FINAL
STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS DIVISION 2

Section 12901. Methods of Detection

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

Specifically, the Act prohibits persons in the course of doing business (as defined) from knowingly discharging or releasing such chemicals "into water or onto or into land where such chemical passes or probably will pass into any source of drinking water" (Health & Saf. Code, §25249.5). (All unidentified section references hereinafter cited are to the Health and Safety Code.) Such persons are also prohibited from knowingly and intentionally exposing any individual to these chemicals without first giving such individual a clear and reasonable warning (§ 25249.6).

Violation of these prohibitions can result in civil penalties of up to twenty-five hundred dollars ($2,500) per day (§ 25249.7). Legal action to enforce the Act may be brought by the Attorney General, any district attorney, certain city attorneys, or, under specified circumstances, "any person in the public interest" (§ 25249.7).

The Act requires the Governor to publish and periodically update a list of chemicals which are subject to its prohibitions (§ 25249.8). An initial list of 29 chemicals was published on February 27, 1987. With additional chemicals added to the list on July 1, 1987 and quarterly thereafter, the current number of chemicals on the list (as of October 1, 1989) has grown to over 320.

According to the terms of the Act, the requirement of warning prior to exposure to these chemicals becomes effective 12 months after they have been listed (§ 25249.10(b)). The prohibition against knowingly discharging these chemicals becomes effective 20 months after the chemicals were listed (§ 25249.9(a)). To date, there are approximately 240 chemicals which are subject to the warning requirement of the Act. On October 27, 1988, the discharge prohibition began to apply to the initial list of 29 chemicals. To date, there are approximately 180 chemicals which are subject to the discharge prohibition of the Act. Since additional chemicals are periodically added to the list, the Act will apply to an increasing number of business activities in the future.

The Act exempts from the discharge prohibition discharges and releases which comply with all applicable requirements, and which will not cause any significant amount of a chemical to enter any

source of drinking water (Health & Saf. Code, § 25249.9). The term "any significant amount" is defined to mean any detectable amount except an amount which would meet the exemption test in subdivision (c) of section 25249.10 (i.e., exposure to such amount would pose no significant risk assuming lifetime exposure at the level in question, or would produce no observable effect assuming exposure at one thousand times the level in question). Although the term "any detectable amount" is used by the Act only in reference to an exemption from the discharge prohibition of section 25249.5 only, detection of regulated chemicals will be necessary as well for purposes of the warning requirement of section 25249.6. In other words, it would be necessary as a practical matter to detect the presence of regulated chemicals regardless of whether a discharge, release or exposure is in question.

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

Procedural Background

Section 12901 of Title 22 of the California Code of Regulations was first adopted as an emergency regulation effective February 27, 1988. That emergency regulation was readopted effective June 27, 1988.

A "Notice of Emergency Rulemaking" issued by the Agency on May 20, 1988 stated the Agency's intent to adopt section 12901, solicited comments on the February regulation, and gave notice of a public hearing which was held on July 29, 1988.

In light of the comments received through that process, the Agency decided to adopt a substantially revised version of the regulation so that affected parties could more quickly gain the advantages of the revised approach. That revised version, which is the version proposed by this notice, initially took effect on October 25, 1988 and readopted effective February 22, 1989, and June 22, 1989.

On July 11, 1989, the Agency issued a notice of emergency rulemaking advising that the Agency intended to adopt the regulation permanently. Notices were also issued that the Agency intended to adopt or amend four other regulations implementing the Act. Pursuant to such notices a public hearing was held on September 13, 1989, to receive public comments on the proposed regulations, including section 12901. Out of 14 pieces of correspondence received commenting on the regulations, 4 contained comments regarding section 12901.

Purpose of Final Statement of Reasons

This final statement of reasons sets forth the reasons for the final language adopted by the Agency for section 12901, and

responds to the objections and recommendations submitted regarding the regulation as originally proposed at the July, 1988 hearing, and as modified by the October, 1988 emergency adoption. Technically, this notice involves a new regulation and this statement of reasons would only have to address the new version. However, in order to assist those who commented on the earlier version, this statement of reasons will discuss the differences between the original version and the current version, as well as the comments received in response to both versions.

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

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

Specific Findings

Throughout the adoption process of this regulation, the Agency has considered the alternatives available to determine which would be more effective in carrying out the purpose for which the regulation was proposed, or would be as effective and less burdensome to affected private persons than the proposed regulation. The Agency has determined that no alternative considered would be more effective than, or as effective and less burdensome to affected 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 12901. However, because regulations other than section 12901 were also the topic of the public hearing on September 13, 1989, the rulemaking file contains some material not relevant to section 12901. This final statement of reasons cites only the relevant material. Comments regarding the regulations other than section 12901 discussed at the September 13, 1989, hearing have been or will be discussed in separate final statements of reasons.

Necessity for Adoption of Regulation

The Act exempts from the discharge prohibition discharges and releases which will not cause any significant amount of the chemical to enter any source of drinking water. The term "any significant amount" is defined to mean any detectable amount except an amount which would meet the exemption test in subdivision (c) of Health and Safety Code section 25249.10, i.e., exposure to such amount would pose no significant risk assuming lifetime exposure at the level in question, or would produce no observable effect assuming exposure at one thousand times the level in question.

Although the term "any detectable amount" is used by the Act in reference to an exemption from the discharge prohibition of section 25249.5 only, detection of regulated chemicals will be necessary for purposes of the warning requirement of section 25249.6 as well. In other words, as a practical matter it would be necessary to detect the presence of regulated chemicals regardless of whether a discharge, release or exposure is in question.

The listed chemicals which are or are about to become subject to the prohibitions of the Act include several chemicals which are widely distributed in the environment and found as trace constituents and contaminants in many consumer products. Such chemicals include, among the original 29 chemicals, inorganic arsenic, asbestos, benzene, certain chromium compounds, ethylene oxide, lead and certain soots, tars and mineral oils, and now nearly 300 other chemicals.

While the Act does not require that warnings be provided for every exposure to these chemicals or that all discharges or releases of listed chemicals to sources of drinking water be stopped (§§ 25249.9 and 25249.10), the prevalence of these chemicals in the environment and consumer products presents a potential of liability to many persons doing business in California. Confusion or uncertainty as to the methods for detecting chemicals could lead to unnecessary restriction on the availability of consumer products, unnecessary consumer product warnings and unnecessary changes in business operations.

These unnecessary steps could impair public health and safety. Potentially affected products include foods and drugs which may be important in preserving the health and well being of Californians. Unnecessary warnings on such products could distract from other important warnings and, thereby, diminish the safe use of such products. Unnecessary interruption of business activities could result in a loss of jobs for Californians, as well as a reduction in the beneficial use of listed chemicals and products which contain listed chemicals.

Since detection is such a crucial element of the Act, the Agency has decided that it is necessary to adopt standards regarding methods of detection so that all potentially affected parties will know whether a particular situation involves a discharge, release, or exposure of a listed chemical. Such predictability will not only help facilitate compliance by persons subject to the Act, but will assist those parties who may enforce its provisions by minimizing confusion over what is a detectable amount.

Uniform state-wide standards for resolving issues of detection will minimize this potential for confusion. Affected businesses may limit changes in their business activities to those necessary to comply. Such standards will also help to minimize the possibility of different and conflicting interpretations of the Act by those who enforce or interpret its provisions. Since the Act allows enforcement by the Attorney General, 58 district attorneys, many city attorneys and, under certain circumstances, any person in the public interest, the potential for conflicts and confusion in the enforcement of the Act is high.

In General

The purpose of this regulation is to provide some guidance for selecting from what may be several possible analytical methods to use to detect a listed chemical in a specific medium. It provides that "any detectable amount" means an amount detected by the methods of sampling and analysis to which the section refers.

The regulation defines the term "method of analysis" to mean the method of detection, or detection and calculation, for a listed chemical in a specific medium, including methods and procedures concerning the number of samples and the frequency and site of sampling that are specific for the listed chemical in question. This definition makes it clear that the methods referred to in the regulation include those for actual measurement, as well as calculation, of the presence of listed chemicals.

This regulation establishes a hierarchy of methods that did not exist in the earlier regulation. In order of priority, the methods listed are as follows: (1) methods adopted or employed by state or local governmental agencies; (2) methods adopted or employed by a federal agency; (3) methods currently accepted in the scientific community; or (4) any scientifically valid method for the detection or measurement of a listed chemical in a given medium.

If a method exists per the hierarchy, then it must be employed for purposes of the Act. If there is more than one such method within the same level of the hierarchy, any may be utilized. Allowing the use of any method that is within the same level of the hierarchy provides some flexibility while still requiring the use of methods that are based on well-accepted scientific principles.

Requiring that the analytical methods of detection used by regulatory agencies (if any methods exist) also be used for purposes of the Act should enable businesses to continue to monitor releases or exposures through methods that they presently use. It will also allow regulatory agencies which currently monitor for compliance under other existing laws and regulations to monitor for compliance with the Act as well. Enforcement of the Act may be facilitated, since those enforcing the Act may be able to consult with regulatory agencies for assistance in determining compliance.

Because regulated entities are often subject to State or local programs which require the use of specific methods for monitoring of chemicals, or which utilize specific methods of analysis in determining compliance, it is likely that these entities are using such methods rather than one adopted or employed by a Federal agency. Often, the selection of methods by State and local regulatory agencies is based on considerations of the availability of the method to the regulated community and of the suitability of the method to characteristics unique to a particular locality. Thus, preference is given to methods adopted or employed by State or local agencies over those adopted or employed by Federal agencies.

For many chemicals to which the Act applies, there may be no method of analysis used by a regulatory agency. However, there may be a method or methods of analysis generally accepted by the scientific community for a given chemical in a given medium. Those methods should be used, as provided by subsection (d), and if more than one method exists, each method may be used. In the absence of such methods, subsection (e) provides that a scientifically valid method which has been developed for a given chemical in a given medium should be used. If more than one such method exists, again, each may be utilized. The purpose of this provision is to ensure that any such method or methods will be used only if their scientific validity can be established.

The Agency believes that predictability and stability benefits all parties who must implement or enforce the provisions of the Act. The hierarchical approach contained in this regulation enhances the predictability and stability of the Act. Both compliance with and enforcement of the Act are enhanced if clear guidance is given on the methods of analysis to be used in detecting a listed chemical when evaluating compliance with the Act.

Providing clear guidance on the methods to be used avoids the confusion which can result from the use of other methods which may lack scientific validity. To allow use of such other methods could encourage disputes over the threshold question of determining whether a listed chemical is present in a particular medium or within legal limits.

By not specifying the exact methods to be used, but instead setting forth the criteria for determining the methods to be used, the proposed regulation creates an environment in which the continuing development of improved testing methodology is encouraged.

An alternative considered by the Agency was to specify the test or tests which would be appropriate for each listed chemical in each medium. The Agency decided against that approach for several reasons. The growing number of chemicals, the large number of media in which an exposure may occur, the increasing number of analytical methods available for some chemicals, the absence of methods for others, and the lack of information readily accessible to the Agency regarding the relative merit and availability of analytical methods appear to make such a regulation impractical and unwieldy. Moreover, requiring the use of specific methods would not permit the use of other methods of equal merit.

Detailed Summary of Regulation and Comparison with Original Version

As previously mentioned, the final language of the regulation is substantially different from the version of the regulation noticed for the July, 1988 hearing. Subsequent to that hearing, the Agency adopted a revised version of the regulation by emergency action effective October 25, 1988. That revised version is still in effect and is the version covered by this Final Statement of Reasons. In order to understand more fully the evolution of the proposed version, an explanation of its provisions and how they differ from the original version are set forth below.

Subsection (a)

This provision sets forth the general rule that a "detectable amount" (§ 25249.11) should be measured in accordance with this regulation. The prior regulation used the terms "analytical method" or "method of analysis" interchangeably when referring to the process of analysis. The new version uses only the term "method of analysis." A "method of analysis" is intended to communicate that the validity of the analytical results should be examined from a broad standpoint. To communicate this point further, the new version contains a definition of "method of analysis." While part of this definition contains language from former subsection (b), there is a new portion which emphasizes that gathering test samples is just as important as the actual analysis and calculation of results.

This definition also specifies that the methods of analysis used must be specifically designed for the detection of the listed chemical in question as well as for the specific media involved. This principle, which is a required component of any method allowed by this section, is unchanged from the original regulation and is restated in subsections (b), (c), (d), (e) and (f) of the new regulation.

Subsection (b)

Former subsection (b) described the possible sources of methods of analysis which could be used to calculate levels for purposes of the Act. The sources included certain state and local government agencies, any federal agency, or the scientific community.

Previously, methods adopted or employed by any of these sources were considered as equally authoritative. The new regulation sets up a strict hierarchy of use. Specified state and local agencies are now set forth at the top of the hierarchy and methods of analysis "adopted or employed" by those agencies must be used if any such method exists. To the extent that more than one such method is adopted or employed by such agencies, any of them will suffice for purposes of the regulation. In order to increase the availability of appropriate methods of analysis, the list of specified state agencies set forth in the original regulation has been expanded by adding the State Water Resources Control Board and any Regional Water Quality Control Board.

If no state or local agency method exists, then a method adopted or employed by a federal agency must be used (subsection (c)). If more than one such federal agency method exists, any of them can be used. If no federal agency method exists, then any method adopted or employed by the scientific community can be used and if more than one such method exists, each may be used (subsection (d)). When redrafting this regulation, the Agency removed the provisions concerning federal agencies and the scientific community from subsection (b). In the new version, federal agencies are discussed in subsection (c) and the scientific community provision is set forth in subsection (d).

Subsection (c)

Former subsection (c) was moved to a newly created subsection (e). The new version of subsection (c) defines the second "tier" of the hierarchy, which encompasses methods of analysis adopted or employed by federal agencies.

The principle that all methods within the same "tier" of the hierarchy are equally valid (see discussion of subsection (b)) is also set forth in this subsection as well as in subsections (d) and (e).

Subsection (d)

The original version of subsection (d) was moved to become new subsection (f). The new version of subsection (d) is the third "tier" of the hierarchy and is defined as those methods which are generally accepted by the scientific community. The criteria by which such a determination is made is set forth and is unchanged from that which was contained in subsection (b) of the original regulation. Most of the new subsection (d) is taken verbatim from the original version of subsection (b). Any method meeting the definition of this subsection is considered to be equivalent, and any may be utilized.

Subsection (e)

This new subsection is based upon the provisions of former subsection (c). This subsection forms the fourth and lowest tier of the hierarchy and is defined as those methods which are scientifically valid. This subsection comes into play only when no method is available under one of the other three "tiers" of the hierarchy.

The fact that this subsection uses the term "scientifically valid" while the other "tiers" do not is not intended to imply that methods defined by those other provisions ((b), (c), (d)) are scientifically invalid. It is presumed that any method adopted or employed by a specified state or local agency (b), a federal agency (c), or generally accepted by the scientific community (d) will be "scientifically valid." However, this presumption of validity is available only if the method chosen is actually performed in a proper manner (see subsection (f)).

When drafting this subsection, two clauses from the original subsection (c) were dropped. The phrase "analytical method has been developed for the detection or measurement" was replaced with "method of analysis has been developed." The phrase "including, but not limited to, water, air, food, or soil," has been dropped altogether. These two changes were because these concepts are set forth in the revised subsection (a) and do not need to be repeated in other subsections.

Subsection (f)

This new subsection is a revised version of subsection (d) from the original regulation. This provision specifies that any analysis must be performed in accordance with generally accepted practices and standards. No method of analysis can be considered to be scientifically valid unless it is both properly designed and performed. New subsection (a) relates to proper design while this subsection deals with the actual performance.

There are two differences between the original version of this provision and the new text. First, "laboratory" was deleted before the phrases "analysis to determine the concentration of a chemical" and "standards and practice." Secondly, the term

"modeling" was added to the list of items considered to be a standard or a practice relating to methods of analysis.

The reason for the first change is that the laboratory work is only part of the total testing process. The process of sampling which precedes the laboratory stage, and the data analysis phase which follows are all required to be done in accordance with generally accepted standards and practices.

The second change was made because "modeling" can be a critical portion of testing. For example, measurements and modeling are important in evaluations of airborne dispersion of chemicals. Thus, modeling is highly relevant to any Proposition 65 case which involves airborne transmission of listed chemicals.

Subsection (g)

This subsection is new in terms of the actual text, but is merely an express statement of that which the Agency considers to have been implied in the original version of this regulation. Subsection (g) expressly states that there can be no discharge, release, or exposure under the Act if the listed chemical involved is not "detectable as provided in this section." This means that no violation of Proposition 65 can be found unless there exists a method of analysis which meets the requirements of this regulation.

Review of Comments Regarding Original Version of Regulation

The comments and suggestions which the Agency received regarding the original version of this regulation are summarized below:

1. Level of detail and specificity regarding analytical methods.

While commentors ranged widely in their specific suggestions, the basic theme underlying all of the comments in this area was that the Agency should provide specific information on either the type of method to be used or the practices and standards to follow when performing tests to determine the level of a listed chemical in a given medium. Some suggested that a specific test be identified for each listed chemical in each medium. Other persons asked that specific test procedure guidelines or regulations published by administrative agencies (such as the Environmental Protection Agency) be required for purposes of detecting listed chemicals. Other persons recommended that there be a hierarchy of tests from specified sources so that an identifiable class of tests would be given priority over other available methods.

The hierarchy approach referred to above has been adopted by the Agency. The reason why specified state and local agency methods were given first priority is because persons doing business in California would tend to be familiar with and used to dealing with state and local regulatory agencies. Also, state and local agencies would tend to call for the use of test methods which are appropriate for use with other state and/or local programs. As a

result, information about these tests should be readily available in this state.

Methods specified by federal agencies were set as the second tier priority because although those methods would share many of the characteristics of the state and local agency methods, the federal methods would tend to be less tailored to California's needs.

Placing these governmental agencies in the top tiers allows persons to rely upon the test results without having to be concerned with proving the scientific validity of such tests. In proposing this hierarchy, the Agency is presuming that methods adopted or employed by governmental agencies for the detection of a specific chemical in a specific medium will be scientifically valid. This presumption is largely extended to the third tier (those methods generally accepted by the scientific community), although there is an additional burden of establishing such general acceptance. Methods taken from the fourth and last tier must be supported by evidence proving their scientific validity.

The Agency also decided to provide more detail regarding the manner by which these analytical methods (renamed "methods of analysis" as discussed earlier) are performed. The new provisions make it clear that the validity of the standards and practices used is to be evaluated by looking to the total process, from test design to the interpretation of results. The original version of the regulation seemed to be viewed by some commentors as being concerned only with the laboratory phase. The Agency has now made it clear that the laboratory phase is but one part of the test process, all of which must be properly performed in a scientifically sound manner.

The Agency has rejected the approach suggested by those who would prefer that specific methods, standards, and practices be specifically identified. The Environmental Protection Agency was mentioned by some as an appropriate source of this information. As discussed earlier, the Agency decided that requiring specific methods, standards, and practices would be counter-productive because it could preclude the use of other equally valid approaches. Also, the development of new approaches would be discouraged if the regulation was specific as to test, standard or practice.

2. Clarify the applicability of the regulation.

Many commentors were concerned that the regulation would be applied only to discharges or releases (§ 25249.5) and not to exposures (§ 25249.6). This belief was apparently based upon the fact that the original version of the regulation did not contain any specific reference concerning its applicability to exposures. Such a reference was made only in the Initial Statement of Reasons for that version. Since it was clearly the Agency's intent that the regulation be applicable to exposures, a specific provision (subsection (g)) has been added to expressly declare the Agency's original intent.

In a related question about the applicability of the regulation, it was asked whether or not the Act applied only to detectable amounts of listed chemicals. That was the Agency's intent in the original regulation and that intent has been made express in subsection (g) of the new regulation.

3. The duration of time upon which test results can be relied.

Comments suggested that once valid results are obtained, a person in the course of doing business should be able to rely upon those results for some specified period of time. Five years was the time suggested. Part of the rationale presented in support of this suggestion was that persons in the course of doing business should not be expected to keep abreast of the day-to-day advances in the scientific development of methods of detection.

The Agency agrees that persons in the course of doing business should not have to expend unreasonable amounts of resources keeping track of new test methods. However, such persons should not be able to ignore information which they can reasonably be expected to obtain or to respond to when presented to them. Proposition 65 applies only to persons who "knowingly" discharge or release listed chemicals or "knowingly and intentionally" expose an individual to a listed chemical.

For example, consider the situation in which a new test method might be developed that is more sensitive than pre-existing methods and a particular business was found, using the new test, to be discharging an amount that would violate the Act. That business had been properly using one of the pre-existing methods and the level of the listed chemical in question was below the limit of detection of the old methods. If the new method is within the same "tier" of the test hierarchy as the highest level tests previously in use (e.g., both the new test and the pre-existing tests are "adopted or employed" by a state agency), then the business should be required to be subject to the more sensitive test, and liability under the Act subsequently might be found (because a "knowing" discharge would thereafter be occurring).

If the new test had just been adopted or employed by a specified state agency, then no retroactive liability should be found. However, if the state agency drops the old, less sensitive test in favor of the new test, there is no justification for allowing the continued reliance upon the old method.

It should be noted that reliance upon the results of a currently valid test method may become unreasonable. For example, a business which knows or reasonably should be expected to know that the relevant conditions existing at the time of the last test have changed would not be able to continue reliance on the old results. In such a case, retesting would be called for and liability under the Act could be found for a discharge, release, or exposure which occurred after the business knew or should have known of the changed conditions. Absent any change in relevant

conditions of which the business should have been aware, reliance upon prior test results would be reasonable and retroactive liability under the Act would not normally be present.

4. Validity of test methods which have not been generally accepted by the scientific community.

It was suggested that any analytical method (method of analysis) which has not been generally accepted by the scientific community should be automatically considered to be of dubious value. It was further suggested that such tests be usable only by its developer.

The Agency disagrees because both the original regulation as well as the new version require that any such method be proven to be "scientifically valid." If its validity can be so proven, then a test is not of dubious value. There is also no justification for limiting the use of a valid test to its developer. To the extent that the method is usable under the hierarchy, it should be available to anybody.

One goal of the regulation proposed by the Agency is to promote the development of new methods where none currently exist, as well as to encourage advances in current methods. The suggestion herein discussed would be counter to that goal.

Review of Comments Regarding Adopted Version of the Regulation.

The Agency received four comments in response to the July 11, 1989 notice which announced the Agency's intent to adopt the revised version of this regulation. A summary of each comment, and the Agency's response to each comment is set forth below.

One commentor urged that the Agency adopt the use of specific methods for each listed chemical in each medium (C-9 pages 3-4). The reasons why the Agency has not adopted the approach suggested by this commentor already has been thoroughly discussed earlier in this Final Statement of Reasons and need not be further elaborated here.

Another commentor felt that the original version of the regulation should be adopted in place of the revised version adopted by the Agency (C-7 pages 2-3). This commentor felt that companies which do business on a nationwide basis should not have to become familiar with California state and local government agency approved methods of detection. However, this commentor also stated that "national companies are familiar with and use methods to ensure that their products comply with federal, state and local standards." The latter statement is inconsistent with the former and seems to strongly indicate that national companies are already used to dealing with such standards and are complying on an on-going basis.

This statement of reasons has thoroughly discussed the Agency's reasons for adopting the hierarchy approach of the regulation and

the rationale behind giving a preference to California state and local agency methods and the reader is directed to those portions of this document.

This same commentor also criticized the revised version of the regulation because, unlike the original version, it did not require use of the most sensitive method available. The commentor's statements are incorrect because neither version of the regulation requires use of the most sensitive method, but instead has given equal dignity to all methods within a defined scope of acceptability. To the extent that more than one method within the same tier of the hierarchy exists, each may be equally relied upon.

Another commentor felt that the regulation should be clarified to state that the defendant in an enforcement action under the Act can rely upon the method of detection chosen by that defendant so long as it is from the highest tier of the hierarchy from which methods are available (C-10 page 3-4). The Agency believes that the regulation already clearly states that all test methods within the same tier can be equally relied upon. This commentor was concerned that a plaintiff in an enforcement action under the Act could require the use of a test within the same tier if that test was more sensitive than the one relied upon by the defendant. So long as the defendant relies upon a test which is within the highest available tier, then the defendant will be entitled to rely upon those results.

This commentor felt that subsections (c) and (d), which relate to methods adopted or employed by federal agencies and methods generally accepted by the scientific community respectively, should be subject to inter-laboratory or collaborative testing before the use of such methods is allowed (C-10 page 5). It should be noted that, in light of this commentor's discussion of this objection, he/she meant to refer to subsections (d) and (e) which refer to methods generally accepted by the scientific community and methods which are scientifically valid respectively. The Agency's response to this comment will be made with the assumption noted.

The Agency does not feel that there is any need to be more specific than that reflected in the regulation. There is an express requirement that all phases of the testing be done in a scientifically valid manner. The ability to obtain consistent test results is an essential principle of scientific validity. The regulation does not need to list every possible way of assessing such validity.

This commentor believed that the regulation should expressly state that no method of analysis should be available for use under this section unless it is reasonably available at a reasonable price to persons in the course of doing business (C-10 page 5). This commentor was concerned that a business could be held to violate the act due to a method of analysis which the business either did not know existed or which was not reasonably available.

This comment fails to recognize that liability under the Act is present only when there is a knowing discharge or release, or a knowing and intentional exposure. If a person in the course of doing business first learns about a discharge, release, or exposure by way of the plaintiff in an enforcement action under the Act, and the defendant could not have reasonably been expected to have known about the available method which would have detected the presence of a listed chemical, then no retroactive liability would exist. However, discharges, releases, or exposures which occurred after the defendant learned of the presence of the listed chemical(s) could result in liability under the Act.

Another commentor noted that a portion of the initial statement of reasons prepared by the Agency contained statements which were inconsistent with the regulation (C-11 page 1-2). The statement to which this commentor refers was phrased in such a way so that no liability under the Act could be found unless the discharge, release, or exposure in question had actually been the subject of a method of analysis authorized by this regulation. This commentor is correct that any such statement is erroneous because the regulation only requires that the listed chemical be "detectable", not actually detected. The fact that a detectable amount of a listed chemical was involved in a discharge, release, or exposure can be proven by any evidence sufficient to carry the burden of proof. As a result, the erroneous portion of the statement of reasons has been corrected.