

Public Input on the Process for Developing Proposition 65 Safe Harbor Levels:

Issues Raised at the
November 2000 Workshop and in
Written Submissions

February 2001

Reproductive and Cancer Hazard
Assessment Section
Office of Environmental Health Hazard
Assessment
California Environmental Protection
Agency



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Introduction

The Office of Environmental Health Hazard Assessment (OEHHA) sought public input on its proposed process for developing safe harbor levels under Proposition 65, as described in its October 2000 document *Proposition 65 Background Document Public Workshop on Developing Safe Harbor Numbers*. Oral input was solicited at a public workshop held November 15, 2000, and written comment during the period October 27 to December 8, 2000. A list of those commenting is provided in Table 1.

Table 1: Individuals Commenting on the Proposed Safe Harbor Development Process

Written Comments

Kate Buehler of Western Crop Protection Association
Lee Coogan of the Sorptive Minerals Institute
Craig Farr of Atofina Chemicals
Jonathan Frisch of Pacific Gas and Electric
Arthur Lawyer of Technology Services Group, Inc. on behalf of
Bayer Corporation and Dow Chemical and an additional client
Stan Oslosky of Bayer Corporation
Jean-Mari Peltier of the California Citrus Quality Council
James L. McGraw of the International Institute of Synthetic
Rubber Producers, Inc.

Oral Comments Delivered at Workshop

Richard Adamson of the National Soft Drink Association
Ghona Sangha of Bayer Corporation
Jim Wells of Novigen Sciences on behalf of the
California Citrus Quality Council
Jeff Wilson of Astraea, Inc.

Copies of written submissions may be obtained from Ms. Cynthia Oshita by telephone at (916) 445-6900 or by mail at California Environmental Protection Agency, Office of Environmental Health Hazard Assessment, P.O. Box 4010, Sacramento, California 95812-4010. The workshop transcript is available on the OEHHA Web site at www.oehha.ca.gov

Issues Raised

The following summarizes and discusses comments received on the proposed process, with the comment summarized in *italic* and discussion given in regular font.

1. *Multiple comments received were supportive of OEHHA's plans to resume the development of safe harbor numbers at the targeted level of 25-30 no significant risk levels (NSRLs) or maximum acceptable daily levels (MADLs) in the coming year.*

OEHHA appreciates the expressions of support for activities related to the development of safe harbor number, and looks forward to continuing input as safe harbors are developed and released. OEHHA requests that comments and other submissions from the public be made in writing to: Ms. Cynthia Oshita at the address given above.

2. *When selecting chemicals for safe harbor development, chemicals that are actually in use in the State of California and have a realistic expectation of exposure to the general public should be emphasized.*

When selecting chemicals and setting priorities for development of safe harbor numbers an important consideration is the potential for exposures to occur in California. Other factors are also considered, such as the availability and quality of data suitable for dose-response assessment, the availability of staff resources, legal commitments, the needs of the public, and of the Office of the Attorney General.

3. *Soot, carbon monoxide, diesel engine exhaust, crystalline silica, and radon were highlighted as chemicals/mixtures that should have high priority for development of safe harbors, based upon potential for exposure to the general public. Crystalline silica should be moved from second to first priority for NSRL development.*

It is recognized that when there are public exposures to a chemical, the development of a safe harbor level is beneficial and desirable. For the five highlighted chemicals however, additional factors considered in assigning priorities, particularly the availability of staff resources, resulted in priority assignments lower than first priority. For each of the five chemicals it is anticipated that development of a safe harbor would require specialized expertise and considerable staff time. Diesel engine exhaust and crystalline silica have both been assigned to the second priority group for development of NSRLs, and radionuclides (including radon) have been moved to the second group, because it is anticipated that assessments could be completed within the next 2 to 4 years. Given the level of effort required and staff resources, it is more doubtful that a safe harbor level for carbon monoxide could be completed within this period and therefore this compound has been assigned to the third MADL priority group. Soot has been placed in the fourth NSRL priority group because given the data available it appears the assessment would be technically challenging and would consume

considerable resources.

4. *In cases where cancer risks differ across exposure pathways, route-specific NSRLs should be developed.*

NSRLs and MADLs apply to all exposure routes, unless indicated otherwise. For cases where risks differ for the same intake amount by different exposure routes, route-specific safe harbor levels should be developed. Indeed, several route-specific numbers have been placed in regulation. Written requests for development of route-specific safe harbor levels for specific chemicals with differential risks across exposure routes should be submitted to Ms. Oshita at the address given on page 1. It would be helpful if such submissions would include scientific information demonstrating the route specificity.

5. *OEHHA was asked to consider assigning chemicals which are endogenous hormones to First Priority for development of NSRLs. Progesterone was given as an example of a hormone for which the development of an NSRL would provide useful public health guidance for women who may be considering taking progesterone therapy.*

OEHHA will consider elevating the NSRL priority assignment of endogenous hormones on a case-by-case basis, and asks that interested parties identify in writing the specific compounds of interest. Progesterone was verbally suggested as a high priority for safe harbor development. While this compound is currently in the third priority group, should scientific information be received that supports more rapid development of a safe harbor for this chemical, OEHHA will move it up in priority.

6. *The assignment of o-phenylphenol to the First Priority category for NSRL development was supported.*

OEHHA appreciates the supportive comment. The NSRL is expected to be released for comment within one year, at which time OEHHA would welcome public input on the proposed safe harbor level.

7. *Methyl iodide should be moved from "First Priority" to "Fourth Priority" for NSRL development.*

Methyl iodide was originally placed in the first priority group for NSRL development as part of the settlement agreement in the case of AFL-CIO et al. v. Deukmejian (Sacramento Superior Court No. 3481295). In response to the comments received, OEHHA has carefully reconsidered the various factors used in the ordering of chemicals for NSRL development (See discussion of comment #2 above). Methyl iodide has been re-assigned to the second priority group, based primarily on the limited nature and quality of the available dose-response data.

8. *The high priority given to the development of a MADL for arsenic was supported, and new scientific information to be considered in its development was identified.*

The identified information is being considered. OEHHA appreciates the submission of the information.

9. *Isoprene and 4-vinylcyclohexene should be moved from “First Priority” to a lower priority for NSRL development.*

In response to the comments received, OEHHA has reconsidered the priority assignments for isoprene and 4-vinylcyclohexene. After taking into account the multiple factors used in setting priorities, isoprene and 4-vinylcyclohexene have been re-assigned to the second priority group. This was based primarily on a reassessment of the quality and quantity of the available dose-response data, and the level of staff resources required to generate safe harbor levels for these two compounds.

10. *Saccharin and sodium saccharin should be removed from the Proposition 65 list of chemicals known to cause cancer. The development of NSRLs for these chemicals, which presently have been assigned to the First Priority group, should cease.*

Sodium saccharin was originally placed in the first priority group for NSRL development as part of the settlement agreement in the case of AFL-CIO et al. v. Deukmejian (Sacramento Superior Court No. 3481295). OEHHA is aware of recent actions by the International Agency for Research on Cancer, the National Toxicology Program, and the U.S. Congress regarding saccharin and sodium saccharin. The implications of these recent actions on the Proposition 65 listing status of these chemicals are under active review. In light of this, saccharin and sodium saccharin have been moved to a lower priority for NSRL development. OEHHA will initiate safe harbor development for these chemicals only if issues regarding the status of their listings are resolved .

11. *OEHHA was asked how mechanistic data, such as that providing evidence of a threshold, would be considered in the development of an NSRL.*

In setting NSRLs, OEHHA considers the mechanism of carcinogenic action. The regulations governing the development of NSRLs provide for the use of non-default approaches, including threshold-based approaches for deriving NSRLs.

12. *OEHHA should make clear in published policy for the development of NSRLs that Title 22, California Code of Regulations, Section 12705(b) states that OEHHA may base an NSRL on “a risk assessment reviewed by the lead agency and determined to be consistent with the guidelines set forth in Section 12703.”*

OEHHA agrees and has revised the document describing the safe harbor development process accordingly.

13. *It was suggested that public notification be given prior to development of a safe harbor number for a particular chemical so that interested parties may submit risk assessments to OEHHA.*

Assignment of a chemical to the First Priority groups for NSRL and MADL development serves to notify the public that safe harbors are under development. The release of safe harbors on chemicals in the first priority can be expected to be developed in the next one or two years. Risk assessments on Proposition 65 listed chemicals may be submitted by interested parties (See discussion of comment #14).

14. *OEHHA was asked to explain the process by which another agency’s (or an interested party’s) risk assessment might be used to develop a safe harbor number, and to explain the role of other Cal/EPA departments in developing NSRLs.*

Submitted assessments or those that come to OEHHA's attention will be considered in safe harbor level development. In some cases, the assessment may serve as a basis for the safe harbor level. If the assessment serves as the basis of an NSRL and has been done by a state or federal government agency, the NSRL will be published in regulation in 22 CCR 12705(c). If instead it has been done by a non-state of California or non-federal entity, the NSRL will be published in 22 CCR 12705(b). The regulations governing review and revision differ slightly for these two cases, and the reader is referred to the regulations for further details. In some cases the assessment will not serve as the basis of a safe harbor, but will be used as a source of information and analysis. It should be noted that the process of review and consideration of submitted assessments can be lengthy and will depend on the complexity of the scientific information underlying the assessment and on available resources.

15. *OEHHA was asked to provide notice to interested parties if a risk assessment conducted by another agency is found to be inadequate for use in the development of safe harbor numbers.*

OEHHA frequently provides scientific peer review of risk assessments generated by Cal/EPA boards and departments, other state agencies, and federal agencies. These risk assessments provide useful information relevant to the development of safe harbor levels, and may even serve as the basis for the safe harbor number (see discussion of comment #13 above). The regulated community is invited to submit material it finds

would be useful in the establishment of a safe harbor level to OEHHA. Development of safe harbor levels for chemicals in the first priority in the February 2001 *Status Report* has been initiated; thus, it is important to submit critical documents for OEHHA's consideration for these chemicals.

Safe harbor levels are adopted as regulations, and as such are subject to the Administrative Procedure Act. As part of the regulatory process, the basis for any proposed safe harbor is clearly delineated in the Statement of Reasons and accompanying documentation. The proposed action, initial statement of reasons, and informative digest are publicly noticed in the *California Regulatory Notice Register*. Any interested party is welcome to comment on the proposal, propose an alternative basis for the development of a safe harbor, refer to earlier submitted material or submit additional supporting materials. In addition, the party may choose to comment at the public hearing held during the 45-day public comment period. As part of this process all substantive oral and written comments must be addressed. After review of the material, OEHHA may change the safe harbor level, or supporting documentation. Any substantive change, including substantive change in documentation, requires public notice and opportunity for public comment.

Next Steps

OEHHA will be developing and releasing for public comment NSRLs and MADLs for chemicals in the first priority this year, and looks forward to public comment on the safe harbors released. The comments received on priority assignments have been considered and on this basis the OEHHA February 2001 *Status Report* has been revised and released. The general process for developing safe harbor levels is documented in the 2001 OEHHA report *Proposition 65 Process for Developing Safe Harbor Numbers*. This document and the most recent *Status Report* are available on OEHHA's website and from Ms. Cynthia Oshita, at the address noted above.