



# AMERICAN INDUSTRIAL HEALTH COUNCIL

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January 18, 1980

## MEMORANDUM FOR AIHC

### Comparison of OSHA Proposal (10/4/77) With Final Regulation

The attached memorandum provides a side-by-side comparison of fundamental aspects of the final OSHA cancer policy and the 1977 proposal. More detailed analyses will be prepared as required.

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PLAINTIFF'S  
EXHIBIT  
AL-1072

ALCOA0005069

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(10/4/77) With Final Regulation

DEFINITIONS

Potential Occupational Carcinogens

1977 Proposal

Any substance which causes, as the result of oral, respiratory, dermal or other exposure resulting in systemic distribution, an increased incidence of benign and/or malignant neoplasms or a significant decrease in the latency period between exposure and onset of neoplasm in humans or in one or more experimental mammalian species.

Final Rule

Similar to Proposal. Includes mixtures and substances which are metabolized into potential carcinogens by mammals. Routes of exposure included are oral, dermal, respiratory and any other which results in induction of tumors away from administration site.

Short-Term Tests

Includes, but is not limited to, positive results in more than one of five specified tests.

Positive results in two or more of same five specified tests.

Scientific Review Panel

No specific provision.

Upon the request of the Secretary, the Director(s) of NIEHS, NCI and/or NIOSH will convene a panel of appropriately qualified government employees "to provide recommendations to the Secretary in the identification, classification, and regulation" of potential carcinogens. The report of the panel (due in 90 days) is not binding on the Secretary but will be placed in the record and an appropriate time for comment thereon will be allowed. No provision is made for public input to the panel. The role of the panel would appear to be circumscribed by the classification criteria contained in the regulation.

## AMENDMENTS TO THE REGULATION

By petition after notice and hearing.

Three mechanisms are provided: (a) no later than every three years, NCI, NIEHS and/or NIOSH shall, upon the Secretary's request, report whether scientific or technical advances warrant any changes; (b) at any time, NIEHS, NCI or NIOSH may recommend changes based on scientific or technical advances; (c) any interested person may petition for change based on substantive new issues or evidence which differ significantly from those presented or reviewed in this generic rulemaking. Such petitions may be presented in connection with an individual substance proceeding.

## CLASSIFICATION CRITERIA

### Category I Potential Carcinogens

A presumption exists that a toxic substance shall be classified by the Secretary as a "Category I Toxic Substance" if; (a) it meets the definition of a potential occupational carcinogen in (1) humans, (2) two mammalian test species; (3) a single mammalian species, if replicated, or (4) a single mammalian species if supported by short-term tests or (b) if the Secretary finds other sufficient evidence to classify the substance in Category I.

A substance shall be classified as Category I if it meets the definition of a potential occupational carcinogen in (1) humans, (2) a single mammalian assay, if in concordance with other evidence, or (3) in a single mammalian assay where the Secretary finds concordance unnecessary. Evidence of concordance may include any of the following: positive results from testing in the same or other species, positive results in short-term tests, and induction of tumors at injection or implantation sites.

### Category II Toxic Substances

Category II includes any substance which meets the definition of a "potential occupational carcinogen" in animal or human studies where the

A substance shall be classified in Category II if it meets the criteria of Category I but the evidence is merely suggestive or it meets the Category I criteria

Secretary finds the evidence only suggestive. This classification is mandatory rather than presumptive. In addition, a presumption exists that a substance shall be classified in Category II if it yields positive results in a single unreplicated animal test or the Secretary finds other sufficient evidence to so classify the substance.

in a single mammalian species without concordance.

#### Category III Potential Carcinogens

Includes substances for which there are insufficient data to classify them in Category I or II.

Not regulated.

#### Category IV Potential Carcinogens

Substances which meet the definition of potential occupational carcinogen but are not found in any American workplace.

Not regulated.

#### PRIORITIES

No provision-comments solicited.

(1) The Secretary will prepare a "candidates list" based on "brief scientific review of available data". Items on this list may be considered for further scientific study and/or regulation. The Secretary may, but need not, tentatively identify substances on the list as Category I or II candidates. This list will be published in the Federal Register at least annually. Sources of "available" data are listed as:  
(1) data submitted by any person;  
(2) data referred to by NIOSH or the U.S. Department of Health and Human Services (HHS) in any communication (including the "Suspected Carcinogens" list);  
(3) literature referred to in

U.S. Public Health Service's, Publication No. 149; (4) IARC monographs; (5) the TSCA Inventory of Chemical Substances; (6) the HHS Annual Report to the President; (7) any other relevant data of which the Secretary has actual knowledge.

(2) The Secretary will also establish two priority lists which will designate approximately 10 Category I and 10 Category II potential carcinogens. These lists are to be published in the Federal Register at least every six months. Placement on a priorities list is merely "a policy determination that the Secretary plans to address some or all of these substances prior to other substances on the candidates list. Factors to be considered in setting priorities include: (1) estimate of workers exposed; (2) estimated exposure levels; (3) reported potency; (4) extent to which regulatory action could reduce other environmental and occupational hazards; (5) similarity of molecular structure to known potential carcinogens; (6) availability of suitable substitutes, or likely low magnitude of social and economic costs of regulation; and (7) actions being taken or planned by other agencies dealing with similar hazards.

#### DATA

Relies on positive human and animal data for the identification and classification of potential carcinogens. Accepts data based on high doses. Determined that there are no threshold or safe levels of exposure; announced that substances are not organ or species specific; considered benign and malignant

Generally similar to proposal. Increases in spontaneous tumors will be considered evidence of qualitative carcinogenicity. Tumors, at site other than induction (for routes of exposure other than oral, dermal or respiratory) will be considered only "concordant" or "suggestive". Thresholds disclaimed at present. Substances

tumors equivalent; allowed only limited consideration of metabolic or pharmacokinetic data; held positive results generally to outweigh negative outcome; and statistical significance to be considered.

are to be considered potential occupational carcinogens if, when metabolized by mammals, they yield one or more potential carcinogens. However, § 1990.144 does allow for the consideration of certain scientific questions in individual proceedings if specified criteria are met. The following exceptions to the general rule are created:

(1) Negative epidemiological studies. Will be considered only if it meets the following criteria: (a) study involved at least 20 years exposure and 30 years observation after initial exposure; (b) documented reasons are provided for predicting the expected tumor site(s) if the substance were a human carcinogen; and (c) the study group was sufficiently large to allow detection of a 50% increase at any of the predicted sites. Arguments that such studies may be used to establish numerical upper limits on human risk will be considered only if criteria (a) and (b) are met and (d) specific data on the level of exposure are provided, based either on direct measurements taken periodically through the exposure period or other unequivocal evidence.

(2) Tumors at site of administration. Arguments against considering tumors at site of administration will only be considered if: (a) the route of administration is not oral, respiratory or dermal; and (b) evidence establishes that induction of local tumors is related to the physical configuration or formulation of the administered material and that tumors are not induced when the same material is administered in a different configuration or formula.

(3) Metabolic differences. Arguments based on differences between human metabolism and that of test animals will be considered only if: (a) a complete metabolic profile,

including identities of trace metabolites, is available for a human group representative of exposed workers; (b) a similar metabolic profile is presented for the experimental animal species; (c) documented evidence is provided for ascribing the carcinogenic activity in the test species to metabolites produced only in that species and not in humans; and (d) documentation is provided that other metabolites produced also in humans are not also carcinogenic.

(4) Use of high doses in animal testing. Arguments against considering studies involving high doses will be entertained only if the following criteria are met: (a) documentation that at the dose levels used the substance is metabolized by the experimental animal into metabolic products which include one or more not produced at lower doses; (b) demonstration that the metabolite(s) produced only at high doses are the ultimate carcinogen(s) and that the low dose metabolites are not carcinogenic; and (c) documented evidence is presented to show that the metabolite(s) produced only at high doses in the animal are not produced in humans exposed to low doses.

(5) Benign tumors. Will consider evidence that substance is capable of producing only benign tumors only if: (a) data are available from at least two well-conducted bioassays in each of two mammal species; (b) each of the bioassays was a full lifetime test; (c) tissue slides are made available to OSHA and the tumors are diagnosed as benign by at least one qualified pathologist not involved in the original study; and (d) all of the tumors are of types known not to progress to malignancy or at a benign stage when observed. In the latter case, data must be presented to

show that multiple sections of the affected organ(s) were adequately examined for invasion and metastases.

(6) Indirect mechanisms. The Secretary will consider disregarding positive animal results if evidence demonstrates that the mechanism by which the observed tumor incidence is effected is indirect and would not occur if humans were exposed (e.g., carcinogenic animal virus or augmented caloric intake).

#### RISK ASSESSMENT

None.

Limited. Will be used to set priorities and estimate residual risk after regulatory action. Risk quantification will not be considered in determining the appropriate level of control. "[C]autious and prudent" assumptions will be used in performing risk assessments.

#### CATEGORY I CONTROL

Lowest feasible level. Engineering and work practice controls given priority over personal protective devices. No consideration of potency.

Model standards to be used as guidelines. Deviation from the model to be on a case-by-case basis. Variation from major control headings only if Secretary explains why heading is inappropriate. Exposure limit to be set as low as feasible. Primary reliance is on "engineering and/or work practice controls". Other controls will require a variance by the Secretary. Personal protective controls may only be used: (1) during period while engineering and work practice controls are being implemented; (2) where employer establishes non-feasibility of engineering and work practice controls; (3) where engineering and work practice controls are insufficient to reduce exposure

below PEL (still must use engineering and work practice controls to reach their lowest achievable level); and (4) emergencies. No occupational exposure will be permitted if a suitable substitute is available. No exposure is generally to be the "lowest level detectable in an industrial environment with existing analytical technology". Lower levels may be set in cases where analytical methodology is poorly developed.

#### CATEGORY II CONTROL

Control for chronic health effects other than cancer.

Model standard adopted as guideline. PEL to be set on case-by-case basis "as appropriate and consistent with the statutory requirements". Primary reliance is placed, as in Category I, on engineering and work practice controls.

#### SUBSTITUTES

No exposure to Category I potential carcinogen if less hazardous suitable substitute is determined by the Secretary to be available.

Same. The Secretary will consider economic and technological feasibility of the substitute, including relative effectiveness, availability, relative degree of hazard and practicability.

#### MIXTURE/ACTION LEVEL EXCLUSIONS

None.

Will be considered in individual proceedings and set as appropriate.

#### MODEL STANDARDS

Generic standards rigidly applied.

Model standards are to be used as guidelines for regulation. Compliance plans must be submitted. Occupational health

programs will be included unless determined and explained to be inappropriate by the Secretary.

#### EMERGENCY TEMPORARY STANDARDS

Automatic for Category I.

Issuance of an ETS will be considered for all Category I potential carcinogens. Employee exposure to Category I substances is to be generically considered a "grave danger". Necessity of ETS to protect workers will be considered according to statutory criteria or a case-by-case basis.

#### SIGNS AND LABELING

Secretary may require labels on goods shipped out of the plant.

Generally the same.

#### PUBLIC NOTICE

Notice of classification to be published in Federal Register.

Candidate and priority lists may be published in the Federal Register without prior notice. Within 30 days after beginning a study concerning the "economic and/or technological feasibility of specific standards" the Secretary will publish an ANPR which will specify, among other things, the scope of the study, the estimated issuance date of the proposal, the date for submitting relevant studies or information and procedural requirements for asserting new issues or evidence.

#### LIMITATION OF ISSUES TO BE CONSIDERED IN RULEMAKING

Issues limited to the following: (a) whether Secretary correctly classified the toxic substance according to Category

Issues limited to the following: (a) appropriateness of substance grouping; (b) whether substance or group meets definition of

I criteria; (b) whether Secretary was correct that Category I classification should not be rebutted; (c) determination of lowest feasible occupational exposure or whether less hazardous suitable substitutes exist; (d) whether substance has unique properties or uses that make protective measures inappropriate or infeasible; (e) environmental impact.

potential occupational carcinogen, including reliability of scientific studies; (c) applicability of data to entirety of substance group; (d) whether evidence submitted on scientific issues (see DATA, supra) is sufficient to warrant exception; (e) whether data submitted regarding new issues or evidence is sufficient to warrant amendment of rule; (f) whether the substance meets the Category I or Category II criteria; (g) the environmental impact from regulation of the substance; (h) any issues required by statute or executive order; (i) the lowest feasible level (for Category I carcinogens) including technological and economic considerations; (j) the appropriate employee exposure level (for Category II carcinogens) consistent with the Act's requirements; (k) the availability of suitable substitutes; (l) whether the provisions of the proposal and model standards are appropriate (except that use of lowest feasible level, reliance on engineering and work practice controls and no occupational exposure where substitutes exist cannot be challenged).

#### COVERAGE

All workplaces.

All workplaces are covered but the manner of regulating will be determined, as appropriate, in individual proceedings. Consideration will be given to setting separate standards for laboratories.

#### MEDICAL REMOVAL

No provision.

No provision. May be considered in individual proceedings. OSHA is currently investigating the possibility of proposing a general removal protection regulation which

would apply to toxic and  
carcinogenic chemicals.

#### ACCESS TO MEDICAL RECORDS

Access.

No provision on access. Will  
be covered by OSHA's soon to be  
published final standard on  
Access to Employee Exposure  
Medical Records.

#### ENVIRONMENTAL IMPACT

To be addressed in individual  
rulemakings.

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rulemakings.

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ALHC MEMO 4/18/80

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Box 3 - Alcoa Documents

3. Organizational Resources  
Counselors Inc.- Memo dated  
2/27/78

Box 3 - Alcoa Documents

4. AIHC Memo dated 1/18/80

Box 3 - Alcoa Documents

5. AIHC Comments on TSSC Report

Box 3 - Alcoa Documents

6. AIHC Cancer Causation  
10/26/79

Box 3 - Alcoa Documents

7. AICH Testimony re: Generic  
Air Standards

Box 3 - Alcoa Documents

8. AICH Reply to Estimates of  
Fraction of Cancer in the  
U.S. Attrib. to Occup.  
factors 9/15/87

Box 3 - Alcoa Documents

9. Article "General Criteria for  
Assessing the Evidence for  
Carcinogenicity of Chemical  
Substances" and OSHA Generic

Box 3 - Alcoa Documents

10. Direct testimony of Dr.  
Robert E. Olson before the  
EPA 3/11/80 re: National  
Emission Standards for