California Environmental Protection Agency
Proposition 65 Review Panel
Summary of Issues

This document summarizes major points raised and issues identified by members of the Proposition 65 Review Panel at its meetings on December 19, 1991, January 9, 1992, and January 30, 1992. It does not present recommendations, nor should it be construed to represent a consensus of the Review Panel membership. The views reflected herein are those of individual Review Panel members.

GENERAL OVERVIEW

The Panel sessions began with a listing by each Panel member of their perspective on the major strengths and weaknesses of Proposition 65 implementation to date. The major items identified are listed below. As is the case throughout this document, not all Panel members agree with any of the identified points.

I. ACHIEVEMENTS

1. By federal standards, Proposition 65 has resulted in 100 years of progress in the areas of hazard identification, risk assessment, and exposure assessment.

2. There have been no legal challenges to any of the standards adopted under Proposition 65.

3. Proposition 65 has resulted in the application of internally consistent scientific criteria, reductions in actual exposures, and the acceptance by industry of primary responsibility for chemical exposures and discharges.

4. Proposition 65 has compelled businesses to know more about their products and has generally resulted in an increase in industry's preventive behavior.

5. Proposition 65's principal success has been in the altering of behavior by industry in the area of source reduction.

6. Proposition 65 has allowed the Attorney General to address risks which, although relatively easy to mitigate, are not on a scale to have been prioritized by other regulatory agencies.

II. PROBLEMS

1. There is a need for better warnings, with warnings only provided in those instances where a significant risk exists.

2. The food, drug, cosmetic and medical device regulation is unnecessary.

3. The mandatory 1,000-fold safety factor for reproductive toxins is scientifically unjustified.

4. Science needs to play a greater role.

5. There is a need for greater certainty regarding compliance and enforcement.

DISCUSSION OF SPECIFIC ISSUES

I. Listing of Chemicals

Views Expressed. In general, some panel members argued for a greater role for the Scientific Advisory Panel (SAP), and greater flexibility regarding the listing of chemicals and related determinations. Other panel members maintained that the mechanism for listing is governed by the statute, and that the approaches being recommended were not in keeping with the statutory requirements. Specific issues noted include:

A. Scientific Advisory Panel Membership and Role

1. How can the scientist's role in the listing process be emphasized?

   (a) Should science play a greater role in listing?

   (b) Should the SAP look at issues of risk or somehow qualify the listing when it lists a chemical?

   (c) What can be done to make scientists feel that serving on the SAP is worthwhile?

2. How can the SAP meetings be made less adversarial?

3. Can the SAP be used for purposes other than listing?

4. Should the SAP be able to question authoritative bodies' listings?

5. Should the SAP be subject to conflict of interest requirements?

6. Is there a need for an expanded forum to examine state risk assessment procedures generally?

B. Criteria for Listing Chemicals Identified by Authoritative Bodies

1. Should the SAP be able to review the scientific validity of listing decisions made by authoritative bodies?

2. Should candidate authoritative bodies be asked whether they would want their lists of chemicals used for regulatory purposes?

C. Process for Reconsideration of Previously Listed Chemicals

1. May chemical listings based upon SAP recommendations be reconsidered?

II. Discharge

Views expressed. It was generally agreed that greater clarity regarding the discharge prohibition would be useful from a compliance and enforcement viewpoint. Issues raised included:

A. Compliance with Other Laws (Hazardous Waste, Pesticides, etc.) Affecting Compliance with Proposition 65

1. Should the lead agency determine where and how to measure a discharge into a source of drinking water?

2. Should the penalties for violation of the discharge prohibition under Proposition 65 be increased?

3. Should discharge permits issued to businesses under other laws protect them from liability for discharge under Proposition 65?

4. How should discharges which are in compliance with state or federal clean-up orders be treated for purposes of Proposition 65?

III. Exposures

A. General

1. Should the state clarify how levels of naturally-occurring chemicals in foods are to be calculated?

   Views Expressed: It is difficult for a company to know what levels of a chemical are naturally-occurring, due to variability in the source of raw materials. This affects the confidence of the company to know the extent to which the exclusion for naturally occurring chemicals applies.

   The current regulation was then characterized as a loophole that should not be enlarged simply because there are problems with it; the marketplace will sort out the problem situations.

2. Should exposures to "naturally-occurring" chemicals from sources other than food, such as dust stirred up during home construction or landscaping, be exempted from the warning requirement?

   Views Expressed: The wisdom of creating exclusions for other naturally-occurring exposures was questioned (the mining industry was cited as an example), particularly for occupational exposures.

IV. Clear and Reasonable Warning

A. Cal-OSHA Plan

No discussion (status report only).

B. Adequacy of Warnings

1. Should the regulations be amended to more completely inform the consumer?

   Views Expressed: Some panel members believe that warnings are working well, and that the current regulation has the needed flexibility.

   This was countered with the assertion that some businesses are "doing it right," but that some aren't. As an example, the use of

qualifiers or disclaimers in warnings may be illegal.

2. Should the lead agency address current warning problems by amending the regulations, or leave it to the courts?

Views Expressed: Enhanced warning requirements may require the expenditure of a huge amount of effort for little benefit, particularly if few products require warnings.

3. Should the regulations clarify that warning qualifiers and disclaimers are illegal?

4. Should there be a nexus between warnings and the source of chemical exposure?

5. Should the specific chemicals to which the warned individual is exposed be identified?

Views Expressed: Warnings have two purposes: (1) to provide the public with meaningful choice, and (2) to provide meaningful knowledge. The latter is defeated if the chemical to which the warned individual is exposed is not identified.

Chemical specificity would not be helpful. Some products contain 10 to 15 chemicals. Identifying each one would be a "nightmare."

6. Should there be an incentive in the warning requirement for businesses to analyze the need for warnings?

Views Expressed: The biggest problems are pervasive or meaningless warnings, which is linked to the over-warning issue. A speaker urged that there be an incentive in the warning requirement for businesses to analyze the need for warnings.

7. Should more information on the amount of exposure or the potency of a chemical be made available?

Views Expressed: A speaker claimed that efforts to provide more information can be a basis for liability.

8. Should warnings give consumers information about patterns and conditions of use, the

route of exposure, or how to avoid exposure, particularly where there is no alternative product?

Views Expressed: A speaker stated that information on the amount of exposure or the potency of a chemical should be made available; it may not be possible to put it on the label, but the information should be available.

Another speaker added that giving meaningful choice means enough information to make the choice rational; information about patterns and conditions of use would be helpful, something which the current system does not provide.

9. Should Cal-EPA adopt a tiered approach to information to help people understand risk?

Views Expressed: The message should be kept concise to keep the consumer interested; a second tier of information may be necessary.

10. Should warnings include information that recommended use of a product is safe, or provide other information?

Views Expressed: Industry would like to add information to warnings that recommended use of a product is safe, or provide other information.

11. Should Cal-EPA prioritize what constitutes genuine public health threats under Proposition 65? If so, should there be different levels of warning?

Views Expressed: One speaker stated that Cal-EPA needs to prioritize what are the genuine public health threats. Others stated that consumers should be given a choice, not have it made for them by Cal-EPA or some other agency. While there are different levels of risk, it is not appropriate for Cal-EPA to determine that some warnings are not necessary.

C. <u>Chain of Distribution</u>

1. Should the regulation specify who in the chain of distribution must provide warnings, especially for consumer products?

Views Expressed: The issue is who should be responsible for warning: the manufacturer, the distributor or the retailer. It was stated that Cal-EPA should adopt a regulation clarifying this issue, especially for consumer products.

2. Should warnings be provided by manufacturers?

Views Expressed: Manufacturers' liability should stop with its transfer of warnings to distributors. If the distributor doesn't pass it on, the manufacturer has no responsibility.

It makes no sense to "pound" retailers. Instead, manufacturers should provide warnings.

3. Should the exclusion for businesses with fewer than 10 employees be amended?

Views Expressed: The exclusion for businesses with fewer than 10 employees works an inequity among retailers. Only some of the 8 different types of retailers are affected by Proposition 65, and only 50,000 out of 155,000 retailers statewide have 10 or more employees.

Many small home builders are exempt from the warning requirement, and many older homes are resold by individuals or small real estate brokerages, which again would be exempt from the warning requirement. Requiring warnings from larger developers is unfair, and puts them at a competitive disadvantage.

The purpose of the warning requirement is to encourage builders to eliminate harmful chemicals from their products to avoid exposure, which would give them a competitive edge.

D. Media Warnings

1. Should the regulations be amended to require that environmental warnings be mailed, not published in the media?

Views Expressed: Media warnings for environmental exposures should be mailed.

Even where warnings are mailed, people don't respond. Because of the cost in light of the

benefit, the speaker recommended against requiring mailed warnings.

2. How can environmental warnings be made more useful?

V. NO SIGNIFICANT RISK

A. SAP Role

1. Should science play a greater role in risk assessment?

   (a) Can this be done while preserving Proposition 65's advantage of moving the process in a timely manner?

2. Should the SAP have a greater role in setting potency and exposure estimates?

Views Expressed: It was observed that potency and exposure estimates are an area for generally greater involvement of the SAP.

The best science should be used, and formulas and defaults avoided. Scientists are often caught between the need for good science and timely quantitation.

The SAP should do good quality control on numbers, but not slow down the development of numbers in the process.

B. 10^{-5}

1. Should the "no significant risk" level for carcinogens be calculated based upon a 10^{-6} risk?

Views Expressed: Other institutions use a more stringent 10^{-6} risk level to ban chemicals. It was urged that Cal-EPA should not use a less stringent level just to require warnings.

It is a policy issue.

The issue cannot be considered in a vacuum; in choosing a risk level one needs to look at other criteria, such as the exposure assumptions.

Changing the risk level to 10^{-6} would generate a great deal of concern in industry, and will cause them to re-spend money which they have already spent analyzing their risks.

C. Food, Drugs, Cosmetics, and Medical Devices

1. Is the food, drug, cosmetic and medical device regulation necessary?

Views Expressed: There is no justification for it, particularly since, according to industry, there are no products which would require a warning.

This regulation was adopted based upon the recommendation of the SAP, which concluded that current state and federal regulation provides considerable protection for food, drug, medical device, and cosmetic products, and thus recommended that the existing state and federal statutory and administrative standards for these products be adopted pending the establishment of specific levels under the act.

The regulation is an interim measure pending the adoption of numbers, and should continue until a court says otherwise.

Is the regulation in fact interim, given that it is now four years old, and there are only 30 chemicals in section 12705? This suggests that the "interim" regulation could end up being permanent.

The Office of Environmental Health Hazard Assessment will be prepared by the end of the year to offer numerical "no significant risk" levels for more than two hundred listed carcinogens.

There is no special regulation for reproductive toxins in food, yet this has resulted in no warnings by the food industry. Why then is this regulation necessary?

No similar regulation for reproductive toxins was appropriate because other state and federal laws do not regulate reproductive toxins at the same standard as does Proposition 65.

Warnings should not be limited to products which could otherwise be banned, and in some cases the permissible exposures are ten time higher than allowed under Proposition 65 for other exposures.

D. Exposure Criteria

1. Should the regulations clarify whether exposures to particular media can be averaged when calculating no significant risk?

Views Expressed: Proposition 65 refers to exposure calculation in time units of one day, not more; you don't wait for people to be exposed for a lifetime. Under Proposition 65, you assume lifetime exposure.

Allowing industry to average in ways additional to those already permitted would eviscerate the warning requirement.

Averaging could make risk calculation too difficult, and a time unit should be established for the sake of simplicity.

This is a policy, not science, issue. For reproductive toxins, a single excursion can pose a significant risk. Averaging exposures assumes that you know about the mechanisms of carcinogenesis.

2. Should averaging for intermittent exposures be permitted?

3. Should averaging where chemical levels vary over time be permitted?

4. Should the regulations clarify how to assess multiple chemical exposure risks?

VI. ENFORCEMENT

A. General

1. Should the regulations provide a mechanism verifying that exposures by a business are in compliance?

2. Should private attorneys generals be allowed to intervene in a case after the Attorney General has taken it?

3. Should Cal-EPA be given the statutory authority to file 60-day notices?

4. Should one prosecutor be able to bind others?

5. Should Cal-EPA adopt criteria for penalties?

6. Should Cal-EPA, not the community, establish the priorities of what is a risk to the public?

7. Should charging standards be adopted?

8. Should Proposition 65's implementation take other laws into account?

VII. 1,000-FOLD SAFETY FACTOR

A. General

1. Should the mandatory 1,000-fold uncertainty factor in the statute be amended?

Views Expressed: This mandatory safety or uncertainty factor was described as "unorthodox."

The mandatory factor creates no incentive to collect better data.

Need to get away from the concept of the "no observed effect level" altogether, because the science in this area is poor.

U.S. EPA uses factors which range from 10 to 1,000.

Five years of the mandatory 1,000-fold factor has not produced unacceptable results.

Legislative compromise will be difficult.

Scientific uncertainty should be resolved in favor of warning to permit choice.

VIII. DETECTABILITY/METHODS OF DETECTION

A. General

1. Should the regulation clarify that an exposure level must be "detectable" in order

for there to be an exposure under Health and Safety Code section 25249.6?

2. Should the regulations specify what kind of equipment may be used to detect chemicals?

3. Should there be criteria for the sensitivity or accuracy of a test method where an official method is not used?

4. Should the regulations describe the limits of detection?

5. Should the regulations reflect different exposure scenarios?

6. Should the regulation consider industry-wide technology in identifying the appropriate method of detection?

7. Should standards be set by the Department of Health Services Division of Laboratories for Proposition 65 chemicals for purposes of certifying laboratories under the Environmental Laboratories Accreditation Program?

IX. INTEGRATION OF PROPOSITION 65 WITH OTHER ISSUES

A. General

1. Should environmental reports filed by businesses in compliance with other laws be available to prosecutors under Proposition 65?

2. Should risk assessment methods be standardized?

3. Should Proposition 65 risk assessments be applied to other areas?

4. Should the requirements under the Hazard Communication Standard be made identical to those under Proposition 65?

5. Should enforcement actions by Cal-OSHA under the Hazard Communication Standard preclude liability under Proposition 65?

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