June 2, 2011

The Honorable Lisa P. Jackson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Biomonitoring Studies Essential for TSCA Section 8(d) Data Calls

Dear Administrator Jackson:

I am writing on behalf of the Environmental Working Group to bring to the attention of the U.S. Environmental Protection Agency a troubling gap in basic health and safety data submitted by chemical companies as part of their reporting obligations under the federal Toxic Substances Control Act.

Environmental Working Group's review of electronic records from tens of thousands of studies submitted by the industry in response to agency data requests indicates that relatively few studies documented Americans' exposures to industrial chemicals and even fewer focused on exposures of children during critical stages of development. This dearth of information is at odds with EPA's instructions to industry to submit "[s]tudies of human health and environmental effects, ***including studies of exposures to people*** and the environment."[1] Such studies, EPA says, "are the fundamental ingredients of any assessment of chemical risk."[2]

EWG's review suggests that either the chemical industry is failing to submit required data to EPA regarding people's exposures to its products, or it is failing to conduct basic research to determine which of its chemicals end up in people's bodies, and at what levels. This basic information is needed to determine if a chemical, as used in products and emitted to the environment, poses unacceptable risks to human health.

Such biomonitoring exposure studies are regularly conducted by industrial hygienists and by academic and government scientists. Logically, the chemical industry should be conducting the same, basic studies to understand the safety of its chemicals for the public. And if not, then why not?

The Environmental Working Group urges the Environmental Protection Agency to explicitly request all available biomonitoring data – including studies of chemicals in umbilical cord blood, breast milk, workers and all others tested – in its calls to industry for health and safety data

[1] See 40 C.F.R. § 716.3 (emphasis added).
[2] Revisions to Reporting Regulations Under TSCA Section 8(d), 63 Fed. Reg. 15,765, 15,766 (Apr. 1, 1998) (to be codified in 40 C.F.R. Part 716).

submissions under the Toxic Substances Control Act (TSCA). EWG also urges the agency to request testing, including cord blood testing, that bears on early-life exposures, when the body is uniquely vulnerable to damage from industrial chemical exposures. Such information will allow EPA more fully to meet its mandate to protect public health.

The importance of biomonitoring and early-life exposures

Biomonitoring helps scientists determine which chemicals people are exposed to in their everyday lives and how much of those chemicals enter their bodies. Health agencies worldwide successfully use biomonitoring data when assessing chemicals for health and safety. EWG strongly advocates that regulators and industry test for synthetic chemical contaminants in people, especially in human umbilical cord blood. These tests demonstrate how readily chemicals enter and accumulate in our bodies, even during the earliest stages of development. In 2005, for example, EWG detected 287 industrial chemicals in the cord blood of 10 newborn babies.[3] In 2009, EWG tested the blood of 10 minority babies and found 232 chemicals.[4] The bottom line: information derived from biomonitoring is critical to understand the health effects of chemical exposures, especially to the fetus and young children.

Chemical manufacturers themselves clearly recognize that chemical exposures at vulnerable times in life are of great concern. EWG's Chemical Industry Archives[5] – a searchable database that contains more than 37,000 pages of internal company documents – shows time and again companies' interest in exposures related to early human development. Consider the following examples from the Chemical Industry Archives:

• 1978 – Chemical Manufacturers Association meeting minutes describe a survey focused on embryotoxic chemicals:

> "Dr. Clyne's recent informal survey showed considerable variation in how different companies handle this matter. Mr. De Martino indicated the 1977 NIOSH Registry of Toxic Effects of Chemical Substances contains a sublist of 541 embryotoxin compounds which he would make available to the group.
>
> "The Committee AGREED a list should be prepared of chemicals used in industry that are considered embryotoxic."[6] [Emphasis in original]

• 1979 – CMA meeting minutes summarize conclusions about how hazardous substances should be labeled. One provision requires labeling of hazards for chemicals that are "embryotoxic," defined as:

[3] EWG, Body Burden: The Pollution in Newborns (2005), http://www.ewg.org/reports/bodyburden2/execsumm.php; see also App. A at 1 (describes types of chemicals found).
[4] EWG, Pollution in People: Cord Blood Contaminants in Minority Newborns (2009), www.ewg.org/files/2009-Minority-Cord-Blood-Report.pdf.
[5] EWG, Chemical Industry Archives, http://www.chemicalindustryarchives.org/ (last visited May 20, 2011).
[6] App. B at 2.

> "A chemical that is capable of causing harm to the developing embryo or fetus from maternal exposure at a concentration that may not harm the mother herself."[7]

• 1980 – CMA executive committee meeting presents guidance for evaluation, risk assessment, and control of chemical embryofetotoxins:

> "Concern for the unborn has generated tremendous pressure upon the industry and regulatory agencies to provide an effective solution for controlling potential chemical embryofetotoxins.
>
> "The issue with exposure to embryofetotoxic chemicals is one of protecting the susceptible embryofetus from chemical substances which can cross the placenta and cause damage to the embryofetus, almost always at concentrations which would have no adverse effect on the female or male adult."[8]
>
> "In assessing the risk of exposure to embryofetotoxic chemicals, two basic . . . principles must be considered: . . . degree of exposure . . . [and a] dose response."[9]

• 1993 – Report by the Bureau of National Affairs, an information publisher for the business and government communities, discusses the American Conference of Industrial Hygienists' determination that workplace safety limits should account for concerns related to early human development:

> ''[An] exposure limit [ ] [should be] designed to protect what we'll call the functional capacity of a worker, not just prevention of overt illness. One of the functions people perform is having kids, hopefully healthy kids."[10]

Other examples of industry's attention to exposure during critical stages of human development include:

• 1981 – DuPont memorandum discusses the company's internal study that tested for perfluorooctanoic acid (PFOA) in umbilical cord blood from several babies to female workers at its Teflon plant in Parkersburg, W. Va.:

> "C-8 Blood Sampling Results. Births and Pregnancies. . . . Unconfirmed eye and tear duct defect. . . . One nostril and eye defect. Babies blood 0.012 ppm."[11]

• 2001 – 3M Company report submitted to federal regulators discusses internal study designed to understand the distribution of fluorochemicals in people by testing blood samples from various health clinics:

---

[7] App. B at 3.
[8] App. B at 5.
[9] App. B at 7-8.
[10] App. B at 10.
[11] EWG, PFCs: Global Contaminants (2003), http://www.ewg.org/node/21715; see also App. B at 11.

> "The purpose of this study was to better characterize the distribution of seven fluorochemicals . . . using individual pediatric samples obtained from a multi-center clinical trial of group A streptococcal infections. The present study is the third formal assessment undertaken by the 3M Company to examine the distribution of PFOS in human sera. . . . The sera analyzed . . . were collected as part of a large multi-center trial of 1,131, ages 2 to 12 years . . . . These findings suggest a different exposure pattern for some children compared to the adult and elderly populations."[12]

The documents cited above provide evidence that industry has long recognized the importance of exposure information, particularly the risks posed by early-life exposures, and has used biomonitoring as a means of assessing chemical hazards. Biomonitoring is a critical means of assessing worker and general population exposures and risks to chemical compounds. Yet industry-generated biomonitoring information is difficult to locate in EPA databases. EWG found few such studies when it reviewed the following:

- **EPA's TSCA Test Submission Database (TSCATS)**

  EWG researchers searched TSCATS,[13] a public repository of more than 50,000 studies submitted by the chemical industry since 1977 in response to EPA data requests concerning the safety of individual chemicals. Among more than 2,600 studies flagged as covering human health, EWG was unable to locate a single study title or abstract that used the terms "cord blood," "umbilical," "pregnant," "biomonitoring," or "chemical exposure." Only one study used the term "pregnancy."[14] A follow-up search of the terms "umbilical," "pregnant," "pregnancy," and "biomonitoring" in EPA's new Chemical Data Access Tool that includes more recent filings returned less than five relevant submissions.

- **EPA's High Production Volume Information System (HPVIS)**

  EWG researchers searched HPVIS, a public database that includes voluntary data submissions on 50 endpoints covering 900 of the most frequently used chemicals in commerce. Worker and general population exposures to these chemicals are not among the specific data endpoints in HPVIS. EWG searched HPVIS for the terms "biomonitoring," "pregnant," and "pregnancy" and received no relevant information in response to such inquiries. A small number of submissions contained information about worker blood monitoring. The only human study generated in response to the search term "umbilical" was one conducted by university researchers in Buenos Aires, Argentina. That study tested the cytotoxicity of 2,6-di-tert-butyl-p-cresol on lymphocytes from human umbilical cord blood.

[12] App. B at 13-15.
[13] Public access to TSCATS is made available by SRC, Inc., the company that developed the database for EPA in 1985. See SRC, TSCATS, http://www.syrres.com/what-we-do/product.aspx?id=136 (last visited May 25, 2011).
[14] Note that the absence of abstracts for many of the studies listed on TSCATS precludes a more detailed review of the database.

The results of EWG's review should disconcert EPA in light of TSCA's statutory framework, particularly with regard to the reporting of unpublished health and safety studies.[15] Under TSCA Section 8(d), EPA has authority to promulgate rules that require companies to submit lists and/or copies of unpublished health and safety studies, regardless of whether they are completed or ongoing.[16] Notably, EPA defines "studies" broadly. According to EPA regulations, health studies include "any study of any effect of a chemical . . . on health or the environment . . . ."[17] The expansive scope of that definition necessarily encompasses studies that monitor for chemical contaminants in the human body. If industry is engaged in biomonitoring for due diligence purposes – especially to address concerns about potential tort liability – then why are there not more of these studies appearing on EPA databases?

To address this apparent gap, EPA should explicitly emphasize the importance of receiving biomonitoring studies when issuing future rules under Section 8(d).[18] EWG also encourages EPA to consider drafting a separate rule that calls for biomonitoring data from companies previously obligated to report studies under TSCA. Finally, EWG asks EPA to remind companies that they have an ongoing duty under TSCA Section 8(e) to notify EPA when they obtain information suggesting that a chemical presents substantial health risks.[19] Without all of this information before it, EPA cannot effectively set priorities for TSCA risk assessments.

Biomonitoring truly is the gateway to fully comprehending the impacts of chemical exposures on public health. In view of that, EWG hopes that EPA will take these requests under serious consideration as it makes the most of its existing authority under TSCA.

Sincerely,

Kenneth A. Cook
President
Environmental Working Group

cc: Steve Owens, Assistant Administrator, Office of Chemical Safety and Pollution Prevention
Wendy Cleland-Hamnett, Director, EPA Office of Pollution Prevention and Toxics

---

[15] EWG understands that industry does not have to submit copies of health and safety studies to EPA if they have been submitted to federal agencies such as the U.S. Occupational Safety and Health Administration. 40 C.F.R. § 716.20(a)(3). However, companies still have to list these studies as part of their reporting obligations under TSCA. See id. To the extent that this exemption prevents biomonitoring studies from appearing on EPA databases, EWG hopes that EPA will develop better information-sharing initiatives with other agencies to give the public easier access to this important data.

[16] 15 U.S.C. § 2607(d); see also 40 C.F.R. Part 716.

[17] 40 C.F.R. § 716.3.

[18] In fact, EPA has already stated that it considers "human blood sampling information confirming transplacental movement" to provide evidence of a "substantial risk of injury to health," in the agency's consideration of the industrial chemical PFOA. Complaint of EPA at 11, In re E. I. du Pont de Nemours and Company, Docket Nos. TSCA-HQ-2004-0016 and RCRA-HQ-2004-0016 (July 8, 2004), http://www.epa.gov/compliance/resources/complaints/civil/mm/dupont-pfoa-complaint.pdf.

[19] 21 U.S.C. § 2607(e).

Appendix A

List of Industry Chemicals Identified in EWG's 2005 *Body Burden* Report

Tests show 287 industrial chemicals in 10 newborn babies

Pollutants include consumer product ingredients, banned industrial chemicals and pesticides, and waste byproducts

Sources and uses of chemicals in newborn blood	Chemical family name	Total number of chemicals found in 10 newborns (range in individual babies)
Common consumer product chemicals (and their breakdown products)		**47 chemicals (23 - 38)**
Pesticides, actively used in U.S.	Organochlorine pesticides (OCs)	7 chemicals (2 - 6)
Stain and grease resistant coatings for food wrap, carpet, furniture (Teflon, Scotchgard, Stainmaster...)	Perfluorochemicals (PFCs)	8 chemicals (4 - 8)
Fire retardants in TVs, computers, furniture	Polybrominated diphenyl ethers (PBDEs)	32 chemicals (13 - 29)
Chemicals banned or severely restricted in the U.S. (and their breakdown products)		**212 chemicals (111 - 185)**
Pesticides, phased out of use in U.S.	Organochlorine pesticides (OCs)	14 chemicals (7 - 14)
Stain and grease resistant coatings for food wrap, carpet, furniture (pre-2000 Scotchgard)	Perfluorochemicals (PFCs)	1 chemicals (1 - 1)
Electrical insulators	Polychlorinated biphenyls (PCBs)	147 chemicals (65 - 134)
Broad use industrial chemicals - flame retardants, pesticides, electrical insultators	Polychlorinated naphthalenes (PCNs)	50 chemicals (22 - 40)
Waste byproducts		**28 chemicals (6 - 21)**
Garbage incineration and plastic production wastes	Polychlorinated and Polybrominated dibenzo dioxins and furans (PCDD/F and PBDD/F)	18 chemicals (5 - 13)
Car emissions and other fossil fuel combustion	Polynuclear aromatic hydrocarbons (PAHs)	10 chemicals (1 - 10)
Power plants (coal burning)	Methylmercury	1 chemicals (1 - 1)
All chemicals found		**287 chemicals (154 - 231)**

Source: Environmental Working Group analysis of tests of 10 umbilical cord blood samples conducted by AXYS Analytical Services (Sydney, BC) and Flett Research Ltd. (Winnipeg, MB).

Appendix B

Manufacturing Chemists Association

Minutes of Meeting

OCCUPATIONAL SAFETY AND HEALTH COMMITTEE

MCA June 22, 1978 Washington, D.C.

Chairman De Martino convened the meeting at 9 a.m. The record of attendance is:

PRESENT

C. De Martino, Chairman	E. I. du Pont de Nemours & Company
L. M. Casey	Ashland Oil, Inc.
E. E. Christofano	Hercules Incorporated
R. M. Clyne	American Cyanamid Company
M. B. Jones (for R. D. Fulwiler)	The Procter & Gamble Company
B. B. Holder	Dow Chemical U.S.A.
R. O. Howard	Virginia Chemicals Inc.
P. C. Holladay (for H. L. Kusnetz)	Shell Oil Company
R. L. O'Connell	Olin Corporation
J. M. Pardee	Eastman Kodak Company
R. E. Rutherford	Gulf Science and Technology Company
W. M. Smith	Air Products and Chemicals, Inc.
J. S. Snyder	Merck & Co., Inc.
F. A. Ubel	Minnesota Mining and Manufacturing Company
F. D. Bess (for A. G. Voress)	Union Carbide Corporation
M. Freifeld	MCA

PRESENT BY INVITATION

A. C. Clark	MCA
B. M. Barackman	MCA
E. B. Frost	MCA
J. A. Young	MCA

* * * * * *

The Committee AGREED labels for Acetaldehyde and Chromic Acid with relevant portions of those SDS's should be circulated to the Committee for a vote with a cut-off date in the next few weeks. The entire draft, including label, of the Chlorosilanes SDS will be the subject of a separate action of the Committee.

For future revisions, the suggestion was made that an early draft of each SDS be circulated to major producers for comment. The new procedure for preparing and approving SDS's should also be formalized.

7.0 Embryotoxins

Dr. Clyne's recent informal survey showed considerable variation in how different companies handle this matter. Mr. De Martino indicated the 1977 NIOSH Registry of Toxic Effects of Chemical Substances contains a sublist of 541 embryotoxin compounds which he would make available to the group.

The Committee AGREED a list should be prepared of chemicals used in industry that are considered embryotoxic.

8.0 Seminars

Preparations for the function scheduled September 14 at Cherry Hill, New Jersey are essentially complete.

There was agreement that planning for the 1979 seminar should commence promptly, taking advantage of the British offer to participate. Their suggestion to hold this function on the West coast will be given consideration. Mr. Christofano accepted the assignment of heading up the effort on next year's seminar and coordinating it with the proposed visit of British counterparts.

9.0 Vapor Cloud Research

The Secretary reported that the Engineering Advisory Committee expressed willingness to accept this project although they felt it properly belonged with OSHC.

MANUFACTURING CHEMISTS ASSOCIATION
OCCUPATIONAL SAFETY AND HEALTH COMMITTEE

INTERNAL MCA GUIDELINES for Description of Significant Chronic Effects Taken from Chemical Safety Data Sheet Texts to be Incorporated in Sample Labels

March 15, 1979

1. Definitions

1.1 Carcinogen. A chemical that is capable of causing cancer in man or animals by a route of exposure likely to be encountered in the workplace.

1.2 Chronic effect. A health effect resulting from exposure to a chemical, and falling within either of the following categories:

(i) An effect that results from repeated exposure at concentrations insufficient to produce such effect from a single exposure, and which may develop at some time after cessation of exposure and persist for an indefinite period of time thereafter.

(ii) An effect that persists for an indefinite period of time after a single exposure.

1.3 Critical level. The level of a hazardous chemical in a mixture below which the mixture itself is not considered to be hazardous.

1.4 Embryotoxin. A chemical that is capable of causing harm to the developing embryo or fetus from maternal exposure at a concentration that may not harm the mother herself.

1.5 Hazardous chemical. A substance falling within either of the following categories:

(i) A chemical or mixture of chemicals that is toxic, highly toxic, an irritant, corrosive, a strong oxidizer, a strong sensitizer, combustible, flammable, extremely flammable, dangerously reactive, or pressure-generating, or which otherwise may cause substantial personal injury or substantial illness during or as a direct result of any customary or reasonably foreseeable handling or use.

AGENDA
CMA EXECUTIVE COMMITTEE MEETING
9:00 a.m., Tuesday, May 13, 1980
CMA Headquarters (Room 407)
Washington, D. C.

			TAB
9:00 a.m.	1.	Call to Order -- Chairman Morley	
9:01-9:02	2.	Minutes of Last Meeting -- B. M. Barackman	1
9:02-9:03	3.	Report on New Member -- B. M. Barackman	
9:03-9:05	4.	Treasurer's Report -- G. C. Herrman	2
9:05-9:10	5.	Report of the Nominating Committee -- J. M. Henske	
9:10-9:30	6.	Superfund Policy Group Report -- W. C. Krumrei	
9:30-10:00	7.	Association Activities -- R. A. Roland	
		a. Formation of Task Groups	3
		b. Formation of Hazards Communications Special Committee	4
		c. Report of Program Committee	
		d. Proposed Guidance for Evaluation, Risk Assessment and Control of Chemical Embryo-fetotoxins -- Gloria Portela-Cubria, The Standard Oil Company (Indiana)	5
10:00-10:10	8.	ChemCAP Update -- J. N. Sites	
10:10-10:20	9.	Report of Director of Government Relations -- W. M. Stover	6
10:20-10:30	10.	Report of General Counsel -- E. B. Frost	7
10:30-10:40	11.	Regulatory Compliance - SOCMA Activities -- E. B. Pollak	
10:40-10:45	12.	New Business	
10:45	13.	Adjournment	

DRAFT

GUIDANCE FOR EVALUATION, RISK ASSESSMENT, AND CONTROL OF CHEMICAL EMBRYOFETOTOXINS

Introduction

Concern for the unborn has generated tremendous pressure upon industry and regulatory agencies to provide an effective solution for controlling potential chemical embryofetotoxins.

The issue with exposure to embryofetotoxic chemicals is one of protecting the susceptible embryofetus from chemical substances which can cross the placenta and cause damage to the embryofetus, almost always at concentrations which would have no adverse effect on the female or male adult. It is not one of the female employee being more susceptible than male employees or the female employee being at greater risk of adverse health effects from exposure. It is not an issue of discrimination against the female employee because she is female. The female is involved only because she is unique by being of the sex capable of becoming pregnant and bearing children.

The determination of the intrinsic embryofetotoxic potential of a chemical and the estimation of risk from exposure are scientific endeavors, while the acceptability of an estimated embryofetotoxic risk for the unborn to a given exposure is a societal and regulatory decision.

APPENDIX C

LEGAL ISSUES

A great many legal issues in various specialized areas are involved in the evaluation, risk assessment, and control of embryofetotoxins. Company counsel should be consulted on all such issues. For example, there are a number of equal employment opportunity matters to be considered when a company concludes that it must exclude women of reproductive potential from workplace areas as a means of controlling exposures.

The Company may be called upon to demonstrate that the embryofetotoxic effect is due to exposure of the embryo or fetus during gestation and not due to toxic effects on the mother due to the exposure during pregnancy. If only women of reproductive potential are excluded, the employer may have to demonstrate that the toxic effects result only from in-utero exposure of the embryo or fetus and not from preconception exposure of either parent. Consideration must be given to what constitutes suitable alternate assignments and compensation for employees excluded from certain jobs because of potential exposures.

Counsel should be consulted at an early date on these and all other legal issues which may be involved.

Scope

This document provides general guidance for evaluating the quality of the data, assessing its significance, and controlling the degree of risk of exposure to embryofetotoxic chemicals. It is not all inclusive nor specific, and recognizes the requirements for sound scientific judgment for each chemical. It does not address either male or female gonadal toxins or mutagens, but is concerned with the conceptus, embryo, or fetus. The importance of the legal considerations involved are also summarized in the paper.

An embryofetotoxin is designated as a chemical which manifests an effect, during any of the stages of gestation, upon the conceptus from fertilization until birth. It may induce death, structural malformations, metabolic or physiological dysfunction, growth retardation, or psychological and behavioral alteration in the offspring that are manifest at birth or in the postnatal period.

Death of the embryo, fetus or newborn is included. For purposes of this document, in-utero-induced carcinogenicity and mutagenic induced abnormalities are not included. This definition is consistent with Environmental Protection Agency definition of teratogen as contained in Code of Federal Regulations, title 40, para. 162.3.

In assessing the risk of exposure to embryofetotoxic chemicals, two basic toxicological principles must be considered:

DRAFT

1. Risk is a function of both the intrinsic embryofetotoxic potential of the chemical and the degree of exposure to the chemical.

2. A dose response relationship holds for each embryofetotoxic response and there exists a threshold exposure level (dose) for each chemical below which no effect is to be expected.

The Appendices to this document provide background and information which will be of assistance in determining if a chemical poses a risk of embryofetotoxicity for which special controls are needed.

Control of Chemicals Posing a Potential Embryofetotoxic Risk

When it has been determined that a substance presents a risk of embryofetotoxicity, the following actions should be considered:

1. Employees who may be affected should be informed of the possible consequences of exposure to such substances and appropriate safe handling procedures established and communicated.

2. Engineering controls should be used to the extent practical to reduce and maintain exposure to the embryofetotoxins to acceptable levels. Such controls should be augmented by administrative controls as appropriate.

rulemaking that would address secondhand smoke in the workplace.

ASH hailed the court action. According to the group's legal counsel, "what's significant is that OSHA tried to get this thrown out of court. We've gotten past the procedural motions and can move on to the merits of the case." The anti-smoking group asked the court in the lawsuit to direct OSHA to develop a timetable for a rulemaking that would specifically address secondhand smoke.

ASH's legal counsel predicted that with the denial of the motion to dismiss, and the impact of an Environmental Protection Agency report that classified tobacco smoke as a "Group A Carcinogen," OSHA is likely to propose a regulation to ban or limit workplace smoking.

In the motion to dismiss, the secretary of labor argued that OSHA has not made a final determination regarding the regulation of secondhand smoke, therefore, a letter from the agency to ASH denying the group's request to initiate rulemaking proceedings does not constitute final agency action that is reviewable by a court of appeals (22 OSHR 1643).

The brief filed in connection with the motion also argued that two previous suits filed by ASH regarding the same subject had been dismissed. In both cases, the court determined that there had been no final agency action relating to the regulation of tobacco smoke in the workplace warranting review, the brief said.

Safety Standards

QUANTITATIVE RISK ASSESSMENT SHOULD BE BASIS OF FUTURE RULEMAKING, D.C. LAW FIRM TELLS REICH

The Occupational Safety and Health Administration squandered an opportunity to clarify its rulemaking process for safety standards and in fact may have muddied the waters by the way it responded to a court remand of the lockout/tagout standard, a law firm said May 26.

In its March 30 explanation to the court, OSHA laid out seven criteria it said must be satisfied in issuing safety standards (22 OSHR 1898). "While we generally view OSHA's new criteria for safety standards as a helpful first step, they appear to be more of a reflection of past practice than a measured prescription for future rulemaking," Lawrence P. Halprin of the Washington law firm Keller and Heckman said in a letter to Labor Secretary Robert B. Reich.

Among the seven criteria, OSHA said a safety standard must substantially reduce a significant risk of material harm to workers. This provided the agency with the chance to clearly state what it considers to be a "significant risk" and then apply that standard on a consistent basis in all rulemakings, Halprin said. But that did not happen, the law firm said.

Halprin said "it appears" the agency considers a one in 1,000 chance of a fatality over a worker's lifetime in a large exposed worker population to be a significant risk when it sets health standards.

"If quantitative risk assessment is appropriate in determining the presence of a significant risk for health standards, it would seem equally applicable to safety standards," he wrote in the six-page letter to Reich and Acting OSHA Administrator David Zeigler.

Halprin said it would be more appropriate to make the significant risk determination based on a quantitative risk assessment "rather than eyeballing absolute numbers."

In setting safety standards, a quantitative risk assessment could be based on either annual fatality and injury rates, or lifetime fatality and injury rates, he recommended.

Regarding lockout/tagout, "while we believe the agency reached the right conclusion as to the existence of a significant risk, the practice of simply eyeballing absolute numbers of injuries and fatalities without regard to the size of the exposed population has no legal or scientific basis," Halprin said in the letter.

"For the agency to be a credible and effective rulemaking body, we believe it must establish clear and objective criteria against which proposed standards can be tested through an accepted form of quantitative analysis," the law firm concluded.

Consensus Standards

The firm said it had concerns with the agency's fifth criterion, which states that a standard must bring about the Occupational Safety and Health Act's goals at least as well as any national consensus standard applied to the same hazard.

This suggests that for future rulemaking, OSHA will treat national consensus standards as the minimum level of protection that the agency will consider in developing an OSHA standard unless it is clearly inappropriate or an interested party can show that it would be inappropriate, Halprin said.

"Depending on how it is implemented, this dramatic change could, in effect, convert the voluntary consensus standards, adaptable to individual company circumstances, into uniformly enforceable rules," the lawyer wrote.

This change also could "significantly transform both the membership and the goals of the national consensus organizations," according to the letter.

OSHA should give careful consideration of consensus standards, but Halprin questioned the implied presumption that all national standards: establish the existence of a significant risk of harm to workers, are technically valid, provide the appropriate level of protection, or satisfy the applicable legal criteria for an OSHA standard.

In developing an OSHA standard, the agency cannot simply convert every "should" in a consensus standard to a "shall," the lawyer said.

ACGIH CONSIDERING ADOPTING LIMIT FOR BLOOD LEVELS OF EXPOSED WORKERS

A voluntary limit for acceptable blood-lead concentrations for U.S. workers that would be far stricter than current federal regulation is under consideration by the American Conference of Governmental Industrial Hygienists, according to ACGIH officials.

The recommended limit of 20 micrograms lead per deciliter of whole blood is aimed primarily at protecting unborn fetuses of lead-exposed workers, according to these officials and ACGIH background documents.

Ronald Ratney, chairman of the ACGIH working group that developed the proposal, told BNA May 27 that recent health effects data on the impact of relatively low blood-lead levels helped his group justify the proposed limit.

ACGIH adopted the proposed 20 µg/dl blood-lead limit May 18 at its annual meeting in New Orleans and the limit could become a final consensus standard in 1994. ACGIH is a membership organization of government-employed industrial hygienists that establishes voluntary workplace exposure limits for hazardous substances called threshold limit values.

TLVs do not carry the weight of regulation, although the Occupational Safety and Health Administration historically has relied heavily on TLVs to establish its regulatory exposure limits for chemicals. ACGIH will carry the recommendation on its "notice of intended change" list for one year to allow for comment before deciding whether to make it a final voluntary standard.

More Stringent Standard

The ACGIH proposal sets out a more stringent standard than the current OSHA regulatory limit. The OSHA standard for general industry, which was developed in the 1970s, and an interim rule promulgated earlier this month for the construction industry allow employees to work with much higher blood-lead levels (Reference File, 31:8421, 31:3154.14).

In updating its TLV for lead, ACGIH recommended a blood-lead limit for the first time and proposed lowering its recommended airborne exposure limit from 0.15 milligrams lead per cubic meter of air to 0.05 mg/m³. That would bring the airborne limit in line with the existing OSHA standard of 50 μg/m³. ACGIH also is recommending that lead be designated as a carcinogen in animals.

Ratney noted that establishment of the blood-lead limit to protect the health of unborn children was a matter of concern among the members of his working group and ACGIH's Chemical Substances TLV Committee, which made the formal recommendation that set the stage for adoption of the proposal in New Orleans.

"There was a great deal of soul searching within the committee on that issue," Ratney said, adding that "some people said, 'Why should an occupational exposure limit refer to the fetus?' That was no easy matter to settle, but one thought was that a TLV or a PEL—any exposure limit—is designed to protect what we'll call the functional capacity of a worker, not just prevention of overt illness. One of the functions people perform is having kids, hopefully healthy kids."

According to the ACGIH background document for lead, available evidence suggests that blood-lead levels below 40 μg/dl will minimize the potential for adverse health effects in adults.

IQ Impairment

However, the document noted there is some evidence, though it is conflicting, that IQ development in children is impaired when blood-lead levels in their mothers or their own umbilical cords during gestation range from 20 μg/dl to 30 μg/dl.

"Accordingly, the TLV Committee feels that workplace conditions that keep a woman's blood lead level below 20 μg/dl will protect her ability to bear children that can develop normally," the document said.

What effect, if any, the ACGIH position will have on OSHA as the agency drafts a permanent standard for the construction industry to replace the interim rule is unclear. However, OSHA has updated its risk assessment for lead as part of that rulemaking, and agency officials have indicated that more stringent regulatory limits are under consideration at the agency (21 OSHR 1634).

Jeffrey Miller, director of environmental, health, and government affairs for the Lead Industries Association, told BNA he did not believe the ACGIH action would have much of an effect on the OSHA rulemaking.

"I think it will have the same impact as if we went to OSHA and asked them to do nothing," Miller said.

"OSHA is undertaking a risk analysis at this time and I believe they will try to do a very thorough job and the public will have an opportunity to comment on it," he said.

Chemicals

ACGIH RETAINS 'SUSPECT CARCINOGEN' LISTING FOR MBOCA, ADOPTS OTHER THRESHOLD LIMIT VALUES

The chemical substance MBOCA will retain its status as a suspected cancer-causing agent on the American Conference of Governmental Industrial Hygienists' list of voluntary occupational exposure limits known as threshold limit values adopted May 18.

In deciding to retain the "suspected carcinogen" designation for 4,4'-methylene bis (2 chloroaniline), ACGIH agreed that scientific evidence was not sufficient to warrant changing MBOCA's status to that of a known human carcinogen.

The conference's Chemical Substances TLV Committee had recommended in 1990 changing MBOCA's status to known carcinogen and removing its 0.01 parts per million TLV on the basis of a National Institute for Occupational Safety and Health epidemiologic study.

However, closer scrutiny of the study showed that MBOCA-exposed workers who contracted bladder cancer may have had exposure to other carcinogens, thus confounding the results, according to ACGIH officials.

ACGIH in 1992 reversed its decision to reclassify MBOCA and instead proposed retaining the suspect classification and placed the substance on its notice-of-intended change list for one year (22 OSHR 53). ACGIH's action this year at its annual meeting in New Orleans establishes the MBOCA classification as official conference policy.

ACGIH members proposed or adopted as final standards threshold limit values and biological exposure indices for a number of other substances as well. The complete TLV and BEI lists are published in the Full Text section of this issue.

Adopted, Proposed TLVs

The conference adopted TLVs for some 25 substances, including MBOCA, cadmium, carbon tetrachloride, perchloroethylene, and trichloroethylene. Other substances placed on the adopted TLV list were acetaldehyde, acetophenone, acetic anhydride, adipic acid, arsenic (elemental and inorganic compounds), arsenic trioxide production, benz[a]anthracene, tert-butyl alcohol, and *p*-tert-butyl-toluene.

Also, *p*-dichlorobenzene, 1,4-dichloro-2-butene, diethylamine, diquat, ethylamine, rosin core solder decomposition products, terephthalic acid, tetranitromethane, triethanolamine, trimellitic anyhdride, and vinyl acetate.

New or revised TLVs were proposed for 25 substances, while TLVs for 14 substances were held over on the notice-of-intended-change list from the previous year for further consideration.

Substances with proposed new or revised TLVs were: acetone cyanohydrin, ammonium perfluorooctanoate, bromine, 1,3-butadiene, chromium (various compounds), 2-N-dibutylaminoethanol, diethanolamine, diethylamine, 2-diethylaminoethanol, dimethylethoxysilane, and EPN.

Also, ethylamine (skin notation), ethyl chloride, heptachlor and heptachlor epoxide, hexachlorobenzene, hydrogen cyanide and cyanide salts, lead, mercury, methyl-tert butyl ether, mineral oil mist, ozone, phenyl glycidyl ether, sodium fluoroacetate, sulfometuron methyl, and triethylamine.

Held over from the previous notice-of-intended-change list were: adiponitrile, asbestos (all forms), benzene, benzyl ace-

Mostly type only
employee number
not name
attached

~~PERSONAL & CONFIDENTIAL~~

~~C-8~~ BLOOD SAMPLING RESULTS

Births and Pregnancies

Current (12) PPM C-8 in Blood ~~(April 1981)~~	Status
0.45	Normal child - born June 1980. Transferred out of Fluorocarbons 4/79.
0.28	Normal child - born April 1981.
0.078	Normal child - born April 1981. Umbilical cord blood 0.055 ppm.
1.5	~~Five months pregnant~~. On pregnancy leave
0.013	~~Five months pregnant~~. Normal child - born August 1
2.5*	Child - 2 plus years. Unconfirmed eye and tear duct defect.
0.048	Child - 4 months. One nostril and eye defect. Babies blood 0.012ppm
2.007	Normal child - born July 1981

*Current blood level - in fluorocarbons area only one month before pregnancy.

FINAL REPORT

Epidemiology
Medical Department
3M Company
St. Paul, MN 55144

Date: March 15, 2002

Title: Identification of Fluorochemicals in Human Sera. III. Pediatric Participants in a Group A Streptococci Clinical Trial Investigation

Study Start Date: September 29, 2000

Protocol Number EPI-0011

Principal Investigator: Geary W. Olsen, D.V.M., Ph.D.[1]

3M Co-investigators: Jean M. Burris, M.P.H., R.N.[1]
James K. Lundberg, Ph.D.[2]
Kristen J. Hansen, Ph.D.[2]
Jeffrey H. Mandel, M.D.[1]
Larry R. Zobel, M.D.[1]

Study Sponsor: Corporate Occupational Medicine, Medical Department, 3M Company, 220-3W-05, St. Paul, MN 55144

1. Medical Department, 3M Company, St. Paul, MN 55144

2. Environmental Laboratory, 3M Company, St Paul, MN 55144

products. PFOS has been detected at low parts per billion (ppb) concentrations in the general population (Hansen et al 2001; 3M Company 2000) although the scope of these investigations has been limited. Using high pressure liquid chromatography/electrospray tandem mass spectrometry, Hansen et al (2001) detected an average PFOS concentration of 28.4 ppb (SD 13.6; range 6.7-81.5) in 65 commercial individual human sera samples. An analysis of pooled blood samples (n = 3 to 6 pooled samples per location with 5 to 10 donors per pooled sample) from 18 blood banks in the United States resulted in a mean measured PFOS serum concentration of 30 ppb with a range from 9 to 56 ppb (3M Company, 2000). Serum PFOS concentrations among production employees working in POSF-related processes were approximately 2 parts per million (ppm) depending on work activity (range 0.1 to 12 ppm) (Olsen et al 1999).

The purpose of this study was to better characterize the distribution of seven fluorochemicals, including PFOS and some of its precursors, using individual pediatric samples obtained from a multi-center clinical trial of group A streptococcal infections. The present study is the third formal assessment undertaken by the 3M Company to examine the distribution of PFOS in human sera. The previous two assessments examined serum fluorochemical levels among American Red Cross adult blood donors (Olsen et al 2000a) and elderly participants of a longitudinal cognitive function study in the Seattle (WA) area (Olsen et al 2000b).

fluorochemicals manufactured by other companies. PFHS, the sulfonate form of perfluorohexane sulfonyl fluoride (PHSF) may be a residual by-product of POSF-related production. 3M produced the PHSF as a building block compound incorporated in fire fighting foams and specific post-market carpet treatment applications.

Sample Collection

The sera analyzed in this study were collected as part of a large multi-center clinical trial of 1,131 children, ages 2 to 12 years, who presented with signs and symptoms of acute-onset pharyngitis (Kaplan et al 1998). All 1,131 children had positive throat cultures for group A streptococci at an initial visit. The objective of the original research was to determine age-specific geometric mean titers and upper limits of normal for antistreptolysin O and anti-deoxyribonuclease B. Sera for the clinical trial were obtained between January 1994 and March 1995. Sera were kept frozen at -20 degrees Celsius by the University of Minnesota Department of Pediatrics prior to the 3M request of an alloquot of 0.1 ml per sample for the present study (additional amounts were obtained for the reliability analysis - see below). Because of the uncertainty regarding the population distribution of PFOS, sample size was estimated by the use of tolerance limits (Natrella 1966). Provided below is the sampling distribution that was used. Percent sampled was the highest for the younger ages and included all samples four years of age and less.

11.9 ppb for a 95% tolerance limit with an upper 95% confidence limit of 14.8 ppb. Finally, for the calculated index of TOF, the mean was 112.1 ppb for the 95% tolerance limit with an upper 95% confidence limit of 125.0 ppb.

DISCUSSION

As seen in Figure 6, the geometric mean measured concentrations for these pediatric samples is consistent with those reported for adult blood donors (Olsen et al 2000a) and elderly participants of a longitudinal study of cognitive function (Olsen et al 2002b). No substantial differences were observed for PFOS or PFOA between the three study populations. Interpretation of the PFHS, PFOSAA and M570 is more problematic because the LLOQs varied slightly between studies and thus the assumption of a midpoint value may unduly influence a geometric mean calculation when comparing mean measured concentrations for the three studies.

Displayed in Figure 7 is another perspective regarding the differences in measured fluorochemical concentration distributions between the pediatric, adult and elderly population data. It is clearly evident that the 95% tolerance limits for PFHS and, to a lesser extent M570, were substantially different in children than compared to the adult and the elderly populations whereas the mean concentrations of the 95% tolerance limits were similar for PFOS, PFOA and PFOSAA. These findings suggest a different exposure pattern for some children compared to the adult and the elderly populations. While residual PFHS related chemistry may have existed in POSF related materials, it was an intentional major ingredient only in fire fighting foam and an after market carpet protector, which was discontinued in 1999. One potential hypothesis to explain the