



CHEMICAL MANUFACTURERS ASSOCIATION

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June 30, 1986

TO: HEALTH AND SAFETY CONTACTS

Enclosed is the first issue of the Health and Safety Newsletter, a quarterly publication of CMA's Health and Safety Committee. It includes valuable information concerning regulatory developments and Congressional and Administration action affecting the chemical manufacturing industry in addition to pertinent activities of Health and Safety Committee task groups.

For additional information on any item, contact the specified individual. As Editor of the Newsletter, I welcome your comments and suggestions. Please feel free to contact me at 202/887-1365.

Sincerely,

Marion R. Herz
Manager
Health, Safety and
Chemical Regulations

MRH:mdm

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DR. A. S. CUMMIN

HEALTH + SAFETY NEWSLETTER

CHEMICAL
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EPA ISSUES INVENTORY UPDATE REPORTING RULE FOR EXISTING CHEMICALS

The EPA Administrator has signed a rule under the Toxic Substances Control Act (TSCA) that will require reporting for chemical substances listed on the TSCA Inventory of Chemicals in Commerce. For chemicals subject to reporting, the rule will require that companies report production volume, plant site location, and use information. As explained further below, the rule includes exemptions for certain small companies and certain classes of substances. EPA published the final rule in the Federal Register on June 12, 1986 (51 Fed. R. g. 21438). Reports will be due by December 23, 1986.

Substances covered by the rule include those originally reported for the Inventory as well as those subsequently added after PMN review and receipt of a notice of commencement of manufacture or import. The following substances are excluded from the rule: polymers, inorganic substances, microorganisms, and naturally occurring chemical substances. In addition, substances manufactured or imported at less than 10,000 pounds per year at a plant site will be exempt from reporting at that site.

Companies will be exempt from the rule if they are small manufacturers who satisfy either of two standards: 1) total annual corporate sales of less than \$40 million and total site-specific production volume (or total amount imported) of a substance below 100,000 pounds per year, or 2) total annual corporate sales of less than \$4 million.

The last group eligible for exemption is companies that manufacture or import chemical substances in limited circumstances or through coincidental manufacture, for example, manufacture or import of substances for research and development, as non-isolated intermediates, or as impurities or by-products with no separate commercial intent.

The initial reporting will occur within 120 days after the beginning of the reporting period. The designated time for recurring reporting is four years after the first reporting period and every four years thereafter. These reporting periods will be 120 days, also.

For further information concerning the final Inventory update rule, review the Federal Register notice. Instruction booklets, reporting forms, and answers to questions can be obtained by calling EPA's special hotline at 202/382-3698 or 202/755-4880.

CMA Contact: R. Garrity Baker, 202/887-1280

BUREAU OF LABOR STATISTICS ISSUES NEW GUIDELINES

New Bureau of Labor Statistics (BLS) Recordkeeping Guidelines for Reporting Occupational Injuries and Illnesses, which went into effect on April 24, 1986, contain clarifications, including that injuries incurred in company-owned parking lots and on company-owned athletic facilities are no longer considered work related injuries.

The Safety Programs Task Group (SPTG) is planning a seminar in conjunction with OSHA and the Bureau of Labor Statistics to address injury and illness recordkeeping and reporting requirements under the new Guidelines. Scheduled for September, the seminar will feature OSHA and BLS professionals discussing issues (provided in advance by members of the chemical industry) relating to reportability, enforcement and interpretation. In addition, the new Guidelines will be compared to the old BLS 412 Guidelines. The SPTG has created a work group which will solicit potential discussion items from CMA members and submit them to the agencies. This seminar will provide an opportunity for industry to obtain clarification and elaboration on critical points.

The Guidelines, coupled with OSHA's present emphasis on recordkeeping, should be required reading for every company officer responsible for reporting workplace injuries.

CMA Contact: Kyle B. Olson, 202/887-1275

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WORKER NOTIFICATION BILL SCHEDULED FOR EDUCATION AND LABOR COMMITTEE MARKUP

Congressman Gaydos' (D-PA) "High Risk Occupational Disease Notification and Prevention Act" (H.R. 1309, as amended) was reported out of a Subcommittee of the Education and Labor Committee on May 14. It is anticipated to be reported to the House floor by the full Committee at a markup scheduled for later this month.

H.R. 1309 proposes new legislation to identify and individually notify past and present workers who are at elevated risk for contracting an occupational disease due to a hazardous occupational exposure. The bill uses an arbitrary trigger to identify worker populations at risk. According to the trigger, if the incidence of associated disease in an exposed worker population is 30 percent more than the incidence of the same disease in a non-exposed population, the exposed population would be labeled at risk.

Although CMA supports the general objectives of this legislation, which are to identify increased risks and facilitate prompt intervention, the Association opposes specific provisions of H.R. 1309, as stated in CMA's on October 9, 1985 testimony before the Subcommittee on Health and Safety of the Committee on Education and Labor:

The arbitrary trigger of 30 percent excess incidence of disease to identify workers at risk is scientifically unsound and unsupportable.

- The bill does little more than duplicate standards already in force under OSHA's Hazards Communication Standard and the Employee Exposure and Medical Records Access Rule.

On May 15, the Senate Subcommittee on Labor held a hearing on Senator Metzenbaum's (D-OH) companion legislation (S. 2050), which is similar to H.R. 1309, as amended. CMA submitted a statement for the record in opposition to the Metzenbaum proposal, reiterating similar concerns expressed in testimony on H.R. 1309.

Congressman Petri (R-WI) recently introduced H.R. 4793, the Republican substitute for the Gaydos bill, which builds upon the existing OSHA Hazards

Communication Standard. The bill expands the scope of the Standard to the non-manufacturing sector and further requires that employers notify former employees whose addresses are known of the health hazards present in the employees' work area during their employment. CMA is working with others in the business community to achieve consideration of the Petri substitute as the Gaydos bill moves through the House.

CMA Contact: Lori M. Ramonas, 202/887-1384

ADMINISTRATION RELEASES BIOTECHNOLOGY POLICY

After two years of study, the White House released its program for federal regulation of biotechnology products on June 18, 1986. The overall agency plan, titled "Coordinated Framework for Regulation of Biotechnology", maps out agency jurisdiction over biotechnology products. The first part of the plan was issued by the Administration in November 1985, providing for the establishment of an interagency review panel to discuss cross-cutting scientific issues and share regulatory information.

EPA's policies that apply to microbial products subject to TSCA or FIFRA include the following requirements:

- Microorganisms deliberately formed to contain genetic material from dissimilar source organisms (inter-generic) will be subject to review before any environmental release, including small-scale field testing and other environmental research and development. EPA is considering a rule to exempt certain contained areas.
- Microorganisms formed by genetic engineering and other inter-genetic combinations will be subject to the following provisions: (a) If any source organism is a pathogen, the resulting microbial products are subject to review prior to any environmental release except if used solely for non-pesticidal agricultural uses, which are subject only to USDA review; (b) If source organisms are not pathogens, the resulting microbial products will be subject to

abbreviated review before any small-scale environmental release.

- Non-engineered microorganisms: (a) Indigenous pathogens will be reviewed prior to use on greater than 10 acres of land and greater than one acre of water, except those that are solely for non-pesticidal agricultural purposes; (b) Nonindigenous pathogens will be reviewed under FIFRA for any environmental release, and under TSCA prior to release at greater than 10 acres; nonindigenous microorganisms that are not pathogen will be subject to abbreviated review before any small-scale environmental release.

Microorganisms containing genetic material from other microorganisms in the same genus (products of deliberate intra-generic combinations) and those developed from a single source microorganism (products of undirected mutagenesis, microorganisms with deletions) will be considered "new" for regulatory purposes. This policy may be revised, however.

The Subcommittee on Natural Resources, Agriculture Research and Environment and the Subcommittee on Science, Research and Technology of the House Committee on Science and Technology held joint hearings on June 4 and 5, 1986, on H.R. 4452, the "Biotechnology Science Coordination Act of 1986", to regulate certain products of the biotechnology industry. Major topics of discussion during the hearings were:

Risk Assessment --- What are the risks associated with biotechnology and how should they be assessed? Is liability insurance available to or should it be required for companies involved in this field?

- Precise definitions of the terms "release into the environment" and "genetically engineered organism"

The committee plans further hearings on this bill and the Administration policy.

CMA Contact: Marion R. Herz, 202/887-1365

EPA POSTPONES EFFECTIVE DATE OF R & D REGULATION

EPA recently postponed for sixty days the effective date of the final rule that defines research and development activities on new chemicals that are exempt from premanufacture notification under the Toxic Substances Control Act. EPA published the rule in the Federal Register on April 22 (51 Fed. Reg. 15096), and it was to take effect June 5. With the 60 day extension, the effective date of the final regulation is now Monday, August 4.

Risk Evaluation

The new final rule places several conditions on research and development without PMN review. First, it requires that companies evaluate the potential risks of substances manufactured for R & D purposes. The rule recognizes the special situation faced in laboratory research. For laboratories, the rule allows the use of prudent laboratory practices for handling new substances in lieu of risk evaluation. Outside of the laboratory setting, however, companies will be required to evaluate the risks of R & D substances. They will be required to review information in their possession and control and information on health effects which accompanies any EPA rule or order issued under TSCA sections 4, 5, or 6.

Notification

Companies must notify persons involved with R & D of any potential health risks associated with the substance. This notification requirement extends to persons who are involved in experimentation, research, or analysis on the R & D chemical, including manufacture, processing, use, transport, storage, and disposal. Persons employed by the manufacturers and to whom the company directly distributes the R & D substance must be notified. For distribution outside the company, the manufacturers must notify in writing that the substance is to be used only for R & D purposes and provide the notice of health risks.

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R cordkeeping

Manufacturers and importers of R & D substances must keep records of certain information for five years to document compliance with the rule. Companies must keep records of: 1) the information reviewed and evaluated to perform the required risk evaluation; 2) the nature and method of the required notification, including copies of labels or written notices; 3) the prudent laboratory practices used in lieu of the required risk evaluation; 4) the names and addresses of persons outside the company to whom the substance is distributed, the identity of the substance, the amount distributed, and copies of required notifications; and, 5) for substances produced or imported in excess of 100 kilograms per year, additional records must be kept of the identity of the substance, the production volume, and the person's disposition of the substance.

In the coming weeks, CMA member companies should review the final rule and bring their R & D activities into compliance with the requirements of the rule.

CMA Contact: R. Garrity Baker, 202/887-1280

LABELING TASK GROUP REVISES ANSI LABELING STANDARD

The primary role of the CMA Labeling Task Group is to represent the Chemical Manufacturers Association as Secretariat for the revision of the "American National Standard for the Precautionary Labeling of Hazardous Industrial Chemicals" (ANSI Z129.1). Since OSHA issued the Hazard Communication Standard, this project has become increasingly important to CMA member companies as an industry consensus on risk communication in the workplace.

In the 1987 Standard, the Labeling Task Group will suggest labeling language for physical, acute, and chronic hazards, and will recommend precautionary labeling for environmental storage and disposal of industrial chemicals. A selection of symbols for acute and physical hazards may also be incorporated in the Standard, depending upon the results of an industrial field test to determine which symbols are most effective in conveying an intended message.

It is projected that the first draft of the 1987 Standard will be available for review in the fall of 1986. At

that time, the Labeling Task Group will canvass organizations targeted to have appreciable interest in the development of the Standard. Through a consensus procedure involving formal vote by the organizations, a final Standard will be developed for publication by the American National Standards Institute in 1987.

CMA Contact: Nancy G. Doerrer, 202/887-1282

CHANGES PROPOSED FOR NEW CHEMICAL FOLLOW-UP PROGRAM

CMA is participating in a consensus project to improve the new chemical follow-up program in EPA's Office of Toxic Substances (OTS). The project was begun by the Conservation Foundation's Toxic Substances Dialogue Group, a multi-partite consensus group formed to address issues in implementation of the Toxic Substances Control Act (TSCA). The Dialogue Group proposed that EPA develop a regulatory mechanism to follow and, where necessary, control the commercial development of new chemicals that have been through the premanufacture notification (PMN) program.

EPA and the Dialogue Group are holding public meetings to develop a TSCA significant new use rule that will implement the Dialogue Group's proposal. As envisioned by the Dialogue Group, the significant new use rule (SNUR) would apply to two groups of chemicals in the PMN review program. The first group consists of those chemicals that are subject to section 5(e) orders in the course of PMN review. The second group that would be subject to the SNUR consists of those chemicals for which the PMN use does not pose a problem but for which increases in exposure would raise EPA's risk concern.

For substances subject to the SNUR, the rule would require notice to EPA before companies undertake activities that are prohibited by the SNUR. Thus, the rule has a direct impact on the commercial development of new chemicals. Basic issues that need to be addressed are how to select chemicals for the SNUR and what use restrictions to place upon selected chemicals. For the two groups of substances subject to the SNUR, the answer to these issues is different.

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For 5(e) chemicals, selection is not an issue because they are candidates for the SNUR by virtue of the 5(). Similarly, the restrictions imposed by the SNUR will mirror the restrictions of the 5(e) order. In effect, the SNUR will extend the 5(e) order to all manufacturers and processors.

Selection is more complex an issue for the new substances which are not subject to a 5(e) order but for which EPA has a concern. EPA and the Dialogue Group are working to develop criteria for health and environmental effects that could be used to select these substances. For the restrictions on these substances, the Dialogue Group is working to develop a list of major use changes that could significantly increase exposure. For example, off-site use in a case where the PMN specified a site-limited use.

The rule will also establish procedures for making substances subject to the rule and for petitioning EPA to change the provision of the SNUR. Because of the important precedent of this rule, all CMA members should review the upcoming drafts that will be publicly available.

CMA Contact: R. Garrity Baker, 202/887-1280

SERIOUS INCIDENT: REACTION OF CHLOROSULFONIC ACID AND HEPTANE

Eastman Kodak Company issued a report to the chemical industry for educational purposes, describing an unexpected reaction of which little documentation had previously appeared in literature. We urge you to share this report with the proper personnel in your company.

A 592 gallon chlorosulfonic weigh tank ruptured violently causing considerable damage to equipment, piping, and the building structure. There were no injuries to personnel. It was estimated that it would require a minimum of 80 psi in the weigh tank to reach the yield point of the steel tank. It was also estimated that a force of 85,000 pounds was necessary to cause the three-and-one-half inch upward deflection of the 18-inch roof beam caused by the rocketing weigh tank.

The weigh tank is used to provide a continuous measured feed to a batch chlorination reaction. It is filled by direct pumping from a storage tank in yard.

The last filling of the weigh tank emptied the storage tank resulting in sludge from the bottom of the storage tank entering the weigh tank. The weigh tank feeds by gravity into the reactor and the sludge plugged the lines preventing complete emptying of the weigh tank. After the batch was completed and the reactor emptied of product, attempts were made to clean the lines with nitrogen, but after several attempts, there still remained approximately 50 gallons of chlorosulfonic acid in the weigh tank.

The normal practice for cleaning the weigh tank and associated piping is to wash with a commercial grade heptane until all chlorosulfonic acid is removed and then wash the tank and piping with water. This procedure had been performed many times without incident.

It was decided to wash the sludge from the weigh tank with heptane, and when 33 gallons of heptane had entered the weigh tank through a bottom outlet, an unexpected reaction occurred. The reaction created sufficient pressure to overcome the one-and-one-half inch relief line and overpressure the vessel. After eliminating the possibilities of contamination by water, alcohols, etc., laboratory work discovered that a vigorous reaction occurred between heptane and chlorosulfonic acid that would create enough gas to overpower the relief valve and overpressure the vessel.

Apparently, this reaction is not well known and has limited documentation in literature. Kodak's experimental work, however, confirmed the reaction with commercial heptane and chlorosulfonic sludge as well as with dry n-heptane and reagent grade chlorosulfonic acid.

CMA Contact: Kyle B. Olson, 202/887-1275

HAZARD ASSESSMENT TASK GROUP ADDRESSES REPRODUCTIVE EFFECTS AND CARCINOGENICITY

The Hazard Assessment Task Group (HATG) acts to provide toxicological and regulatory expertise in the development and advocacy of CMA positions on hazard identification, test requirements and methodologies, and interpretation of toxicological studies.

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Current testing efforts of the HATG focus on two chronic hazard areas: reproductive/developmental effects and carcinogenicity. The task group commissioned a report on a proposed tier system for developmental toxicity evaluations. The paper, to be submitted for publication in *Teratology*, describes a tier approach that markedly reduces the time and cost of developmental toxicity evaluations, and reduces the number of animals normally required for routine *in vivo* tests. The system makes use of recently devised *in vitro* assays to quantitatively rank chemicals according to their developmental hazard index, in conjunction with appropriate exposure considerations. The Hazard Assessment Task Group hopes to promote the use of this approach in future EPA test rule proposals and in the Agency's reproductive/developmental test guidelines review.

A second major effort has been in the area of carcinogenicity. A joint industry association group has been formed under the HATG to provide scientific input at several upcoming meetings of the International Agency for Research on Cancer (IARC). Dr. L. Tomatis, Director of IARC, has invited CMA to provide critical comments to an IARC Committee prior to a planning meeting in September 1986. The intent of the meeting is to review IARC's scientific criteria for making carcinogen evaluations. With industry input from CMA, AIHC, PMA, NACA and API, Ian C. Munro, Ph.D., of the Canadian Centre for Toxicology is writing a document addressing the scientific criteria for carcinogen evaluations.

In another series of meetings in late 1986 and early 1987, IARC will evaluate a list of 200 chemicals/exposures for activity in short-term tests and for carcinogenic risk to humans based on experimental and epidemiological data. CMA has been invited to nominate an observer to these meetings. The joint industry association group is currently planning a method by which CMA member companies will provide chemical-specific carcinogenicity evaluations in advance of these IARC meetings. The CMA observer will then be briefed and trained to represent to the IARC Committee scientific issues of concern to the industry.

CMA Contact: Nancy G. Doerrer, 202/887-1282

CMA AIR TOXICS EFFORT INCORPORATES MANY GROUPS

The Safety Programs Task Group (SPTG) is addressing the management of the acute emissions portion of CMA's Air Toxics Control Policy implementation project. Working in conjunction with the Environmental Management Committee and an ad hoc group of communications professionals, the SPTG will compile guidance materials that address the elimination of uncontrolled air releases. This activity is designed to fulfill the commitment made by the Chemical Manufacturers Association earlier this year to identify and, to the extent feasible, reduce emissions into the atmosphere.

The SPTG is coordinating the labors of several groups, including the Hazard Assessment, Risk Assessment, and Process Safety Task Groups, and the Engineering Advisory Committee. The end product will be a compilation of documents that can be used by a plant manager or a designee to evaluate existing air release problems and formulate responses to them.

Among the materials being prepared: a discussion of risk assessment methodologies, a review of current lists of hazardous materials and suggestions of how the plant manager can use them, a list of commercially available training programs as well as examples of internally developed training courses, and a discussion of administrative and engineering measures for reducing the chance of accidental releases into the air.

CMA Contact: Kyle B. Olson, 202/887-1275

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CAER GROWS IN NUMBERS, ACTIVITIES

CMA's Community Awareness and Emergency Response (CAER) program continues to grow. One hundred forty-five CMA member companies have identified more than 1400 sites currently active in the program. CAER is also gaining advocates outside the Chemical Manufacturers Association. The Chamber of Commerce of the U.S., the Metal Finishing Suppliers Association, the Chlorine Institute, the American Trucking Association, and the Synthetic Organic Chemical Manufacturers Association have endorsed the program and are encouraging their members to implement it.

The CAER Task Group has established several projects to assist companies and communities in implementing the program:

- The task group is developing an Emergency Response Drill Training Module booklet and other course materials that will help communities conduct emergency response simulations to test their contingency plans.

- The task group has prepared three videotapes describing the CAER program, how to establish a community coordinating group, and how to work with the media.

- A National CAER Conference, held in Washington, D.C. addressed subjects including the preparing of a site emergency response plan; establishing inter-industry coordination at the local level and how to work with your state chemical industry organizations; approaching local government to set up community coordinating groups; involving the media in local emergency response planning; and actual experiences in conducting community drills.

CMA continues to work with state organizations to implement the CAER program. Proposals for specific programs to help state CICs have come from Florida, Michigan, New Jersey, Ohio, and Texas. Programs will focus on first responder training workshops, developing CAER brochures, and activities designed to reach small communities and other manufacturers and users of chemicals.

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Task Group Organization

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