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CALIFORNIA PROP 65 UPDATE

California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop 65) is of growing importance to a large number of firms doing business in California or whose products find their way to that state. Paul, Hastings, Janofsky and Walker, which advises and represents several clients on Prop 65 matters, will issue a Prop 65 Update on a periodic basis. The Update is intended to provide clients with general information about the California law and related developments of a regulatory or enforcement nature.

Prop 65 has two major components. The first, as the name suggests, prohibits the discharge into drinking water of chemicals which are known to the state to cause cancer or reproductive toxicity. The second prohibits persons in the course of doing business from "knowingly and intentionally exposing" any individual to chemicals known to the state to cause cancer or reproductive toxicity without first giving "clear and reasonable" warning. The warning requirement became effective February 27, 1988 for the first 29 chemicals that were listed by the Governor. This memorandum focuses on certain issues of importance regarding the implementation of these warning requirements.^{1/}

^{1/} Please call one of the authors of this update, Norman Dupont (Los Angeles) (213) 489-4000, or Bruce Dickson or Lorie Schmidt-Praul (Washington, D.C.) (202) 223-9000 if you have further questions about those provisions.

RECENT DEVELOPMENTS

At the January 29, 1988 meeting of the California Science Advisory Panel, the Panel completed its review of the candidate chemicals proposed for inclusion on the list of substances known to the state to cause cancer or reproductive toxicity. Nonetheless, ongoing litigation concerning which chemicals must be placed on the list will continue to be important in the future. The listing procedures and the impact of ongoing litigation are discussed below in Section A.

On February 16, 1988 California issued a set of regulations (February 16 Regulations) regarding the implementation of Prop 65. All of these regulations went into effect on or before February 27, 1988, the date on which Prop 65 warning requirements became effective for the first 29 chemicals listed by the Governor. Several of the regulations were issued as "emergency regulations" that did not have the full benefit of the normal notice and comment rulemaking provided for by California law. Following is a summary of the issues addressed by the February 16 Regulations, which are discussed in more detail in Section B:

- California adopted previously proposed regulations regarding Prop 65 general practices, definitions, procedures for obtaining interpretive guidelines and safe use determinations, and creating and establishing procedures for the Science Advisory Panel. Cal. Admin. Code tit. 22, §§ 12101-305. The general practice regulations do not differ significantly from the proposed regulations.
- California adopted an emergency regulation defining "in the course of doing business." Cal. Admin. Code tit. 22, § 12201.
- California adopted emergency regulations excluding from the definition of "exposure" certain exposures to drinking water and ambient air. Cal. Admin. Code tit. 22, §§ 12501-505. The emergency regulations are refined and clarified versions of earlier proposed regulations.
- California adopted emergency regulations establishing recommended methods and suggested language for meeting the "clear and reasonable warning" requirement. Cal. Admin. Code tit. 22, § 12601. The emergency regulations are primarily refined and clarified versions of an earlier proposed regulation.

- California adopted emergency regulations regarding the establishment of no significant risk and no observable effect levels. In addition to general guidance for setting levels in the future, interim no significant risk levels were established and no observable effects levels were also set. Cal. Admin. Code tit. 22, §§ 12701-821. Although the content of the regulations has been discussed at several hearings, in some instances, the specific language is new. Additionally, the specific levels established by the regulations had not previously been published.
- California adopted emergency regulations defining and describing methods of detecting listed chemicals. Cal. Admin. Code tit. 22, § 12901. This regulation had not previously been issued in draft form.

One note of caution, it has been reported in some trade press that occupational exposure to pesticides shall be deemed to pose no significant risk so long as the requirements of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) are met. This is untrue. Although exposures to pesticide residue in food are deemed to pose no significant risk if FIFRA requirements are met, occupational exposures to pesticides are deemed to pose no significant risk if they meet California's Pesticide and Worker Safety requirements authorized in Food and Agricultural Code § 12980 et seq.

A. LISTING PROCEDURES

The Governor is required to publish a list of those chemicals known to the state to cause cancer or reproductive toxicity (Prop 65 List). Cal. Health & Safety Code § 25249.8(a). The initial list, published February 27, 1987, contained 29 chemicals and has been updated three times since then. The most recent list was published January 1, 1988 and contained 177 chemical substances. An updated list will be published April 1, 1988.

1. Current Listing Procedures --
Science Advisory Panel Review

At this time, chemicals are included on the Prop 65 List only after review by the Science Advisory Panel (established pursuant to Prop 65 to advise the California Health and Welfare Agency (Health and Welfare) on Prop 65 matters). The

Panel systematically reviews information on each chemical contained on a candidate list of chemicals to recommend whether each should be included in the Prop 65 List. The candidate list included all chemicals designated as probable carcinogens by the National Toxicology Program (NTP) or the International Agency for Research on Cancer (IARC), as well as certain chemicals regulated as probable carcinogens or reproductive toxins by the federal Occupational Safety and Health Administration (OSHA). Although the Panel has completed its review of the initial candidate list, the listing process will continue to be important as IARC and NTP revise their lists.

Notice was given to the public before the Panel held the meeting at which it considered listing a specific chemical. Oral and written comments were received. Before making a listing recommendation, the Panel reviewed and considered comments regarding the adequacy of animal and other studies upon which the listing would be based. However, to determine whether a chemical should be listed as one known to the state to cause cancer, the Panel looked only at whether the chemical is an animal carcinogen and did not consider whether the chemical does or does not pose a hazard to human health. With the exception of several chemicals for which the studies were technically inadequate, the Panel has rejected suggestions that carcinogenicity data did not support listing.

During a discussion which resulted in a recommendation to list saccharin, one panel member stated:

"I believe that in setting up the criteria that we have adopted for listing, sufficient evidence in animals is to be our test; and we are not going to consider the implications for risk to humans as we make our decision to list." Transcript of December 11, 1987 Meeting of the Prop 65 Science Advisory Panel at 191 (emphasis added).

In the same discussion, other members expressed the view that implications for risk to humans should be considered only in the determination of the no significant risk level -- not in the decision to list.

This view is consistent with the decision to list other chemical substances, including:

- di(2-ethylhexyl)phthalate -- despite CMA's argument that it is a carcinogen in rodents only and that listing was inappropriate until additional research was conducted regarding the pharmacokinetic differences between rodents and humans; and
- formaldehyde -- despite similar arguments regarding the species-specific carcinogenic response and testimony regarding the negative occupational exposure studies.

2. Automatic Listing -- Effect of
NTP/IARC Listing

One of the most controversial issues surrounding implementation of Prop 65 by Health and Welfare is the effect of the NTP Annual Report on Carcinogens and the IARC carcinogen list on the inclusion of chemical substances in the Prop 65 List. Whether the designation of a chemical as a probable carcinogen by IARC or NTP requires the Governor automatically to include such substance on the Prop 65 List is a question that is currently the subject of litigation.

The Governor has taken the position that a substance designated as a probable carcinogen by IARC or NTP cannot be added to the Prop 65 List until the state's scientific experts have reviewed the data and recommended that the substance be listed. The AFL-CIO and a coalition of environmental groups (including the Sierra Club and Natural Resources Defense Council) have filed suit contending that Prop 65 requires the Governor automatically to include on the Prop 65 List chemicals designated as probable carcinogens by IARC or NTP and certain chemicals subject to OSHA's hazard communication standard.

In April 1987 the trial court ruled in favor of the AFL-CIO and environmental groups, and ordered the Governor to list 200 other chemicals identified as carcinogenic by IARC and NTP. This order has been stayed pending an appeal filed by the Governor. A hearing was held on this appeal on November 16, 1987, with a decision expected within the next two months.

Action by Health and Welfare and the Science Advisory Panel during the last year has decreased the potential immediate impact of a final court decision on this issue. All NTP- and IARC-listed chemicals have been reviewed by the

Science Advisory Panel. The Panel recommended that nearly all of the NTP- and IARC-listed chemicals be added to the Prop 65 List. For fewer than five of the NTP- and IARC-listed chemicals, the Panel made a recommendation that they not be listed, and the Panel deferred action on 6 or 7 chemicals until further information was available. The case is still important, however, because it will determine how the Governor will handle chemicals added to the NTP or IARC lists in the future.

B. WARNING REQUIREMENTS

1. No Significant Risk/No
Observable Effect Levels

Prop 65 prohibits persons from exposing any individual to listed chemicals without first giving "clear and reasonable" warning. The law does not require warnings for exposure to a listed chemical if the responsible person can show that the exposure was at or below the level which poses no significant risk (NSRL) for carcinogens and one one-thousandth (1/1000) of the no observable effects level (NOEL) for reproductive toxins. Cal. Health & Safety Code § 25249.10(c). It is expected that considerable controversy will arise over the determination of NSRLs and NOELs. It is in determining the NSRL that controversies will arise regarding the hazard posed to humans by listed chemicals.

Although Health and Welfare, acting on the recommendation of the Science Advisory Panel, will eventually establish specific NSRLs and NOELs for many listed chemicals, this will not occur in all instances before warnings are required by Prop 65. In an enforcement action, which may be brought 60 days after the warning requirement becomes effective for a given chemical, the burden is on the person causing the exposure to prove that the exposure was at a level that posed no significant risk (for carcinogens) or that was no higher than 1/1000 of the NOEL (for reproductive toxicants). Id. Compliance with a Health and Welfare-established NSRL should preclude or be a defense against enforcement actions. However, exposing someone to a level above an established NSRL without prior warning is not necessarily a violation of Prop 65 because the Prop 65 regulations state that no significant risk may be posed by exposure at levels higher than an NSRL they set.

The failure of Health and Welfare to set a standard will not be a defense in an enforcement action. Although only exposures knowingly done are prohibited, "knowingly" refers only to the fact that an exposure is occurring. Cal. Admin. Code tit. 22, § 12201(c). Knowledge that an exposure is unlawful is not a defense in an enforcement action. However, an exposure which is the result of acts omitted or committed through "misfortune or accident and without evil design, intention or negligence" is not in violation of Prop 65. Id.

On February 16, 1988, Health and Welfare adopted regulations establishing procedures whereby a "safe use determination" could be requested to obtain the state's "best judgment concerning application of the Act to the particular facts presented in the request." Cal. Admin. Code tit. 22, § 12104(a). Although this procedure might provide guidance as to whether a given exposure requires warnings, it cannot ensure against adverse enforcement actions. A "safe use determination" is "advisory only," does not preclude enforcement actions, and does not "affect the responsibility of courts to interpret the Act and apply the provisions of the Act to particular facts." Id.

a. No Significant Risk Levels for Carcinogens

The February 16 Regulations provide two methods by which Health and Welfare can set regulations establishing that a particular type of exposure to a listed chemical poses no significant risk. Health and Welfare can either set a no significant risk level (Section 12705) or find that exposure by a specified route poses no significant risk from a given chemical (Section 12707). The February 16 Regulations also establish three methods by which Health and Welfare can set interim NSRLs that will remain in effect until such time as Health and Welfare establishes a "final" NSRL under Section 12705.

(1) NSRL Regulations

Eventually, pursuant to Section 12705, Health and Welfare will set "final" NSRLs for many, though not all, listed chemicals.^{2/} However, "final" NSRLs have not yet been

^{2/} Although these levels would be "final" vis-a-vis the interim NSRLs, they could be amended at a later date.

established for any chemicals. It is anticipated that the order in which these NSRLs will be set will be based on a Health and Welfare-developed prioritized list of 50 or so listed chemicals, which prioritized list is to be adopted at the next Science Advisory Panel meeting in April 1988. Chemicals will probably be placed on the list based on the probability of human exposure.

After the prioritized list is adopted, Health and Welfare will solicit relevant data from knowledgeable sources (including the affected industry), perform a risk assessment in most cases (or review an existing one) and recommend an NSRL. Adoption of an NSRL usually would be preceded by the notice and comment requirements of California administrative law. Additionally, the Science Advisory Panel must be given the opportunity to review the proposed NSRL and comment upon it before the close of the public comment period.

The February 16 Regulations also establish "default assumptions" to be used, absent more scientifically appropriate data or principles, in conducting a quantitative risk assessment.^{3/} Cal. Admin. Code tit. 22, § 12703. For chemicals assessed under this section, no significant risk is the level calculated to result in one excess case of cancer in an exposed population of 100,000, assuming lifetime exposure at the level in question. The "default assumption" are as follows:

- Animal bioassays should meet generally accepted scientific principles, some of which are specified in the regulation.
- The quality and suitability of available human epidemiological data should be appraised.
- Risk analysis should be based on the most sensitive study of sufficient quality, which should be applied to all routes of exposure for which the results are relevant.
- The risk assessment should use a no-threshold model.

^{3/} These default assumptions are essentially the same as the risk assessment principles issued in Interpretive Guideline 87-5.

- Absent other scientifically appropriate models, there is a preference for the linearized multi-stage model for extrapolation from high to low doses, and the upper 95% confidence limit of the linear term is the most appropriate for expressing the upper bound. Time-to-tumor models are appropriate in some circumstances.
- Interspecies conversion of animal to human cancer potency would usually be determined by multiplying by a surface area scaling factor equal to the ratio of human to animal body weight, taken to the one-third power. Alternatively, scaling factors of 14 and 6.5 may be used when extrapolating from mouse and rat data, respectively.
- Pharmacokinetic, physiologic and metabolic data may be used in the risk analysis for interspecies, inter-dose and inter-route extrapolations if the data is of such quality that it can be used with confidence.
- The human body weight of the general population is assumed to be 70 kg per person. Body weights are specified for other subpopulations.
- Additionally, Section 12721 establishes parameters necessary to determine exposure levels.

(2) Routes of Exposure

The February 16 Regulations provide that Health and Welfare may establish a route of exposure as posing no significant risk for a specific chemical. Cal. Admin. Code tit. 22, § 12707. This method of establishing no significant risk may be used where appropriate absorption studies demonstrate that absorption through a specific route of exposure can reasonably be anticipated to present no significant risk of cancer at levels at or below current regulatory standards. An exposure by that route would be deemed to pose no significant risk to the extent it results in exposure to humans by the identified route and does not exceed the level established in any other applicable federal or state standard. The February 16 Regulations establish the route of ingestion as posing no significant risk for beryllium, cadmium, and chromium (hexavalent compounds).

(3) Chemicals in Foods, Drugs,
Cosmetics and Medical Devices

The February 16 Regulations, in accordance with the Science Advisory Panel's recommendation, provide that exposure to chemicals in foods, cosmetics, over-the-counter drugs, prescription pharmaceuticals and medical devices which are regulated under federal or state law are deemed to pose no significant risk within the meaning of Prop 65, providing that the exposure is in compliance with all applicable administrative standards. Cal. Admin. Code tit 22, § 12713.

(4) NSRLs Based on Federal or State Standards

The February 16 Regulations establish interim NSRLs based on federal or state standards. These interim NSRLs are subject to being superseded by "final" NSRLs adopted pursuant to Section 12703. Section 12703 establishes on an interim basis that, where a federal or state agency has developed a regulatory level for a listed carcinogen at a level calculated to result in not more than one excess case of cancer per 100,000 exposed persons, that level is the NSRL for Prop 65 purposes. Cal. Admin. Code tit. 22, § 12711(a)(1). The regulation did not provide a list of any NSRLs established pursuant to this subsection.

Section 12703 also established interim NSRLs for 33 chemicals (including asbestos, DDT, and PCB) based on existing federal or state risk assessments. NSRLs for these chemicals are also subject to revision by Health and Welfare under Section 12703.

(5) NSRLs for Trace Elements

The February 16 Regulations provide for the establishment of interim NSRLs for the trace elements arsenic, beryllium and cadmium. Cal. Admin. Code tit. 22, § 12709. These NSRLs (and any others established pursuant to this section) would be superseded by NSRLs established pursuant to Section 12703.

b. No Observable Effect Levels for
Reproductive Toxicants

The February 16 Regulations provide that NOELs can be determined either by conducting an assessment to determine the maximum dose level having no observable effect -- the NOEL (which must be divided by 1,000 to determine the maximum allowable dose level) or by application of a specific regulatory level. Cal. Admin. Code tit. 22, § 12801.

Section 12805 establishes specific NOELs for lead and ethylene oxide. For reproduction toxins for which no level is specified, the maximum allowable daily dose level can be established by a federal or state assessment that is equivalent to the one prescribed in the Prop 65 Regulations and that establishes a maximum daily dose level that is one-one thousandth of the NOEL. Cal. Admin. Code tit. 22, § 12805. Definitions and parameters regarding calculation of exposure levels are given in Section 12821.

The February 16 Regulations establish the following "default assumptions" to be used in assessing a reproduction toxin, in the absence of more scientifically appropriate principles or data.^{4/}

- The NOEL shall be the highest dose level which results in no observable effect.
- Only studies producing the reproductive effect which provides the basis for the determination that a chemical is known to the state to cause reproductive toxicity should be used to determine the NOEL.
- The quality and suitability of available human data should be appraised.
- Animal bioassays should meet generally accepted scientific principles.
- The NOEL should be based on the most sensitive study deemed to be of sufficient quality, and the results from such study should be applicable

^{4/} These "default assumptions" vary slightly from the proposed assessment guidelines circulated earlier as Interpretive Guideline 87-6.

to all routes of exposure for which the results are relevant.

- When available anatomic, physiologic, pharmacokinetic and metabolic data are of such quality that they could be taken into account with confidence, such data can be used in the assessment.
- Procedures are set forth for the establishment of a NOEL for assessment purposes when the lowest observable effect level, but not the NOEL, can be determined from the data.

2. Exposure Assessment

The February 16 Regulations included regulations defining "expose" and excluding certain types of exposures from the definition. The proposed regulations define "expose" as "to cause to ingest, inhale, contact via body surfaces or otherwise come into contact with a chemical," as was proposed in the proposed regulations. Cal. Admin. Code tit. 22, § 12201(e). The February 16 Regulations refine the proposed descriptions of those types of exposures excluded from being an "exposure" under the statute. The excluded exposures include:

- Human consumption of food when the person responsible for the exposure shows that the chemical that is present is naturally occurring or is only the result of washing, preparing or processing the food with drinking water from a public water system, provided that the person has not added to the water any listed chemical in an amount in excess of the NSRL, Cal. Admin. Code tit. 22, § 12501;
- Exposure to water from specified sources when the responsible person has not added any listed chemical to the water in an amount in excess of the NSRL, Cal. Admin. Code tit. 22, § 12503; and
- Breathing or other individual contact with air when the person responsible for the exposure shows that he has not added the listed chemical to the ambient air in a significant level and that the listed chemical was present in the ambient air. Cal. Admin. Code tit 22, § 12503(c).

3. Warning Messages

The February 16 Regulations provide descriptions of appropriate warning messages. Cal. Admin. Code tit. 22, § 12601. The key terms of the requirement hold that the method employed to communicate a warning must be

"reasonably calculated . . . to make the warning message available to the individual prior to exposure. The message must clearly communicate that the chemical in question is known to the state to cause cancer, or birth defects or other reproductive harm." Cal. Admin. Code tit. 22, § 12601(a).

The regulations also recommend specific language for the warning message. Following are two examples:

"WARNING: This product contains a chemical known to the State of California to cause cancer."

"WARNING: This area contains a chemical known to the State of California to cause birth defects or other reproductive harm."

The specific wording of the recommended warning message varies slightly depending on the type of exposure (e.g., consumer products, occupational, or environmental exposures). The regulations allow the use of a warning message other than the recommended ones if the message meets the requirements quoted above.

The regulations allow warnings to be communicated through the use of labels, signs, shelf labeling, menus, notices mailed or otherwise delivered to individuals at least once every three months, or public media announcements at least once every three months. The recommended method of communication varies with the type of exposure (e.g., shelf labeling for exposure through consumer products, mailings for environmental exposures).

The February 16 Regulations contain an important provision regarding occupational exposures that was not in the proposed regulations. Section 12601(c)(1)C. now provides that an employer meets its Prop 65 requirement of providing clear and reasonable warning by providing a warning to the exposed employee about the chemical in question which complies with

"all information, training and labeling requirements of the federal Hazard Communication Standard (29 CFR § 1910.1200), the California Hazard Communication Standard (8 CCR § 5194), or, for pesticides, the Pesticides and Worker Safety requirements authorized in Food and Agricultural Code section 12980 and following (3 CCR § 6700, et seq.)."

C. IMPACT ON TOXICS LITIGATION

Toxics litigation in California is expected to be significantly impacted in 1988 by the combined effects of the Prop 65 warning requirement deadline and "bounty hunter" enforcement actions, together with the reporting deadlines under the federal Emergency Planning and Community Right-to-Know Act of 1986, 42 U.S.C. §§ 11001 - 11050 (EPCRA). Companies should carefully assess the combined impacts of these two laws in 1988.

As early as April 28, 1988, citizen suits to enforce the Prop 65 warning requirements may be filed. EPCRA reporting requirements effective March 1, 1988 and July 1, 1988 may provide potential Prop 65 plaintiffs with easy access to information regarding the types and location of chemicals at a given facility, and the amount of toxic chemicals released into the environment. The information required by both types of EPCRA reporting requirements could significantly aid plaintiffs in "bounty hunter" enforcement actions under Prop 65.

1. Prop 65 Enforcement Actions

The enforcement provision of Prop 65 provides for civil penalties of up to \$2500 per day for each violation of the warning requirements. Cal. Health & Safety Code § 25249.7(b). The civil penalties can be awarded in an action brought by the Attorney General, any district attorney, certain city attorneys or prosecutors, and ANY PERSON IN THE PUBLIC INTEREST. Cal. Health & Safety Code § 25249.7(c) and (d).

Prop 65 includes certain "bounty hunter" provisions to encourage persons suing in the public interest to bring enforcement actions. Such persons are entitled to 25% of the civil penalty awarded in any action they bring. Cal. Health & Safety Code § 25192(a)(2). The Sierra Club conducted a seminar in California on February 4 and 5 discussing how to litigate Prop 65 cases. The seminar materials included sample

complaints and plaintiffs' discovery requests for hypothetical cases. "Bounty hunter" suits cannot be brought until 60 days after the person has notified the alleged violator, the Attorney General and certain district and city attorneys of the violation which is the subject of the action. Cal. Health & Safety Code § 25249.7(d). Furthermore, the action cannot be brought if the Attorney General or any district or city attorney or prosecutor is diligently prosecuting an action based on the same violation. Id.

2. Federal Reporting Requirements

Supplementing the impact of the Prop 65 enforcement actions will be the reporting requirements mandated by EPCRA. As of March 1, 1988, owners and operators of certain facilities are required to submit Tier I inventory information forms which must contain estimates of the amount and location of hazardous chemicals at the facilities. 42 U.S.C. § 11022. Noteworthy provisions include the following:

- Tier I information is provided by category of chemical rather than on a chemical-specific basis.
- Chemical-specific information can be required on a Tier II inventory form, which can be requested by state and local officials, and in some circumstances, by members of the public.

Additionally, as of July 1, 1988, owners or operators will be required to file a toxic chemical release form where toxic chemicals have been released into the environment from normal business operations. 42 U.S.C. § 11023. Owners or operators will be required to submit information for each listed toxic chemical, including the annual quantity of the toxic chemical entering each environmental medium. (These reports do not cover abnormal emergency releases covered by a different EPCRA reporting requirement.)

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