FINAL
STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS, DIVISION 2, PART 2

CHAPTER 3. SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986

ARTICLE 5. EXTENT OF EXPOSURE

Section 12501. Exposures To Naturally Occurring Chemicals In Food

The Safe Drinking Water and Toxic Enforcement Act (Health & 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 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 the individual. (Health and Saf. Code, § 25249.6.) The Act creates a limited exemption from this warning requirement for "an exposure for which the person responsible can show that the exposure poses no significant risk [of cancer] and that the exposure will have no observable effect [of reproductive toxicity] assuming exposure at one thousand (1000) times the level in question." (Health & Saf. Code, § 25249.10, subd. (c).) The Act requires the Governor to publish and to periodically revise and republish a list of chemicals which are known to the state to cause cancer or reproductive toxicity. (Health & Saf. Code, § 25249.7.) The requirement of warning prior to exposure to a listed chemical becomes effective twelve months after it has been listed. (Health & Saf. Code, § 25249.10, subd. (b).) There are currently 279 chemicals on this list, almost all of which are subject to the warning requirement.

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.

Effective February 27, 1988, the Agency adopted emergency regulations to implement Health and Safety Code section 25249.6 and to interpret the terms "expose" and "exposure" as they are used in the Act. Pursuant to Government Code section 11346.1, these emergency regulations have been readopted on a number of occasions so as to remain in effect.

On June 10, 1988, a Notice of Proposed Rule Making for a newly proposed amended version of the regulations was issued pursuant to Government Code section 11346.4. (Register 88, No. 24-Z,

p. 2017.) These newly proposed regulations (hereinafter the "July 29 text") are the subject of this rule making. A public hearing on these regulations was held on July 29, 1988, at which substantial oral and written comments were submitted. On April 13, 1989, the Agency issued a notice of the post-hearing changes to the proposed regulations (hereinafter the "April 13 text"). The notice afforded interested parties the opportunity to provide to the Agency their comments on the proposed modifications to the July 29 text. The comment period closed on April 28, 1989. There were no amendments made to the regulations subsequent to the April 13 proposal.

This final statement of reasons sets forth the reasons for the final language adopted by the Agency for the regulations in Article 5, and responds to the objections and recommendations submitted regarding those regulations as originally proposed and modified. The Administrative Procedure Act (APA) requires that the final statement of reasons submitted with an adopted regulation contain a summary of each objection or recommendation made regarding the specific adoption, amendment, or repeal proposed, together with an explanation of how the proposed action has been changed to accommodate each objection or recommendation, or the reasons for making no change. (Gov. Code § 11346.7, subd. (b)(3).) It specifically provides that this requirement applies only to objections or recommendations specifically directed at the agency's proposed action or to the procedures followed by the agency in proposing or adopting the action.

Many parties included in their written or oral comments, observations about these regulations or other regulations which do not constitute an objection or recommendation directed at the proposed action or the procedures followed. Also, many parties offered their interpretation of these regulations or other regulations, sometimes in connection with their support of, or decision not to object to the regulations, which again does not constitute an objection or recommendation directed at the proposed action or the procedures followed. Accordingly, the Agency is not required under the APA to respond to such remarks in this final statement of reasons. Since the Agency is constrained by limitations upon its time and resources, and is not obligated by law to respond to such remarks, the Agency does not attempt any response to such remarks in this final statement of reasons. However, the absence of response to such remarks in this final statement of reasons should not be construed to mean that the Agency in any way concurs with them.

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

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

The rule making file submitted with the final regulations and this final statement of reasons is the complete rule making file for the regulations in Article 5. However, because regulations other than Article 5 were also the topic of the public hearing on July 29, 1988, the rule making file contains some material not relevant to Article 5. This final statement of reasons cites only the relevant material; responses to comments regarding regulations other than Article 5 have been or will be made in separate statements of reason.

The Agency has determined that the adoption of these regulations is necessary in order to implement the warning requirement of the Act in a reasonable manner, and to facilitate compliance with the Act by defining key terms and making them more specific and relevant to the regulated business activities. The regulations in Article 5 define specific conditions where exposure to a listed chemical will not be deemed an "exposure" for purposes of the warning requirement. Keeping in mind that the Act itself provides for an exemption for exposures which pose no significant risk, the Agency felt compelled to keep these exemptions fairly limited, in furtherance of the purposes of the Act.

Section 12501

Chemicals which are currently subject to the requirement of warning prior to exposure include several chemicals which are naturally occurring constituents of food. The Act does not differentiate between exposures to naturally occurring chemicals and exposures to chemicals added by man. However, due to the abundance of foods which in their natural unprocessed state inherently contain low levels of carcinogens or reproductive toxicants, warnings could appear on a large number of food products, and consequently, diminish the overall significance of food warnings.

This regulation provides that human consumption of food containing a listed chemical does not constitute an "exposure" within the meaning of the Act to the extent that it is shown that the chemical is naturally occurring. This exemption is derived from the distinction in state and federal food adulteration laws between naturally occurring substances in food and those which are added substances. (Health and Saf. Code, § 26520; 21 U.S.C. § 342(a).) The laws make it easier to prove adulteration where a deleterious substance was introduced into food by man, than where a substance was naturally occurring in the food. This distinction is limited to food, and has not been extended to drugs, cosmetics, or other consumer products. The rationale for this special treatment of food is the historical desire to preserve naturally occurring foods in the American food supply, despite the presence in those foods of small amounts of

potentially deleterious substances, as well as a recognition of the general safety of unprocessed foods as a matter of consumer experience. (U.S. v. Anderson Seafoods, Inc., 622 F.2d 157, 160 (1980); U.S. v. Coca-Cola, 241 U.S. 265, 282-83 (1916); 39 Fed.Reg. 42743 (Dec. 6, 1974); For these same reasons, it is reasonable and appropriate to implement the Act so that warnings are not required for naturally occurring chemicals in food.

At least seven commentators expressed support of this exemption, including an environmental advocacy group and numerous food industry groups. Only one commentator opposed this exemption, recommending deletion in full, on the grounds that it is illogical, unscientific, and contrary to the intent of the Act. (Exh. 1, pp. 1-2.) The Agency believes that this exemption is reasonable for the reasons set forth above. Absence of such an exemption could unnecessarily reduce the availability of certain foods or could lead to unnecessary warnings, which could distract the public from other important warnings on consumer products. Although this exemption is not based on controlled clinical studies, it does have some scientific underpinnings to the extent that consumer experience over time has demonstrated that naturally occurring unprocessed foods are generally safe to consume. Moreover, this exemption is consistent with the intent of Proposition 65 and the concerns expressed in the ballot arguments about preventing exposures from toxic chemicals "put" into the environment, which indicate that the Act was primarily directed at added chemicals. There is nothing in the language of the Act which specifically requires warnings for naturally occurring substances in food, and there is nothing in the summary, the Legislative Analyst analysis, or the ballot arguments which mentions such a requirement.

The majority of commentators urged extension of the exemption for naturally occurring chemicals beyond food, to include all consumer products, including non-prescription drugs, medical devices, and cosmetics. (Exh. 2, pp.2-4; Exh. 7, pp. 18-19; Exh. 8, p. 7; C-8, p. 1; C-18, p. 6; C-36, pp. 2-3; C-44, p. 5; PH-3, p. 1; PH-5, pp. 1-2; PH-9, pp.2-3; PH-11, p.2.) They argued that there is no sound basis for differentiating between naturally occurring chemicals in food and those in non-food products. For the same reason, many of the same commentators objected to the deletion of the exemption in the emergency regulation section 12505, subdivision (b) for chemicals from "natural sources" in any consumer product. The Agency believes that it is reasonable to limit the exemption described in section 12501 to naturally occurring chemicals in food. This distinction is not without precedent. As discussed above, state and federal food adulteration laws dating from the turn of the century have regulated added substances in food more stringently than naturally occurring substances, a distinction which has not been applied to any other consumer product, including those regulated by the federal Food and Drug Administration (FDA). One of the purposes of the Act is to inform the consumer about the presence

of toxic chemicals and to facilitate the ability of the consumer to choose among exposures. Food is a basic daily necessity of life on a par with the water that we drink and the air that we breathe. For public health reasons, it is important to maintain an abundant supply of nutritious naturally occurring foods. Warnings for naturally occurring chemicals in food would not significantly enlighten the consumer about his or her options, and are more likely to cause confusion for the consumer who would be unable to differentiate between risks inherent in a food and those from added chemicals. The reference to chemicals from "natural sources" in the emergency regulation section 12505, while somewhat ambiguous, was never intended to create an unqualified exemption for all naturally occurring chemicals. This ambiguous term has been eliminated from the regulations.

Several comments pointed out that this exemption should be extended to non-foods because low-levels of naturally occurring chemicals are present in almost all consumer products, and that it is extremely difficult, if not impossible, to remove them from the product. (Exh. 2, p. 2-4; C-18, p. 6; C-36, pp. 2-3; PH-3, p. 1.) This situation is adequately addressed in section 12502 which provides an exemption for chemicals in drinking water and in section 12709 which specifies levels of no significant risk for ubiquitous trace elements, and an additional exemption is not needed.

Another comment suggested an exemption for naturally occurring chemicals in any product regulated by the FDA because the safety of these products is assured by existing law. (Exh. 2, pp. 2-4; PH-5, pp. 1-2.) This concern has been addressed in section 12713 which adopts federal and state standards for food, drugs, cosmetics, and medical devices as interim standards for determination of no significant risk for these products.

There was a recommendation to amend certain references to "food" and "naturally occurring chemicals" to refer respectively to "a food" and "a naturally occurring chemical" because exposure is to a specific listed chemical in a specific food and not to food and chemicals generally. (Exh. 7, pp. 10-11.) These references in section 12501 have been changed pursuant to this suggestion.

Another suggestion was made to put the term "exposure" in section 12501, subdivision (a) within quotation marks and to add "within the meaning of section 25249.6" in order to emphasize the statutory term and to make the language more consistent with subdivision (b). The regulation puts the term "exposure" in quotes, and appends the phrase "for purposes of Health and Safety Code section 25249.6" because the term "exposure" does not specifically appear in section 25249.6. The phrase "for purposes of" is sufficiently clear to communicate that the term "exposure" refers to the prohibition set forth in Health and Safety Code section 25249.6. Although they are not identical, the effect of this phrase is intended to be consistent with that of subdivision (b).

One comment urged deletion of the phrase "the person responsible for the contact can show that" from the first sentence of subdivision (a) for the reason that it is improper to allocate the burden of proof in a regulation. (Exh. 7, p. 7.) This change was not adopted because the regulation does not reallocate the burden of proof set forth in the Act. The statute clearly places the burden of showing that an exposure falls within an exemption on the person responsible for the exposure. (See Health and Saf. Code, § 25249.10, subd. (c).) Deletion of this phrase would arguably shift the burden of proof from the person responsible for the exposure to the plaintiff. Requiring the plaintiff to prove that a defendant does not qualify for any of the exemptions is clearly contrary to the intent of the Act.

Subsection (a)(1) defines the term "naturally occurring" for the purpose of the exemption. This definition is derived in part from a federal regulation which defines a "natural occurring substance" as one which is an "inherent natural constituent of a food, and is not the result of environmental, agricultural, industrial, or other contamination". (21 C.F.R. § 109.3.) Several federal cases have held that "added substances" are those toxins which were added through human activity, including past environmental pollution. (Anderson Seafoods, supra, [mercury in swordfish]; Seabrook International Foods v. Harris, 501 F.Supp. 1086 (1980) [salmonella in shrimp]; Continental Seafood v. Schweiker, 674 F.2d 38 (1982) [salmonella in shrimp].) One comment requested that the regulation include the full federal definition of "naturally occurring substance" in order to maintain a uniform standard and to have legal precedent to draw upon. (C-26.) Another comment recommended against the use of the terms "natural" and "naturally occurring" because the federal definition is ambiguous and the case law has been inconsistent. (C-2, pp. 6-8.) The terminology of the "naturally occurring substance" definition was borrowed from existing federal and state law so that the general concept of and the rationale for the exemption would be somewhat familiar to the food industry and other interested persons. Certain aspects of the definition in the federal regulation are not entirely consistent with some of the cases. Rather than using the federal definition in its entirety, the language of subdivision (a) was carefully selected and tailored to clearly describe the scope of the exemption so as to implement the Act in a reasonable manner.

One comment suggested that "natural" be deleted before "absorption or accumulation" in subdivision (a)(1) because it is impossible to determine whether a chemical has been naturally absorbed. (C-2, p. 5.) This change has been made to the regulation.

Another comment requested that in the phrase "naturally present in the environment," the word "naturally" be replaced with "unavoidably," because "naturally" is ambiguous. (C-2, pp.4-6.) The meaning of "natural" and "naturally" is sufficiently clear in the context of subdivision (a), which provides specific examples

of naturally occurring chemicals. These terms have commonly understood meanings: the dictionary definition of "natural" is "present in or produced by nature; not artificial or man-made." (Amer. Heritage Dict. (2d college ed. 1985) p. 832.) "Unavoidably" is clearly inconsistent with this meaning and with the intent of section 12501. This comment further argued that unavoidable chemicals should be considered naturally occurring, where they are not the result of human activity, because most food cannot be produced without these chemicals. This reasoning is illogical because unavoidable chemicals are not necessarily natural, and man-made chemicals are certainly the result of human activity, whether they are avoidable or not.

Another comment recommended that a listed chemical be considered naturally occurring pursuant to subdivision (a)(1), "if based on past experience or scientifically valid data, it is documented that the chemical is a natural constituent of a food." This amendment, it is argued, would permit food producers to assume that the chemicals in their products are naturally occurring, unless the food producer has reasonable notice to the contrary. (C-2, pp. 5-6.) This additional language is unnecessary because the regulation allows businesses to show that a chemical is naturally occurring by introduction of relevant evidence, including past experience and scientifically valid data, but it is not reasonable to assume that the entire amount of a chemical in a food is naturally occurring, simply because the chemical has been scientifically documented to be a natural constituent of that food.

Given the difficulty of establishing the exact amount of "naturally occurring" chemical in a particular food, subdivision (a)(2) allows the level of chemical in food to be established using the natural background level of chemical in the area in which the food was raised, grown, or obtained, based on relevant and reliable local or regional data. One comment pointed out that levels of certain natural contaminants vary from year to year, from region to region, or from grower to grower, and that the regulations should take into account this variability. (C-32, p. 2-3.) The Agency has made every effort to make its regulations reasonable and flexible. In this case, the variable nature of a chemical contaminant may be demonstrated with relevant local or regional data as provided in the regulation.

One comment recommended that the regulation expressly provide that the naturally occurring level may be established "by reference to a scientifically valid determination" or "by use of scientifically valid methods of analysis which are generally recognized by qualified experts." It was argued that if specific levels are scientifically established for a particular food, such as those in the Food Chemicals Codex, it should be not necessary to show background levels of the chemical in the environment, because testing as a normal part of production would be redundant and costly. Thus, food producers would not be required to independently establish the naturally occurring level of a listed

chemical, unless they have "reason to believe" that the level exceeds the naturally occurring. (C-2, pp. 9-12.) The Food Chemicals Codex is a reference that sets forth the generally accepted industry standards of identity and purity for chemical food additives. These standards are not necessarily indicative of the natural background level of a chemical in the environment. The regulation implicitly allows businesses to present relevant evidence of a scientific nature to demonstrate that a chemical is naturally occurring, but it would not be reasonable to assume that a chemical is naturally occurring just because it meets generally accepted standards, such as the Food Chemicals Codex.

Another comment suggested that the regulation be amended to specify that background levels may be used "when practical," because it is often difficult to determine the background level of a food for a commodity pooled from various sources. (C-44, p.2.) This amendment is not necessary and could cause confusion because businesses are not required to use background levels; the language "may" in subdivision (a)(2) is permissive, not mandatory.

One comment suggested amending the regulation to provide that where determination of background level is not feasible, "exposure" is deemed not to occur if good manufacturing practices (GMPs) have been used to reduce the presence of the listed chemical. (C-15, p. 7.) The use of GMPs does not necessarily rid a food of all added chemicals, leaving behind only those chemicals which are naturally occurring. This change was not adopted in the regulation.

Since naturally occurring chemicals do not give rise to an "exposure", subdivision (a)(3) clarifies that where a food contains a chemical which is part natural and part added, only that portion of the chemical which was added as a result of known human activity can result in an "exposure." A comment suggested adding "such" before "human activity" in the second sentence of subdivision (a)(3) to clarify that the term refers back to "any known human activity" as used in the preceding sentence. (Exh. 7, p. 16-17.) In order to clarify any possible ambiguity about the second sentence relating back to the first sentence, the word "known" was added before "human activity" in the second sentence.

Another comment recommended that "'exposure' can only occur" in the second sentence be amended to "'exposure' only occurs" in order to be more authoritative. A similar comment was also made for subdivision (b). (C-16, pp. 1-2.) This change was not adopted because the phrase "can only occur" more accurately describes the nature of this exemption in relation to the other exemptions in Article 5. For example, even if a listed chemical does not qualify for the exemption under section 12501, it may meet the standards for an exemption as a chemical in drinking water under section 12502.

One comment recommended that compliance with GMPs be the sole measure of whether a listed chemical is present in a food as a result of any known human activity. (C-15, p. 8.) A similar comment urged that where it is impractical to determine a background level for a listed chemical, the chemical should be deemed "naturally occurring" if the chemical was not intentionally added to the food and the food producer complied with GMPs. (C-44, p. 3.) These proposals were not adopted because the scope of chemicals which could be present in food as the result of human activity is much broader than intentionally added chemicals or chemicals which could have been avoided by compliance with GMPs. However, the regulation did incorporate compliance with GMPs as a standard for naturally occurring chemical contaminants in subdivision (a)(4), discussed below.

Several comments requested that "human activity" exclude "customary methods of food processing" because they are such an integral part of the food supply system that they are not discretionary human activities. (Exh. 6, p. 5; C-44, p. 3.) Since chemicals in food which are caused by cooking, fermentation, or any other processing are added to the food by human agency, they are the result of known human activity, and thus cannot be considered naturally occurring. Another comment suggested several amendments to subdivisions (a)(1) and (a)(3) which would define "naturally occurring chemical" to include chemicals in a food which develop as a result of "natural processes" from natural sources in the food or the environment, and would provide that a chemical is naturally occurring to the extent that the chemical "is not added or is otherwise not an intended result of any known human activity." (C-11, pp. 1-2.) This change was not adopted because chemical changes in food initiated by a known human activity are the "result of known human activity" for purposes of subdivision (a)(3), even if these changes are not intended and even if they involve "natural processes."

One comment recommended an amendment to clarify that addition of a food containing a naturally occurring chemical to another food does not constitute an "exposure." (C-2, P. 13.) This amendment is not necessary because it is evident from the regulation as a whole that once a chemical is exempt as a naturally occurring chemical in food, the exempt status of that particular chemical will "carry over" to any other food to which it is added. Subdivision (b) provides that this exempt status will even "carry over" to other consumer products.

The definition of "human activity" excludes ordinary cultivation practices, such as planting, plowing, and irrigation, which are basic to crop production and are not likely to cause an increased level of a listed chemical in food. However, under this definition, a chemical in food is not naturally occurring to the extent that it results from the addition of fertilizers, pesticides, nematocides, or other chemicals to the irrigation water applied to soil or crops (i.e., chemigation). One comment

requested that this exception to "human activity" be extended to include mechanical harvesting practices because injury to the food caused by mechanical harvesting may increase the risk of chemical contamination. (C-15, pp. 4, 8.) Another comment suggested expanding the exception to include chemicals which are "emitted from everyday past or present activity" (e.g., harvest machinery, and auto exhaust and other by-products). These changes were not adopted because this language was intended to be a limited exception for basic cultivation practices which are not expected to increase the amount of chemicals in food.

Subdivision (a)(4) provides that even where a chemical contaminant in food may be naturally occurring, any increase in the amount of chemical which was avoidable by good agricultural or good manufacturing practices is not naturally occurring. It specifically requires the use of quality control measures that reduce natural contaminants to the lowest level currently feasible. Some toxic chemicals (such as aflatoxin, which is produced by the natural growth of fungi on food) are naturally occurring substances in that the presence of the chemical may not be the result of human activity. However, the level of these toxins will increase with prolonged storage in damp, unventilated areas, a condition which could be avoided by good storage practices. Contaminated food items may also be eliminated from distribution by careful inspection and sorting. By encouraging food producers to use good agricultural and good manufacturing practices and to take all actions necessary to keep natural contaminant levels down to the lowest level feasible, this regulation accommodates the recommendation that the standard be achievable and realistic in light of currently available technology. (C-32.)

Subdivision (a)(4) of the July 29 text provided that a natural contaminant in food is naturally occurring only to the extent that it was not avoidable by GMPs "or other intervening measures." There were numerous objections to this language on the grounds that it was too vague, confusing, inappropriate, unnecessary, and redundant of GMPs. It was also criticized as being devoid of any known meaning, content, or point of reference, and thus impossible to comply with. (Exh. 3, pp. 3-4; Exh. 6, p. 6; Exh. 7, p. 17; C-15, pp. 3, 8, 9; C-44, p. 4.) One of these commentators also recommended that this standard should be based solely on the use of GMPs, which is a generally accepted, widely recognized term. (Exh. 3, pp. 3-4.) This troublesome phrase was deleted in the April 13 text. In its stead, a sentence was added at the end of subdivision (a)(4) to reinforce the responsibility of the food producer to utilize state-of-the-art quality control measures to reduce contaminants to the lowest level feasible. This language, in a slightly modified form, was taken directly from the current federal good manufacturing practices regulation for natural defects in food. (21 C.F.R. § 110.110, subdivision (c).) This requirement has been in existence for a substantial period of time, and should be quite familiar to the food industry. After these changes were

made to the proposed regulation, a post-hearing comment urged the retention of the phrase "or other intervening measures" because it emphasizes that "good . . . practices" refer to actions that can be taken to intervene between a food and a potential source of chemical contamination. (PH-4, p. 2.) This language is not needed, because the added sentence more clearly communicates that quality control measures should be taken to reduce and prevent contamination of food. In view of the considerable confusion and criticism which this phrase elicited, it has been removed from the final regulation.

A post-hearing comment from a cosmetic industry group recommended the deletion of the added sentence because it employs a "qualitative concept of feasibility to define the quantitative value of the lowest level of a natural chemical contaminant." That comment observed that uncertainty would result because views may vary on what is feasible. (PH-2.) On the other hand, many comments, representing both industry and consumer concerns, praised the same sentence as useful and adding certainty and clarity to the process. (PH-4, p. 2; PH-6, p. 2; PH-11, p. 2.) They noted that the concepts of "quality control measures" and "lowest level currently feasible" are well understood by the affected industries. In light of the generally favorable comments, this sentence has been retained in the regulation.

One comment recommended that subdivision (a)(4) be amended to require only utilization of "measures consistent with good agricultural, good manufacturing, or good storage and transportation practices to minimize the occurrence of chemical contaminants," because quality control measures by themselves are incapable of reducing the levels of natural chemical contaminants. (PH-3, p. 1.) This amendment is not needed because the term "quality control measures" refers to all actions necessary to prevent food from being adulterated, including appropriate storage and transportation practices. (See 21 C.F.R. § 110.3, subd. (g).) The level of natural chemical contaminants in food is certainly capable of being reduced, as evidenced by several of the comments received during this rule-making describing in detail the quality control operations for various agricultural commodities. The FDA apparently thought that this proviso was reasonable, because the federal good manufacturing practices regulation for natural defects in food requires the use of quality control operations to reduce the defects to the lowest level currently feasible. (21 C.F.R. § 110.110, subd. (c).)

One post-hearing comment suggested that "or" be changed to "and/or" in the last sentence of subdivision (a)(4) in order to clarify that quality control measures are to be utilized at all points in the production/distribution chain. (PH-4, p. 2.) This change is not necessary because it is already clear that the obligation applies to all parties named in this subdivision.

The term "good agricultural . . practices" was added to the first sentence of subdivision (a)(4) to clarify that the need to

use "good . . . practices" to avoid contamination applies to agriculture as well as to manufacturing. A post-hearing comment expressed concern that the meaning of this term was not indicated, and that virtually all agricultural practices could arguably fall within this class. The same commentator pointed out that the following sentence on "quality control measures" acts as a partial gloss on the meaning of "good agricultural practices." But to reduce potential ambiguity, it was suggested that the language be amended to cross-reference the definition of "human activity" in subdivision (a)(3). (PH-4, p. 2.) This amendment is not necessary, because it is reasonably clear that subdivision (a)(4) applies only to naturally occurring chemical contaminants in food, as determined under the criteria described in the preceding paragraphs. There is no question that section 12501 is intended to be read as whole in its delineation of the scope of the exemption.

Subsection (b) provides that where human consumption of a naturally occurring chemical in a food would not cause an "exposure" pursuant to subsection (a), the same naturally occurring chemical will similarly not give rise to an "exposure" if the food is subsequently used in the production or processing of a consumer product other than food. In general, chemicals in food are more readily absorbed into the body by way of ingestion than by dermal contact or other routes. Therefore, it is reasonable to provide that where there is not an "exposure" to a naturally occurring chemical in food by the route of ingestion, there is not an "exposure" to the same chemical when the food is used as a component of a consumer product other than food. One commentator recommended deletion of the phrase "otherwise responsible for an exposure," or deletion of "otherwise" and substitution of "contact" for "exposure." This phrase was felt to be misleading and potentially confusing because there is no "exposure" within the meaning of the Act for naturally occurring chemicals. (Exh. 7, pp. 20-21; PH-1, p. 2.) For purposes of clarity, it was necessary to describe the "person" who is the subject of this sentence, so the language "person responsible for an exposure" was taken from section 25249.10, subdivision (c) of the Act, and "otherwise" was added to indicate that the regulation provides for an exemption. When read with the Act and the other regulations, this phrase is not misleading or confusing. The regulations in Article 4 have similar language relating to persons "otherwise responsible for a discharge or a release."

One comment requested the deletion of "the person can show that" in the first sentence of subdivision (b), because the burden of proof should not be allocated by regulation. (Exh. 7, p. 20.) This comment is similar to one made for subdivision (a), and the Agency's decision not to adopt the change and rationale therefor are the same. (See discussion <u>ante</u> at p. 6.)

Another comment contended that the phrase "can only" as used in the regulation may be used to argue that persons responsible for

an exposure are relieved of the burden on specific subissues, and recommended that the last sentence of subdivision (b) be amended to read: ". . . 'exposure' does not occur as to that portion of the chemical which is naturally occurring in food." (PH-4, p. 2.) This concern is unfounded because the first sentence of subdivision (a) clearly states that this exemption is available only "to the extent that the person responsible for the contact can show that" a particular chemical meets all of the criteria for a naturally occurring chemical in a food. The amendment was not adopted because it is not necessary and would not improve the clarity of the regulation. Another comment recommended that "can only occur" be changed to "only occurs" in order to be more authoritative. (C-16, pp. 1-2.) This comment is similar to one made for subdivision (a)(3), and the Agency's decision not the adopt the change and rationale therefor are the same. (See discussion ante at p. 8.)

Although the emergency language of section 12501 is to be repealed, the substance of that regulation is carried over with little change into the final regulations. Subsection (a) of the emergency regulation, governing the use of drinking water in food, has been merged into section 12502 (§ 12503(a) in the July 29 text), a similar provision relating to any exposure "which involves the use of drinking water, including the use of drinking water in food or any other consumer product." By eliminating unnecessary and repetitive verbiage, clarity is enhanced and the regulation is allowed to focus on exposures to naturally occurring chemicals in food.

Furthermore, for the purpose of determining whether a chemical in food is naturally occurring or added by human activity, the reference in emergency regulation section 12501, subdivision (b)(3) to human activity "other than ordinary cultivation practices" is overbroad in that it may be interpreted to exempt the application of fertilizers or other agricultural chemicals, contrary to the intent of the Agency. This ambiguity is corrected in section 12501(a)(3) by specifically listing those agricultural practices which fall outside the scope of "human activity."

Section 12502. Exposure to a Listed Chemical in Drinking Water

In the July 29 text, this regulation which relates to exposure to a listed chemical in drinking water was a subdivision of section 12503, then titled "Environmental Exposures," which also related to exposures to air and to water. In the April 13 text, that general regulation was divided into three separate regulations for purposes of clarity. Section 12502 is the first of these three regulations.

Entities in the operation of a public water system are exempt from the Act pursuant to Health and Safety Code section 25249.11, subdivision (b), and thus are not required to provide warnings

for exposure to chemicals in drinking water which they deliver to their customers. Since most businesses have little control over the drinking water which comes to them from a public water system, it is reasonable that businesses which have little choice but to use this drinking water should not be required to provide warnings for chemicals which were in the drinking water. Section 12502 provides an exemption from the warning requirement for chemicals contained in drinking water which was received from a public water system. For consistency, the exemption also applies to the use of drinking water from commercial drinking water suppliers, which are required to meet the same or more stringent water quality standards for chemicals than public water systems are expected to meet. (Health & Saf. Code, §§ 26592, 26593.6, 26594; 21 C.F.R. §§ 103.35, 129.35.) Where the source of a listed chemical is partly from drinking water and partly from other sources, this exemption applies only to that portion of the chemical which originated from drinking water as specified in subsection (a), and not to the portion from any other sources.

One comment recommended that the exemption for drinking water from public water systems be extended to all plumbing products, provided that the water provided meets the standards applicable to all public water systems. (C-40, pp. 10-11.) Such an extension would not be appropriate because the extension is based on the Act's exemption for public water systems and plumbing is not considered as part of a public water system.

One comment suggested that the title of this regulation as set forth in the July 29 text be changed from "Environmental Exposures" to "Exposures to a Chemical in Water and Air," because the subject of the regulation was not limited to environmental exposures, but also included consumer products. (Exh. 7, p. 23.) The general term "environmental exposure" was originally selected for the title because it was broad enough to encompass all types of exposures from the human environment, including consumer products. However, when that general regulation was divided into three separate regulations, the titles were also rewritten in a manner which is in accord with the substance of this comment.

The same commentator urged the deletion of the phrase "otherwise responsible for an exposure" in the first sentence of subdivision (a) in order to avoid ambiguity and the legally incorrect implication that a "person otherwise responsible for an exposure" is still subject to the Act. (Exh. 7, p. 24; PH-1, pp. 2-3.) This comment is similar to one made for section 12501, subdivision (b), and the Agency's decision not to adopt the change and rationale therefor are the same. (See discussion <u>ante</u> at p. 12.) It was also recommended that for clarity, the phrases "which involves the use of" and "the use of" be deleted before "drinking water." (Exh. 7, p. 24.) This language was chosen to indicate that the exemption was not limited to exposures to drinking water per se, but also includes exposures to consumer products or any other types of exposure which involve the use of drinking water. This change was not adopted because the existing

wording of the regulation more clearly describes the scope of the exemption. It was also recommended that the phrase "the person can show that" be deleted because the burden of proof should not be allocated in a regulation. (Exh. 7, p. 24.) This comment is similar to ones made for section 12501, subdivisions (a) and (b), and the Agency's decision not to adopt the change and rationale therefor are the same. (See discussion ante at p. 6.)

Subdivision (a)(3) extends the exemption to sources of drinking water, other than a public water system or a commercial drinking water supplier, for chemicals which are in the drinking water as a result of treatment for compliance with primary drinking water standards, provided that the water is in compliance with all applicable primary drinking water standards for all listed chemicals. This provision was included in the regulation in recognition of the public policy that all drinking water must be made to comply with primary drinking water standards for the protection of public health, and the fact that chlorination of drinking water, the most common method of disinfection, results in the presence of listed chemicals. (See C-43, p. 1-2.)

Several changes were made in the April 13 text to improve the clarity of subdivision (a)(3). In the first line, "state and federal" primary drinking water standards was changed to "applicable" primary drinking water standards, in order to clarify that the drinking water is expected to comply with the requirements at its point of origin. Many products sold in California originate outside of the State. Although the drinking water used cannot always be expected to meet the more stringent California standards, it is reasonable that all drinking water should meet the applicable standards at the point of origin. This concept and reference should be familiar to and understood by the affected industries. For example, a good manufacturing practices regulation for bottled drinking water requires that the product water supply be in conformance with "the applicable laws and regulations of the government agency or agencies having jurisdiction." (Emphasis added.) (21 C.F.R. § 129.35, subd. (a)(1).)

One commentator recommended that "primary drinking water standards" in subdivision (a)(3) be amended to "maximum contaminant levels" or "primary drinking water requirements" to clarify that it refers to legal requirements promulgated by regulation. (Exh. 7, p. 25; PH-1, p. 3.) This change is not necessary because the drinking water statutes define "primary drinking water standards" to mean standards which specify maximum levels of contaminants which may have an adverse effect on the health of persons. (Health & Saf. Code, § 4010.1, subd. (b)(1).) Under State law, these primary drinking water standards are adopted by regulation as maximum contaminant levels (MCLs) in the California Code of Regulations, title 22, sections 64421 et seq. There is little danger that this would be interpreted to include action levels or maximum contaminant level "goals," as feared by the commentator. The same commentator urged that the phrase "all

applicable primary drinking water standards" be made to expressly reference the National Primary Drinking Water Regulations and the California Primary Drinking Water Standards. (PH-1, p. 3.) This change has not been adopted because as explained above, "applicable primary drinking water standards" refers not to federal or California requirements, but to the applicable requirements at the drinking water's point of origin.

Another comment objected that the exemption for drinking water sources other than a public water system or a commercial drinking water supplier, is conditioned on the drinking water meeting the maximum contaminant levels for all listed chemicals. This was felt to be unfair because many public water systems are not in compliance with all MCLs, and there is no reason for other drinking water sources to be subjected to a stricter standard. (PH-7, p.2.) The fact that some public water systems are not in compliance with all primary drinking water standards is not relevant because public water systems are exempt from the requirements of the Act. The exemption of subdivision (a)(1) is for the benefit of those businesses who subsequently use water from a public water system. The Act's concern for the safety of drinking water is obvious from its title, "Safe Drinking Water and Toxic Enforcement Act of 1986." Since subdivision (a)(3) provides an exemption for chemicals caused by treatment to comply with primary drinking water standards, it is reasonable to require, for the protection of public health, that the drinking water meet all relevant MCLs. In the July 29 text, the exemption was conditioned on compliance with all primary drinking water standards. In the April 13 text, this was changed to primary drinking water standards "for all listed chemicals" in order to limit the provision to chemicals which are subject to the Act.

One comment suggested that for clarity, the phrase "in compliance with" be changed to "meets or exceeds" because some water which is very pure may "exceed" standards. (Exh. 2, pp. 8-9.) This change was not adopted because the existing language is clearer. The suggested language is ambiguous and confusing because usually, when water is said to "exceed" primary drinking water standards, this means that the water contains contaminants in excess of the MCLs. On the other hand, drinking water which is "in compliance" with primary drinking water standards refers to water in which contaminants are at or below the MCLs.

Two comments correctly observed that subdivision (a)(3) only exempts chemicals added to drinking water to achieve compliance with primary drinking water standards, and does not exempt naturally occurring chemicals in drinking water. They suggested it be amended to provide an exemption "whether the chemical is naturally occurring or" the result of treatment. (Exh. 6, p. 6; Exh. 7, pp. 25-26.) Such an amendment is inappropriate because many of the drinking water maximum contaminant levels apply to naturally occurring contaminants, and an exemption for naturally occurring chemicals in drinking water would conflict with the public policy of ensuring the purity and potability of our

drinking water. To clear up any possible confusion about the scope of subdivision (a)(3), the term "chemical" was changed to "chemical in question."

Another comment recommended that the exemption in section 12502 be extended to include process water which is used in non-food product manufacturing, because trace amounts of listed chemicals result as an unavoidable consequence of the use of process water which does not meet drinking water standards. (C-44, p. 5.) This extension is inappropriate, because if these manufacturers elect to use water which does not meet drinking water standards, they have the obligation to monitor the listed chemicals that result from that use. If in fact the residue is a trace amount, a warning is not likely to be required if it poses no significant risk. (See discussion post at p. 24.)

A comment recommended that "can only occur" in the last sentence of subdivision (a) be changed to "only occurs" in order to be more authoritative. (C-16, pp. 1-2.) This comment is similar to one made for section 12501, subdivision (a)(3), and the Agency's decision not the adopt the change and rationale therefor are the same. (See discussion ante at p. 8.) Another comment contended that the phrase "can only" as used in the regulation may be used to argue that persons responsible for an exposure are relieved of the burden on specific subissues, and recommended that the last sentence of subdivision (a) be amended to read: ". . . 'exposure' does not occur as to that portion of the listed chemical from drinking water." (PH-4, p. 2.) This comment is similar to one made for section 12501, subdivision (a)(3), and the Agency's decision not the adopt the change and rationale therefor are the same. (See discussion ante at p. 13.)

Subdivision (b) describes the methods for measuring the amount of a listed chemical in drinking water for the purpose of determining the extent of the exemption, where the chemical in question originates in part from drinking water and in part from other sources. The preferred method of measurement is by sampling of the drinking water at the point of delivery and by testing using specified methods of analysis. However, if sampling and testing are impractical, the measurement shall be based on the most recent sample of the drinking water taken by the public water system or the commercial drinking water supplier, or shall be calculated at 5 percent of the MCL set forth in the primary drinking water standard for the listed chemical. Subdivision (b) was added to section 12502 in the April 13 text in response to numerous objections to the proposed repeal of emergency regulation section 12505, subdivision (a), which reads as follows:

> Where a product is washed, prepared or processed with drinking water, a chemical may be established to be present in the product as a result of the water by reliable scientific evidence and shall be deemed to be

present as a result of that water to the extent that the amount does not exceed the primary drinking water standard.

This particular emergency regulation was proposed for repeal, because it arguably creates an irrebuttable presumption that a listed chemical in any product processed with drinking water is present at the MCL as the result of the use of that water, which is not the intent of the Agency. Products which are simply "washed, prepared or processed with drinking water" may or may not necessarily incorporate all of the chemicals in that water into the finished product. Even for those products that do, it is not reasonable to assume that the chemicals are always present in the drinking water at the maximum contaminant level, when most drinking water supplies contain chemicals at levels far below the maximum amount allowed.

Several commentators strenuously urged the retention of this irrebuttable presumption. It was contended that without this "rule of thumb," businesses would be forced to perform impractical and expensive analyses of drinking water at the time of use in the manufacturing process and to calculate differing levels of chemical. (Exh. 6, p. 6; Exh. 7, p. 28; C-38, p. 5.) One comment recommended that any level of chemical at or below the chemical level in drinking water be deemed to be from drinking water, because of proof problems. (Exh. 8, p. 7.) In response to these comments, the Agency reconsidered its position and concluded that a modified "rule of thumb" presumption could be appropriately included in the final regulation as set forth in section 12502, subdivision (b). This approach, which was introduced in the April 13 text, is both reasonable and more closely akin to reality than section 12505, subdivision (a). The amount of a listed chemical from drinking water is based on test results of the water actually used, but if this is impractical, the amount can be based on the test results of the most recent sample of the water taken by the public water system or commercial drinking water supplier or be set at a small percentage of the MCL, if one exists. Public water systems and commercial suppliers of drinking water are required by law to monitor and test the levels of certain chemicals in their water at regular intervals, and the resulting information is readily available to the public from these sources or from the regulatory agency. (See Health and Saf. Code, § 4028; Cal. Code Regs., tit. 22, § 64463; 40 C.F.R. §§ 141.31, 141.32.)

Several comments objected that the addition of subdivision (b) is a substantial change to the regulation which is not sufficiently related to the original proposed text, and that therefore, full APA notice and comment procedure is required prior to adoption. (PH-8, p. 1-2; PH-10, p. 1-2.) Government Code section 11346.8, subdivision (c) permits substantial changes from the original proposed text where the change is sufficiently related to the original text that the public was adequately placed on notice

that the change could result from the originally proposed regulatory action. From the background described above, it is abundantly clear that subdivision (b) is simply a revision of the "rule of thumb" presumption in section 12505, subdivision (a) which was originally proposed for repeal in the July 29 text. The addition of this subdivision was in direct response to several comments objecting to the outright repeal of the "rule of thumb." The public was certainly adequately put on notice of the possibility of such a change from the proposed repeal of section 12505, subdivision (a) in the original text. In the April 13 proposal, the full text of the change was made available to the public for 15-day comment as required by Government Code section 11346.8, subdivision (c).

One comment objected that subdivision (b) would impose unnecessary sampling and testing requirements, because it saw no need for sampling and testing if all the water was received from a public water system or a commercial drinking water supplier. (PH-10, p. 2.) Subdivision (b) describes methods of measuring the amount of a listed chemical attributable to drinking water for the purpose of the exemption described in subdivision (a). It is necessary to use these methods to calculate the exemption, even where all the water was received from public water system, because other sources may have contributed to the total amount of the chemical in question. Another comment was concerned that subdivision (b) could "result in unnecessary activity as a result of inappropriate sampling technique." (PH-3, p. 2.) Assuming that the commentator is referring to poor sampling technique by the public water system or commercial drinking water supplier in a manner other than that required by law, the resulting test results could not be used under subdivision (b). However, the business still has the option under subdivision (b) of calculating the amount based on 5 percent of the MCL, without the need to independently sample and test the drinking water.

Another comment suggested that the phrase "most recent sample" be changed to "most recent sampling." (PH-3, p. 2.) This change was not adopted because the existing language is clearer. Another comment asked for clarification on what part of the water distribution system constitutes the "point of delivery" and argued that this should be the "free flowing outlet" or the tap. (PH-7, pp. 1-2.) The term "point of delivery" means the point of entry into the service line of the user (e.g., at the water meter of the consumer). The federal Safe Drinking Water Act defines "maximum contaminant level" as "the maximum permissible level of a contaminant in water which is <u>delivered to any user</u> of a public water system." (Emphasis added.) (42 U.S.C. § 300f, subd. (3).) This "point of delivery" is understood in the regulated community to refer to the point of entry into the service line, and no further clarification in the regulation is necessary.

A substantial number of post-hearing comments objected to setting the "rule of thumb" presumption at 5 percent of the MCL for a listed chemical on the grounds that this level is unjustifiably

low, unfair, arbitrary, and without apparent reason. (PH-1, p.5; PH-3, p.2; PH-7, p. 1-2; PH-8, p. 1-2; PH-10, p.3.) The Agency disagrees with this characterization. To determine the appropriateness of using the MCL of a listed chemical for the "rule of thumb," the Agency sought some actual data on the concentration of listed chemicals in drinking water relative to the MCLs. The Agency began its research by requesting drinking water quality data from the Public Water Supply Branch of the Department of Health Services, which regulates all public drinking water systems in California. The Agency specifically asked for a compilation and analysis of monitoring data on six listed chemicals for which State primary drinking water standards exist and which are fairly widely distributed throughout the State. The six representative chemicals are listed below with their respective maximum contaminant levels:

		Maximum contaminant level in micrograms per liter
Inorganics:	Arsenic (As)	50
	Cadmium (Cd)	10
	Chromium (Cr)	50
	Lead (Pb)	50
Organics:	Tetrachloroethylene (PCE)	5
	Trichloroethylene (TCE)	5

The resulting data, which were collected from community and non-transient, non-community public water systems, are summarized on the tables in Appendix A, which is incorporated herein by reference. These tables represent the most recent information available about these six chemicals in the Public Water Supply Branch computer database, which spans from 1984-1988.

For the inorganic chemicals, approximately 2,100 sites from 490 systems were sampled, and from these, roughly 2,800 analyses were performed. The results indicated that few of the sites contained detectable levels of any of the four chemicals: only 17 percent were positive for arsenic, 4 percent for cadmium, 13 percent for chromium, and 10 percent for lead. Some of these positive findings were in excess of the MCL. Data that exceed the MCL were not included in further analyses, because concentrations over the MCL are not permitted in drinking water and where the drinking water exceeds these standards, water suppliers are required to take immediate steps to bring their water supply into compliance.

The statistical summary of all test results, excluding those that exceed the MCL, indicates that the average (mean) levels of all four inorganic chemicals fall below 3 percent of their respective MCLs. The mean arsenic level was 1.3 micrograms per liter, or (1.3/50 =) 2.6 percent of the MCL. The mean cadmium level was 0.12 micrograms per liter, or (0.12/10 =) 1.2 percent of the MCL. The mean chromium level was 1.06 micrograms per liter, or (1.06/50 =) 2.1 percent of the MCL. The mean lead level was 0.99

median value, the mid-point at which half of the samples are below and half are above, is below the level of detection.

For the organic chemicals, approximately 7,300 sites from 4,400 systems were sampled, and from these, roughly 14,000 analyses were performed. These test results also indicated that few of the sites contained detectable levels of the two chemicals of concern. For tetrachloroethylene (PCE), only 19 percent of the test results were positive, and for trichloroethylene (TCE), only 16 percent were positive. After excluding the results for the organics that exceed the MCL, the mean PCE level was 0.25 micrograms per liter, or (0.25/5 =) 5 percent of the MCL. The mean TCE level was 0.21 micrograms per liter, or (0.231/5 =) 4.2 percent of the MCL. Once again, the median value was below the level of detection.

This research, which is based on actual test data from about 40,000 analyses of samples taken from about 4,400 California water systems, unequivocably demonstrates that listed chemicals in California drinking water are not generally found at the maximum contaminant levels. In fact, they are most often totally absent, and on the average, amount to only a minute fraction of the maximum contaminant level. In light of this information, the Agency disagrees with several comments which urged that the "rule of thumb" assumption be set at the maximum contaminant level. (PH-3, p. 2; PH-7, p. 3; PH-10, p. 3.) In order to obtain an exemption under section 12502 at the MCL, a business must show that the drinking water contained the chemical in question at the MCL by sampling and testing, or with test information from the public water system or the commercial drinking water supplier. However, if a business chooses to use a "rule of thumb" assumption to estimate the level of a contaminant contained in drinking water, the Agency believes that such a rule should be based on actual data and reflect the approximate levels that exist in our drinking water supplies, which the Agency has identified as 5 percent of the MCL.

A post-hearing comment suggested that the "rule of thumb" assumption be set at 50 or 60 percent of the MCL, based on the lead data in Appendix A. This recommendation is specifically based on the average (mean) lead level of the positive samples only, which is 14.5 micrograms per liter. This level is equivalent to 30 percent of the lead MCL (14.5/50 = 0.30). The upper end of the range was projected to be twice the 30 percent value, resulting in a standard of 60 percent of the MCL. (PH-1, p. 5.) This reasoning is erroneous because less than 10 percent of the analyses (268 of 2,800 findings) were positive for lead. The remaining 90 percent of samples contained no detectable levels of lead. The "rule of thumb" assumption should reflect actual data, and not be set artificially high. To base the "rule of thumb" on a value representing only 10 percent of the analyses distorts the data by skewing the results upward by a factor of 15. The average (mean) lead level of 0.99 micrograms per liter, which is based on all samples that are in compliance with the

lead MCL, is equivalent to only 2 percent of the MCL. Even if the six samples in excess of the lead MCL are included in the calculations, the difference is slight: the average (mean) level would be 1.3 micrograms per liter, or (1.3/50 =) 2.8 percent of the lead MCL. Therefore, setting the "rule of thumb" assumption at 50 or 60 percent of the MCL is clearly inappropriate.

A post-hearing comment objected that 5 percent assumption could operate as an "automatic exemption," even if a chemical is concentrated during processing, and requested clarification on whether the 5 percent assumption operates only in the absence of any other testing data, in very limited circumstances, where sampling and testing is not feasible. (PH-4, p. 4.) A business may choose to use the 5 percent "rule of thumb," if sampling and testing are impractical. It is clearly set forth in the regulation as an alternative method of measurement, and it is not necessary to show that test results from the public water system or commercial drinking water supplier are not available. As described above, several other comments indicated that sampling and testing can be very expensive and may be impractical in many situations. Public water system data may not be available or usable. The Agency believes that the 5 percent assumption is a reasonable accommodation, given that it is set at a very low level and roughly approximates the current state of our drinking water.

One post-hearing comment criticized the 5 percent level for being inconsistent with subdivision (a), which the commentator believes allows for an exemption up the the MCL. (PH-8, p. 1-2.) Subdivision (a) describes an exemption for chemicals in drinking water, but it does not specify that this is to be measured at the MCL. Thus, subdivisions (a) and (b) are not inconsistent.

Another post-hearing comment objected that the 5 percent level was based on data from most public water systems, but not <u>all</u> public water systems. (PH-3, p. 2.) Because of the large number of samples analyzed, the Agency believes the data to be representative of California drinking water supplies. From a total of approximately 5,300 public water systems in California, over 4,400 systems (83 percent) were sampled. Furthermore, in order to obtain a more accurate picture of the general condition of the State's drinking water supplies, test results which exceed the MCL were not included in final analyses because levels in excess the MCL are not permitted in drinking water. (Cal. Code Regs., tit. 22, § 64444.5; see also discussion <u>ante</u> at p. 20.)

One post-hearing comment observed that it is unclear whether subdivision (b) applies to subdivisions (a)(1), (a)(2), and (a)(3), and in particular, whether the 5 percent "rule of thumb" applies to subdivision (a)(3), which purportedly "recognizes" drinking water sources which comply with all primary drinking water standards for listed chemicals. This was thought to be inappropriate because the levels for these chemicals would be assumed to be at 5 percent of MCL if sampling and testing are

impractical. (PH-10, p. 2.) Subdivision (b) refers to subdivision (a) in its entirety, and so it is intended to apply. This commentator's confusion apparently stems from the misapprehension that subdivision (a)(3) provides an exemption for all listed chemicals in drinking water provided that they are in compliance with the MCLs, whereas subdivision (a)(3) only exempts chemicals which result from treatment to achieve compliance with primary drinking water standards.

Section 12503

Section 12503 (formerly § 12503, subd. (b)) provides that where the movement of water containing a listed chemical is not deemed a "discharge" or "release" pursuant to section 12401, this activity will likewise not give rise to an "exposure" within the meaning of the Act. The purpose of this regulation is to make the application of the exposure provisions more consistent with the discharge provisions in Article 4.

The last sentence of this section is intended to clarify that the described exemption is not intended to affect the responsibility for any exposure which arises from any activity other than that described in section 12401. In the original July 29 text, this sentence read as follows: "Nothing in this subdivision shall be interpreted to affect the responsibility for an exposure which occurs before such an event." Since an exposure does not occur until a listed chemical is caused to come in contact with an individual (§ 12201, subd. (f)), it does not make sense that an individual could be exposed to a chemical contained in water which was moved before the water was actually moved. Because the meaning of the phrase "exposure which occurs before such an event" was unclear in the original text, this phrase was replaced in the April 13 text with "arises from any activity other than that described in section 12401." One post-hearing comment commended this amendment as an appropriate and effective clarification. (PH-4, p. 4.) Also, "subdivision" in the last sentence was changed to "section" in the April 13 text as a result of the re-numbering of sections 12502, 12503, and 12504, and "listed" was inserted before "chemical" in the first sentence for consistency with the prior reference to "listed chemical."

A comment suggested that the phrase "Health and Safety Code" be deleted from this section so that the reference would be consistent with section 12501, subdivision (b). (Exh. 7, p. 28.) This change has not been adopted because this language is enhances clarity and is consistent with the reference to the Health and Safety Code in section 12501, subdivision (a). The same comment alternatively suggested that "Health and Safety Code" precede all section references to the Act. This change was not adopted because it is easily inferred from the context of the regulations that all section references to the Act are to the Health and Safety Code.

This same commentator recommended the deletion of the phrase "otherwise responsible for an exposure to a listed chemical." (Exh. 7, p. 28; PH-1, p. 6.) This comment is similar to one made for section 12501, subdivision (b), and the Agency's decision not the adopt the change and rationale therefor are the same. (See discussion ante at p. 12.)

Several comments on the July 29 text observed that that the reference to section 12401 was unclear because at the time, this section did not yet exist. (C-23, p.3; C-27, p. 1; C-43, p. 1.) This oversight was corrected when section 12401 became effective on October 17, 1988. Another comment on the July 29 text objected that section 12401 as proposed included an "illegal" exemption for compliance with the Porter-Cologne Water Quality Act. (C-27, p. 1.) This point is now moot because that provision was not adopted in the final language of section 12401.

One comment urged that section 12503 also exempt trace levels of chemicals resulting from the use of "process water" from sources other than drinking water, because these traces are the unavoidable result of the use of process water in manufacturing. (PH-11, p. 2-3.) Such an amendment would in effect be an extension of the exemption for chemicals in drinking water to include the use of process water, which does not meet primary drinking water standards. An exemption for water which is not drinking water and which may pose a significantly higher health risk is not justified. If a business chooses to use process water, the listed chemicals which result from that use should be monitored to determine whether they present a significant risk.

Another comment to the July 29 text recommended an exemption for chemicals in degraded water, provided that the water is returned to its source or to an area where the water would have flowed, and the business did not add any listed chemical in an amount which would cause a significant risk of cancer or reproductive toxicity. (C-45, p. 2.) This comment is not directly relevant to the regulations in this rule making. In the interest of consistency, section 12503 incorporates by reference and exempts those activities described in section 12401. No change to section 12503 is needed because the issue raised by this comment has already been adequately addressed by the subsequent adoption of section 12401. Subdivision (b) of section 12401 exempts chemicals from sources other than drinking water supplies, including degraded water, provided that the water is returned to the same source of water supply. Another comment recommended an exemption for naturally occurring chemicals discharged as result of mining and earth moving. (Exh. 8, pp. 6-7, exh. 4.) This comment is also not directly relevant to the regulations at hand. This issue has been adequately addressed in the rule-making for section 12401, in the course of which the Agency declined to extend the exemption from the discharge prohibition to chemicals from mining operations. For a more detailed discussion of section 12401, please refer to the Final Statement of Reasons for Article 4 which was filed with and approved by the Office of

Administrative Law. Any changes to section 12503 in this regard would create an inconsistency with the existing regulations. Accordingly, these recommendations were not adopted.

Section 12504

Although the Act regulates exposures by inhalation of toxic chemicals in the air, most individual businesses are not in a position to control the quality of the ambient air which enters their property, or to avoid exposing people to ambient air. Section 12504 provides an exemption from the warning requirement for chemicals which are contained in air that the responsible person received from the ambient air.

The last sentence of the original July 29 text read as follows:

> Where the source of the listed chemical is in part from the ambient air and in part from other sources, "exposure" can only occur as to that portion of the listed chemical from sources other than the ambient air.

One comment urged the elimination of a "loophole" for situations where a business is drawing in air from ambient surroundings that the same business polluted, such as a smokestack upwind. (C-19, p. 2.) This was certainly not the intent of the regulation, and the Agency recognized the need for some clarification in this regard. To correct this problem, the comment suggested that 1) the term "ambient air" be defined so as not to include chemicals which the person put into the air, or 2) the last clause of the last sentence be amended to state that "exposure" occurs as to all portions of the listed chemical for the person is responsible, even when the portion is contained in the ambient air. Ibid. These suggested amendments were not used in the April 13 text because they are awkward and confusing. Defining "ambient air," which normally means the surrounding outside air, to exclude chemicals in the outside air as they relate to some people but not others, is very awkward. The language of the second suggestion is rather circular: it basically provides that a person is responsible for chemicals in the ambient air for which the person is responsible, but it is unclear in this context what "responsible" means.

In the April 13 text, the last clause was modified to read: "'exposure' does not occur as to that portion of the listed chemical from the ambient air to the extent that the person did not put the listed chemical into the ambient air." This language simply and clearly communicates the message that where the source of a listed chemical is partly from the ambient air and partly from other sources, the exemption of section 12504 applies only to that portion of the chemical which is in the air solely as a result of its presence in the ambient air, and not to the portion from any other sources, including that which is placed into the ambient air by the person responsible for the exposure. In a post-hearing comment, the same commentator recommended a return

post-hearing comment, the same commentator recommended a return to the original text, with an added sentence to the effect that measurement of the amount of a listed chemical in the ambient air shall not include any of the listed chemical placed into the ambient air by the person responsible for the exposure. (PH-4, p. 4.) This recommendation was not adopted because the existing language of the regulation achieves substantially the same result.

One comment complained that the burden of proof for a business to qualify for the ambient air exemption is "impossible" for some listed chemicals, and cited a need for a better definition of the proof needed to meet this burden. (C-17, p. 3.) Another comment recommended that any level of chemical at or below the chemical level in the ambient air be deemed to be from the ambient air, because of proof problems. (Exh. 8, p. 7.) Evidence that the level of a listed chemical is at or below the level in the ambient air is persuasive evidence that the chemical is from the ambient air, but it is not necessary to create an irrebuttable presumption to deal with this issue. The person responsible for the exposure may introduce any scientifically valid and relevant evidence, including monitoring data collected by government agencies on the level of the chemical in the ambient air, to show that the source of the chemical in question was the ambient air, and it is not necessary to enumerate these in the regulation.

Miscellaneous Exposures

A building industry group requested an exemption for chemicals in building materials which were not manufactured by the builder, so long as the builder used the product for the intended use and did not add any listed chemical. (C-28.) This proposal was not adopted because an exemption is not appropriate where builders have substantial control over the types of building materials they use, and how they are used. A utilities group recommended the addition of two exemptions for "water in/air out" to allow for evaporation of chemicals from water into the air, and for "air in/water out" to allow for condensation or absorption of chemicals from air into water. The example given was a holding pond which may collect chemicals from the ambient air from a source not controlled by the business. (C-45, p. 2.) Neither situation warrants an exemption because they result from activities, such as the management of a holding pond, which are subject to the control of the business. In response to these comments and all the other comments which requested special exemptions, it should be noted that the exemptions which the Agency created by regulation were intended to be quite limited, because the Act itself provides an exemption for exposures which pose no significant risk of cancer or reproductive toxicity.

Another comment requested an exemption for exposures where a business can show compliance with the federal OSHA Hazard Communication Standard. (C-44, p. 6.) This change is not needed because this issue has already been specifically addressed in

section 12601, subdivision (c)(1)(C), which provides that a warning in compliance with all information, training, and labeling requirements of the federal Hazard Communication Standard is an adequate warning under the Act.

The Agency's responses to a comment relating to preemption of the warning requirement by the Egg Products Inspection Act (C-31) and a request for a permanent exemption of medical devices from the warning requirement (Exh. 4, p. 1-2) are in the Final Statement of Reasons for Articles 7 and 8.

Repeal of the Emergency Regulations

All of the emergency regulations in Article 5 are to be repealed. Emergency regulation sections 12501 and 12503 are basically similar to the final regulations, and will no longer be needed once the final regulations are effective.

Emergency regulation section 12505, titled "Miscellaneous", is to be repealed because it deals with an area which has already been more fully addressed in section 12502 regarding exposures associated with the use of drinking water. The "rule of thumb" presumption in emergency regulation section 12505, subdivision (a) has been substantially modified and added to final regulation section 12502, subdivision (b). The language of emergency regulation section 12505, subdivision (b), except for an ambiguous reference to chemicals from "water and other natural sources," has been incorporated into the final regulations sections 12502 and 12504. The new language presents a clearer statement of the limited application of the exemption from the warning requirement when the source of the listed chemical is partly from drinking water or the ambient air, and partly from other sources, and is similar to language in section 12501. It replaces language in emergency regulation section 12503, subdivisions (a) and (c), relating to the "addition" of a listed chemical to drinking water or to the ambient air, which has caused some confusion.

AMENDMENT TO FINAL STATEMENT OF REASONS
CALIFORNIA CODE OF REGULATIONS, TITLE 22

Section 12504: Exposure to Air

Add a new paragraph to page 26, prior to the first full paragraph:

One comment supported the concept of the exemption for chemicals in the ambient air, but commented that there needed to be a practical means of measuring ambient levels. (C-25, p. 11.) The Act provides that a "significant amount" of a listed chemical means any detectable amount (except an amount which meets the exemption test of § 25249.10, subd. (c)). Emergency regulation section 12901 describes the methods of analysis to be used for measuring listed chemicals, including those employed by the Air Resources Board and the local air pollution control districts. These methods are practicable and currently employed by air quality regulatory agencies. The same commentator recommended that a procedural approach, such as implementation of an operations and maintenance (O & M) program, would be far more practical. While the Agency encourages the use of O & M programs as a means of keeping levels of chemicals below the level posing a significant risk, it appears to be more practical to set a target level, and leave any determination whether a particular O & M program successfully keeps exposures below the target level to the courts. Further, it may be possible to devise O & M programs in only a handful of situations covered by the Act. Accordingly, this recommendation was not adopted.

Add at the end of the Final Statement of Reasons:

One commentator at the public hearing stated that despite an assertion in the Notice that the regulations would not have a significant adverse economic effect on small businesses, small medical device manufacturers are being required to expend significant amounts of money to test for listed chemicals in their products, and if necessary, to disseminate warnings. (Transcript, p. 33.) The basic warning requirement is a provision of the Act (Health & Saf. Code, § 25249.6), which is self-executing in that its provisions may be enforced by public prosecutors or any person in the public interest, regardless of whether the Agency adopts any regulations. Therefore, these regulations do not impose any additional burden on small businesses, but merely implement and clarify the statute.