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FINAL
STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS

Section 12705(b) - Specific Regulatory Levels Posing No Significant Risk

The Safe Drinking Water and Toxic Enforcement Act of 1986 (hereinafter the Act) prohibits a person in the course of doing business from knowingly and intentionally exposing any individual to a chemical that has been listed as known to the State to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual (Health and Safety Code Section 25249.6). The Act also prohibits a business from knowingly discharging a listed chemical into water or onto or into land where such chemical passes or probably will pass into a source of drinking water (Health and Safety Code Section 25249.5).

For chemicals known to the state to cause cancer, an exemption is provided by the Act when a person in the course of doing business is able to demonstrate that an exposure for which it is responsible poses no significant risk, or that a discharge which otherwise complies with applicable requirements would result in an exposure through drinking water at a level which poses no significant risk (Health and Safety Code Sections 25249.10 and 25249.11). A determination that a level of exposure poses no significant risk can be made utilizing regulations that have previously been adopted by the Health and Welfare Agency (Section 12701 to 12721, Title 22, California Code of Regulations). Section 12701 describes alternative methods for making such a determination. One such method is through the application of the specific regulatory level established for the chemical in question in Section 12705. Section 12705(b) supersedes Section 12709 (Exposure to Trace Elements), Section 12711 (Levels Based on State or Federal Standards), or Section 12713 (Exposure to Food, Drugs, Cosmetics and Medical Devices).

Procedural Background

On July 11, 1989 the Agency issued a notice of proposed rulemaking advising that the Agency intended to adopt a "no significant risk" level for benzidine. Pursuant to such notice, on September 13, 1989, a public hearing was held to receive public comments on the proposed regulation. Two pieces of correspondence commenting on Section 12705(b) was received; no comments were received at the public hearing.

Purpose of Final Statement of Reasons

This final statement of reasons sets forth the reasons for the final regulation adopted by the Agency for Section 12705(b), and responds to the objections and recommendations submitted regarding the regulation. 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.

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 12705(b). However, because regulations other than Section 12705(b) were also the topic of the public hearing on September 13, 1989, the rulemaking file contains some material not relevant to Section 12705(b). This final statement of reasons cites only the relevant material. Comments regarding the regulations other than Section 12705(b) discussed at the September 13, 1989 hearing have been or will be discussed in separate final statements of reasons.

Necessity for Adoption of Regulations

The Agency has determined that the adoption of this regulation is necessary. For chemicals known to the State to cause cancer, the Act exempts discharges, releases and exposure which, making certain assumptions, pose no significant risk. The Act specifies that any claim of exemption under Health and Safety Code section 25249.10, subsection (c) must be based upon evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of the chemical. However, the Act does not further clarify when a chemical risk is not significant, nor specify levels of chemical exposure posing no significant risk. Existing regulations describe methods for calculating levels which pose no significant risk.

The purpose of this regulation is to provide a "safe harbor" no significant risk level which will assist persons in determining whether a discharge, release or exposure is exempt from the provisions of the Act.

Section 12705(b)

This proposed regulation adopts a no significant risk level for benzidine of 0.001 microgram per day for purposes of the Act in Section 12705(b), and repeals the no significant risk level for this chemical in Section 12711. Although Section 12701 explicitly states that Section 12711 applies only when no specific level is established for the chemical in Section 12705, deletion of the chemical and its level from Section 12711 is necessary for clarity and to avoid confusion. This proposed level represents the level of exposure which is calculated to result in no more than one excess case of cancer in an exposed population of 100,000, assuming exposure over a 70-year lifetime (10^{-5} lifetime risk of cancer), and is based on the risk assessment document prepared by the California Department of Health Services utilizing the principles in Section 12703 ("Risk-Specific Intake Levels for the Proposition 65 Carcinogen Benzidine," Reproductive and Cancer Hazard Assessment Section, Office of Environmental Health Hazard Assessment, California Department of Health Services, November 1, 1988). The findings of this risk assessment document are summarized as follows:

Based on an epidemiological study of workers who developed bladder tumors after occupational exposure to benzidine, a cancer potency of 500 $(mg/kg\text{-}day)^{-1}$ has been selected for estimating risks from exposure to benzidine. From this value, the intake level associated with a 10^{-5} lifetime risk of cancer is 0.001 microgram per day.

One commentor (C-9) felt that the public should be invited to participate in the Department of Health Services' preparation of a health risk assessment, and that the Health and Welfare Agency should retain its authority as the "ultimate decision maker" for any decisions associated with the implementation of the Act.

The commentor evidently is unaware that the Agency did publish in 1988 a schedule of risk assessments to be performed by the Department of Health Services with an invitation to submit pertinent information. Many interested parties have participated in this process and continue to do so. In addition, the agenda of the Scientific Advisory Panel meetings indicate risk assessments to be discussed, and interested parties may provide information to the Agency and to the Panel. Finally, the commentor appears to be unaware that the Health and Welfare Agency is the "lead agency" for the implementation of the Act, and therefore is the "ultimate decision maker" in these matters.

One commentor (C-11) contended that the no significant risk levels did not represent the "plausible upper bound limits" of the actual risk posed by the chemicals to individuals. The commentor believes the risk assessments are "particularly weak" in their handling of highly sensitive subpopulations, and that the risk to highly exposed individuals is also likely to be underestimated.

The Agency believes these concerns to be important, but already addressed in the regulations. Because the assessment of risk is based upon the upper 95 percent confidence level, this means that the assessment is unlikely to underestimate the actual risk. Further, where there are highly sensitive subpopulations, more often than not the greatest source of increased susceptibility will reflect an increased exposure by a subpopulation. For example, the average quantity of milk ingested per day per kilogram of body weight by an infant (e.g., 1 liter per 10 kilograms = 0.1 liter per kilogram) is much greater than that ingested by an 70-kilogram adult (e.g., 0.3 liter per 70 kilograms = 0.04 liter per kilogram). The Agency anticipated special concerns about specific subpopulations in Section 12721(d)(2), which sets forth assumptions for exposures to certain subpopulations.

The question of highly exposed individuals is also addressed in Section 12721(b) and 12721(d). In order to determine the significance of an exposure, one must make realistic assumptions about exposures. A business cannot reasonably anticipate exposures that are aberrant and excessive. To the extent that the "high" exposures are predictable (e.g., workplace exposures or age- or gender-related exposures), they are already addressed in the subsections mentioned above.

In addition, the commentor offered general statements on risk assessment, selection of chemicals, priorities, and timing of the regulation, which are not comments on the specific regulation, and therefore do not require a response from the Agency.

The proposed level for benzidine and the risk assessment document which provides the basis for the proposed regulation were submitted to the Scientific Advisory Panel for review and comment on April 14, 1989. While the members of the Panel provided general comments on the document, they did not comment on the proposed level.

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Section 12705(b) - Specific Regulatory Levels Posing No Significant Risk

The Safe Drinking Water and Toxic Enforcement Act of 1986 (hereinafter the Act) prohibits a person in the course of doing business from knowingly and intentionally exposing any individual to a chemical that has been listed as known to the State to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual (Health and Safety Code Section 25249.6). The Act also prohibits a business from knowingly discharging a listed chemical into water or onto or into land where such chemical passes or probably will pass into a source of drinking water (Health and Safety Code Section 25249.5).

For chemicals known to the state to cause cancer, an exemption is provided by the Act when a person in the course of doing business is able to demonstrate that an exposure for which it is responsible poses no significant risk, or that a discharge which otherwise complies with applicable requirements would result in an exposure through drinking water at a level which poses no significant risk (Health and Safety Code Sections 25249.10 and 25249.11). A determination that a level of exposure poses no significant risk can be made utilizing regulations that have previously been adopted by the Health and Welfare Agency (Section 12701 to 12721, Title 22, California Code of Regulations). Section 12701 describes alternative methods for making such a determination. One such method is through the application of the specific regulatory level established for the chemical in question in Section 12705. Section 12705(b) supersedes Section 12709 (Exposure to Trace Elements), Section 12711 (Levels Based on State or Federal Standards), or Section 12713 (Exposure to Food, Drugs, Cosmetics and Medical Devices).

Procedural Background

On July 11, 1989 the Agency issued a notice of proposed rulemaking advising that the Agency intended to adopt a "no significant risk" level for bis(2-chloroethyl)ether. Pursuant to such notice, on September 13, 1989, a public hearing was held to receive public comments on the proposed regulation. Two pieces of correspondence commenting on Section 12705(b) was received; no comments were received at the public hearing.

Purpose of Final Statement of Reasons

This final statement of reasons sets forth the reasons for the final regulation adopted by the Agency for Section 12705(b), and responds to the objections and recommendations submitted regarding the regulation. 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.

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 12705(b). However, because regulations other than Section 12705(b) were also the topic of the public hearing on September 13, 1989, the rulemaking file contains some material not relevant to Section 12705(b). This final statement of reasons cites only the relevant material. Comments regarding the regulations other than Section 12705(b) discussed at the September 13, 1989 hearing have been or will be discussed in separate final statements of reasons.

Necessity for Adoption of Regulations

The Agency has determined that the adoption of this regulation is necessary. For chemicals known to the State to cause cancer, the Act exempts discharges, releases and exposure which, making certain assumptions, pose no significant risk. The Act specifies that any claim of exemption under Health and Safety Code section 25249.10, subsection (c) must be based upon evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of the chemical. However, the Act does not further clarify when a chemical risk is not significant, nor specify levels of chemical exposure posing no significant risk. Existing regulations describe methods for calculating levels which pose no significant risk.

The purpose of this regulation is to provide a "safe harbor" no significant risk level which will assist persons in determining whether a discharge, release or exposure is exempt from the provisions of the Act.

Section 12705(b)

This proposed regulation adopts a no significant risk level for bis(2-chloroethyl)ether of 0.3 microgram per day for purposes of the Act in Section 12705(b). This proposed level represents the level of exposure which is calculated to result in no more than one excess case of cancer in an exposed population of 100,000, assuming exposure over a 70-year lifetime (10^{-5} lifetime risk of cancer), and is based on the risk assessment document prepared by the California Department of Health Services utilizing the principles in Section 12703 ("Risk-Specific Intake Levels for the Proposition 65 Carcinogen Bis(2-chloroethyl)ether," Reproductive and Cancer Hazard Assessment Section, Office of Environmental Health Hazard Assessment, California Department of Health Services, November 1, 1988). The findings of this risk assessment document are summarized as follows:

A cancer potency of 2.5 $(mg/kg\text{-}day)^{-1}$ was estimated from bis(2-chloroethyl)ether dose-response data for hepatomas in hybrid (C57BL/6 X C3H/Anf) male mice, the most sensitive sex, strain and species tested. Using this value to estimate cancer risks from exposure to bis(2-chloroethyl)ether, the intake level associated with a 10^{-5} lifetime risk of cancer is 0.3 microgram per day.

One commentor (C-9) felt that the public should be invited to participate in the Department of Health Services' preparation of a health risk assessment, and that the Health and Welfare Agency should retain its authority as the "ultimate decision maker" for any decisions associated with the implementation of the Act.

The commentor evidently is unaware that the Agency did publish in 1988 a schedule of risk assessments to be performed by the Department of Health Services with an invitation to submit pertinent information. Many interested parties have participated in this process and continue to do so. In addition, the agenda of the Scientific Advisory Panel meetings indicate risk assessments to be discussed, and interested parties may provide information to the Agency and to the Panel. Finally, the commentor appears to be unaware that the Health and Welfare Agency is the "lead agency" for the implementation of the Act, and therefore is the "ultimate decision maker" in these matters.

One commentor (C-11) contended that the no significant risk levels did not represent the "plausible upper bound limits" of the actual risk posed by the chemicals to individuals. The commentor believes the risk assessments are "particularly weak" in their handling of highly sensitive subpopulations, and that the risk to highly exposed individuals is also likely to be underestimated.

The Agency believes these concerns to be important, but already addressed in the regulations. Because the assessment of risk is based upon the upper 95 percent confidence level, this means that the assessment is

unlikely to underestimate the actual risk. Further, where there are highly sensitive subpopulations, more often than not the greatest source of increased susceptibility will reflect an increased exposure by a subpopulation. For example, the average quantity of milk ingested per day per kilogram of body weight by an infant (e.g., 1 liter per 10 kilograms = 0.1 liter per kilogram) is much greater than that ingested by an 70-kilogram adult (e.g., 0.3 liter per 70 kilograms = 0.04 liter per kilogram). The Agency anticipated special concerns about specific subpopulations in Section 12721(d)(2), which sets forth assumptions for exposures to certain subpopulations.

The question of highly exposed individuals is also addressed in Section 12721(b) and 12721(d). In order to determine the significance of an exposure, one must make realistic assumptions about exposures. A business cannot reasonably anticipate exposures that are aberrant and excessive. To the extent that the "high" exposures are predictable (e.g., workplace exposures or age- or gender-related exposures), they are already addressed in the subsections mentioned above.

In addition, the commentor offered general statements on risk assessment, selection of chemicals, priorities, and timing of the regulation which are not comments on the specific regulation, and therefore do not require a response from the Agency.

The proposed level for bis(2-chloroethyl)ether and the risk assessment document which provides the basis for the proposed regulation were submitted to the Scientific Advisory Panel for review and comment on April 14, 1989. While the members of the Panel provided general comments on the document, they did not comment on the proposed level.

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Section 12705(b) - Specific Regulatory Levels Posing No Significant Risk

The Safe Drinking Water and Toxic Enforcement Act of 1986 (hereinafter the Act) prohibits a person in the course of doing business from knowingly and intentionally exposing any individual to a chemical that has been listed as known to the State to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual (Health and Safety Code Section 25249.6). The Act also prohibits a business from knowingly discharging a listed chemical into water or onto or into land where such chemical passes or probably will pass into a source of drinking water (Health and Safety Code Section 25249.5).

For chemicals known to the state to cause cancer, an exemption is provided by the Act when a person in the course of doing business is able to demonstrate that an exposure for which it is responsible poses no significant risk, or that a discharge which otherwise complies with applicable requirements would result in an exposure through drinking water at a level which poses no significant risk (Health and Safety Code Sections 25249.10 and 25249.11). A determination that a level of exposure poses no significant risk can be made utilizing regulations that have previously been adopted by the Health and Welfare Agency (Section 12701 to 12721, Title 22, California Code of Regulations). Section 12701 describes alternative methods for making such a determination. One such method is through the application of the specific regulatory level established for the chemical in question in Section 12705. Section 12705(b) supersedes Section 12709 (Exposure to Trace Elements), Section 12711 (Levels Based on State or Federal Standards), or Section 12713 (Exposure to Food, Drugs, Cosmetics and Medical Devices).

Procedural Background

On July 11, 1989 the Agency issued a notice of proposed rulemaking advising that the Agency intended to adopt a "no significant risk" level for N-nitrosodiethylamine. Pursuant to such notice, on September 13, 1989, a public hearing was held to receive public comments on the proposed regulation. Two pieces of correspondence commenting on Section 12705(b) was received; no comments were received at the public hearing.

Purpose of Final Statement of Reasons

This final statement of reasons sets forth the reasons for the final regulation adopted by the Agency for Section 12705(b), and responds to the objections and recommendations submitted regarding the regulation. 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.

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 12705(b). However, because regulations other than Section 12705(b) were also the topic of the public hearing on September 13, 1989, the rulemaking file contains some material not relevant to Section 12705(b). This final statement of reasons cites only the relevant material. Comments regarding the regulations other than Section 12705(b) discussed at the September 13, 1989 hearing have been or will be discussed in separate final statements of reasons.

Necessity for Adoption of Regulations

The Agency has determined that the adoption of this regulation is necessary. For chemicals known to the State to cause cancer, the Act exempts discharges, releases and exposure which, making certain assumptions, pose no significant risk. The Act specifies that any claim of exemption under Health and Safety Code section 25249.10, subsection (c) must be based upon evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of the chemical. However, the Act does not further clarify when a chemical risk is not significant, nor specify levels of chemical exposure posing no significant risk. Existing regulations describe methods for calculating levels which pose no significant risk.

The purpose of this regulation is to provide a "safe harbor" no significant risk level which will assist persons in determining whether a discharge, release or exposure is exempt from the provisions of the Act.

Section 12705(b)

This proposed regulation adopts a no significant risk level for N-nitrosodiethylamine of 0.02 microgram per day for purposes of the Act in Section 12705(b), and repeals the no significant risk level for this chemical in Section 12711. Although Section 12701 explicitly states that Section 12711 applies only when no specific level is established for the chemical in Section 12705, deletion of the chemical and its level from Section 12711 is necessary for clarity and to avoid confusion. This proposed level represents the level of exposure which is calculated to result in no more than one excess case of cancer in an exposed population of 100,000, assuming exposure over a 70-year lifetime (10^{-5} lifetime risk of cancer), and is based on the risk assessment document prepared by the California Department of Health Services utilizing the principles in Section 12703 ("Risk-Specific Intake Levels for the Proposition 65 Carcinogen N-Nitrosodiethylamine," Reproductive and Cancer Hazard Assessment Section, Office of Environmental Health Hazard Assessment, California Department of Health Services, October 1, 1988). The findings of this risk assessment document are summarized as follows:

Cancer potency values were estimated from several chronic animal bioassays and found to range from 12 to 175 $(mg/kg\text{-}day)^{-1}$. An experiment in Colworth rats was found to be most appropriate for estimating potency because multiple dose levels were used and some dose groups received N-nitrosodiethylamine in very small amounts. From this study, a cancer potency of 36 $(mg/kg\text{-}day)^{-1}$ was estimated. This potency value is within a factor of three of those estimated from malignant tumor data from other experiments. From this value, the intake level associated with a 10^{-5} lifetime risk of cancer is 0.02 microgram per day.

One commentor (C-9) felt that the public should be invited to participate in the Department of Health Services' preparation of a health risk assessment, and that the Health and Welfare Agency should retain its authority as the "ultimate decision maker" for any decisions associated with the implementation of the Act.

The commentor evidently is unaware that the Agency did publish in 1988 a schedule of risk assessments to be performed by the Department of Health Services with an invitation to submit pertinent information. Many interested parties have participated in this process and continue to do so. In addition, the agenda of the Scientific Advisory Panel meetings indicate risk assessments to be discussed, and interested parties may provide information to the Agency and to the Panel. Finally, the commentor appears to be unaware that the Health and Welfare Agency is the "lead agency" for the implementation of the Act, and therefore is the "ultimate decision maker" in these matters.

One commentor (C-11) contended that the no significant risk levels did not represent the "plausible upper bound limits" of the actual risk posed by the chemicals to individuals. The commentor believes the risk

assessments are "particularly weak" in their handling of highly sensitive subpopulations, and that the risk to highly exposed individuals is also likely to be underestimated.

The Agency believes these concerns to be important, but already addressed in the regulations. Because the assessment of risk is based upon the upper 95 percent confidence level, this means that the assessment is unlikely to underestimate the actual risk. Further, where there are highly sensitive subpopulations, more often than not the greatest source of increased susceptibility will reflect an increased exposure by a subpopulation. For example, the average quantity of milk ingested per day per kilogram of body weight by an infant (e.g., 1 liter per 10 kilograms = 0.1 liter per kilogram) is much greater than that ingested by an 70-kilogram adult (e.g., 0.3 liter per 70 kilograms = 0.04 liter per kilogram). The Agency anticipated special concerns about specific subpopulations in Section 12721(d)(2), which sets forth assumptions for exposures to certain subpopulations.

The question of highly exposed individuals is also addressed in Section 12721(b) and 12721(d). In order to determine the significance of an exposure, one must make realistic assumptions about exposures. A business cannot reasonably anticipate exposures that are aberrant and excessive. To the extent that the "high" exposures are predictable (e.g., workplace exposures or age- or gender-related exposures), they are already addressed in the subsections mentioned above.

The same commentor stated that the level for N-nitrosodiethylamine was not calculated using the highest experimentally determined potency. The risk assessment which was used as the basis for establishing the level was conducted following the provisions of Section 12703. The default assumptions in Section 12703 were used in the absence of scientifically more appropriate assumptions. Where there was scientifically valid evidence indicating that assumptions other than the default were more appropriate, alternative assumptions were used.

The commentor is correct in stating that the highest cancer potency was not selected in calculating the no significant risk level for N-nitrosodiethylamine. The rationale for this is explained in the risk assessment document. Briefly, the cancer potency selected by CDHS is based on a sensitive low-dose study which was most representative of the chemical's cancer potency. Although larger potency values were derived from other experiments, those experiments were run at higher dose levels with fewer animals and are unlikely to provide as representative an estimate of low dose potency.

In addition, the commentor offered general statements on risk assessment, selection of chemicals, priorities, and timing of the regulation which are not comments on the specific regulation, and therefore do not require a response from the Agency.

The proposed level for N-nitrosodiethylamine and the risk assessment document which provides the basis for the proposed regulation were submitted to the Scientific Advisory Panel for review and comment on December 16, 1988. While the members of the Panel provided general comments on the document, they did not comment on the proposed level.

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Section 12705(b) - Specific Regulatory Levels Posing No Significant Risk

The Safe Drinking Water and Toxic Enforcement Act of 1986 (hereinafter the Act) prohibits a person in the course of doing business from knowingly and intentionally exposing any individual to a chemical that has been listed as known to the State to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual (Health and Safety Code Section 25249.6). The Act also prohibits a business from knowingly discharging a listed chemical into water or onto or into land where such chemical passes or probably will pass into a source of drinking water (Health and Safety Code Section 25249.5).

For chemicals known to the state to cause cancer, an exemption is provided by the Act when a person in the course of doing business is able to demonstrate that an exposure for which it is responsible poses no significant risk, or that a discharge which otherwise complies with applicable requirements would result in an exposure through drinking water at a level which poses no significant risk (Health and Safety Code Sections 25249.10 and 25249.11). A determination that a level of exposure poses no significant risk can be made utilizing regulations that have previously been adopted by the Health and Welfare Agency (Section 12701 to 12721, Title 22, California Code of Regulations). Section 12701 describes alternative methods for making such a determination. One such method is through the application of the specific regulatory level established for the chemical in question in Section 12705. Section 12705(b) supersedes Section 12709 (Exposure to Trace Elements), Section 12711 (Levels Based on State or Federal Standards), or Section 12713 (Exposure to Food, Drugs, Cosmetics and Medical Devices).

Procedural Background

On July 11, 1989 the Agency issued a notice of proposed rulemaking advising that the Agency intended to adopt a "no significant risk" level for N-nitrosodimethylamine. Pursuant to such notice, on September 13, 1989, a public hearing was held to receive public comments on the proposed regulation. Two pieces of correspondence commenting on Section 12705(b) was received; no comments were received at the public hearing.

Purpose of Final Statement of Reasons

This final statement of reasons sets forth the reasons for the final regulation adopted by the Agency for Section 12705(b), and responds to the objections and recommendations submitted regarding the regulation. 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.

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 12705(b). However, because regulations other than Section 12705(b) were also the topic of the public hearing on September 13, 1989, the rulemaking file contains some material not relevant to Section 12705(b). This final statement of reasons cites only the relevant material. Comments regarding the regulations other than Section 12705(b) discussed at the September 13, 1989 hearing have been or will be discussed in separate final statements of reasons.

Necessity for Adoption of Regulations

The Agency has determined that the adoption of this regulation is necessary. For chemicals known to the State to cause cancer, the Act exempts discharges, releases and exposure which, making certain assumptions, pose no significant risk. The Act specifies that any claim of exemption under Health and Safety Code section 25249.10, subsection (c) must be based upon evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of the chemical. However, the Act does not further clarify when a chemical risk is not significant, nor specify levels of chemical exposure posing no significant risk. Existing regulations describe methods for calculating levels which pose no significant risk.

The purpose of this regulation is to provide a "safe harbor" no significant risk level which will assist persons in determining whether a discharge, release or exposure is exempt from the provisions of the Act.

Section 12705(b)

This proposed regulation adopts a no significant risk level for N-nitrosodimethylamine of 0.04 microgram per day for purposes of the Act in Section 12705(b), and repeals the no significant risk level for this chemical in Section 12711. Although Section 12701 explicitly states that Section 12711 applies only when no specific level is established for the chemical in Section 12705, deletion of the chemical and its level from Section 12711 is necessary for clarity and to avoid confusion. This proposed level represents the level of exposure which is calculated to result in no more than one excess case of cancer in an exposed population of 100,000, assuming exposure over a 70-year lifetime (10^{-5} lifetime risk of cancer), and is based on the risk assessment document prepared by the California Department of Health Services utilizing the principles in Section 12703 ("Risk-Specific Intake Levels for the Proposition 65 Carcinogen N-Nitrosodimethylamine," Reproductive and Cancer Hazard Assessment Section, Office of Environmental Health Hazard Assessment, California Department of Health Services, October 1, 1988). The findings of this risk assessment document are summarized as follows:

Cancer potency was estimated from several chronic animal bioassays and was found to range from 12 to 49 $(mg/kg\text{-}day)^{-1}$. An experiment on Colworth rats was found to be the most appropriate for estimating potency for several reasons: multiple dose levels and adequate numbers of animals were used; a dose response was obtained over a wide dose range and down to low doses; and time-to-tumor data were considered in the analysis. The potency estimated from this experiment was within a factor of 4 of potencies estimated from other experiments using dose-response data for malignant tumors. From this study, a cancer potency of 16 $(mg/kg\text{-}day)^{-1}$ was estimated. From this value, the intake level associated with a 10^{-5} lifetime risk of cancer is 0.04 microgram per day.

One commentor (C-9) felt that the public should be invited to participate in the Department of Health Services' preparation of a health risk assessment, and that the Health and Welfare Agency should retain its authority as the "ultimate decision maker" for any decisions associated with the implementation of the Act.

The commentor evidently is unaware that the Agency did publish in 1988 a schedule of risk assessments to be performed by the Department of Health Services with an invitation to submit pertinent information. Many interested parties have participated in this process and continue to do so. In addition, the agenda of the Scientific Advisory Panel meetings indicate risk assessments to be discussed, and interested parties may provide information to the Agency and to the Panel. Finally, the commentor appears to be unaware that the Health and Welfare Agency is the "lead agency" for the implementation of the Act, and therefore is the "ultimate decision maker" in these matters.

One commentor (C-11) contended that the no significant risk levels did not represent the "plausible upper bound limits" of the actual risk posed by the chemicals to individuals. The commentor believes the risk assessments are "particularly weak" in their handling of highly sensitive subpopulations, and that the risk to highly exposed individuals is also likely to be underestimated.

The Agency believes these concerns to be important, but already addressed in the regulations. Because the assessment of risk is based upon the upper 95 percent confidence level, this means that the assessment is unlikely to underestimate the actual risk. Further, where there are highly sensitive subpopulations, more often than not the greatest source of increased susceptibility will reflect an increased exposure by a subpopulation. For example, the average quantity of milk ingested per day per kilogram of body weight by an infant (e.g., 1 liter per 10 kilograms = 0.1 liter per kilogram) is much greater than that ingested by an 70-kilogram adult (e.g., 0.3 liter per 70 kilograms = 0.04 liter per kilogram). The Agency anticipated special concerns about specific subpopulations in Section 12721(d)(2), which sets forth assumptions for exposures to certain subpopulations.

The question of highly exposed individuals is also addressed in Section 12721(b) and 12721(d). In order to determine the significance of an exposure, one must make realistic assumptions about exposures. A business cannot reasonably anticipate exposures that are aberrant and excessive. To the extent that the "high" exposures are predictable (e.g., workplace exposures or age- or gender-related exposures), they are already addressed in the subsections mentioned above.

The same commentor stated that the level for N-nitrosodimethylamine was not calculated using the highest experimentally determined potency. The risk assessment which was used as the basis for establishing the level was conducted following the provisions of Section 12703. The default assumptions in Section 12703 were used in the absence of scientifically more appropriate assumptions. Where there was scientifically valid evidence indicating that assumptions other than the default were more appropriate, alternative assumptions were used.

The commentor is correct in stating that the highest cancer potency was not selected in calculating the no significant risk level for N-nitrosodimethyalmine. The rationale for this is explained in the risk assessment document. Briefly, the cancer potency selected by CDHS is based on a sensitive low-dose study which was most representative of the chemical's cancer potency. Although larger potency values were derived from other experiments, those experiments were run at higher dose levelswith fewer animals and are unlikely to provide as representative an estimate of low dose potency.

In addition, the commentor offered general statements on risk assessment, selection of chemicals, priorities, and timing of the regulation which are not comments on the specific regulation, and therefore do not require a response from the Agency.

The proposed level for N-nitrosodimethylamine and the risk assessment document which provides the basis for the proposed regulation were submitted to the Scientific Advisory Panel for review and comment on December 16, 1988. While the members of the Panel provided general comments on the document, they did not comment on the proposed level.

ndpa

FINAL
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Section 12705(b) - Specific Regulatory Levels Posing No Significant Risk

The Safe Drinking Water and Toxic Enforcement Act of 1986 (hereinafter the Act) prohibits a person in the course of doing business from knowingly and intentionally exposing any individual to a chemical that has been listed as known to the State to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual (Health and Safety Code Section 25249.6). The Act also prohibits a business from knowingly discharging a listed chemical into water or onto or into land where such chemical passes or probably will pass into a source of drinking water (Health and Safety Code Section 25249.5).

For chemicals known to the state to cause cancer, an exemption is provided by the Act when a person in the course of doing business is able to demonstrate that an exposure for which it is responsible poses no significant risk, or that a discharge which otherwise complies with applicable requirements would result in an exposure through drinking water at a level which poses no significant risk (Health and Safety Code Sections 25249.10 and 25249.11). A determination that a level of exposure poses no significant risk can be made utilizing regulations that have previously been adopted by the Health and Welfare Agency (Section 12701 to 12721, Title 22, California Code of Regulations). Section 12701 describes alternative methods for making such a determination. One such method is through the application of the specific regulatory level established for the chemical in question in Section 12705. Section 12705(b) supersedes Section 12709 (Exposure to Trace Elements), Section 12711 (Levels Based on State or Federal Standards), or Section 12713 (Exposure to Food, Drugs, Cosmetics and Medical Devices).

Procedural Background

On July 11, 1989 the Agency issued a notice of proposed rulemaking advising that the Agency intended to adopt a "no significant risk" level for N-nitrosodiphenylamine. Pursuant to such notice, on September 13, 1989, a public hearing was held to receive public comments on the proposed regulation. Two pieces of correspondence commenting on Section 12705(b) was received; no comments were received at the public hearing.

Purpose of Final Statement of Reasons

This final statement of reasons sets forth the reasons for the final regulation adopted by the Agency for Section 12705(b), and responds to the objections and recommendations submitted regarding the regulation. 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.

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 12705(b). However, because regulations other than Section 12705(b) were also the topic of the public hearing on September 13, 1989, the rulemaking file contains some material not relevant to Section 12705(b). This final statement of reasons cites only the relevant material. Comments regarding the regulations other than Section 12705(b) discussed at the September 13, 1989 hearing have been or will be discussed in separate final statements of reasons.

Necessity for Adoption of Regulations

The Agency has determined that the adoption of this regulation is necessary. For chemicals known to the State to cause cancer, the Act exempts discharges, releases and exposure which, making certain assumptions, pose no significant risk. The Act specifies that any claim of exemption under Health and Safety Code section 25249.10, subsection (c) must be based upon evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of the chemical. However, the Act does not further clarify when a chemical risk is not significant, nor specify levels of chemical exposure posing no significant risk. Existing regulations describe methods for calculating levels which pose no significant risk.

The purpose of this regulation is to provide a "safe harbor" no significant risk level which will assist persons in determining whether a discharge, release or exposure is exempt from the provisions of the Act.

Section 12705(b)

This proposed regulation adopts a no significant risk level for N-nitrosodiphenylamine of 80 micrograms per day for purposes of the Act in Section 12705(b), and repeals the no significant risk level for this chemical in Section 12711. Although Section 12701 explicitly states that Section 12711 applies only when no specific level is established for the chemical in Section 12705, deletion of the chemical and its level from Section 12711 is necessary for clarity and to avoid confusion. This proposed level represents the level of exposure which is calculated to result in no more than one excess case of cancer in an exposed population of 100,000, assuming exposure over a 70-year lifetime (10^{-5} lifetime risk of cancer), and is based on the risk assessment document prepared by the California Department of Health Services utilizing the principles in Section 12703 ("Risk-Specific Intake Levels for the Proposition 65 Carcinogen N-Nitrosodiphenylamine," Reproductive and Cancer Hazard Assessment Section, Office of Environmental Health Hazard Assessment, California Department of Health Services, November 1, 1988). The findings of this risk assessment document are summarized as follows:

Cancer potency estimates derived from data on urinary bladder cancers in male and female Fischer 344 rats were 0.0032 and 0.0034 $(mg/kg\text{-}day)^{-1}$, respectively. The potency of 0.061 $(mg/kg\text{-}day)^{-1}$, estimated from the data for hepatomas in male C57BL/6 X C3H/Anf mice, exceeds these values by a factor of 20. Because no potency value appears clearly the most representative value, the geometric mean of the potency value estimated from positive studies is selected. Thus, the potency value of 0.009 $(mg/kg\text{-}day)^{-1}$ is recommended for the estimation of intake levels associated with a specific cancer risk from exposure to N-nitrosodiphenylamine. From this value, the intake level associated with a 10^{-5} lifetime risk of cancer is 80 micrograms per day.

One commentor (C-9) felt that the public should be invited to participate in the Department of Health Services' preparation of a health risk assessment, and that the Health and Welfare Agency should retain its authority as the "ultimate decision maker" for any decisions associated with the implementation of the Act.

The commentor evidently is unaware that the Agency did publish in 1988 a schedule of risk assessments to be performed by the Department of Health Services with an invitation to submit pertinent information. Many interested parties have participated in this process and continue to do so. In addition, the agenda of the Scientific Advisory Panel meetings indicate risk assessments to be discussed, and interested parties may provide information to the Agency and to the Panel. Finally, the commentor appears to be unaware that the Health and Welfare Agency is the "lead agency" for the implementation of the Act, and therefore is the "ultimate decision maker" in these matters.

One commentor contended that the no significant risk levels did not represent the "plausible upper bound limits" of the actual risk posed by the chemicals to individuals. The commentor believes the risk assessments are "particularly weak" in their handling of highly sensitive subpopulations, and that the risk to highly exposed individuals is also likely to be underestimated.

The Agency believes these concerns to be important, but already addressed in the regulations. Because the assessment of risk is based upon the upper 95 percent confidence level, this means that the assessment is unlikely to underestimate the actual risk. Further, where there are highly sensitive subpopulations, more often than not the greatest source of increased susceptibility will reflect an increased exposure by a subpopulation. For example, the average quantity of milk ingested per day per kilogram of body weight by an infant (e.g., 1 liter per 10 kilograms = 0.1 liter per kilogram) is much greater than that ingested by an 70-kilogram adult (e.g., 0.3 liter per 70 kilograms = 0.04 liter per kilogram). The Agency anticipated special concerns about specific subpopulations in Section 12721(d)(2), which sets forth assumptions for exposures to certain subpopulations.

The question of highly exposed individuals is also addressed in Section 12721(b) and 12721(d). In order to determine the significance of an exposure, one must make realistic assumptions about exposures. A business cannot reasonably anticipate exposures that are aberrant and excessive. To the extent that the "high" exposures are predictable (e.g., workplace exposures or age- or gender-related exposures), they are already addressed in the subsections mentioned above.

In addition, the commentor offered general statements on risk assessment, selection of chemicals, priorities, and timing of the regulation which are not comments on the specific regulation, and therefore do not require a response from the Agency.

The proposed level for N-nitrosodiphenylamine and the risk assessment document which provides the basis for the proposed regulation were submitted to the Scientific Advisory Panel for review and comment on April 14, 1989. While the members of the Panel provided general comments on the document, they did not comment on the proposed level.

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FINAL
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Section 12705(b) - Specific Regulatory Levels Posing No Significant Risk

The Safe Drinking Water and Toxic Enforcement Act of 1986 (hereinafter the Act) prohibits a person in the course of doing business from knowingly and intentionally exposing any individual to a chemical that has been listed as known to the State to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual (Health and Safety Code Section 25249.6). The Act also prohibits a business from knowingly discharging a listed chemical into water or onto or into land where such chemical passes or probably will pass into a source of drinking water (Health and Safety Code Section 25249.5).

For chemicals known to the state to cause cancer, an exemption is provided by the Act when a person in the course of doing business is able to demonstrate that an exposure for which it is responsible poses no significant risk, or that a discharge which otherwise complies with applicable requirements would result in an exposure through drinking water at a level which poses no significant risk (Health and Safety Code Sections 25249.10 and 25249.11). A determination that a level of exposure poses no significant risk can be made utilizing regulations that have previously been adopted by the Health and Welfare Agency (Section 12701 to 12721, Title 22, California Code of Regulations). Section 12701 describes alternative methods for making such a determination. One such method is through the application of the specific regulatory level established for the chemical in question in Section 12705. Section 12705(b) supersedes Section 12709 (Exposure to Trace Elements), Section 12711 (Levels Based on State or Federal Standards), or Section 12713 (Exposure to Food, Drugs, Cosmetics and Medical Devices).

Procedural Background

On July 11, 1989 the Agency issued a notice of proposed rulemaking advising that the Agency intended to adopt a "no significant risk" level for N-nitroso-n-dibutylamine. Pursuant to such notice, on September 13, 1989, a public hearing was held to receive public comments on the proposed regulation. Two pieces of correspondence commenting on Section 12705(b) was received; no comments were received at the public hearing.

Purpose of Final Statement of Reasons

This final statement of reasons sets forth the reasons for the final regulation adopted by the Agency for Section 12705(b), and responds to the objections and recommendations submitted regarding the regulation. 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.

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 12705(b). However, because regulations other than Section 12705(b) were also the topic of the public hearing on September 13, 1989, the rulemaking file contains some material not relevant to Section 12705(b). This final statement of reasons cites only the relevant material. Comments regarding the regulations other than Section 12705(b) discussed at the September 13, 1989 hearing have been or will be discussed in separate final statements of reasons.

Necessity for Adoption of Regulations

The Agency has determined that the adoption of this regulation is necessary. For chemicals known to the State to cause cancer, the Act exempts discharges, releases and exposure which, making certain assumptions, pose no significant risk. The Act specifies that any claim of exemption under Health and Safety Code section 25249.10, subsection (c) must be based upon evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of the chemical. However, the Act does not further clarify when a chemical risk is not significant, nor specify levels of chemical exposure posing no significant risk. Existing regulations describe methods for calculating levels which pose no significant risk.

The purpose of this regulation is to provide a "safe harbor" no significant risk level which will assist persons in determining whether a discharge, release or exposure is exempt from the provisions of the Act.

Section 12705(b)

This proposed regulation adopts a no significant risk level for N-nitroso-n-dibutylamine of 0.06 microgram per day for purposes of the Act in Section 12705(b), and repeals the no significant risk level for this chemical in Section 12711. Although Section 12701 explicitly states that Section 12711 applies only when no specific level is established for the chemical in Section 12705, deletion of the chemical and its level from Section 12711 is necessary for clarity and to avoid confusion. This proposed level represents the level of exposure which is calculated to result in no more than one excess case of cancer in an exposed population of 100,000, assuming exposure over a 70-year lifetime (10^{-5} lifetime risk of cancer), and is based on the risk assessment document prepared by the California Department of Health Services utilizing the principles in Section 12703 ("Risk-Specific Intake Levels for the Proposition 65 Carcinogen N-Nitroso-n-dibutylamine," Reproductive and Cancer Hazard Assessment Section, Office of Environmental Health Hazard Assessment, California Department of Health Services, November 1, 1988). The findings of this risk assessment document are summarized as follows:

Estimates of the cancer potency for humans were derived by fitting the multistage polynomial to several sets of dose-response data obtained from animal bioassays. A potency of 10.8 $(mg/kg\text{-}day)^{-1}$ was estimated from dose-response data for combined esophageal and bladder tumors in male C57BL/6 mice exposed for a lifetime to N-nitroso-n-dibutylamine in drinking water. From this value, the intake level associated with a 10^{-5} lifetime risk of cancer is 0.06 microgram per day.

One commentor (C-9) felt that the public should be invited to participate in the Department of Health Services' preparation of a health risk assessment, and that the Health and Welfare Agency should retain its authority as the "ultimate decision maker" for any decisions associated with the implementation of the Act.

The commentor evidently is unaware that the Agency did publish in 1988 a schedule of risk assessments to be performed by the Department of Health Services with an invitation to submit pertinent information. Many interested parties have participated in this process and continue to do so. In addition, the agenda of the Scientific Advisory Panel meetings indicate risk assessments to be discussed, and interested parties may provide information to the Agency and to the Panel. Finally, the commentor appears to be unaware that the Health and Welfare Agency is the "lead agency" for the implementation of the Act, and therefore is the "ultimate decision maker" in these matters.

One commentor (C-11) contended that the no significant risk levels did not represent the "plausible upper bound limits" of the actual risk posed by the chemicals to individuals. The commentor believes the risk

assessments are "particularly weak" in their handling of highly sensitive subpopulations, and that the risk to highly exposed individuals is also likely to be underestimated.

The Agency believes these concerns to be important, but already addressed in the regulations. Because the assessment of risk is based upon the upper 95 percent confidence level, this means that the assessment is unlikely to underestimate the actual risk. Further, where there are highly sensitive subpopulations, more often than not the greatest source of increased susceptibility will reflect an increased exposure by a subpopulation. For example, the average quantity of milk ingested per day per kilogram of body weight by an infant (e.g., 1 liter per 10 kilograms = 0.1 liter per kilogram) is much greater than that ingested by an 70-kilogram adult (e.g., 0.3 liter per 70 kilograms = 0.04 liter per kilogram). The Agency anticipated special concerns about specific subpopulations in Section 12721(d)(2), which sets forth assumptions for exposures to certain subpopulations.

The question of highly exposed individuals is also addressed in Section 12721(b) and 12721(d). In order to determine the significance of an exposure, one must make realistic assumptions about exposures. A business cannot reasonably anticipate exposures that are aberrant and excessive. To the extent that the "high" exposures are predictable (e.g., workplace exposures or age- or gender-related exposures), they are already addressed in the subsections mentioned above.

In addition, the commentor offered general statements on risk assessment, selection of chemicals, priorities, and timing of the regulation which are not comments on the specific regulation, and therefore do not require a response from the Agency.

The proposed level for N-nitroso-n-dibutylamine and the risk assessment document which provides the basis for the proposed regulation were submitted to the Scientific Advisory Panel for review and comment on April 14, 1989. While the members of the Panel provided general comments on the document, they did not comment on the proposed level.

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Section 12705(b) - Specific Regulatory Levels Posing No Significant Risk

The Safe Drinking Water and Toxic Enforcement Act of 1986 (hereinafter the Act) prohibits a person in the course of doing business from knowingly and intentionally exposing any individual to a chemical that has been listed as known to the State to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual (Health and Safety Code Section 25249.6). The Act also prohibits a business from knowingly discharging a listed chemical into water or onto or into land where such chemical passes or probably will pass into a source of drinking water (Health and Safety Code Section 25249.5).

For chemicals known to the state to cause cancer, an exemption is provided by the Act when a person in the course of doing business is able to demonstrate that an exposure for which it is responsible poses no significant risk, or that a discharge which otherwise complies with applicable requirements would result in an exposure through drinking water at a level which poses no significant risk (Health and Safety Code Sections 25249.10 and 25249.11). A determination that a level of exposure poses no significant risk can be made utilizing regulations that have previously been adopted by the Health and Welfare Agency (Section 12701 to 12721, Title 22, California Code of Regulations). Section 12701 describes alternative methods for making such a determination. One such method is through the application of the specific regulatory level established for the chemical in question in Section 12705. Section 12705(b) supersedes Section 12709 (Exposure to Trace Elements), Section 12711 (Levels Based on State or Federal Standards), or Section 12713 (Exposure to Food, Drugs, Cosmetics and Medical Devices).

Procedural Background

On July 11, 1989 the Agency issued a notice of proposed rulemaking advising that the Agency intended to adopt a "no significant risk" level for N-nitroso-N-ethylurea. Pursuant to such notice, on September 13, 1989, a public hearing was held to receive public comments on the proposed regulation. Two pieces of correspondence commenting on Section 12705(b) was received; no comments were received at the public hearing.

Purpose of Final Statement of Reasons

This final statement of reasons sets forth the reasons for the final regulation adopted by the Agency for Section 12705(b), and responds to the objections and recommendations submitted regarding the regulation. 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.

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 12705(b). However, because regulations other than Section 12705(b) were also the topic of the public hearing on September 13, 1989, the rulemaking file contains some material not relevant to Section 12705(b). This final statement of reasons cites only the relevant material. Comments regarding the regulations other than Section 12705(b) discussed at the September 13, 1989 hearing have been or will be discussed in separate final statements of reasons.

Necessity for Adoption of Regulations

The Agency has determined that the adoption of this regulation is necessary. For chemicals known to the State to cause cancer, the Act exempts discharges, releases and exposure which, making certain assumptions, pose no significant risk. The Act specifies that any claim of exemption under Health and Safety Code section 25249.10, subsection (c) must be based upon evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of the chemical. However, the Act does not further clarify when a chemical risk is not significant, nor specify levels of chemical exposure posing no significant risk. Existing regulations describe methods for calculating levels which pose no significant risk.

The purpose of this regulation is to provide a "safe harbor" no significant risk level which will assist persons in determining whether a discharge, release or exposure is exempt from the provisions of the Act.

Section 12705(b)

This proposed regulation adopts a no significant risk level for N-nitroso-N-ethylurea of 0.03 microgram per day for purposes of the Act in Section 12705(b), and repeals the no significant risk level for this chemical in Section 12711. Although Section 12701 explicitly states that Section 12711 applies only when no specific level is established for the chemical in Section 12705, deletion of the chemical and its level from Section 12711 is necessary for clarity and to avoid confusion. This proposed level represents the level of exposure which is calculated to result in no more than one excess case of cancer in an exposed population of 100,000, assuming exposure over a 70-year lifetime (10^{-5} lifetime risk of cancer), and is based on the risk assessment document prepared by the California Department of Health Services utilizing the principles in Section 12703 ("Risk-Specific Intake Levels for the Proposition 65 Carcinogen N-Nitroso-N-ethylurea," Reproductive and Cancer Hazard Assessment Section, Office of Environmental Health Hazard Assessment, California Department of Health Services, October 1, 1988). The findings of this risk assessment document are summarized as follows:

Based on the incidence of leukemia in female rats in an oral study, a cancer potency of 27 $(mg/kg\text{-}day)^{-1}$ was selected for estimating risks from exposure to N-nitroso-N-ethylurea. From this value, the intake level associated with 10^{-5} lifetime risk of cancer is 0.03 microgram per day.

One commentor (C-9) felt that the public should be invited to participate in the Department of Health Services' preparation of a health risk assessment, and that the Health and Welfare Agency should retain its authority as the "ultimate decision maker" for any decisions associated with the implementation of the Act.

The commentor evidently is unaware that the Agency did publish in 1988 a schedule of risk assessments to be performed by the Department of Health Services with an invitation to submit pertinent information. Many interested parties have participated in this process and continue to do so. In addition, the agenda of the Scientific Advisory Panel meetings indicate risk assessments to be discussed, and interested parties may provide information to the Agency and to the Panel. Finally, the commentor appears to be unaware that the Health and Welfare Agency is the "lead agency" for the implementation of the Act, and therefore is the "ultimate decision maker" in these matters.

One commentor (C-11) contended that the no significant risk levels did not represent the "plausible upper bound limits" of the actual risk posed by the chemicals to individuals. The commentor believes the risk assessments are "particularly weak" in their handling of highly sensitive subpopulations, and that the risk to highly exposed individuals is also likely to be underestimated.

The Agency believes these concerns to be important, but already addressed in the regulations. Because the assessment of risk is based upon the upper 95 percent confidence level, this means that the assessment is unlikely to underestimate the actual risk. Further, where there are highly sensitive subpopulations, more often than not the greatest source of increased susceptibility will reflect an increased exposure by a subpopulation. For example, the average quantity of milk ingested per day per kilogram of body weight by an infant (e.g., 1 liter per 10 kilograms = 0.1 liter per kilogram) is much greater than that ingested by an 70-kilogram adult (e.g., 0.3 liter per 70 kilograms = 0.04 liter per kilogram). The Agency anticipated special concerns about specific subpopulations in Section 12721(d)(2), which sets forth assumptions for exposures to certain subpopulations.

The question of highly exposed individuals is also addressed in Section 12721(b) and 12721(d). In order to determine the significance of an exposure, one must make realistic assumptions about exposures. A business cannot reasonably anticipate exposures that are aberrant and excessive. To the extent that the "high" exposures are predictable (e.g., workplace exposures or age- or gender-related exposures), they are already addressed in the subsections mentioned above.

In addition, the commentor offered general statements on risk assessment, selection of chemicals, priorities, and timing of the regulation which are not comments on the specific regulation, and therefore do not require a response from the Agency.

The proposed level for N-nitroso-N-ethylurea and the risk assessment document which provides the basis for the proposed regulation were submitted to the Scientific Advisory Panel for review and comment on December 16, 1988. While the members of the Panel provided general comments on the document, they did not comment on the proposed level.

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FINAL
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Section 12705(b) - Specific Regulatory Levels Posing No Significant Risk

The Safe Drinking Water and Toxic Enforcement Act of 1986 (hereinafter the Act) prohibits a person in the course of doing business from knowingly and intentionally exposing any individual to a chemical that has been listed as known to the State to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual (Health and Safety Code Section 25249.6). The Act also prohibits a business from knowingly discharging a listed chemical into water or onto or into land where such chemical passes or probably will pass into a source of drinking water (Health and Safety Code Section 25249.5).

For chemicals known to the state to cause cancer, an exemption is provided by the Act when a person in the course of doing business is able to demonstrate that an exposure for which it is responsible poses no significant risk, or that a discharge which otherwise complies with applicable requirements would result in an exposure through drinking water at a level which poses no significant risk (Health and Safety Code Sections 25249.10 and 25249.11). A determination that a level of exposure poses no significant risk can be made utilizing regulations that have previously been adopted by the Health and Welfare Agency (Section 12701 to 12721, Title 22, California Code of Regulations). Section 12701 describes alternative methods for making such a determination. One such method is through the application of the specific regulatory level established for the chemical in question in Section 12705. Section 12705(b) supersedes Section 12709 (Exposure to Trace Elements), Section 12711 (Levels Based on State or Federal Standards), or Section 12713 (Exposure to Food, Drugs, Cosmetics and Medical Devices).

Procedural Background

On July 11, 1989 the Agency issued a notice of proposed rulemaking advising that the Agency intended to adopt a "no significant risk" level for N-nitroso-N-methylurea. Pursuant to such notice, on September 13, 1989, a public hearing was held to receive public comments on the proposed regulation. Two pieces of correspondence commenting on Section 12705(b) was received; no comments were received at the public hearing.

Purpose of Final Statement of Reasons

This final statement of reasons sets forth the reasons for the final regulation adopted by the Agency for Section 12705(b), and responds to the objections and recommendations submitted regarding the regulation. 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.

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 12705(b). However, because regulations other than Section 12705(b) were also the topic of the public hearing on September 13, 1989, the rulemaking file contains some material not relevant to Section 12705(b). This final statement of reasons cites only the relevant material. Comments regarding the regulations other than Section 12705(b) discussed at the September 13, 1989 hearing have been or will be discussed in separate final statements of reasons.

Necessity for Adoption of Regulations

The Agency has determined that the adoption of this regulation is necessary. For chemicals known to the State to cause cancer, the Act exempts discharges, releases and exposure which, making certain assumptions, pose no significant risk. The Act specifies that any claim of exemption under Health and Safety Code section 25249.10, subsection (c) must be based upon evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of the chemical. However, the Act does not further clarify when a chemical risk is not significant, nor specify levels of chemical exposure posing no significant risk. Existing regulations describe methods for calculating levels which pose no significant risk.

The purpose of this regulation is to provide a "safe harbor" no significant risk level which will assist persons in determining whether a discharge, release or exposure is exempt from the provisions of the Act.

Section 12705(b)

This proposed regulation adopts a no significant risk level for N-nitroso-N-methylurea of 0.006 microgram per day for purposes of the Act in Section 12705(b), and repeals the no significant risk level for this chemical in Section 12711. Although Section 12701 explicitly states that Section 12711 applies only when no specific level is established for the chemical in Section 12705, deletion of the chemical and its level from Section 12711 is necessary for clarity and to avoid confusion. This proposed level represents the level of exposure which is calculated to result in no more than one excess case of cancer in an exposed population of 100,000, assuming exposure over a 70-year lifetime (10^{-5} lifetime risk of cancer), and is based on the risk assessment document prepared by the California Department of Health Services utilizing the principles in Section 12703 ("Risk-Specific Intake Levels for the Proposition 65 Carcinogen N-Nitroso-N-methylurea," Reproductive and Cancer Hazard Assessment Section, Office of Environmental Health Hazard Assessment, California Department of Health Services, October 1, 1988). The findings of this risk assessment document are summarized as follows:

To estimate risks from exposure to N-nitroso-n-methylurea, a cancer potency of 124 $(mg/kg\text{-}day)^{-1}$ was estimated from data on the total tumor incidence (nasal cavity, larynx, trachea and lungs) in female hamsters from a subcutaneous injection study. This potency value is nearly the same as that estimated from a study in which N-nitroso-N-methylurea was administered via the oral route over a short period of time. From this value, the intake level associated with a 10^{-5} lifetime risk of cancer is 0.006 microgram per day.

One commentor (C-9) felt that the public should be invited to participate in the Department of Health Services' preparation of a health risk assessment, and that the Health and Welfare Agency should retain its authority as the "ultimate decision maker" for any decisions associated with the implementation of the Act.

The commentor evidently is unaware that the Agency did publish in 1988 a schedule of risk assessments to be performed by the Department of Health Services with an invitation to submit pertinent information. Many interested parties have participated in this process and continue to do so. In addition, the agenda of the Scientific Advisory Panel meetings indicate risk assessments to be discussed, and interested parties may provide information to the Agency and to the Panel. Finally, the commentor appears to be unaware that the Health and Welfare Agency is the "lead agency" for the implementation of the Act, and therefore is the "ultimate decision maker" in these matters.

One commentor (C-11) contended that the no significant risk levels did not represent the "plausible upper bound limits" of the actual risk posed by the chemicals to individuals. The commentor believes the risk assessments are "particularly weak" in their handling of highly sensitive

subpopulations, and that the risk to highly exposed individuals is also likely to be underestimated.

The Agency believes these concerns to be important, but already addressed in the regulations. Because the assessment of risk is based upon the upper 95 percent confidence level, this means that the assessment is unlikely to underestimate the actual risk. Further, where there are highly sensitive subpopulations, more often than not the greatest source of increased susceptibility will reflect an increased exposure by a subpopulation. For example, the average quantity of milk ingested per day per kilogram of body weight by an infant (e.g., 1 liter per 10 kilograms = 0.1 liter per kilogram) is much greater than that ingested by an 70-kilogram adult (e.g., 0.3 liter per 70 kilograms = 0.04 liter per kilogram). The Agency anticipated special concerns about specific subpopulations in Section 12721(d)(2), which sets forth assumptions for exposures to certain subpopulations.

The question of highly exposed individuals is also addressed in Section 12721(b) and 12721(d). In order to determine the significance of an exposure, one must make realistic assumptions about exposures. A business cannot reasonably anticipate exposures that are aberrant and excessive. To the extent that the "high" exposures are predictable (e.g., workplace exposures or age- or gender-related exposures), they are already addressed in the subsections mentioned above.

In addition, the commentor offered general statements on risk assessment, selection of chemicals, priorities, and timing of the regulation which are not comments on the specific regulation, and therefore do not require a response from the Agency.

The proposed level for N-nitroso-N-methylurea and the risk assessment document which provides the basis for the proposed regulation were submitted to the Scientific Advisory Panel for review and comment on December 16, 1988. While the members of the Panel provided general comments on the document, they did not comment on the proposed level.

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Section 12705(b) - Specific Regulatory Levels Posing No Significant Risk

The Safe Drinking Water and Toxic Enforcement Act of 1986 (hereinafter the Act) prohibits a person in the course of doing business from knowingly and intentionally exposing any individual to a chemical that has been listed as known to the State to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual (Health and Safety Code Section 25249.6). The Act also prohibits a business from knowingly discharging a listed chemical into water or onto or into land where such chemical passes or probably will pass into a source of drinking water (Health and Safety Code Section 25249.5).

For chemicals known to the state to cause cancer, an exemption is provided by the Act when a person in the course of doing business is able to demonstrate that an exposure for which it is responsible poses no significant risk, or that a discharge which otherwise complies with applicable requirements would result in an exposure through drinking water at a level which poses no significant risk (Health and Safety Code Sections 25249.10 and 25249.11). A determination that a level of exposure poses no significant risk can be made utilizing regulations that have previously been adopted by the Health and Welfare Agency (Section 12701 to 12721, Title 22, California Code of Regulations). Section 12701 describes alternative methods for making such a determination. One such method is through the application of the specific regulatory level established for the chemical in question in Section 12705. Section 12705(b) supersedes Section 12709 (Exposure to Trace Elements), Section 12711 (Levels Based on State or Federal Standards), or Section 12713 (Exposure to Food, Drugs, Cosmetics and Medical Devices).

Procedural Background

On July 11, 1989 the Agency issued a notice of proposed rulemaking advising that the Agency intended to adopt a "no significant risk" level for toxaphene. Pursuant to such notice, on September 13, 1989, a public hearing was held to receive public comments on the proposed regulation. Two pieces of correspondence commenting on Section 12705(b) was received; no comments were received at the public hearing.

Purpose of Final Statement of Reasons

This final statement of reasons sets forth the reasons for the final regulation adopted by the Agency for Section 12705(b), and responds to the objections and recommendations submitted regarding the regulation. 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.

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 12705(b). However, because regulations other than Section 12705(b) were also the topic of the public hearing on September 13, 1989, the rulemaking file contains some material not relevant to Section 12705(b). This final statement of reasons cites only the relevant material. Comments regarding the regulations other than Section 12705(b) discussed at the September 13, 1989 hearing have been or will be discussed in separate final statements of reasons.

Necessity for Adoption of Regulations

The Agency has determined that the adoption of this regulation is necessary. For chemicals known to the State to cause cancer, the Act exempts discharges, releases and exposure which, making certain assumptions, pose no significant risk. The Act specifies that any claim of exemption under Health and Safety Code section 25249.10, subsection (c) must be based upon evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of the chemical. However, the Act does not further clarify when a chemical risk is not significant, nor specify levels of chemical exposure posing no significant risk. Existing regulations describe methods for calculating levels which pose no significant risk.

The purpose of this regulation is to provide a "safe harbor" no significant risk level which will assist persons in determining whether a discharge, release or exposure is exempt from the provisions of the Act.

Section 12705(b)

This proposed regulation adopts a no significant risk level for toxaphene of 0.6 microgram per day for purposes of the Act in Section 12705(b), and repeals the no significant risk level for this chemical in Section 12711. Although Section 12701 explicitly states that Section 12711 applies only when no specific level is established for the chemical in Section 12705, deletion of the chemical and its level from Section 12711 is necessary for clarity and to avoid confusion. This proposed level represents the level of exposure which is calculated to result in no more than one excess case of cancer in an exposed population of 100,000, assuming exposure over a 70-year lifetime (10^{-5} lifetime risk of cancer), and is based on the risk assessment document prepared by the California Department of Health Services utilizing the principles in Section 12703 ("Risk-Specific Intake Levels for the Proposition 65 Carcinogen Toxaphene," Reproductive and Cancer Hazard Assessment Section, Office of Environmental Health Hazard Assessment, California Department of Health Services, October 1, 1988). The findings of this risk assessment document are summarized as follows:

A cancer potency of 1.2 $(mg/kg\text{-}day)^{-1}$ for toxaphene was estimated from dose-response data for hepatocellular carcinomas induced in male and female B6C3F1 mice after oral administration. From this value, the intake level associated with a 10^{-5} lifetime risk of cancer is 0.6 microgram per day.

One commentor (C-9) felt that the public should be invited to participate in the Department of Health Services' preparation of a health risk assessment, and that the Health and Welfare Agency should retain its authority as the "ultimate decision maker" for any decisions associated with the implementation of the Act.

The commentor evidently is unaware that the Agency did publish in 1988 a schedule of risk assessments to be performed by the Department of Health Services with an invitation to submit pertinent information. Many interested parties have participated in this process and continue to do so. In addition, the agenda of the Scientific Advisory Panel meetings indicate risk assessments to be discussed, and interested parties may provide information to the Agency and to the Panel. Finally, the commentor appears to be unaware that the Health and Welfare Agency is the "lead agency" for the implementation of the Act, and therefore is the "ultimate decision maker" in these matters.

One commentor (C-11) contended that the no significant risk levels did not represent the "plausible upper bound limits" of the actual risk posed by the chemicals to individuals. The commentor believes the risk assessments are "particularly weak" in their handling of highly sensitive subpopulations, and that the risk to highly exposed individuals is also likely to be underestimated.

The Agency believes these concerns to be important, but already addressed in the regulations. Because the assessment of risk is based upon the upper 95 percent confidence level, this means that the assessment is unlikely to underestimate the actual risk. Further, where there are highly sensitive subpopulations, more often than not the greatest source of increased susceptibility will reflect an increased exposure by a subpopulation. For example, the average quantity of milk ingested per day per kilogram of body weight by an infant (e.g., 1 liter per 10 kilograms = 0.1 liter per kilogram) is much greater than that ingested by an 70-kilogram adult (e.g., 0.3 liter per 70 kilograms = 0.04 liter per kilogram). The Agency anticipated special concerns about specific subpopulations in Section 12721(d)(2), which sets forth assumptions for exposures to certain subpopulations.

The question of highly exposed individuals is also addressed in Section 12721(b) and 12721(d). In order to determine the significance of an exposure, one must make realistic assumptions about exposures. A business cannot reasonably anticipate exposures that are aberrant and excessive. To the extent that the "high" exposures are predictable (e.g., workplace exposures or age- or gender-related exposures), they are already addressed in the subsections mentioned above.

In addition, the commentor offered general statements on risk assessment, selection of chemicals, priorities, and timing of the regulation which are not comments on the specific regulation, and therefore do not require a response from the Agency.

The proposed level for toxaphene and the risk assessment document which provides the basis for the proposed regulation were submitted to the Scientific Advisory Panel for review and comment on December 16, 1988. While the members of the Panel provided general comments on the document, they did not comment on the proposed level.

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FINAL
STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS

Section 12705(b) - Specific Regulatory Levels Posing No Significant Risk

The Safe Drinking Water and Toxic Enforcement Act of 1986 (hereinafter the Act) prohibits a person in the course of doing business from knowingly and intentionally exposing any individual to a chemical that has been listed as known to the State to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual (Health and Safety Code Section 25249.6). The Act also prohibits a business from knowingly discharging a listed chemical into water or onto or into land where such chemical passes or probably will pass into a source of drinking water (Health and Safety Code Section 25249.5).

For chemicals known to the state to cause cancer, an exemption is provided by the Act when a person in the course of doing business is able to demonstrate that an exposure for which it is responsible poses no significant risk, or that a discharge which otherwise complies with applicable requirements would result in an exposure through drinking water at a level which poses no significant risk (Health and Safety Code Sections 25249.10 and 25249.11). A determination that a level of exposure poses no significant risk can be made utilizing regulations that have previously been adopted by the Health and Welfare Agency (Section 12701 to 12721, Title 22, California Code of Regulations). Section 12701 describes alternative methods for making such a determination. One such method is through the application of the specific regulatory level established for the chemical in question in Section 12705. Section 12705(b) supersedes Section 12709 (Exposure to Trace Elements), Section 12711 (Levels Based on State or Federal Standards), or Section 12713 (Exposure to Food, Drugs, Cosmetics and Medical Devices).

Procedural Background

On July 11, 1989 the Agency issued a notice of proposed rulemaking advising that the Agency intended to adopt a "no significant risk" level for 2,4,6-trichlorophenol. Pursuant to such notice, on September 13, 1989, a public hearing was held to receive public comments on the proposed regulation. Two pieces of correspondence commenting on Section 12705(b) was received: no comments were received at the public hearing.

Purpose of Final Statement of Reasons

This final statement of reasons sets forth the reasons for the final regulation adopted by the Agency for Section 12705(b), and responds to the objections and recommendations submitted regarding the regulation. 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.

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 12705(b). However, because regulations other than Section 12705(b) were also the topic of the public hearing on September 13, 1989, the rulemaking file contains some material not relevant to Section 12705(b). This final statement of reasons cites only the relevant material. Comments regarding the regulations other than Section 12705(b) discussed at the September 13, 1989 hearing have been or will be discussed in separate final statements of reasons.

Necessity for Adoption of Regulations

The Agency has determined that the adoption of this regulation is necessary. For chemicals known to the State to cause cancer, the Act exempts discharges, releases and exposure which, making certain assumptions, pose no significant risk. The Act specifies that any claim of exemption under Health and Safety Code section 25249.10, subsection (c) must be based upon evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of the chemical. However, the Act does not further clarify when a chemical risk is not significant, nor specify levels of chemical exposure posing no significant risk. Existing regulations describe methods for calculating levels which pose no significant risk.

The purpose of this regulation is to provide a "safe harbor" no significant risk level which will assist persons in determining whether a discharge, release or exposure is exempt from the provisions of the Act.

Section 12705(b)

This proposed regulation adopts a no significant risk level for 2,4,6-trichlorophenol of 10 micrograms per day for purposes of the Act in Section 12705(b), and repeals the no significant risk level for this chemical in Section 12711. Although Section 12701 explicitly states that Section 12711 applies only when no specific level is established for the chemical in Section 12705, deletion of the chemical and its level from Section 12711 is necessary for clarity and to avoid confusion. This proposed level represents the level of exposure which is calculated to result in no more than one excess case of cancer in an exposed population of 100,000, assuming exposure over a 70-year lifetime (10^{-5} lifetime risk of cancer), and is based on the risk assessment document prepared by the California Department of Health Services utilizing the principles in Section 12703 ("Risk-Specific Intake Levels for the Proposition 65 Carcinogen 2,4,6-Trichlorophenol," Reproductive and Cancer Hazard Assessment Section, Office of Environmental Health Hazard Assessment, California Department of Health Services, November 1, 1988). The findings of this risk assessment document are summarized as follows:

Cancer potency in humans was estimated from dose-response data from animal bioassays with dose related increases in carcinogenicity. From data on hepatocellular tumors (adenomas and carcinomas) in male and female B6C3F1 mice, the human potency is estimated to be 0.021 and 0.0080 $(mg/kg\text{-}day)^{-1}$, respectively. The human potency is estimated to be 0.47 $(mg/kg\text{-}day)^{-1}$ from data on reticulum cell sarcomas in male C57BL/6 X C3H/Anf mice, and 0.28 $(mg/kg\text{-}day)^{-1}$ from data on hepatomas in female mice of the same strain. The estimate of cancer potency for 2,4,6-trichlorophenol is calculated as the geometric mean of these four estimates. Accordingly, a cancer potency of 0.07 $(mg/kg\text{-}day)^{-1}$ has been selected for estimating risk from exposure to 2,4,6-trichlorophenol. From this value, the intake level associated with a 10^{-5} lifetime risk of cancer is 10 micrograms per day.

One commentor (C-9) felt that the public should be invited to participate in the Department of Health Services' preparation of a health risk assessment, and that the Health and Welfare Agency should retain its authority as the "ultimate decision maker" for any decisions associated with the implementation of the Act.

The commentor evidently is unaware that the Agency did publish in 1988 a schedule of risk assessments to be performed by the Department of Health Services with an invitation to submit pertinent information. Many interested parties have participated in this process and continue to do so. In addition, the agenda of the Scientific Advisory Panel meetings indicate risk assessments to be discussed, and interested parties may provide information to the Agency and to the Panel. Finally, the commentor appears to be unaware that the Health and Welfare Agency is the "lead agency" for the implementation of the Act, and therefore is the "ultimate decision maker" in these matters.

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The Agency believes these concerns to be important, but already addressed in the regulations. Because the assessment of risk is based upon the upper 95 percent confidence level, this means that the assessment is unlikely to underestimate the actual risk. Further, where there are highly sensitive subpopulations, more often than not the greatest source of increased susceptibility will reflect an increased exposure by a subpopulation. For example, the average quantity of milk ingested per day per kilogram of body weight by an infant (e.g., 1 liter per 10 kilograms = 0.1 liter per kilogram) is much greater than that ingested by an 70-kilogram adult (e.g., 0.3 liter per 70 kilograms = 0.04 liter per kilogram). The Agency anticipated special concerns about specific subpopulations in Section 12721(d)(2), which sets forth assumptions for exposures to certain subpopulations.

The question of highly exposed individuals is also addressed in Section 12721(b) and 12721(d). In order to determine the significance of an exposure, one must make realistic assumptions about exposures. A business cannot reasonably anticipate exposures that are aberrant and excessive. To the extent that the "high" exposures are predictable (e.g., workplace exposures or age- or gender-related exposures), they are already addressed in the subsections mentioned above.

In addition, the commentor offered general statements on risk assessment, selection of chemicals, priorities, and timing of the regulation, which are not comments on the specific regulation, and therefore do not require a response from the Agency.

The proposed level for 2,4,6-trichlorophenol and the risk assessment document which provides the basis for the proposed regulation were submitted to the Scientific Advisory Panel for review and comment on April 14, 1989. While the members of the Panel provided general comments on the document, they did not comment on the proposed level.