FINAL
STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS DIVISION 2

Section 12713 - Exposure to Foods, Drugs, Cosmetics and Medical Devices

The Safe Drinking Water and Toxic Enforcement Act of 1986 (Health and Saf. Code, 25249.5 et seq.) (hereinafter the "Act") was adopted as an initiative statute at a general election on November 4, 1986. The Act prohibits any person in the course of doing business from knowingly and intentionally exposing any individual to a chemical known to the state to cause cancer without first giving a clear and reasonable warning. (Health & Saf. Code, 25249.6.)

The Act also creates limited exceptions to this prohibition. Health and Safety Code section 25249.10(c) provides that section 25249.6 does not apply where the exposure poses "no significant risk assuming lifetime exposure at the level in question" for substances known to the state to cause cancer.

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

Procedural Background

Effective February 27, 1988, the Agency adopted Article 7 of Chapter 3 of Division 2 of Title 22 of the California Code of Regulations to implement the no significant risk exemption of the Act. (Henceforth, all references are to Title 22 of the California Code of Regulations unless otherwise indicated.) Pursuant to Government Code section 11346.1, those emergency regulations were readopted on a number of occasions so as to remain in effect.

On June 10, 1988, the Agency issued a notice of emergency rulemaking advising that the Agency intended to permanently adopt Article 7. (See Register 88, No. 24-2, pp. 2020-2024.) Pursuant to such notice a public hearing was held on July 29, 1988, to receive public comments on the proposed regulations, including Article 7. On June 9, 1989, the Agency filed with the Office of Administrative Law documents to certify that the Agency had complied with the requirements of the Administrative Procedure Act for the adoption of Article 7.

Among the regulations adopted in Article 7 was section 12713. Subsection (c) of section 12713 provided generally that, unless a specific no significant risk level is set forth in section 12705,

proof of compliance with specific standards found in federal and state law may be sufficient to prove that a chemical in a food, drug, cosmetic or medical device poses no significant risk. Subsection (d) of section 12713 provided that, in the absence of a specific standard described in subsection (c), proof of compliance with qualitative standards would be sufficient to prove that an exposure to one of these products poses no significant risk.

This proposed amendment would repeal subsection (d) effective October 1, 1990.

Notice of this regulatory action was published on August 11, 1989. The notice advised that the Agency would accept public comment on the action then proposed for a period of no less than 45 days, and that a public hearing would be held on October 4, 1989. In response to this notice, 24 written comments were submitted to the Agency, and seven commentors testified at the public hearing.

Purpose of Final Statement of Reasons

This final statement of reasons sets forth the reasons for the amendment to section 12713 proposed on August 11, 1989, and responds to the objections and recommendations submitted regarding those amendments. Government Code section 11346.7, subsection (b)(3) requires that the final statement of reasons submitted with an amended 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.

Parties may have included in their written or oral comments remarks or observations about these regulations or other regulations which do not constitute an objection or recommendation directed at the proposed action or the procedures followed. Also, parties may have offered their interpretation of the intent or meaning of the proposed regulations or other regulations. Again, this does not constitute an objection or recommendation directed at the proposed action or the procedures followed. Accordingly, the Agency is not obligated under Government Code section 11346.7 to respond to such remarks in this final statement of reasons. Since the Agency is constrained by limitations upon its time and resources, and is not obligated by law to respond to such remarks, the Agency has not responded to these remarks in this final statement of reasons. The absence of response in this final statement of reasons to such remarks

should not be construed to mean that the lead agency agrees with them.

Intended Effect of Section 12713

To understand the effect of a repeal of subsection (d), it is important to understand what the Agency intended by adopting section 12713. The Final Statement of Reasons which accompanied the adoption of section 12713 explained the intended effect of the regulation. In response to comments which interpreted section 12713 to provide an exemption from the Act for foods, drugs, cosmetics and medical devices simply because they were already regulated under certain federal and state laws, the Agency stated:

> "This is incorrect. This section refers to standards only. Each of these product categories is subject to some kind of administrative standard. In every case there are non-specific qualitative standards. In many cases there are specific quantitative standards. In order for a product to be deemed to pose no significant risk, it must be in compliance with all applicable administrative standards.
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> The fact that an administrative agency, such as the federal Food and Drug Administration (FDA), has not taken action against persons causing exposure to a product which may not be in compliance with the applicable administrative standards does not mean that the product poses no significant risk. The absence of administrative action may simply mean that the FDA has yet to discover the violation, or that the FDA has, for administrative reasons, decided not to take action. It cannot be taken as conclusive proof that the applicable standards have been met.
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> It is the intention of the Agency that an action under the Act be available to make certain that these standards are satisfied. Accordingly, the "safe harbor" afforded by this section is available only where all applicable administrative standards have been complied with. Public prosecutors or persons in the public interest may bring actions where such products result in exposures to listed chemicals. The defendant in such an action may prove compliance with all applicable administrative standards and avoid liability. If the defendant cannot show such compliance, then the "safe harbor" is not available, but the defendant may still attempt to prove that there is no significant risk within the meaning of the Act by some other means not reflected in the regulations." (Final Statement of Reasons, 22 C.C.R., sections 12701, et seq., June 9, 1989, p. 45-46.)

This statement was followed by a lengthy discussion of the processes surrounding the application of the qualitative and quantitative standards by federal agencies to foods, drugs, cosmetics and medical devices. This discussion was designed to demonstrate the range of administrative experience and precedent in applying these standards. Particularly in the case of qualitative standards, the Agency believed that reference to this administrative experience could provide at least some guidance as to the meaning of the standards.

Unfortunately, many parties appear to have taken the discussion to mean that a product poses no significant risk under section 12713 if it is regulated by the FDA and has not been determined by FDA to violate the federal Food, Drug and Cosmetic Act. This interpretation is contrary to the quoted language above.

It is also contrary to the position taken by the Agency in response to a lawsuit to have the regulation declared invalid, filed by a coalition of environmental and labor groups who adopted the same interpretation of section 12713 as the commentors. In its arguments to the court, the Agency cited the language from the Final Statement of Reasons quoted above (AFL-CIO, et al. v. Deukmejian, et al., Sacramento County Superior Court, Case No. 502541, Defendant's Memorandum of Points and Authorities in Opposition to Plaintiffs' Motion for Summary Judgment, Nov. 3, 1989, pp. 19-20.), and further explained that, even with section 12713 as it exists, liability may arise for failure to warn about exposures if it cannot be proven that the product causing the exposure complies with all qualitative and quantitative standards applicable to the product. Where there are no specific, quantitative standards, the defendant in an enforcement action brought pursuant to the Act must prove that qualitative standards have been satisfied, i.e. that the product is "safe." ((AFL-CIO, et al. v. Deukmejian, et al., Sacramento County Superior Court, Case No. 502541, Defendants' Supplemental Memorandum of Points and Authorities in Opposition to Tentative Ruling, January 22, 1990, p. 9, fn. 4.)

Thus, the Agency has repeatedly explained that the reference to standards in section 12713, including subsection (d), was intended to define, not lessen the burden of persons in the food, drug, cosmetic and medical device industries. Nevertheless, in light of some of the comments received regarding the proposed repeal of subsection (d) of section 12713, it is apparent that many interested parties believe the opposite. Section 12713 and the effect of the proposed repeal of subsection (d) were characterized in the following ways:

> "The food and drug exemption (section 12713(a)-(d)), as it presently exists, coordinates the federal and State regulatory systems by, in effect, linking the "no

> significant risk" status under Proposition 65 of a chemical exposure in a food, drug, cosmetic or medical device to the Food and Drug Administration (FDA) status of the exposure." (C-4, p. 2; C-6, p. 5.)
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> "The Health and Welfare Agency's proposed revocation of the administrative standards exemption would interfere with the comprehensive Federal regulatory scheme outlined above and call into question the reliability of FDA's determinations that regulated substances do not pose a significant risk to consumers." (C-11, p. 6.)

As a result, many commentors predict dire consequences if section 12713(d) is repealed, including confusion among consumers and industry, loss of product availability, undue and unnecessary burdens on commerce, needless conflict with the federal regulatory scheme, and spurious cancer warnings. In other words, the prevailing view among commentors, most of which represent the food, drug, cosmetic and medical device industries, is that, so long as subsection (d) is in effect, products regulated by the FDA require no warnings. Once subsection (d) is repealed, these commentors believe, warnings will need to be given.

Section 12713 applies only to chemicals known to the state to cause cancer. It does not apply to chemicals known to cause reproductive toxicity, and there is no regulation for reproductive toxicants in foods, drugs, cosmetics and medical devices. Exposures to reproductive toxicants are exempted by the Act only if the exposure would produce "no observable effect" assuming exposure at 1000 times the level in question. This is, in many cases, a much more stringent standard than the "no significant risk" standard for carcinogens. Nevertheless, persons doing business in foods, drugs, cosmetics and medical devices have not felt compelled to provide warnings on most products, and they have not been subjected to unreasonable enforcement actions as a result. None of the consequences predeicted if section 12713(d) is repealed have come to pass. This suggests that the predictions about the consequences of repealing subsection (d) of section 12713 represent an overreaction.

Thus, predictions that repeal of subsection (d) will produce drastic results do not reflect the true impact of the repeal. Instead, they represent a misunderstanding of the requirements under existing law and an exageration of the consequences. The Act already requires persons causing exposures to prove that exposures to chemicals known to the state to cause cancer pose no significant risk (Health & Saf. Code, section 25249.10 (c)). Section 12713 did nothing more than adopt standards to define "no significant risk." Compliance with those standards must be proven before exemption may be obtained. The repeal of subsection (d) will not significantly increase the burden on businesses. Instead, it encourages businesses to find the

quantitative means to meet the burden they already have.

Interim Status of Section 12713

Subsection (a) of section 12713 plainly states that the section is interim. In other words, the regulation was not intended to permanently define "no significant risk" for purposes of exposures to chemicals in foods, drugs, cosmetics and medical devices. Rather, it was designed as a bridge to provide standards for proving "no significant risk" until the state and industry had an opportunity to develop specific, quantitative standards for certain chemicals of concern.

Although some commentors to Article 7 objected that section 12713 had expressly been made interim (Final Statement of Reasons, 22 C.C.R., 12701, et seq., p. 47), the need for the section's interim status was dictated by the very nature of many of the standards to which the section referred. The Agency recognized that existing law includes specific, quantitative standards and non-specific, qualitative standards. Quantitative standards generally advise what levels of a specific chemical are permissible in a particular product (see subsection (c) of section 12713, which refers to several categories of specific standards). Quantitative standards provide the surest, most useful approach for making specific the "no significant risk" standard of the Act.

Every food, drug, cosmetic and medical device is also subject to non-specific qualitative standards, e.g., foods may not bear or contain any added poisonous or deleterious substance which may render it injurious to health. These standards are subjective, just as the "no significant risk" exemption under the Act is subjective. Thus, subsection (d), by referring to non-specific, qualitative standards, simply substitutes a collection of subjective standards for the subjective "no significant risk" standard of the Act.

The qualitative standards in existing law are more specific than the "no significant risk" standard of the Act, due to the many years of administrative experience surrounding their application. In adopting section 12713, the Agency reasoned that, absent a quantitative standard, it would be better to have a qualitative standard more specific than "no significant risk" than it would be to have no standard at all. At the same time, however, the Agency recognized that this did not resolve the uncertainties with the standards and the potential that "no significant risk" determinations will be made on a case-by-case basis. Thus, the regulation was made interim to reflect the Agency's preference for specific standards, and the fact that the passage of time would permit the Agency, industry and the enforcement community to develop specific standards.

Timeliness of Repeal

Section 12713 also provided that the administrative standards recognized in that section would be applicable only in the absence of a standard for the chemical in question in section 12705. On March 16, 1988, the Agency requested the Department of Health Services (DHS) to conduct risk assessments on approximately 50 carcinogens expressly for this purpose. The Agency published a timetable for the conduct of risk assessments anticipating completion by July, 1989. Thirty of the levels resulting from these assessments have been adopted in section 12705. The Agency also advised repeatedly that it intended to repeal section 12713 one year following the scheduled completion of the risk assessments. (See Updated and Revised Schedule of Risk Assessment for Proposition 65, dated September 16, 1988, October 26, 1988, and December 1, 1988.) The Agency also encouraged persons to determine whether their products comply with available specific standards, and to develop their own specific standards for the chemicals which may be found in their products.

The Agency believes that, in light of the number of specific standards now included in section 12705, and the amount of time which interested persons will have had by October 1, 1990, to develop specific standards, the interim standard provided by subsection (d) is no longer necessary. Further, the process of developing specific standards will be accelerated by eliminating the applicability of subsection (d). This is particularly true in light of the belief expressed by several commentors that subsection (d) provides an exemption from the Act for all foods, drugs, cosmetics and medical devices regulated by FDA. So long as some businesses believe that subsection (d) provides a categorical exemption, they may never undertake to develop specific standards or otherwise examine their operations.

Response to Comments

Several commentors objected on the ground that the repeal is premature in the absence of specific regulatory levels for each of the 50 chemicals of concern. (Trans., p. 15; Trans., p. 19; Exh. 3, p. 8; Trans., p. 21; C-4, p. 6; C-4, p. 6; C-6, p. 17; C-7, p. 7; C-9, p. 2; C-11, p. 10; C-12, p. 1; C-20, p. 1; C-21, p. 2; C-22, p. 2; C-24, p. 1; C-6, p. 4, 18.) Similarly, one commentor objected to the repeal because it does not provide manufacturers sufficient notice to comply. (C-1, p. 1; C-19, p. 11.) One commentor recommended that the Agency postpone the effective date of the repeal until after all 50 levels are adopted under section 12705 and industry has had an opportunity to determine whether they are affected, a period of approximately five years. (Exh. 3, p. 11.)

Many of these objections were based on the fact that, at the time the notice of this regulatory action was issued, no specific levels had been finally adopted. This is no longer the case.

Thirty levels are present in section 12705. Further, these objections appear to assume that subsection (d) provides an exemption for FDA regulated products, so that businesses which do not have specific levels available on the effective date of the repeal will suddenly be exposed to liability. In fact, subsection (d) provided no such exemption. The repeal will not increase the responsibility of persons causing exposures to prove that the exposures pose no significant risk. Moreover, postponing the effective date of the repeal, in light of these assumptions by the commentors, might encourage businesses to postpone the development of their own specific "no significant risk" levels or otherwise make a quantitative determination of risk. Accordingly, these recommendations were not adopted.

One commentor objected to the repeal of section 12713 (d) on the ground that there will be an adverse fiscal affect on small businesses, who would have to spend a lot of time and money as a result of the repeal. (Custom-Made, Inc., Trans., p. 14, C-2, p. 1.) This objection also appears to assume that subsection (d) provides an exemption for FDA regulated products, so that businesses which do not have specific levels available on the effective date of the repeal will suddenly be exposed to liability, or the additional costs associated with developing a defense. In fact, subsection (d) provided no such exemption, and these businesses have been exposed to liability all along. The repeal will not exaggerate the responsibility of persons causing exposures to prove that their exposures pose no significant risk. Any costs which businesses incur will be the result of the Act, not this rulemaking.

Some commentors recommended that the repeal of subsection (d) be deferred until the Agency has compiled levels for the full list of Proposition 65 carcinogens. (Trans., p. 16, Exh. 2, p. 5; C-6, p. 4, 18; C-22, p. 3.) Similarly, one commentor recommended that the Agency withdraw the proposal because the Agency is about to add a large number of chemicals to the list of chemicals known to the state to cause cancer. (C-6, p. 9.) Since this list of chemicals under the Act is constantly being expanded, the adoption of this recommendation would make subsection (d) permanent. This is contrary to the intent expressed for section 12713. For reasons stated above, the Agency believes that interim status is necessary. Further, there is no reason to adopt specific levels for all the chemicals listed as carcinogenic. Some of these chemicals result from industrial processes not found in this state. Others are drugs which are intended to be administered in amounts which would far exceed a level which poses "no significant risk." Many are unlikely to be found in any food, drug, cosmetic or medical device. Therefore, adopting specific levels for many chemicals would serve no purpose.

One commentor objected that the list of chemicals originally scheduled for risk assessment is not a comprehensive list of all

chemicals which might occur as unintentional, low-level contaminants in foods, drugs, cosmetics and medical devices. (C-19, p. 12.) The list of chemicals for which the Agency requested the Department of Health Services to conduct risk assessments was issued following a request to the regulated community to specify the chemicals of concern in foods, drugs, cosmetics and medical devices. Presumably the list contains most of the chemicals of concern. If there are other chemicals of concern, the Agency has repeatedly offered to consider additional risk assessments upon request. Further, the petition process established in Government Code section 11347.1 is available to any individual who proposes to have the agency add specific levels for other chemicals in section 12705.

This same commentor recommended that the public be permitted to submit the names of chemicals for which risk assessments are necessary, and that subsection (d) not be repealed as to those chemicals until 18 months after a level has been established. (C-19, p. 12.) Similarly, one commentor recommended that the Agency ask DHS to review all listed chemicals to determine whether they are found in food, and, if they are, adopt a specific level under section 12705 as soon as possible. (Exh. 3, p. 11.) The public has always been permitted to advise the Agency of chemicals of concern. Indeed, the regulated industries themselves are in a much better position than DHS or the Agency to determine what chemicals concern them. This commentor's request to delay the effective date of specific levels appears to assume that subsection (d) provides an exemption for FDA regulated products, and that the adoption of a specific standard will create an unnecessary hardship for persons using the chemical. As the discussion above indicates, this assumption is incorrect.

Some commentors based their objections upon their understanding that the Agency had promised not to repeal any part of section 12713 until one year after the adoption of standards for the 50 chemicals of concern. (Exh. 1, p. 7; C-1, p. 1.) One commentor objected on the ground that October 1, 1990, date is arbitrary. (C-16, p. 3.) As indicated above, the Agency repeatedly stated that it intended to repeal section 12713 one year following the <u>scheduled</u> date for completion of the risk assessment, not the date of actual completion or adoption of a level based upon the risk assessment. Thus, it was the Agency's stated intention to repeal section 12713 effective July 1, 1990. The decision to repeal only subsection (d) as of October 1, 1990, is actually more favorable to these commentors than the Agency's original timetable.

Some commentors based their objection on the ground that the state must show that businesses will be able to develop their own specific risk standards prior to the effective date of the repeal. (Exh. 2, p. 9.) This objection appears to assume that subsection (d) provides an exemption for FDA regulated products,

so that businesses which do not have specific levels available on the effective date of the repeal will suddenly be exposed to liability. In fact, subsection (d) provided no such exemption. To require the state to show that businesses will be able to develop their own specific risk standards prior to the effective date of the repeal would not alter the burden of proof already placed on these businesses.

The Act provides that, in any action brought to enforce the discharge prohibition or the warning requirement, the burden of showing that an exposure poses no significant risk shall be on the defendant, i.e., the person causing the exposure, discharge or release. It is not the responsibility of the State to ensure that businesses will be able to prove "no significant risk." The Agency can and has attempted to define "no significant risk" in order to assist persons in determining whether an exposure poses no significant risk. But the Agency cannot lighten the burden, or shield persons from it.

Several commentors objected that the Agency's findings for adopting the regulation support a continuation of the regulation. In other words, if there were good reasons for adopting the regulation in February, 1988, those reasons still apply and support retention rather than repeal. (Trans., p. 5-6, Exh. 1, p. 2; Trans., p. 10, C-19, p. 5; Exh. 2, p. 5; C-6, p. 3; C-9, p. 3; C-11, p. 6; C-21, p. 2.) There were good reasons for adopting this regulation. There were good reasons for making it interim. The repeal of section 12713(d) simply effectuates in part the Agency's original intention to make section 12713 an interim regulation, and to move toward specific, quantitative standards to provide greater certainty in the enforcement of and compliance with the Act.

Similarly, several commentors objected that there is no necessity for repeal, on the ground that there are no changed circumstances. (Trans., p. 7, C-19, p. 4; C-7, p. 6; C-9, p. 2.) The changed circumstances are (1) the adoption of 30 specific levels in section 12705, and (2) the passage of time which provided interested parties an opportunity to analyze their chemicals of concern and their exposures pursuant to sections 12703 and 12721.

Several commentors objected that, since the regulation is self-repealing, express repeal is unnecessary. (Trans., p. 5-6, Exh. 1, p. 8, Exh. 2, p. 3; C-6, p. 3, 16; C-11, p. 13; C-16, p. 2; C-19, p. 5.) While it is true that section 12713 will not apply to those chemicals for which levels are adopted in section 12705, the regulation does not provide that, upon the adoption of the last of the approximately 50 levels for chemicals of concern in food, drug, cosmetic and medical device products, section 12713 is automatically repealed. Without further regulatory action, it could be argued that, contrary to the intention of the Agency, section 12713 continues as to all other chemicals.

One commentor objected to the repeal on the ground that it will subject cosmetics to greater scrutiny than warranted by the risk which they present. (Trans., p. 8; C-19, p. 9.) Similarly, another commentor objected because the repeal may result in warnings on food products which present less risk than the products which would continue to be covered by subsection (c). The safest food substances (those for which FDA has so little concern about safety that no use level other than "good manuacturing practices" has been specified) would no longer be determined to pose no significant risk. (Trans., p. 18, Exh. 3, p. 6.) The repeal of section 12713(d) will not result in warnings on these products that should not have been given under the existing regulation. Further, if these products are as safe as the commentors claim, their safety should be demonstrable. If their safety is demonstrable, then businesses using them should ba able to show that the products pose no significant risk.

One commentor objected that the standards referred to by subsection (d), including the non-specific standards, are not primarily subjective, and are far more precise and meaningful than the "no significant risk" standard in the Act. The FDA statutory food safety provisions, food additive regulations, GRAS (Generally Recognized as Safe) regulations, action levels and other administrative standards, this commentor argued, provide precise and meaningful guidance, even if there is no tolerance. (Exh. 2, p. 9; C-17, p. 2; C-21, p. 2.) Similarly, one commentor objected to the repeal because the federal standards are familiar. (C-3, p. 1.) As indicated above, the statutory food, drug, cosmetic and medical device safety provisions are more specific than the "no significant risk" standard due to the many years of administrative experience surrounding their application. However, they are subjective and, therefore, imprecise. Food additives and GRAS regulations, on the other hand, are covered in subsection (c) and do not appear to be affected by the proposed repeal.

There are some standards arguably included in subsection (d), such as action levels, which are specific and quantitative. However, in light of federal case law holding that the FDA action levels are not binding (CNI v. Young, (D.C. Cir., 1987) 818 F.2d 943.), and subsequent pronouncements by FDA that it may consider products containing chemicals at levels below or above the action level to be adulterated (53 Fed. Reg. 5043; 54 Fed. Reg. 16128.), it is questionable whether the regulations should provide that these levels are a basis for enforcement actions under the Act. It should also be noted that, of the 25 substances subject to action levels, 8 are not listed for purposes of the Act. Of the 14 substances listed as carcinogens, half already have a specific level in section 12705. One substance, lindane, is an isomer of hexacholorocyclohexane. The regulations contain a specific level for technical grade hexachlorocyclohexane, which consists mostly of the same isomer.

The level for another substance, aflatoxin, is currently undergoing DHS review. Only 5 listed carcinogens for which there are action levels have no specific level in section 12705. (See 22 C.C.R., sections 12000, 12705.)

As indicated above, there were many predictions that the repeal will result in dire consequences. One commentor predicted confusion among the public because they will be suddenly bombarded with warnings or faced with a drastic reduction in the availability of goods. (C-1, p. 1.) Some commentors objected on the ground that repeal will result in uncertainty for the State and industry. (Trans., p. 5-6; C-17, p. 2; C-20, p. 1; C-23, p. 1. Others predicted that repeal will lead to needless conflict with the federal regulatory scheme by requiring spurious cancer warnings. (C-6, p. 3; C-10, p. 1; C-11, p. 2.) These commentors apparently assume that subsection (d) provides an exemption for FDA regulated products, so that businesses which do not have specific levels available on the effective date of the repeal will suddenly be exposed to liability. For example, one commentor wrote that, under the regulation, it is impossible for a product to meet FDA safety requirements and require a warning. (C-6, p. 3.) Compliance with the Act or the regulation is not measured by the action or inaction of FDA. Under the regulation, the issue is whether the product can be shown to satisfy the standards. It is difficult to know when standards have been met when those standards are subjective.

Further, these predictions seem contradictory. On the one hand, it is claimed that the products are so safe that they must be deemed to pose no significant risk. On the other hand, it is argued that, without a complete, categorical exemption, the public will be bombarded with warnings for these products. No warning is required under the Act where it can be shown that the product poses no significant risk. If the products are as safe as the commentors claim, there should be no need for warnings.

Some commentors insist that the repeal will increase the compliance burden on FDA-regulated industries with no commensurate gain in public health or safety. (C-4, p. 6; C-6, p. 3; C-14, p. 1.) Since the existing regulation does not provide an exemption, and FDA-regulated industries have long had the burden to prove their compliance with the standards referred to in subsection (d), the Agency believes that any increase in compliance burden as a result of this regulation will be slight.

Some commentors objected on the ground that repeal will interfere with pending litigation, and is inappropriate while the regulation is being defended. (Trans., p. 5-6, Exh. 1, p. 10; C-19, p. 3.) Similarly, one commentor objected, arguing that the repeal is inconsistent with the Agency's defense of section 12713 in AFL-CIO, et al. v. Deukmejian, et al. (Sacramento County Superior Court, Case No. 502541). (Exh. 2, p. 11.) The Agency's position in defense of the regulation is consistent with its

intention in adopting it. This regulatory action carries out the original intention that the regulation be interim. If this renders all or a portion of the challenge to the regulation moot, it simply points out a defect in the challenge, not this regulatory action.

One commentor objected that the repeal is premature due to the pendency of the Committee for Uniform Regulation and Labeling v. Allenby et al., (N.D. Cal., Case No. C 880730 EFL), otherwise known as the CURL case. (C-7, p. 8.) The CURL case involves a constitutional challenge to the Act itself, not to this regulation. The plaintiff seeks to have the application of the Act to foods declared an unconstitutional burden on interstate commerce and preempted by the federal Food, Drug and Cosmetic Act. If the repeal of section 12713 is premature due to the pendency of the CURL case, then so was its adoption, since any regulatory action would be contrary to claims of unconstitutionality.

One commentor objected to the repeal on the ground that the Act permits the use of qualitative standards. (Exh. 1, p. 8.) The Agency agrees that the Act does permit the use of qualitative standards to define "no significant risk," since the "no significant risk" standard of the Act itself establishes a qualitative standard. However, the fact that the "no significant risk" standard was qualitative, and not quantified, has been a source of concern to the Agency as well as those who enforce or comply with the Act. To implement this qualitative standard with another qualitative standard does little to improve the ability of persons to enforce or comply with the Act. For this reason, the Agency's preference is for quantitative standards.

One commentor objected that the repeal is too narrow, because it leaves undisturbed a large number of "non-specific" qualitative standards. (C-5, p. 2.) In particular, this commentor is referring to the fact that in subsection (c), qualitative standards may be superimposed upon the quantitative standards to make certain that the quantitative standards in existing law are sufficiently protective that products complying with them pose no significant risk of cancer. In the case of subsection (d), there is no quantitative standard at all. The distinction between subsections (c) and (d) is justifiable.

Similarly, one commentor recommended repeal of section 12713 in its entirety, on the ground that it denies Californians the right to receive information regarding chemicals that cause cancer in foods, drugs, and cosmetics. (Transcript, p. 22.) This objection appears to assume that subsection (d) provides an exemption for FDA regulated products, so that products which pose a significant risk will not carry a warning. As indicated above, this assumption is incorrect.

Amendments to 12713(c)

Several commentors recommended amendments to subsection (c) of section 12713. The notice of this regulatory action described the repeal of subsection (d), not the amendment of subsection (c). Thus, any proposal to amend subsection (c) is outside the scope of this regulatory action. (See Govt. Code, section 11436.8.) Accordingly, the Agency declines to make any amendments to subsection (c) in this rulemaking. Under separate rulemaking, the Agency will consider making amendments to subsection (c) as indicated below.

One commentor recommended amendments to subsection (c) to cover the following categories of food additives determined by FDA to be safe but for which no specific use levels have been established:

> 1) color additives so safe that no level is necessary,
> 2) unavoidable food substances with action levels, not tolerances,
> 3) food additives so safe that no level is necessary,
> 4) pesticide chemicals so safe that they are exempted from a tolerance,
> 5) substances not specifically listed on either of the two FDA GRAS lists,
> 6) substances produced by food processing, and substances produced by cooking. (Trans,, p. 18-20, Exh. 3, p. 5.)

Numbers 1, 3, and 4 refer to substances which are so safe that no level is necessary. If these substances are so safe, then it is unlikely they will be listed under the Act, and their should be an abundance of evidence to prove that the substances pose no significant risk. Thus, it is unclear why the Agency would need to exercise its rulemaking authority. Further, since it is unlikely that these categories of substances specifically include any listed carcinogen, the adoption of the regulation could set a precedent for a product-by-product approach to the "no significant risk" issue, rather than a chemical-by-chemical approach. This would be impractical, since the Act applies to every conceivable product.

Number 5 refers to substances which do not appear on the GRAS lists. This is similar to another comment, which recommended that the Agency amend (c)(2) to read:

> "the chemical is a food substance identified by the federal Food and Drug Administration <u>in a Federal Register notice or in its regulations</u> . . ." to be GRAS. (C-7, p. 10.)

Of course, if a chemical or substance does not appear on any GRAS list, it is difficult to point to any standard which would define

"no significant risk." While the Federal Register may provide a source of information as to food substances which are GRAS, it is doubtful that any of these substances will be listed chemicals or food additives. The Agency has not been advised of any listed chemical which is considered GRAS by the federal government and does not appear upon a GRAS list. Therefore, the Agency questions the necessity for such a regulation. If the substance is a naturally occurring chemical in food, and not a food additive, then the chemical is not subject to the warning requirement anyway. (See 22 C.C.R., section 12501)

Number 6 relates to chemicals produced by cooking and food processing. The commentor recommends that these chemicals be deemed to pose no significant risk. This same commentor similarly recommended that section 12501 be revised to provide that chemicals produced in food by traditional forms of processing such as cooking are "naturally occurring" and exempt from Proposition 65. (Exh. 3, p. 10.) Substances produced by food processing and cooking were the subject of a recent amendment to section 12703 (b). The amendment included cooking necessary to avoid microbial contamination or to render the food palatable as an example of a public health consideration which would justify a level of risk other than one case of cancer in an exposed population of 100,000 persons. During the rulemaking procedure, this same recommendation was made. The Agency considered the recommendation and declined to adopt it because the Agency could not be certain that all exposures which result from all manner of cooking pose no significant risk.

Amendments to section 12501 would be outside the scope of this notice. The Agency has already declined to adopt a similar recommendation in the rulemaking for section 12703(b) on the ground that the definition of "naturally-occurring," which was derived from federal regulation, requires an absence of human activity, and cooking is a human activity.

Unavoidable food substances with action levels but no tolerances do constitute specific standards, and could be helpful for a small number of listed chemicals. Another commentor made a similar recommendation. (C-17, p. 2.) As indicated above, it is questionable whether the Agency should include action levels in subsection (c) in light of case law governing FDA's use of action levels. The Agency may examine the feasibility of such an amendment for future consideration.

One commentor recommended that the Agency amend section 12713(c), subsections (1), (4), (5), and (6) to delete the requirement for a specified level or a specific tolerance level, and replace it with the requirement that FDA or DHS have determined that the chemical is "safe under the conditions of its intended use." (Exh. 3, p. 10.) In effect, this would rewrite subsection (c) from a reference to specific standards to a reference to non-specific standards. It would be tantamount to a deletion of

subsection (c), and a reaffirmation of subsection (d). This was not the Agency's intention.

One commentor recommended that the Agency recognize and allow continued reliance on the food specifications monographs established by the Food Chemicals Codex (3d ed. 1981), which establishes permissible, safe levels for trace levels of contaminants in various foods. (C-18, p. 3) The Agency will consider this recommendation for possible amendment to subsection (c) under separate notice upon the receipt of additional information, e.g. proof that the levels established for trace contaminants take carcinogenicity into consideration.

One commentor recommended that the Agency amend subsection (c) to add subparagraph (9) as follows:

"(9) the chemical is a substance which is a component of food packaging materials, or is used in food processing equipment, but is not reasonably expected to become a component of food when the food contact surface is tested in accordance with the Federal Food and Drug Administration's extraction testing guidelines (set forth in FDA's "Recommendations for Chemistry Data for Indirect Food Additive Petitions" (Sept. 1988)) using a method of suitable analytical sensitivity to determine whether or not the chemical substance will become a component of food in an amount considered to be toxicologically significant by experts qualified by scientific training and experience to evaluate its safety. In reaching a conclusion as to whether or not a substance is or is not reasonably expected to become a component of food, due recognition shall be taken of all decisions made by the Federal Food and Drug Administration under its constituents policy, which governs the presence of minute, toxicologically innocuous quantities of impurities in food additives and color additives.

"Further, in making this determination, due recognition shall be given to the fact that if a substance has been used in food packaging for an extensive period of time and is not the subject of a specific regulation by the Food and Drug Administration, it is reasonable to conclude that such a substance may not reasonably be expected to become a component of foods, drugs, or cosmetics, or is generally recognized as safe, under its intended conditions of use." (C-6, p. 13-15.)

In other words, if a chemical in food packaging is unlikely to cause an exposure in food, it poses no significant risk. If a chemical is unlikely to cause an exposure, it should not be detectable. Section 12901 of the regulations already provides that, if a chemical is not detectable, there is no exposure. If there is no exposure, there is no reason to prove "no significant risk," since this applies only where there is an exposure. If for some reason the chemical is detectable in spite of all reasonable expectations, it appears there would be a strong argument that the resultant exposure is not a "knowing" one.

Again, there would be no need to prove no significant risk. Therefore, the need for this amendment has not been demonstrated.

One commentor recommended that the Agency amend of section 12713(c) to include cosmetic ingredients found to be safe by the Cosmetic Ingredient Review Expert Panel, as follows:

"(9) the chemical is contained in a cosmetic within the meaning of section 321 of Title 21 of the United States Code and is generally recognized among experts qualified by scientific training and experience to evaluate the safety of cosmetics as safe to use under the conditions prescribed, recommended, or suggested in the labeling thereof, and is in compliance with all applicable administrative standards." (Trans,, p. 7, C-19, p. 14.)

Similarly, another commentor recommended that the Agency add an alternative (c)(9) to read: "The chemical is a fragrance within the meaning of section 321(i) of Title 21 of the United States Code, and section 700.3(d) of Title 21 of the Code of Federal Regulations, and is used at safe levels pursuant to the Federal Food, Drug, and Cosmetic Act, and the Sherman Food, Drug and Cosmetic Act, and is in compliance with all applicable administrative standards." (C-7, p. 9.)

The difficulty with the first recommendation is that the Cosmetic Ingredient Review Panel (CIR) has found to be safe some chemicals which the FDA has banned for use in cosmetic products. (Cf. 50 Fed. Reg. 51551.; C-19, Exh. A (Journal of the American College of Toxicology, Fifteenth Report of the Cosmetic Ingredients Review Expert Panel, Volume 7, No. 6, "Final Report on the Safety Assessment of Methylene Chloride," p. 741, 1988.) The Agency may consider adopting some conclusions of the CIR on a case-by-case basis for listed chemicals where there are quantitative risk assessments, but not without limitation.

The second recommendation does not appear to refer to any specific standard. It is more like a restatement of subsection (d) for fragrances only. Such a provision would be contrary to the Agency's intention in this regulatory action.

Several commentors recommended that the Agency add a new paragraph to subsection (c) to read:

"(9) the chemical is a medical device (including constituents and contaminants) within the meaning of Section 321(h) of Title 21 of the United States Code including a medical device marketed prior to 1976 or marketed during or after 1976 pursuant to a premarket notification cleared by the FDA under 21 U.S.C. section 360 (k) or pursuant to a premarket approval application approved by the FDA under 21 U.S.C. section 360(e), and is in compliance with al applicable administrative standards." (C-8, p. 2; C-9, p. 3; C-10, p. 2; C-13, p. 2.) Similarly, one commentor recommended

that the Agency make permanent the safe harbor for drugs and medical devices. (C-15, p. 2.)

The medical device amendments to the Food, Drug and Cosmetic Act took effect in 1976. The 1976 amendments included provisions for premarket approval in some, but not all cases. Where a medical device is not the subject of premarket approval, or is at least determined definitively to be generally recognized as safe, it does not appear that any specific standard is applied. Rather, the standards applied are qualitative and non-specific. Therefore, the adoption of such an amendment might be contrary to the purpose of repealing subsection (d). However, the Agency will consider proposing a more limited amendment under a separate regulatory notice.

The Agency has considered the available alternatives to these regulations to determine whether any would be more effective in carrying out the purpose for which the regulation is proposed, or would be as effective and less burdensome to affected private persons than the regulation. The Agency has determined that no alternative considered would be more effective than the regulation.

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