, both the message and the method must be used in order for the warning to be deemed clear and reasonable. Where only a "safe harbor" method, but not a corresponding message, is provided, then the method is deemed reasonable, but the clarity of the message will be a question of fact.

Environmental Exposures Defined

Subsection (d) defines "environmental exposures" as those which may foreseeably occur as the result of contact with an environmental medium, including, but not limited to, ambient air, indoor air, drinking water, standing water, running water, soil, vegetation, or manmade or natural substances, either through inhalation, ingestion, skin contact or otherwise. Thus, if it is reasonably foreseeable that an environmental exposure may occur, to a particular person or group of persons, warning must be given as provided.

One commentator objected that environmental exposures are defined as those which "foreseeably" may occur." (Exh. 21, p. 21.) This commentator is apparently concerned that requiring exposures to be foreseeable detracts from the requirement that exposures be knowing and intentional before a warning is required. The Agency interprets the requirement that exposures be "knowing and intentional" to include exposures about which there is constructive knowledge. Use of the term "foreseeable" is

intended to define the limits of that constructive knowledge and of exposures for which businesses can reasonably be held responsible.

One commentator recommended that the regulation define what are "manmade or natural substances." (C-38, p. 3.) However, it does not appear desirable to do so. The phrase "natural or manmade substances" is used as an example to describe in part the universe of environmental media which can result in an environmental exposure. To define the term might serve to limit it. Further, distinctions between natural and manmade chemicals are made in other sections of the Agency's regulations implementing the Act. (See e.g., C.C.R., tit. 22, § 12501.) Defining the term in this provision might have an unintended impact on those other provisions or their interpretation.

One commentator recommended that the need for environmental warnings be based upon the frequency of exposure. (Exh. 13, p. 6.) In fact, this is already the case. Under other regulations adopted by the Agency, the reasonably anticipated rate of exposure must be taken into consideration to determine whether the exposure poses no significant risk. If, based upon the rate of exposure, the exposure poses no significant risk, then no warning is required. Therefore, it was not necessary to adopt this recommendation.

Exposures which do not fall within the meaning of the consumer products or occupational exposure definitions are treated as environmental exposures. Thus, an exposure to a person not in the course of his or her employment on the premises of the business causing it, such as a schoolchild visiting a factory, would require an environmental warning.

Environmental Exposure "Safe Harbor" Warning Methods

Subsection (d)(1) provides that the method employed to transmit environmental warnings must include the most appropriate of the specified alternative methods. Two commentators objected that the "most appropriate" of the alternatives must be used, with one recommending that "most appropriate method" be defined. (Exh. 19, p. 3; C-1, p. 2.)

This provision establishes a "safe harbor" for a broad category of exposures. Environmental exposures may occur on a small scale, or they may occur on a massive scale. They can result from the application of chemicals to a suburban residence, or from the operation of a chemical production or manufacturing facility.

No single warning methodology is appropriate in every type of environmental exposure, and the Agency, therefore, cannot point to the use of one method or another as reasonable in all circumstances. It is very possible that many environmental exposures could result from the acts of a single business. Air

emissions from a production facility could result in environmental exposures to plant visitors, immediate neighbors and even outlying areas. Discharges into groundwater could impact many foreseeable users of that water. Thus, a business may need to provide a variety of warnings to address the foreseeable environmental exposures which result from its acts.

Signs in the affected area may be appropriate where the exposure occurs on-site, or in surrounding neighborhoods, but may become less appropriate as the signs are removed from the source of the exposure. Mailed-warnings may be effective for off-site exposures, but the logistics of providing such warnings on a large scale may be prohibitive. Media warnings may be well-suited to warn large segments of the population, but not plant visitors.

The dividing line where one method of warning ceases to be appropriate and another becomes more suitable is not clear. In each case, it will require an exercise of judgment whether to provide one warning method or another, or several. Because of the variety of environmental exposure situations, the Agency does not believe that it can regulate where to draw the dividing line in every case. Accordingly, this regulation requires the exercise of judgment as to which method is most appropriate. The need for flexibility outweighs the problems created by any uncertainty which attends such an exercise of judgment. Where there is uncertainty, a business can always protect itself by providing several types of warnings for anticipated exposures.

One commentator recommended that the regulation set out an order of preference or priority, along with the conditions under which the methods should be used. (Exh. 20, p. 7.) The methods specified, however, are each intended to address different environmental exposure situations. An order of preference could only be established where several methods were applicable to the same situation. Further, as indicated above, prescribing the conditions under which the methods should be used involves the exercise of judgment. The Agency does not believe that it can regulate a dividing line for every situation. Accordingly, this recommendation was not adopted.

One commentator recommended the regulation provide that signs and warnings may be presented jointly by an industry association which shares an exposure. (C-38, p. 3.) Pursuant to subsection (a), such joint warnings may be used provided that they are clear and reasonable, so it appears unnecessary to adopt this recommendation. Further, the phrase "warnings presented jointly" does not describe any particular method, and could be construed to mean that any method jointly will always be deemed reasonable. Therefore, the Agency did not adopt this recommendation.

Two commentators recommended that the regulations specify that environmental warnings be accomplished by compliance with Health

and Safety Code section 25500, et seq. and the Superfund Amendments and Reauthorization Act of 1986. (C-14, p. 18; C-38, p. 3.) These provisions require the filing by businesses of reports with governmental agencies about hazardous materials released. There is no assurance that the governmental agencies will provide warnings to individuals foreseeably exposed. The Act prohibits businesses from exposing individuals "without first giving" clear and reasonable warning "to such individual." This does not appear to permit warnings to agencies other than the individuals exposed. Therefore, this recommendation was not adopted.

1. Signs

Health and Safety Code Section 25249.11 provides that the warning required by section 25249.6:

> . . . need not be provided separately to each exposed individual and may be provided by general methods such as . . . inclusion of notices in mailings to water customers, posting of notices, placing notices in public news media, and the like, provided that the warning accomplished is clear and reasonable.

Subsection (d)(1)(A) includes the posting of signs in the affected area as one of the methods which may be deemed reasonable. Warning signs have the advantage of continuous presence and, where posted in the immediate vicinity of the business operations causing the exposure, easy association with the source of the exposure. Even where posted off the business premises, signs could still appropriately provide warning information. However, as a practical matter, the greater the distance between the sign and the source of exposure, the greater the need that the sign contain additional information identifying the source. At some point the distance between the sign and the source may become so great as to make the use of signs unworkable, and other forms of warning may be more appropriate.

The term "affected area" is defined to mean the area in which an exposure to a chemical known to the state to cause cancer or reproductive toxicity is at a level that requires a warning. One commentator recommended that the term be further defined, and that the phrase "level that requires a warning" also be defined. (C-38, p. 3.) The Agency believes that no further definition is necessary. The Act plainly provides that no warning is required if the exposure poses no significant risk or would have no observable effect at 1000 times the level in question. Thus, if the level of a chemical exposure at a location meets these exemption tests, then the location is not within the affected area.

One commentator recommended that the regulation clarify whether the "level that requires a warning" includes naturally occurring chemicals. (C-21, p. 4.) The regulations provide no "naturally occurring" exception for environmental exposures. However, under

other regulations, a person is not responsible for a chemical in air to the extent that the person can show that the chemical was contained in ambient air received. This commentator's attention is directed to that provision.

As originally proposed, the regulation contained no provision governing the placement of signs to obtain the "safe harbor" protection. One commentator recommended that the regulation expressly permit signs on the business perimeter. (Exh. 21, p. 20.) The Agency adopted this suggestion in part by referring in the regulation to the posting requirement of section 6776 (e)(1) of title 3 of the California Code of Regulations. That section provides for the posting of entrances, and every 600 feet where a facility is unfenced and adjacent to a right-of-way. This should cover, but is not limited to, most agricultural operations, where the entire posted location presents a potential for exposure and the purpose of the posting is to keep people out of the field. Adopting the same approach may not be appropriate for fenced sites, such as industrial plants, where the exposure occurs at a discrete location inside the facility but it is intended that people will enter the premises. The Agency will consider additional "safe harbor" posting standards if necessary.

2. Mailed Notices

Subsection (b)(1)(B) includes mailed notices provided once in any three-month period as a method which may be deemed reasonable. Several commentators objected to quarterly warnings, preferring instead annual warning. (Exh. 1, p. 3; C-20, p. 3; C-24, p. 2; C-27, p. 4; C-39, p. 4.) However, for some other types of exposures, the "safe harbor" warning requirements call for the availability of warning information on a much more frequent basis. Less frequent warnings for some environmental exposures are accepted only due to the practical barriers.

The apparent purpose of any warning under the Act is to permit the persons exposed to make choices about the exposure. The "Argument in Favor of Proposition 65" stated:

> Proposition 65 also tells businesses: Don't expose us to any of these same chemicals without first giving us a clear warning. We each have a right to know, and to make our own choices about being exposed to these chemicals.

In order for individuals to know about environmental exposures, the Agency believes that warnings should be of sufficient frequency that individuals who move into an area between warnings receive information without undue delay. Also, lengthy periods of time between warnings may cause people to incorrectly believe that the exposure is past, or has been eliminated, when that is not the case. When balancing the need to warn against the practical difficulties of providing such warnings, quarterly warnings appear to the Agency to present the minimum frequency which can be considered reasonable. Therefore, the regulation continues to require that environmental "safe harbor" warnings be

given once in any three-month period.

3. Media Warnings

Subsection (d)(1)(C) includes public media announcements targeting the affected area and provided once in any three-month period as a method which may be deemed reasonable. Several commentators recommended that warnings by this method be required annually, rather than quarterly. (Exh. 19, p. 8; Exh. 21, p. 17; C-19, p. 2; C-20, p. 3; C-21, p. 4; C-29, p. 2; C-52, p. 3; C-55, p. 3; T. p. 50:1-3.) The reasons stated above for quarterly, rather than annual, mailed notices apply equally to media notices. In addition, it is unlikely that all individuals will be reached by the media selected, and less likely that the notice will be seen amid the other messages carried by the media. Not everyone subscribes to a newspaper, and fewer still read every item in each paper. To leave warning to the chance that individuals will notice an item in a newspaper on a single day each year appears to the Agency too tenuous to find reasonable. Therefore, it remains a question of fact whenever annual media warnings are used whether the method used is reasonable.

One commentator recommended the addition of a new safe harbor method for pesticide warnings based upon the Pesticide Information Safety Series bulletin where a person is likely to enter an area where exposure may occur. (C-25, p. 4.) The Agency anticipates that most exposures which are the result of persons entering an area treated by pesticides will be occupational exposures, and such exposures have been addressed in subsection (c). It is anticipated that environmental exposures will result from pesticide drift following application of the chemical, and that the people exposed will already be in the area where exposure may occur. The Agency believes that such exposures are more appropriately addressed by the methods already set forth in this subsection.

Subsection (d)(2) requires that "safe harbor" warnings for environmental exposures be provided in a conspicuous manner and under such conditions as to make it likely to be read, seen or heard and understood by an ordinary individual in the course of normal daily activity. This provision avoids the late night public service announcements designed to be seen or heard only by relatively few television viewers, and signs of unsuitably small dimensions. Further, it requires that the warning be reasonably associated with the location and source of the exposure.

One commentator recommended that mailed and media notices should clearly indicate the source of the exposure. (C-45, p. 5.) The Agency anticipates that, where such methods are used, the only way that the warning could be associated with the source would be through specific identification in the warning of the business providing it, and identification of the location causing the exposure. Therefore, no specific requirement appears necessary.

One commentator recommended that the term "reasonably associated"

be defined. (C-1, p. 2.) It does not appear, however, that such a definition could be provided other than by example. Such a definition may unduly limit the application of this term, or restrict the available means of providing such association. The Agency believes that an approach allowing maximum flexibility is desirable, and, therefore, has chosen to avoid further definition of this term.

Environmental Exposure "Safe Harbor" Warning Messages

The warning message for exposures to a chemical known to the state to cause cancer which will be deemed clear must read:

> WARNING: This area contains a chemical known to the State of California to cause cancer.

For exposures to a chemical known to the state to cause reproductive toxicity, the warning portion of any sign or notice must read:

> WARNING: This area contains a chemical known to the State of California to cause birth defects or other reproductive harm.

As explained under the discussion of consumer products warnings, the use of the words "birth defects or other reproductive harm" is more appropriate than the term "reproductive toxicity", and is supported by the language of the Act.

One commentator recommended that the required warning permit the inclusion of other information, such as the degree of risk presented by the exposure, that the toxicity of the chemical has been established by testing in lab animals only, or that the route of exposure of the tests differs from the route through which the individuals will be exposed. (C-38, p. 38.) Such information, however, could potentially confuse or mislead the intended recipients of the warning. For example, the reference to testing in lab animals could be construed to mean that there is no real danger to humans, when in fact the potency of the chemical is high but there simply is no available epidemiologic data. The reference to routes of exposure could be misconstrued to mean that there is no risk by the route of human exposure, when in fact the absence of such risk has yet to be established. Therefore, the Agency cannot provide that a clear warning will result where such information is provided without some further factual showing.

Subsection (a) permits the use of other warning language. If a business chooses to provide more information to the recipients of the warning, it may do so. Whether the resulting warning is clear will be a question of fact.

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

regulation is proposed, or would be as effective and less burdensome to affected private persons than the proposed regulation. The Agency has determined that no alternative considered would be more effective than, or as effective and less burdensome to affected private persons than, the adopted regulations.

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