BEVERIDGE & DIAMOND, P.C.

For your information from
SCOTT W. BOWEN

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MEMORANDUM TO TSCA FILE

I. Health and Safety Reporting Rules

EPA recently published a final rule under TSCA Section 8(d) requiring chemical manufacturers and processors to submit unpublished health and safety studies for specifically listed chemicals (47 Fed. Reg. 38780, September 2, 1982). (See attached list.) The rule applies to studies conducted within the last 10 years and during the next three years. The rule affects 39 substances and categories that the Interagency Testing Committee (ITC) recommended for additional testing from June 1977 through June 1981. The rule also requires similar reporting for all new additions to the ITC priority list.

As originally proposed on December 31, 1979 (44 Fed. Reg. 77470), the regulation would have required industry to retrieve health and safety data from the past 20 years instead of 10 years as required in the final rule. Other major changes in the final rule are the addition of exemptions for distributors; research and development chemicals not on the TSCA chemical inventory; and certain specified studies including certain data on physical and chemical properties and impurities, published studies, nonconfidential studies already submitted to other agencies and EPA, and monitoring data. Moreover, manufacturers and processors of mixtures containing the listed chemicals are not required to submit studies on acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, primary eye irritation, primary dermal irritation, or physical and chemical properties.

The Agency also published a proposed rule on September 2 that would require industry to submit unpublished health and safety studies on 14 other chemicals or chemical categories recommended for testing by the ITC since June 1981 (47 Fed Reg. 38800). Under both the final and proposed rules EPA is seeking exposure monitoring studies, industrial hygiene studies, environmental and health studies, and other physical and chemical data that indicate the potential effects of a chemical. The final rule, which became effective October 2, allows industry 60 days to submit the unpublished reports.

II. PCBs

A. Final Electrical Rule

EPA recently published a final rule amending portions of the existing PCB rule (44 Fed. Reg. 31514, May 31, 1979, recodified at 47 Fed. Reg. 19527, May 6, 1982) banning, after October 1, 1985, transformers and electromagnets that contain more than 500 parts per million (ppm) polychlorinated biphenyls (PCBs) and that pose an exposure risk in food or feed facilities. Until the ban goes into effect, the rule, which became effective September 24, requires that they be inspected weekly. Large PCB capacitors will be authorized for the remainder of their useful lives if they are located in restricted access electrical substations or in contained and restricted access indoor installations. (47 Fed. Reg. 37342, August 25, 1982.) All other large PCB capacitors will be banned after October 1, 1988 instead of after 10 years as the Agency had earlier proposed (47 Fed. Reg. 17426, April 22, 1982). (See B&D memoranda of March 31, May 5, June 16, and July 30, 1982.)

In additional modifications to the April proposal, EPA did not define the extent to which PCB spills must be cleaned up; reduced the length of time inspection and maintenance histories must be maintained on disposed PCB transformers from five years to three years; authorized the storage of large, nonleaking high-voltage PCB capacitors and PCB-contaminated electrical equipment outside of qualified storage facilities after January 1, 1983; and declared that oil-filled cables can be assumed to contain less than 50 ppm PCBs if the actual PCB concentration is unknown. Consequently, such cable equipment is not regulated under the new PCB rule.

The revision of the rule was mandated by the U.S. Court of Appeals for the D.C. Circuit in a 1980 decision that concluded that exclusions from the original PCB rules were without adequate supporting data and that new rules should be promulgated. Environmental Defense Fund v. EPA, No. 79-1580, October 30, 1980. (See B&D memorandum of November 5, 1980.) The court required EPA to publish new rules by August 19, but the Agency petitioned the court in the beginning of August to extend the date until November 1.

In a related development, the Environmental Defense Fund and Natural Resources Defense Council sued EPA September 8, seeking judicial review of the new rule. The groups complained that the rule's allowance of continued use of PCB transformers does not prevent water contamination from spilled PCBs.

B. Citizen's Petition

On August 25, EPA rejected a citizen's petition from Dow Chemical Company to initiate rulemaking to exempt monochlorinated biphenyls from regulation. (47 Fed. Reg. 37258). (See B&D memo-

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randa of June 16 and July 30, 1982.) The Agency said another rule is currently being developed to address incidental polychlorinated biphenyls generated as byproducts in chemical streams and that Dow's processes "fall within the scope of this rulemaking".

Dow submitted the petition May 13 under TSCA Section 21, which allows citizens to petition the Agency to amend, issue, or repeal rules.

C. Closed and Controlled Incidental PCBs

Under a new draft final rule on closed and controlled incidental PCBs, PCB byproducts produced by chemical reactions would not be subject to regulation if their concentrations did not exceed specific limits set for the medium in which they are contained, i.e., air, water, or solid waste and finished products. PCBs are often spontaneously formed in chemical reactions, particularly where organic chemicals and high temperatures are present. The draft final rule follows a proposal published on June 8 that would exempt all closed and controlled incidental PCBs from regulation if owners certify that "no quantifiable releases" into the environment result from their use. (47 Fed. Reg. 24976)

Whereas the June proposal set the limit for exemption of closed and controlled incidental PCBs at nonquantifiable release, the draft rule specifies individual cutoff levels for each medium, as follows:

- In air, 10 micrograms per cubic liter;
- In water, 100 micrograms per liter; and
- In finished products and waste, 2 micrograms per gram of inorganic chemical reactants (2 ppm).

EPA has labeled these levels "practical limits of quantitation," or the lowest limits that the Agency believes can be practically quantified in air, water, and waste, because, according to the draft rule, it would be impossible to determine whether regulation of PCBs below these levels had any effect on actually reducing releases of PCBs. (See B&D memorandum of June 16, 1982).

While the draft rule would require the same recordkeeping and certification as the proposal did for the processes that qualify for exclusion from the PCB regulations, it would add a new requirement that firms report to EPA if they claim an exclusion. Recertification and renotification would be required whenever a chemical process undergoes "significant process changes." Firms would be allowed either to measure their chemical stream contamination levels or use a theoretical assessment to estimate the PCB concentrations.

III. Premanufacture Notification Exemptions

EPA recently published two proposals to exempt polymers and site-limited intermediate chemicals and low-volume chemicals from premanufacture notification requirements under TSCA Section 5 (47 Fed. Reg. 33896, 33924, August 4, 1982). (See B&D memoranda of February 22 and July 30, 1982.) Under the proposals, about 50% of the new chemicals produced in the U.S. would be exempt from major portions of the PMN process if industry-selected "qualified experts" certified that the new substances meet certain toxicity criteria.

Polymers that would not be covered by the proposed exemption are those for which the Agency has insufficient data and review experience to determine that they will not present an unreasonable risk, or those that the Agency has found may present significant risk.

Manufacturers of chemicals exempted from all PMN requirements would still be required to submit a brief notice to the Agency when manufacture begins in order to insure that substances meet the conditions of the exemption. The notice would include the manufacturer's name, production site, type of exemption, chemical identity, and the polymer's number-average molecular weight and polydispersity.

Polymers with a number-average molecular weight of 1,000 or greater would be eligible for a limited PMN submission where manufacturers would submit a PMN to the Agency at least 14 days in advance of manufacture. The proposal stated that two weeks would allow the Agency enough time to identify polymers that present serious unresolved issues concerning toxicity or exposure. Polymers subject to the 14-day PMN reviews under the proposed exemption would have to submit the manufacturer's name, chemical identity, production site, residual monomer and low molecular weight species content, number-average molecular weight, production volume and use, test data available to the firm and a certification from the qualified expert that the chemical met the criteria for exemption.

Under the proposal, site-limited intermediates and low-volume chemicals would be eligible for a shortened review period after a qualified expert certified that the substances would produce no serious chronic or acute affects in humans or significant environmental affects. The low-volume exemption is only available to the first manufacturer or importer of a chemical. Only manufacturers could qualify for the site-limited intermediates exemption, however.

Chemicals manufactured in quantities of less than 1,000 kilograms per year would be eligible for a nearly total exemption. Manufacturers of such substances would be required to submit written notification to EPA 14 days before commencing production, but only when the chemical may cause serious acute or chronic health effects in humans or significant environmental effects.

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Industry would be required to submit a shortened notice 14 days prior to production for chemicals produced in quantities above 1,000 kilograms and below 10,000 kilograms and for site-limited intermediates. The qualified expert certification that the chemical met all criteria for the exemption must be included in the notice in addition to the firm's name, exemption sought, chemical identification, use (except for site-limited intermediates), annual production, and site of manufacture.

IV. Asbestos

On August 30 a final rule became effective requiring asbestos manufacturers, importers, and processors to report data on quantities of asbestos used in making products, employee exposure, and waste disposal pollution control equipment, under TSCA Section 8(a). (47 Fed. Reg. 33198, July 30, 1982). (See B&D memorandum of July 30, 1982.) The rule was originally proposed on January 26, 1981 to obtain information on industrial and commercial uses of asbestos for possible future regulation (46 Fed. Reg. 8200).

The final rule differs from the proposal principally in two respects: first, firms must report data on production exposure and disposal from the last three years instead of the last five years as was proposed; and, second, a proposal provision that would have required industry to maintain records on customer lists of monitoring data was deleted.

The rule requires that secondary asbestos producers--that is, those who make asbestos products from asbestos mixtures--report data to the Agency in a two-part process. First, companies must identify themselves and the asbestos mixtures they process or import, and second, some of the firms will be chosen by EPA to complete an extensive second phase reporting form.

Under the rule those firms that mine, mill, or import bulk asbestos or process it to form an asbestos mixture byproduct must complete a four-page reporting form within 90 days of the effective date concerning their products' production volumes, asbestos consumption, number of employees, workplace exposure, waste and disposal procedures, pollution control equipment, and estimated amount of emissions. Secondary processors must complete a single page form within 60 days of the effective date. This form requires the companies to identify asbestos mixtures or components, the amounts consumed or imported in 1981, and the products into which these mixtures and components are incorporated. From the 5,700 short forms the Agency anticipates receiving from secondary processors, the Agency will select about 1,500 processors to complete the longer report form.

V. TSCA Oversight Hearing

The Senate Environment and Public Works Subcommittee on Toxic Substances and Environmental Oversight held a hearing on August 4 to evaluate EPA's approach to implementing the Toxic Substances Control Act of 1976.

Dr. John A. Todhunter, EPA Assistant Administrator for the Office of Pesticides and Toxic Substances, discussed the new pre-manufacture review proposals (see Part III of this memorandum) voluntary testing programs, and enforcement actions under TSCA. Todhunter said that PMN exemption proposals will "assure that only clearly nonrisk chemicals are able to receive reduced review and that a high level of public health and environmental protection would be maintained more cost-effectively." Regarding voluntary testing programs, Todhunter defended the Agency by maintaining that the negotiated testing approach can lead to testing sooner than formal rulemaking by at least one year. He also commented that compliance inspections and enforcement actions have increased under the present administration.

VI. Guidelines for Development of Test Data

EPA announced the availability of guidelines for testing chemicals under TSCA on July 30 (47 Fed. Reg. 33001) through the National Technical Information Service. The guidelines outline methodologies that can be used when the Agency requires industry to test a chemical under a TSCA Section 4(a) test rule. The guidelines address methodologies for health effects, environmental effects, and chemical fate tests.

On September 22 the Agency announced that it will be conducting an annual review of the generic test guidelines to insure that testing methodologies recommended by the Agency remain current and consistent with advances in science (47 Fed Reg. 41858). Comments are due on the test guidelines January 3, 1983.

Attachment