FINAL
STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS DIVISION 2

Section 12703 - Quantitative Risk Assessment

The Safe Drinking Water and Toxic Enforcement Act of 1986 (Health & Saf. Code, sec. 25249.5, et seq.) (henceforth referred to as 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 discharging or releasing a chemical known to the state to cause cancer or reproductive toxicity into water or onto or into land where such chemical passes or probably will pass into a source of drinking water. (Health & Saf. Code, sec. 25249.5.) It further prohibits such persons from knowingly and intentionally exposing any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving a clear and reasonable warning. (Health & Saf. Code, sec. 25249.6.)

The Act also creates limited exceptions to these prohibitions. For chemicals known to the state to cause cancer, the Act provides that no warning is required if the person responsible for the exposure can show that the exposure would pose no significant risk assuming lifetime exposure at the level in question. (Health & Saf. Code, sec. 25249.10(c).) An exception to the discharge prohibition applies where the discharge or release complies with other legal requirements and does not cause a significant amount of the chemical to enter a source of drinking water. (Health & Saf. Code, sec. 25249.9.) A "significant amount" of a chemical is defined as a detectable amount or an amount which would not require a warning for an exposure in drinking water under section 25249.10(c).

The Act neither defines the phrase "no significant risk" nor provides any guidance on how to determine whether an exposure poses a significant risk. Health and Safety Code section 25249.12 gives agencies designated to implement the Act authority to adopt regulations as necessary to conform with and implement the provisions of the Act and to further its purposes. The Health and Welfare Agency ("Agency") has been designated the lead agency for the implementation of the Act.

By regulation, the Agency established a methodology for quantifying the risk from daily exposure to chemicals. (Cal. Code Regs., tit. 22, sec. 12703.) Subsection (b) of that regulation provides that daily exposure to a chemical over a lifetime poses no significant risk if the risk of cancer does not exceed one excess case in a population of 100,000 exposed persons, except where sound considerations of public health support an alternative level. As an example of a public health consideration, the regulation referred to cleanups and resulting

discharges ordered and supervised by an appropriate governmental agency or court of competent jurisdiction. No further examples were provided.

This regulatory action amends subsection (b) of section 12703 to add two additional examples of public health considerations: (1) Where chemicals in food are produced by cooking necessary to render the food palatable or to avoid microbiological contamination; and (2) where chlorine disinfection in compliance with all applicable state and federal safety standards is necessary to comply with sanitation requirements.

Procedural Background

The version of section 12703 which this regulatory action amends was adopted finally on June 9, 1989. On October 13, 1989, the Agency issued a Notice of Proposed Rulemaking which scheduled a public hearing for November 28, 1989, to consider proposed amendments to section 12703, and to amend or add two other regulations. Two comments were presented at the public hearing, and 23 other persons or organizations provided comments before the close of the comment period. Of these commentors, 17 commented on the proposed amendment to section 12703(b).

By notice dated March 19, 1990, the Agency made changes to the proposed regulation (March 19 version) and provided a 15-day period in which interested persons could comment on the changes. No comments were received.

Purpose of Final Statement of Reasons

This final statement of reasons sets forth the reasons for the final language adopted by the Agency in section 12703(b), and responds to the objections and recommendations submitted regarding that section as originally proposed in the October 13 proposal and modified by the March 19 proposal. Government Code section 11346.7, subsection (b)(3) requires that the final statement of reasons submitted with an amended or adopted regulation contain a summary of each objection or recommendation made regarding the adoption or amendment, together with an explanation of how the proposed action has been changed to accommodate each objection or recommendation, or the reasons for making no change. It provides that this requirement applies only to objections or recommendations specifically directed at the Agency's proposed action, or to the procedures followed by the Agency in proposing or adopting the action.

Some parties included in their written or oral comments remarks or observations about these regulations or other regulations which do not constitute an objection or recommendation directed at the proposed action or the procedures followed. Also, some parties offered their interpretation of the intent or meaning of the proposed regulations or other regulations, sometimes in

connection with their support of or decision not to object to the October 13 proposal. Again, this does not constitute an objection or recommendation directed at the proposed action or the procedures followed. Accordingly, the Agency is not obligated under Government Code section 11346.7 to respond to such remarks in this final statement of reasons. Since the Agency is constrained by limitations upon its time and resources, and is not obligated by law to respond to such remarks, the Agency has not responded to these remarks in this final statement of reasons. The absence of response should not be construed to mean that the Agency agrees with the remarks.

Specific Findings

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

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

Rulemaking File

The rulemaking file submitted with the final regulation and this final statement of reasons is the complete rulemaking file for section 12703. However, because regulations other than section 12703 were also the topic of the public hearing on November 28, 1990, the rulemaking file contains some material not relevant to section 12703. This final statement of reasons cites only the relevant material. Comments regarding regulations other than section 12703 have been or will be discussed in separate final statements of reason.

Necessity for the Regulation

The Agency has determined that the adoption of this amendment to section 12703 is necessary. The Act exempts discharges, releases and exposures which pose no significant risk of cancer assuming lifetime exposure at the level in question, based upon scientifically valid evidence and standards. However, the Act provides no guidance on what exposures are "significant," including where the exposure is the consequence of practices motivated by competing considerations of public health, such as the avoidance of disease. Section 12703 provides that a chemical risk is significant if daily exposure to the chemical over a 70-year lifetime will produce more than one excess case of cancer in a population of 100,000 exposed persons (1×10^{-5}).

The Agency made an exception where sound considerations of public health support an alternative level of risk. To illustrate what constitutes a sound consideration of public health, the existing regulation provides a single example. The Agency believes that additional examples will better serve to illustrate what kinds of public health considerations warrant special treatment.

The public health exception is justified because the Act was intended by the voters as a measure to protect the public health and well-being. (Ballot pamphlet, Safe Drinking Water and Toxic Enforcement Act of 1986, Section 1.) It might contravene this intent if the Act were construed to prohibit activities which protect the public health. It would be ironic and counterproductive if, as the result of warnings, the public avoided practices which protect the public health.

SECTION 12703

Cooking

The public health benefits of cooking food are widely recognized Cooking food significantly minimizes the possibility of food-borne infections and food intoxication. The high temperatures that foods are subjected to during cooking are effective in killing pathogenic bacteria, helminths and other organisms (e.g., Salmonella, Shigella, Campylobacter, and Trichinella), and, in most cases, breaking down their toxins. (See Manual for Control of Communicable Diseases in California, California State Department of Health, 1977, pp. 160-165, 370-377, 384-388, 441-444.) State and federal laws require that food establishments ensure that certain foods be thoroughly cooked prior to serving. (21 C.F.R. sec. 110.80; Health & Saf. Code, secs. 26209, 27591, 27601.)

In addition to its anti-microbial benefits, cooking is often necessary to make foods palatable. Experience has shown that, when food is not palatable, people tend not to eat. This can have health consequences as well.

On the other hand, there is extensive information in the scientific literature which indicates that chemicals having mutagenic and/or carcinogenic properties are formed as a result of cooking food. The chemicals formed and their amounts vary with such factors as the method of cooking (e.g., boiling, pan frying, grilling, etc.), the temperature and duration of cooking, and the type of food. Chemicals that have been found in cooked food include benzo[a]pyrene and other polycyclic aromatic hydrocarbons, tryptophan-P-1 and other amino acid pyrolysates, nitrosamines, and aldehydes. A number of these chemicals have been listed as known to the state to cause cancer.

Prior to this regulatory action, interested parties have expressed their concern that the Act would impact upon the practice of cooking. (See Cal. Code Regs., tit. 22, sec. 12501, Final Statement of Reasons, June 9, 1989, p. 9.) They have variously requested that the Agency prevent the potential of liability under the Act as the result of the cooking of food. A petition from 13 food, drug, cosmetic and medical device organizations requested that the Agency provide that exposure to chemicals which result from cooking pose no significant risk. (See Exh. 1, p. 1.) This proposal was not adopted, however, because the Agency could not be certain that all exposures which result from all manner of cooking in fact pose no significant risk.

Several commentors to section 12501 of the regulations recommended that chemicals formed by cooking be considered as "naturally occurring" chemicals which do not cause an exposure under the Act. (See Cal. Code Regs., tit. 22, sec. 12501, Final Statement of Reasons, June 9, 1989, p. 9.) This recommendation was also not adopted, since the definition of "naturally-occurring," which was derived from federal regulation (Id.), requires an absence of human activity, and cooking is a human activity.

Nevertheless, the Agency believes that some relief from a strict 10^{-5} standard is indicated for necessary cooking. Strict compliance with the 10^{-5} standard may not be possible where necessary cooking takes place. The concentration of chemical by-product may vary with each item prepared. Businesses may have considerable difficulty determining in any particular case whether cooking has resulted in the concentrations of listed chemicals which meet the 10^{-5} standard. Thus, businesses may feel compelled to provide a warning to protect them from liability in the event the level of risk does exceed 10^{-5}.

The confusion which would result if all purveyors of cooked or heat-processed foods provide a warning with their product, to avoid any potential liability, could be enormous. If the warning were to specify that it is given for cooking, it could generate undue public fear about cooking food, leading some to undercook their food or avoid cooking altogether. This could result in an increase in the transmission of food-borne diseases. If the warning did not specify that it is given for cooking, consumers might avoid foods carrying the warning in favor of raw foods, which more likely would not carry a warning. Since most consumers cook raw food, they would expose themselves to the same listed chemicals anyway. Thus, consumers are likely to be exposed to these chemical by-products of cooking in any event. In light of the offsetting public health benefit that the cooking of food provides, the Agency takes the position that businesses which utilize cooking necessary for the processing or preparation of food should not be strictly held to the 10^{-5} standard.

Subsection (b)(1) of this regulation specifically includes cooking necessary to avoid microbiological contamination or to make food palatable as an example of a public health consideration which supports the use of a no significant risk level other than 1×10^{-5}. Under the previous version of the regulation, cooking was arguably an example of a public health consideration. Specifically including necessary cooking as an example dispenses with the need for argument.

This approach has the advantage of flexibility. It does not establish a rigid line with which businesses must comply or face liability. Necessary cooking may result in varying amounts of chemical by-products. To the extent that the cooking is necessary to avoid contamination or to render the food palatable, the level which is considered to pose no significant risk should vary with the level of chemical by-product, and the public health benefit to be obtained.

One commentor objected that the proposal does not draw a specific dividing line. (Exh. 1, p. 4.) However, as indicated above, necessary cooking will produce varying amounts of chemical by-products, which makes the establishment of a dividing line difficult. Further, the public health exception to the 1×10^{-5} dividing line was created due to dissatisfaction with an absolute dividing line. There is no indication that the establishment of a different fixed dividing line will prove to be any more satisfactory.

This same commentor recommended that the Agency instead provide that chemical by-products of cooking do not result in an "exposure" pursuant to the Act, similar to the treatment given to "naturally-occurring" chemicals under section 12501 of the regulations. (Exh. 4, p. 3.) However, unlike "naturally-occurring" chemicals in food, chemical by-products of cooking are arguably "put out into the environment." (See Ballot pamphlet, Argument in Favor of Proposition 65, as presented to the voters, Nov. 4, 1986.) The "naturally-occurring" chemicals regulation is currently under judicial review. (Nicolle-Wagner v. Deukmejian, Los Angeles County Superior Court, Case No. 0689725.) Including chemical by-products of cooking in section 12501 would likely generate additional litigation. Accordingly, this recommendation was not adopted.

One commentor objected that the word "cooking" is unclear, since it can apply arguably to any manner of operation which involves the application of heat. (C-22, p.2.) The word was selected for its broad applicability to domestic and commercial food processing and preparation. Therefore, it represents an accurate expression of the Agency's intention.

The word "necessary" is not intended to favor one cooking practice over another. If a food could be boiled or broiled to avoid contamination or render the food palatable, but broiling

produces more chemical by-products than boiling, broiling does not become unnecessary. The Agency's intention is that, whatever method of cooking is chosen, the amount of cooking which is necessary to avoid bacterial contamination or to render the food palatable should provide a basis for the application of a risk level other than a risk of 1×10^{-5}.

One commentor objected that the phrase "necessary to avoid" is susceptible to different interpretations, and pointed out that cooking may not be necessary to avoid contamination where preservatives have been added to food. (C-22, p. 2.) The Agency agrees that different circumstances will raise questions of fact as to whether cooking is necessary to avoid contamination and, if the cooking is not also necessary to make the food palatable, whether warnings should be provided. This does not render the regulation unclear, or provide any other valid basis for objection. Since there was no recommendation of more appropriate language, the phrase has been retained.

As originally proposed, subsection (b)(1) would have applied only to cooking necessary to avoid bacterial or microbial contamination. Upon further review, it was determined that the words "bacterial or microbial" could be replaced by the word "microbiological," which covers the whole spectrum of parasitical, bacterial, viral and other microbial contamination. Accordingly, the March 19 proposal made this replacement. No objections were received.

Two commentors observed that cooking is performed to make food edible and palatable, as well as to avoid microbiological contamination, objected that the regulation as proposed would apply only to cooking necessary to avoid contamination, and recommended that it be expanded to include cooking necessary to render food edible, palatable, or otherwise fit for consumption. (Exh. 1, pp. 4-5; C-3, pp. 3-4.) Fitness for consumption arguably occurs when the cooking eliminates any microbiological contamination. Thus, reference to fitness for consumption appears duplicative. Food which is "palatable" appears to include that which is "edible," since food which is palatable due to cooking is usually edible, though not all food which is edible is palatable. Accordingly, the Agency determined that the needs of these commentors would be satisfied by the phrase "to render the food palatable." This language was included in the March 19 proposal. No objections were received.

The word "palatable" means "acceptable to the taste; sufficiently agreeable in flavor to be eaten." (American Heritage Dictionary, 2d Ed., Houghton Mifflin, "palatable," p. 893.) This raises the question of whose taste provides the standard of palatability. Cooking may render a food palatable to one person, but not to another. It is the Agency's intention that the word "palatable" refer to the taste of an ordinary person. This is consistent with the treatment of other elements of risk assessment. For

example, exposure to consumer products is based upon the average rate of exposure to the average consumer.

Chlorine Disinfection

According to the U.S. Environmental Protection Agency:

> "Chlorination is the most widely used method of disinfecting drinking water in the United States. It is convenient to use, effective in destroying or inactivating pathogens, and continues to disinfect in the distribution system. Chlorination is the standard against which all other disinfection techniques and disinfectants are compared." (52 Fed.Reg. 25728, July 8, 1987.)

Following the introduction of gaseous-feed chlorination systems in 1912, the death rate from typhoid fever and paratyphoid dropped from 25 in every 100,000 persons to fewer than 10 waterborne outbreak cases annually in the U.S. at large. (See Sawyer and McCarty, Chemistry for Environmental Engineering, 3d Ed., McGraw-Hill, 1978, pp. 385-388.) The public health benefits of water chlorination are considerable. Chlorine disinfection is also routinely employed in food processing plants, barns and dairies to disinfect equipment, tools and surfaces of organisms which may contaminate food. Food establishments are required to disinfect reusable eating and serving utensils with chlorine in order to prevent the transmission of certain infectious diseases through these items. (Health & Saf. Code, sec. 27613.) Swimming pool water must contain adequate amount of chlorine to minimize the growth of, or kill, microorganisms which may cause disease. (Cal. Code Regs., tit. 17, sec. 65529.)

Chlorine is also a highly reactive substance. Reactions between chlorine and various organics may result in the formation of chlorinated compounds which may be listed as known to the state to cause cancer, such as chloroform. Chlorine disinfection may, therefore, result in exposures to listed carcinogens via contact with food or other media. Wastewater discharged from facilities that disinfect with chlorine may likewise contain listed carcinogens.

The drafters of the Act were apparently aware of the problems surrounding chlorination. The Act specifically exempts any entity in its operation of a public water system, as defined in Health and Safety Code section 4010.1, most of which utilize chlorination, as indicated by the EPA (supra). Consistent with this exemption, the regulations adopted by this Agency provide that the discharge or release of water received from a public water system and other sources of drinking water is not a "discharge or release" of a listed chemical within the meaning of the Act to the extent that chemicals were contained in the water

received. (Cal. Code Regs., tit. 22, sec. 12401(a).) Similarly, the use of water containing listed chemicals received from these sources of drinking water does not cause an exposure within the meaning of the Act to the extent that chemicals were contained in the water received. (Cal. Code Regs., tit. 22, sec. 12502.) Thus, exposures to chlorination by-products in drinking water are generally exempt from the Act.

The exemption of drinking water suggests an intent on the part of the voters that chlorine disinfection practices not be disrupted at the expense of the public's health. In keeping with this intent, the Agency believes that some specific relief from a strict 10^{-5} standard is necessary for chlorine disinfection.

Prior to this regulatory action, interested parties have expressed their concern that the Act would impact upon the practice of chlorine disinfection. (See Cal. Code Regs., tit. 22, sec. 12401, Final Statement of Reasons, October 6, 1988, pp. 8-9.) Strict compliance with the 10^{-5} standard may not be possible where chlorine disinfection is required. The concentration of chemical by-product may vary with the situation. Businesses may have considerable difficulty of determining in any particular case whether chlorination has resulted in the concentrations of listed chemicals which meet the 10^{-5} standard. Thus, businesses may feel compelled to provide a warning to protect them from liability in the event the level of risk does exceed 10^{-5}, or to minimize their disinfection practices. In light of the offsetting public health benefit that the chlorine disinfection provides, the Agency takes the position that chlorine disinfection is a consideration of public health which should not be strictly held to the 10^{-5} standard.

Subsection (b)(2) of this regulation specifically includes chlorine disinfection necessary to comply with sanitation requirements and in compliance with all applicable state and federal safety standards as an example of a public health consideration which supports the use of a no significant risk level other than 1×10^{-5}. Previously, chlorine disinfection was arguably an example of a public health consideration. Specifically including safe and necessary chlorine disinfection as an example dispenses with the need for argument.

Addressing chlorination by this approach has the advantage of flexibility. It does not establish a rigid line with which businesses must comply or face liability. Necessary chlorination may result in varying amounts of chemical by-products. To the extent that chlorine disinfection is necessary, and is in compliance with all applicable state and federal safety standards, the level which is considered to pose no significant risk should vary with the level of chemical by-product, and the public health benefit to be obtained.

One commentor objected to the reference to state and federal safety standards on the ground that it is unauthorized, and cited AFL-CIO, et al. v. Deukmejian, et al., Sacramento County Superior Court, Case No. 502541, in support of this position. The Agency maintains that section 12713, the regulation which is the subject of that action, is consistent with the Act and valid as construed by the Agency. Therefore, even if this regulation accomplished the same result as section 12713, it would be valid and consistent with the Act.

In addition, the references to state and federal safety standards in section 12713 and section 12703 are distinguishable. Section 12713 provides that foods, drugs, cosmetics and medical devices which comply with specific safety standards and which, in addition, are safe, should be deemed to pose no significant risk. Thus, the safety standards referred to can provide a basis for exemption from the Act. The reference to safety standards in section 12703, on the other hand, requires compliance with state and federal standards in the practice of chlorine disinfection before an exception to the 10^{-5} no significant risk standard may be taken. The references, therefore, do not accomplish the same result.

ADDENDUM TO THE
FINAL STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS

Section 12703 - Quantitative Risk Assessment

On page 7, insert the following paragraph after the existing first paragraph:

The commentor also stated that "Chemicals formed generically by the ordinary process of cooking should be distinguished from chemicals formed (or formed in much greater quantities) when specific precursor chemicals are intentionally added to a food product, which are known to form potent listed carcinogens or reproductive toxins under predictable and commonly occurring conditions of cooking." The commentor appears to believe that this regulation provides an exemption for listed chemicals formed as a result of cooking. This is not the case. A person responsible for an exposure to a listed chemical formed as a result of cooking has the burden of proving that "sound considerations of public health support an alternative level" (sec. 12703(b)). For example, in the situation described by the commentor, the person responsible for the exposure must be able to show that the beneficial health effects of the additive outweigh the risks. If the proposed alternative level cannot be so supported, then subsection (b)(1) is not available and the 10^{-5} standard applies.