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001. fax	SSN, DOB (Partial) (1 page)	02/20/1997	P6/b(6)
002. fax	Phone No. (Partial) (1 page)	02/10/1997	P6/b(6)

COLLECTION:

Clinton Presidential Records
 Domestic Policy Council
 Elena Kagan
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FOLDER TITLE:

Kids EO [1]

2009-1006-F

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RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Article 5. Extent of Exposure

§ 12501. Exposure to a Naturally Occurring Chemical in a Food.

(a) Human consumption of a food shall not constitute an "exposure" for purposes of Health and Safety Code Section 25249.6 to a listed chemical in the food to the extent that the person responsible for the contact can show that the chemical is naturally occurring in the food.

(1) For the purposes of this section, a chemical is "naturally occurring" if it is a natural constituent of a food, or if it is present in a food solely as a result of absorption or accumulation of the chemical which is naturally present in the environment in which the food is raised, or grown, or obtained; for example, minerals present in the soil solely as a result of natural geologic processes, or toxins produced by the natural growth of fungi.

(2) The "naturally occurring" level of a chemical in a food may be established by determining the natural background level of the chemical in the area in which the food is raised, or grown, or obtained, based on reliable local or regional data.

(3) A chemical is naturally occurring only to the extent that the chemical did not result from any known human activity. Where a food contains a chemical, in part naturally occurring and in part added as a result of known human activity, "exposure" can only occur as to that portion of the chemical which resulted from such human activity. For purposes of this section, "human activity" does not include sowing, planting, irrigation, or plowing or other mechanical preparation of soil for agricultural purposes; but does include the addition of chemicals to irrigation water applied to soil or crops.

(4) Where a chemical contaminant can occur naturally in a food, the chemical is naturally occurring only to the extent that it was not avoidable by good agricultural or good manufacturing practices. The producer, manufacturer, distributor, or holder of the food shall at all times utilize quality control measures that reduce natural chemical contaminants to the "lowest level currently feasible," as this term is used in the Code of Federal Regulations, Title 21, Section 110.110, subdivision (c) (1988).

(b) A person otherwise responsible for an exposure to a listed chemical in a consumer product, other than food, does not "expose" an individual within the meaning of Section 25249.6, to the extent that the person can show that the chemical was a naturally occurring chemical in food, and the food was used in the manufacture, production, or processing of the consumer product. Where a consumer product contains a listed chemical, and the source of the chemical is in part from a naturally occurring chemical in food and in part from other sources, "exposure" can only occur as to that portion of the chemical from other sources.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Section 25249.6, Health and Safety Code.

HISTORY

1. New section refiled 6-19-89 as an emergency; operative 6-22-89 (Register 89, No. 30). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 10-20-89. For prior history, see Register 89, No. 10.

2. Emergency Section 12501 repealed 7-10-89; repealer operative 8-9-89. New Section 12501 filed 7-10-89; operative 8-9-89 (Register 89, No. 30).

§ 12502. Exposure to a Listed Chemical in Drinking Water.

(a) A person otherwise responsible for an exposure to a listed chemical which involves the use of drinking water, including the use of drinking water in food or any other consumer product, does not "expose" an individual within the meaning of Section 25249.6 to the extent that the person can show that the listed chemical was contained in drinking water which was received from:

(1) a public water system, as defined in Section 4010.1 of the Health and Safety Code;

(2) a commercial supplier of drinking water; or

(3) a source of drinking water in compliance with all applicable primary drinking water standards for all listed chemicals and the chemical in

question is the result of treatment of the water in order to achieve compliance with primary drinking water standards.

Where the source of the listed chemical is in part from such drinking water and in part from other sources, "exposure" can occur only as to that portion of the listed chemical from sources other than such drinking water.

(b) For purposes of subdivision (a), the amount of a listed chemical contained in drinking water shall be determined by sampling of the drinking water at the point of delivery and by testing pursuant to Section 12901. If sampling and testing is impractical, the amount of a listed chemical shall be based on test results of the most recent sample of the drinking water taken by the public water system or the commercial drinking water supplier, provided that all sampling and testing has been conducted at the frequency and in the manner required by law, or alternatively, such amount shall be calculated at five percent of the maximum contaminant level set forth in the primary drinking water standard for the listed chemical.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.6 and 25249.11, Health and Safety Code.

HISTORY

1. New section filed 7-10-89; operative 8-9-89 (Register 89, No. 30).

§ 12503. Exposure to Water.

A person otherwise responsible for an exposure to a listed chemical does not "expose" an individual within the meaning of Health and Safety Code Section 25249.6 to the extent that the person can show that the listed chemical was contained in water which the person moved or which was handled in the manner described in Section 12401. Nothing in this section shall be interpreted to affect the responsibility for an exposure which arises from any activity other than that described in Section 12401.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.6 and 25249.11, Health and Safety Code.

HISTORY

1. New section refiled 6-19-89 as an emergency; operative 6-22-89 (Register 89, No. 30). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 10-20-89. For prior history, see Register 89, No. 10.

2. Emergency Section 12503 repealed 7-10-89; repealer operative 8-9-89. New Section 12503 filed 7-10-89; operative 8-9-89 (Register 89, No. 30).

§ 12504. Exposure to Air.

A person otherwise responsible for an exposure to a listed chemical in air does not "expose" an individual within the meaning of Health and Safety Code Section 25249.6 to the extent that the person can show that the listed chemical was contained in air that the person received from the ambient air. Where the source of the listed chemical is in part from the ambient air and in part from other sources, "exposure" does not occur as to that portion of the listed chemical from the ambient air to the extent that the person did not put the listed chemical into the ambient air.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Section 25249.6, Health and Safety Code.

HISTORY

1. New section filed 7-10-89; operative 8-9-89 (Register 89, No. 30).

§ 12505. Miscellaneous.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.6 and 25249.11, Health and Safety Code.

HISTORY

1. New section refiled 6-19-89 as an emergency; operative 6-22-89 (Register 89, No. 30). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 10-20-89. For prior history, see Register 89, No. 10.

2. Emergency Section 12505 repealed 7-10-89; repealer operative 8-9-89 (Register 89, No. 30).

Article 6. Clear and Reasonable Warnings

§ 12601. Clear and Reasonable Warnings.

(a) Whenever a clear and reasonable warning is required under section 25249.6 of the Health and Safety Code, the method employed to transmit the warning must be reasonably calculated, considering the alternative

methods available under the circumstances, to make the warning message available to the individual prior to exposure. The message must clearly communicate that the chemical in question is known to the state to cause cancer, or birth defects or other reproductive harm. Nothing in this section shall be construed to preclude a person from providing warnings other than those specified in subdivisions (b), (c), and (d) which satisfy the requirements of this subdivision, or to require that warnings be provided separately to each exposed individual.

(b) Warnings for consumer products exposures which include the methods of transmission and the warning messages as specified by this subdivision shall be deemed to be clear and reasonable. A "consumer products exposure" is an exposure which results from a person's acquisition, purchase, storage, consumption, or other reasonably foreseeable use of a consumer good, or any exposure that results from receiving a consumer service.

(1) The warning may be provided by using one or more of the following methods singly or in combination:

(A) A warning that appears on a product's label or other labeling. The term "label" means a display of written, printed or graphic matter upon a product or its immediate container. The term "labeling" means any label or other written, printed or graphic matter affixed to or accompanying a product or its container or wrapper.

(B) Identification of the product at the retail outlet in a manner which provides a warning. Identification may be through shelf labeling, signs, menus, or a combination thereof.

(C) A system of signs, public advertising identifying the system and toll-free information services, or any other system, that provides clear and reasonable warnings.

(D) For alcoholic beverages, including, without limitation, beer, malt beverages, wine and distilled spirits:

1. Primarily intended for consumption on the premises where sold or distributed:

(i) at least one notice or sign, no smaller than 10 inches wide by 10 inches high, and bearing the warning message set forth in paragraph (4)(E) of this subsection; or

(ii) at least one horizontal strip marker no smaller than 10 1/2 inches wide by 1 1/4 inches high, and bearing the warning message set forth in paragraph (4)(E) of this subsection; or

(iii) a notice no smaller than 5 inches by 5 inches, and bearing the warning message set forth in (4)(E) of this subsection.

(iv) If signs 10 inches high by 10 inches wide are used, the word "warning" shall be centered three-quarters of an inch from the top of the sign in ITC Garamond bold condensed type face all in one-inch capital letters. Three-sixteenths of an inch from the base of the word "warning" shall be a line extending from left to right across the width of the sign one-sixteenth of an inch in thickness. Centered one-half inch below the line shall be the body of the warning message in 36/50 ITC Garamond bold condensed type face with the initial letter of each word, other than the conjunctive "and," capitalized. For the body of the warning message, left and right margins of at least one-half of an inch, and a bottom margin of at least one-half inch shall be observed. Larger signs shall bear substantially the same proportions of type size and spacing to sign dimension as the sign 10 inches high by 10 inches wide.

(v) If the 10 1/2 inch by 1 1/4 inch horizontal strip markers are used, the word "WARNING," punctuated by a colon, shall be justified left and located three-sixteenths of an inch from the top of the strip notice in ITC Garamond bold condensed type face all in capital letters measuring eleven sixteenths of an inch in height. Three thirty-seconds of an inch from the base of the word "WARNING" shall be a line extending from left to right across the width of the word "WARNING" and the punctuating colon one thirty-second of an inch in thickness. Located one-fourth of an inch from the top and one-fourth of an inch from the bottom of the strip notice, and to the immediate right of the word "WARNING," shall be the body of the warning message in 12/16 point ITC Garamond bold condensed type face with the initial letter of each word, other than the con-

conjunctive "and," capitalized. The word "WARNING" shall be one-half inch from the left edge of the strip notice and the requisite warning message shall extend to within one-half inch from the right edge.

(vi) If the 5 inch by 5 inch signs are used, they shall bear substantially the same proportions of type size and spacing to sign dimension as the sign 10 inches high by 10 inches wide, with both the word "WARNING" and the warning text set in white on a contrasting red background.

(vii) Such sign or notice shall be placed in the retail establishment so as to assure that it is readable and likely to be read either at each retail point of sale or each point of display. Such sign or notice shall be placed either at all retail points of sale or all points of display, but need not be placed at both. If 10 inch by 10 inch signs or notices are placed at the point of display, each shall be placed no more than ten feet from any alcoholic beverage container and in a manner associating the sign or notice with the display. If horizontal strip notices are used, they shall be placed at ten foot intervals horizontally along the display. If a 5 inch by 5 inch sign is used, it shall be conspicuously placed at each retail point of sale (e.g., check-out counter, cash register, cash box) so that it is likely to be read and understood during the sales transaction.

(viii) All measurements specified or referred to in paragraphs (iv), (v) and (vi), above, are not required to be precisely accurate.

2. Provided for consumption on the premises at tables served by food or beverage persons, or sold or distributed through over the counter service:

(i) a notice or sign displayed at each of the tables where alcoholic beverages are served or may be consumed at least 5 inches high by 5 inches wide bearing substantially the same type face and substantially the same proportion of type size and spacing to sign dimension as described in paragraph (D)1, (vi); or

(ii) the warning message set forth in paragraph (4)(E) of this subdivision, placed upon a menu or list in association with the alcoholic beverages listed thereon and served at such premises, or if alcoholic beverages are not listed thereon, on any menu or list provided to patrons in association with the listing of food or beverage offerings, in type size and design, such that the text is conspicuous and likely to be read prior to consumption of alcoholic beverages or.

(iii) at least one 10 inch by 10 inch sign, meeting the specifications set forth in paragraph (D)1, (iv) of this subsection, placed so that it is readable and likely to be read by patrons as they enter each public entrance to the establishment. If the establishment does not have clearly defined physical boundaries delineating those areas where, by permit or license, alcoholic beverages are served, the 10 inch by 10 inch sign shall be posted so that it is readable and likely to be read by patrons as they enter the area or areas where, by permit or license, alcoholic beverages are served; and

(iv) If sold or distributed through over-the-counter service, at least one sign, meeting the specifications set forth in paragraph (D)1, (iv) of this subsection, placed in the retail establishment so that the warning message is, prior to the consumption of alcoholic beverages, readable and likely to be read from all counter locations available to the public. Therefore, a retail establishment providing a warning pursuant to the preceding sentence, also would be required to provide a warning in accordance with either paragraph 2.(i), 2.(ii) or 2.(iii) of this subsection.

3. For premises which are specially licensed to sell and serve alcoholic beverages both on and off the licensed premises (e.g., in facilities that offer both "tasting" and retail sales), the off-sale portion of the premises shall comply with the provisions of subsection (D)1, above, and the portion of the premises where alcoholic beverages are served shall comply with the provisions of subsection (D)2, above.

4. For alcoholic beverages sold or distributed to consumers through the mail or package delivery services, warnings may be provided by incorporating or placing the warning message set forth in paragraph (4)(E) on or in the shipping container or delivery package in such a manner so that the warning message is likely to be read by the recipient prior to consumption of the alcoholic beverages).

5. All signs or notices referred to in subsections (D)1., (D)2., and (D)3., above, shall be displayed so that they are clearly visible under all lighting conditions normally encountered during business hours.

(2) To the extent practicable, warning materials such as signs, notices, menu suckers, or labels shall be provided by the manufacturer, producer, or packager of the consumer product, rather than by the retail seller. For alcoholic beverages, the placement and maintenance of the warning shall be the responsibility of the manufacturer or its distributor at no cost to the retailer, and any consequences for failure to do the same shall rest solely with the manufacturer or its distributor, provided that the retailer does not remove, deface, or obscure the requisite signs or notices, or obstruct, interfere with, or otherwise frustrate the manufacturer's reasonable efforts to post, maintain, or periodically replace said materials. For prescription drugs, the labeling approved or otherwise provided under federal law and the prescriber's accepted practice of obtaining a patient's informed consent shall be deemed to be a clear and reasonable warning.

(3) The warnings provided pursuant to paragraphs (1)(A) and (1)(B) shall be prominently placed upon a product's label or other labeling or displayed at the retail outlet with such conspicuousness, as compared with other words, statements, designs, or devices in the label, labeling or display as to render it likely to be read and understood by an ordinary individual under customary conditions of purchase or use.

(4) The warning message must include the following language:

(A) For consumer products that contain a chemical known to the state to cause cancer:

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

(B) For consumer products that contain a chemical known to the state to cause reproductive toxicity:

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

(C) For food, other than alcoholic beverages, sold, served, or otherwise provided in food facilities, as defined in Health and Safety Code section 27521(a), which is intended for immediate consumption:

"WARNING: Chemicals known to the State of California to cause cancer, or birth defects or other reproductive harm may be present in foods or beverages sold or served here."

(D) For fresh fruits, nuts and vegetables:

"WARNING: This product may contain a chemical known to the State of California to cause cancer, or birth defects or other reproductive harm."

(E) For alcoholic beverages, including, without limitation, beer, malt beverages, wine and distilled spirits:

"WARNING: Drinking Distilled Spirits, Beer, Coolers, Wine and Other Alcoholic Beverages May Increase Cancer Risk, and, During Pregnancy, Can Cause Birth Defects."

(5) A person in the course of doing business, who manufactures, produces, assembles, processes, handles, distributes, stores, sells or otherwise transfers a consumer product which he or she knows to contain a chemical known to the state to cause cancer or reproductive toxicity in an amount which requires a warning shall provide a warning to any person to whom the product is sold or transferred unless the product is packaged or labeled with a clear and reasonable warning.

(c) Warnings for occupational exposures which include the methods of transmission and the warning messages as specified by this subdivision shall be deemed clear and reasonable. An "occupational exposure" is an exposure, in the workplace of the employer causing the exposure, to any employee.

(1) The method employed to transmit the warning must include one of the following alternative methods:

(A) A warning that appears on the label or labeling of a product or substance present or used in the workplace. The label or labeling shall be prominently displayed on the product or substance and the product or substance shall be used under circumstances which make it likely that the

warnings will be read and understood by employees or other individuals prior to the exposure for which the warning is given.

(B) A warning that appears on a sign in the workplace posted in a conspicuous place and under conditions that make it likely to be read and understood by employees and other individuals prior to the exposure for which the warning is given.

(C) A warning to the exposed employee about the chemical in question which fully complies with all information, training and labeling requirements of the federal Hazard Communication Standard (29 CFR section 1910.1200, as amended and filed September 30, 1986), the California Hazard Communication Standard (Cal. Code Regs., title 8, section 5194, as amended and filed May 26, 1987), or, for pesticides, the Pesticides and Worker Safety requirements (Cal. Code Regs., title 3, ch. 6, subch. 3, group 3, section 6700 et seq., in effect on February 16, 1988) authorized in Food and Agricultural Code section 12981 (as amended by Statutes of 1980, ch. 926, p. 2945, section 1).

(2) For purposes of paragraph (1)(A) of this subdivision, the warning shall be provided in terms which would provide a clear warning for a consumer product as specified above.

(3) For purposes of paragraph (1)(B) of this subdivision, the following specific warning messages shall be deemed to clearly communicate that an individual is being exposed to a chemical known to the state to cause cancer, or birth defects or other reproductive harm.

(A) For exposure to a chemical known to the state to cause cancer:

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

(B) For exposure to a chemical known to the state to cause reproductive toxicity:

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

(d) Warnings for environmental exposures which include the methods of transmission and the warning messages as specified by this subdivision shall be deemed clear and reasonable. An "environmental exposure" is an exposure which may foreseeably occur as the result of contact with an environmental medium, including, but not limited to, ambient air, indoor air, drinking water, standing water, running water, soil, vegetation, or manmade or natural substances, either through inhalation, ingestion, skin contact or otherwise. Environmental exposures include all exposures which are not consumer products exposures, or occupational exposures.

(1) The method employed to transmit the warning must include the most appropriate of the following alternative methods under the circumstances:

(A) A warning that appears on a sign in the affected area. The term "sign" means a presentation of written, printed or graphic matter. The term "affected area" means the area in which an exposure to a chemical known to the state to cause cancer or reproductive toxicity is at a level that requires a warning. A posting of signs in the manner described in section 6776(e)(1) of title 3 of the California Code of Regulations (as amended and filed August 15, 1986) shall be sufficient for purposes of this paragraph.

(B) A warning which is in a notice mailed or otherwise delivered to each occupant in the affected area. Such notice shall be provided at least once in any three-month period.

(C) A warning provided by public media announcements which target the affected area. Such announcements shall be made at least once in any three-month period.

(2) Environmental exposure warnings shall be provided in a conspicuous manner and under such conditions as to make it likely to be read, seen or heard and understood by an ordinary individual in the course of normal daily activity, and reasonably associated with the location and source of the exposure.

(3) For purposes of paragraph (1)(A) of this subdivision, the following specific warning messages shall be deemed to clearly communicate that

an individual is being exposed to a chemical known to the state to cause cancer, or birth defects or other reproductive harm.

(A) For exposure to a chemical known to the state to cause cancer:

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

(B) For exposure to a chemical known to the state to cause reproductive toxicity:

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

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.6 and 25249.11, Health and Safety Code.

HISTORY

1. Amendment of subsection (b) filed 6-7-89 as an emergency; operative 7-1-89 (Register 89, No. 24). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 10-30-89. For prior history, see Register 88, No. 53.
2. Certificate of Compliance as to 6-7-89 order transmitted to OAL 10-23-89 and filed 11-22-89 (Register 89, No. 48).
3. Editorial correction of printing error in subsection (c)(1)(C) (Register 91, No. 31).

Article 7. No Significant Risk Levels

§ 12701. General.

(a) The determination of whether a level of exposure to a chemical known to the state to cause cancer poses no significant risk for purpose of Health and Safety Code Section 25249.10(c) shall be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of the chemical as known to the state to cause cancer. Nothing in this article shall preclude a person from using evidence, standards, risk assessment methodologies, principles, assumptions or levels not described in this article to establish that a level of exposure to a listed chemical poses no significant risk.

(b) A level of exposure to a listed chemical, assuming daily exposure at that level, shall be deemed to pose no significant risk provided that the level is determined:

(1) By means of a quantitative risk assessment that meets the standards described in Section 12703;

(2) By application of Section 12707 (Routes of Exposure); or

(3) By one of the following, as applicable:

(A) If a specific regulatory level has been established for the chemical in question in Section 12705, by application of that level.

(B) If no specific level is established for the chemical in question in Section 12705, by application of Section 12709 (Exposure to Trace Elements), 12711 (Levels Based on State or Federal Standards) or 12713 (Exposure to Food, Drugs, Cosmetics and Medical Devices), unless otherwise provided.

(c) The chemicals, routes of exposure and conditions of use specifically listed in this article do not include all chemicals, routes of exposure and conditions of use that pose no significant risk. The fact that a chemical, route of exposure or condition of use does not appear in this article does not mean that it poses a significant risk.

(d) This article establishes exposure levels posing no significant risk solely for purposes of Health and Safety Code Section 25249.10(c). Nothing in this article shall be construed to establish exposure or risk levels for other regulatory purposes.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11, Health and Safety Code.

HISTORY

1. New section filed 2-24-88 as an emergency; operative 2-27-88 (Register 88, No. 11). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 6-27-88.
2. New section refiled 6-27-88 as an emergency; operative 6-27-88 (Register 88, No. 27). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 10-25-88.
3. New section refiled 10-17-88 as an emergency; operative 10-25-88 (Register 88, No. 44). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 2-22-89.

4. New section refiled 2-21-89 as an emergency; operative 2-22-89 (Register 89, No. 10). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 6-22-89.

5. Certificate of Compliance including amendment transmitted to OAL 6-9-89 and filed 7-10-89 (Register 89, No. 30).

§ 12703. Quantitative Risk Assessment.

(a) A quantitative risk assessment which conforms to this section shall be deemed to determine the level of exposure to a listed chemical which, assuming daily exposure at that level, poses no significant risk. The assessment shall be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for listing the chemical as known to the state to cause cancer. In the absence of principles or assumptions scientifically more appropriate, based upon the available data, the following default principles and assumptions shall apply in any such assessment:

(1) Animal bioassay studies for quantitative risk assessment shall meet generally accepted scientific principles, including the thoroughness of experimental protocol, the degree to which dosing resembles the expected manner of human exposure, the temporal exposure pattern, the duration of study, the purity of test material, the number and size of exposed groups, the route of exposure, and the extent of tumor occurrence.

(2) The quality and suitability of available epidemiologic data shall be appraised to determine whether the study is appropriate as the basis of a quantitative risk assessment, considering such factors as the selection of the exposed and reference groups, reliable ascertainment of exposure, and completeness of follow-up. Biases and confounding factors shall be identified and quantified.

(3) Risk analysis shall be based on the most sensitive study deemed to be of sufficient quality.

(4) The results obtained for the most sensitive study deemed to be of sufficient quality shall be applicable to all routes of exposure for which the results are relevant.

(5) The absence of a carcinogenic threshold dose shall be assumed and no-threshold models shall be utilized. A linearized multistage model for extrapolation from high to low doses, with the upper 95 percent confidence limit of the linear term expressing the upper bound of potency shall be utilized. Time-to-tumor models may be appropriate where data are available on the time of appearance of individual tumors, and particularly when survival is poor due to competing toxicity.

(6) Human cancer potency shall be derived from data on human or animal cancer potency. Potency shall be expressed in reciprocal milligrams of chemical per kilogram of bodyweight per day. Interspecies conversion of animal cancer potency to human cancer potency shall be determined by multiplying by a surface area scaling factor equivalent to the ratio of human to animal bodyweight, taken to the one-third power. This is equivalent to a scaling factor of 14 when extrapolating from mouse data, and a scaling factor of 6.5 when extrapolating from rat data.

(7) When available data are of such quality that physiologic, pharmacokinetic and metabolic considerations can be taken into account with confidence, they may be used in the risk assessment for inter-species, inter-dose, and inter-route extrapolations.

(8) When the cancer risk applies to the general population, human body weight of 70 kilograms shall be assumed. When the cancer risk applies to a certain subpopulation, the following assumptions shall be made, as appropriate:

Subpopulation	Kilograms of Body Weight
Man (18+ years of age)	70
Woman (18+ years of age)	58
Woman with conceptus	58
Adolescent (11-18 years of age)	40
Child (2-10 years of age)	20
Infant (0-2 years of age)	10

(b) For chemicals assessed in accordance with this section, the risk level which represents no significant risk shall be one which is calculated to result in one excess case of cancer in an exposed population of 100,000, assuming lifetime exposure at the level in question, except where sound

Article 5. Extent of Exposure

§ 12501. Exposure to a Naturally Occurring Chemical in a Food.

(a) Human consumption of a food shall not constitute an "exposure" for purposes of Health and Safety Code Section 25249.6 to a listed chemical in the food to the extent that the person responsible for the contact can show that the chemical is naturally occurring in the food.

(1) For the purposes of this section, a chemical is "naturally occurring" if it is a natural constituent of a food, or if it is present in a food solely as a result of absorption or accumulation of the chemical which is naturally present in the environment in which the food is raised, or grown, or obtained; for example, minerals present in the soil solely as a result of natural geologic processes, or toxins produced by the natural growth of fungi.

(2) The "naturally occurring" level of a chemical in a food may be established by determining the natural background level of the chemical in the area in which the food is raised, or grown, or obtained, based on reliable local or regional data.

(3) A chemical is naturally occurring only to the extent that the chemical did not result from any known human activity. Where a food contains a chemical, in part naturally occurring and in part added as a result of known human activity, "exposure" can only occur as to that portion of the chemical which resulted from such human activity. For purposes of this section, "human activity" does not include sowing, planting, irrigation, or plowing or other mechanical preparation of soil for agricultural purposes; but does include the addition of chemicals to irrigation water applied to soil or crops.

(4) Where a chemical contaminant can occur naturally in a food, the chemical is naturally occurring only to the extent that it was not avoidable by good agricultural or good manufacturing practices. The producer, manufacturer, distributor, or holder of the food shall at all times utilize quality control measures that reduce natural chemical contaminants to the "lowest level currently feasible," as this term is used in the Code of Federal Regulations, Title 21, Section 110.110, subdivision (c) (1988).

(b) A person otherwise responsible for an exposure to a listed chemical in a consumer product, other than food, does not "expose" an individual within the meaning of Section 25249.6, to the extent that the person can show that the chemical was a naturally occurring chemical in food, and the food was used in the manufacture, production, or processing of the consumer product. Where a consumer product contains a listed chemical, and the source of the chemical is in part from a naturally occurring chemical in food and in part from other sources, "exposure" can only occur as to that portion of the chemical from other sources.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Section 25249.6, Health and Safety Code.

HISTORY

1. New section refiled 6-19-89 as an emergency; operative 6-22-89 (Register 89, No. 30). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 10-20-89. For prior history, see Register 89, No. 10.
2. Emergency Section 12501 repealed 7-10-89; repealer operative 8-9-89. New Section 12501 filed 7-10-89; operative 8-9-89 (Register 89, No. 30).

§ 12502. Exposure to a Listed Chemical in Drinking Water.

(a) A person otherwise responsible for an exposure to a listed chemical which involves the use of drinking water, including the use of drinking water in food or any other consumer product, does not "expose" an individual within the meaning of Section 25249.6 to the extent that the person can show that the listed chemical was contained in drinking water which was received from:

- (1) a public water system, as defined in Section 4010.1 of the Health and Safety Code;
- (2) a commercial supplier of drinking water; or
- (3) a source of drinking water in compliance with all applicable primary drinking water standards for all listed chemicals and the chemical in

question is the result of treatment of the water in order to achieve compliance with primary drinking water standards.

Where the source of the listed chemical is in part from such drinking water and in part from other sources, "exposure" can occur only as to that portion of the listed chemical from sources other than such drinking water.

(b) For purposes of subdivision (a), the amount of a listed chemical contained in drinking water shall be determined by sampling of the drinking water at the point of delivery and by testing pursuant to Section 12901. If sampling and testing is impractical, the amount of a listed chemical shall be based on test results of the most recent sample of the drinking water taken by the public water system or the commercial drinking water supplier, provided that all sampling and testing has been conducted at the frequency and in the manner required by law, or alternatively, such amount shall be calculated at five percent of the maximum contaminant level set forth in the primary drinking water standard for the listed chemical.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.6 and 25249.11, Health and Safety Code.

HISTORY

1. New section filed 7-10-89; operative 8-9-89 (Register 89, No. 30).

§ 12503. Exposure to Water.

A person otherwise responsible for an exposure to a listed chemical does not "expose" an individual within the meaning of Health and Safety Code Section 25249.6 to the extent that the person can show that the listed chemical was contained in water which the person moved or which was handled in the manner described in Section 12401. Nothing in this section shall be interpreted to affect the responsibility for an exposure which arises from any activity other than that described in Section 12401.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.6 and 25249.11, Health and Safety Code.

HISTORY

1. New section refiled 6-19-89 as an emergency; operative 6-22-89 (Register 89, No. 30). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 10-20-89. For prior history, see Register 89, No. 10.
2. Emergency Section 12503 repealed 7-10-89; repealer operative 8-9-89. New Section 12503 filed 7-10-89; operative 8-9-89 (Register 89, No. 30).

§ 12504. Exposure to Air.

A person otherwise responsible for an exposure to a listed chemical in air does not "expose" an individual within the meaning of Health and Safety Code Section 25249.6 to the extent that the person can show that the listed chemical was contained in air that the person received from the ambient air. Where the source of the listed chemical is in part from the ambient air and in part from other sources, "exposure" does not occur as to that portion of the listed chemical from the ambient air to the extent that the person did not put the listed chemical into the ambient air.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Section 25249.6, Health and Safety Code.

HISTORY

1. New section filed 7-10-89; operative 8-9-89 (Register 89, No. 30).

§ 12505. Miscellaneous.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.6 and 25249.11, Health and Safety Code.

HISTORY

1. New section refiled 6-19-89 as an emergency; operative 6-22-89 (Register 89, No. 30). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 10-20-89. For prior history, see Register 89, No. 10.
2. Emergency Section 12505 repealed 7-10-89; repealer operative 8-9-89 (Register 89, No. 30).

Article 6. Clear and Reasonable Warnings

§ 12601. Clear and Reasonable Warnings.

(a) Whenever a clear and reasonable warning is required under section 25249.6 of the Health and Safety Code, the method employed to transmit the warning must be reasonably calculated, considering the alternative

methods available under the circumstances, to make the warning message available to the individual prior to exposure. The message must clearly communicate that the chemical in question is known to the state to cause cancer, or birth defects or other reproductive harm. Nothing in this section shall be construed to preclude a person from providing warnings other than those specified in subdivisions (b), (c), and (d) which satisfy the requirements of this subdivision, or to require that warnings be provided separately to each exposed individual.

(b) Warnings for consumer products exposures which include the methods of transmission and the warning messages as specified by this subdivision shall be deemed to be clear and reasonable. A "consumer products exposure" is an exposure which results from a person's acquisition, purchase, storage, consumption, or other reasonably foreseeable use of a consumer good, or any exposure that results from receiving a consumer service.

(1) The warning may be provided by using one or more of the following methods singly or in combination:

(A) A warning that appears on a product's label or other labeling. The term "label" means a display of written, printed or graphic matter upon a product or its immediate container. The term "labeling" means any label or other written, printed or graphic matter affixed to or accompanying a product or its container or wrapper.

(B) Identification of the product at the retail outlet in a manner which provides a warning. Identification may be through shelf labeling, signs, menus, or a combination thereof.

(C) A system of signs, public advertising identifying the system and toll-free information services, or any other system, that provides clear and reasonable warnings.

(D) For alcoholic beverages, including, without limitation, beer, malt beverages, wine and distilled spirits:

1. Primarily intended for consumption off the premises where sold or distributed:

(i) at least one notice or sign, no smaller than 10 inches wide by 10 inches high, and bearing the warning message set forth in paragraph (4)(E) of this subsection; or

(ii) at least one horizontal strip marker no smaller than 10 1/2 inches wide by 1 1/4 inches high, and bearing the warning message set forth in paragraph (4)(E) of this subsection; or

(iii) a notice no smaller than 5 inches by 5 inches, and bearing the warning message set forth in (4)(E) of this subsection.

(iv) If signs 10 inches high by 10 inches wide are used, the word "warning" shall be centered three-quarters of an inch from the top of the sign in ITC Garamond bold condensed type face all in one-inch capital letters. Three-sixteenths of an inch from the base of the word "warning" shall be a line extending from left to right across the width of the sign one-sixteenth of an inch in thickness. Centered one-half inch below the line shall be the body of the warning message in 36/50 ITC Garamond bold condensed type face with the initial letter of each word, other than the conjunctive "and," capitalized. For the body of the warning message, left and right margins of at least one-half of an inch, and a bottom margin of at least one-half inch shall be observed. Larger signs shall bear substantially the same proportions of type size and spacing to sign dimension as the sign 10 inches high by 10 inches wide.

(v) If the 10 1/2 inch by 1 1/4 inch horizontal strip markers are used, the word "WARNING," punctuated by a colon, shall be justified left and located three-sixteenths of an inch from the top of the strip notice in ITC Garamond bold condensed type face all in capital letters measuring eleven sixteenths of an inch in height. Three thirty-seconds of an inch from the base of the word "WARNING" shall be a line extending from left to right across the width of the word "WARNING" and the punctuating colon one thirty-second of an inch in thickness. Located one-fourth of an inch from the top and one-fourth of an inch from the bottom of the strip notice, and to the immediate right of the word "WARNING," shall be the body of the warning message in 12/16 point ITC Garamond bold condensed type face with the initial letter of each word, other than the con-

conjunctive "and," capitalized. The word "WARNING" shall be one-half inch from the left edge of the strip notice and the requisite warning message shall extend to within one-half inch from the right edge.

(vi) If the 5 inch by 5 inch signs are used, they shall bear substantially the same proportions of type size and spacing to sign dimension as the sign 10 inches high by 10 inches wide, with both the word "WARNING" and the warning text set in white on a contrasting red background.

(vii) Such sign or notice shall be placed in the retail establishment so as to assure that it is readable and likely to be read either at each retail point of sale or each point of display. Such sign or notice shall be placed either at all retail points of sale or all points of display, but need not be placed at both. If 10 inch by 10 inch signs or notices are placed at the point of display, each shall be placed no more than ten feet from any alcoholic beverage container and in a manner associating the sign or notice with the display. If horizontal strip notices are used, they shall be placed at ten foot intervals horizontally along the display. If a 5 inch by 5 inch sign is used, it shall be conspicuously placed at each retail point of sale (e.g., check-out counter, cash register, cash box) so that it is likely to be read and understood during the sales transaction.

(viii) All measurements specified or referred to in paragraphs (iv), (v) and (vi), above, are not required to be precisely accurate.

2. Provided for consumption on the premises at tables served by food or beverage persons, or sold or distributed through over the counter service:

(i) a notice or sign displayed at each of the tables where alcoholic beverages are served or may be consumed at least 5 inches high by 5 inches wide bearing substantially the same type face and substantially the same proportion of type size and spacing to sign dimension as described in paragraph (D)1. (vi); or

(ii) the warning message set forth in paragraph (4)(E) of this subdivision, placed upon a menu or list in association with the alcoholic beverages listed thereon and served at such premises, or if alcoholic beverages are not listed thereon, on any menu or list provided to patrons in association with the listing of food or beverage offerings, in type size and design, such that the text is conspicuous and likely to be read prior to consumption of alcoholic beverages or.

(iii) at least one 10 inch by 10 inch sign, meeting the specifications set forth in paragraph (D)1. (iv) of this subsection, placed so that it is readable and likely to be read by patrons as they enter each public entrance to the establishment. If the establishment does not have clearly defined physical boundaries delineating those areas where, by permit or license, alcoholic beverages are served, the 10 inch by 10 inch sign shall be posted so that it is readable and likely to be read by patrons as they enter the area or areas where, by permit or license, alcoholic beverages are served; and

(iv) If sold or distributed through over-the-counter service, at least one sign, meeting the specifications set forth in paragraph (D)1. (iv) of this subsection, placed in the retail establishment so that the warning message is, prior to the consumption of alcoholic beverages, readable and likely to be read from all counter locations available to the public. Therefore, a retail establishment providing a warning pursuant to the preceding sentence, also would be required to provide a warning in accordance with either paragraph 2.(i), 2.(ii) or 2.(iii) of this subsection.

3. For premises which are specially licensed to sell and serve alcoholic beverages both on and off the licensed premises (e.g., in facilities that offer both "tasting" and retail sales), the off-sale portion of the premises shall comply with the provisions of subsection (D)1. above, and the portion of the premises where alcoholic beverages are served shall comply with the provisions of subsection (D)2. above.

4. For alcoholic beverages sold or distributed to consumers through the mail or package delivery services, warnings may be provided by incorporating or placing the warning message set forth in paragraph (4)(E) on or in the shipping container or delivery package in such a manner so that the warning message is likely to be read by the recipient prior to consumption of the alcoholic beverages.

5. All signs or notices referred to in subsections (D)1., (D)2., and (D)3., above, shall be displayed so that they are clearly visible under all lighting conditions normally encountered during business hours.

(2) To the extent practicable, warning materials such as signs, notices, menu suckers, or labels shall be provided by the manufacturer, producer, or packager of the consumer product, rather than by the retail seller. For alcoholic beverages, the placement and maintenance of the warning shall be the responsibility of the manufacturer or its distributor at no cost to the retailer, and any consequences for failure to do the same shall rest solely with the manufacturer or its distributor, provided that the retailer does not remove, deface, or obscure the requisite signs or notices, or obstruct, interfere with, or otherwise frustrate the manufacturer's reasonable efforts to post, maintain, or periodically replace said materials. For prescription drugs, the labeling approved or otherwise provided under federal law and the prescriber's accepted practice of obtaining a patient's informed consent shall be deemed to be a clear and reasonable warning.

(3) The warnings provided pursuant to paragraphs (1)(A) and (1)(B) shall be prominently placed upon a product's label or other labeling or displayed at the retail outlet with such conspicuousness, as compared with other words, statements, designs, or devices in the label, labeling or display as to render it likely to be read and understood by an ordinary individual under customary conditions of purchase or use.

(4) The warning message must include the following language:

(A) For consumer products that contain a chemical known to the state to cause cancer:

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

(B) For consumer products that contain a chemical known to the state to cause reproductive toxicity:

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

(C) For food, other than alcoholic beverages, sold, served, or otherwise provided in food facilities, as defined in Health and Safety Code section 27521(a), which is intended for immediate consumption:

"WARNING: Chemicals known to the State of California to cause cancer, or birth defects or other reproductive harm may be present in foods or beverages sold or served here."

(D) For fresh fruits, nuts and vegetables:

"WARNING: This product may contain a chemical known to the State of California to cause cancer, or birth defects or other reproductive harm."

(E) For alcoholic beverages, including, without limitation, beer, malt beverages, wine and distilled spirits:

"WARNING: Drinking Distilled Spirits, Beer, Coolers, Wine and Other Alcoholic Beverages May Increase Cancer Risk, and, During Pregnancy, Can Cause Birth Defects."

(5) A person in the course of doing business, who manufactures, produces, assembles, processes, handles, distributes, stores, sells or otherwise transfers a consumer product which he or she knows to contain a chemical known to the state to cause cancer or reproductive toxicity in an amount which requires a warning shall provide a warning to any person to whom the product is sold or transferred unless the product is packaged or labeled with a clear and reasonable warning.

(c) Warnings for occupational exposures which include the methods of transmission and the warning messages as specified by this subdivision shall be deemed clear and reasonable. An "occupational exposure" is an exposure, in the workplace of the employer causing the exposure, to any employee.

(1) The method employed to transmit the warning must include one of the following alternative methods:

(A) A warning that appears on the label or labeling of a product or substance present or used in the workplace. The label or labeling shall be prominently displayed on the product or substance and the product or substance shall be used under circumstances which make it likely that the

warnings will be read and understood by employees or other individuals prior to the exposure for which the warning is given.

(B) A warning that appears on a sign in the workplace posted in a conspicuous place and under conditions that make it likely to be read and understood by employees and other individuals prior to the exposure for which the warning is given.

(C) A warning to the exposed employee about the chemical in question which fully complies with all information, training and labeling requirements of the federal Hazard Communication Standard (29 CFR section 1910.1200, as amended and filed September 30, 1986), the California Hazard Communication Standard (Cal. Code Regs., title 8, section 5194, as amended and filed May 26, 1987), or, for pesticides, the Pesticides and Worker Safety requirements (Cal. Code Regs., title 3, ch. 6, subch. 3, group 3, section 6700 et seq., in effect on February 16, 1988) authorized in Food and Agricultural Code section 12981 (as amended by Statutes of 1980, ch. 926, p. 2945, section 1).

(2) For purposes of paragraph (1)(A) of this subdivision, the warning shall be provided in terms which would provide a clear warning for a consumer product as specified above.

(3) For purposes of paragraph (1)(B) of this subdivision, the following specific warning messages shall be deemed to clearly communicate that an individual is being exposed to a chemical known to the state to cause cancer, or birth defects or other reproductive harm.

(A) For exposure to a chemical known to the state to cause cancer:

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

(B) For exposure to a chemical known to the state to cause reproductive toxicity:

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

(d) Warnings for environmental exposures which include the methods of transmission and the warning messages as specified by this subdivision shall be deemed clear and reasonable. An "environmental exposure" is an exposure which may foreseeably occur as the result of contact with an environmental medium, including, but not limited to, ambient air, indoor air, drinking water, standing water, running water, soil, vegetation, or manmade or natural substances, either through inhalation, ingestion, skin contact or otherwise. Environmental exposures include all exposures which are not consumer products exposures, or occupational exposures.

(1) The method employed to transmit the warning must include the most appropriate of the following alternative methods under the circumstances:

(A) A warning that appears on a sign in the affected area. The term "sign" means a presentation of written, printed or graphic matter. The term "affected area" means the area in which an exposure to a chemical known to the state to cause cancer or reproductive toxicity is at a level that requires a warning. A posting of signs in the manner described in section 6776(e)(1) of title 3 of the California Code of Regulations (as amended and filed August 15, 1986) shall be sufficient for purposes of this paragraph.

(B) A warning which is in a notice mailed or otherwise delivered to each occupant in the affected area. Such notice shall be provided at least once in any three-month period.

(C) A warning provided by public media announcements which target the affected area. Such announcements shall be made at least once in any three-month period.

(2) Environmental exposure warnings shall be provided in a conspicuous manner and under such conditions as to make it likely to be read, seen or heard and understood by an ordinary individual in the course of normal daily activity, and reasonably associated with the location and source of the exposure.

(3) For purposes of paragraph (1)(A) of this subdivision, the following specific warning messages shall be deemed to clearly communicate that

an individual is being exposed to a chemical known to the state to cause cancer, or birth defects or other reproductive harm.

(A) For exposure to a chemical known to the state to cause cancer:

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

(B) For exposure to a chemical known to the state to cause reproductive toxicity:

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

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.6 and 25249.11, Health and Safety Code.

HISTORY

1. Amendment of subsection (b) filed 6-7-89 as an emergency; operative 7-1-89 (Register 89, No. 24). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 10-30-89. For prior history, see Register 88, No. 53.
2. Certificate of Compliance as to 6-7-89 order transmitted to OAL 10-23-89 and filed 11-22-89 (Register 89, No. 48).
3. Editorial correction of printing error in subsection (c)(1)(C) (Register 91, No. 31).

Article 7. No Significant Risk Levels

§ 12701. General.

(a) The determination of whether a level of exposure to a chemical known to the state to cause cancer poses no significant risk for purpose of Health and Safety Code Section 25249.10(c) shall be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of the chemical as known to the state to cause cancer. Nothing in this article shall preclude a person from using evidence, standards, risk assessment methodologies, principles, assumptions or levels not described in this article to establish that a level of exposure to a listed chemical poses no significant risk.

(b) A level of exposure to a listed chemical, assuming daily exposure at that level, shall be deemed to pose no significant risk provided that the level is determined:

(1) By means of a quantitative risk assessment that meets the standards described in Section 12703;

(2) By application of Section 12707 (Routes of Exposure); or

(3) By one of the following, as applicable:

(A) If a specific regulatory level has been established for the chemical in question in Section 12705, by application of that level.

(B) If no specific level is established for the chemical in question in Section 12705, by application of Section 12709 (Exposure to Trace Elements), 12711 (Levels Based on State or Federal Standards) or 12713 (Exposure to Food, Drugs, Cosmetics and Medical Devices), unless otherwise provided.

(c) The chemicals, routes of exposure and conditions of use specifically listed in this article do not include all chemicals, routes of exposure and conditions of use that pose no significant risk. The fact that a chemical, route of exposure or condition of use does not appear in this article does not mean that it poses a significant risk.

(d) This article establishes exposure levels posing no significant risk solely for purposes of Health and Safety Code Section 25249.10(c). Nothing in this article shall be construed to establish exposure or risk levels for other regulatory purposes.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11, Health and Safety Code.

HISTORY

1. New section filed 2-24-88 as an emergency; operative 2-27-88 (Register 88, No. 11). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 6-27-88.
2. New section refiled 6-27-88 as an emergency; operative 6-27-88 (Register 88, No. 27). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 10-25-88.
3. New section refiled 10-17-88 as an emergency; operative 10-25-88 (Register 88, No. 44). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 2-22-89.

4. New section refiled 2-21-89 as an emergency; operative 2-22-89 (Register 89, No. 10). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 6-22-89.

5. Certificate of Compliance including amendment transmitted to OAL 6-9-89 and filed 7-10-89 (Register 89, No. 30).

§ 12703. Quantitative Risk Assessment.

(a) A quantitative risk assessment which conforms to this section shall be deemed to determine the level of exposure to a listed chemical which, assuming daily exposure at that level, poses no significant risk. The assessment shall be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for listing the chemical as known to the state to cause cancer. In the absence of principles or assumptions scientifically more appropriate, based upon the available data, the following default principles and assumptions shall apply in any such assessment:

(1) Animal bioassay studies for quantitative risk assessment shall meet generally accepted scientific principles, including the thoroughness of experimental protocol, the degree to which dosing resembles the expected manner of human exposure, the temporal exposure pattern, the duration of study, the purity of test material, the number and size of exposed groups, the route of exposure, and the extent of tumor occurrence.

(2) The quality and suitability of available epidemiologic data shall be appraised to determine whether the study is appropriate as the basis of a quantitative risk assessment, considering such factors as the selection of the exposed and reference groups, reliable ascertainment of exposure, and completeness of follow-up. Biases and confounding factors shall be identified and quantified.

(3) Risk analysis shall be based on the most sensitive study deemed to be of sufficient quality.

(4) The results obtained for the most sensitive study deemed to be of sufficient quality shall be applicable to all routes of exposure for which the results are relevant.

(5) The absence of a carcinogenic threshold dose shall be assumed and no-threshold models shall be utilized. A linearized multistage model for extrapolation from high to low doses, with the upper 95 percent confidence limit of the linear term expressing the upper bound of potency shall be utilized. Time-to-tumor models may be appropriate where data are available on the time of appearance of individual tumors, and particularly when survival is poor due to competing toxicity.

(6) Human cancer potency shall be derived from data on human or animal cancer potency. Potency shall be expressed in reciprocal milligrams of chemical per kilogram of bodyweight per day. Interspecies conversion of animal cancer potency to human cancer potency shall be determined by multiplying by a surface area scaling factor equivalent to the ratio of human to animal bodyweight, taken to the one-third power. This is equivalent to a scaling factor of 14 when extrapolating from mouse data, and a scaling factor of 6.5 when extrapolating from rat data.

(7) When available data are of such quality that physiologic, pharmacokinetic and metabolic considerations can be taken into account with confidence, they may be used in the risk assessment for inter-species, inter-dose, and inter-route extrapolations.

(8) When the cancer risk applies to the general population, human body weight of 70 kilograms shall be assumed. When the cancer risk applies to a certain subpopulation, the following assumptions shall be made, as appropriate:

Subpopulation	Kilograms of Body Weight
Man (18+ years of age)	70
Woman (18+ years of age)	58
Woman with conceptus	58
Adolescent (11-18 years of age)	40
Child (2-10 years of age)	20
Infant (0-2 years of age)	10

(b) For chemicals assessed in accordance with this section, the risk level which represents no significant risk shall be one which is calculated to result in one excess case of cancer in an exposed population of 100,000, assuming lifetime exposure at the level in question, except where sound

C O V E R**FAX****S H E E T**

To: Addressees
From: Gary Guzy, Counselor to the Administrator, EPA
Phone: 202-260-7960
Fax: 202-260-3684
Subject: Children's Environmental Health
Date: February 10, 1997
Pages: 2, including cover sheet

COMMENTS:**Addressees**

Jason Shogren/CEA
Pamela Beth Gilbert/CPSC
Eric Rubel/CPSC
Jeffrey Hunker/DOC
Bob Nordhaus/DOE
Polly Milius/DOJ
Seth Harris/DOL
Fred Siskind/DOL
Janno Lieber/DOT
Bill Dinkelacker/DOT
Diane Regas/DPC ✓
Leslie Kux/FDA
Mary Agocs/HHS
Dalton Paxman/HHS
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Dan Arbuckle/OIRA
Sally Katzen/OIRA
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Ronald Matzner/SBA
David Shark/USTR

Bradley Campbell/CEQ
Ron Lee Medford/CPSC
Ken Clark/DOC
Steve Galson/DOE
Sylvia Liu/DOJ
Jim Simon/DOJ
Geri Palast/DOL
Robert Clark/DOT
Camille Mittelholtz/DOT
Elizabeth Drye/DPC ✓
Sharon Holston/FDA
Catherine Lorraine/FDA
Richard Jackson/HHS
Andrea Wargo/HHS
Dave Jacobs/HUD
Elgie Holstein/NEC
Kathy Wallman/NEC
Mike Fitzpatrick/OIRA
Carrie Jelsma/OMB
Barbara Walton/OSTP
Cheryl Tates-Macias/USDA

Juni for
✓



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

FEB 10 1997

OFFICE OF
THE ADMINISTRATOR

MEMORANDUM TO AGENCY CHILDREN'S EXECUTIVE ORDER CONTACTS

From:

Gary S. Guzy 
Counselor to the Administrator

Subject:

Proposed Revision to Draft Executive Order

As you know from our several discussions, EPA believes that one of the principles underlying the Executive Order should be our efforts to share with the public how much we do and do not know about the effects of regulatory actions upon children. The current draft (2.5.p.m.1) generalizes this objective through the annual report requirement in section 3-304. While useful, we do not believe that this goes far enough in addressing the draft Order's basic objective of either protecting children, affirmatively explaining why an agency may be making a different choice, or indicating that information is lacking to allow for a fully informed decision on child-specific concerns.

At the same time, we are very mindful of the concern expressed by a number of agencies that the Order not require agencies to set forth a "Kick Me" sign with findings that could have adverse litigation consequences.

We therefore propose including the following language, added as subsection (d) of 5-501:

"A description of the data or information, if any, which was employed to assess child-specific risks or hazards."

It is our view that this language would move towards providing more transparency in the context of particular rulemakings, but that it would remove any adverse judgments from such statements and the likelihood of any statements being used successfully against an agency in litigation. It is intended only to require neutral explanations of the information used to reach the judgments contained in a regulatory action.

Please contact me at (202) 260-7960, or Bob Dreher at (202) 260-8040 if you would like to discuss this approach further or if you have any particular concerns about it. Thank you for your continuing prompt attention to this matter.



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- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
 Office of the Secretary
 Office of Public Health and Science
 Office of Disease Prevention and Health Promotion
 200 Independence Ave, S.W., Room 738-G
 Washington, D.C. 20201

FACSIMILE TRANSMISSION

TOTAL PAGES (including this cover page): 1

DATE: February 20, 1997

TO: Diane Regas, DPC 456-5589

FROM: Dalton Paxman, Ph.D.
 Senior Health Sciences Advisor

TELEPHONE: 202/205-5829

FAX: 202/205-9478

Message:

Diane, here is the necessary information for clearance for the meeting on the Children's Environmental Health Executive Order:

Dalton Paxman (OPHS) BD [redacted] P6/(b)(6)

Earl Fox BD (OPHS) [redacted] P6/(b)(6)

Kenneth Olden (NIEHS) BI [redacted]

Richard Jackson (CDC) BD [redacted] P6/(b)(6)

William Raub (ASPE) BD [redacted] P6/(b)(6)

Catherine Lorraine (FDA) will be joining us by phone from Houston

Please let me know if you need anything else.

Dalton

[001]

4pm
 all



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

COPY

National Institutes of Health
National Institute of Child Health
and Human Development
Building 31, Room 2A03
31 Center Dr. MSC - 2425
Bethesda, Maryland 20892 - 2425
Phone: (301)496 - 3454
FAX: (301)402 - 1104

DATE: February 4, 1997

TO: Leslie L. Clunc
Associate General Counsel, Office of the General Counsel, OS

FROM: Director, National Institute of Child Health and Human Development, NIH

SUBJECT: Proposed Executive Order Entitled "Protection of Children in Federal Environmental, Health, and Safety Actions"

COMMENTS ON DOCUMENT #154954

The NIH has serious concerns about this draft Executive Order. The topics it is intended to encompass are inconsistent, unclear, and confusing throughout the document. Commas make a big difference here. It is one thing to address protecting children in environmental health and safety actions. It is far broader and more complex to do so for environmental, health and safety actions, where health and safety must be considered separately and not just in relation to the modifier "environmental." If the intent is to have this order affect just environmental health and safety concerns, as much of the language implies, the wording needs extensive revision to make this clear. If not, the effects are so broad that this issue needs extensive discussion--it is inappropriate to be asked to agree to something this sweeping out of the blue in one day. The aim is difficult to take issue with, but the mechanism and scope need discussion.

Duane Alexander, M.D.

TOM DASCHLE, SOUTH CAROLINA, CHAIRMAN
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 DANIEL PATRICK MOYNIHAN, NEW YORK
 JOHN D. ROCKEFELLER IV, WEST VIRGINIA

Diane/Elizabeth-

The idea proposed here is related to one
 Diane is working on. Could you look into
 this and get back to me as to
 whether we should set in motion a policy
 process? Thanks

OFFICE
 OFFICE

Elena

cc Poruce

DATE:

12-1

TO:

RAHM

Copies for

Me

Eliz Dye

Diane Rojas

Poruce Reed

- 6423

JOHNSON

atic Policy Committee
 t Senate Office Building
 one: (202) 224-3232
 ax: (202) 228-3432

MESSAGES:

THIS IS THAT "DRUGS FOR
KIDS" ISSUE. I ASKED FOR
AN ACTION PLAN - AND I ENCLOSE
IT. I AM NOT OBSESSED WITH THIS.
JUST DOING FRIENDS A FAVOR -
BUT THE IDEA HAS MERIT...

of Pages including cover:

4

CALL AT YOUR EARLIEST OPPORTUNITY.

TO: Joel Johnson
FROM: Susan DeLaurentis
DATE: December 5, 1996
RE: Pediatric Data for Pharmaceuticals

Thank you for your willingness to pass along our proposal to the appropriate White House staff for such matters. As you have requested, I will briefly describe here the "best case scenario" from our view. We have been discussing this issue (i.e., the need for pediatric data) with David Kessler, Bill Schultz (his deputy), and their lawyers over the past year, and I think you will find them supportive as well. Everyone has put a lot of time into this and it has been productive.

The following scenario presents the President with the most visibility on what we believe will be a very popular, "Christmas-present-to-all-children" initiative. If this seems right to the White House, we can -- and must -- begin work immediately. (It would be particularly helpful if there were a White House staff contact for us. With most of our issues we would go directly to the AIDS staff, but this is obviously broader than AIDS alone.)

We propose that some time during the week of December 16, the President issue an Executive Order, directing the FDA to take immediate regulatory action to ensure that all drugs be proven safe and effective for use by children prior to their approval by the FDA. We propose that the President sign the Order in the Oval Office, with children, parents, and pediatricians present. We would ask that the President dedicate this action to Elizabeth Glaser and her work to improve child health, and that the Pediatric AIDS Foundation be included in the event.

A proposed action plan detailing the steps that need to be taken, including what should be included in the President's Executive Order and accompanying statement, is attached to this memo. We would be happy to help in effectuating this plan in any way possible -- from drafting the Executive Order, to generating support in the media, to making physicians, parents, and advocates available for comment. Just let us know what we can do.

We are very excited about this proposal, and appreciate your attempt to steer us toward the appropriate decision makers.

Thanks again for everything.

PROPOSED ACTION PLAN

- During the week of December 16, the President would issue an Executive Order and accompanying statement, directing the FDA to take immediate regulatory action to ensure that all drugs be proven safe and effective for use by children prior to their approval by the FDA.
- The Executive Order would:
 - ***Describe the dire need for pediatric data.*** The Order would explain that 80% of all drugs currently on the market have not been proven safe and effective for use by children. The Order would explain the ramifications of this situation, namely that (1) children are being denied life-saving therapies because physicians are afraid to prescribe potentially toxic drugs that have not been approved for use by children, and (2) children may be exposed to an increased risk of adverse reactions or decreased effectiveness of the drugs prescribed because pediatricians do not have appropriate dosage data.
 - ***Explain that FDA has the statutory authority to require pediatric data prior to its approval of a new drug.*** The Order would explain that pursuant to the approval and labeling requirements of the Food, Drug, and Cosmetic Act, the FDA has the authority to require pediatric data.
 - ***Direct the FDA to promulgate regulations requiring, as a condition of approval for all new drugs for which children are foreseeable users, that pharmaceutical manufacturers submit pediatric safety data, and, as appropriate, pediatric efficacy data.¹*** The Order would direct the FDA to promulgate new regulations in accordance with the "notice and comment" procedures of the Administrative Procedure Act.
 - ***Direct the FDA to issue the proposed regulations as soon as possible.*** The Order would direct the FDA to publish, within 90 days, new proposed regulations for public comment.

¹ In most instances, efficacy data for use by children can be extrapolated from adult efficacy data.

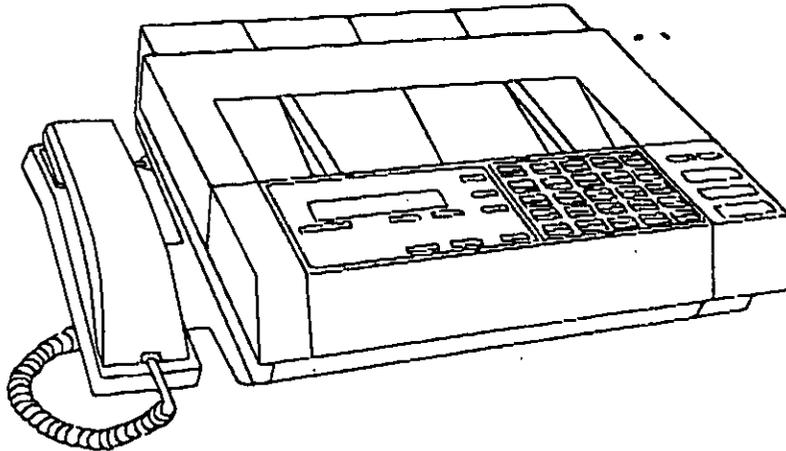
- The statement accompanying the Executive Order would:
 - *Describe the urgent need for pediatric data.*
 - *Declare that drugs should be safe and effective for all foreseeable users, not just adults.*
 - *Speak about the need to ensure that children share in and benefit from therapeutic progress.*
 - *Dedicate this action to Elizabeth Glaser, and her work to improve child health.* (Note: December 3rd was the 2nd anniversary of Elizabeth's death from AIDS-related complications.)
- Prior to issuance of the Executive Order, David Kessler and Bill Schultz (as well as PAF representatives) would be consulted about the wording of the Order to ensure that is on clear legal footing.
- Children, pediatricians, scientists, and advocates would be present when the President signs the Order. Attendees could include:
 - Representatives from the Pediatric AIDS Foundation
 - Children with life-threatening illnesses, such as AIDS and cancer
 - Parents of children with life-threatening illnesses who have been denied needed therapies because of the lack of pediatric data
 - Pediatricians and scientists who have advocated for the need for pediatric data
- Pediatric AIDS Foundation and other child advocacy organizations would issue press releases lauding the President's efforts to protect the health and safety of American children.

U.S. Department of Labor

Office of the Assistant
Secretary for Policy
Washington, D.C. 20210



FAX COVER SHEET



DATE: 1/31/97

TO: BRADLEY CAMPBELL
COMPANY: _____
FROM: SETH HARRIS

FAX NO: (202) 456-0753
PHONE NO: (202) 395-5750
PHONE NO: (202) 219-6181

FAX NO: (202) 219-6924

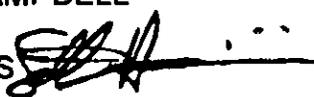
NUMBER OF PAGES INCLUDING COVER: 3

MESSAGE: _____

U.S. Department of LaborAssistant Secretary for Policy
Washington, D.C. 20210

January 31, 1997

MEMORANDUM FOR: BRADLEY CAMPBELL

FROM: SETH HARRIS 

SUBJECT: Preliminary Comments on the Children's Environmental Health Executive Order

You asked that we send you preliminary comments on the draft executive order (E.O.) for inclusion in the version being prepared for Monday. We will have additional comments next week.

As indicated during the conference calls, DOL's preference is to limit the E.O. to children under the age of 14. This could be accomplished in the definitions section and by including a statement in the opening section along the lines of EPA's comments this morning (e.g., the science indicates problems manifest in younger children; therefore, the focus of the E.O. is on children under 14). We would be willing to explore other options for excluding teenagers 14 and older.

An alternative (but less acceptable) approach would be to insert the following language into the opening section:

While some health or safety agencies have statutory missions predominantly directed toward certain age groups, such as the working-age population or the elderly, other agencies have more general mandates to protect public health or the environment for the benefit of all Americans. The intent of this Executive Order is to assure that the latter agencies adequately consider health and safety hazards to children when developing regulations and programs.

If the final decision is to include older teenagers, we recommend the following language changes:

- Section 3-302. The Department of Labor should be included in the IWG. NIOSH should also be included because it does the bulk of the research on occupational safety and health.

- 2 -

- Section 3-303(c). Cut sentence requiring pamphlet. Allow IWG to determine best outreach approach.

- Section 6-601. Suggest "For each significant regulatory action initiated after the effective date of this E.O. that addresses the environment, health or safety, each agency shall provide the following information, to the extent practicable, ..." We need some language to assure that these requirements do not (1) interfere with current rulemakings, and (2) impose huge analytical burdens on the agencies. OSHA risk assessments and regulatory analyses already consume considerable resources.

FDA COMMENTS ON
DRAFT EXECUTIVE ORDER TO PROTECT CHILDREN
FROM ENVIRONMENTAL HEALTH THREATS

- While parts of the draft executive order (such as the second bullet) appear to address a wide range of health threats to children, other parts (such as the title and first bullet) appear to be limited to environmental health threats. FDA recommends that the scope of the executive order be broadened beyond just environmental health threats. Limiting an executive order to environmental health threats could imply that the most significant health threats faced by children are environmental ones. In FDA's view, while environmental threats are important, they are not the only significant health threats faced by children.

- While FDA recognizes the benefit of focusing specific attention on health threats to children, FDA is concerned about layering additional requirements on the regulatory process in circumstances where they will not add "value" to the process. Thus, FDA recommends that any new analysis regarding effects on children's health be targeted at regulations that (1) have potential disparate health impacts upon children and (2) are significant regulatory actions as defined in Exec. Order 12866.

The first limitation (that an analysis of effects on children be limited to regulations with a potential disparate impact on children) will insure that new regulatory reviews are not required unless there is a specific reason to be concerned about children. The second limitation (that an analysis of effects on children be limited to significant regulatory actions) will target the new analysis to the regulations which have the greatest effects and which are already required to be subject to a formal cost-benefit analysis. If the executive order is targeted in this way, it will formalize what FDA should be -- and is -- already doing.

- The draft executive order requires that certain regulations be "adequately protective" of children's health. FDA suggests that this standard be made less vague and more affirmative by requiring that the regulations "protect" children's health. In addition, whichever standard is used, it may be necessary to clarify that the requirement to protect children's health applies "to the extent permitted by law." Without such a qualification, the executive order could be construed as an attempt to override existing statutory authorities.

- The draft executive order also requires an "affirmative finding" that certain regulations are adequately protective of children's health. A better approach might be to follow the Food Quality Protection Act and require "a specific determination regarding the safety ... for infants and children" (sec. 408(b)(2)(C)(ii)(II)). The specific determination language has the advantage of not requiring an affirmative finding where this would be impossible due to lack of complete information or a conflicting statutory mandate.

- FDA does not object to restricting the pamphlet for families (which is addressed in the third bullet) to just environmental health threats. However, FDA does have questions about implementation, including whether the pamphlet is a one-time project or an annual one, whether a significant commitment of resources will be required, and who will take the lead in preparing the pamphlet.

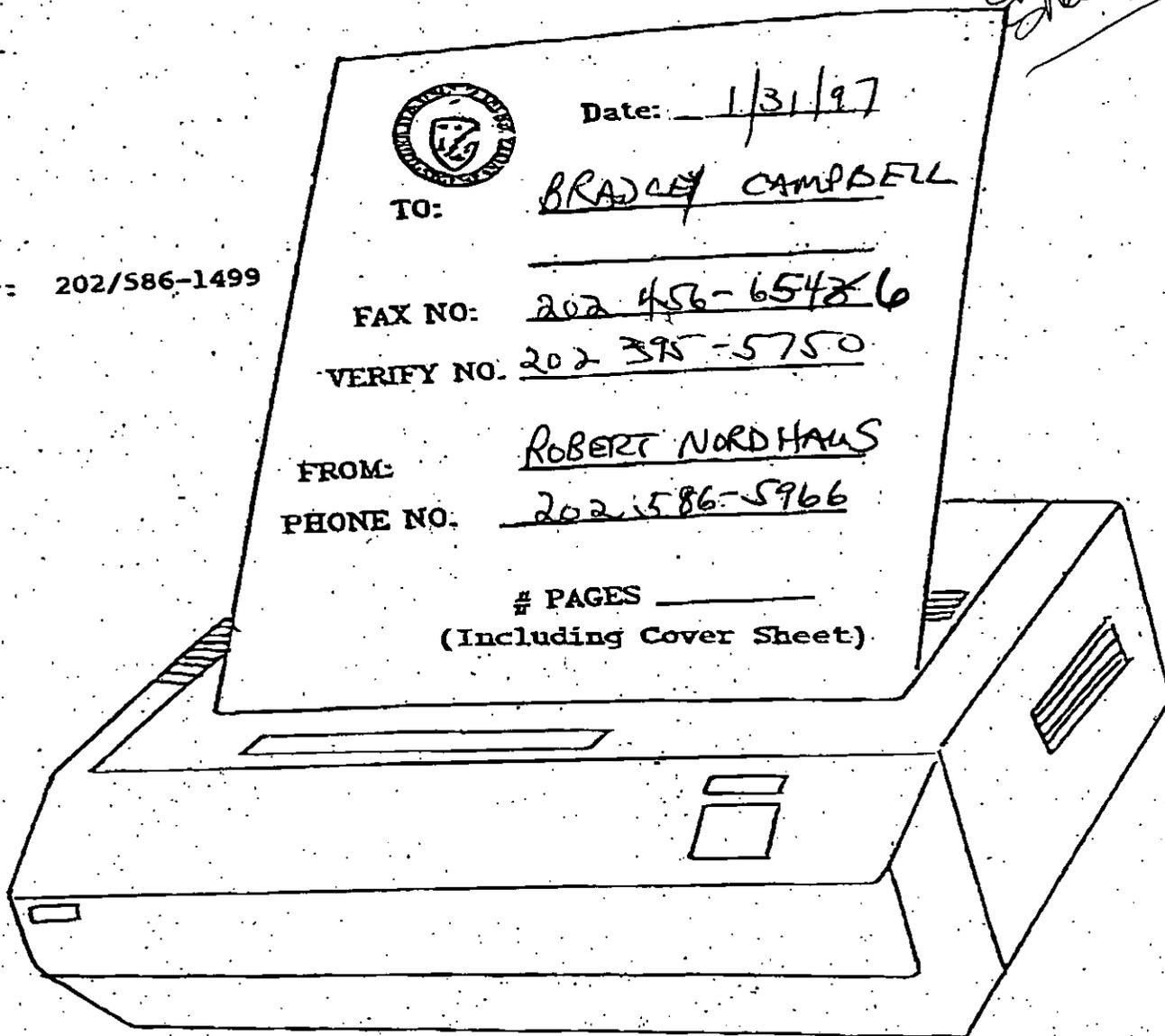
OFFICE OF THE GENERAL COUNSEL

U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

Amul Perito

*Effecter last
alternates date
exigence
recognition*

FAX Number: 202/586-1499



REMARKS: Brad - These are our
initial drafting suggestions - we
may have further comments later in
the day. *RN*

DISCUSSION DRAFT – DO NOT CITE OR RELEASE

*Effect on
lets*

**PROTECTION OF CHILDREN
IN FEDERAL ENVIRONMENTAL, HEALTH, AND SAFETY ACTIONS**

America's children are this country's future. Preparing our children for the 21st century is among our most important national priorities. To fulfill this task we must recognize that America's children face significant and unique threats from an array of hazards. A growing body of scientific knowledge demonstrates that children are particularly at risk from environmental hazards:

- Children's immunological, digestive and other bodily systems are still developing, making them more susceptible to toxic pollutants and other environmental hazards;
- 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;
- Children are less able than adults to recognize and to protect themselves from exposure to toxic pollutants and other environmental hazards, and
- Children face potential exposures to toxic pollutants over their entire lifetime, with the possibility of more significant health impacts.

Our experience tells us that children have different needs when we act to protect health and safety:

- Children's size and weight can affect how well they are protected by safety features;
- Children have activity patterns that are different from those of adults, which affects their exposure to health and safety risks;
- Children are less able to protect themselves from risk, and less responsive to warning regimes.

While responsible Federal agencies consider the effect of their work on children, existing standards were derived in many instances principally from data on adults. The array and complexity of environmental, health, and safety 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 and safety.

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, accounting for children in the development of new standards for passive restraints in cars, 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, health, and safety hazards, and apply its resources, including its scientific research capabilities, in a coordinated and efficient manner to address these threats 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 and other health and safety hazards 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, health, and safety 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, health, and safety 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, health, and safety 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, health, or safety 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.

1-103. The head of each Federal agency shall carry out this section in accordance with policies, principles, and priorities established by the EWG.

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.

2-202. Significant regulatory action means ~~any regulatory action that is likely to result in a rule that may~~ a proposed or final rule for which a regulatory impact assessment is required under Executive Order

- CEU
- (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;~~
 - (b) ~~Create a serious inconsistency or otherwise interfere with an action planned or taken by another agency;~~
 - (c) ~~Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or~~
 - (d) ~~Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.~~

[NOTE: 2-202 is taken verbatim from EO 12866]

Section 3. Children's Environmental Health IWG.

3-301. Within 60 days of the signing of this order, there shall be established an interagency working group (IWG) on Children's Health IWG, which shall have general oversight of the implementation of this order.

3-302. The IWG 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, health, or safety hazards, or whose activities may substantially affect such hazards, or which conducts scientific or medical research related to such risks or hazards. Member agencies shall include, but are not limited to, the Consumer Product Safety Commission (CPSC); the Council on Environmental Quality (CEQ); the Department of Agriculture (USDA); 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 Department of Justice (DOJ); the Domestic Policy Council (DPC); the Environmental Protection Agency (EPA); the Office of Management and Budget (OMB); and the Office of Science and Technology Policy (OSTP).

the Department of Energy;

3-303. The IWG shall develop a coordinated Federal strategy for Children's Health and Safety, to include at least the following elements:

- (a) Statements of guiding principles, general policy, *carrying out* 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, including steps to implement the plan for the consolidated research database developed 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) Recommendations 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 IWG shall publish a joint pamphlet for distribution to families assessing children's environmental, health, or safety threats, and providing practical tips for family protection and additional sources of governmental information.
 - (d) An identification of ten high-priority initiatives for the Federal government to undertake in advancing protection of children's health and safety.
 - (e) A statement regarding the desirability of new legislation to ensure that the purposes of this Executive Order are carried out.

3-304. The IWG 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 IWG may establish subcommittees and working groups as appropriate to assist the IWG in carrying out its obligations and responsibilities under this order.

3-306. The Administrator of the Environmental Protection Agency shall serve as interim chair of the IWG with responsibility for arranging the first meeting. At the first meeting, the IWG shall elect a permanent chair, who will serve for a period of one year. Subsequent chairs shall be elected by the IWG to serve for one-year terms, with no one member agency holding the chairmanship of the IWG for more than two consecutive one-year periods.

3-307. The IWG shall exist for a period of four years. At least six months prior to the expiration of that period, the member agencies shall assess the need for continuation of the IWG or its functions, and make appropriate recommendations to the President.

Section 4. Research Coordination and Integration

4-401. Within six months of the date of signature of this order, the White House Office of Science and Technology Policy and the National Science and Technology Committee shall present to the IWG 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 and infants resulting from exposure to toxic pollutants or other environmental, health, or safety hazards. This plan shall include recommendations to ensure that the activities of the IWG and other requirements of this Executive order are fully integrated with, and not duplicative of, other current or planned initiatives with respect to children's health and safety.

4-402. The proposed plan shall promote the submission of information on academic

and other private research for inclusion in the data base.

4-403. The plan shall include provisions to ensure that the consolidated research data base is available to the public, to the scientific and academic communities, and to all Federal agencies.

Section 5. Data Needs

5-501. Annual Report on Data Needs. The head of each agency subject to this Executive Order shall present an annual report to the IWG on research, data, or other information that should be developed to enhance the agency's ability to understand, analyze, and respond to environmental, health, and safety risks to children. This report shall include particular data needs that have been identified in the course of the agency's programs and activities, and shall be provided to the White House Office of Science and Technology Policy and the National Science and Technology Committee for consideration in establishing research priorities.

Section 6. Agency environmental, health, or safety regulations.

6-601. For each significant regulatory action addressing the environment, health, or safety, each agency shall provide the following information, developed as part of the agency's ~~decisionmaking process (unless prohibited by law)~~ its regulatory impact assessment: ✓
Under EO 12866

- (a) An evaluation of whether the proposed regulatory action addresses an area in which children may be at greater risk than the general population;
- (b) An assessment of potentially effective and reasonably feasible alternatives to the proposed regulatory action that have been identified by the agency or the public and that may be more protective of children; and
- (c) An explanation of why the proposed regulatory action is preferable to the identified potential alternative(s).

[Query: same requirement for any draft or final EIS?]

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

DRAFT - 1/30; 1:00 pm

FDA COMMENTS ON**DRAFT EXECUTIVE ORDER TO PROTECT CHILDREN
FROM ENVIRONMENTAL HEALTH THREATS**

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The first limitation (that an analysis of effects on children be limited to regulations with a potential disparate impact on children) will insure that new regulatory reviews are not required unless there is a specific reason to be concerned about children. The second limitation (that an analysis of effects on children be limited to significant regulatory actions) will target the new analysis to the regulations which have the greatest effects and which are already required to be subject to a formal cost-benefit analysis. If the executive order is targeted in this way, it will formalize what FDA should be -- and is -- already doing.
- The draft executive order requires that certain regulations be "adequately protective" of children's health. FDA suggests that this standard be made less vague and more affirmative by requiring that the regulations "protect" children's health. In addition, whichever standard is used, it may be necessary to clarify that the requirement to protect children's health applies "to the extent permitted by law." Without such a qualification, the executive order could be construed as an attempt to override existing statutory authorities.
- The draft executive order also requires an "affirmative finding" that certain regulations are adequately protective of children's health. A better approach might be to follow the Food Quality Protection Act and require "a specific determination regarding the safety ... for infants and children" (sec. 408(b)(2)(C)(ii)(II)). The specific determination language has the advantage of not requiring an affirmative finding where this would be impossible due to lack of complete information or a conflicting statutory mandate.
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
THE ADMINISTRATOR

TO: ELGIE HOLSTEIN
DIANE ALGAS

FROM: GARY GUY

COMMENTS: FYI on PAST FDA and CPSC SUPPORT.

Number of Pages to follow: _____
 Date: _____
 Time: _____

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

Office of the Administrator
 401 M Street, S.W.
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FROM THE OFFICE OF ANN BROWN
CHAIRMAN

U.S. CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

Office: 301-504-0213
Facsimile: 301-504-0768

Please deliver the following fax to:

Name: Gary Grogg

Organization: EPA

Fax Number: (202) 260-3684

Number of Pages (Including cover sheet) 2

From: WACT SANDERS

Telephone: (301) 504-0213

Message: HERE ARE STAFF COMMENTS REGARDING
THE PROPOSED OUTLINE OF THE Executive Order -

NOTE: If all pages are not received, or if you have any problems with this transmittal, please contact the person listed above.

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**CPSC STAFF* DRAFT
September 16, 1996**

Recommended Changes to:

**"Discussion Draft
Executive Order to Protect Children
From Environmental Health Threats"**

The goals of the draft outline for the Executive Order ("outline") are laudable. However, it could have the unintended consequences of greatly increasing the regulatory burden on agencies and significantly delaying important health, safety and environmental standards. CPSC staff believes one important modification to the outline is needed.

As currently drafted, the outline would require agencies to make "*affirmative findings*" that infants and children would be protected by any regulation of a chronic chemical hazard to which they could be exposed. To gather the data to do this could be very costly with little overall health and safety benefit, particularly in many cases for consumer products that contain a potentially chronic chemical hazard.

Thus, a change in the draft language of the Executive Order should be made to take the above into account. Specifically, we would replace the sentence in the second bullet beginning "*It would require an affirmative finding ...*" with:

"It would require that any new regulation contain a statement that the health risk to infants and children was considered during the development of the regulation and the reasonably available information supports a conclusion that they are adequately protected."

* This draft does not necessarily reflect the opinions of the Commissioners

Office of Policy
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
Room 15-74 HF-23

Phone (301) 827-3380
Fax (301) 443-6906

Date: 9-20

To: Gary Guzy

Fax Number: 260-3684 fx

From:

Phil Barnett
Director, Policy Research Staff

Number of Pages (including cover sheet) 2

This document is intended for the use of the party whom it is addressed and may contain information that is privileged, confidential, and protected from disclosure under applicable law. If you are not the addressee, or the person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by telephone at (301) 827-3380, and return it to the above address by mail. Thank you.

EXECUTIVE OFFICE OF THE PRESIDENT
COUNCIL ON ENVIRONMENTAL QUALITY

TO: Those Who attended the Mtg. on
The Children's Environmental Health

FROM: Brad Campbell

DATE: January 30, 1997

FAX: _____

Number of pages including cover: 3

COMMENTS: Conference call today
at 5:45 p.m.



PHONE (202) 395-5750 FAX: (202) 456-6546

722 Jackson Place, N.W.
Washington, D.C. 20503

MEMORANDUM TO:

FROM: BRADLEY M. CAMPBELL

RE: THE CHILDREN'S ENVIRONMENTAL HEALTH EXECUTIVE ORDER

There will be a conference call meeting from 5:45 to 6:45 today *1/30/97*
to follow up on the past meetings held regarding the Children's
Environmental Health Executive Order.

The phone lines are: (202) 456-6755
(202) 456-6766
(202) 456-6777
(202) 456-6799

code number: 6219

DeVora

Children's Environmental Health Executive Order

MEETING ATTENDEES:

<u>Name</u>	<u>Agency</u>	<u>Telephone</u>	<u>FAX</u>
Bradley M. Campbell	CEQ	(202) 456-6224	456-0753
Bill Dinkelacker	DOT	(202) 622-1258	622-1294
Elizabeth Drye	WH/DPC	(202) 456-5573	456-7028
Lynn Goldman	EPA/OPPTS	(202) 260-2902	260-1847
Gary Guzy	EPA	(202) 260-7960	260-3684
Diane Regas	WH/DPC	(202) 456-5589	456-7028
Polly Milius	DOJ/ENRD	(202) 514-1442	514-4231
Sylvia Liu	DOJ/ENRD	(202) 305-0639	514-4231
Kathy Wallman	NEC	(202) 456-2620	456-2878
Michael Fitzpatrick	OMB/OIRA	(202) 395-1247	395-3047
Don Arbuckle	OMB/OIRA	(202) 395-5897	395-7245
Richard Jackson	NCEH/CDC/HHS	(770) 488-7000	770 488-7015
Ronald Matzner	SBA	(202) 205-6882	205-6846
Jason Shogren	CEA	(202) 395-5012	395-6853
Leslie Kux	FDA	(301) 827-1127	301 443-0739
Sharon Smith Holston	FDA	(301) 827-3450	301 443-5930
Catherine Lorraine	FDA	(301) 827-3360	301 594-6777
Mary Agocs	CDC/HHS	(202) 690-8598	690-7519
Ron Medford	CPSC	(301) 504-0554	301 504-0407
Pamela Gilbert	CPSC	(301) 504-0550	301 504-0121
Camille Mittelholtz	DOT	(202) 366-4861	366-7618
Carrie Jelsma	OMB	(202) 395-4727	395-5836
Dalton Paxman	OPHS/HHS	(202) 205-5829	205-9478
Jim Simon	DOJ	(202) 514-3370	514-0557
Elgie Holstein	NEC	(202) 456-2800	456-2223
Jim Aidala	EPA	(202) 260-2897	260-1847
Eric Rubel	CPSC	(301) 504-0980	301 504-0403
Jeffrey Hunker	Commerce	(202) 482-6055	482-4636
Rob Fairweather	OMB	(202) 395-6827	395-5836
Bob Dreher	EPA	(202) 260-8040	260-8046
Bob Nordhaus	DJG		586-1499
Camille Asaredeo			401-0349

EXECUTIVE OFFICE OF THE PRESIDENT
COUNCIL ON ENVIRONMENTAL QUALITY

TO: Brad

FROM: Katie McGinty Robert Kapla

DATE: 1/31

FAX: _____

Number of pages including cover: 8

COMMENTS: More comments



PHONE (202) 456-6224 FAX: (202) 456-2710
OLD EXECUTIVE OFFICE BUILDING, ROOM 360
WASHINGTON, D.C. 20501

**U.S. DEPARTMENT OF JUSTICE
OFFICE OF LEGAL COUNSEL
WASHINGTON, D.C. 20530**

FACSIMILE TRANSMISSION SHEET

DATE: JANUARY 31, 1997

FROM: DANIEL HALBERSTAM
ATTORNEY ADVISOR

OFFICE PHONE: 202/514-4409

TO: MAC REED
OFFICE OF MANAGEMENT & BUDGET

OFFICE PHONE: 202/395-3563

FACSIMILE NUMBER: 202/395-7294

NUMBER OF PAGES: 7 (PLUS COVER SHEET)

REMARKS:

Mac - Comments on Executive Order regarding Children's Health TWG

ANY QUESTIONS, PLEASE CONTACT OUR ADMINISTRATIVE OFFICE ON 514-2067
OFFICE OF LEGAL COUNSEL FACSIMILE MACHINE NUMBER - 514-0563 (FTS - 363-0563)

DISCUSSION DRAFT - DO NOT CITE OR RELEASE

**PROTECTION OF CHILDREN
IN FEDERAL ENVIRONMENTAL, HEALTH, AND SAFETY ACTIONS**

America's children are this country's future. Preparing our children for the 21st century is among our most important national priorities. To fulfill this task we must recognize that America's children face significant and unique threats from an array of hazards. A growing body of scientific knowledge demonstrates that children are particularly at risk from environmental hazards:

- Children's immunological, digestive and other bodily systems are still developing, making them more susceptible to toxic pollutants and other environmental hazards;
- 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;
- Children are less able than adults to recognize and to protect themselves from exposure to toxic pollutants and other environmental hazards. and
- Children face potential exposures to toxic pollutants over their entire lifetime, with the possibility of more significant health impacts.

No
bullets
in
EOS.

Our experience tells us that children have different needs when we act to protect health and safety:

- Children's size and weight can affect how well they are protected by safety features;
- Children have activity patterns that are different from those of adults, which affects their exposure to health and safety risks;
- Children are less able to protect themselves from risk, and less responsive to warning regimes.

While responsible Federal agencies consider the effect of their work on children, existing standards were derived in many instances principally from data on adults. The array and complexity of environmental, health, and safety 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 and safety.

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, accounting for children in the development of new standards for passive restraints in cars, 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, health, and safety hazards, and apply its resources, including its scientific research capabilities, in a coordinated and efficient manner to address these threats to children.

h, Only by tailoring governmental actions, including the setting of health and safety standards, to recognize and address the oftentimes greater impact that environmental pollutants and other health and safety hazards 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, health, and safety 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, health, and safety hazards, and by the authority vested in me as President by the Constitution and ^{the} 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, health, and safety 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, health, or safety 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 applicable law.

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. Do you mean to include independent agencies? If so, we should discuss possible use of hortatory language.

2-202. Significant regulatory action means any regulatory action 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;
- (b) Create a serious inconsistency or otherwise interfere with an action planned or taken by another agency;
- (c) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
- (d) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

[NOTE: 2-202 is taken verbatim from EO 12866]

Section 3 Children's Environmental Health

environmental
Interagency Working Group

3-301. Within 60 days of the ^{date} signing of this order, there shall be established an interagency working group (IWG) on Children's Health (IWG) which shall have general oversight of the implementation of this order.

3-302. The IWG 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, health, or safety hazards, or ^(e) whose activities may substantially affect such hazards, or ^(f) which conducts scientific or medical research related to such risks or hazards. Member agencies shall include, but are not limited to, the Consumer Product Safety Commission (CPSC); the Council on Environmental Quality (CEQ); the Department of Agriculture (USDA); 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 Department of Justice (DOJ); the Domestic Policy Council (DPC); the Environmental Protection Agency (EPA); the Office of Management and Budget (OMB); and the Office of Science and Technology Policy (OSTP).

Note: CPSC is independent agency.

Note: Parentheticals not needed because most agencies are never mentioned again.

3-303. The IWG shall develop a coordinated Federal strategy for Children's Health and Safety, ⁽¹⁴⁾ ⁽¹⁵⁾ to 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, including steps to implement the plan for the consolidated research database developed 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.

the study of

DRAFT - 1/30; 1:00 pm
be more specific

(are states to be included as well?)
state and local?

interagency?

l.c.

encourage the establishment of partnerships within the private sector to

[else this wd be redundant w/ 3-207(b)]

- academic, and non-profit sectors.
- (c) Recommendations 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 to cooperatively achieving the goals of this order. As part of this effort, the IWG shall publish a joint pamphlet for distribution to families assessing children's environmental, health, or safety threats, and providing practical tips for family protection and additional sources of governmental information.
- (d) An identification of ten high-priority initiatives for the Federal government to undertake in advancing protection of children's health and safety.
- (e) A statement regarding the desirability of new legislation to ensure that the purposes of this Executive Order are carried out.

as consumers

Who pays for pamphlet?

by office

3-304. The IWG 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.

(representatives)

3-305. The IWG may establish subcommittees and working groups as appropriate to assist the IWG in carrying out its obligations and responsibilities under this order.

3-306. The Administrator of the Environmental Protection Agency shall serve as interim chair of the IWG with responsibility for arranging the first meeting. At the first meeting, the IWG shall elect a permanent chair, who will serve for a period of one year. Subsequent chairs shall be elected by the IWG to serve for one-year terms, with no one member agency holding the chairmanship of the IWG for more than two consecutive one-year periods.

by office

and offices

3-307. The IWG shall exist for a period of four years. At least six months prior to the expiration of that period, the member agencies shall assess the need for continuation of the IWG or its functions, and make appropriate recommendations to the President.

Section 4. Research Coordination and Integration

4-401. Within six months of the date of signature of this order, the White House Office of Science and Technology Policy and the National Science and Technology Committee shall present to the IWG 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 and infants resulting from exposure to toxic pollutants or other environmental, health, or safety hazards. This plan shall include recommendations to ensure that the activities of the IWG and other requirements of this Executive order are fully integrated with, and not duplicative of, other current or planned initiatives with respect to children's health and safety.

Is this a member

4-402. The proposed plan shall promote the submission of information on academic

and other private research for inclusion in the data base.

4-403. The plan shall include provisions to ensure that the consolidated research data base is available to the public, to the scientific and academic communities, and to all Federal agencies.

Section 5. Data Needs

5-501. Annual Report on Data Needs. The head of each agency subject to this Executive Order shall present an annual report to the IWG on research, data, or other information that should be developed to enhance the agency's ability to understand, analyze, and respond to environmental, health, and safety risks to children. This report shall include particular data needs that have been identified in the course of the agency's programs and activities, and shall be provided to the White House Office of Science and Technology Policy and the National Science and Technology Committee for consideration in establishing research priorities.

L.C.

or office!

member agency or office?

All agencies are subject to this order:

don't you want to limit report requirements?

or offices

Section 6. Agency environmental health or safety regulations.

6-601. For each significant regulatory action addressing the environment, health, or safety, each agency shall provide the following information, developed as part of the agency's decisionmaking process (unless prohibited by law):

or office

to the fullest extent permitted by applicable law

- (a) An evaluation of whether the proposed regulatory action addresses an area in which children may be at greater risk than the general population;
- (b) An assessment of potentially effective and reasonably feasible alternatives to the proposed regulatory action that have been identified by the agency or the public and that may be more protective of children; and
- (c) An explanation of why the proposed regulatory action is preferable to the identified potential alternative(s).

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



U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, D.C. 20207

Fax Message Cover Sheet

DATE: 1/31/97 TIME: 5pm

FAX TO: Name: Brad Campbell

Fax Number: (202) 456-0753

Voice Phone Number: _____

FROM: Office of the Executive Director

Name: Pamela Gilbert

Voice Phone Number: (301) 504-0550

Fax Number: (301) 504-0121

Subject: See you Monday

Number of Pages to follow: 3



United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

Office of the Executive Director

MEMORANDUM

DATE: January 31, 1997

TO : Brad Campbell
Associate Director
Council on Environmental Quality

Mac Reed
Office of the General Counsel
Executive Office of the President
Office of Management and Budget

FROM : Pamela Gilbert *PG*
Executive Director

SUBJECT: CPSC Staff Comments on 1/30/97 Draft of the Children's Health and Safety Executive Order¹

We want to reiterate that, as an agency with no greater priority than protecting the health and safety of children, we strongly support the stated intent of the draft Executive Order -- to establish a "national policy to protect the health of American children from environmental, health and safety hazards." We had a number of serious concerns about the previous draft of this Executive Order, and we are pleased to see many of the changes that have been made to address those concerns.

This memo outlines our most serious remaining concerns with the contents of the current draft Order. We also anticipate that we may have more comments, questions, and recommendations once we have reviewed the comments of other participating agencies. Finally, we are still reviewing the Preamble to the draft Order, and may have further comments after that review is completed.

Section 1-102: This section is overly prescriptive and could arguably require agencies to spend unlimited resources to address a particular hazard, unless prohibited by statute.

Proposal: Section 1-102 should be modified to read, "The head of each Federal agency shall ensure that the potential impacts upon children of environmental,

¹This memorandum does not necessarily reflect the views of the Commissioners.

health, or safety hazards arising from or related to the activities of that agency are considered and addressed, as appropriate, by that agency."

Section 3. Children's Health IWG

We agree that there needs to be coordination among federal agencies on children's health and safety issues, particularly in the area of research. However, as originally drafted, the Executive Order would have established a new Children's Environmental Health Council with a broad mandate that went well beyond simple coordination among agencies. CPSC staff commented that the creation of a new, cumbersome bureaucratic entity was counter to the Administration's reinvention efforts, and that its broad responsibilities could impose inappropriate burdens and mandates on member agencies. While we are pleased that the original proposal has been considerably scaled back, we still have a number of concerns about the proposed Interagency Working Group (IWG).

Sections 3-301 and 3-302. We agree with many of the comments that have been made by representatives of the Office of Information and Regulatory Affairs (OIRA) about creating a new bureaucracy to coordinate efforts among agencies. We are eager to review OIRA's written comments and recommendations to revise this proposal.

Section 3-303. We have a number of questions and concerns about the list of elements that make up the coordinated Federal strategy:

- (a) What is meant by statements of "guiding principles" and "general policy?" How would those principles and policies differ from what has already been stated in the Executive Order? We would be strongly opposed if those principles and policies included specific directions regarding scientific or technical assessments done by individual agencies.

Isn't it redundant to require a statement of "targeted annual priorities" in this subsection when subsection (d) lists the same requirement? How would these priorities differ from those mentioned in (d)?

- (b) As an agency with a broad mandate and a very limited budget -- and no separate research budget -- we would oppose any requirement for the CPSC to contribute in any manner to a "cross-cutting budget" for conducting research.
- (c) We support a coordinated effort to reach out to, and educate the public about, health and safety risks to infants and children. However, we believe it is inappropriate to dictate the form of that outreach by requiring the publication of a pamphlet that includes specific information.
- (d) There is no reason to require the identification of a specific number (ten) of

high-priority initiatives for the Federal government to undertake.

Proposal: Subsections 3-303 (a), (b), (c), and (d) should be modified as follows:

- (a) Delete this subsection entirely.
- (b) Delete the requirement to prepare a cross-cutting budget.
- (c) Delete the second sentence of this subsection.
- (d) Delete the word "ten."

Scope: CPSC already focuses its priorities and efforts on protecting children from injury and death. We endorse an Executive Order to help advance children's health and safety issues government-wide, and would recommend that the CPSC adhere to its terms. However, it would be inappropriate, for example, to alter an independent agency's statutory rule making requirements through an Executive Order.² Indeed, the administration implicitly recognized this principle in E.O. 12866, which exempts independent agencies from its provisions that directly affect an agency's regulatory authority (see E.O. 12866, sec. 6), and requires those agencies only to prepare a "regulatory plan" and "regulatory agenda." (E.O. 12866, sec. 4(b) and (c).) Similarly, we believe that CPSC should be part of any Interagency Working Group that is created and submit research proposals for consideration, but that CPSC should otherwise be exempt from the draft Executive Order's requirements.

Proposal: The following language, quoted directly from E.O. 12866, should replace the definition of "federal agency" in section 2-201:

"Agency," unless otherwise indicated, 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, as defined in 44 U.S.C. 3502[(5)]."³

²As the Supreme Court has held, an independent agency

"cannot in any proper sense be characterized as an arm or an eye of the executive. Its duties are performed without executive leave and, in the contemplation of [its enabling] statute, must be free from executive control." Humphrey's v. United States, 55 S.Ct. 869, 874 (1935).

³ Since the issuance of E.O. 12866, 44 U.S.C. 3502(10) has been renumbered as 44 U.S.C. 3502(5).

EXECUTIVE OFFICE OF THE PRESIDENT
COUNCIL ON ENVIRONMENTAL QUALITY

TO: BRAD

FROM: Katie McGinty Robert Kapla

DATE: 1/31/97

FAX: _____

Number of pages including cover: 18

COMMENTS: Children's Health EO comments



PHONE (202) 456-6224 FAX: (202) 456-2710
OLD EXECUTIVE OFFICE BUILDING, ROOM 360
WASHINGTON, D.C. 20501



U. S. Department of Housing and Urban Development
Washington, D.C. 20410

Office of Lead Hazard Control
202-755-1785
202-755-1000 (fax)

January 31, 1997

MEMORANDUM

TO: Bradley Campbell, CEQ (fax: 456-0753)
Mack Reed, OMB (fax: 395-7294)
Gury Gury, HPA (fax: 260-3684)

FROM: Dave Jacobs *DJ*

SUBJECT: Comments on Children's Health Executive Order

Thank you for the opportunity to comment on the Draft Executive Order dated January 30, 1997 (1 pm draft). I apologize for our tardiness in getting these to you. In the future, please include the following names and fax numbers on your list of principal contacts for HUD:

Dave Jacobs (HUD OLHC)	voice: 202-755-4973 fax: 202-755-1000
John Kennedy (HUD OGC)	voice: 202-708-2203 fax: 202-708-5698
Camille Acevedo (HUD/OGC)	voice: 202-708-3055 fax: 202-401-0349

This will facilitate a more rapid response from us in the future. Please note that Bruce Katz is no longer at HUD.

The comments are shown in the order in which they appear in the draft, not in priority.

p. 1, first bullet: Add "neurological" to the body systems listed here. Neurological effects control behavior, intelligence, learning acuity and a host of other important outcomes. Furthermore, a number of toxicants are known to affect this system (e.g. lead).

p. 1, second bullet: Children may also be at increased risk due to differences in exposure pathways, such as higher hand-to-mouth activity and other mouthing activity. Pica (the ingestion of non-food items) has been shown to occur at far higher rates in children than in adults in a number of tracer and observational studies.

p. 2, second paragraph: There should be a discussion about how coordinating the federal response to children's issues will result in increased efficiencies in getting needed protection to children at risk, avoid duplication, etc.

p. 2, section 2. The definition of "significant regulatory action" used here leaves it unclear as

to whether this Executive Order covers only environmental, health, and safety regulations (as indicated later in section 6) or also includes other regulations. For example, would proposed housing regulations also be covered?

p. 3, section 3-302. The IWG should include HUD. HUD has conducted significant research and programmatic activity and has regulatory authority in the following areas which affect children's health and safety:

- Fatherhood stabilization in at-risk communities
- Lead poisoning prevention and control of lead-based paint hazards in private and federally-assisted housing
- Childhood immunization campaigns

Of course, our housing and community development programs also have much to do with children's well-being. A list of research projects we have completed is available at your request.

p. 5, section 6. We are concerned that this section as currently drafted is unnecessarily broad. When implemented, the requirements could become either a meaningless "boilerplate" exercise or impose open-ended analytical duties. For example, the requirement to assess "...feasible alternatives to the proposed regulation..." could require analysis of a dozen or more policy alternatives with little payoff in improved decisionmaking. It could also result in a simplistic analysis that the E.O. doesn't cover a particular regulation without a serious assessment of children's interests. Both outcomes are undesirable and at odds with the spirit of the order. We suggest that the section be redrafted to more tightly target rules which could conceivably affect children (not just environmental, health or safety regulations) and somehow put a limit on the number and scope of regulatory alternatives to be analyzed for a proposed rule.

Thanks again for the opportunity to comment. We look forward to reviewing the next draft.

Office of General Counsel
 U.S. Department of Transportation
 400 Seventh Street, S.W.
 C-40, Room 10100
 Washington, D.C. 20590
 Telephone: (202)366-4687
 Telefax: (202)366-7153

This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, and exempt from disclosure under applicable law. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution, or copying of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately by telephone, and return the original message to us at the above address via the U.S. Postal Service. Thank you.

TO: Mr. Mac Reed FROM: Jane DeCell

FAX #: OMB & C

Number of pages (including this page)	2
DATE AND TIME	1/31/97 - 1:20
DATE COMMENTS / RESPONSE (IF ANY) ARE DUE	-

Remarks: E.O. "Protection of Children"

1. Please add Transportation to list of agencies on page 3.
2. Should a bullet be added re safety risks to children in transportation (passengers, pedestrians, bicyclists).

Jane DeCell

- (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;
- (b) Create a serious inconsistency or otherwise interfere with an action planned or taken by another agency;
- (c) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
- (d) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

[NOTE: 2-202 is taken verbatim from EO 12866]

Section 3. Children's Environmental Health IWG.

3-301. Within 60 days of the signing of this order, there shall be established an interagency working group (IWG) on Children's Health IWG, which shall have general oversight of the implementation of this order.

3-302. The IWG 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, health, or safety hazards, or whose activities may substantially affect such hazards, or which conducts scientific or medical research related to such risks or hazards. Member agencies shall include, but are not limited to, the Consumer Product Safety Commission (CPSC); the Council on Environmental Quality (CEQ); the Department of Agriculture (USDA); 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 Department of Justice (DOJ); the Domestic Policy Council (DPC); the Environmental Protection Agency (EPA); the Office of Management and Budget (OMB); and the Office of Science and Technology Policy (OSTP),

Department of Transportation (DOT)
3-303. The IWG shall develop a coordinated Federal strategy for Children's Health and Safety, to 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, including steps to implement the plan for the consolidated research database developed 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.



DEPARTMENT OF THE TREASURY
WASHINGTON

OFFICE OF THE ASSOCIATE GENERAL COUNSEL
(LEGISLATION, LITIGATION & REGULATION)

1500 PENNSYLVANIA AVENUE, N.W.
ROOM 1417
WASHINGTON, D.C. 20220

FAX: (202) 622-1188 VOICE: (202) 622-0650

DATE: January 31, 1997 PAGES TO FOLLOW: 2

TO:	Mac Read	FAX:	_____
TO:	_____	FAX:	_____
TO:	_____	FAX:	_____
TO:	_____	FAX:	_____

FROM: Karen Dorsey

SUBJECT: Draft Executive Order: Protection of Children

COMMENTS/SPECIAL INSTRUCTIONS

See 2 pages attached.

**TREASURY COMMENTS RE PROPOSED EXECUTIVE ORDER
PROTECTION OF CHILDREN IN FEDERAL ENVIRONMENTAL,
HEALTH AND SAFETY ACTIONS**

Comments from the Office of the Assistant Secretary (Economic Policy):

EPA has proposed a Children's Environmental Health Executive Order, designed to "establish a coordinated federal strategy for the protection of children from the risks of exposure to toxic pollutants and other environmental hazards." Obviously the goal of the order is laudable. It is likely, however, that it would cause agencies to over-regulate risks to children's health, even though the resources wasted in doing so could be more effectively used to help children (e.g., the Center for Disease Control says that 90% of the environmental risks faced by children are related to poverty; resources that reduce poverty would likely be more effective at reducing environmental risk). We recommend the EO be substantially redrafted before it is approved.

The structure of the proposed EO raises the following potential problems:

- ◆ Section 1-102 requires the head of each federal agency to "ensure that the potential impacts upon children of environmental, health, or safety hazards arising from or related to the activities of that agency are considered and addressed by that agency to fullest extent permitted by that agency's statutory authority." In other words, an agency's efforts are limited only by statute, not by whether efforts bear positive net benefits.
- ◆ Section 2-202 defines a "significant regulatory action," for which agencies must address risks to children. It is unclear how many actions would be affected by the order. If it is large, and, as I would expect, the order results in excessive regulation, the potential costs will also be large.
- ◆ Section 6-601 mandates agencies to:
 - (a) Evaluate whether a proposed regulatory action addresses an area in which children may be at greater risk than the general population.
 - (b) Assess potentially feasible alternative actions that may be more protective of children.
 - (c) Explain why the proposed regulatory action is preferable to the identified potential alternatives.

These steps have two possible outcomes:

- (1) The agency would do a reasoned cost-benefit analysis and choose the action with highest net benefit. In this case the agency could appear insensitive to children's health, placing at least an implicit—and potentially explicit—value on the life of a child.
- (2) To avoid appearing insensitive, the agency would choose an option that was overly protective of children, causing excessive regulatory burden.

We believe the latter outcome is more likely. At the very least, the business community will be wary of overprotectiveness, especially in light of the recent proposed rules pursuant to the Clean

Air Act on ozone and particulate matter concentrations. Also, the purpose of step (a) is unclear. If an agency determines that there is no differential risk to children, does that obviate the need to perform steps (b) and (c)? Why do we only care about relative risk?



FAX TRANSMITTAL

DATE: 1-31-97

TIME: 2:40

TO:

Max Reed
OMB

FROM: GERALDINE BROADWAY
USDA, OBPA RM 118-E

TOTAL NUMBER OF PAGES INCLUDING THIS COVER SHEET: 7

RECIPIENT'S FAX NO.:

RECIPIENT'S TELEPHONE NO.:

COMMENTS:

ATTACHED ARE THE DEPARTMENT'S COMMENTS
ON THE ATTACHED PROPOSED EXECUTIVE
ORDER. IF YOU HAVE ANY QUESTIONS OR
NEED CLARIFICATIONS, PLEASE LET US KNOW

Thank you

NOTE: IF YOU DON'T RECEIVE ALL OF THE PAGES PLEASE CALL AS SOON AS POSSIBLE

OUR TELEPHONE NO.: (202) 720-1272

OUR FAX NO.: (202) 690-3673

DISCUSSION DRAFT - DO NOT CITE OR RELEASE

**PROTECTION OF CHILDREN
IN FEDERAL ENVIRONMENTAL, HEALTH, AND SAFETY ACTIONS**

America's children are this country's future. Preparing our children for the 21st century is among our most important national priorities. To fulfill this task we must recognize that America's children face significant and unique threats from an array of hazards. A growing body of scientific knowledge demonstrates that children are particularly at risk from environmental hazards:

- Children's immunological, digestive and other bodily systems are still developing, making them more susceptible to toxic pollutants and other environmental hazards;
- 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;
- Children are less able than adults to recognize and to protect themselves from exposure to toxic pollutants and other environmental hazards, and
- Children face potential exposures to toxic pollutants over their entire lifetime, with the possibility of more significant health impacts.

lot clear

then what is when?

Does this duplicate and bulk?

Our experience tells us that children have different needs when we act to protect health and safety:

- Children's size and weight can affect how well they are protected by safety features;
- Children have activity patterns that are different from those of adults, which affects their exposure to health and safety risks; and
- Children are less able to protect themselves from risk, and less responsive to warning regimes.

While responsible Federal agencies consider the effect of their work on children, existing standards were derived in many instances principally from data on adults. The array and complexity of environmental, health, and safety 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 and safety.

by
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+ several
H.A.C.C.P.

Smoking

Foodborne illness

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, accounting for children in the development of new standards for passive restraints in cars, and taking administrative action to protect children from asbestos, 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, health, and safety hazards, and apply its resources, including its scientific research capabilities, in a coordinated and efficient manner to address these threats to children.

1490

Only by tailoring governmental actions, including the setting of health and safety standards, to recognize and address the oftentimes greater impact that environmental pollutants and other health and safety hazards 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, health, and safety 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, health, and safety 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, health, and safety 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, health, or safety 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.

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.

2-202. Significant regulatory action means any regulatory action 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;
- (b) Create a serious inconsistency or otherwise interfere with an action planned or taken by another agency;
- (c) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
- (d) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

[NOTE: 2-202 is taken verbatim from EO 12866]

Section 3. Children's Environmental Health IWG.

Environmental

3-301. Within 60 days of the signing of this order, there shall be established an interagency working group ~~(IWG)~~ ^{entitled the} on Children's Health ~~(IWG)~~, which shall have general oversight of the implementation of this order.

3-302. The IWG 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, health, or safety hazards, or whose activities may substantially affect such hazards, or which conducts scientific or medical research related to such risks or hazards. Member agencies shall include, but are not limited to, the Consumer Product Safety Commission (CPSC); the Council on Environmental Quality (CEQ); the Department of Agriculture (USDA); 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 Department of Justice (DOJ); the Domestic Policy Council (DPC); the Environmental Protection Agency (EPA); the Office of Management and Budget (OMB); and the Office of Science and Technology Policy (OSTP).

*DOJ
+
DOE
should
be
included.*

3-303. The IWG shall develop a coordinated Federal strategy for Children's Health and Safety, to 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, including steps to implement the plan for the consolidated research database developed pursuant to section 4 of this order, ~~and a program of research and development~~ ^{responsibilities}. 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.

*Delete
"budget"
clause*



academic, and non-profit sectors.

- (c) Recommendations 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 IWG shall publish a joint pamphlet for distribution to families assessing children's environmental, health, or safety threats, and providing practical tips for family protection and additional sources of governmental information.
- (d) An identification of ~~the~~ high-priority initiatives for the Federal government to undertake in advancing protection of children's health and safety.
- (e) A statement regarding the desirability of new legislation to ensure that the purposes of this Executive Order are carried out. This is unclear.

informed

*Delete
by 10/1/97?*



3-304. The IWG 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 IWG may establish subcommittees and working groups as appropriate to assist the IWG in carrying out its obligations and responsibilities under this order.

3-306. The Administrator of the Environmental Protection Agency shall serve as interim chair of the IWG with responsibility for arranging the first meeting. At the first meeting, the IWG shall elect a permanent chair, who will serve for a period of one year. Subsequent chairs shall be elected by the IWG to serve for one-year terms, with no one member agency holding the chairmanship of the IWG for more than two consecutive one-year periods.

3-307. The IWG shall exist for a period of four years. At least six months prior to the expiration of that period, the member agencies shall assess the need for continuation of the IWG or its functions, and make appropriate recommendations to the President.

Section 4. Research Coordination and Integration

4-401. Within six months of the date of signature of this order, the White House Office of Science and Technology Policy and the National Science and Technology Committee shall present to the IWG 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 and infants resulting from exposure to toxic pollutants or other environmental, health, or safety hazards. This plan shall include recommendations to ensure that the activities of the IWG and other requirements of this Executive order are fully integrated with, and not duplicative of, other current or planned initiatives with respect to children's health and safety.

4-402. The proposed plan shall promote the submission of information on academic

and other private research for inclusion in the data base.

4-403. The plan shall include provisions to ensure that the consolidated research data base is available to the public, to the scientific and academic communities, and to all Federal agencies.

Section 5. Data Needs

5-501. Annual Report on Data Needs. The head of each agency subject to this Executive Order shall present an annual report to the IWC on research, data, or other information that should be developed to enhance the agency's ability to understand, analyze, and respond to environmental, health, and safety risks to children. This report shall include particular data needs that have been identified in the course of the agency's programs and activities, and shall be provided to the White House Office of Science and Technology Policy and the National Science and Technology Committee for consideration in establishing research priorities.

Section 6. Agency environmental, health, or safety regulations.

6-601. For each significant regulatory action addressing the environment, health, or safety, each agency shall provide the following information, developed as part of the agency's decisionmaking process (unless prohibited by law):

- (a) An evaluation of whether the proposed regulatory action addresses an area in which children may be at greater risk than the general population;
- (b) An assessment of potentially effective and reasonably feasible alternatives to the proposed regulatory action that have been identified by the agency or the public and that may be more protective of children; and
- (c) An explanation of why the proposed regulatory action is preferable to the identified potential alternative(s).

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

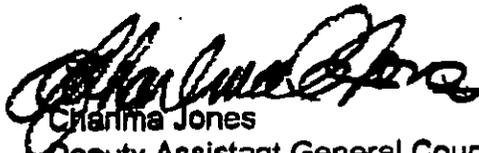
January 31, 1997

To: Mac Reed
OMB

From: Department of Veterans Affairs

Subject: Proposed Executive Order Entitled "Protection of Children in Federal Environmental, Health, and Safety Actions"

As relayed on my voice mail to you on this date, the Department of Veterans Affairs has concerns about the proposed Executive Order (EO) because the vagueness and ambiguity of the requirements makes it difficult to determine applicability. For example, the term "potential impacts" needs to be clarified in such a way to better define and/or limit when a federal agency must consider the effect of what it does on the health and safety of children. The definition of "significant regulatory action" should be clarified to exclude regulatory actions which are unlikely to affect the health and safety of children. The annual reporting requirement in Section 5-501 should be discretionary so that a report will not be required if an agency determines that there is nothing to report. It is also unclear what impact the proposed EO will have on an agency's budget for research or the degree to which the EO will impact an agency's contractual relations.



Charima Jones
Deputy Assistant General Counsel
273-8615

395-7294



UNITED STATES DEPARTMENT OF EDUCATION
OFFICE OF THE GENERAL COUNSEL

Division of Legislative Counsel
(Telephone # - 401-8313)

Telefax Transmittal Sheet
(Telefax # - 401-3391)

TO: Mac Reed
FROM: Jack Kristy
DATE/TIME: 1/31
PAGES SENT (including transmittal) 2
COMMENTS:

Re EPA's draft Executive Order ("Protection of Children in Federal Environmental, Health, and Safety Actions"),
Ed:

- (1) offers the attached comment (p.5);
- (2) generally defers to more affected agencies; and
- (3) does not understand the necessity (or wisdom) of the absurdly short timeframe for review and comments

JAN-30-97 19:25 FROM:OMB

ID.

and other private research for inclusion in the data base.

4-403. The plan shall include provisions to ensure that the consolidated research data base is available to the public, to the scientific and academic communities, and to all Federal agencies.

When + they all? Why should agencies that don't share their mission w/ required to submit annual reports?

Section 5. Data Needs

5-501. Annual Report on Data Needs The head of each agency subject to this Executive Order shall present an annual report to the IWG on research, data, or other information that should be developed to enhance the agency's ability to understand, analyze, and respond to environmental, health, and safety risks to children. This report shall include particular data needs that have been identified in the course of the agency's programs and activities, and shall be provided to the White House Office of Science and Technology Policy and the National Science and Technology Committee for consideration in establishing research priorities.

Section 6. Agency environmental, health, or safety regulations.

6-601. For each significant regulatory action addressing the environment, health, or safety, each agency shall provide the following information, developed as part of the agency's decisionmaking process (unless prohibited by law):

- (a) An evaluation of whether the proposed regulatory action addresses an area in which children may be at greater risk than the general population;
- (b) An assessment of potentially effective and reasonably feasible alternatives to the proposed regulatory action that have been identified by the agency or the public and that may be more protective of children; and
- (c) An explanation of why the proposed regulatory action is preferable to the identified potential alternative(s).

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



U.S. CONSUMER PRODUCT SAFETY COMMISSION

WASHINGTON, D.C. 20207

Fax Message Cover Sheet

DATE: 1/31/97 TIME: 5pm

FAX TO: Name: Brad Campbell

Fax Number: (202) 456-0753

Voice Phone Number: _____

FROM: Office of the Executive Director

Name: Pamela Gilbert

Voice Phone Number: (301) 504-0550

Fax Number: (301) 504-0121

Subject: See you Monday

Number of Pages to follow: 3



United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

Office of the Executive Director

MEMORANDUM

DATE: January 31, 1997

TO : Brad Campbell
Associate Director
Council on Environmental Quality

Mac Reed
Office of the General Counsel
Executive Office of the President
Office of Management and Budget

FROM : Pamela Gilbert *PG*
Executive Director

SUBJECT: CPSC Staff Comments on 1/30/97 Draft of the Children's Health and Safety Executive Order¹

We want to reiterate that, as an agency with no greater priority than protecting the health and safety of children, we strongly support the stated intent of the draft Executive Order -- to establish a "national policy to protect the health of American children from environmental, health and safety hazards." We had a number of serious concerns about the previous draft of this Executive Order, and we are pleased to see many of the changes that have been made to address those concerns.

This memo outlines our most serious remaining concerns with the contents of the current draft Order. We also anticipate that we may have more comments, questions, and recommendations once we have reviewed the comments of other participating agencies. Finally, we are still reviewing the Preamble to the draft Order, and may have further comments after that review is completed.

Section 1-102: This section is overly prescriptive and could arguably require agencies to spend unlimited resources to address a particular hazard, unless prohibited by statute.

Proposal: Section 1-102 should be modified to read, "The head of each Federal agency shall ensure that the potential impacts upon children of environmental,

¹This memorandum does not necessarily reflect the views of the Commissioners.

JHN-51-71 FRI 10:57

health, or safety hazards arising from or related to the activities of that agency are considered and addressed, as appropriate, by that agency."

Section 3. Children's Health IWG

We agree that there needs to be coordination among federal agencies on children's health and safety issues, particularly in the area of research. However, as originally drafted, the Executive Order would have established a new Children's Environmental Health Council with a broad mandate that went well beyond simple coordination among agencies. CPSC staff commented that the creation of a new, cumbersome bureaucratic entity was counter to the Administration's reinvention efforts, and that its broad responsibilities could impose inappropriate burdens and mandates on member agencies. While we are pleased that the original proposal has been considerably scaled back, we still have a number of concerns about the proposed Interagency Working Group (IWG).

Sections 3-301 and 3-302. We agree with many of the comments that have been made by representatives of the Office of Information and Regulatory Affairs (OIRA) about creating a new bureaucracy to coordinate efforts among agencies. We are eager to review OIRA's written comments and recommendations to revise this proposal.

Section 3-303. We have a number of questions and concerns about the list of elements that make up the coordinated Federal strategy:

- (a) What is meant by statements of "guiding principles" and "general policy?" How would those principles and policies differ from what has already been stated in the Executive Order? We would be strongly opposed if those principles and policies included specific directions regarding scientific or technical assessments done by individual agencies.

Isn't it redundant to require a statement of "targeted annual priorities" in this subsection when subsection (d) lists the same requirement? How would these priorities differ from those mentioned in (d)?

- (b) As an agency with a broad mandate and a very limited budget -- and no separate research budget -- we would oppose any requirement for the CPSC to contribute in any manner to a "cross-cutting budget" for conducting research.
- (c) We support a coordinated effort to reach out to, and educate the public about, health and safety risks to infants and children. However, we believe it is inappropriate to dictate the form of that outreach by requiring the publication of a pamphlet that includes specific information.
- (d) There is no reason to require the identification of a specific number (ten) of

high-priority initiatives for the Federal government to undertake.

Proposal: Subsections 3-303 (a), (b), (c), and (d) should be modified as follows:

- (a) Delete this subsection entirely.
- (b) Delete the requirement to prepare a cross-cutting budget.
- (c) Delete the second sentence of this subsection.
- (d) Delete the word "ten."

Scope: CPSC already focuses its priorities and efforts on protecting children from injury and death. We endorse an Executive Order to help advance children's health and safety issues government-wide, and would recommend that the CPSC adhere to its terms. However, it would be inappropriate, for example, to alter an independent agency's statutory rule making requirements through an Executive Order.² Indeed, the administration implicitly recognized this principle in E.O. 12866, which exempts independent agencies from its provisions that directly affect an agency's regulatory authority (see E.O. 12866, sec. 6), and requires those agencies only to prepare a "regulatory plan" and "regulatory agenda." (E.O. 12866, sec. 4(b) and (c).) Similarly, we believe that CPSC should be part of any Interagency Working Group that is created and submit research proposals for consideration, but that CPSC should otherwise be exempt from the draft Executive Order's requirements.

Proposal: The following language, quoted directly from E.O. 12866, should replace the definition of "federal agency" in section 2-201:

"Agency," unless otherwise indicated, 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, as defined in 44 U.S.C. 3502[(5)]."³

²As the Supreme Court has held, an independent agency

"cannot in any proper sense be characterized as an arm or an eye of the executive. Its duties are performed without executive leave and, in the contemplation of [its enabling] statute, must be free from executive control." Humphrey's v. United States, 55 S.Ct. 869, 874 (1935).

³ Since the issuance of E.O. 12866, 44 U.S.C. 3502(10) has been renumbered as 44 U.S.C. 3502(5).



U.S. Department of Justice

Environment and Natural Resources Division

Office of the
Deputy Assistant Attorney General

Washington, D.C. 20530

January 31, 1997

Memorandum

To: Brad Campbell, Associate Director
Council on Environmental Quality

From: Jim Simon 
Deputy Assistant Attorney General

Re: Suggested edits to Children's Health E.O.

Thank you for the opportunity to comment on the proposed Children's Health Executive Order. Following are the Department of Justice's preliminary edits and comments. We look forward to seeing another draft on Monday, and are happy to work with you or any agency on specific areas of concern. Suggestions are in bold, with explanations below. Our comments follow the order of the draft text.

Suggested Edits

1. Shorten or delete the preamble, and place the information in an accompanying memo or press release.

Some agencies have expressed concern that the preamble's emphasis on environmental hazards may confuse agencies and the public about the scope of the Executive Order. The preambulatory language could be shortened to place less emphasis on environmental hazards and clarified to provide a general statement of intent to protect children.

2. Section 1-102: Replace the phrase, "to the fullest extent permitted by that agency's statutory authority" with "to the fullest extent permitted by applicable laws."

DOJ's Office of Legal Counsel recommends this change, because other authorities exist that bind an agency, such as their regulations and of course, the Constitution.

3. Section 2-202: Tie the definition of "significant regulatory action" more closely with the purpose of the Executive

Order, the protection of children from environmental, health and safety risks. This section could read,

"Significant regulatory action means any regulatory action determined to be a significant rule for purposes of Executive Branch review under Executive Order 12866, and that addresses environmental, health, or safety risks."

Some of the language derived from the regulatory reform context does not work in the context of regulations protecting health, safety, and the environment. For example, references to "user fees" and "loan programs," which are not within the scope of the Executive Order, could cause confusion about whether they are within the scope of the Order. If the goal of the Executive Order is to protect children from environmental, health, and safety hazards, then the definition should limit the types of regulatory actions covered by the order to those that address environmental, health or safety risks.

Although this proposed edit may result in some redundancy in other parts of the Order (ie., 6-601 talks about "significant regulatory action addressing the environment, health, and safety"), it would make clear that part of the trigger for applying the Executive Order is that the action must specifically address environmental, health or safety risks.

3. Section 5-501: Limit the number of agencies required to provide an annual report to the IWG member agencies (but broaden the membership of the IWG). Thus: "The head of each agency ~~subject to this Executive Order on the IWG~~ shall present an annual report. . ."

Because the IWG is composed of agencies with responsibility for regulating environmental, health or safety hazards, or whose activities may substantially affect such hazards, it makes sense to limit the annual reporting requirement to those agencies. Otherwise, agencies with a tenuous connection to the work of the Executive Order (such as the SEC or FCC, to name a few), may be required to generate paper without much substance. The IWG, however, should be broadened to include other agencies that deal with environmental, safety, and health issues, such as DOE, Commerce (NOAA, NMFS), DOD (the Army Corps of Engineers issues wetlands permits), HUD, DOI, DOL, and DOT.

4. Section 6-601(a) should be incorporated as part of the trigger for the requirements in 6-601(b) and (c). In addition, the language can be sharpened to clarify the covered regulatory actions, and the language, "unless prohibited by law," can be narrowed. Thus, Section 6-601 could read:

"For each significant regulatory action addressing the environment, health, or safety, each agency shall provide

~~the following information, developed, as part of the agency's decisionmaking process (unless prohibited by law), and to the extent permitted by applicable law, evaluate whether the proposed regulatory action addresses environmental, health, or safety risks to children that may be greater than those faced by the general population. If an agency determines this to be the case, it shall:~~

~~(a) An evaluation of whether the proposed regulatory action addresses an area in which children may be at greater risk than the general population;~~

~~(b) (a) An assessment of ~~Assess~~ potentially effective and reasonably feasible alternatives to the proposed regulatory action that have been identified by the agency or the public and that may be more protective of children; and~~

~~(c) (b) An explanation of ~~Explain~~ why the proposed regulatory action is preferable to the identified potential alternative(s)."~~

We propose incorporating Section 6-601(a) into the triggering clause, because a proposed regulatory action not involving environmental, health and safety risks that are greater for children should not be subject to an analysis of whether other regulatory actions may be more protective of children. The example posed in today's conference call -- an FAA rule governing de-icing of airplanes -- is a good example of a safety rule that would not need the additional analysis, because its protective effect is the same for all passengers. This proposed change does not make Section 6 any "weaker." Instead, it clarifies that broad rules not implicating specific environmental, health, and safety risks to children will not be swept into the analytical framework. This language is "narrowly tailored" to the purpose of the Executive Order.

In addition, we suggest changing the language of 6-601(a), which vaguely states that agencies should evaluate whether a proposed action "addresses an area in which children may be at a greater risk," to requiring agencies "to evaluate whether the proposed regulatory action addresses environmental, health, or safety risks to children that may be greater than those faced by the general population." This language is more precise and clarifies the types of regulations that are covered by the E.O.

In addition, we suggest changing the vague phrase, "each agency shall provide the following information," because it raises questions about what "provide" means, and to whom the information must be provided. Instead, this section requires an agency to "evaluate," "assess," and "explain." In addition to eliminating the vagueness, these words are action-oriented and are more appropriate for an Executive Order directing agencies to

fulfill its mandates (rather than simply requiring agencies to provide information about how well it is fulfilling the Order's mandates).

5. Section 7-701: The disclaimer should read, "This order is intended only for the internal management of the Executive Branch. This order is not intended, and should not be construed"

As we mentioned on Thursday's conference call, case law makes clear that the Executive Order itself cannot be privately enforced unless the order was intended to allow such private enforcement. See, e.g., Zhang v. Slattery, 55 F.3d 732, 748 (2d Cir. 1995); Chen Zhou Chai v. Carroll, 48 F.3d 1331, 1339 (4th Cir. 1995); Environmental Defense Fund v. Massey, 986 F.2d 528, 530 (D.C. Cir. 1993); Women's Equity Action League v. Cavazos, 906 F.2d 742, 750 (D.C. Cir. 1990) (Ruth Bader Ginsburg, Circuit Judge); Michigan v. Thomas, 805 F.2d 176, 187 (6th Cir. 1986); see also 5 Op. Off. Legal Counsel 59, 67-68 (1981) (opining that an executive order that "states that [the order] is not intended to create any rights or benefits enforceable by a party to litigation against the United States" does not permit "direct judicial review of an agency's compliance with the order").

In most cases, the language on "internal management" was found in the Executive Order, and some courts specifically point to it in holding that an Executive Order does not create an enforceable right. See Chen Zhou Chai v. Carroll, 48 F.3d 1331, 1339; Meyer v. Bush, 981 F.2d 1288, 1296 n.8 (D.C. Cir. 1993) (suggesting that, where an executive order states that "its purpose was only for internal management and that it created no private rights", "it is doubtful that [the order] had any legal significance"). Many recent Executive Orders include the "internal management" phrase. See, e.g., E.O. 13007, 61 Fed. Reg. 26771 (1996) (directing agencies to accommodate access to and ceremonial use of Indian sacred sites); E.O. 12898, 59 Fed. Reg. 7629 (1994) (directing agencies to identify and address disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority and low-income populations); E.O. 12807, 57 Fed. Reg. 23134 (1992) (directing Coast Guard to intercept Haitian refugees at sea and return them to Haiti). Thus, we suggest including this language as well to alleviate agencies' concerns about litigation risk.

We note that to the extent agencies issue rules pursuant to lawmaking authority delegated by Congress to implement the E.O., those rules may have the force of law and be judicially enforceable. Also, any information considered by the agency in compliance with the E.O. during the rulemaking process would likely become part of the rulemaking record, and could be

subject to a challenge under the "arbitrary and capricious" standard.

6. Delete Section 7-703 (that says, "This order shall be effective immediately and shall continue to be in effect until revoked."

DOJ's Office of Legal Counsel recommends deleting this section from the Order, because it is obvious and unnecessary. The presence of this phrase raises questions about why it is needed.

Stylistic/Minor Edits

1. Section 3-301: Replace "Within 60 days of the signing of this order," with "Within 60 days of the date of this order."

2. Section 3-302: Replace "The IWG shall be comprised of representatives . . ." with "The IWG shall be composed of representatives . . ."

3. Section 4-401: Replace "Within six months of the date of signature of this order," with "Within six months of the date of this order."

cc: Gary Guzy, Bob Dreher (EPA)

02-21-97 03:41PM

FROM ODPHP/DHHS

TO 94567028

P002/002

SENT BY:NIEHS RTP

2-21-97 12:42PM

NIEHS-

202 205 9478:# 2/ 2

Environment includes:

- **Industrial chemicals**
- **Agricultural chemicals**
- **Physical agents (e.g., heat, radiation)**
- **By-products of combustion and industrial processes**
- **Foods and nutrients**
- **Prescription drugs**
- **Lifestyle choices and substance abuse**
- **Social and economic factors**

From HHS

*BRAD
6-0753*

THE WHITE HOUSE
WASHINGTON

June 21, 1996

MEMORANDUM FOR T.J. GLAUTHIER

FROM: Carol Rasco 
SUBJECT: Family Right to Know Initiative

The Family Right to Know Initiative is a very positive concept that has the potential to fill an important void in the current protection of children's health from environmental risks. When parents and families know about the unique risks to children they can use that information to make wise choices. Responsible decisions by parents can have an aggregate benefit today and in the future.

In framing this concept we have agreed to a commitment to work with parents, scientists, the business community, and others to achieve the goals of getting better information to families. As we work with the stakeholders we can build on the concept of a family's right to know, and decide whether legislation is or is not needed to achieve our goals. As the Administration moves forward we should continue to emphasize our belief that we can achieve our goals in a common sense, cost effective way. That emphasis is needed to respond to concerns that we will put into place unnecessarily expensive approaches.

I plan to continue to be involved in this initiative; please contact Diane Regas of my staff with new information as it arises.

THE WHITE HOUSE
WASHINGTON

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I plan to continue to be involved in this initiative; please contact Diane Regas of my staff with new information as it arises.

I found this
last night
: interesting?
JB



Helpline Questions & Answers from Alert

Cal/OSHA Corner

Federal OSHA to Look at Prop. 65 as Part of Hazard Communication

○ *Is federal OSHA holding hearings on the California Hazard Communication Program?*

Yes. OSHA announced in the September 13 *Federal Register* a 60-day comment period on a "supplement to the California occupational safety and health plan." The request "concerns the state's adoption of a hazard communication standard, which incorporates provisions of the Safe Drinking Water and Toxic Enforcement Act, also called Proposition 65."

The Proposition 65 "clear and reasonable warning" requirement was included in Title 8, Section 5194, Hazard Communication Program, by court order in 1992. So far, OSHA has failed to review this change to the state plan as required in the OSHA Act of 1970 to determine if it is "at least as effective as" the federal program.

The inclusion of Proposition 65 requirements in the state Hazard Communication Program has been more than worrisome to California manufacturers and employers and to manufacturers in other states as well.

OSHA officials have raised serious concerns about the enforcement mechanism and the potential burden on interstate commerce that Proposition 65 represents. These concerns have gone unanswered and the final determination and approval or rejection of the Proposition 65 requirements in the California Hazard Communication Program have languished at OSHA.

The U.S. Senate Appropriations Committee sent a letter to Secretary of Labor Robert Reich on September 20, directing OSHA to "proceed expeditiously to seek formal comment and issue a final decision of the California amendment by January 1, 1997."

The original date for the end of the comment period was November 12. However, OSHA received more than 45 requests for an extension of the comment period. Noting that approval or rejection of the standard was due to Congress by January 1, 1997, OSHA extended the comment period by two weeks, until November 26.

Should you wish to comment to OSHA on this subject, send it to: Docket Office (Docket T-032), Room N-2625, U.S. Department of Labor, OSHA, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

[Home](#)

In what appears to be a boost to Turco, Mason stated that, "[i]n responding to these issues. . . the appropriate standard governing the adequacy" of the warning will be 8 CCR §5194(g) [HAZCOM], and not 22 CCR §12601(a) [Prop 65].

Coalition of Manufacturers for the Responsible Implementation of Prop 65 v. Stratton is an action filed in U.S. District Court for the Southern District of California. It seeks declaratory relief and an injunction against enforcement of Prop 65 for products subject to the federal Hazardous Materials Transportation Act and federal Occupational Safety & Health Act. The suit argues that Prop 65 is inconsistent with these federal acts, and cannot be implemented without federal approval. The suit further alleges that Prop 65 constitutes an undue burden on interstate commerce for products subject to these acts.

The Coalition suit is currently in the discovery process, with the state seeking information regarding the identity of the members of the Coalition. It has been joined co-plaintiff National Paint & Coatings Association.

If you have any information you would like to include on the current development page, or if you have any written materials you would like to post to (or link from) this site, please contact jmargulies@earthlink.net

The Prop 65 Page

Welcome to The Prop 65 Page!

This site provides background and current information on Proposition 65, California's Safe Drinking Water and Toxic Enforcement Act of 1986. Prop 65 requires warnings for exposures to carcinogens and reproductive toxins, and prohibits the discharge of these chemicals into drinking water.

This page is updated on a semi-regular basis (about once a month), to include the most recent developments on the legislative, regulatory, and litigation fronts. If you are aware of any developments you think should be included, e-mail to jmargulies@earthlink.net.



We are now offering e-mail notification when this site is updated. Go to our [e-mail page](#) and sign up.

We welcome any comments you have on **The Prop 65 Page** and are always looking for ways in which we can improve it for you.

The Prop 65 Page has been developed and is brought to you by Jeffrey B. Margulies of the Environmental Department at Haight, Brown & Bonesteel, one of the leading law firms providing Proposition 65 representation to companies throughout the United States. In addition to assisting clients in compliance with the Act, we have successfully negotiated settlements of enforcement actions brought by both the California Attorney General and private citizen enforcers. We are currently representing a consumer products manufacturer challenging the statute on federal preemption grounds in the California Court of Appeal, and the National Paint & Coatings Association, seeking declaratory relief against private enforcement of the Act under the constitutional separation of powers provision.

For further information, contact

jmargulies@earthlink.net

this is
the law
firm
"reping"
the coalition
of Man.....

The Prop 65 Page

Prop 65 Regulatory Update--1/4/97

NEW! An expert panel called by state legislation to review the risk assessment practices of OEHHA issued its report on December 3, 1996. The report is entitled A Review of the California Environmental Protection Agency's Risk Assessment Practices, Policies and Guidelines, and is available for download directly from OEHHA as compressed Word 7 and Excel 7 files. The report finds that OEHHA's practices are generally of good quality, but makes some specific recommendations for harmonization between state and federal governments and strengthening the peer review process.

Governor Wilson's Executive Order of December 10, 1996, required Cal/EPA to implement most of the recommendations. Notably absent was any mention of the RAAC's recommendation that the 1000-fold safety factor for reproductive toxins be replaced with a scientific basis. View the Cal/EPA News Release, letter from Governor Wilson to Dr. Seiber, head of the RAAC, and Executive Order W-137-96.

NEW! In a Special Report in the November 15, 1996 edition of *California Environmental Insider*, OEHHA Director Richard A. Becker, Ph.D., D.A.B.T., offered his views on OEHHA's past efforts and future plans for Prop 65. "Using Sound Science and Common Sense to Improve Proposition 65 Implementation," reprinted with permission from *CEI*.

NEW! OEHHA counsel announced at a December 4, 1996 DART Committee meeting, that OEHHA will not pursue listing of chemicals under Prop 65 solely on the basis of potential post-natal effects. This potential regulation was first raised by the DART in May 1995, and will still be an area of concern under other substantive laws administered by OEHHA.

**
The US Occupational Safety and Health Administration announced in the Federal Register on September 13, 1996, that it was seeking comments on whether California's implementation of Prop 65 in the state hazard communication standard should be approved. This action was in response to a petition filed by The Coalition for the Responsible Administration of Prop 65. OSHA seeks comments [closed 11/12] on the following issues:

Is the California standard at least as effective as the federal standard? Because the incorporation of Proposition 65 imposes requirements that go beyond those in the federal standard, it might be viewed as more effective than the federal standard. However, some persons say that the different warnings required by Proposition 65 for exposures not otherwise covered by the hazard communication standard make the standard less effective by engendering confusion. Questions have also been raised about whether occupational safety and health standards can be as effectively enforced by local attorneys and private parties in addition to the state occupational safety and health officials.

I will try
and locate
these results

OSHA is also seeking comment on whether the California standard:

1. is applicable to products that are distributed or used in interstate commerce;

2. if so, whether it is required by compelling local conditions; and
3. unduly burdens interstate commerce.

Individual employers and employer groups have said that manufacturers may need to have products labeled as carcinogens or reproductive toxins in California but not in other states, and must include specific language not required for products destined for other states, thus creating a burden on interstate commerce.

They also have said that private parties may create a burden on interstate commerce by subjecting out-of-state employers and suppliers to inconsistent requirements depending upon the circumstances of individual lawsuits and the settlement of those cases.

[Excerpted from OSHA Press Release USDL: 96-381, September 13, 1996.]

I will get a copy of this.

Web-available comments on the OSHA proceeding. Currently available is a comment from the Synthetic Organic Chemical Manufacturer's Association (SOCMA).

OEHHA gets busy in September and October, issuing a number of new documents.

Notice to Interested Parties (10/4/96) advises of the availability of the draft procedure for prioritizing chemicals under consideration for listing, the 11/15/96 public workshop on the prioritization procedure, the 11/15/96 forum to receive comments on draft prioritized chemicals, request for information on chemicals to be considered by the Carcinogen Identification Committee, and the 12/4/96 meeting of the Developmental and Reproductive Toxicant Identification Committee.

November 15, 1996 workshop on refinement of prioritization procedure.

OEHHA will present its revised draft procedure at this public workshop. On the notice is a preliminary list of prioritized carcinogens and reproductive toxins. OEHHA later issued a notice postponing prioritization of carbamazepine and progesterone.

Request for information on chemicals to be considered by the Carcinogen Identification Committee. This involves only three chemicals:

- 5-chloro-*ortho*-toluidine and its hydrochloride
- 2,4,5-trimethylaniline and its hydrochloride
- quinoline

December 4 meeting of the Science and Advisory Board's Developmental and Reproductive Toxicant Identification (DART) Committee. On the agenda are inorganic arsenic and cadmium. The committee will also discuss its proposed mechanism for removing chemicals from the Prop 65 list and prioritization of candidate chemicals.

Request for relevant information on other chemicals being considered for listing. Includes

A. Chemicals which may meet the criteria set forth in 22 CCR Section 12306 for listing as carcinogens via the "authoritative bodies" mechanism:

FAX TRANSMITTAL SHEET



RECEIVER TELECOPIER NUMBER: _____

TO: DIANE REGAS

FROM: FRED CISKIND

DATE: 2/18/97 TIME: 1:00

PAGE NUMBER ONE OF 2 PAGES

TRANSMITTER TELECOPIER: (202) 219-6523

ADDITIONAL COMMENTS:

ATTACHED PER YOUR DISCUSSION WITH SETH HARRIS IS OUR NOTE TO BRAD CAMPBELL WITH LANGUAGE SUGGESTIONS FOR E.O.

IF YOU HAVE QUESTIONS REGARDING THIS FAX CALL: _____

February 10, 1997

To: Bradley Campbell
From: Fred Siskind
Subject: Comments on the revised discussion draft of the Children's Environmental E.O.

While we believe the revised discussion draft of the Children's Environmental E.O. is much improved, as I noted in the voice mail I left for you on Friday, it still presents problems for DOL programs. We have developed several options that we believe would eliminate the burden for DOL without affecting the basic thrust of the E.O. As you know, our particular concern is that OSHA and MSHA focus on workplace hazards regardless of who is exposed. They do not address risk to particular demographic groups, but to all workers.

The following options are in order of our preference, with one of the first three strongly preferred to the fourth:

Option 1. Add to definitions: "Environmental, health, or safety risks include only those risks or hazards to which members of the general public regularly may be exposed."

Option 2. Add to definitions: "Federal agency includes those agencies listed as members of the IWG in Section 3-302 and such agencies as may be designated at a later date." In addition, the phrase "but are not limited to," should be stricken from Section 3-302.

Option 3. Add to definitions: Disproportionate or disproportionately affect does not include any safety or health hazard or risk that occurs in workplaces in which the regular exposure of significant numbers of children to the hazard or risk cannot reasonably be anticipated.

Option 4. Add to definitions: Disproportionate or disproportionately affect does not include any safety or health hazard or risk that occurs in workplaces in which the regular exposure of children to the hazard or risk cannot reasonably be anticipated.

If you have any questions, please call Seth Harris (219-6181) or me (219-6197).

Withdrawal/Redaction Marker

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
002. fax	Phone No. (Partial) (1 page)	02/10/1997	P6/b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Elena Kagan
OA/Box Number: 14361

FOLDER TITLE:

Kids EO [1]

2009-1006-F
ke664

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]



OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Science Division

Executive Office of the President
436 Old Executive Office Building
Washington, DC 20502

202-456-~~6027~~ 4133

202-456-6027 (FAX)

FAX TRANSMITTAL SHEET

DATE:

TO: BRADLEY CAMPBELL, Diane Resau

PHONE NUMBER: 456-6549

FAX NUMBER: 456-6546 456-7028

FROM:

Carolyn Huntoon

NUMBER OF PAGES (INCLUDING COVER SHEET): 8 + 1

One More

Brad: At Diane's request, I have worked with Duane Alexander and Lynn Goldman to try and merge more of the Children's Initiative Report with the draft Ex. Order while still maintaining emphasis on the environmental/hazard regulatory language. This is a first attempt so please give me some feedback and I'll be happy to try again.

My home phone # is P6(b)(6) and I plan to be around most of the weekend, so please call if I can help. [002]

Thanks, Carolyn

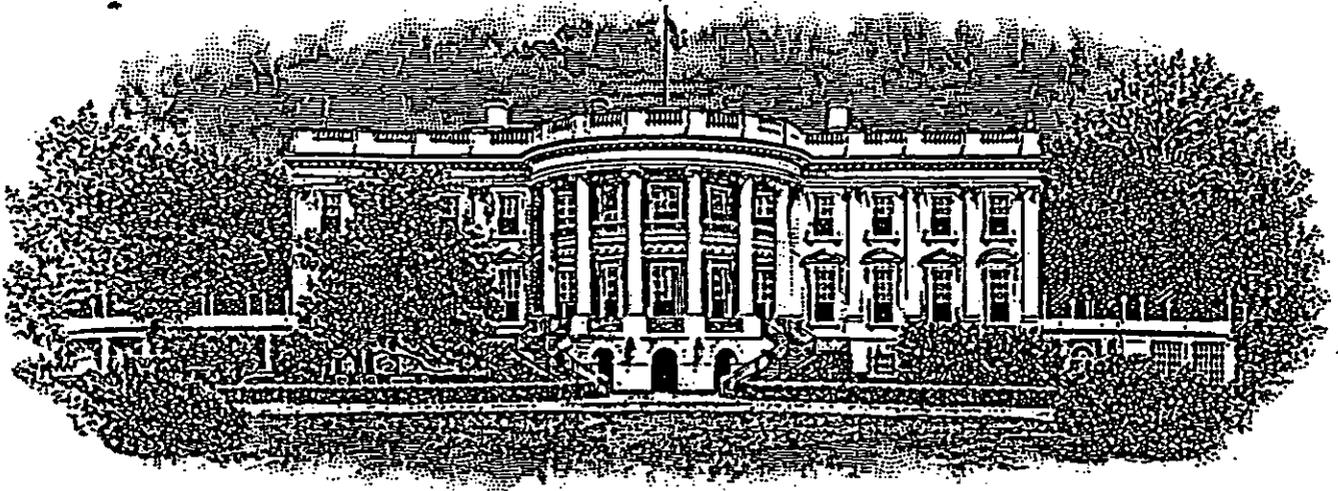
3-301. Within 60 days of the date of this order, there shall be established ^a ~~an~~ Task Force ~~interagency working group (TWG)~~ on Children's Health ^{and Safety}, which shall implement and promote the purposes of this Executive order. ^(Children's health includes developmental, mental and physical health) ~~ensuring the health, safety and well being of children~~

3-302. The ^{TF} ~~TF~~ shall be composed of representatives of Federal agencies and White House offices with responsibility for ~~the regulation of risks from toxic pollutants or other environmental, health, or safety hazards~~, or whose activities may substantially affect such hazards, or ^{related} ~~which conducts~~ scientific or medical research ~~related to such risks or hazards~~. Member agencies shall include, but are not limited to, the Consumer Product Safety Commission (CPSC); the Council on Environmental Quality (CEQ); the Department of Agriculture (USDA); the Department of Energy (DOE), 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 Department of Housing and Urban Development (IUD); the Department of Justice (DOJ); the Department of Transportation; Domestic Policy Council (DPC); the Environmental Protection Agency (EPA); the Office of Management and Budget (OMB); and the Office of Science and Technology Policy (OSTP), ^{National Science Foundation (NSF), Dept. of Education and Dept. of Defense.}

3-303. The ^{TF} ~~TF~~ shall develop a coordinated Federal strategy for Children's Health and Safety, to include at least the following elements:

- (a) ^{specific regulatory actions pertaining to environmental health and safety hazards.}
- (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 ^{children's} research agenda for the Federal government, including steps to implement the plan for ^a ~~the consolidated~~ research database developed pursuant to section 4 of this order, and ^{for a cross-cutting budget to accomplish this research.}
- (c) Recommendations for appropriate partnerships among Federal, state, 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 infants and children and in making informed consumer choices;
- (e) An identification of high-priority initiatives for the Federal government to undertake in advancing ~~protection~~ of children's health and safety.

The White House



DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

TO: Gary Guzy

FAX NUMBER: 260-3684

TELEPHONE NUMBER: _____

FROM: DIANE Regan

TELEPHONE NUMBER: _____

PAGES (INCLUDING COVER): _____

COMMENTS: Pls call when this goes out.

Lead CONTACT

We need a labor contract

White House Environmental Meeting Attendees and Contact Numbers

<u>Name</u>	<u>Office/Agency</u>	<u>Phone</u>	<u>Fax</u>
Janno Lieber	TRANSPORTATION		
KATHERINE LORRAINE	FDA	301-827-3360	301-594-6777
PAMELA BETH GILBERT	CPSC	301-504-0550 x2342 (301) 504-0121	
RON LEE MEDFORD	CPSC	301-504-0554 x2233 (301) 504-0907	
LYNN GOLDMAN	EPA OPPTS	202 260 2902	202 260 1847
JAMES AIDALA	EPA	202 260 2897	260 1847
CHERYL TATES-MACIAS	USDA	202-395-7320	202-395-4579
DAVID SHARK			
ROBERT W. HICKMOTT	EPA	260-5200	260-4046
GARY GUZY	EPA	260-7960	260-3684
BILL DINKELACHER	TREASURY	622-2350	
DALTON PAXMAN	HHS	202 205-5829	202 205-9478
Sally Katze			
MIKE FITZPATRICK	OMB	395-4852	395-3047
KATHERINE LORRAINE	FDA		
Diane Regas	WH	456 2216	456 7025
Jim Simon	DOJ	514-3370	514-0557
Bradley Campbell	CEQ/WH	456-6224	456-6546
Elyse Halstein	NEC	6-2800	6-2223
Robert Clarke	USDOR	366-2916	366-7618
Jon Kaplan	NEC	6-5350	
BARBARA WALTON	OSTP	x 6-6080	6-6025
Catherine Lorraine			
Doris Freedman	SBA	205-6568	205-6873
JASON SHOGREN	CEA	395-5012	395-6835
Carrie Jelsma	OMB	395-4727	395-5836
Bill Dinkelacker	Treasury	622-1285	622-1294



*** ACTIVITY REPORT ***

TRANSMISSION OK

TX/RX NO.	2501
CONNECTION TEL	92603684
CONNECTION ID	
START TIME	01/23 15:24
USAGE TIME	01'16
PAGES	2
RESULT	OK

THE WHITE HOUSE
WASHINGTON

January 27, 1997

MEMORANDUM TO Bruce Reed
 Elena Kagan

FROM: Diane Regas 

SUBJECT: Environmental Issues for State of the Union

There are two leading ideas for an environmental message in the State of the Union Address. This memo gives you a short background and status on each.

Protecting Kids

Background

In August the President directed federal departments to identify ways to provide better information to families about products that pose a special risk to children. Since that time, EPA has been working on a proposal to fulfill this direction. The proposal on the table has two components: first is an Executive Order that would direct federal departments to consider all information about risks to kids when developing environmental health standards, second is principles for toxics labeling legislation.

The Executive Order, the "Children's Environmental Health Executive Order" would require departments, when taking regulatory action, to make a finding either that the action protects children or that there is insufficient information to make such a determination. In addition, the draft creates a "Children's Environmental Health Council" to oversee the implementation of the Executive Order, to coordinate federal research, and, among other duties, to consult with OIRA on regulatory actions that may affect children's environmental health.

The primary conceptual questions about the Executive Order are: which federal actions should be covered; how should federal departments deal with limited information; and whether the Executive Order is consistent with the Administration's position on regulatory reform legislation. The draft text has been in circulation only a few days, and I expect that new issues will arise based on the text. (Our next interagency meeting is Tuesday, January 28.)

The second part of the proposal, principles for labeling legislation, would express the Administration's support for a requirement that manufacturers label products with information about special risks to children. This proposal is modeled on "Proposition 65" a ten year old law in California. The key to the proposal is that it does not add to government regulation of product content, instead it requires manufacturers to test products and label them

appropriately. The government's role is limited to identifying which substances are of concern, and perhaps identifying level below which labeling will not be required. Proponents of this approach argue that labeling will provide families with the tools they need to make choices among products and create a strong incentive for manufacturers to reformulate potentially unsafe products. The proposal would exempt food and drugs.

Federal agencies and White House staff have raised concerns about legislation in this arena. There is little solid data regarding the costs and benefits of a national proposal, and the California model has not been rigorously studied. (We lack data on the costs and benefits of the California law partly because companies have been very reluctant to release information about their costs.) In addition, there are difficult trade and small business implications that need to be hammered out.

Status

The Executive Order is in draft and could probably be finalized quickly if EPA generates support within the White House for that position. The process of coming to closure quickly could, however, cause us to miss some more subtle issues, and will likely lead us to draft an Order that is narrowly tailored to environmental health, rather than considering an approach that applies to all health-based regulations.

EPA has drafted about a dozen principles to support labeling legislation. While these too could be finalized for the State of the Union, the lack of detailed understanding of the policy and political implications counsel continuing the staff discussions. Both OMB and NEC have serious concerns about the need for legislation, and how to structure it most efficiently. (Recall that EPA proposed this concept at an NEC meeting in June and the proposal was tabled.)

Recommendation

The President should commit to issuing an Executive Order to ensure that federal decisions use the best information we can get to protect children, or more narrowly, children's environmental health. The interagency process to finalize the Executive Order could then be completed in coming weeks.

The discussion of legislative principles should be brought to a deputies' or principals' meeting to allow for a full airing of the issues.

American Heritage Rivers

Background

A new proposal to create a federal designation "American Heritage River" is being discussed in a process convened by CEQ. The President would announce a commitment to this idea and work some of the details, including an Executive Order, later. Currently CEQ staff is proposing that identification be based primarily on the cultural value of rivers. The implication of designation is still under discussion, but would include a call for partnerships with the private sector, federal support for local initiatives and federal steps to protect designated waters. Initially departments have raised some concerns: a designation process

will create false expectations that we can solve problems in many places; choosing waters for cultural significance conflicts with targeting environmental money to solve problems; as described, the new designation does not clearly add to current work; and we have not thought through potential political opposition.

The biggest challenge we face in making this idea work is to make designation as an American Heritage River meaningful. I am continuing to work with CEQ as they identify ways to accomplish this goal, but I remain concerned that we may not have good solutions by next week. I have attached the current iteration of this idea.

Status

CEQ staff are committed to adding enough detail to a proposal so that a decision can be made about whether to go forward next week. They envision that further detail would be developed in coming weeks.

Recommendation

There are thousands of people across the country who are working to restore enjoyment of their local waterways, and who would welcome new tools to achieve their ends. They need incentives to create jobs and revitalize rundown urban waterfronts; small grants to catalyze their work; better processes for participating in federal decisions; more information about environmental threats in their local area; and a federal commitment to work in ways that are consistent with local needs. We can do this, and we should focus the effort where people really need it--urban waterways. The current proposal, if it remains focussed on historically or culturally significant waters, is unlikely to bring these tools to communities.

White House staff should be tasked with coming up with an urban waterways initiative that contributes jobs and environmental benefits. Such an initiative could be announced in a few months.

American Heritage Rivers Initiative

America's rivers [and other waterways] are at the heart of our identity and history as a nation. They are engines of our local economies, and vital parts of the natural legacy we must preserve for generations of 21st century Americans. They have been our reference points and our sustenance from the earliest settlements on the James River through the Mississippi of Mark Twain and the bold exploits of Lewis and Clark. Today this heritage includes the splendor of natural places like the Yellowstone River, local trout streams that link generations of fishermen, avenues of commerce like the Hudson River, and urban waterfronts that have become the centerpieces of sustainable redevelopment in distressed areas left behind by the old economy.

Today, President Clinton is announcing a major Federal effort to preserve this heritage as we move to the 21st century through federal protection and through partnership with the private sector and local initiative, using the enterprise of the American spirit.

Under this initiative, the President will direct the Secretary of Interior to lead a process among federal agencies, state and local governments, community groups, and the private sector for designating American Heritage Rivers [bays and estuaries] for special protection. The Secretary will also identify candidate rivers (or sections of rivers) for the President to propose for designation.

Partnership. President Clinton is providing the leadership and the tools needed to protect our American Heritage Rivers for a new generation. The future of these rivers cannot be charted in Washington, so President Clinton is challenging states, communities, tribes, and the private sector to forge a new partnership to identify and protect American Heritage Rivers.

A call to private stewardship. President Clinton is challenging the private sector to become partners in stewardship of the rivers essential to our heritage: by protecting natural areas from harm; by designing development projects to protect heritage values; by working with local land conservancies to place idle properties along these rivers into conservation easements; and by adopting policies that go beyond requirements of the law in protecting watersheds of our American Heritage Rivers.

[Note: Tees up conservation easement announcement by DuPont on the Chester River in Maryland; would mirror CEO bully-pulpit efforts Sec. Rubin has undertaken on urban reinvestment.]

Support for Local Initiatives. The Department of the Interior will create a

process for local community groups to establish American Heritage river designations. The Federal government will make agency personnel, resources, and expertise available to support local planning and protection initiatives, particularly where local resources are being invested.

All agencies will provide assistance to these groups in seeking grants and information needed for designation and for local planning. EPA and HUD will give high priority to brownfields grant applications that are built around American Heritage Rivers. USDA will give high priority to CRP and CREP efforts that help protect water quality of American Heritage Rivers. The National Endowment for the Arts and National Endowment for the Humanities shall give special consideration to cultural and educational works that highlight riverine heritage. All agencies will develop a catalog of resources available to community groups in seeking and implementing designation as an American Heritage River.

[Note: Rollouts include targeted Brownfields Grants, CRP/CREP announcements]

A call-for comprehensive, community-oriented decisions affecting American Heritage Rivers. Federal, state, and local planning and permitting decisions affecting American Heritage Rivers often take place at different times, are made by different agencies, and address problems without regard to comprehensive management of the ecosystem or watershed. This leads to poorer decisions, and handicaps community groups with limited resources to engage in multiple government processes. President Clinton is directing federal agencies to pilot a process of synchronized permitting and decisionmaking along American Heritage Rivers, so that comprehensive planning and community participation result in better conservation of these natural and cultural assets.

Right to know about American Heritage Rivers. Community organizations often know too little about the quality and vulnerability of rivers that lie at the center of their history and future as a community. President Clinton is directing EPA in consultation with USGS and other agencies, to empower communities with information and training to that will give communities access to information about the quality and vulnerability of their local rivers.

[Note: This is an effort distinct from Kalamazoo that EPA's Office of Water already has underway.]

Protection. President Clinton is directing cabinet departments and other agencies to develop a strategy to protect American Heritage Rivers. This strategy should identify an initial list of rivers [waterways] that warrant special protection, and should adhere to

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the following principles:

Smart Growth. Wherever possible, federal funding should be used to enhance protection of American Heritage Rivers. President Clinton is directing Federal agencies to eliminate requests for funding, and otherwise avoid making funding decisions, that would diminish the cultural, economic, or environmental amenities associated with American Heritage Rivers. [N.b. Tees up Elwa dam, Red River Chloride budget issues].

Smart Decisionmaking. Federal agencies must accord higher protection to American Heritage Rivers when issuing permits, re-licensing dams, making cleanup decisions, or taking other steps that may affect these cherished assets. New legislation that may affect these rivers (IST, others) must incorporate the flexibility and resources to enforce this principle.

High-Priority Actions. President Clinton is directing Federal agencies to identify an agenda of high-priority actions that can be achieved over the next two years to protect American Heritage Rivers, including protective designation under existing laws, land exchanges to enhance protection, and focusing of federal programs to protect and enhance American Heritage Rivers (examples include such as the conservation reserve program, the conservation reserve enhancement program).

Targeting Enforcement. President Clinton is directing agencies both to strengthen and to modify their enforcement efforts with respect to American Heritage Rivers. Enforcement actions must ensure greater protection and faster cleanup of American Heritage Rivers, but agencies also must use greater flexibility to develop alternatives to money damages, such as Supplemental Environmental Projects (SEPs) to improve public access and Habitat Conservation Plans (HCPs) to protect wildlife habitat.

Issues

1. Should this be limited to rivers, or should bays and estuaries be eligible to the extent that they meet the criteria?

2. What should the criteria for selection be? Possibilities include the following:

- importance to our development as a nation;
- rivers important to national defense;
- rivers of exploration;
- rivers important to trade and commerce;

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- rivers important to our music, literature.
- a substantial demonstration of community and private investment in protecting the heritage values of the river.

3. How do we structure the designation/selection process?