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LATION EFFECT THE ONLY CHANGE IN SMALL BUSINESS EXEMPTION RULE

Provisions for exempting "small business" from TSCA Section 8(a) were expected to be finalized by Federal Register publication this week or next, the only change from a long-standing proposal traceable to inflation (See June 23, 1982, Page 19).

Instead of a total annual sales cutoff of \$3 million as in the original proposal, the company will qualify for the exemption -- in reporting production under Section 8(a) requirements -- only if its annual sales revenue in the preceding year was less than \$4 million. Companies can qualify for the exemption if they meet the \$4 million standard or:

"Total annual sales revenue of the manufacturer during the most recent complete corporate fiscal year is less than \$40 million and the manufacturer's annual volume of production of a Section 8(a) subject chemical at a particular plant site . . . is less than 45,400 kg (100,000 lbs.)."

When discussing total annual sales revenue, EPA said it includes sales of chemical and non-chemical products and those by any foreign or domestic parent company or subsidiary of the manufacturer.

ONES TESTING NEGATIVE; SOME POSITIVE RESULTS NOTED FOR GLYCOL ETHER

Negotiated TSCA testing results on three related substances produced no reproducible ill effects in short-term exposures, EPA was told in a "for your information" report from the Chemical Manufacturers Association Ketones Program Panel.

Another "FYI" report from Union Carbide showed teratologic effects at highest dose levels for a glycol ether, 2-ethoxyethylacetate.

The CMA Ketones Panel report covered the substances methyl ethyl ketone (MEK), methyl isobutyl ketone (MIBK) and isophorone. CMA summarized:

"None of the data developed during the panel's testing programs indicates that MEK, MIBK or isophorone may pose an unreasonable risk to human health during current or anticipated conditions of use and exposure for these compounds. In addition, when evaluated by the criteria specified in the negotiated testing agreements, none of the data provides a basis for initiating further testing."

Short-term tests carried out for MEK were an Ames assay, mouse lymphoma, unscheduled DNA synthesis, micronucleus cytogenetic assay and morphological transformation assay in mouse embryo cells. For MIBK, the same tests were run, although some positive results, at a level of 96% cell lethality, were disproved by a second mouse lymphoma assay. Also for MIBK, a 90-day subchronic study at levels up to 1,000 p.p.m. found only increased liver weight as a toxic effect. CMA said of a teratology study of MIBK in rats and mice:

"In both animal species, signs of maternal toxicity and fetotoxicity occurred at the highest exposure level tested, 3,000 p.p.m. There was no evidence of treatment-related maternal or embryo-fetal (including malformations) toxicity in either species at the 1,000 or 300 p.p.m. exposure level. No treatment-related increases in fetal malformations were seen at any exposure level tested."

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Four mutagenicity tests conducted for isophorone were negative, according to the report, which said teratology testing for the substance has been completed and will be submitted soon.

Union Carbide's report on inhalation exposure of rats and rabbits to the company's Cellosolve Acetate summarized results in part:

"In rabbits, exposure to 100, 200 or 300 p.p.m. resulted in maternal toxicity . . . Embryo-toxicity was observed at 200 and 300 p.p.m. (an increased incidence of totally resorbed litters at 200 or 300 p.p.m., an increase in non-viable fetuses at 300 p.p.m. and a decrease in viable implants or live fetuses per litter at 200 or 300 p.p.m.). Fetal body weight appeared reduced at 300 p.p.m. (but not significantly) based on only three litters with a total of 11 live fetuses. The incidence of fetal malformations (external, visceral and skeletal) was elevated at 200 and 300 p.p.m. The incidence of total malformations was 100% at 300 p.p.m. and significantly elevated at 200 p.p.m., exposure concentrations at which maternal toxicity was observed. Fetotoxicity (reduced ossification) was observed at 100, 200 or 300 p.p.m. At 50 p.p.m., there was no evidence in rabbits of any maternal, embryo or fetal toxicity or teratogenicity.

"In rats . . . embryo/feto toxicity was observed at 300 p.p.m. . . . The incidence of visceral, skeletal and total malformations was elevated at 200 and 300 p.p.m. External variations, indicative of fetotoxicity, were elevated at 300 p.p.m. The incidence of visceral and skeletal variations was elevated at 100, 200 and 300 p.p.m., including those indicative of fetotoxicity. These exposure concentrations also produced maternal toxicity. At 50 p.p.m. in rats, there was no evidence of maternal, embryo or fetal toxicity or teratogenicity."

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EARLY PUBLIC INVOLVEMENT NEEDED IN SITING WASTE SITES, WORST SAYS

"Early and substantive public involvement is required" for a successful siting of a hazardous waste site, Nancy Worst, Empak, Inc., told the Hazardous Materials Control Research Institute (HMCRI) conference Nov. 7. She additionally noted that the public needs scientific, technical and procedural information and that the information must be implementable.

Worst outlined the Keystone siting process used in Texas to manage conflict in controversial siting issues. She said the structure of the committee should be "objective, represent different interests and backgrounds, reflect local concerns and be committed to developing the report."

There are 18 regional members on the Texas Keystone committee, Worst said, including "environmental groups, academic professionals, industry, community planners, public interest groups and members from the medical profession." "Their report is used to identify local concerns, but they do not approve or disapprove the facility," she said.

The system allows "early citizen input, permits conflict identification and resolution in an informal forum, provides reliable information to the community and provides an informal exchange between the applicant and the community," Worst said.

"Joint cooperation between government, the public and industry will foster responsible participation" in siting the cleanup of hazardous waste sites, Nancy Juor, CH2M Hill, said in speaking to the same session as Worst. She said a central issue is, "What does the public really need to know?" Juor said some of the central issues commonly raised are on "health effects and risk assessment, costs and benefits, groundwater protection and treatment and contaminants standards."