NLWJC - Kagan

DPC - Box 023 - Folder 003

Kids EO [2]

COVER SHEET

FAX

To: Addressees
From: Gary Guzy, Counselor to the Administrator, EPA
Phone: 202-260-7960
Fax: 202-260-3684
Subject: Children's Environmental Health
Date:
Pages: 8, including cover sheet

COMMENTS:

Attached please find a redraft of EPA's proposed Children's Environmental Health Executive Order. This is an effort to reflect the discussions at yesterday's meeting and results from our continuing direct conversation with several agencies.

Please contact me (260-7960) or Bob Dreher (260-8040) with any comments in advance of today's meeting.

Addressees

Jason Shogren/CEA
Pamela Beth Gilbert/CPSC
Jim Simon/DOJ
Janno Lieber/DOT
Diane Regas/DPC
Lynn Goldman/EPA
Catherine Lorraine/FDA
Elgie Holstein/NEC
Mike Fitzpatrick/OIRA
Carrie Jelsma/OMB
Cheryl Tates-Macias/USDA
David Shark/USTR
Richard Jackson/HHS
Bradley Campbell/CEQ
Ron Lee Medford/CPSC
Robert Clark/DOT
Bill Dinkelacker/DOT
James Aidala/EPA
Robert Hickmott/EPA
Dalton Paxman/HHS
Jon Kaplan/NEC
Sally Katzen/OIRA
Barbara Walton/OSTP
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DISCUSSION DRAFT -- DO NOT CITE OR RELEASE

PROTECTION OF CHILDREN FROM ENVIRONMENTAL HEALTH THREATS

America's children today face significant and unique threats from an array of environmental hazards. A growing body of scientific knowledge demonstrates that children are particularly at risk from environmental hazards for several reasons:

- o Children's immunological, digestive and other bodily systems are still developing, making them more susceptible to toxic pollutants and other environmental hazards;
- o Children eat more food, drink more fluids, and breathe more air in proportion to their body weight than adults, and spend more time outside in play, so they may be more exposed to toxic pollutants and other environmental hazards;
- o Children are less able than adults to recognize and to protect themselves from exposure to toxic pollutants and other environmental hazards, and
- o Children face potential exposures to toxic pollutants over their entire lifetime, with the possibility of more significant health impacts.

While responsible Federal agencies are addressing many environmental hazards, existing environmental standards were derived in many instances principally from data on adults. The array and complexity of environmental health threats facing children today, and the uncertainties in the adequacy of existing protections derived principally to protect adults, pose a significant challenge to our ability to protect our children's health.

The Federal government is responding vigorously to this challenge, acting to address threats to children's environmental health in the new Food Quality Protection Act, and taking administrative action to protect children from tobacco, lead, and other hazards. But we should do more. The Federal government must establish a national policy to protect the health of American children from environmental hazards, and apply its resources, including its scientific research capabilities, in a coordinated and efficient manner to address this threat to children.

Only by tailoring governmental actions, including the setting of

health and safety standards, to recognize and address the oftentimes greater impact that environmental pollutants have upon the health of our children, can we ensure our children's healthy and productive futures. The task before us is large -- developing the basic scientific knowledge of how toxic chemicals and other environmental hazards may differentially impact on children may take years. But the need to act, and to act promptly, to protect the future of our nation cannot be disregarded.

NOW, THEREFORE, to establish a coordinated federal strategy for the protection of children from the risks of exposure to toxic pollutants and other environmental hazards, and by the authority vested in me as President by the Constitution and laws of the United States of America, it is hereby ordered as follows:

Section 1. Policy.

1-101. The head of each Federal agency shall, to the greatest extent practicable, permitted by law, and consistent with the agency's mission, establish the protection of children from environmental hazards as a priority for that agency.

1-102. The head of each Federal agency shall ensure that the potential impacts upon children of environmental hazards arising from or related to the activities of that agency are considered and addressed by that agency to the fullest extent permitted by that agency's statutory authority.

[NOTE: Throughout this draft, EPA has not attempted to address comprehensively the protection of children from all hazards, only from environmental hazards. Other agencies, upon review, may desire to be included in this effort and seek to broaden the applicability of this draft Executive Order beyond health and safety regulations implicating environmental health issues.]

Section 2. Definitions. The following definitions shall apply to this order.

2-201. Federal agency means an Executive agency, as defined in 5 U.S.C. 105. For purposes of this order, military departments, as defined in 5 U.S.C. 102, are covered under the auspices of the Department of Defense.

Section 3. Children's Environmental Health Council.

3-301. Within 60 days of the signing of this order, there shall be established the Children's Environmental Health Council, which shall have general oversight of the implementation of this order.

3-302. The Children's Environmental Health Council ("Council") shall be comprised of representatives of Federal agencies and White House offices with responsibility for the regulation of risks from toxic pollutants or other environmental hazards, or whose activities may substantially affect such hazards, or which conducts scientific or medical research related to such risks or environmental hazards. Member agencies shall include, but are not limited to, the Consumer Product Safety Commission (CPSC), the Environmental Protection Agency (EPA), the United States Department of Agriculture (USDA), the Department of Justice (DOJ), the Department of Health and Human Services (HHS) including, the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH), the Council on Environmental Quality (CEQ), the office of Science and Technology Policy (OSTP), and the Office of Management and Budget (OMB).

3-303. The Council's functions shall include:

(a) Preparation and dissemination of guidance for compliance with this order.

(b) Coordination of the development of the Coordinated Federal Strategy established pursuant to Section 6 of this Order, including the coordinated research agenda for the Federal government established by that section to ensure the best deployment of federal assets to address the policies of this order and to foster linkages between emerging research and policy development.

(c) Encouraging and facilitating the coordination of Federal regulatory initiatives among member agencies, including recommendations to member agencies for joint development of regulations.

(d) Establishment and maintenance of the Research Data Base established pursuant to section 5 of this order.

(e) Preparation and submission to the President of an annual report beginning on October 1, 1997, on the progress made on the Coordinated Federal Strategy described in section 6 of this order.

(f) Consultation with the Office of Management and Budget to provide expertise for Executive Branch review of regulations affecting children's environmental health.

(g) Other actions determined to be appropriate to advance the objectives of this order.

3-304. The Council shall be composed of the Secretary or head of each of the member agencies, or their designees at the Assistant Secretary level or its equivalent.

3-305. The Council shall be consulted by and shall provide advice to the Administrator of the Office of Information and Regulatory Affairs during the review of regulatory actions under

Executive Order 12866 that may affect children's environmental health.

3-306. The Council may establish subcommittees and working groups as appropriate to assist the Council in carrying out its obligations and responsibilities under this order.

3-307. The Administrator of the Environmental Protection Agency shall serve as interim chair of the Council with responsibility for arranging the first meeting. At the first meeting, the Council shall elect a permanent chair, who will serve for a period of one year. Subsequent chairs shall be elected by the Council to serve for one-year terms, with no one member agency holding the chairmanship of the Council for more than two consecutive one-year periods.

3-308. The Council shall exist for a period of five years. At least six months prior to the expiration of that period, the member agencies shall assess the need for continuation of the Council or its functions, and make appropriate recommendations to the President.

Section 4. Research Data Base.

4-401. Within nine months of the date of signature of this order, the member agencies, under the auspices of the Council, shall establish, maintain, and keep current a consolidated research data base that lists and describes all research conducted or funded by the Federal government that is related to adverse health effects in children and infants resulting from exposure to toxic pollutants or other environmental hazards.

4-402. The Council shall encourage the submission of information on academic and other private research for inclusion in the data base.

4-403. The research data base established pursuant to this section shall be available to the public, to the scientific and academic communities, and to all Federal agencies.

Section 5. Coordinated Federal Strategy.

5-501. Within eight months of the signature of this order, the member agencies, coordinated through the Council, shall prepare and publish in the FEDERAL REGISTER a coordinated Federal strategy for the identification and management of risks to children related to exposure to toxic pollutants and other environmental hazards.

5-502. The coordinated Federal strategy required by this section shall include at least the following elements:

(a) Statements of guiding principles, general policy, and targeted annual priorities that will govern the Federal approach to achieving the goals of this order.

(b) A coordinated research agenda for the Federal government, which takes into account the availability of the research listed in the Research Data Base established pursuant to section 4 of this order and a preparation of a cross-cutting budget to accomplish this research. This agenda shall address future research needs, including addressing multiple exposures and cumulative health risks facing infants and children. It should explore appropriate partnerships between the Federal government and other branches of government and the private, academic, and non-profit sectors.

(c) Specific Federal plans for public outreach and information-sharing to assist families in evaluating risks to infants and children in making informal consumer choices, and to establish private-sector partnerships for cooperatively achieving the goals of this order. As part of this effort, the Council shall publish a joint pamphlet for distribution to families assessing children's environmental health threats, and providing practical tips for family protection and additional sources of governmental information.

(d) A statement regarding the desirability of new legislation to ensure that the purposes of this Executive Order are carried out.

(e) The head of each member agency shall prepare for inclusion in the Coordinated Federal Strategy a specific regulatory plan that describes how the agency intends to address the issue of risks to children resulting from exposure to pollutants and other environmental hazards. These plans shall discuss past, current, and future activities and regulatory actions, and shall specifically address utilization of existing authority, regulatory and voluntary initiatives, outreach and information-sharing, and stakeholder involvement, as well as any particular steps to address environmental justice considerations. The Strategy shall also address coordination with governmental social welfare programs, including housing and anti-poverty efforts, profoundly affecting children's health. Member agencies shall involve the public in developing the plans required by this section to the extent consistent with their statutory authority. The Council shall foster coordination of the activities identified in these plans.

Section 6. Agency environmental or health regulations.

6-601. In developing any regulation, rule or standard that

is related to toxic pollutants, environmental hazards, or other environmental health threats, and that is determined to be a significant rule for purposes of Executive Branch review under Executive Order 12866, each Federal agency shall, to the fullest extent consistent with its mission and statutory authority, consider any environmental health risk to children in connection with the proposed regulation, rule or standard. To avoid needless duplication and to promote governmental efficiency, agencies shall incorporate such consideration into their existing procedures.

6-602. If a Federal agency lacks information necessary to make a reasoned evaluation of the health risk to infants and children related to such proposed regulation, rule or standard, the agency shall obtain or work with or direct others to obtain such information if it can reasonably do so, considering the cost of obtaining such information, the time required to obtain it, the availability of scientific means to obtain it, and other relevant factors.

6-603. In promulgating such regulation, rule or standard related to environmental hazards, or other environmental health threats, each agency shall ensure that such final regulation, rule or standard adequately protects the health of children. An agency, may determine, in the exercise of its rulemaking authority and judgment, not to meet this requirement if: (1) the regulation, rule or standard does not potentially implicate any risk to children's health; (2) the agency is precluded by law from considering children's health in reaching its decision; (3) the responsible agency lacks information necessary to make a reasoned evaluation of the effect of the regulation, rule or standard upon the health of children and the cost or time period to acquire such information is unreasonable, or the means of acquiring such information is unknown; or (4) the agency has determined, after full consideration of the potential impacts of the regulation, rule or standard upon children's health, that other considerations within the agency's statutory mandate justify taking an action in this instance that does not fully protect children's health. Each agency shall provide to the public, upon promulgation of such rule, a statement fully setting forth the manner in which it has complied with the requirements of this section.

Section 7. General Provisions.

7-701. This order is not intended, and should not be construed to create any right, benefit, or trust responsibility, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies, its officers, or its employees. This order shall not be construed to create any right to judicial review involving the compliance or noncompliance with this order by the United States, its agencies,

its officers, or any other person.

7-702. Federal agencies should implement this order consistent with, and to the extent permitted by, existing law.

7-703. This order shall be effective immediately and shall continue to be in effect until revoked.

The White House
_____ __, 1997

Federal Register
Vol. 52, No. 174
Wednesday, September 9, 1987

Presidential Documents

Title 3—

The President

Executive Order 12606 of September 2, 1987

The Family

By the authority vested in me as President by the Constitution and laws of the United States of America, and in order to ensure that the autonomy and rights of the family are considered in the formulation and implementation of policies by Executive departments and agencies, it is hereby ordered as follows:

Section 1. *Family Policymaking Criteria.* In formulating and implementing policies and regulations that may have significant impact on family formation, maintenance, and general well-being, Executive departments and agencies shall, to the extent permitted by law, assess such measures in light of the following questions:

(a) Does this action by government strengthen or erode the stability of the family and, particularly, the marital commitment?

(b) Does this action strengthen or erode the authority and rights of parents in the education, nurture, and supervision of their children?

(c) Does this action help the family perform its functions, or does it substitute governmental activity for the function?

(d) Does this action by government increase or decrease family earnings? Do the proposed benefits of this action justify the impact on the family budget?

(e) Can this activity be carried out by a lower level of government or by the family itself?

(f) What message, intended or otherwise, does this program send to the public concerning the status of the family?

(g) What message does it send to young people concerning the relationship between their behavior, their personal responsibility, and the norms of our society?

Sec. 2. *Governmentwide Family Policy Coordination and Review.*

(a) Executive departments and agencies shall identify proposed regulatory and statutory provisions that may have significant potential negative impact on the family well-being and provide adequate rationale on why such proposal should be submitted. The head of the department or agency shall certify in writing that, to the extent permitted by law, such measure has been assessed in light of the criteria in Section 1 of this Order and how such measures will enhance family well-being. Such certification shall be transmitted to the Office of Management and Budget. Departments and agencies shall give careful consideration to family-related concerns and their impact in notices of proposed rulemaking and messages transmitting legislative proposals to the Congress.

(b) The Office of Management and Budget shall, to the extent permitted by law, take action to ensure that the policies of the Executive departments and agencies are applied in light of the criteria set forth in Section 1 of this Order.

(c) The Office of Policy Development shall assess existing and proposed policies and regulations that impact family well-being in light of the criteria established by Section 1 of this Order, provide evaluations on those measures that have significant potential impact on the family to the Office of Management and Budget, and advise the President on policy and regulatory actions that may be taken to strengthen the institutions of marriage and family in America.

Sec. 3. *Report.* The Office of Policy Development shall submit preliminary reports including specific recommendations to the Domestic Policy Council and shall submit a final report to the President no later than 180 days from the date of this Order. Each year thereafter, a report, including recommendations shall be submitted, through the Domestic Policy Council to the President.

Sec. 4. *Judicial Review.* This Order is intended to improve the internal management of the Executive branch and is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any person.

Ronald Reagan

THE WHITE HOUSE,
September 2, 1987.

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Filed 9-8-87; 11:56 am]
Billing code 3195-01-M

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

COVER SHEET

OFFICE OF CONGRESSIONAL AND LEGISLATIVE AFFAIRS

Transmission Number:	202-260-5185
Verification Number:	202-260-5417 202-260-5422

OFFICE OF CONGRESSIONAL AND LEGISLATIVE AFFAIRS

TO: Attached Kids Distribution List

FROM: Louise Cohen / Gary Guzy (202) 260-5417 (Louise)
(202) 260-7960 (Gary)

COMMENTS: Attached please find draft Everglades Cross Cut Budget for F.Y. 98. You may find this useful in thinking about budget for Kids' Initiative

Number of Pages to Follow: ___ DATE: 2-10-97 TIME: ___

Mail Code 1301, West Tower 811

Children's Environmental Health Executive Order

MEETING ATTENDEES:

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John Kennedy	HUD/OGC	(202) 708-2203	708-5698
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THE WHITE HOUSE

WASHINGTON

January 24, 1997

MEMORANDUM FOR DISTRIBUTION

From: **Bradley M. Campbell/CEQ, Elgie Holstein/NEC, Diane Regas/DPC**

Subject: **Children's Health/Right-to-know issues**

A number of agencies have raised fundamental concerns with respect to both the executive order and the legislation proposed for the children's health/right to know initiative. We need to address these issues as quickly as possible as we move forward.

We appreciate EPA's prompt circulation of the draft executive order, and expect that most concerns about that proposal can be addressed and resolved in the course of reviewing the text. The legislative issues, however, are more varied and complex, and all agencies will need to devote focused attention to these issues to resolve them quickly.

Recognizing that resolution of these issues is a priority, we have listed the questions raised in last week's meeting and subsequent discussions. We are asking that all agencies be prepared to address these questions at a meeting on **Tuesday, January 28, at 11:00 a.m. in Room 180 of the Old Executive Office Building.** Please send clearance information by telecopier (date of birth and social security number) to Brad Campbell at 202/456-0753.

Executive Order

1. **Agency Burden.** What are the likely cost and other resource burdens that the Executive Order will place on regulatory agencies? In particular, what affirmative obligations to research and consider risks to children does the Executive Order contemplate when those risks are not known or readily discoverable from existing data that is available to the agency? Can EPA provide examples where Administrator Browner's policy on this issue has been applied?

2. **Regulatory Reform.** How do we present an executive order on this issue without undermining our message on the regulatory reform bills – i.e. our opposition to one-size-fits-all approaches, our discomfort with "best available evidence" approaches.

Legislation

1. **Costs and Benefits.** While we recognize that a full-blown cost-benefit analysis is impractical at this stage, we do need a greater understanding of the expected costs and benefits

of the proposed labeling regime. If possible, this should include consideration not only of the private costs of compliance, but also of the benefits associated with developing the broad range of toxicity data that currently does not exist. Information about the benefits (and effectiveness) of labeling regimes also would be useful. Do we have any data about the likely percentage of products where toxicity data is known and a label will not be needed.

EPA also may want to present the anticipated costs and benefits of not proceeding with such a proposal. These should include not only the costs associated with avoidable child illness or injury, but also costs associated with current gaps in our toxicity database.

2. **Process.** The proposal would shift to private industry the burden of toxicity testing and standard-setting. How will standards for toxicity data be set and reviewed in practice?

3. **Phasing.** To the extent that there may be uncertainty associated with the costs and benefits of the proposal, are there ways to proceed by phases (perhaps by sector or by type of risk) that permit considered judgments about cost to be made at appropriate points in the course of implementation. For example, could the first "phase" relate to carcinogens, with subsequent phase-in of reproductive risks etc.

4. **Potential for Multiple and Inconsistent Burdens.** Is there a way that compliance with California's Proposition 65 can be deemed compliance with this proposal *per se* with respect to covered risks (carcinogens), thus avoiding the charge of creating a new and potentially inconsistent labeling burden.

5. **Small business/trade implications.** Under current trade agreements and policy, is there a way to reduce the burden on small business without relieving importers of the labeling obligation altogether? Separately, is there a possibility of support from domestic industry that must compete with potentially more toxic products from overseas?

6. **Offsetting Regulatory Relief.** If we are requiring new testing, reporting, and labeling requirements, are there existing and less useful requirements that we can propose for elimination as part of the package?

7. **Right-to-know improvements/integration.** Industry objections to right-to-know expansion typically begin with a recital of the multiple reporting obligations they face under current law, and the limitations on access and use of existing requirements. These concerns have been exacerbated by EPA's TRI facility expansion rule and its work toward a materials accounting or "use" data reporting proposal. Are there opportunities for us to create balance in this right-to-know package by integrating and streamlining reporting requirements under current quilt of environmental statutes and regulations?

8. **Regulatory context.** The need for this legislation, in terms of current gaps in the regulatory structure (TSCA failings, overall dearth of toxicity information, etc.), ultimately

will need to be fully set forth.

9. **Bounty.** EPA proposes no bounty for citizen enforcement, yet a bounty may be necessary for citizen groups to establish standing. Should we include at least a nominal bounty (e.g. $1000) to bolster the argument for citizen standing

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 27 1997

To: Gary Guzy, Counselor to the Administrator, EPA

From: William B. Schultz, Deputy Commissioner for Policy
Food and Drug Administration

Subject: FDA Comments on EPA's Children's Environmental Health Proposal

In response to EPA's request for comments on its proposed Executive Order on Children's Environmental Health, the following points summarize FDA's most significant concerns about the proposed action.

Re: Application to FDA

- FDA should be explicitly exempt from the proposed Executive Order.

FDA recognizes the need to consider and protect children, along with other potentially sensitive or special subpopulations, and has taken a number of actions within its organic statutory authority, especially in the last six years, directly protective of children. However, the vast majority of products that FDA regulates cannot be conceived of as "toxic pollutants, environmental hazards, or other environmental health threats". Thus, FDA does not believe that the process established by the proposed Executive Order (see below) adds value to FDA current activities. Indeed, if applied to FDA, the proposed executive order would not produce any benefit for children's health, and would place unreasonable and unnecessary burdens on the agency and the regulated industry.

We note that, after 20 years of experience in applying the analoguous requirements of the National Environmental Policy Act of 1969 (NEPA) to FDA-regulated products, FDA, in consultation with the Council on Environmental Quality, has concluded that the compliance of its regulated manufacturers with NEPA has rarely produced any benefit to the environment, and has placed unnecessary and unreasonable regulatory burdens on the regulated industry and the agency. Consequently, as part of the President's reinventing government initiatives, FDA is drastically reducing the number of situations to which NEPA requirements will apply.

Having just determined that the requirements of NEPA produce so little benefit for one of its most important product areas, FDA is extremely concerned that the requirements of the proposed Executive Order, while potentially useful in other settings, will

likewise result in no benefits to children's health, but will increase costs and impose new burdens on the agency and its regulated industry unnecessarily.

Re: Burdens on Product Approvals

- Complying with the proposed Executive Order will slow product development and will slow the agency's product approval times.

In the last 5 years, FDA has worked extremely hard, in cooperation with regulated industry, to bring product approval times down. These efforts have paid off, and FDA's drug approval times are among the best in the world. If a product is not intended for use in children, there will be no value to manufacturers generating, or FDA reviewing, data on children. The need to generate new data will delay the submission of new product applications to FDA and will result in longer review times by the agency. In addition, the agency is concerned that the proposed order could be read to require statements in regulations and product labeling that might discourage manufacturers from seeking product approvals in the first place.

Re: Scope/definition of Terms

- The scope of the proposed executive is not clear because a number of key terms are not defined.

A. The terms, "environmental hazard", "environmental health threats", and "toxic pollutants" are not defined. As noted above, the vast majority of products that FDA regulates do not fall into a straightforward reading of these terms. The exclusion of FDA-regulated products should be made explicit in the proposed order.

In addition, until the meaning of these triggering terms is defined, it is not clear if the proposed Executive Order applies to predictable exposures to products used as intended, or rather to any possible exposure to any possibly harmful substance that is in a child's environment. If the latter is the case, the burdens that would be imposed on government and industry alike would be staggering.

B. The term "standard" is not defined. Normally, these kinds of Executive Orders do not apply to specific product approval actions. Yet, EPA has stated that the term "standards" is intended to cover product approvals and standard-setting for drugs, biologics, medical devices, and food. As discussed above, we believe that FDA product approvals and product standards should be explicitly exempt from the executive order.

C. The proposed order would also apply to regulations and rules. It is not clear whether "rule" is meant to have the very broad definition it has in the Administrative Procedure Act. If it is, then not only would substantive regulations be covered, but all interpretive rules and general statements of policy would be subject to the requirements as well. The amount of work this would create for FDA (and other covered agencies) is significant and might discourage agencies from taking otherwise beneficial regulatory actions. We note that Executive Order 12866, for example, only applies to "significant" regulations. FDA has previously recommended that the proposed order be limited to significant regulatory actions as defined in Executive Order 12866. The agency reiterates this recommendation.

D. Infants and children are not defined as separate terms. It is thus unclear whether the proposed order would require separate evaluations of these two groups.

Re: Impact on Judicial Review of Covered Actions

- The statements required by the proposed Executive Order could make agency actions more vulnerable to challenge under the Administrative Procedure Act.

Section 7 of the proposed Executive Order provides that it is not intended, and should not be construed, to be judicially enforceable. Section 3-303, however, requires an agency to state that it "lacks information necessary to make a reasoned evaluation of the effect of the regulation, rule or standard upon the health of infants and children, as found in section 3-302" where that is the case for any individual covered action. Putting such statements in administrative records could create a significant legal vulnerability in these actions. FDA thinks that administrative records containing this statement would be open to challenge as arbitrary and capricious or not based on an adequate factual record under the Administrative Procedure Act. This concern is exacerbated by the extremely broad wording of section 3-303: "[the action] does not in any manner potentially implicate any special risk to children's environmental health." This language requires every agency to achieve an impossibly high standard of proof that can never be met because science cannot prove with absolute certainty that no harm will ever result from a product or substance under all potential circumstances.

FDA has an additional substantive concern about the wording of the finding that must be made under section 3 of the proposed executive order. It is possible that it could be construed by a reviewing court as supplementing, and thus changing, the legal standards in the Food, Drug, and Cosmetic Act for the approval of regulated products. This would be highly undesirable.

Re: Policy and Political Considerations

- The increased burdens imposed on government and industry alike and the "one-size-fits all" approach of the proposed order will be used against the Administration by advocates for regulatory reform legislation.

While FDA supports the goals of providing greater public health protection for children, as well as for other sensitive or special subpopulations, we are concerned that aspects of the proposed executive order, in particular the data-gathering, will not be well-received by regulated communities and may generate considerable hostility on the Hill, prompting renewed cries for "regulatory reform". First, to the extent that regulated industry must generate or gather the data, the proposed executive order will impose additional private-sector costs. Second, to the extent that agencies have to gather or generate the data, it will slow down the regulatory and approval processes and may keep beneficial products off the market. Third, to the extent that agencies are responsible for conducting the required research, it imposes significant costs at a time when all resources are shrinking and are therefore at a premium. FDA also notes that the costs associated with the establishment and maintenance of the research data base will be high, and it is not clear which agency would bear these costs. No additional burdens should be placed on federal agencies without proof that significant and important benefits will result.

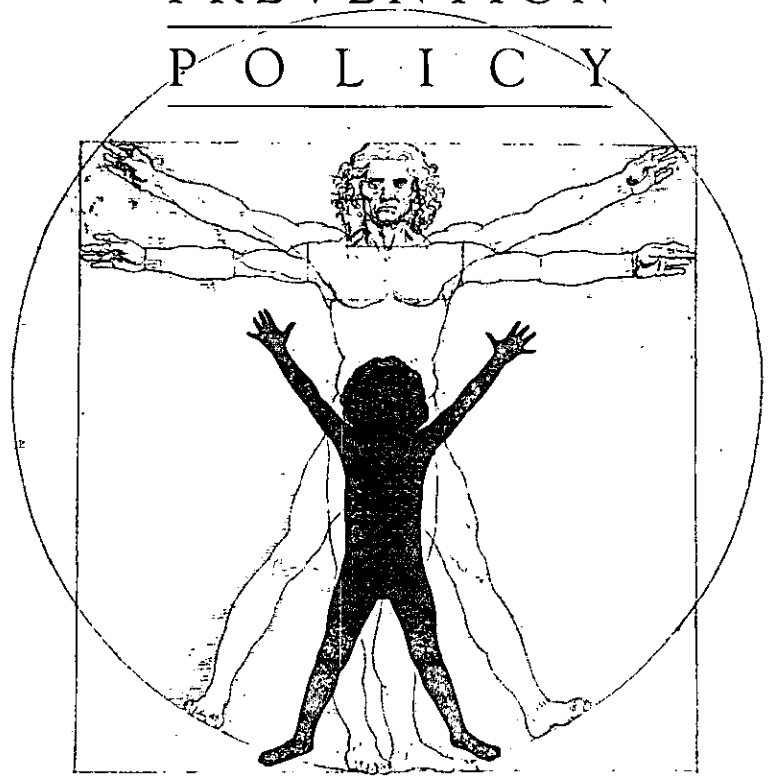
1st National Research Conference on Children's Environmental Health: Research, Practice, Prevention, Policy; February 21-23, 1997

Children's Environmental Health Network
5900 Hollis Street, Suite E
Emeryville, CA 94608

1st National Research Conference on

CHILDREN'S ENVIRONMENTAL HEALTH:

RESEARCH
PRACTICE
PREVENTION
POLICY



FEBRUARY 21-23, 1997

Hyatt Regency Hotel on Capitol Hill
Washington, DC

Children's Environmental Health Network

Research in the field of children's environmental health is growing in importance and stature. In recent years, concerns about environmental exposures and their effects on children have been foremost in the minds of many of the nation's leading researchers and clinicians.

Seventy thousand chemicals are currently allowed for use in the United States and at least 300 new ones are introduced into the environment each year. For the majority of these chemicals little is known about their effects on human health. Scientists are only beginning to understand the relationships that exist among the environment, toxicants, and human health. What is known is that children are uniquely sensitive and uniquely exposed to toxicants.

The Research Committee of the Children's Environmental Health Network has identified five priority areas for research in the field of pediatric environmental health:

- Asthma and respiratory diseases
- Childhood cancer
- Endocrine disorders
- Neurodevelopmental effects
- Cross-cutting issues

The first national research conference on pediatric environmental health offers a unique opportunity for researchers and clinicians to discuss these crucial issues. The nation's preeminent pediatric scientists from basic, clinical, epidemiological, and community-oriented research will come together to provide a unique multi-disciplinary approach in presenting the latest findings in the priority areas.

As an open forum, the Conference will encourage and facilitate discussion, showcase current research, and highlight future research issues in this emerging field. Plenary sessions will address environmental exposures as they pertain to the research priority areas. New approaches, including developmentally based exposures, genetic susceptibility, childhood-based biomarkers, and risk assessment will be interwoven throughout the plenary presentations.

Conference Goals

The Conference is designed to:

- Provide a national forum to present and discuss the latest research findings on pediatric environmental health
- Stimulate collaborative and innovative research efforts among a variety of research disciplines
- Raise the next set of research questions to be investigated and develop research recommendations
- Encourage further research in the field of children's environmental health

Who Should Attend

The Conference is designed for scientists, clinicians, and researchers (basic, clinical, epidemiological, and community-oriented) who have a special interest in children's environmental health in both scientific research and clinical care. Medical and public health professionals from other disciplines are also welcome.

CONFERENCE AGENDA

Thursday Night, February 20, 1997

Early Registration

Friday, February 21, 1997

Registration

Keynote Address

Plenary Session I: *Asthma and Respiratory Diseases*

Presentation: *Environmental Health, Research, and Environmental Justice*

Panel Discussion: *Current and Future Federal Commitment to Children's Environmental Health.* Presenters include the Directors of:

Agency for Toxic Substances and Disease Registry
Centers for Disease Control and Prevention
United States Environmental Protection Agency (invited)
National Cancer Institute (invited)
National Institute of Environmental Health Sciences
National Institute of Child Health and Human Development
National Heart, Lung, and Blood Institute

Saturday, February 22, 1997

Plenary Session II: *Endocrine Disrupters and Children*

Plenary Session III: *Childhood Cancer*

Plenary Session IV: *Neurodevelopmental Effects*

Poster Session

Sunday, February 23, 1997

Plenary Session V: *Cross-Cutting Issues*

- Risk Assessments
- Biomarkers
- Genetic Susceptibilities
- Interdisciplinary Approaches

Research Recommendations and Open Discussion

Adjourn at Noon

Please note: Conference agenda is subject to change. Updated agendas will be sent with registration confirmation letters.

Registration

Registration fee for the full Conference is $275 and includes two lunches, Friday night reception, all conference materials, and a post-conference report. **Early registration deadline is January 17, 1997.** A $50 late fee will apply to registration received after this date. Please note that the registration fee on the day of the Conference is $375.

Make your checks payable to the **Public Health Institute** (Federal ID# is 94-1646278) and send with the attached registration form to:

Rod Armstrong
Children's Environmental Health Network
5900 Hollis Street, Suite E
Emeryville, CA 94608

Cancellation Policy

For cancellations prior to February 7th, the full registration fee, less a $50 processing fee, will be refunded. **There will be no refund for cancellations made after February 7, 1997.** All cancellation requests must be made in writing and sent to:

Rod Armstrong
Children's Environmental Health Network
5900 Hollis Street, Suite E
Emeryville, CA 94608

All refunds will be issued after the Conference.

Hotel Accommodations

The Conference will be held at the Hyatt Regency Hotel on Capitol Hill. A block of guest rooms has been reserved at the Hotel for the nights of Thursday, February 20 through Sunday, February 23, 1997 at the special rate of $129 single/$154 double (plus 13% tax and $1.50 per room night occupied). **Please note: after January 20, 1997 rates will be subject to space availability.** Make your hotel reservation early to guarantee a room at the discounted group rate.

To make your reservation, call toll-free 1-800-233-1234 or (202) 737-1234 and refer to the group name: Research Conference. Please be sure to record your reservation confirmation number. All guest rooms are available on a first come, first served basis. Hotel reservation and costs are the responsibility of attendees.

The Hyatt is located two blocks from the US Capitol, and the House and Senate Office Buildings, and is in close proximity to the Mall, Smithsonian Museums, and the Lincoln, Washington, Jefferson and Vietnam Veteran monuments. The Hotel's amenities include 24-hr room service, indoor valet parking, and a pool and health club.

Ground Transportation

The Hotel is located ten minutes away from Washington National Airport and 45 minutes from Washington-Dulles and Baltimore-Washington International Airports. From Washington National Airport, the average cab fare is $14; from Washington-Dulles and Baltimore-Washington Airports, the fare is approximately $40-50. The Hotel is two blocks from the Amtrak's Union Station and Metro Subway. The average temperature of Washington DC in February is 46° Fahrenheit.

Conference Sponsors

We wish to thank and gratefully acknowledge our sponsors for their generous support:

National Institute of Environmental Health Sciences

Environmental Hazards Assessment Program
Medical University of South Carolina

United States Environmental Protection Agency

National Center for Environmental Health
Centers for Disease Control and Prevention

Agency for Toxic Substances and Disease Registry

Division of Cancer, Epidemiology, and Genetics
National Cancer Institute

National Institute for Child Health and Human Development

Public Health Institute

Environmental Health Investigations Branch
California Department of Health Services

Children's Environmental Health Network

The Children's Environmental Health Network is a multi-disciplinary and multi-cultural national project whose mission is to promote a healthy environment and protect the fetus and the child from environmental hazards. The Network is comprised of national experts in research, medicine, and policy representing numerous national professional organizations concerned with children's environmental health. The three areas of concentration for the Network are: research, education, and policy.

For more information about the Network, its publications, and other activities, please contact us at:

Children's Environmental Health Network
5900 Hollis Street, Suite E
Emeryville, CA 94608

Phone (510) 450-3818
Fax (510) 450-3773
E-mail cehn@aimnet.com
or visit our website at: http:\\www.cehn.org

Call For Posters

Abstract deadline is January 10, 1997

A special multi-disciplinary poster session will allow participants to discuss their research with interested colleagues in an informal setting on Saturday afternoon, immediately following the last plenary of the day. This direct, personal exchange of information and discourse is one of the most important aspects of the Conference and provides an opportunity for authors to present their research in detailed discussion.

Posters from a variety of fields and disciplines that pertain to children's health and the environment are welcome. Abstracts that address one of the five Conference Plenary topics are especially encouraged. These topics are: asthma and respiratory diseases; childhood cancer; endocrine disorders; neurodevelopmental effects; and cross-cutting issues.

Please submit your abstract on the attached Abstract Form (see reverse side of Poster Submission Form) or on a sheet of 5 1/2" x 8 1/2" plain white paper and include a concise description of the proposed presentation in narrative form. Abstracts will be included in the conference packets and printed as they appear on the original submissions. In case we need to make any changes to your submission, please also provide your abstract on a 3.5 inch diskette in Microsoft Word 5.1, Word for Windows 2.0, or Word Perfect 5.1. No Fax submissions will be accepted. Call **Carol Harris for an abstract packet with complete instructions.**

Mail your Poster Submission Form, the original abstract (please place in a protective cover and do not fold), and four copies of the abstract to:

Carol Harris
Children's Environmental Health Network
5900 Hollis Street, Suite E
Emeryville, CA 94608

Each presenter will receive a confirmation letter and poster number. If you have any questions about the poster session, please contact:

Carol Harris
Phone: (510) 450-3818
e-mail: charris2@hw1.cahwnet.gov

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Poster Submission Form

Abstract Deadline is January 10, 1997.
Please provide all information requested.

Presenting Author:

Name _____

Affiliation/Institution _____

Mailing Address _____

_____

Telephone _____ FAX _____

E-Mail _____

Topic of Poster:

___ Asthma and respiratory diseases
___ Childhood cancer
___ Endocrine disorders
___ Neurodevelopmental effects
___ Cross-cutting issues (genetics, biomarkers, etc.)
___ Other (please specify _____)

Presentation Title:

_____

_____

Additional Authors (List the names, degrees, addresses, phone, fax numbers, and e-mail for all additional authors. Use a separate sheet if necessary.):

_____

_____

_____

_____

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Registration Form

(please type or print)

_____
Name

_____
Title

_____
Organization

_____
Address

_____
City State Zip Country

_____
Phone Fax

_____
E-mail

Special Services or Dietary Needs (please specify):

_____

Conference Fees

$_____ **$275 Early Registration**
(received by January 17, 1997)

$_____ **$325 Late Registration**
(received after January 17 until on-site)

$_____ **$375 On-Site Registration**
(February 21, 1997)

$_____ **$150 One Day Only and/or Guest**

$_____ **$150 Students, Residents, and Interns**
(please include a letter from your institution to verify your status)

$_____ **Total** *(enclose check payable to:* **Public Health Institute***)*

___ Yes, I plan to attend and stay at the Hyatt.
___ Yes, I plan to attend and do not plan to stay at the Hyatt.
___ No, I do not plan to attend, but please send additional information.

Abstract Form

Conference Presenters and Speakers Include:

Duane Alexander, MD, National Institute of Child Health and Human Development
Cynthia Bearer, MD, PhD, Case Western Reserve University
W. Archie Bleyer, MD, University of Texas
Robert Bullard, PhD, Clark Atlanta University
Luz Claudio, PhD, Mount Sinai Medical Center (invited)
Katsi Cook, American Indian Program at Cornell University
Joan Cranmer, PhD, University of Arkansas for Medical Sciences
Ruth Etzel, MD, PhD, Air Pollution and Respiratory Health Branch, CDC
Lynn Goldman, MD, MPH, United States Environmental Protection Agency
Patrick Holt, DSc, Institute for Child Health Research, Australia
Richard Jackson, MD, MPH, National Center for Environmental Health, CDC
Barry Johnson, PhD, Agency for Toxic Substances and Disease Registry
Richard Klausner, MD, National Cancer Institute (invited)
Philip Landrigan, MD, MSc, Mount Sinai Medical Center
Claude Lenfant, MD, National Heart, Lung, and Blood Institute
John McLachlan, PhD, Tulane-Xavier Center for Bioenvironmental Research
Gary Myers, MD, University of Rochester
Herbert Needleman, MD, University of Pittsburgh, School of Medicine
Kenneth Olden, PhD, National Institute of Environmental Health Sciences
J. Routt Reigart, MD, Medical University of South Carolina
Leslie Robison, PhD, University of Minnesota
David Satcher, MD, PhD, Centers for Disease Control and Prevention
Lawrence Schell, PhD, University at Albany, SUNY
Bernard Schwetz, DVM, PhD, Food and Drug Administration (invited)
Kevin Shannon, MD, University of California, San Francisco
Martyn Smith, PhD, University of California, Berkeley
William Suk, PhD, MPH, National Institute of Environmental Health Sciences
Alice Tarbell, First Environment Research Projects
Hugh Tilson, PhD, United States Environmental Protection Agency
H. James Wedner, MD, Washington University School of Medicine (invited)

Keynote Addresses by:

The Honorable Albert Gore, Jr., Vice President of the United States (invited)
The Honorable Carol Browner, Administrator of the United States Environmental Protection Agency

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
THE ADMINISTRATOR

TO: Diane Regas

FROM: Loretta Ucelli

COMMENTS: I thought the attached would be helpful in terms of language on Childrens health

Number of Pages to follow: 6
Date: 3/20
Time:

Transmission Number: (202) 260-3684
Verification Number: (202) 260-7960 or 260-9828

Office of the Administrator
401 M Street, S.W.
Room 1204 West Tower
Mail Code: 1101

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Carol M. Browner
Administrator, U.S. Environmental Protection Agency
Report on Environmental Health Risks to Children
National Agenda to Protect Children from Environmental Threats

OFFICE OF
COMMUNICATIONS, EDUCATION AND
PUBLIC AFFAIRS

Prepared for Delivery
September 11, 1996

Today I am pleased to release a major EPA report on environmental health threats faced by children. Today's report details the health threats faced by children from toxics in the environment and sets forth a new national agenda to protect children from those risks more comprehensively than ever before.

As you know, protecting children from environmental harm has been a goal of mine and a goal of the Clinton Administration from the very beginning. Today's report brings together in one place the information we have about environmental threats to children's health and outlines how we as an Agency can address those threats.

Children face significant, long-term, and unique threats from environmental toxics. We must take a comprehensive approach to providing children with stronger health protection against those threats. Only when we have protected our children can we be sure that we are providing adequate public health protection for all Americans.

Among the findings about children's special vulnerabilities and exposure to environmental threats are these:

Asthma deaths among children and young people increased by 118 percent between 1980 and 1993. Asthma is now the leading cause of hospital admissions for children.

Children exposed to tobacco smoke at home have 16 million more days of restricted activity, 10 million more days of bed confinement, and miss 7 million more school days each year than other children.

Lead poisoning affects as many as 1.7 million young children.

Ten million children under the age of 12 live within four miles of a toxic waste dump.

Children are more at risk from toxics because their systems are still developing and because they consume more food and fluids, relative to their body size, than adults.

Children's unique behavior -- crawling on the floor or playing outside -- exposes them more to pollution and related health threats.

We must meet the challenge of protecting our children from toxics in our environment. An awareness of children's unique susceptibility, their unique exposure to toxic threats, must guide every action we take to protect public health and our environment.

Our National Agenda to Protect Children's Health from Environmental Threats is to be undertaken by EPA, other government agencies, health professionals, parents, teachers, and other groups. Among the actions outlined in the Agenda are these:

1. In setting public health and environmental standards, EPA will take into account the unique vulnerabilities of children, to ensure that all standards protect children. This new policy will apply to standards we set in the future -- but in addition, we will review our most significant current standards to ensure that they protect children. We will select five of our most significant current standards to be re-evaluated on an expedited basis.

2. To ensure that EPA applies the best science to our efforts to protect children, we will expand research on environmental health threats to children. We will seek to establish and fund two National Centers of Excellence on Children's Environmental Health at established medical institutions.

3. To ensure that children's health is approached comprehensively, EPA will address children's total exposure to toxic chemicals, moving beyond the chemical-by-chemical approaches of the past, so that we can address cumulative and simultaneous exposures.

4. EPA will expand our right-to-know program. We will seek to provide better consumer information to families about children's health risks; to educate parents, teachers, and community leaders about those risks and what they can do to address them; and to educate health professionals to identify, prevent, and reduce toxic threats to children.

The Agenda we outline today builds on a series of aggressive actions taken by this Agency and this Administration over the past three-and-a-half years to protect children -- unprecedented actions to protect children from pesticide risks in their food -- tough new standards for industrial air pollution -- accelerating the pace of toxic waste cleanup -- expanding the right to know about toxic pollution -- new safety controls and public information on toxic hazards in the home.

All of these actions will help to ensure for our children a healthy environment and a healthy future. By protecting children, the most vulnerable among us, we protect all of us.

###

g: children.wh

Talking Points -- Children's Health Risks
White House Event -- December 18, 1995

Today I presented to the President a report from EPA on children's environmental health risks. I want to summarize for you what the report says.

Children are particularly vulnerable to environmental health risks.

Children are not just little adults.

They are still developing. Exposure to pollution can impair their development.

They are more exposed because they eat more food per body weight, breathe more air per body weight, drink more water per body weight.

Their behavior is different: They have a different diet, crawl around on the ground, put things in their mouths.

We have evidence that children's health is increasingly at risk from environmental problems.

Pesticide exposure is a significant concern. Two years ago, the National Academy of Sciences report called on EPA to address risks to children of pesticide residues on food.

Asthma is on the rise in children -- it increased by 42% between 1980 and 1987.

Contaminants in drinking water pose a particular risk to infants, who drink more per body weight and whose immature immune systems cannot fend off microbial contaminants.

Polluted water is a particular risk to children who eat fish, children who swim.

Lead poisoning remains a concern. Three million children have significant amounts of lead in their blood.

Children continue to be at risk from toxic waste sites that remain to be cleaned up.

PCB's persist in the environment; children whose mothers are exposed during pregnancy may have developmental problems.

The Clinton Administration's EPA has made protecting children's health a priority.

In response to the 1993 report from the National Academy of Sciences on children and pesticides, the Clinton Administration took aggressive action to reduce pesticide risks to children and all Americans.

. EPA accelerated evaluation of older pesticides and registration of newer, safer pesticides.

. EPA launched a major effort to gather reliable data on children's exposure and risk.

. In June of 1993, the Clinton Administration announced an inter-agency policy to reduce pesticide use and pesticide risk nationwide.

. EPA launched a Pesticide Environmental Stewardship Program to work with growers and pesticide manufacturers to reduce pesticide risks;

In October of this year, EPA adopted a new policy to protect children from pollution by ensuring, for the first time, that children's health risks will be consistently and explicitly evaluated in all scientific and standard-setting activities.

The Clinton Administration has also taken many other actions that protect children and all Americans: we strengthened our enforcement of environmental laws and took action to reduce air pollution, reduce children's lead exposure, accelerate toxic waste cleanups, and expand the public's right-to-know about toxic chemicals in their neighborhoods.

But more remains to be done.

To continue our progress in reducing children's pesticide risks, we must continue to gather data, conduct basic research, carry out risk assessments on multiple exposures, take regulatory action, and educate the public.

And, we must continue our progress in reducing air pollution, water pollution, and exposure to lead and other toxic materials that endanger children's health.

President Clinton's budget reflects a strong and explicit commitment to protecting children's health.

The Republican budget threatens our ability to continue our progress and meet the challenges of the future in protecting children's health in four ways:

The Republican budget cuts EPA funds for standard-setting by 17% as compared with the President's request.

The President's budget includes funding for specific actions to protect children: by setting new standards for pesticides in food, contaminants in drinking water, and dangerous air pollutants.

This includes a third year of funding -- $2.3 million in FY 96 -- for standard-setting as part of the initiative on pesticides and children.

The Republican budget cuts science and technology funds by 22% compared to the President's budget.

These cuts could delay vital research on children's health, which would result in putting yet another generation of children at risk.

The President's budget for EPA makes children's health a priority, including:

$5.5 million for EPA research as part of the initiative on children and pesticides, plus up to $3 million for outside research on children and pesticides

$8.4 million for research to support new drinking water standards and controls on microbial contaminants

$25 million for research on ground-level ozone (smog) and $7 million for research on tiny particles of air pollution, which cause respiratory illness to which children are particularly vulnerable

research on children and toxic urban air pollutants

$5 million for research on endocrine disruptors that cause reproductive disorders

The Republican budget cuts environmental enforcement cut by 27%.

> Their budget cuts "low priority" enforcement. Does that include the two children who died when they crawled into a Dumpster where toxic waste had been dumped?

The Republican budget cuts by 45% funding to guard against drinking water contamination.

> The President provided $500 million in loan funds to help communities upgrade drinking water facilities to guard against microbial threats and other contamination.

The Republican budget cuts funding that would help communities keep raw sewage out of rivers and beaches.

> Their budget cuts funds for communities by 30% -- a special threat for children whose drinking water comes from polluted rivers, lakes; and a threat to children who swim, boat, and fish.

Protecting our children is fundamental. We must not allow the Republican assault on public health and our environment to place our children at risk.

President Clinton's plan balances the budget without sacrificing the health of our children.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
THE ADMINISTRATOR

TO: Diane Regas
456 -

FROM: Loretta Hall

COMMENTS: One more memo —

Number of Pages to follow: 1
Date: 3/20
Time:

Transmission Number: (202) 260-3684
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Office of the Administrator
401 M Street, S.W.
Room 1204 West Tower
Mail Code: 1101

Clinton Administration Accomplishments in Reducing Environmental Threats to Children

- **Putting children's health first in assessing environmental risks.** In 1995, the Clinton Administration initiated the first ever national policy to consistently and explicitly take into account health risks to children and infants from environmental hazards when conducting assessments of environmental risks.

- **Expanding research on environmental risks and exposures unique to children.** The Clinton Administration has increased the research and testing needed to learn more about children's exposure to toxic substances, such as pesticides in food, and to establish new standards to protect children and infants from health risks, such as dietary health risks posed by pesticides.

- **Reducing children's health risks from food pesticides.** In 1993, the Clinton Administration announced a new policy to reduce the use of high-risk pesticides. The Administration has also canceled some of the most dangerous pesticides while moving safer substitutes onto the market more quickly.

- **Protecting children from lead poisoning.** Because lead poisoning can cause serious learning disabilities in children, the Clinton Administration has expanded the federal government's efforts to remove lead paint remaining in the nation's housing, including removing lead paint from housing where children live, or are likely to live; conducting research on lead poisoning and lead abatement; and implementing a new right-to-know program requiring homeowners to inform potential buyers and renters of lead in the home.

- **Set tough environmental and public health standards to protect children.** The Clinton Administration has set tough standards to keep raw sewage and toxic pollution from flowing into our rivers, lakes and streams and contamination in our drinking water. Children drink proportionately more water than adults.

- **Accelerating toxic waste cleanups.** Nationally, 10 million children under the age of 12 live within four miles of a Superfund hazardous waste site. The Clinton Administration has streamlined the Superfund program, cleaning up more Superfund sites in the last three years than in the entire 12 year history of the program.

- **Expanding Community Right-to-Know Laws.** The Clinton Administration has expanded the Community-Right-to-Know laws -- doubling the number of chemicals that must be reported and increasing enforcement of the law -- so that parents will know what toxic chemicals their children are being exposed to in their neighborhoods.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503
March 17, 1997

MEMORANDUM FOR ELENA KAGAN (DPC)
KATHLEEN WALLMAN (NEC)
KATIE MCGINTY (CEQ)
ALICE MUNNELL (CEA)
T.J. GLAUTHIER (OMB/NRES)

FROM: Mac Reed MR2

SUBJECT: Proposed Executive Order Entitled "Protection of Children from Environmental Health Risks and Safety Risks"

Attached is a revised draft of the proposed Executive order entitled "Protection of Children from Environmental Health Risks and Safety Risks." It reflects Sally Katzen's suggested deletions and additions based on her discussions with you at the 6:00 p.m. meeting on Thursday March 13, 1997. Deletions are bracketed and additions are underlined.

Please review the order and provide any comments to Sally by 12:00 noon Tuesday, March 18, 1997. She may be reached by phone at 395-4852 ~~and by fax at 395-3047~~.

Thank you.

Attachment

cc: Bob Damus

I will give you my thoughts in writing -- unless you request otherwise.

Diane.

Alec -- Paul wants to discuss staffing of this with you.

DRAFT
3-17-97
1:00

Executive Order

- - - - - -

Protection of Children from Environmental Health Risks and Safety Risks

By the authority vested in me as President by the Constitution and the laws of the United States of America, I hereby order as follows:

Section 1. Policy.

1-101. A growing body of scientific knowledge demonstrates that children may suffer disproportionately from environmental health risks and safety risks. These risks arise because: children's neurological, immunological, digestive and other bodily systems are still developing; children eat more food, drink more fluids, and breathe more air in proportion to their body weight than adults; children's size and weight may diminish their protection from standard safety features, and children's behavior patterns may make them more susceptible to accidents because they are less able to protect themselves. Therefore, to the extent permitted by law and [to the fullest extent] appropriate and consistent with the agency's mission, each federal agency:

(a) shall make it a [high] priority to identify and assess environmental health risks and safety risks that may disproportionately affect children; and

(b) shall ensure that its policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks or safety risks.

1-102. Each independent regulatory agency is encouraged to participate in the implementation of this Executive order and comply with its provisions.

Sec. 2. Definitions. The following definitions shall apply to this order.

2-201. Federal agency means any authority of the United States that is an agency under 44 U.S.C. 3502(1) other than those

considered to be independent regulatory agencies under 44 U.S.C. 3502(5). For purposes of this order, military departments, as defined in 5 U.S.C. 102, are covered under the auspices of the Department of Defense.

2-202. Covered regulatory action means any substantive [regulatory] action in a rulemaking initiated after the date of this Executive order that is likely to result in a rule that may:

(a) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; and

(b) concern an environmental health risk or safety risk that may disproportionately affect children.

2-203. Environmental health risks and safety risks mean risks to health or safety that are attributable to[: industrial, household or agricultural chemicals (including those added to food); physical agents (such as heat, radiation, fire, explosives, or electricity); machinery and equipment; transportation accidents; by-products of combustion or industrial processes; prescription drugs; consumer products; activity patterns; and substance abuse.] products or substances with which the child [would ordinarily] come in contact with or ingest (such as the air we breath, the food we eat, the water we drink, the soil we live on, and the products we live or play with.)

Sec. 3. Task Force on Environmental Health Risks and Safety Risks to Children.

3-301. There is hereby established the Task Force on Environmental Health Risks and Safety Risks to Children ("Task Force").

3-302. The Task Force will report to the President in consultation with the Domestic Policy Council, the National Science and Technology Council, [and] the Council on Environmental Quality, and the Office of Management and Budget ("OMB").

3-303. Membership. The Task Force shall be composed of the:

(a) Secretary of Health and Human Services, who shall serve as a Chair of the Council;

(b) Administrator of the Environmental Protection Agency, who shall serve as a Chair of the Council;

(c) Secretary of Education;

(d) Secretary of Labor;

(e) Attorney General;

(f) Secretary of Energy;

(g) Secretary of Housing and Urban Development;

(h) Secretary of Agriculture;

(i) Secretary of Transportation;

(j) Chair of the Consumer Product Safety Commission;

(k) Chair of the Council on Environmental Quality;

(l) Director of the Office of Management and Budget;

(m) Assistant to the President for Economic Policy;

(n) Assistant to the President for Domestic Policy;

(o) Assistant to the President and Director of the Office of Science and Technology Policy;

(p) Chair, Council of Economic Advisers; and

(q) Such other officials of Executive departments and agencies as the President may, from time to time, designate. Members of the Task Force may delegate their responsibilities under the order to subordinates.

3-304. Functions. The Task Force shall develop a recommended Federal strategy for children's environmental health and safety, [within the limits of the Balanced Budget Plan,] within the limits of the Administration's budget, to include the following elements:

(a) Statements of principles, general policy, and targeted annual priorities to guide the federal approach to achieving the goals of this order.

(b) [A coordinated research agenda for the Federal Government, including steps to implement the plan for

the consolidated research database developed pursuant to section 4 of this order. [and for budget proposals that reflect investments of Task Force members to accomplish this research.]] A coordinated research agenda for the Federal Government, including steps to implement the review of research databases described in section 4 of this order.

(c) Recommendations for appropriate partnerships among federal, state, tribal and local governments and the private, academic, and non-profit sectors.

(d) Proposals to enhance public outreach and communication to assist families in evaluating risks to children and in making informed consumer choices;

(e) An identification of high-priority initiatives [for] that the Federal Government [to undertake] has undertaken or will undertake in advancing protection of children's environmental health and safety.

(f) A statement regarding the desirability of new legislation to fulfill or promote the purposes of this Executive order.

3-305. The Task Force shall prepare a biennial report on research, data, or other information that would enhance our ability to understand, analyze, and respond to environmental health risks and safety risks to children. For purposes of this report, cabinet agencies and other agencies identified by the Task Force shall identify and specifically describe for the Task Force key data needs related to environmental health risks and safety risks to children that have arisen in the course of the agency's programs and activities. The Task Force shall incorporate agency submissions into its report and ensure that this report is publicly available and widely disseminated. The White House Office of Science and Technology Policy and the National Science and Technology Council shall ensure that this report is fully considered in establishing research priorities.

3-306. The Task Force shall exist for a period of four years from the first meeting. At least six months prior to the expiration of that period, the member agencies shall assess the need for continuation of the Task Force or its functions, and make appropriate recommendations to the President.

Sec. 4. Research Coordination and Integration.

4-401. [Within six months of the date of this order, the White House Office of Science and Technology Policy and the National Science and Technology Council shall present to the Task Force a proposed plan for establishing, maintaining, and keeping current a consolidated research data base that lists and describes all research conducted or funded by the Federal Government that is related to adverse health effects in children resulting from exposure to environmental health risks or safety risks. This plan shall include recommendations to ensure that the activities of the Task Force and other requirements of this order are fully integrated with, and not duplicative of, other current or planned initiatives with respect to children's health and safety.] Within six months of the date of this order, the White House Office of Science and Technology Policy and the National Science and Technology Council shall present to the Task Force a review of existing and planned data resources and a proposed plan for ensuring that researchers and federal research agencies have access to information on all research conducted or funded by the Federal Government that is related to adverse health risks in children resulting from exposure to environmental health risks or safety risks.

4-402. [The plan shall promote the submission of information on academic and other private research for inclusion in the data base.] The plan shall promote the sharing of information on academic and private research. It shall include recommendations to encourage that such data is available to the public, the scientific and academic communities, and all federal agencies.

4-403. The plan shall include provisions to ensure that, to the extent permitted by law, the consolidated research data base

is available to the public, the scientific, and academic communities, and all Federal agencies.

Sec. 5. Agency environmental health risk or safety risk regulations.

5-501. For each covered regulatory action submitted to OMB's Office of Information and Regulatory Affairs ("OIRA") for review, the issuing agency shall provide to OIRA the following information developed as part of the agency's decisionmaking process, [to the fullest extent permitted by law] unless prohibited by law:

(a) An evaluation of the environmental health or safety effects of the [covered regulatory action] planned regulation on children;

(b) An assessment of potentially effective and reasonably feasible alternatives to the [covered regulatory action,] planned regulation, ~~that have been~~ identified by the agency or the public, that provide different degrees of protection [and that may more effectively mitigate or reduce risks to children]; and

(c) An explanation of why the covered regulatory action is preferable to the identified potential alternative(s).

5-502. In emergency situations, or when an agency is obligated by law to act more quickly than normal review procedures allow, the agency shall comply with the provisions of this section to the extent practicable. For those covered regulatory actions that are governed by a court-imposed or statutory deadline, the agency shall, to the extent practicable, schedule rulemaking proceedings so as to permit sufficient time for completing the analysis required by this section.

5-503. The analysis required by this section may be included as part of any other required analysis, and shall be made part of the administrative record for the covered regulatory action or otherwise made available to the public, to the extent permitted by law.

Sec. 6. Interagency Forum on Child and Family Statistics. (a) Establishment. The Director of the OMB ("Director") shall establish an Interagency Forum on Child and Family Statistics ("Forum"). The Forum would include representatives from the appropriate Federal statistics and research agencies. The Forum would produce an annual compendium ("report") of the most important indicators of the health and well-being of children.

(b) Procedures. The Forum shall determine the indicators to be included in the Report and identify the sources of data to used for the indicators. The Forum shall also provide an ongoing review of overall Federal activity in the collection of data on children and families. It shall also make recommendations to improve the coordination of data collection and to reduce duplication and overlap.

(c) Report. The Report shall be published by the Forum in consultation with the National Institute for Child Health and Human Development. The Forum shall issue the first annual report to the President, through the Director, by July 31, 1997. The report shall be submitted annually thereafter, using the most recently available data.

Sec. 7. General provisions.

7-701. This order is intended only for internal management of the Executive Branch. This order is not intended, and should not be construed to create, any right, benefit, or trust responsibility, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies, its officers, or its employees. This order shall not be construed to create any right to judicial review involving the compliance or noncompliance with this order by the United States, its agencies, its officers, or any other person.

7-702. Executive Order 12606 of September 2, 1987 is revoked.

THE WHITE HOUSE,

THE WHITE HOUSE

WASHINGTON

March 17, 1997

MEMORANDUM TO Elena Kagan

FROM: Diane Regas

SUBJECT: Protection of Children from Environmental Health Risks and Safety Risks – Comments on 3/17 version

I have some questions and comments about some of the changes in the version that was circulated to you this afternoon. Most of the changes are straightforward and positive, below I only list the ones I have concerns about. The key concern I have is that section 5 does not, as written, require an analysis of how the alternative regulatory approaches affect children.

Page 1 1–101(a): Take out [redacted]high[redacted]. This change seems to leave the meaning of para. (A) ambiguous because making something [redacted]a priority[redacted] does not answer whether it should be a high or low priority. Given that the para. is already limited to those actions that are legal, appropriate and consistent with agency mission I think [redacted]high[redacted] priority is appropriate. Alternative modifiers, like [redacted]important[redacted] could also be considered.

Sally agreed to leave in 'high'

Page 2: sec 2–203: This definition as a whole is a big improvement and moves us along by an order of magnitude. I have a couple of concerns: [redacted]would ordinarily[redacted] seems too subjective, although we want to build in discretion. I would suggest [redacted]is likely to[redacted] retains discretion, clearly limits agencies to likely scenarios, but clearly does not exclude predictable accidental exposures.

✓

[redacted]products we live or play with[redacted] is either redundant (products we live with are products we play with--true at my house) or it is exclusive of an important category of products that we should cover, namely products children are exposed to at work. For example products (like carpet) used in day care centers that aren't played with; products used in work places where children are disproportionately exposed (a cleaning solvent used in McDonald's that has developmental effects on 15 year–olds). I would suggest just [redacted]products[redacted] or [redacted]products we live with[redacted] or [redacted]products children may be exposed to[redacted].

Live w/

Page 4, sec 3–304(b) This change to remove the consolidated budget loses a good idea. While I understand the budget concern, we have done an integrated budget for other issues (see Everglades budget attached). This integration is an important catalyst for agency coordination and makes agencies focus on whether the federal government as a whole is spending wisely.

Talk to T.J.

Page 4, sec 3–304(e) This change highlights a need to clarify that the public should be consulted in this process. I would suggest a sentence like, [redacted]The selection of these initiatives should take into account public views.[redacted]

Page 6, Sec 5–501(a): I do not understand why the text should deviate from the defined terms.

Page 6, Sec 5–501(b): This section is unclear about the absolutely key point that the alternatives analysis needs to include an analysis of the effect of the regulation ***on kids***. I would suggest that the intro to section (b) track section (a) so that it reads: [redacted]An evaluation of the environmental health or safety effects on children of potentially effective and reasonably feasible....etc.

CALIFORNIA ENVIRONMENTAL
PROTECTION AGENCY

Office of Environmental Health Hazard Assessment

Safe Drinking Water and Toxic Enforcement Act of 1986--Proposition 65

INFORMATION PACKET

TABLE OF CONTENT

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT
PROPOSITION 65 IMPLEMENTATION
P. O. BOX 942732
SACRAMENTO, CALIFORNIA 94234-7320
(916) 445-6900
(916) 327-1097 FAX

Internet Address: http://www.calepa.cahwnet.gov/oehha

Cal/EPA

California
Environmental
Protection
Agency

Office of
Environmental
Health Hazard
Assessment

Headquarters

Location:
601 N. 7th Street
Sacramento, CA
Mailing Address:
P.O. Box 942732
Sacramento, CA
94234-7320

(916) 324-7572
(916) 327-1097 FAX

Berkeley Office

Location:
2120 University Avenue
Berkeley, CA
Mailing Address:
2151 Berkeley Way
Annex 11
Berkeley, CA 94704

Pete Wilson
Governor

James M. Strock
Secretary for
Environmental
Protection

Dear Interested Party:

Thank you for your recent request for information about the Safe Drinking Water and Toxic Enforcement Act of 1986 (Act), also known as Proposition 65. The Act is codified in California Health and Safety Code Section 25249.5, *et seq.*

The following publications will help you keep informed about the Act:

Regulations pertaining to the Act as well as the list of chemicals known to the State to cause cancer or reproductive toxicity are published in Division 2 of Title 22 beginning with Section 12000 of the California Code of Regulations. Information on purchasing Division 2 of Title 22 and on subscribing to updates to the regulations is available from Barclays Law Publishers, P. O. Box 3066, South San Francisco, California 94083, (800) 888-3600. The current cost of the copy of the regulations is $69.12 (including handling and shipping charge) and the annual subscription for the updates is $101.00.

Notices of proposed regulatory actions, notices of public interest, agenda of meetings, draft regulations, and updates of the list of chemicals known to the State to cause cancer or reproductive toxicity are published in the California Regulatory Notice Register, which is published weekly by the Office of Administrative Law, 555 Capitol Mall, Suite 1290, Sacramento, California 95814. The Register is printed by the Office of State Printing and is offered by subscription for an annual fee of $152.00. To order, call (916) 322-0472, or FAX (916) 322-2497.

A copy of the most recent update of the list of chemicals, dated September 1, 1996, is enclosed.

Sincerely,

Richard A. Becker, Ph.D., D.A.B.T.
Deputy Director for Scientific Affairs

Enclosure

STATE OF CALIFORNIA
ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT
SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986

CHEMICALS KNOWN TO THE STATE TO CAUSE CANCER OR REPRODUCTIVE TOXICITY

September 1, 1996

The Safe Drinking Water and Toxic Enforcement Act of 1986 requires that the Governor revise and republish at least once per year the list of chemicals known to the State to cause cancer or reproductive toxicity. The identification number indicated in the following list is the Chemical Abstracts Service (CAS) Registry Number. No CAS number is given when several substances are presented as a single listing. The date refers to the initial appearance of the chemical on the list.

CHEMICALS KNOWN TO THE STATE TO CAUSE CANCER

Chemical	CAS Number	Date
A-alpha-C (2-Amino-9H-pyrido[2,3-b]indole)	26148685	January 1, 1990
Acetaldehyde	75070	April 1, 1988
Acetamide	60355	January 1, 1990
Acetochlor	34256821	January 1, 1989
2-Acetylaminofluorene	53963	July 1, 1987
Acifluorfen	62476599	January 1, 1990
Acrylamide	79061	January 1, 1990
Acrylonitrile	107131	July 1, 1987
Actinomycin D	50760	October 1, 1989
Adriamycin (Doxorubicin hydrochloride)	23214928	July 1, 1987
AF-2;[2-(2-furyl)-3-(5-nitro-2-furyl)]acrylamide	3688537	July 1, 1987
Aflatoxins	—	January 1, 1988
Alachlor	15972608	January 1, 1989
Alcoholic beverages, when associated with alcohol abuse	—	July 1, 1988
Aldrin	309002	July 1, 1988
Allyl chloride	107051	January 1, 1990
2-Aminoanthraquinone	117793	October 1, 1989
p-Aminoazobenzene	60093	January 1, 1990
ortho-Aminoazotoluene	97563	July 1, 1987
4-Aminobiphenyl (4-aminodiphenyl)	92671	February 27, 1987
3-Amino-9-ethylcarbazole hydrochloride	6109973	July 1, 1989
1-Amino-2-methylanthraquinone	82280	October 1, 1989
2-Amino-5-(5-nitro-2-furyl)-1,3,4-thiadiazole	712685	July 1, 1987
Amitrole	61825	July 1, 1987

Chemical	CAS Number	Date
Analgesic mixtures containing phenacetin	—	February 27, 1987
Aniline	62533	January 1, 1990
ortho-Anisidine	90040	July 1, 1987
ortho-Anisidine hydrochloride	134292	July 1, 1987
Antimony oxide (Antimony trioxide)	1309644	October 1, 1990
Aramite	140578	July 1, 1987
Arsenic (inorganic arsenic compounds)	—	February 27, 1987
Asbestos	1332214	February 27, 1987
Auramine	492808	July 1, 1987
Azacitidine	320672	January 1, 1992
Azaserine	115026	July 1, 1987
Azathioprine	446866	February 27, 1987
Azobenzene	103333	January 1, 1990
Benz[a]anthracene	56553	July 1, 1987
Benzene	71432	February 27, 1987
Benzidine [and its salts]	92875	February 27, 1987
Benzidine-based dyes	—	October 1, 1992
Benzo[b]fluoranthene	205992	July 1, 1987
Benzo[j]fluoranthene	205823	July 1, 1987
Benzo[k]fluoranthene	207089	July 1, 1987
Benzofuran	271896	October 1, 1990
Benzo[a]pyrene	50328	July 1, 1987
Benzotrichloride	98077	July 1, 1987
Benzyl chloride	100447	January 1, 1990
Benzyl violet 4B	1694093	July 1, 1987
Beryllium and beryllium compounds	—	October 1, 1987
Betel quid with tobacco	—	January 1, 1990
2,2-Bis(bromomethyl)-1,3-propanediol	3296900	May 1, 1996
Bis(2-chloroethyl)ether	111444	April 1, 1988
N,N-Bis(2-chloroethyl)-2-naphthylamine (Chlornapazine)	494031	February 27, 1987
Bischloroethyl nitrosourea (BCNU) (Carmustine)	154938	July 1, 1987
Bis(chloromethyl)ether	542881	February 27, 1987
Bitumens, extracts of steam-refined and air refined	—	January 1, 1990
Bracken fern	—	January 1, 1990
Bromodichloromethane	75274	January 1, 1990
Bromoform	75252	April 1, 1991
1,3-Butadiene	106990	April 1, 1988
1,4-Butanediol dimethanesulfonate (Busulfan)	55981	February 27, 1987
Butylated hydroxyanisole	25013165	January 1, 1990
beta-Butyrolactone	3068880	July 1, 1987

Chemical	CAS Number	Date
Cacodylic acid	75605	May 1, 1996
Cadmium and cadmium compounds	—	October 1, 1987
Caffeic acid	331395	October 1, 1994
Captafol	2425061	October 1, 1988
Captan	133062	January 1, 1990
Carbazole	86748	May 1, 1996
Carbon tetrachloride	56235	October 1, 1987
Carbon-black extracts	—	January 1, 1990
Ceramic fibers (airborne particles of respirable size)	—	July 1, 1990
Certain combined chemotherapy for lymphomas	—	February 27, 1987
Chlorambucil	305033	February 27, 1987
Chloramphenicol	56757	October 1, 1989
Chlordane	57749	July 1, 1988
Chlordecone (Kepone)	143500	January 1, 1988
Chlordimeform	6164983	January 1, 1989
Chlorendic acid	115286	July 1, 1989
Chlorinated paraffins (Average chain length, C12; approximately 60 percent chlorine by weight)	108171262	July 1, 1989
p-Chloroaniline	106478	October 1, 1994
Chlorodibromomethane	124481	January 1, 1990
Chloroethane (Ethyl chloride)	75003	July 1, 1990
1-(2-Chloroethyl)-3-cyclohexyl-1-nitrosourea (CCNU) (Lomustine)	13010474	January 1, 1988
1-(2-Chloroethyl)-3-(4-methylcyclohexyl)-1-nitrosourea (Methyl-CCNU)	13909096	October 1, 1988
Chloroform	67663	October 1, 1987
Chloromethyl methyl ether (technical grade)	107302	February 27, 1987
3-Chloro-2-methylpropene	563473	July 1, 1989
4-Chloro-ortho-phenylenediamine	95830	January 1, 1988
p-Chloro-o-toluidine	95692	January 1, 1990
Chlorothalonil	1897456	January 1, 1989
Chlorotrianisene	569573	September 1, 1996
Chlorozotocin	54749905	January 1, 1992
Chromium (hexavalent compounds)	—	February 27, 1987
Chrysene	218019	January 1, 1990
C. I. Acid Red 114	6459945	July 1, 1992
C. I. Basic Red 9 monohydrochloride	569619	July 1, 1989
Ciclosporin (Cyclosporin A; Cyclosporine)	59865133 79217600	January 1, 1997
Cinnamyl anthranilate	87296	July 1, 1989
Cisplatin	15663271	October 1, 1988
Citrus Red No. 2	6358538	October 1, 1989

Chemical	CAS Number	Date
Clofibrate	637070	September 1, 1996
Cobalt metal powder	7440484	July 1, 1992
Cobalt [II] oxide	1307966	July 1, 1992
Coke oven emissions	—	February 27, 1987
Conjugated estrogens	—	February 27, 1987
Creosotes	—	October 1, 1988
para-Cresidine	120718	January 1, 1988
Cupferron	135206	January 1, 1988
Cycasin	14901087	January 1, 1988
Cyclophosphamide (anhydrous)	50180	February 27, 1987
Cyclophosphamide (hydrated)	6055192	February 27, 1987
D&C Orange No. 17	3468631	July 1, 1990
D&C Red No. 8	2092560	October 1, 1990
D&C Red No. 9	5160021	July 1, 1990
D&C Red No. 19	81889	July 1, 1990
Dacarbazine	4342034	January 1, 1988
Daminozide	1596845	January 1, 1990
Dantron (Chrysazin; 1,8-Dihydroxyanthraquinone)	117102	January 1, 1992
Daunomycin	20830813	January 1, 1988
DDD (Dichlorodiphenyldichloroethane)	72548	January 1, 1989
DDE (Dichlorodiphenyldichloroethylene)	72559	January 1, 1989
DDT (Dichlorodiphenyltrichloroethane)	50293	October 1, 1987
DDVP (Dichlorvos)	62737	January 1, 1989
N,N'-Diacetylbenzidine	613354	October 1, 1989
2,4-Diaminoanisole	615054	October 1, 1990
2,4-Diaminoanisole sulfate	39156417	January 1, 1988
4,4'-Diaminodiphenyl ether (4,4'-Oxydianiline)	101804	January 1, 1988
2,4-Diaminotoluene	95807	January 1, 1988
Diaminotoluene (mixed)	—	January 1, 1990
Dibenz[a,h]acridine	226368	January 1, 1988
Dibenz[a,j]acridine	224420	January 1, 1988
Dibenz[a,h]anthracene	53703	January 1, 1988
7H-Dibenzo[c,g]carbazole	194592	January 1, 1988
Dibenzo[a,e]pyrene	192654	January 1, 1988
Dibenzo[a,h]pyrene	189640	January 1, 1988
Dibenzo[a,i]pyrene	189559	January 1, 1988
Dibenzo[a,l]pyrene	191300	January 1, 1988
1,2-Dibromo-3-chloropropane (DBCP)	96128	July 1, 1987
2,3-Dibromo-1-propanol	96139	October 1, 1994
Dichloroacetic acid	79436	May 1, 1996
p-Dichlorobenzene	106467	January 1, 1989

Chemical	CAS Number	Date
3,3'-Dichlorobenzidine	9194	October 1, 1987
1,4-Dichloro-2-butene	764410	January 1, 1990
3,3'-Dichloro-4,4'-diaminodiphenyl ether	28434868	January 1, 1988
1,1-Dichloroethane	75343	January 1, 1990
Dichloromethane (Methylene chloride)	75092	April 1, 1988
1,2-Dichloropropane	78875	January 1, 1990
1,3-Dichloropropene	542756	January 1, 1989
Dieldrin	60571	July 1, 1988
Dienestrol	84173	January 1, 1990
Diepoxybutane	1464535	January 1, 1988
Diesel engine exhaust	—	October 1, 1990
Di(2-ethylhexyl)phthalate	117817	January 1, 1988
1,2-Diethylhydrazine	1615801	January 1, 1988
Diethyl sulfate	64675	January 1, 1988
Diethylstilbestrol	56531	February 27, 1987
Diglycidyl resorcinol ether (DGRE)	101906	July 1, 1989
Dihydrosafrole	94586	January 1, 1988
Diisopropyl sulfate	2973106	April 1, 1993
3,3'-Dimethoxybenzidine (ortho-Dianisidine)	119904	January 1, 1988
3,3'-Dimethoxybenzidine dihydrochloride (ortho-Dianisidine dihydrochloride)	20325400	October 1, 1990
Dimethyl sulfate	7778	January 1, 1988
4-Dimethylaminoazobenzene	6011 7	January 1, 1988
trans-2-[(Dimethylamino)methylimino]-5-[2-(5-nitro-2-furyl)vinyl]-1,3,4-oxadiazole	33738540	January 1, 1988
7,12-Dimethylbenz(a)anthracene	57976	January 1, 1990
3,3'-Dimethylbenzidine (ortho-Tolidine)	119937	January 1, 1988
3,3'-Dimethylbenzidine dihydrochloride	612828	April 1, 1992
Dimethylcarbamoyl chloride	79447	January 1, 1988
1,1-Dimethylhydrazine (UDMH)	57147	October 1, 1989
1,2-Dimethylhydrazine	540738	January 1, 1988
Dimethylvinylchloride	513377	July 1, 1989
1,6-Dinitropyrene	42397648	October 1, 1990
1,8-Dinitropyrene	42397659	October 1, 1990
Dinitrotoluene mixture, 2,4-/2,6-	—	May 1, 1996
2,4-Dinitrotoluene	121142	July 1, 1988
2,6-Dinitrotoluene	606202	July 1, 1995
Di-n-propyl isocinchomeronate (MGK Repellent 326)	136458	May 1, 1996
1,4-Dioxane	3737222	
Diphenylhydantoin (Phenytoin)	123911	January 1, 1988
Diphenylhydantoin (Phenytoin), sodium salt	57410	January 1, 1988
	630933	January 1, 1988

Chemical	CAS Number	Date
Direct Black 38 (technical grade)	1937377	January 1, 1988
Direct Blue 6 (technical grade)	2602462	January 1, 1988
Direct Brown 95 (technical grade)	16071866	October 1, 1988
Disperse Blue 1	2475458	October 1, 1990
Epichlorohydrin	106898	October 1, 1987
Erionite	12510428	October 1, 1988
Estradiol 17β	50282	January 1, 1988
Estrone	53167	January 1, 1988
Ethinylestradiol	57636	January 1, 1988
Ethyl acrylate	140885	July 1, 1989
Ethyl methanesulfonate	62500	January 1, 1988
Ethyl-4,4'-dichlorobenzilate	510156	January 1, 1990
Ethylene dibromide	106934	July 1, 1987
Ethylene dichloride (1,2-Dichloroethane)	107062	October 1, 1987
Ethylene oxide	75218	July 1, 1987
Ethylene thiourea	96457	January 1, 1988
Ethyleneimine	151564	January 1, 1988
Folpet	133073	January 1, 1989
Formaldehyde (gas)	50000	January 1, 1988
2-(2-Formylhydrazino)-4-(5-nitro-2-furyl)thiazole	3570750	January 1, 1988
Furan	110009	October 1, 1993
Furazolidone	67458	January 1, 1990
Furmecyclox	60568050	January 1, 1990
Fusarin C	79748815	July 1, 1995
Gasoline engine exhaust (condensates/extracts)	—	October 1, 1990
Glasswool fibers (airborne particles of respirable size)	—	July 1, 1990
Glu-P-1 (2-Amino-6-methyldipyrido[1,2-a:3',2'-d]imidazole)	67730114	January 1, 1990
Glu-P-2 (2-Aminodipyrido[1,2-a:3',2'-d]imidazole)	67730103	January 1, 1990
Glycidaldehyde	765344	January 1, 1988
Glycidol	556525	July 1, 1990
Griseofulvin	126078	January 1, 1990
Gyromitrin (Acetaldehyde methylformylhydrazone)	16568028	January 1, 1988
HC Blue 1	2784943	July 1, 1989
Heptachlor	76448	July 1, 1988
Heptachlor epoxide	1024573	July 1, 1988
Hexachlorobenzene	118741	October 1, 1987
Hexachlorocyclohexane (technical grade)	—	October 1, 1987
Hexachlorodibenzodioxin	34465468	April 1, 1988

Chemical	CAS Number	Date
Hexachloroethane	67721	July 1, 1990
Hexamethylphosphoramide	680319	January 1, 1988
Hydrazine	302012	January 1, 1988
Hydrazine sulfate	10034932	January 1, 1988
Hydrazobenzene (1,2-Diphenylhydrazine)	122667	January 1, 1988
Indeno [1,2,3-cd]pyrene	193395	January 1, 1988
IQ (2-Amino-3-methylimidazo[4,5-f]quinoline)	76180966	April 1, 1990
Iprodione	36734197	May 1, 1996
Iron dextran complex	9004664	January 1, 1988
Isobutyl nitrite	542563	May 1, 1996
Isoprene	78795	May 1, 1996
Isosafrole	120581	October 1, 1989
Lactofen	77501634	January 1, 1989
Lasiocarpine	303344	April 1, 1988
Lead acetate	301042	January 1, 1988
Lead and lead compounds	—	October 1, 1992
Lead phosphate	7446277	April 1, 1988
Lead subacetate	1335326	October 1, 1989
Lindane and other hexachlorocyclohexane isomers	—	October 1, 1989
Mancozeb	8018017	January 1, 1990
Maneb	12427382	January 1, 1990
Me-A-alpha-C (2-Amino-3-methyl-9H-pyrido[2,3-b]indole)	68006837	January 1, 1990
Medroxyprogesterone acetate	71589	January 1, 1990
MeIQ(2-Amino-3,4-dimethylimidazo[4,5-f]quinoline)	77941 12	October 1, 1994
MeIQx(2-Amino-3,8-dimethylimidazo[4,5-f]quinoxaline)	7500040	October 1, 1994
Melphalan	148823	February 27, 1987
Merphalan	531760	April 1, 1988
Mestranol	72333	April 1, 1988
8-Methoxypsoralen with ultraviolet A therapy	298817	February 27, 1987
5-Methoxypsoralen with ultraviolet A therapy	484208	October 1, 1988
2-Methylaziridine (Propyleneimine)	75558	January 1, 1988
Methylazoxymethanol	590965	April 1, 1988
Methylazoxymethanol acetate	592621	April 1, 1988
3-Methylcholanthrene	56495	January 1, 1990
5-Methylchrysene	3697243	April 1, 1988
4,4'-Methylene bis(2-chloroaniline)	101144	July 1, 1987
4,4'-Methylene bis(N,N-dimethyl)benzenamine	101611	October 1, 1989
4,4'-Methylene bis(2-methylaniline)	838880	April 1, 1988
4,4'-Methylenedianiline	101779	January 1, 1988
4,4'-Methylenedianiline dihydrochloride	13552448	January 1, 1988
Methylhydrazine and its salts	—	July 1, 1992
Methyl iodide	74884	April 1, 1988
Methylmercury compounds	—	May 1, 1996
Methyl methanesulfonate	66273	April 1, 1988
2-Methyl-1-nitroanthraquinone (of uncertain purity)	129157	April 1, 1988
N-Methyl-N'-nitro-N-nitrosoguanidine	70257	April 1, 1988
N-Methylolacrylamide	924425	July 1, 1990
Methylthiouracil	56042	October 1, 1989
Metiram	9006422	January 1, 1990
Metronidazole	443481	January 1, 1988
Michler's ketone	90948	January 1, 1988
Mirex	2385855	January 1, 1988
Mitomycin C	50077	April 1, 1988
Monocrotaline	315220	April 1, 1988
5-(Morpholinomethyl)-3-[(5-nitro-furfurylidene)-amino]-2-oxazolidinone	139913	April 1, 1988
Mustard Gas	505602	February 27, 1987
Nafenopin	3771195	April 1, 1988
1-Naphthylamine	134327	October 1, 1989
2-Naphthylamine	91598	February 27, 1987
Nickel and certain nickel compounds	—	October 1, 1989
Nickel carbonyl	13463393	October 1, 1987
Nickel refinery dust from the pyrometallurgical process	—	October 1, 1987
Nickel subsulfide	12035722	October 1, 1987
Niridazole	61574	April 1, 1988
Nitrilotriacetic acid	139139	January 1, 1988
Nitrilotriacetic acid, trisodium salt monohydrate	18662538	April 1, 1989
5-Nitroacenaphthene	602879	April 1, 1988
5-Nitro-o-anisidine	99592	October 1, 1989
o-Nitroanisole	91236	October 1, 1992
4-Nitrobiphenyl	92933	April 1, 1988
6-Nitrochrysene	7496028	October 1, 1990
Nitrofen (technical grade)	1836755	January 1, 1988
2-Nitrofluorene	607578	October 1, 1990
Nitrofurazone	59870	January 1, 1990
1-[(5-Nitrofurfurylidene)-amino]-2-imidazolidinone	555840	April 1, 1988
N-[4-(5-Nitro-2-furyl)-2-thiazolyl]acetamide	531828	April 1, 1988
Nitrogen mustard (Mechlorethamine)	51752	January 1, 1988
Nitrogen mustard hydrochloride (Mechlorethamine hydrochloride)	55867	April 1, 1988

Chemical	CAS Number	Date
Nitrogen mustard N-oxide	126852	April 1, 1988
Nitrogen mustard N-oxide hydrochloride	302705	April 1, 1988
2-Nitropropane	79469	January 1, 1988
1-Nitropyrene	5522430	October 1, 1990
4-Nitropyrene	57835924	October 1, 1990
N-Nitrosodi-n-butylamine	924163	October 1, 1987
N-Nitrosodiethanolamine	1116547	January 1, 1988
N-Nitrosodiethylamine	55185	October 1, 1987
N-Nitrosodimethylamine	62759	October 1, 1987
p-Nitrosodiphenylamine	156105	January 1, 1988
N-Nitrosodiphenylamine	86306	April 1, 1988
N-Nitrosodi-n-propylamine	621647	January 1, 1988
N-Nitroso-N-ethylurea	759739	October 1, 1987
3-(N-Nitrosomethylamino)propionitrile	60153493	April 1, 1990
4-(N-Nitrosomethylamino)-1-(3-pyridyl)-1-butanone	64091914	April 1, 1990
N-Nitrosomethylethylamine	10595956	October 1, 1989
N-Nitroso-N-methylurea	684935	October 1, 1987
N-Nitroso-N-methylurethane	615532	April 1, 1988
N-Nitrosomethylvinylamine	4549400	January 1, 1988
N-Nitrosomorpholine	59892	January 1, 1988
N-Nitrosonornicotine	16543558	January 1, 1988
N-Nitrosopiperidine	100754	January 1, 1988
N-Nitrosopyrrolidine	930552	October 1, 1987
N-Nitrososarcosine	13256229	January 1, 1988
Norethisterone (Norethindrone)	68224	October 1, 1989
Ochratoxin A	303479	July 1, 1990
Oil Orange SS	2646175	April 1, 1988
Oral contraceptives, combined	—	October 1, 1989
Oral contraceptives, sequential	—	October 1, 1989
Oxadiazon	19666309	July 1, 1991
Oxymetholone	434071	January 1, 1988
Oxazepam	604751	October 1, 1994
Panfuran S	794934	January 1, 1988
Pentachlorophenol	87865	January 1, 1990
Phenacetin	62442	October 1, 1989
Phenazopyridine	94780	January 1, 1988
Phenazopyridine hydrochloride	136403	January 1, 1988
Phenesterin	3546109	July 1, 1989
Phenobarbital	50066	January 1, 1990
Phenoxybenzamine	59961	April 1, 1988
Phenoxybenzamine hydrochloride	63923	April 1, 1988
Phenyl glycidyl ether	122601	October 1, 1990
Phenylhydrazine and its salts	—	July 1, 1992
o-Phenylphenate, sodium	132274	January 1, 1990
PhIP(2-Amino-1-methyl-6-phenylimidazol[4,5-b]pyridine)	105650235	October 1, 1994
Polybrominated biphenyls	—	January 1, 1988
Polychlorinated biphenyls	—	October 1, 1989
Polychlorinated biphenyls (containing 60 or more percent chlorine by molecular weight)	—	January 1, 1988
Polychlorinated dibenzo-p-dioxins	—	October 1, 1992
Polychlorinated dibenzofurans	—	October 1, 1992
Polygeenan	53973981	January 1, 1988
Ponceau MX	3761533	April 1, 1988
Ponceau 3R	3564098	April 1, 1988
Potassium bromate	7758012	January 1, 1990
Procarbazine	671169	January 1, 1988
Procarbazine hydrochloride	366701	January 1, 1988
Procymidone	32809168	October 1, 1994
Progesterone	57830	January 1, 1988
Pronamide	23950585	May 1, 1996
1,3-Propane sultone	1120714	January 1, 1988
Propargite	2312358	October 1, 1994
beta-Propiolactone	57578	January 1, 1988
Propylene oxide	75569	October 1, 1988
Propylthiouracil	51525	January 1, 1988
Radionuclides	—	July 1, 1989
Reserpine	50555	October 1, 1989
Residual (heavy) fuel oils	—	October 1, 1990
Saccharin	81072	October 1, 1989
Saccharin, sodium	128449	January 1, 1988
Safrole	94597	January 1, 1988
Selenium sulfide	7446346	October 1, 1989
Shale-oils	68308349	April 1, 1990
Silica, crystalline (airborne particles of respirable size)	—	October 1, 1988
Soots, tars, and mineral oils (untreated and mildly treated oils and used engine oils)	—	February 27, 1987
Sterigmatocystin	10048132	April 1, 1988
Streptozotocin	18883664	January 1, 1988
Styrene oxide	96093	October 1, 1988
Sulfallate	95067	January 1, 1988

Chemical	CAS Number	Date
Talc containing asbestiform fibers	—	April 1, 1990
Tamoxifen and its salts	10540291	September 1, 1996
Terrazole	2593159	October 1, 1994
Testosterone and its esters	58220	April 1, 1988
2,3,7,8-Tetrachlorodibenzo-para-dioxin (TCDD)	1746016	January 1, 1988
1,1,2,2-Tetrachloroethane	79345	July 1, 1990
Tetrachloroethylene (Perchloroethylene)	127184	April 1, 1988
p-a,a,a-Tetrachlorotoluene	5216251	January 1, 1990
Tetranitromethane	509148	July 1, 1990
Thioacetamide	62555	January 1, 1988
4,4'-Thiodianiline	139651	April 1, 1988
Thiourea	62566	January 1, 1988
Thorium dioxide	1314201	February 27, 1987
Tobacco, oral use of smokeless products	—	April 1, 1988
Tobacco smoke	—	April 1, 1988
Toluene diisocyanate	26471625	October 1, 1989
ortho-Toluidine	95534	January 1, 1988
ortho-Toluidine hydrochloride	636215	January 1, 1988
para-Toluidine	106490	January 1, 1990
Toxaphene (Polychorinated camphenes)	8001352	January 1, 1988
Treosulfan	299752	February 27, 1987
Trichlormethine (Trimustine hydrochloride)	817094	January 1, 1992
2,4,6-Trichlorophenol	88062	January 1, 1988
1,2,3-Trichloropropane	96184	October 1, 1992
Triphenyltin hydroxide	76879	July 1, 1992
Trichloroethylene	79016	April 1, 1988
Trimethyl phosphate	512561	May 1, 1996
Tris(aziridinyl)-para-benzoquinone (Triaziquone)	68768	October 1, 1989
Tris(1-aziridinyl)phosphine sulfide (Thiotepa)	52244	January 1, 1988
Tris(2-chloroethyl) phosphate	115968	April 1, 1992
Tris(2,3-dibromopropyl)phosphate	126727	January 1, 1988
Trp-P-1 (Tryptophan-P-1)	62450060	April 1, 1988
Trp-P-2 (Tryptophan-P-2)	62450071	April 1, 1988
Trypan blue (commercial grade)	72571	October 1, 1989
Unleaded gasoline (wholly vaporized)	—	April 1, 1988
Uracil mustard	66751	April 1, 1988
Urethane (Ethyl carbamate)	51796	January 1, 1988
Vinyl bromide	593602	October 1, 1988
Vinyl chloride	75014	February 27, 1987
4-Vinylcyclohexene	100403	May 1, 1996
4-Vinyl-1-cyclohexene diepoxide (Vinyl cyclohexenedioxide)	106876	July 1, 1990
Vinyl trichloride (1,1,2-Trichloroethane)	79005	October 1, 1990
2,6-Xylidine (2,6-Dimethylaniline)	87627	January 1, 1991
Zineb	12122677	January 1, 1990

CHEMICALS KNOWN TO THE STATE TO CAUSE REPRODUCTIVE TOXICITY

Developmental toxicity

Chemical	CAS Number	Date
Acetohydroxamic acid	546883	April 1, 1990
Actinomycin D	50760	October 1, 1992
All-trans retinoic acid	302794	January 1, 1989
Alprazolam	28981977	July 1, 1990
Amikacin sulfate	39831555	July 1, 1990
Aminoglutethimide	125848	July 1, 1990
Aminoglycosides	—	October 1, 1992
Aminopterin	54626	July 1, 1987
Angiotensin converting enzyme (ACE) inhibitors	—	October 1, 1992
Anisindione	117373	October 1, 1992
Aspirin (NOTE: It is especially important not to use aspirin during the last three months of pregnancy, unless specifically directed to do so by a physician because it may cause problems in the unborn child or complications during delivery.)	50782	July 1, 1990
Azathioprine	446866	September 1, 1996
Barbiturates	—	October 1, 1992
Benomyl	17804352	July 1, 1991
Benzphetamine hydrochloride	5411223	April 1, 1990
Benzodiazepines	—	October 1, 1992
Bischloroethyl nitrosourea (BCNU) (Carmustine)	154938	July 1, 1990
Bromoxynil	1689845	October 1, 1990
Butabarbital sodium	143817	October 1, 1992
1,4-Butanediol dimethylsulfonate (Busulfan)	55981	January 1, 1989
Carbon disulfide	75150	July 1, 1989
Carbon monoxide	630080	July 1, 1989
Carboplatin	41575944	July 1, 1990
Chenodiol	474259	April 1, 1990

Chemical	CAS Number	Date
Chlorcyclizine hydrochloride	1620219	July 1, 1987
Chlorambucil	305033	January 1, 1989
Chlordecone (Kepone)	143500	January 1, 1989
Chlordiazepoxide	58253	January 1, 1992
Chlordiazepoxide hydrochloride	438415	January 1, 1992
1-(2-Chloroethyl)-3-cyclohexyl-1-nitrosourea (CCNU) (Lomustine)	13010474	July 1, 1990
Cladribine	4291638	September 1, 1996
Clomiphene citrate	50419	April 1, 1990
Clorazepate dipotassium	57109907	October 1, 1992
Cocaine	50362	July 1, 1989
Colchicine	64868	October 1, 1992
Conjugated estrogens	—	April 1, 1990
Cyanazine	21725462	April 1, 1990
Cycloheximide	66819	January 1, 1989
Cyclophosphamide (anhydrous)	50180	January 1, 1989
Cyclophosphamide (hydrated)	6055192	January 1, 1989
Cyhexatin	13121705	January 1, 1989
Cytarabine	147944	January 1, 1989
Danazol	17230885	April 1, 1990
Daunorubicin hydrochloride	23541506	July 1, 1990
Demeclocycline hydrochloride (internal use)	64733	January 1, 1992
Diazepam	439145	January 1, 1992
Dicumarol	66762	October 1, 1992
Diethylstilbestrol (DES)	56531	July 1, 1987
Dinocap	39300453	April 1, 1990
Dinoseb	88857	January 1, 1989
Diphenylhydantoin (Phenytoin)	57410	July 1, 1987
Doxycycline (internal use)	564250	July 1, 1990
Doxycycline calcium (internal use)	94088854	January 1, 1992
Doxycycline hyclate (internal use)	24390145	October 1, 1991
Doxycycline monohydrate (internal use)	17086281	October 1, 1991
Ergotamine tartrate	379793	April 1, 1990
Ethyl alcohol in alcoholic beverages	—	October 1, 1987
Ethylene glycol monoethyl ether	110805	January 1, 1989
Ethylene glycol monomethyl ether	109864	January 1, 1989
Ethylene glycol monoethyl ether acetate	111159	January 1, 1993
Ethylene glycol monomethyl ether acetate	110496	January 1, 1993
Ethylene thiourea	96457	January 1, 1993
Etoposide	33419420	July 1, 1990
Etretinate	54350480	July 1, 1987
Fluorouracil	51218	January 1, 1989
Fluoxymesterone	76437	April 1, 1990
Flurazepam hydrochloride	1172185	October 1, 1992
Flutamide	13311847	July 1, 1990
Halazepam	23092173	July 1, 1990
Halothane	151677	September 1, 1996
Hexachlorobenzene	118741	January 1, 1989
Ifosfamide	3778732	July 1, 1990
Iodine-131	10043660	January 1, 1989
Isotretinoin	4759482	July 1, 1987
Lead	—	February 27, 1987
Lithium carbonate	554132	January 1, 1991
Lithium citrate	919164	January 1, 1991
Lorazepam	846491	July 1, 1990
Lovastatin	75330755	October 1, 1992
Medroxyprogesterone acetate	71589	April 1, 1990
Megestrol acetate	595335	January 1, 1991
Melphalan	148823	July 1, 1990
Menotropins	9002680	April 1, 1990
Meprobamate	57534	January 1, 1992
Mercaptopurine	612761	July 1, 1990
Mercury and mercury compounds	—	July 1, 1990
Methacycline hydrochloride	3963959	January 1, 1991
Methimazole	60560	July 1, 1990
Methotrexate	59052	January 1, 1989
Methotrexate sodium	15475566	April 1, 1990
Methyl bromide as a structural fumigant	74839	January 1, 1993
Methyl mercury	—	July 1, 1987
Methyltestosterone	58184	April 1, 1990
Midazolam hydrochloride	59467968	July 1, 1990
Minocycline hydrochloride (internal use)	13614987	January 1, 1992
Misoprostol	59122462	April 1, 1990
Mitoxantrone hydrochloride	70476823	July 1, 1990
Nafarelin acetate	86220420	April 1, 1990
Neomycin sulfate (internal use)	1405103	October 1, 1992

Chemical	CAS Number	Date
Netilmicin sulfate	56391572	July 1, 1990
Nickel carbonyl	13463393	September 1, 1996
Nicotine	54115	April 1, 1990
Nitrogen mustard (Mechlorethamine)	51752	January 1, 1989
Nitrogen mustard hydrochloride (Mechlorethamine hydrochloride)	55867	July 1, 1990
Norethisterone (Norethindrone)	68224	April 1, 1990
Norethisterone acetate (Norethindrone acetate)	51989	October 1, 1991
Norethisterone (Norethindrone)/Ethinyl estradiol	68224/57636	April 1, 1990
Norethisterone (Norethindrone)/Mestranol	68224/72333	April 1, 1990
Norgestrel	6533002	April 1, 1990
Oxazepam	604751	October 1, 1992
Oxytetracycline (internal use)	79572	January 1, 1991
Oxytetracycline hydrochloride (internal use)	2058460	October 1, 1991
Paramethadione	115673	July 1, 1990
Penicillamine	52675	January 1, 1991
Pentobarbital sodium	57330	July 1, 1990
Pentostatin	53910251	September 1, 1996
Phenacemide	63989	July 1, 1990
Phenprocoumon	435972	October 1, 1992
Pipobroman	54911	July 1, 1990
Plicamycin	18378897	April 1, 1990
Polybrominated biphenyls	922660	October 1, 1994
Polychlorinated biphenyls	—	January 1, 1991
Procarbazine hydrochloride	366701	July 1, 1990
Propylthiouracil	51525	July 1, 1990
Retinol/retinyl esters, when in daily dosages in excess of 10,000 IU, or 3,000 retinol equivalents. (NOTE: Retinol/retinyl esters are required and essential for maintenance of normal reproductive function. The recommended daily level during pregnancy is 8,000 IU.)	—	July 1, 1989
Ribavirin	36791045	April 1, 1990
Secobarbital sodium	309433	October 1, 1992
Streptomycin sulfate	3810740	January 1, 1991
Tamoxifen citrate	54965211	July 1, 1990
Temazepam	846504	April 1, 1990
Teniposide	29767202	September 1, 1996
Testosterone cypionate	58208	October 1, 1991
Testosterone enanthate	315377	April 1, 1990

Chemical	CAS Number	Date
2,3,7,8-Tetrachlorodibenzo-para-dioxin (TCDD)	1746016	April 1, 1991
Tetracyclines (internal use)	—	October 1, 1992
Tetracycline (internal use)	60548	October 1, 1991
Tetracycline hydrochloride (internal use)	64755	January 1, 1991
Thalidomide	50351	July 1, 1987
Thioguanine	154427	July 1, 1990
Tobacco smoke (primary)	—	April 1, 1988
Tobramycin sulfate	49842071	July 1, 1990
Toluene	108883	January 1, 1991
Triazolam	28911015	April 1, 1990
Trilostane	13647353	April 1, 1990
Trimethadione	127480	January 1, 1991
Uracil mustard	66751	January 1, 1992
Urethane	51796	October 1, 1994
Urofollitropin	26995915	April 1, 1990
Valproate (Valproic acid)	99661	July 1, 1987
Vinblastine sulfate	143679	July 1, 1990
Vincristine sulfate	2068782	July 1, 1990
Warfarin	81812	July 1, 1987

Female reproductive toxicity

Aminopterin	54626	July 1, 1987
Anabolic steroids	—	April 1, 1990
Aspirin (NOTE: It is especially important not to use aspirin during the last three months of pregnancy, unless specifically directed to do so by a physician because it may cause problems in the unborn child or complications during delivery.)	50782	July 1, 1990
Carbon disulfide	7150	July 1, 1989
Cocaine	50362	July 1, 1989
Cyclophosphamide (anhydrous)	50180	January 1, 1989
Cyclophosphamide (hydrated)	6055192	January 1, 1989
Ethylene oxide	75218	February 27, 1987
Lead	—	February 27, 1987

Chemical	CAS Number	Date
Tobacco smoke (primary)	—	April 1, 1988
Uracil mustard	66751	January 1, 1992
Male reproductive toxicity		
Anabolic steroids	—	April 1, 1990
Benomyl	17804352	July 1, 1991
Carbon disulfide	75150	July 1, 1989
Colchicine	64868	October 1, 1992
Cyclophosphamide (anhydrous)	50180	January 1, 1989
Cyclophosphamide (hydrated)	6055192	January 1, 1989
1,2-Dibromo-3-chloropropane (DBCP)	96128	February 27, 1987
m-Dinitrobenzene	99650	July 1, 1990
o-Dinitrobenzene	528290	July 1, 1990
p-Dinitrobenzene	100254	July 1, 1990
Dinoseb	88857	January 1, 1989
Epichlorohydrin	106898	September 1, 1996
Ethylene glycol monoethyl ether	110805	January 1, 1989
Ethylene glycol monomethyl ether	109864	January 1, 1989
Ethylene glycol monoethyl ether acetate	111159	January 1, 1993
Ethylene glycol monomethyl ether acetate	110496	January 1, 1993
Hexamethylphosphoramide	680319	October 1, 1994
Lead	—	February 27, 1987
Nitrofurantoin	67209	April 1, 1991
Tobacco smoke (primary)	—	April 1, 1988
Uracil mustard	66751	January 1, 1992

Date: September 1, 1996

SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986
(Chapter 6.6 added by Proposition 65 1986 General Election)

25249.5. *Prohibition On Contaminating Drinking Water With Chemicals Known to Cause Cancer or Reproductive Toxicity*. No person in the course of doing business shall knowingly discharge or release a chemical known to the state to cause cancer or reproductive toxicity into water or onto or into land where such chemical passes or probably will pass into any source of drinking water, notwithstanding any other provision or authorization of law except as provided in Section 25249.9.

25249.6. *Required Warning Before Exposure To Chemicals Known to Cause Cancer Or Reproductive Toxicity*. No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in Section 25249.10.

25249.7. *Enforcement*.

(a) Any person violating or threatening to violate Section 25249.5 or Section 25249.6 may be enjoined in any court of competent jurisdiction.

(b) Any person who has violated Section 25249.5 or Section 25249.6 shall be liable for a civil penalty not to exceed $2500 per day for each such violation in addition to any other penalty established by law. Such civil penalty may be assessed and recovered in a civil action brought in any court of competent jurisdiction.

(c) Actions pursuant to this section may be brought by the Attorney General in the name of the people of the State of California or by any district attorney or by any city attorney of a city having a population in excess of 750,000 or with the consent of the district attorney by a city prosecutor in any city or city and county having a full-time city prosecutor, or as provided in subdivision (d).

(d) Actions pursuant to this section may be brought by any person in the public interest if (1) the action is commenced more than sixty days after the person has given notice of the violation which is the subject of the action to the Attorney General and the district attorney and any city attorney in whose jurisdiction the violation is alleged to occur and to the alleged violator, and (2) neither the Attorney General nor any district attorney nor any city attorney or prosecutor has commenced and is diligently prosecuting an action against such violation.

25249.8. *List Of Chemicals Known to Cause Cancer Or Reproductive Toxicity*.

(a) On or before March 1, 1987, the Governor shall cause to be published a list of those chemicals known to the state to cause cancer or reproductive toxicity within the meaning of this chapter, and he shall cause such list to be revised and republished in light of additional knowledge at least once per year thereafter. Such list shall include at a minimum those substances identified by reference in Labor Code Section 6382(b)(1) and those substances identified additionally by reference in Labor Code Section 6382(d).

(b) A chemical is known to the state to cause cancer or reproductive toxicity within the meaning of this chapter if in the opinion of the state's qualified experts it has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or

reproductive toxicity, or if a body considered to be authoritative by such experts has formally identified it as causing cancer or reproductive toxicity, or if an agency of the state or federal government has formally required it to be labeled or identified as causing cancer or reproductive toxicity.

(c) On or before January 1, 1989, and at least once per year thereafter, the Governor shall cause to be published a separate list of those chemicals that at the time of publication are required by state or federal law to have been tested for potential to cause cancer or reproductive toxicity but that the state's qualified experts have not found to have been adequately tested as required.

(d) The Governor shall identify and consult with the state's qualified experts as necessary to carry out his duties under this section.

(e) In carrying out the duties of the Governor under this section, the Governor and his designates shall not be considered to be adopting or amending a regulation within the meaning of the Administrative Procedure Act as defined in Government Code Section 11370.

25249.9. *Exemptions from Discharge Prohibition.*

(a) Section 25249.5 shall not apply to any discharge or release that takes places less than twenty months subsequent to the listing of the chemical in question on the list required to be published under subdivision (a) of Section 25249.8.

(b) Section 25249.5 shall not apply to any discharge or release that meets both of the following criteria:

(1) The discharge or release will not cause any significant amount of the discharged or released chemical to enter any source of drinking water.

(2) The discharge or release is in conformity with all other laws and with every applicable regulation, permit, requirement, and order. In any action brought to enforce Section 25249.5, the burden of showing that a discharge or release meets the criteria of this subdivision shall be on the defendant.

25249.10. *Exemptions from Warning Requirement.* Section 25249.6 shall not apply to any of the following:

(a) An exposure for which federal law governs warning in a manner that preempts state authority.

(b) An exposure that takes place less than twelve months subsequent to the listing of the chemical in question on the list required to be published under subdivision (a) of Section 25249.8.

(c) An exposure for which the person responsible can show that the exposure poses no significant risk assuming lifetime exposure at the level in question for substances known to the state to cause cancer, and that the exposure will have no observable effect assuming exposure at one thousand (1000) times the level in question for substances known to the state to cause reproductive toxicity, based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of such chemical pursuant to subdivision (a) of Section 25249.8. In any action brought to enforce Section 25249.6, the burden of showing that an exposure meets the criteria of this subdivision shall be on the defendant.

25249.11. *Definitions.* For purposes of this chapter:

(a) "Person" means an individual, trust, firm, joint stock company, corporation, company,

partnership, limited liability company, and association.

(b) "Person in the course of doing business" does not include any person employing fewer than 10 employees in his or her business; any city, county, or district or any department or agency thereof or the state or any department or agency thereof or the federal government or any department or agency thereof; or any entity in its operation of a public water system as defined in Section 4010.1.

(c) "Significant amount" means any detectable amount except an amount which would meet the exemption test in subdivision (c) of Section 25249.10 if an individual were exposed to such an amount in drinking water.

(d) "Source of drinking water" means either a present source of drinking water or water which is identified or designated in a water quality control plan adopted by a regional board as being suitable for domestic or municipal uses.

(e) "Threaten to violate" means to create a condition in which there is a substantial probability that a violation will occur.

(f) "Warning" within the meaning of Section 25249.6 need not be provided separately to each exposed individual and may be provided by general methods such as labels on consumer products, inclusion of notices in mailings to water customers, posting of notices, placing notices in public news media, and the like, provided that the warning accomplished is clear and reasonable. In order to minimize the burden on retail sellers of consumer products including foods, regulations implementing Section 25249.6 shall to the extent practicable place the obligation to provide any warning materials such as labels on the producer or packager rather than on the retail seller, except where the retail seller itself is responsible for introducing a chemical known to the state to cause cancer or reproductive toxicity into the consumer product in question.

25249.12. *Implementation*. The Governor shall designate a lead agency and such other agencies as may be required to implement the provisions of this chapter including this section. Each agency so designated may adopt and modify regulations, standards, and permits as necessary to conform with and implement the provisions of this chapter and to further its purposes.

25249.13. *Preservation Of Existing Rights, Obligations, and Penalties*. Nothing in this chapter shall alter or diminish any legal obligation otherwise required in common law or by statute or regulation, and nothing in this chapter shall create or enlarge any defense in any action to enforce such legal obligation. Penalties and sanctions imposed under this chapter shall be in addition to any penalties or sanctions otherwise prescribed by law.

25180.7. (a) Within the meaning of this section, a "designated government employee" is any person defined as a "designated employee" by Government Code Section 82019, as amended.

(b) Any designated government employee who obtains information in the course of his official duties revealing the illegal discharge or threatened illegal discharge of a hazardous waste within the geographical area of his jurisdiction and who knows that such discharge or threatened discharge is likely to cause substantial injury to the public health or safety must, within seventy-two hours, disclose such information to the local Board of Supervisors and to the local health officer. No disclosure of information is required under this subdivision when otherwise prohibited by law, or when law enforcement personnel have determined that such disclosure would adversely

affect an ongoing criminal investigation, or when the information is already general public knowledge within the locality affected by the discharge or threatened discharge.

(c) Any designated government employee who knowingly and intentionally fails to disclose information required to be disclosed under subdivision (b) shall, upon conviction, be punished by imprisonment in the county jail for not more than one year or by imprisonment in state prison for not more than three years. The court may also impose upon the person a fine of not less than five thousand dollars ($5000) or more than twenty-five thousand dollars ($25,000). The felony conviction for violation of this section shall require forfeiture of government employment within thirty days of conviction.

(d) Any local health officer who receives information pursuant to subdivision (b) shall take appropriate action to notify local news media and shall make such information available to the public without delay.

25192. (a) All civil and criminal penalties collected pursuant to this chapter or Chapter 6.6 (commencing with Section 25249.5) shall be apportioned in the following manner:

(1) Fifty percent shall be deposited in the Hazardous Substance Account in the General Fund.

(2) Twenty-five percent shall be paid to the office of the city attorney, city prosecutor, district attorney, or Attorney General, whichever office brought the action, or in the case of an action brought by a person under subdivision (d) of Section 25249.7 to such person.

(3) Twenty-five percent shall be paid to the department and used to fund the activity of the local health officer to enforce the provisions of this chapter pursuant to Section 25180. If investigation by the local police department or sheriff's office or California Highway Patrol led to the bringing of the action, the local health officer shall pay a total of forty percent of his portion under this subdivision to said investigating agency or agencies to be used for the same purpose. If more than one agency is eligible for payment under this provision, division of payment among the eligible agencies shall be in the discretion of the local health officer.

(b) If a reward is paid to a person pursuant to Section 25191.7, the amount of the reward shall be deducted from the amount of the civil penalty before the amount is apportioned pursuant to subdivision (a). (c) Any amounts deposited in the Hazardous Substance Account pursuant to this section shall be included in the computation of the state account rebate specified in Section 25347.2.

California Environmental Protection Agency
Office of Environmental Health Hazard Assessment

The Implementation of Proposition 65: A Progress Report

September 1, 1996

Summary of the Proposition

The Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) was passed by the voters of California in November, 1986, and became effective January 1, 1987. The Act required the Governor to publish a list of chemicals known to the State to cause cancer or reproductive toxicity no later than March 1, 1987, with updates and revisions no less frequently than annually thereafter. For chemicals so listed, warnings are required 12 months after listing for knowing and intentional exposures, and knowing discharges to the State's drinking water sources are prohibited 20 months after listing.

The Act contains several exemptions:

- First, no warning is required if exposures to listed carcinogens would result in a risk lower than the level of "no significant risk," (defined as one excess case of cancer per 100,000 individuals exposed over a 70-year lifetime) or if exposures to listed reproductive toxicants are less than one one-thousandth of the no observable effect level (NOEL). Similarly, discharges to the State's drinking water sources are not prohibited if they pose no significant risk or if they do not exceed one one-thousandth of the NOEL.

- Second, the Act is not applicable to businesses employing fewer than 10 employees.

- Third, the Act is not applicable to government agencies.

- Fourth, the Act is not applicable to drinking water utilities.

Enforcement is via the attorney general, district attorneys, certain city attorneys, and private citizens. The burden of proof is as follows: the plaintiff is required to show that an exposure or a discharge occurred and then the burden shifts to the defendant to show that such action did not result in exposures or discharges greater than those allowed by the Act.

Lead Agency

In January, 1987, the Governor designated the Health and Welfare Agency to be the lead agency for the implementation of the Act. On July 17, 1991, this role was transferred to the California Environmental Protection Agency's (Cal/EPA) Office of Environmental Health Hazard Assessment (OEHHA) by Executive Order W-15-91. OEHHA is directed to implement the Act in a manner that is fair, predictable, and based on a firm foundation of science, and to ensure that the implementation is harmonized and coordinated with other chemical regulatory programs in state government.

List of Known Carcinogens and Reproductive Toxicants

The Act provides three mechanisms by which a chemical is listed:

- A chemical is listed if in the opinion of the state's qualified experts it has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity. A Science Advisory Board serves as the state's qualified experts for the purpose of Proposition 65. The Developmental and Reproductive Toxicant (DART) and the Cancer Identification Committees have been established to address the listing of chemicals under Proposition 65.

- A chemical is also listed if a body considered to be authoritative by the state's qualified experts has formally identified it as causing cancer or reproductive toxicity. The U. S. Environmental Protection Agency, the U. S. Food and Drug Administration, the International Agency for Research on Cancer, the National Institute for Occupational Safety and Health, and the National Toxicology Program have been designated as "authoritative bodies" for purposes of the Act.

- Finally, a chemical is listed if an agency of the state or federal government has formally required it to be labeled or identified as causing cancer or reproductive toxicity. Title 22, California Code of Regulations (22 CCR), Sections 12306 and 12902, respectively, address the last two listing mechanisms.

With regular updates (usually quarterly), the Governor's chemical list has increased in number, and now includes 580 chemicals (420 carcinogens and 160 reproductive toxicants).

Regulatory Levels

Levels which require no warnings, and which are not prohibited for discharge into sources of drinking water are found in 22 CCR Sections 12705, 12709 and 12711 for carcinogens, and Section 12805 for reproductive toxicants.

Additional Sources of Information

- **Chemical List:** The list of chemicals is updated in the California Regulatory Notice Register, which is published by the California Office of Administrative Law [(916) 323-6225] and obtained by subscription.

- **Regulations:** The list and the Agency's implementing regulations are found in Title 22 of the California Code of Regulations, Division 2, beginning with Section 12000. They are also printed in Title 26, Division 21.5, beginning with Section 22-12000. These may be purchased from Barclays Law Publishers [(800) 888-3600]. Update services are also available.

- **Exposure Levels:** A status report of risk assessments developed for chemicals subject to the Act is available from OEHHA [(916) 445-6900].

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986
(PROPOSITION 65)

STATUS REPORT:
NO SIGNIFICANT RISK LEVELS
FOR CARCINOGENS
AND
ACCEPTABLE INTAKE LEVELS
FOR REPRODUCTIVE TOXICANTS

JANUARY 1994

Note to Reader: This document reports on the status of the development and adoption of daily intake levels calculated for purposes of the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65). Parts A and B provide a compilation of daily intake levels for carcinogens and reproductive toxicants, respectively, and include levels which have been formally adopted into regulation as well as levels that are in various stages of the adoption process. Carcinogens for which dose-response assessments have not been performed are listed in Part C under four priority levels.

This status report will be updated on a regular basis.

A. No Significant Risk Levels for Carcinogens

The following table lists the "no significant risk levels" that have been calculated for Proposition 65 carcinogens. The table includes levels which have been formally adopted into regulation as well as levels that are in various stages of the adoption process (see "Status" column).

Levels adopted into regulation (Title 22, California Code of Regulations, Sections 12705 and 12709) are intended to provide "safe harbors" for persons subject to the Act, and do not preclude the use of alternative levels that can be demonstrated by their users as being scientifically valid. "No significant risk levels" represent the daily intake level calculated to result in a cancer risk not exceeding one excess case of cancer in 100,000 individuals exposed over a 70-year lifetime.

Carcinogen	Level (µg/day)	Status[a]
A-alpha-C (2-Amino-9H-pyrido[2,3-b]indole)	2	A/12705d
Acetaldehyde	90 (inhalation)	A/12705c
Acetamide	10	A/12705d
Acetochlor	70	USEPA
2-Acetylaminofluorene	0.2	A/12705d
Acifluorfen	20	USEPA
Acrylamide	0.2	A/12705c
Acrylonitrile	0.7	A/12705b
Actinomycin D	0.00008	A/12705d
AF-2; [2-(2-furyl)-3(5-nitro-2-furyl)acrylamide]	3	A/12705d
Aflatoxins	0.02	RA/SAP
Alachlor	9	USEPA
Aldrin	0.04	A/12705b
Allyl chloride	30	A/12705c
2-Aminoanthraquinone	20	A/12705d
o-Aminoazotoluene	0.2	A/12705d
4-Aminobiphenyl	0.03	A/12705d
3-Amino-9-ethylcarbazole hydrochloride	9	A/12705d
1-Amino-2-methylanthraquinone	5	A/12705d
2-Amino-5-(5-nitro-2-furyl)-1,3,4-thiadiazole	0.04	A/12705d
Amitrole	0.7	A/12705d
Aniline	0.6	USEPA
o-Anisidine	100	A/12705c
o-Anisidine hydrochloride	5	A/12705d
Aramite	7	A/12705d
Arsenic	20	A/12705d
	0.06 (inh)	A/12705b
Asbestos	10 (except inh)	A/12709
Auramine	100 fibers[b]/d (inh)	A/12705b
	0.8	A/12705d

a. Legend:
A/12705b = Adopted in Section 12705, subsection (b).
A/12705c = Adopted in Section 12705, subsection (c).
A/12705d = Adopted in Section 12705, subsection (d).
A/12709 = Adopted in Section 12709. Levels established under Section 12709 are intended to be used only when the chemical in question is present as a "trace element".
DPR = Level based on cancer potency value calculated by the California Department of Pesticide Regulation
DRAFT(e) = External draft document completed.
OEHHA = Level based on cancer potency value calculated by the Office of Enviromental Health Hazard Assessment for purposes of other regulatory programs.
RA/SAP = OEHHA risk assessment completed; document has been reviewed by the Scientific Advisory Panel.
RA/nSAP = OEHHA risk assessment completed but has not been reviewed by the Scientific Advisory Panel.
USEPA = Level based on cancer potency value calculated by the U.S. Environmental Protection Agency; may be proposed for adoption by OEHHA.

b. Fibers equal to or greater than 5 micrometers in length and 0.3 micrometers in width, with a length/width ratio greater than or equal to 3:1 as measured by phase contrast microscopy.

Azaserine	0.06	A/12705d
Azathioprine	0.4	A/12705d
Azobenzene	6	A/12705c
Benz[a]anthracene	0.04	DRAFT(e)
Benzene	7	A/12705b
Benzidine	0.001	A/12705b
Benzo[b]fluoranthene	0.04	DRAFT(e)
Benzo[j]fluoranthene	0.09	DRAFT(e)
Benzo[a]pyrene	0.06	A/12705c
Benzofuran	1	RA/nSAP
Benzotrichloride	0.05 (oral)	USEPA
	0.0002	DRAFT(e)
Benzyl chloride	4	A/12707c
Benzyl violet 4B	30	A/12705d
Beryllium	0.1	A/12709
Beryllium oxide	0.1	A/12705c
Beryllium sulfate	0.0002	A/12705c
Bis(2-chloroethyl)ether	0.3	A/12705b
Bis(chloromethyl)ether	0.02	A/12705b
Bromodichloromethane	5	A/12705c
Bromoform	90	USEPA
1,3-Butadiene	0.4	A/12705c
	1	OEHHA
Butylated hydroxyanisole	4000	A/12705b
beta-Butyrolactone	0.7	A/12705d
Cadmium	0.05 (inh)	A/12705b
Captafol	5	A/12705d
	10	USEPA
Captan	300	A/12705d
	200	USEPA
Carbon tetrachloride	5	A/12705b
Chlorambucil	0.002	A/12705d
Chlordane	0.5	A/12705c
Chlordecone (Kepone)	0.04	A/12705d
Chlordimeform	0.5	USEPA
Chlorendic acid	8	A/12705d
Chlorinated paraffins (Ave. chain length C12; approx. 60% chlorine by weight)	8	A/12705d
Chlorodibromomethane	7	A/12705d
Chloroethane (Ethyl chloride)	200	RA/nSAP
Chloroform	20 (oral)	A/12705c
	40 (inh)	A/12705c
Chloromethyl methyl ether (technical grade)	0.3	A/12705d
3-Chloro-2-methylpropene	5	A/12705d
4-Chloro-ortho-phenylenediamine	40	A/12705d
Chlorothalonil	200	A/12705d
	60	USEPA
p-Chloro-ortho-toluidine	3	A/12705d
Chlorozotocin	0.003	A/12705d
Chromium (hexavalent)	0.001 (inh)	A/12705b

Chrysene	0.2	DRAFT(e)
C.I. Basic Red 9 monohydrochloride	3	A/12705d
Cinnamyl anthranilate	200	A/12705d
Coke oven emissions	0.3	A/12705c
p-Cresidine	5	A/12705d
Cupferron	3	A/12705d
Cyclophosphamide (anhydrous)	1	A/12705d
Cyclophosphamide (hydrated)	1	A/12705d
D&C Red No. 9	100	A/12705d
Dacarbazine	0.01	A/12705d
Daminozide	40	A/12705d
	80	USEPA
Dantron (Chrysazin; 1,8-Dihydroxyanthraquinone)	9	A/12705d
DDT, DDE, DDD (in combination)	2	A/12705b
DDVP (Dichlorvos)	2	A/12705c
2,4-Diaminoanisole	30	A/12705d
2,4-Diaminoanisole sulfate	50	A/12705d
4,4'-Diaminodiphenyl ether (4,4'-Oxydianiline)	5	A/12705d
2,4-Diaminotoluene	0.2	A/12705d
Dibenz[a,h]anthracene	0.2	A/12705d
7H-Dibenzo[c,g]carbazole	0.0009	DRAFT(e)
Dibenzo[a,h]pyrene	0.002	DRAFT(e)
Dibenzo[a,i]pyrene	0.002	DRAFT(e)
1,2-Dibromo-3-chloropropane	0.1	A/12705b
p-Dichlorobenzene	20	A/12705b
3,3'-Dichlorobenzidine	0.6	A/12705b
1,1-Dichloroethane	100	A/12705d
1,2-Dichloroethane (Ethylene dichloride)	10	A/12705b
Dichloromethane (Methylene chloride)	200 (inh)	A/12705b
	50	A/12705c
1,3-Dichloropropene	4 (oral)	OEHHA
	20 (inh)	DPR
Dieldrin	0.04	A/12705b
Diethyl sulfate	0.7	DRAFT(e)
Di(2-ethylhexyl)phthalate	80	A/12705c
Diethylstilbesterol	0.002	A/12705d
Diglycidyl resorcinol ether (DGRE)	0.4	A/12705d
Dihydrosafrole	20	A/12705d
3,3'-Dimethoxybenzidine (o-Dianisidine)	0.1	DRAFT(e)
3,3'-Dimethoxybenzidine dihydrochloride	0.2	DRAFT(e)
Dimethyl sulfate	0.05	RA/nSAP
4-Dimethylaminoazobenzene	0.2	A/12705d
trans-2-[(Dimethylamino)methylimino]-5-[2-(5-nitro-2-furyl)vinyl]-1,3,4-oxadiazole	2	A/12705d
7,12-Dimethylbenz(a)anthracene	0.003	A/12705d
3,3'-Dimethylbenzidine (o-Toluidine)	0.009	DRAFT(e)
3,3'-Dimethylbenzidine dihydrochloride	0.01	DRAFT(e)
Dimethylcarbamoyl chloride	0.05	A/12705d
1,1-Dimethylhydrazine (UDMH)	0.3	RA/nSAP
1,2-Dimethylhydrazine	0.001	A/12705d
Dimethylvinylchloride	20	A/12705d

1,6-Dinitropyrene	0.02	DRAFT(e)
1,8-Dinitropyrene	0.01	DRAFT(e)
2,4-Dinitrotoluene	2	A/12705c
1,4-Dioxane	30	A/12705b
Direct Black 38 (technical grade)	0.09	A/12705d
Direct Blue 6 (technical grade)	0.09	A/12705d
Direct Brown 95 (technical grade)	0.1	A/12705d
Disperse Blue 1	200	A/12705d
Epichlorohydrin	9	A/12705b
Estradiol 17b	0.02	A/12705d
Ethyl-4,4'-dichlorobenzilate (Chlorobenzilate)	7	A/12705d
Ethylene dibromide	0.2 (oral)	A/12705b
	3 (inh)	A/12705b
Ethylene oxide	2	A/12705b
Ethylene thiourea	20	A/12705d
	6	USEPA
Ethyleneimine	0.01	A/12705d
Folpet	200	A/12705c
Formaldehyde (gas)	40	A/12705c
2-(2-Formylhydrazino)-4-(5-nitro-2-furyl)thiazole	0.3	A/12705d
Furmecyclox	20	A/12705c
Glu-P-1 (2-Amino-6-methyldipyrido[1,2-a:3',2'-d]-imidazole	0.1	A/12705d
Glu-P-2 (2-Aminodipyrido[1,2-a:3',2'-d]-imidazole)	0.5	A/12705d
Glycidol	0.4	DRAFT(e)
Griseofulvin	50	RA/nSAP
Gyromitrin (Acetaldehyde methylformylhydrazone)	0.07	A/12705d
HC Blue 1	10	A/12705d
Heptachlor	0.2	A/12705c
Heptachlor epoxide	0.08	A/12705c
Hexachlorobenzene	0.4	A/12705b
Hexachlorocyclohexane		
alpha isomer	0.3	A/12705c
beta isomer	0.5	A/12705c
gamma isomer	0.6	A/12705c
technical grade	0.2	A/12705b
Hexachlorodibenzodioxin	0.0002	A/12705b
Hexachloroethane	20	A/12705d
Hexamethylphosphoramide	0.01	DRAFT(e)
Hydrazine	0.04	A/12705c
Hydrazine sulfate	0.2	A/12705c
Hydrazobenzene (1,2-Diphenylhydrazine)	0.8	A/12705d
IQ (2-Amino-3-methylimidazo[4,5-f]quinoline)	0.5	A/12705d
Lactofen	4	USEPA
Lasiocarpine	0.09	A/12705d
Lead acetate	3	A/12705d

Lead subacetate	20	A/12705d
Me-A-alpha-C (2-Amino-3-methyl-9H-pyrido-[2,3-b]indole)	0.6	A/12705d
Melphalan	0.005	A/12705d
2-Methylaziridine (Propyleneimine)	0.03	RA/nSAP
3-Methylcholanthrene	0.03	A/12705d
5-Methylchrysene	0.005	DRAFT(e)
4,4'-Methylene bis(2-chloroaniline)	0.5	A/12705d
4,4'-Methylene bis(N,N-dimethyl)benzeneamine	20	A/12705c
4,4'-Methylene bis(2-methylaniline)	0.8	A/12705d
4,4'-Methylenedianiline	0.4	A/12705d
4,4'-Methylenedianiline dihydrochloride	0.6	A/12705d
Methylhydrazine	0.6	DRAFT(e)
Methylhydrazine sulfate	0.2	DRAFT(e)
Methyl methanesulfonate	7	A/12705d
2-Methyl-1-nitroanthraquinone (of uncertain purity)	0.2	A/12705d
N-Methyl-N'-nitro-N-nitrosoguanidine	0.08	A/12705d
N-Methylolacrylamide	2	RA/nSAP
Methylthiouracil	2.	A/12705d
Metronidazole	4	RA/nSAP
Michler's ketone	0.8	A/12705d
Mirex	0.04	A/12705d
Mitomycin C	0.00009	A/12705d
Monocrotaline	0.07	A/12705d
5-(Morpholinomethyl)-3-[(5-nitrofurfurylidene)-amino]-2-oxalolidinone	0.2	DRAFT(e)
2-Naphthylamine	0.4	A/12705d
Nickel refinery dust	0.8	A/12705c
Nickel subsulfide	0.4	A/12705c
Nitrilotriacetic acid	100	A/12705d
Nitrilotriacetic acid, trisodium salt monohydrate	70	A/12705d
5-Nitroacenaphthene	6	A/12705d
5-Nitro-o-anisidine	10	A/12705d
6-Nitrochrysene	0.002	DRAFT(e)
Nitrofen (technical grade)	9	A/12705d
2-Nitrofluorene	0.09	DRAFT(e)
Nitrofurazone	0.5	A/12705d
1-[(5-Nitrofurfurylidene)-amino]-2-imidazolidinone	0.4	A/12705d
N-[4-(5-Nitro-2-furyl)-2-thiazolyl]acetamide	0.5	A/12705d
2-Nitropropane	30	DRAFT(e)
1-Nitropyrene	0.6	DRAFT(e)
4-Nitropyrene	0.03	DRAFT(e)
N-Nitroso-n-dibutylamine	0.06	A/12705b
p-Nitrosodiphenylamine	30	A/12705d
N-Nitrosodiethanolamine	0.3	A/12705c
N-Nitrosodiethylamine	0.02	A/12705b
N-Nitroso-N-ethylurea	0.03	A/12705b
N-Nitrosodimethylamine	0.04	A/12705b
N-Nitrosodiphenylamine	80	A/12705b
N-Nitrosodipropylamine	0.1	A/12705b

N-Nitrosomethylethylamine	0.03	A/12705c
N-Nitroso-N-methylurea	0.006	A/12705b
N-Nitroso-N-methylurethane	0.006	A/12705d
N-Nitrosomethylvinylamine	0.004	DRAFT(e)
N-Nitrosomorpholine	0.1	A/12705d
N-Nitrosonornicotine	0.5	A/12705d
N-Nitrosopiperidine	0.07	A/12705d
N-Nitrosopyrrolidine	0.3	A/12705c
N-Nitrososarcosine	5	DRAFT(e)
Ochratoxin A	0.03	RA/nSAP
Pentachlorophenol	40	A/12705c
Phenacetin	300	A/12705d
Phenazopyridine	4	A/12705d
Phenazopyridine hydrochloride	5	A/12705d
Phenesterin	0.005	A/12705d
Phenobarbital	2	A/12705d
Phenoxybenzamine	0.2	A/12705d
Phenoxybenzamine hydrochloride	0.3	A/12705d
Phenyl glycidyl ether	5	RA/nSAP
Phenylhydrazine	0.6	DRAFT(e)
Phenylhydrazine hydrochloride	0.8	DRAFT(e)
o-Phenylphenate, sodium	200	A/12705d
Polybrominated biphenyls	0.02	A/12705b
Polychlorinated biphenyls	0.09	A/12705c
Polychlorinated biphenyls (≥ 60% chlorine by weight)	0.1	RA/SAP
Poligeenan	200	DRAFT(e)
Ponceau MX	200	A/12705d
Ponceau 3R	40	A/12705d
Potassium bromate	1	A/12705d
Procarbazine	0.05	A/12705d
Procarbazine hydrochloride	0.06	A/12705d
1,3-Propane sultone	0.3	A/12705d
beta-Propiolactone	0.05	A/12705d
Propylene oxide	3 (oral)	USEPA
	60 (inh)	USEPA
Propylthiouracil	0.7	A/12705d
Reserpine	0.06	A/12705d
Saccharin	2800 to 840000[c]	DRAFT(e)
Saccharin, sodium	2800 to 840000[c]	DRAFT(e)
Safrole	3	A/12705d
Sterigmatocystin	0.02	A/12705d
Streptozotocin	0.006	A/12705d
Styrene oxide	4	A/12705d

c. OEHHA is evaluating several possible approaches for deriving NSRLs for saccharin and sodium saccharin. The range corresponds to the options being considered. In addition, if the evidence supports a finding that saccharin is carcinogenic by a species-specific mechanism of action, further alternative approaches to deriving NSRLs for these compounds will be considered.

Sulfallate	4	A/12705d
Tetrachlorodibenzo-p-dioxin	0.000005	A/12705b
1,1,2,2-Tetrachloroethane	3	A/12705d
Tetrachloroethylene	14	A/12705c
Tetranitromethane	0.05	RA/nSAP
Thioacetamide	0.1	A/12705d
4,4'-Thiodianiline	0.05	A/12705d
Thiourea	10	A/12705d
Toluene diisocyanate	20	A/12705d
ortho-Toluidine	4	A/12705d
ortho-Toluidine hydrochloride	5	A/12705d
para-Toluidine	4	DRAFT(e)
Toxaphene	0.6	A/12705b
Trichloroethylene	50 (oral)	A/12705b
	80 (inh)	A/12705b
2,4,6-Trichlorophenol	10	A/12705b
Tris(1-aziridinyl)phosphine sulfide (Thiotepa)	0.06	A/12705d
Tris(2,3-dibromopropyl)phosphate	0.3	A/12705d
Trp-P-1 (Tryptophan-P-1)	0.03	A/12705d
Trp-P-2 (Tryptophan-P-2)	0.2	A/12705d
Urethane (Ethyl carbamate)	0.7	A/12705b
Vinyl bromide	1 (oral)	RA/nSAP
	4 (inh)	RA/nSAP
Vinyl chloride	3	A/12705b
Vinyl trichloride (1,1,2-Trichloroethane)	10	A/12705d
2,6-Xylidine	100	RA/nSAP

B. Acceptable Intake Levels for Reproductive Toxicants

The following table is a compilation of acceptable intake levels for reproductive toxicants, including levels that have been adopted in regulation, and levels that have been derived by OEHHA staff but have not been established in regulation. These levels represent the no observable effect level for the reproductive toxicant, divided by 1,000.

Reproductive Toxicant	Level (µg/day)	Status[e]
Carbon disulfide	600 (oral)	RA
	1000 (inh)	RA
1,2-Dibromo-3-chloropropane	5	DRAFT(i)
m-Dinitrobenzene	80	RA
Ethylene oxide	20	A/12805
Lead	0.5	A/12805
Methyl bromide	1000	DRAFT(i)

e. Legend:
A/12805 = Adopted in Section 12805.
DRAFT(i) = Internal draft document completed.
RA = Risk assessment document completed.

Methyl mercury	0.3	RA
Toluene	7000 (oral)[f]	A/12805
	13000 (inh)[f]	RA[g]

C. Priority List for the Development of Dose-Response Assessments for Carcinogens

OEHHA has developed the following priority list, which classifies carcinogens for which dose-response assessments have not been completed into four priorities. First Priority carcinogens will be given the highest priority, and Fourth Priority carcinogens, the lowest. The placement of carcinogens into each of the four groups is dependent upon known uses of the chemical and potential for exposure, and the availability and quality of scientific data for use in conducting dose-response assessments. In addition, complex mixtures have generally been assigned to the Fourth Priority.

Any interested party may submit recommendations to OEHHA on revising the priority assignment for any of the chemicals listed. Recommendations should be accompanied by appropriate documentation supporting the alternative priority assignment suggested.

1. First Priority

A. *Identified as high priority in 12/23/92 settlement of AFL-CIO et al. vs. Deukmeijian ("Duke II"):*

Benzo[k]fluoranthene
Dibenz[a,h]acridine
Dibenz[a,j]acridine
Dibenzo[a,e]pyrene
Dibenzo[a,l]pyrene
Diepoxybutane
Lead phosphate
Methyl iodide
Nickel carbonyl
4-Nitrobiphenyl

B. *Other*

Acetaldehyde (oral)
Antimony oxide
1,2-Dichloropropane
Ethyl acrylate
4-Nitropyrene
Polychlorinated dibenzo-p-dioxins
Polychlorinated dibenzofurans
Selenium sulfide

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f. Level represents absorbed dose (rounded from 6,525 mg/day) via oral administration. Since absorption of ingested toluene is at 100%, absorbed dose is equivalent to administered dose by the oral route. On the other hand, the rate of absorption of toluene via inhalation is assumed to be at 50 percent, producing an administered dose which is twice the oral exposure value (i.e., 13,050 mg/day rounded off to 13,000 mg/day).

g. Section 12805 will be amended to establish route-specific levels reflecting differences in absorption rates in future rulemaking.

2. Second Priority

p-Aminoazobenzene
C. I. Acid Red 114
Cobalt metal powder
Cobalt [II] oxide
Diaminotoluene (mixed)
1,4-Dichloro-2-butene
Isosafrole
Lead and lead compounds
1-Naphthylamine
Nickel and nickel compounds
o-Nitroanisole
Oxadiazon
Silica, crystalline (airborne particles of respirable size)
p-a,a,a-Tetrachlorotoluene
1,2,3-Trichloropropane
Triphenyltin hydroxide
Tris(2-chloroethyl)phosphate
Trypan blue (commercial grade)
4-Vinyl-1-cyclohexene diepoxide

3. Third Priority

Adriamycin (Doxorubicin hydrochloride)
Azacitidine
N,N-Bis(2-chloroethyl)-2-naphthylamine
Bischloroethyl nitrosourea (BCNU) (Carmustine)
1,4-Butanediol dimethanesulfonate (Busulfan)
Ceramic fibers (airborne particles of respirable size)
Chloramphenicol
1-(2-Chloroethyl)-3-cyclohexyl-1-nitrosourea (CCNU)
1-(2-Chloroethyl)-3-(4-methylcyclohexyl)-1-nitrosourea
Ciclosporin (Cyclosporin A; Cyclosporine)
Cisplatin
Daunomycin
N,N'-Diacetylbenzidine
3,3'-Dichloro-4,4'-diaminodiphenyl ether
Dienestrol
1,2-Diethylhydrazine
Diisopropyl sulfate
Diphenylhydantoin (Phenytoin)
Diphenylhydantoin (Phenytoin), sodium salt
Estrone
Ethinylestradiol
Furazolidone
Glasswool fibers (airborne particles of respirable size)
Glycidaldehyde
Medroxyprogesterone acetate
Merphalan
Mestranol
Mustard Gas

Nafenopin
Niridazole
Nitrogen mustard (Mechlorethamine)
Nitrogen mustard hydrochloride (Mechlorethamine HC1)
4-(N-Nitrosomethylamino)-1-(3-pyridyl)1-butanone
Norethisterone (Norethindrone)
Oxymetholone
Panfuran S
Progesterone
Radionuclides
Testosterone and its esters
Thorium dioxide
Treosulfan
Trichlormethine (Trimustine hydrochloride)
Uracil mustard

4. Fourth Priority

Alcoholic beverages.
Analgesic mixtures containing phenacetin
Betel quid with tobacco
Bitumens, extracts of steam-refined
Bracken fern
Carbon-black extracts
Certain combined chemotherapy for lymphomas
Citrus Red No. 2
Conjugated estrogens
Creosotes
Cycasin
D&C Orange No. 17
D&C Red No. 8
D&C Red No. 19
Diesel engine exhaust
Erionite
Ethyl methanesulfonate
Gasoline engine exhaust (condensates/extracts)
Iron dextran complex
8-Methoxypsoralen with ultraviolet A therapy
5-Methoxypsoralen with ultraviolet A therapy
Methylazoxymethanol
Methylazoxymethanol acetate
Nitrogen mustard N-oxide
Nitrogen mustard N-oxide hydrochloride
3-(N-Nitrosomethylamino)propionitrile
Oil Orange SS
Oral contraceptives, combined
Oral contraceptives, sequential
Residual (heavy) fuel oils
Shale-oils
Soots, tars, and mineral oils
Talc containing asbestiform fibers
Tobacco, oral use of smokeless products

Tobacco smoke
Tris(aziridinyl)-para-benzoquinone (Triaziquone)
Unleaded gasoline (wholly vaporized)

THE SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986 (PROPOSITION 65)

Q: What is Proposition 65?

A: Proposition 65, formally known as the Safe Drinking Water and Toxic Enforcement Act of 1986 (Health and Safety Code, Chapter 6.6, Sections 25249.5 through 25249.13), was enacted as a ballot initiative in November, 1986. Among other things, it was intended by its authors to protect California citizens and the State's drinking water sources from chemicals known to cause cancer, or birth defects or other reproductive harm, and to inform the citizens about exposures to such chemicals.

Proposition 65 requires the Governor to publish by March 1, 1987, and to update at least annually, a list of chemicals known to the State to cause cancer or reproductive toxicity. As of September 1, 1996, 580 chemicals have been listed: 420 carcinogens and 160 reproductive toxicants. The requirements imposed by Proposition 65 on persons doing business in California apply to chemicals that appear on the list. The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) is designated by the Governor as the lead agency for Proposition 65 implementation.

Q: Who is subject to the requirements of Proposition 65?

A: Proposition 65 applies to all persons doing business -- whether or not for profit -- in California, except those which have fewer than ten employees. Governmental entities and drinking water utilities are exempt.

Q: What does Proposition 65 require affected businesses to do?

A: Proposition 65 created two provisions which persons doing business in California must comply with:

(1) A warning requirement -- Twelve months after a chemical is listed, businesses are prohibited from knowingly and intentionally exposing individuals to that chemicals without first giving a clear and reasonable warning to such individuals; and,

(2) A discharge prohibition -- Twenty months after a chemical is listed, businesses are prohibited from knowingly discharging or releasing that chemical into water or onto land where it could contaminate a source of drinking water.

Q: Do these requirements apply regardless of the level of the chemical involved?

A: No. Warnings are not required and discharges into sources of drinking water are not prohibited if the business responsible for the exposure or discharge is

able to demonstrate that the exposure or discharge poses "no significant risk" of cancer – defined in regulation as a cancer risk of less than one excess case of cancer in 100,000 individuals exposed over a 70-year lifetime – or that the exposure or discharge will produce no observable adverse effect on reproduction assuming exposure at 1,000 times the level in question. Discharges must, in addition, not be violative of other applicable legal requirements.

Chemical-specific daily intake levels representing the "no significant risk" level and the one one-thousandth of the no observable effect level are established by OEHHA in regulation to assist the regulated community in determining whether exposures or discharges for which they are responsible are exempt.

Q: *How would a business determine whether an exposure to a reproductive toxicant is exempt? Please explain the 1,000-fold safety factor for reproductive toxicants?*

A: For chemicals known to the State to cause reproductive toxicity, an exemption is provided by the Act if the business responsible for the exposure can show "that the exposure will have no observable effect assuming exposure at one thousand (1,000) times the level in question".

The highest dose level at which a chemical has no observable reproductive or developmental effect is referred to as the no observable effect level (NOEL). When the available scientific data do not indicate a dose at which no reproductive or development effects have been observed, the NOEL may be derived by dividing the lowest observable effect level by 10.

Uncertainty factors are generally applied to a NOEL to adjust for uncertainties in the dose-response assessment, and are intended to reflect the risk assessor's confidence in how well the data enable prediction of the NOEL in humans. Under Proposition 65, no flexibility is provided in selecting the magnitude of the uncertainty factor to be applied to the NOEL – i.e., a mandatory 1,000-fold uncertainty factor must be applied to the NOEL, as required by statute, to determine the maximum allowable level of exposure for which the exemption applies. If the level of exposure to a reproductive toxicant – as determined by a business through an exposure assessment – is below this maximum allowable level, that exposure is exempt from the warning requirement.

Although the 1,000-fold uncertainty factor is considered by some to be too stringent, it does not always result in extremely low allowable exposure levels that are impossible to meet, as some have contended. For example, if a pesticide were listed and concerns about meeting the 1,000-fold standard arise as it relates to pesticide residues, the business may want to look at other use situations. Existing regulations to protect workers in the field may already be based on reproductive concerns, and the allowable exposure levels may have been set using a 100-fold factor. Consequently, it may be reasonable to project that, given the time between application, harvest and retail sale, the residual levels would result in exposures below the 1000-fold standard. Certainly, the

information used in other regulatory settings can be utilized for purposes of Proposition 65.

Q: *How is Proposition 65 enforced?*

A: Enforcement of Proposition 65 is carried out through civil lawsuits filed by the Attorney General, district attorneys, certain city attorneys, or private citizens. A penalty of up to $2,500 per day per violation is specified in statute.

A citizen may initiate an enforcement action by first notifying the Attorney General, the appropriate district or city attorney, and the business involved,. of the alleged violation. If no action is taken by any of the public officials 60 days after receipt of the notice, the citizen may file a lawsuit against the business. If successful, the citizen is entitled to 25% of the penalties assessed against the violator. This provision for a "reward" has been referred to by some parties as the Act's "bounty hunter" provision.

Q: *What is the OEHHA Science Advisory Board?*

A: The Act provides for the listing of chemicals that are determined by the "state's qualified experts" as having been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity. In 1987, the Health and Welfare Agency (then the lead agency for Proposition 65 implementation) created a panel of independent scientists to act as the "state's qualified experts" for purposes of listing chemicals. In 1992, Cal/EPA reconstituted the panel to be composed entirely of State scientists. On September 1993, OEHHA formed a new Science Advisory Board made up of two committees: the Developmental and Reproductive Toxicant (DART) Identification Committee and the Carcinogen Identification Committee. While it has been the State's practice to utilize a panel of scientists for listing chemicals that cannot be addressed by administrative mechanisms, the statute does not require the use of such a board.

Q: *A recent settlement agreement entered into by the State with the plaintiffs in a lawsuit challenging the validity of the regulation dealing with foods, drugs, cosmetics and medical devices (commonly referred to as the "Duke II" lawsuit) provides for the repeal of the regulation by July 1, 1993. Does this mean that these products will be subject to Proposition 65 as of that date?*

A: Foods, drugs, cosmetics and medical devices have always been subject to the Proposition 65 warning requirement for chemicals that cause cancer, or birth defects or other reproductive harm. Although it is widely perceived as such, the regulation which was the subject of the lawsuit (Title 22, California Code of Regulations, Section 12713) is not designed, and was never intended to "exempt" foods, drugs, cosmetics and medical devices from the cancer warning requirement of Proposition 65. Such a categorical exemption for these products would have no basis in statute. Instead, the regulation provides that, in the absence of a regulatory "no significant risk" level for the carcinogen in question, an exposure to such carcinogen in a food, drug, cosmetic or medical device is

exempt from the warning requirement if the business responsible for the exposure is able to demonstrate that the product fully complies with all applicable State and federal standards. There is no similar provision for reproductive toxicants.

When it was adopted in 1988, the regulation was intended to provide an interim standard, until chemical-specific levels were established. The regulation was to have been repealed after the adoption of "no significant risk" levels for 50 chemicals, consistent with the Scientific Advisory Panel's recommendation. To date, the interim standard no longer applies to foods, drugs, cosmetics or medical devices which cause exposures to any of the 216 carcinogens for which regulatory levels have been established. OEHHA is developing regulatory levels for additional chemicals (including about 30 carcinogens that were identified as being of high priority in the settlement agreement), which would assist affected businesses in determining whether a warning is necessary for their product.

Where a business is responsible for an exposure to a carcinogen in a food, drug, cosmetic or medical device for which no regulatory level has been established, it must either provide a warning about such exposure, or be able to demonstrate that the level of exposure poses no significant risk — i.e., results in a cancer risk not exceeding one in 100,000. OEHHA has, as part of the settlement, established a prioritization scheme to identify other chemicals which present a realistic likelihood of liability under Proposition 65.

Q: *With this settlement and the repeal of 22 CCR Section 12713, haven't the manufacturers of foods, drugs, cosmetics, and medical devices lost an exemption from Proposition 65?*

A: The concern about the settlement of the "Duke II" lawsuit (AFL-CIO, et al. v. Deukmejian, et al., Sacramento Superior Court No. 502541), which includes a repeal of 22 CCR Section 12713, suggests that misconceptions exist about the so-called "exemptions" for foods, drugs, cosmetics and medical devices.

Section 12713 is of limited applicability, as described below:

First, the regulation never applied to chemicals identified as causing birth defects or reproductive harm. Hence, exposures from foods, drugs, cosmetics and medical devices to any of the 150 chemicals listed as causing reproductive toxicity were never covered by the regulation.

Second, the regulation never did provide an exemption. Those products causing exposures to carcinogens were subject to Proposition 65, but under the regulation, federal standards could be used to prove their safety.

Third, the regulation only applied to carcinogens for which there were no numeric "no significant risk" levels. In 1988, following the recommendation of the Scientific Advisory Panel, the regulation was adopted as "interim" pending

the development of levels for 50 chemicals, after which the regulation was to have been repealed.

Fourth, there are now 216 no significant risk levels in regulation. For these 216 carcinogens, 22 CCR Section 12713 no longer applies. In addition, the 216 levels far exceed the target of 50 chemicals mentioned above as the trigger for repealing the regulation.

All together, Section 12713 no longer applies to 542 chemicals (150 reproductive toxicants plus 216 carcinogens) that are listed for purposes of Proposition 65. The affected industries appear to be complying with Proposition 65, judging from the absence of warnings to consumers for foods, drugs, cosmetics, or medical devices.

At this point, OEHHA has identified very few chemicals that are of specific, genuine concern to the manufacturers of foods, drugs, cosmetics and medical devices. However, OEHHA has developed a priority list for the future development of additional risk assessments. Interested parties are invited to suggest changes in the prioritization.

Q: *Proposition 65 standards have been characterized as being more stringent than federal standards. Why is there a need for standards stricter than those which the federal government considers "safe"?*

A: The passage of Proposition 65, in large part, reflected the voters' belief that existing regulatory standards do not provide adequate protection from carcinogens and reproductive toxicants. No latitude is allowed by the Act for "aceptable" levels of exposure to consider non-health based factors such as technical feasibility and cost, which are generally considered as part of the standard setting process in federal regulatory programs, and which generally result in levels higher than those indicated by health-based considerations alone. An acceptable level under Proposition 65 is the level of detection, unless a higher level can be demonstrated to pose no significant risk or produce no observable effect at 1,000 times the level in question.

The degree of protection afforded by federal standards has often been called into question. For example, an acceptable daily intake level of 0.5 microgram per day is set forth in regulation for lead as a reproductive toxicant. This level is calculated to correspond to levels of leachable lead from ceramic tableware which are significantly lower than current U.S. Food and Drug Administration (FDA) standards (e.g., 50 times lower than the standards for flatware). More recent information indicating that lead can cause adverse health effects in the fetus, in young children, and in adults at levels well below those that were of concern at the time the lead standards were adopted by the FDA approximately 12 years ago. As a result, FDA is considering reducing its acceptable lead levels in order to provide a greater degree of public health protection.

Q: *Why is OEHHA proposing to amend the current regulations which define what constitutes a "clear and reasonable" warning?*

A: In proposing to amend the warning regulation, it is OEHHA's intent to accomplish the following: (1) to ensure that warnings provided for purposes of Proposition 65 reflect the requirement of the statute that warnings be provided for exposures to listed chemicals; (2) to provide for warnings that include sufficient information to permit recipients to make informed choices to avoid or minimize exposures; and (3) to discourage the issuance of unnecessary warnings that obscure those given for truly significant exposures. In addition, the proposal provides more specific guidance and a greater degree of certainty of compliance to the regulated community regarding the elements of warnings that are deemed by the State to be adequate -- particularly for warnings given for environmental exposures.

10/07/96

PROPOSITION 65 IN PLAIN ENGLISH!

What Is Proposition 65?

In November 1986, California voters overwhelmingly approved an initiative to address growing concerns about exposures to toxic chemicals. That initiative became *The Safe Drinking Water and Toxic Enforcement Act of 1986*, better known by its original name:

What Does Proposition 65 Require?

Proposition 65 requires the Governor to publish a list of chemicals that are known to the State of California to cause cancer, birth defects or other reproductive harm. Agents that cause cancer are called ***carcinogens***; those that cause birth defects or other reproductive harm are called ***reproductive toxicants***. This list must be updated at least once a year. Over 550 chemicals have been listed as of April 1, 1996.

Proposition 65 imposes certain controls that apply to chemicals that appear on this list. These controls are designed to protect California's drinking water sources from contamination by these chemicals, to allow California consumers to make informed choices about the products they purchase, and to enable residents or workers to take whatever action they deem appropriate to protect themselves from exposures to these harmful chemicals.

Thus, Proposition 65 also provides a market-based incentive for manufacturers to remove listed chemicals from their products.

The benefits of the Proposition have their costs. Businesses have incurred expenses to test products, develop alternatives, reduce discharges, provide warnings and otherwise comply with the requirements of the Proposition. Recognizing that compliance with the Proposition comes at a price, Cal/EPA and the Office of Environmental Health Hazard Assessment (the lead agency for Proposition 65 implementation) have worked hard to minimize any unnecessary regulatory burdens and ensure that placement of a chemical on the list is done in accordance with rigorous science in an open public process.

What kinds of chemicals are on the list?

The list contains a wide range of chemicals, including dyes, solvents, pesticides, drugs, food additives, and by-products of certain processes. These chemicals may be naturally occurring, or synthetic. Some of them are ingredients of common household products, others are specialty chemicals used in very specific industrial applications.

How Does a Chemical Get Listed?

The State of California relies upon information that already exists in the scientific literature when determining the threat of a chemical. A chemical is listed if the "state's qualified experts" -- two independent committees of scientists and health professionals appointed by the Governor – find that the chemical has been clearly shown to cause cancer or birth defects or other reproductive harm.

In addition, a chemical can be listed if it has been classified as a carcinogen or as a reproductive toxicant by an organization that has been designated as "authoritative". Organizations that have been designated as authoritative are U.S. Environmental Protection Agency, U.S. Food and Drug Administration, National Institute for Occupational Safety and Health, the National Toxicology Program and the International Agency for Research on Cancer for purposes of Proposition 65, or if it is required to be labeled or identified as a carcinogen or as a reproductive toxicant by an agency of the state or federal government.

What Are the Responsibilities of Companies Doing Business in California?

Any company with ten or more employees that operates within the State or sells products in California must comply with the requirements of Proposition 65.

Under Proposition 65, businesses are:

1) prohibited from knowingly discharging listed chemicals into sources of drinking water; and

2) required to provide a "clear and reasonable" warning before knowingly and intentionally exposing anyone to a listed chemical. This warning can be given by a variety of means, such as by labeling a consumer product, by posting signs at the workplace, or by publishing notices in a newspaper.

What Does A Warning Mean?

If you are given a warning or if a warning is posted in a workplace, a facility or an area in your community, this means that the business issuing the warning knows that one or more listed chemicals is present in its product, in its workplace, or in its emissions into the environment. Under the law, a warning must be given unless a business demonstrates that the exposure it causes poses no significant risk.

For a chemical that is listed as a carcinogen, the "no significant risk" level is defined as the level which is calculated to result in not more than one excess case of cancer in 100,000 individuals exposed over a 70-year lifetime. In other words, if you are exposed to the

chemical in question at this level every day for 70 years, theoretically it will increase your chances of getting cancer by no more than 1 case in 100,000 individuals so exposed.

For chemicals that are on the list as reproductive toxicants, the no significant risk level is defined as the level of exposure which, even if multiplied by 1,000, will not produce birth defects or other reproductive harm. That is, the level of exposure is below the "no observable effect level (NOEL)," divided by 1,000. (The "no observable effect level" is the highest dose level which has not been associated with an observable reproductive harm in humans or test animals.)

When a warning is given by a business, it means one of two things:

(1) the business has evaluated the exposure and has concluded that it exceeds the no significant risk level; or

(2) the business has chosen to provide a warning simply based on its knowledge about the presence of a listed chemical, without attempting to evaluate the exposure. In these cases, exposure could be below the Proposition 65 level of concern, or could even be zero.

Since businesses do not file reports with the State regarding what warnings they have issued and why, the State is not able to provide further information about any particular warning which you may have received. The business issuing the warning is the appropriate party to contact if you seek more specific information about the warning, such as what chemicals are involved, in what manner these chemicals are present, and how exposures to those chemicals may or may not occur.

What has been accomplished as a result of Proposition 65?

Proposition 65 has provided an effective mechanism for reducing certain exposures that may not have been adequately controlled under existing federal or State laws. For example, a Proposition 65 enforcement action has resulted in the reduction of the amount of lead in ceramic tableware. Air emissions of certain chemicals - including ethylene oxide, hexavalent chromium, and chloroform - from facilities in California have been significantly reduced as a result of Proposition 65.

Certain chemicals on the list are no longer used as constituents of some commonly used products - for example, trichloroethylene is no longer used in most correction fluids, toluene has been removed from many nail care products, and foil caps on wine bottles no longer contain lead.

Proposition 65 has resulted in the extensive dissemination of important information regarding the dangers to the unborn child of drinking alcoholic beverages during pregnancy. The warnings about alcoholic beverage consumption during pregnancy are

perhaps the most widespread and visible type of warning issued as a result of Proposition 65.

This is a draft of the "plain English" brochure produced by the Office of Environmental Health Hazard Assessment (OEHHA) explaining The Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65). It is intended to demystify the Proposition and shed light on the process OEHHA uses to determine whether or not compounds are "known the state" to be carcinogens or reproductive toxicants. This brochure was drafted by OEHHA as part of Cal/EPA's Regulatory Reform Initiative, in keeping with Governor Wilson's Executive Order W127-95 which calls for reform of regulatory processes throughout state government.

Your comments are welcome.

For Further Information

Contact the Office of Environmental Health Hazard Assessment's Proposition 65 Implementation Office at (916) 445-6900.

This document can be found on the Internet at the following address:
http://www.calepa.cahnet.gov/oehha/docs/

Office of Environmental Health Hazard Assessment (OEHHA)
California Environmental Protection Agency (Cal/EPA)
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Publications

Publications on the first three pages are free. To receive these publications, check off desired titles, and mail us this sheet with the form on page three. Most of the publications starting on page four involve a charge for the general public to cover printing and handling costs, and they must be ordered separately, as instructed. An exception is that public agencies in California may request any publication free of charge directly from us or from the specific agency indicated with the title.

Electronic access: Some Office of Environmental Health Hazard Assessment (OEHHA) publications as well as documents from other boards and departments in the California Environmental Protection Agency (Cal/EPA) are available free online through Cal/EPA ACCESS (BBS: 1-916-322-5041, 14,400 bps, 8 bits, no parity, 1 stop bit. Internet: home page http://www.cahwnet.gov/epa/oehha.htm; or gopher://www.cahwnet.gov and select Cal/EPA).

General Documents

These reviews report on a variety of environmental health hazards and related issues in California. The "T" or "NT" following the title indicates whether they are intended for "technical" or "nontechnical" audiences. To order, place check in front of title and mail or fax with form on page 3.

__OEHHA Brochure. *Lists major personnel and describes the programs within OEHHA.*

__The Air Toxics "Hot Spots" Information and Assessment Act (NT, 1994, 1 pg.)

__Answers to Health Questions About Aerial Application of Malathion-Bait: Questions and Answers (NT, Revised 1995, 7 pgs. Also in Spanish.)

__Art Hazards Program Fact Sheet

__California Environmental Laws: A Summary of (NT, updated 1993, 41 pgs.)

__Chemical Sensitivity: Fact or Fad? (NT, May 1987, 11 pgs.) *Looks at the subject of hypersensitivity to environmental chemicals.*

__Chemical Contamination of California Drinking Water (NT, Nov. 1987, 8 pgs.)

__Dioxins in California: A Widespread Problem (T-NT, May 1992, 13 pgs.)

__Environmental Abbreviations and Acronyms. *A 9-page list of terms produced by the Registered Environmental Assessor Program in OEHHA.*

__Electric and Magnetic Fields: Measurements and Possible Effects on Public Health from Appliances, Power Lines, and Other Common Sources (NT, 1992, 15 pgs.)

__Health Risk Assessment of Aerial Application of Malathion-Bait—Summary Report (NT, 1991, 27 pgs.)

__Health Risk Evaluation of the Metam Spill: Questions and Answers (NT, 1992, 6 pgs.) *Summarizes report listed later under paid publications.*

__Major Federal Environmental Laws: Summary of Toxic Substances Provisions (NT, updated 1991, 6 pgs.)

__Resources on Health Effects of Toxic Substances (NT, Updated January 1994). *This is Section 1 of the Toxics Directory (See following listing under "From the State Publications Section). It contains the listings and descriptions of agencies.*

__Risk Assessment for Carcinogens Under California's Proposition 65 (T-NT, reprint from Risk Analysis, 1990;10:255-271)

__Urban Pest Eradication Programs need a Strong Dose of Public Information (NT, March 1986, 13 pgs.) *Lessons learned from the experience of the 1980-82 Medfly eradication campaign in San Jose, including the value of an independent health advisory committee, are summarized.*

__Wood Preservatives on Playground Equipment: An Evaluation of the Hazard (T, Aug. 1988, 35 pgs.) *This document evaluates the potential health hazard of arsenic compounds used to prevent rotting of wooden playground structures.*

Water-Related Publications

Fact Sheets: Chemical Contaminants in Drinking Water

These fact sheets provide information on chemical uses, regulatory standards, environmental fate, health effects, and environmental levels. They contain technical and nontechnical information. Some nontechnical question and answer documents are provided in the list above. Check off individual titles.

__Introduction to fact sheets. (Explains in lay language concepts and terms used in the fact sheets.)

1986 fact sheets: __benzene, __chloroform, __dibromochloropropane (DBCP), __methylene chloride, __trichloroethane (TCA), __trichloroethylene (TCE)

1988 fact sheets: __aluminum, __bentazon, __carbaryl, __p-dichlorobenzene (p-DCB), __1,1-dichloroethane (1,1-DCA), __ethylbenzene, __simazine, __1,1,2-trichloroethane (1,1,2-TCA), __thiobencarb (Bolero), __vinylidene chloride, __uranium

1991-present fact sheets: __arsenic __atrazine __copper __1,2-dichloropropane (1,2-DCP) __cis-1,2-dichloroethylene (cis-1,2-DCE), __trichlorofluoromethane (Freon-11), __1,1,2-trichloro-1,2,2-trifluoroethane (freon-113), __nitrate, __pentachlorophenol (PCP), __vinyl chloride

Other Water-Related Publications

__Arsenic in Drinking Water: Questions and Answers (NT, 1991, 8 pgs. Also in Spanish)

__DBCP in Drinking Water: What Does It Mean? (NT, Dec. 1989, 10 pgs. Also in Spanish.) *DBCP is a pesticide that has contaminated ground water in agricultural areas of the Central Valley.*

__Nitrate in Drinking Water: An Evaluation of the Current Standard (T, March 1987, 5 pgs.) *Nitrate is one of California's most common ground water contaminants. It is associated with the use of fertilizers, leaking septic systems, and animal feed lots.*

Fish-Related Publications

Sport fish have been found to be contaminated in various locations in the state. OEHHA evaluates data from studies on contamination levels in fish and issues health advisories on consumption of the sport fish when warranted. The advisories are printed in the California Sport Fishing Regulations booklet, which is available where fishing licenses are sold, and are available from OEHHA as listed below. See also reports listed later in this publications list.

__Health Advisory on Catching and Eating Fish in California (NT, 1994). *Illustrated brochure giving general advice, including how to prepare and cook fish in ways that reduce chemical levels. Available in English, Spanish, Chinese, Vietnamese, Cambodian, and Korean.*

__Health Warnings. *These are the health advisories for the entire state that were printed in the California Sport Fishing Regulations booklet 1994 edition and updated for 1995. The San Francisco Bay interim advisory is listed separately below.*

__Health Advisory on Catching and Eating Fish: Interim Sport Fish Advisory for San Francisco Bay. December 1994. *Available in English, Spanish, Chinese, Vietnamese, Cambodian, and Korean.*

__Methylmercury in Sport Fish: Answers to Questions on Health Effects (NT, 1994, 4 pgs.).

__PCBs in Sport Fish: Answers to Questions on Health Effects (NT, 1994, 7 pgs.)

__Chemical Contamination in Fish from San Francisco Bay: Study Results. 1995. (NT, 5 pgs.) *Summary of pilot study conducted by the San Francisco Bay Regional Water Quality Control Board, Oakland, CA.*

__Summary of Chemicals of Concern Found in Fish: San Francisco Bay Pilot Study, 1994. (NT, 5 pgs.) *Summarizes the health effects of the chemicals of concern found in the sport fish.*

__Chemical Contamination of Marine Fish from Southern California, A Study of (NT, Sept. 1991, 11 pgs.) *Summary from report listed later. Contains consumption guidelines.*

__Methyl Mercury in Northern Coastal Mountain Lakes: Guidelines for Sport Fish Consumption (T-NT, May 1987, 15 pgs.) *Mercury is found in many lakes where it occurs naturally in the surrounding rocks.*

__Risk Assessment of Dioxin Contamination of Fish (T, Aug. 1989, 28 pgs.) *This assessment was prompted by findings of dioxin traces in fish in the Sacramento River.*

To receive the free publications, compete this form and mail it with your selections from the first three pages to PETS/OEHHA, 2151 Berkeley Way, Berkeley, CA 94704-1011.

Name

Business or organization

Street address

City, state and zip code

Publications Involving a Charge

Most of the publications on this and the following pages require payment to cover printing and handling costs and must be ordered from other sources as explained below. (Exception: public agencies within California may request free copies of these publications. Requests must be sent directly to OEHHA or the specific program identified.)

From the State Publications Section

To receive these publications, mail a check made out to "State of California" to Publications Section, P.O. Box 1015, North Highlands, CA 95660, (916) 574-2200. No fax orders or P.O.s. Price includes tax and shipping. Include the title and publication number in your order. Provide your street address and an attention line with the name of the person receiving the shipment for UPS shipping. Allow 2 to 4 weeks for delivery.

The Toxics Directory (Fourth Edition, 1994)

Lists and describes nearly 100 governmental, educational, and public interest organizations on the national, state, and local levels that can respond to all types of toxic problems and information needs. Also includes directories of many state and local offices in California that deal with toxics, as well as laboratories that analyze hazardous materials and contaminants. Much of the directory consists of references to books, scientific journal articles, and literature for the layperson. References cover textbooks and handbooks, guides on clean-up and management of toxics, on-line environmental databases, and books and articles on risk assessment, risk communication, and many types of toxic substances. The staff have worked to select the best references in each area. Fourth edition, 1994, (updates the 1990 edition), 144 pages. $9.90, Publication No. 7540-958-1300-3.

Pesticides: Health Aspects of Exposure & Issues Surrounding Their Use

This is a course syllabus and manual developed for a continuing education seminar for health personnel. June 1988, 145 pages, $11.30, Publication No. 7540-958-1301-5.

Miscellaneous Titles

Consumer's Guide to California Drinking Water

A comprehensive review for the layperson written under contract to OEHHA. 80 pgs. (1989) $3.50 (Call for discounts on bulk orders). Purchase from the Local Government Commission, 909 12th St., Ste. 205, Sacramento, CA 95814 (Phone: 916-448-1198).

Evaluation of Health Risks Associated with the Metam Spill in the Upper Sacramento River, Draft 1992

Discusses the health effects and risks related to the spill of the pesticide metam into the Sacramento River on July 14, 1991, near Dunsmuir, California. (1992) Purchase from Copies Unlimited, 5904 Sunset Blvd. Los Angeles, CA 90028, (213) 462-5532. The price is $8.24 including tax for a loose-leaf, three-hole-

punch copy, plus $3.50 for shipping and handling. For more information on binding options, mailing, and discounts for multiple copies, call Copies Unlimited.

Monterey Bay Marine Environmental Health Survey

This report presents an evaluation of the potential health effects of consuming seafood from Monterey Bay, California, and describes the results of a study of chemical contaminant concentrations in fish from the bay. The results of the study showed that the levels of contaminants in fish were low and that the risks of consuming the fish were low and usually below levels of concern. 300 pages. (1991) $14.00 plus tax and handling. (Comes 3-hole punched; call for other options on binding, bulk discounts, etc.) Order from Copies Unlimited, 5904 Sunset Blvd., Los Angeles, CA 90028, (213) 462-5532 or 462-5688.

A Study of Chemical Contamination of Marine Fish from Southern California

During the 1960s and 1970s, the discharge of industrial chemicals from the manufacturing of pesticides and other products contaminated ocean sediments along the coast of southern California. This study examined the presence of DDT, PCBs, chlordane, tributyltin, and mercury in 15 species of fish and evaluated the risks of consuming these fish. Consumption guidelines are given for specific areas and fish species. (A free summary of this report is available. See the list of Tox-Epi Reviews on page 1.) 300 pages. (1991) $14.00 plus tax and handling. (Comes 3-hole punched; call for other options on binding, bulk discounts, etc.) Order from Copies Unlimited, 5904 Sunset Blvd., Los Angeles, CA 90028, (213) 462-5532 or 462-5688.

Malathion-Related Documents

Health Risk Assessment of Aerial Application of Malathion-Bait

During 1989-90 a campaign involving aerial application of malathion-bait was conducted to eradicate the Mediterranean fruit fly (Medfly) in southern California. A study was conducted by the California Department of Health Services to assess the risks to the exposed population. This report includes a comprehensive review of the scientific literature, and provides dose estimations of public exposure and recommendations for further investigations to reduce uncertainty. (A free summary of this report is available. See the list of Tox-Epi Reviews on page 1.) 300 pages. (1991) $15.00 plus tax and handling. (Comes 3-hole punched; call for other options on binding, bulk discounts, etc.) Order from Copies Unlimited, 5904 Sunset Blvd., Los Angeles, CA 90028, (213) 462-5532 or 462-5688.

Charges and Recommendations: Submitted by the Malathion Public Health Effects Advisory Committee, 1990-1991

This is the report of the advisory committee. March 1992. $6.20, plus postage. California residents add $.51 for sales tax. Order from Copies Unlimited.

Urban Pesticide Spraying Symposium: Charting a Course for Public Health Protection

This document outlines proceedings from a symposium held on October 2-4, 1991, Holiday Inn BayView Plaza, Santa Monica, California. April 1993. The symposium's purpose was to bring together all interested parties including state agencies and the public. $5.26 plus postage. Order from Copies Unlimited.

Proposition 65-Related Documents

Information Packet on Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) (Includes list of chemicals)

This free information packet includes a copy of the act. Updated at least annually, it tells how to keep informed about the act, lists the chemicals known to the state to cause cancer or reproductive toxicity, and lists no significant risk levels for carcinogens and acceptable intake levels for reproductive toxicants. Request this document from the Office of Environmental Health Hazard Assessment, P.O. Box 942732, Sacramento, CA 94234-7320, (916) 445-6900. (Note: The Proposition 65 list of chemicals was issued in October 1994. Updates of the list are expected to occur in July and October of ensuing years. Proposition 65 information is available on the BBS and Internet, as noted on page 1.)

Expedited Cancer Potency Values and Proposed Regulatory Levels for Certain Proposition 65 Carcinogens

This report presents methodology for the derivation of cancer potency values using an expedited procedure, and provides potency estimates and regulatory values (No Significant Risk Levels [NSRLs]) for a number of agents listed as carcinogens under Proposition 65. April 1992. 92 pgs. Others may purchase the document from Copies Unlimited, 5904 Sunset Blvd., Los Angeles, CA 90028, (213) 462-5532 or 462-5688. The price is $2.98 plus postage. Government agencies may obtain this free from Office of Environmental Health Hazard Assessment, P.O. Box 942732, Sacramento, CA 94234-7320, (916) 445-6900.

California Cancer Potency Factors: Update

The cancer potency values listed in this document were developed or approved by several programs within the California Environmental Protection Agency (Cal/EPA), and have been used as a basis for regulatory actions such as the establishment of maximum contaminant levels for drinking water, identification of toxic air contaminants, and setting of no significant risk levels for purposes of the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65). A major purpose of the list is to reduce duplication of effort on the part of state agencies that must review the same chemicals for different programs and to promote consistency in risk assessment efforts across state government. The list is updated approximately every one or two years. There is no charge for this list at present, but may be in the future as it expands. Request it directly from the Hazardous Waste Toxicology Section in the Office of Environmental Health Hazard Assessment, P.O. Box 942732, Sacramento, CA 94234-7320, (916) 324-2829.

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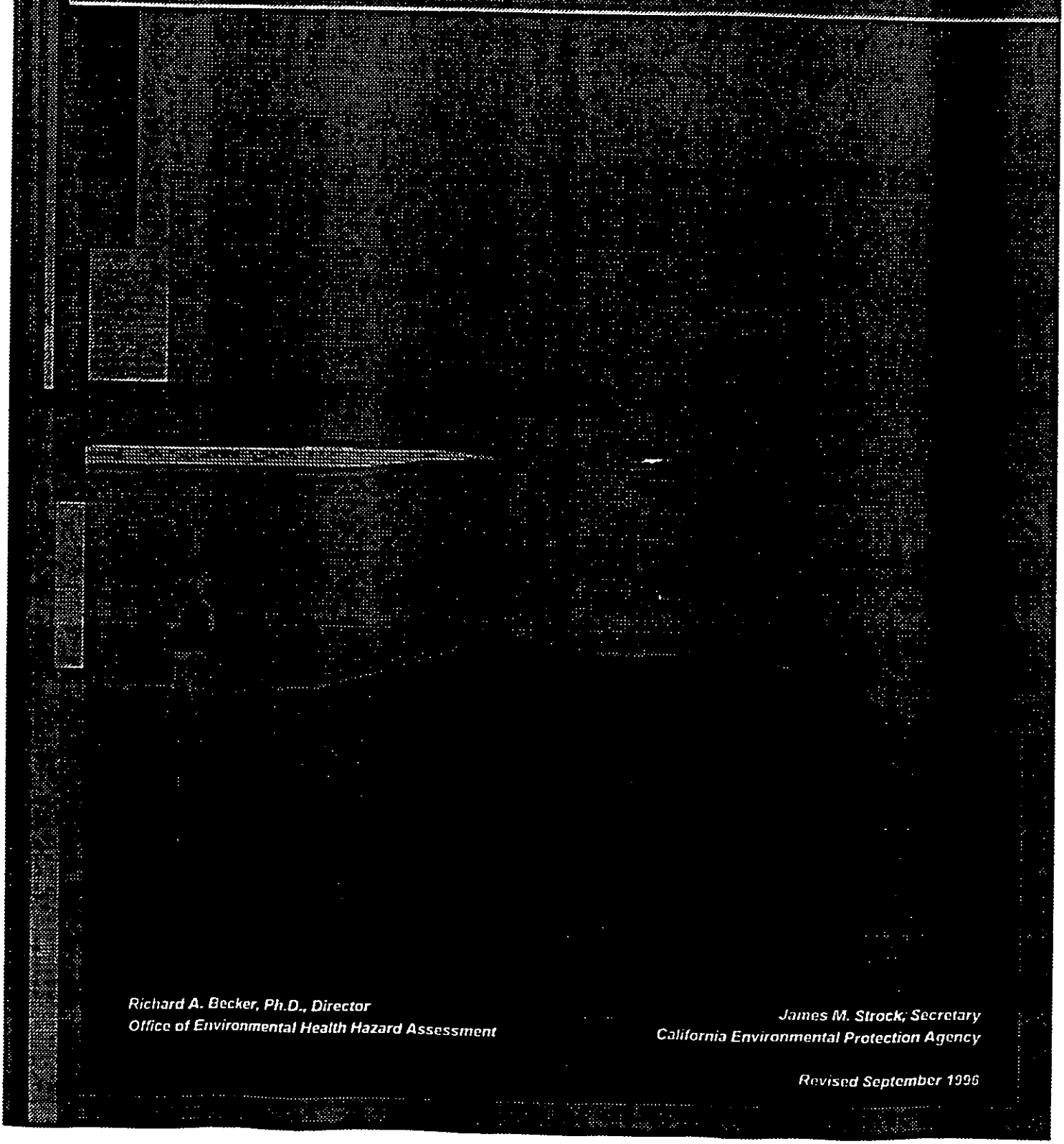
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

California Environmental Protection Agency



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The Office of Environmental Health Hazard Assessment

The mission of the Office of Environmental Health Hazard Assessment (OEHHA) is to protect and enhance public health and the environment by objective scientific evaluation of risks posed by hazardous substances.

While OEHHA does not promulgate environmental regulations directly, it is responsible for developing and providing risk managers in state and local government agencies with toxicological and medical information relevant to decisions involving public health. State agency users of such information include all boards and departments within Cal/EPA, as well as the Department of Health Services, the Department of Food and Agriculture, the Office of Emergency Services, the Department of Fish and Game, and the Department of Justice. OEHHA also works with Federal agencies, the scientific community, industry and the general public on issues of environmental as well as public health. Examples of current OEHHA functions and responsibilities include:

* Developing health-protective exposure standards for different media (air, water, land) to recommend to regulatory agencies, including ambient air quality standards for the Air Resources Board and drinking water chemical contaminant standards for the Department of Health Services.

* Carrying out special investigations of potential environmental causes of illness, diseases and deaths. Current and recent activities include investigation of the health effects of air pollutants, pesticides, and other chemical exposures.

* Continuing public health oversight of environmental regulatory programs within Cal/EPA.

* Making recommendations to the Department of Fish and Game and the State Water Resources Control Board with respect to sport and commercial fishing in areas where fish may be contaminated.

* Assessing health risks to the public from air pollution, pesticide and other chemical contamination of food, seafood, drinking water, and consumer products.

* Providing guidance to local health departments, environmental departments, and other agencies with specific public health problems, including appropriate actions to take in emergencies that may involve chemicals.

* Implementing the provisions of the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65).

These responsibilities are fulfilled by a highly trained professional staff of about 100 individuals. Of these staff, 45 hold doctoral degrees, six are physicians, seven hold masters degrees in public health or science, and two are registered nurses. OEHHA is budgeted in fiscal year 1995-96 for approximately $12 million. OEHHA is headquartered in Sacramento and has a field office in Berkeley.

Office of Environment Health Hazard Assessment
Program Summaries

EXECUTIVE OFFICE

The Executive Office provides the direction and leadership necessary to plan, develop and administer programs and activities in OEHHA. Other functions provided by the executive office include legal support to various programs, legislative analysis and liaison, and communication and public information support.

ADMINISTRATION AND PROGRAM SUPPORT SECTION

The Administration and Program Support Section carries out the various administrative tasks necessary to support the Office, including business support, personnel, contract management, data processing, and office support services. Fiscal services, formerly provided through an Interagency Agreement with the Department of Toxic Substance Control, have been added to the Section's responsibility effective July 1, 1995.

PROPOSITION 65 IMPLEMENTATION PROGRAM

Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986, was enacted as a ballot initiative in November, 1986. The Proposition was intended by its authors to protect California citizens and the State's drinking water sources from chemicals known to cause cancer, birth defects or other reproductive harm, and to inform citizens about exposures to such chemicals.

Proposition 65 requires the Governor to publish at least annually a list of chemicals known to the state to cause cancer or reproductive toxicity. As of January 1, 1995, 555 chemicals have been listed: 402 carcinogens and 153 reproductive toxicants. The requirements imposed by Proposition 65 on persons doing business in California apply to chemicals that appear on the list. The Office of Environmental Health Hazard Assessment is the lead agency for Proposition 65 implementation.

HAZARDOUS WASTE TOXICOLOGY SECTION

The Hazardous Waste Toxicology Section (HWTS) has a variety of functions dealing with potential health threats from exposures to hazardous and solid wastes. The Section assists the Department of Toxic Substances Control (DTSC) in evaluating hazardous waste sites where people are exposed or have a high potential of exposure to hazardous waste, and provides peer review of risk assessment documents for those sites. The Section works with the Department of Health Services (DHS) in their investigation of sites where health studies may need to be done. HWTS provides technical assistance in risk assessment for DTSC's and local air districts' permitting processes for hazardous waste incinerators. HWTS works with and assists other state agencies dealing with hazardous materials issues. The Section provides risk assessment expertise to the Integrated Waste Management Board (IWMB) on new strategies dealing with solid waste disposal and recycling and assists the Board in question concerning potential health effects of emissions from municipal waste landfills. The Section also assists local agencies and individual citizens that have concerns about health risks from exposures to hazardous materials. HWTS annually prepares and updates the Railroad Hazardous Commodities List, which lists commodities that may pose a hazard to people, the environment or property when spilled.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT SECTION

The Reproductive and Cancer Hazard Assessment Section (RCHAS) provides scientific support for all risk assessment programs within OEHHA, with specific responsibilities for the implementation of Proposition 65. RCHAS provides technical support for listing carcinogens and reproductive toxicants under Proposition 65; develops guidelines for conducting risk assessments; and develops an annual list of chemicals in need of future testing. In addition, RCHAS evaluates the hazards from consumer use of drugs, cosmetics, and other consumer products; prepares and develops guidelines for ecotoxicological risk assessment; and assists other Cal/EPA departments as well as the Air Toxicology and Epidemiology Section and the Pesticide and Environmental Toxicology Section in their evaluations of air, water and food contamination risks. RCHAS has the lead for supporting an external review of Cal/EPA risk assessment policies and procedures, as mandated by SB 1082.

AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION

The Air Toxicology and Epidemiology Section (ATES) is responsible for carrying out risk assessments of chemical contamination in various media, such as air, water and food. Information developed by the section is provided to air quality management districts, local health departments, the Air Resources Board (ARB), the U.S. Environmental Protection Agency, other governmental agencies, regulated industries and the public.

ATES is composed of two units: the Criteria Air Pollutants Unit and the Toxic Hot Spots Unit. The Criteria Air Pollutants Unit's responsibilities include: (1) making health-based recommendations to ARB for ambient air quality standards; (2) evaluating major new studies and data that may affect existing recommendations for ambient air quality standards; and (3) providing consultation to other agencies, including local air pollution control districts and local health officers.

The Toxic Hot Spots Unit's responsibilities include: (1) providing health effects evaluations and risk assessments to support the regulatory program of ARB for toxic air contaminants; (2) reviewing risk assessments for municipal waste incinerators; and (3) preparing guidelines, reviewing risks assessments and providing health risk-related assistance to the ARB and air pollution control districts (APCDs) for the statewide air toxic hot spots information and assessment effort. Other major responsibilities include providing consultation to other agencies (APCDs, local health officers or federal agencies) regarding airborne toxicants, providing risk assessment information for emergency planning, and undertaking studies regarding effects of ambient air toxicants.

PESTICIDE AND ENVIRONMENTAL TOXICOLOGY SECTION

The Pesticide and Environmental Toxicology Section (PETS) is composed of three units. The Pesticide and Food Toxicology Unit carries out risk assessment and hazard evaluation activities related to pesticide and other chemical contaminants in food and consumer products. These include evaluating chemical contamination of raw agricultural commodities, processed foods, and fish and game animals, as well as issuing health advisories, recommending acceptable levels for chemicals in food, and assessing the adequacy of existing pesticide tolerances for public health protection. The program also conducts mandated marine pollution studies, including the development of sediment quality objectives. Staff within the program perform activities required by legislation to develop and evaluate pesticide tolerances and to establish acceptable pesticide levels in groundwater.

The activities of the Pesticide Unit include the following legislatively mandated programs: a pesticide illness reporting system, epidemiological and other assistance to local health officers in the event of an outbreak of pesticide poisoning, joint and mutual responsibility with the Department of Pesticide Regulation (DPR) to develop regulations to protect workers exposed to agriculture pesticides, and a program for reducing groundwater contamination from pesticides. OEHHA has a mandated membership on committees advisory to DPR – the Pesticide Advisory Committee and the Pesticide Registration Evaluation Committee. In addition, members of the Unit are participants in DPR's Worker Health and Safety Advisory Committee.

The Unit also provides education and training on the recognition, management, and reporting of pesticide poisoning to health professionals and others, responds to requests for information and assistance, and provides guidelines for medical supervision and cholinesterase monitoring of agricultural pest control workers. Risk communication activities carried out by the Unit include education for the public and county health departments.

The Water Toxicology Unit performs major risk assessment and hazard evaluation activities relating to chemical contaminants in drinking water. These activities include developing health advisories, action levels, proposed maximum contaminant levels, and recommended public health goals for chemical substances, additives, and pollutants in drinking water and on chemical monitoring activities for the drinking water supply. The program also provides education to the public and other governmental agencies on drinking water contamination and regulatory standards development.

REGISTERED ENVIRONMENTAL ASSESSOR PROGRAM

The Registered Environmental Assessor Program (REA) program registers environmental compliance experts on a voluntary basis. The REA program is fully funded by application and registration fees paid by the registrants. Information regarding each registrant is maintained in a database. The purpose of the program is to connect small-and medium-sized business with assessors who have the particular kinds of expertise to assist them with complying or maintaining compliance with environmental regulations. Currently, the REA program has more than 4,700 registrants, and continues to register approximately 500 to 700 new assessors per year.

HAZARDOUS SUBSTANCE CLEANUP ARBITRATION PANEL

The purpose of The Hazard Substance Cleanup Arbitration Panel (HSCAP) is to render final, binding allocations of the costs of cleanup at sites named on the California State Superfund list. The HSCAP offers a swift, conclusive alternative to litigation. Expert arbitrators are chosen by the parties from a pool maintained by the HSCAP program. Upon selection, arbitrators are placed under state contracts. The HSCAP is funded by an interagency agreement with the Department of Toxic Substances Control (DTSC) and by fees the parties pay to defray the costs of arbitration. SB 923 (Chapter 435, Statutes of 1994) expanded the HSCAP program by creating a pilot program to provide alternative methods for voluntary remedial actions at hazardous waste sites.