The planned system would be more efficient, the official explained, and would allow better use of agency personnel by allowing them to set aside quickly those notices which present little concern.

At one time, EPA treated all notices the same throughout the review period. The agency, however, quickly learned that such an approach would not work once the volume of notices being submitted increased. It then established the 40-day preliminary screening and discovered that one of every six or seven notices needs a more detailed review, the EPA official told Chemical Regulation Reporter March 17.

While the new review system would establish a "slow track" and a "fast track" for different new chemicals, the EPA official stressed that the agency still will review every new chemical.

A new chemical cannot be dismissed on the basis of its chemical structure alone, he said. Even though its structure may be similar to an existing chemical or the substance may be part of a group of chemicals considered to be innocuous, the agency cannot dismiss the chemical without considering its application and exposure, he noted.

Even structurally related chemicals may vary in fat solubility, in ability to be broken down by light, or in other characteristics which alter their potential for creating hazards, he said.

Continuing Lack of Data

The agency is trying to find more ways to get data on individual notices. The EPA official noted that after many months of receiving notices, the amount and quality of data received on new chemicals has improved very little.

There are two troubling trends, he said. The first, one which the agency has complained about on numerous occasions, is the lack of test data on new substances. Many of the notices contain no test data and almost none have presented any subchronic or chronic studies, he noted.

Industry is not keeping promises it made to submit information on new chemicals, he said. Some of the submiters, many of them large firms with long-term experience in the chemical industry, have refused to provide use information, he said.

He complained that some of the firms which promised a cooperative effort in submitting PMN information now are refusing to supply basic information.

Industry is shirking responsibility for testing new chemicals, he said, adding that he sees no evidence of a trend indicating industry intends to assume such a responsibility.

Exemption Requests

The second problem facing the agency in the review of the notices is an industry trend to submit a test marketing exemption (TME) request with the premanufacture notice.

Since the TME must be approved or disapproved within 45 days, the agency is forced to perform the review more quickly, he explained.

The trend could lead to instances where the agency lacks evidence at 45 days to disapprove the TME but decides later in the PMN review period to take some regulatory action on the new substance, he noted. If the trend continues, the agency will have to uncouple the two reviews, he said.

In recent weeks EPA has taken several actions to reinforce its position that PMNs and TMEs should include adequate information and test data.

Such efforts include the rejection of some submissions as inadequate. Another is increasing interest in using significant new use rules to require future reporting for substances which complete review without any regulatory action being taken.

Vinyl Chloride

ALCOHOL INCREASES CANCER EFFECTS, UNIVERSITY RESEARCHER TELLS CONFERENCE

Alcohol drinkers may have increased susceptibility to the carcinogenic effects of vinyl chloride vapors, a Government-sponsored conference was told March 20.

Martha Radike, of the University of Cincinnati, reported the results of a study in which laboratory rats were given water containing 5 percent ethanol and were exposed to vinyl chloride.

The animals that received alcohol had a much higher incidence of vinyl-chloride-induced malignant tumors than the rats exposed to vinyl chloride alone, she said.

The test animals were exposed to a concentration of 600 part per million vinyl chloride vapor, four hours each day, five days a week for one year.

Control groups exposed to vinyl chloride alone and to alcohol alone had elevated tumor rates in comparison with a control group not exposed to either substance, Radike reported

The tumors in the alcohol-only group tended to be benign, rather than malignant, she said.

Radike compared the level of alcohol given to the test animals to a moderate drinking level, similar to a six-pack of beer or a few glasses of wine.

She said the experiment was suggested by the fact that ethanol and vinyl chloride are known to share a step in the metabolic pathway.

Radike suggested that epidemiological studies should be carried out on human populations exposed to vinyl chloride to determine whether chronic alcohol use is related to cancer incidence.

The two-day conference on vinyl chloride toxicity was sponsored by the National Institute of Environmental Health and Safety, the National Institute for Occupational Safety and Health, and the Occupational Safety and Health Administration.

The conferees heard reports from 37 researchers, including Caesar Maltoni of the Institute of Oncology and Tumor Center in Bologna, Italy.

Inhalation Studies

Maltoni reported the results of extensive inhalation studies in rodents at various dose levels ranging from one to 30,000 ppm.

In long-term studies, test rats developed increased incidences of cancer at levels as low as 10 ppm, Maltoni said.

The OSHA standard for worker exposure to vinyl chloride sets a maximum limit of one ppm, averaged over an eight-hour period.

Maltoni's experiments involved exposure of test animals for four hours a day, five days a week, for varying periods.

He reported that the test animals exposed to vinyl chloride suffered a variety of tumors, including cancer of the liver, lung, kidney, stomach, skin, brain, mammaries, and Zymbal's gland.

May Affect Fetus

Maltoni also reported a study suggesting that exposure of a pregnant animal to vinyl chloride can increase the incidence of cancer in her offspring.

He described experiments in which female rats were exposed during pregnancy to vinyl chloride vapors at concentrations of 6,000 and 10,000 ppm.

The offspring of the exposed rats later developed a higher incidence of liver cancer than the offspring of unexposed control rats, Maltoni said.

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The increase was over 30 percent in all exposed groups, according to Maltoni.

Short Exposures

Robert Hehir of the Consumer Product Safety Commission reported the results of experiments involving relatively brief exposures to vinyl chloride.

He described studies in which test rodents were given between one and 100 one-hour exposures to vinyl chloride vapors.

No statistically significant response resulted from single one-hour exposures, even at concentrations as high as 50,000 ppm, Hehir said.

However, a significant increase in lung tumors did occur in a group of animals given 49 one-hour exposures to 500 ppm of vinyl chloride over a 10-week period.

He told the conference that a comparison of this result with other published reports suggests that vinyl-chloride-induced cancer incidence is related to the total dosage received.

Reporting

MORE DETAILED RULEMAKING RECORDS MUST BE KEPT ON EACH CHEMICAL, CMA SAYS

The Chemical Manufacturer's Association is asking the Environmental Protection Agency to extend the comment period on its recently proposed reporting requirements for 8,300 chemicals until the agency develops individual dossiers for each chemical.

The March 17 request, asking for a more detailed rulemaking record and a lengthier comment period on the rule proposed February 29 under Section 8(a) of the Toxic Substances Control Act, is in keeping with the group's oft-repeated stance stressing the need for rulemaking accountability for each and every substance included in the rule (Current Report, February 29, p. 1798, 1831).

The industry position is diametrically opposed to the generic approach EPA has been developing under TSCA.

The petition also reinforces CMA's position that EPA must make an "unreasonable risk" finding for each individual chemical the agency plans to include in a labeling rule.

The petition is CMA's latest effort urging EPA to set up chemical-by-chemical selection criteria. Using the CMA plan for manufacturer review of agency decisions, however, might cause manufacturers to spend more time checking agency data than they would spend filling out the relatively short Section 8(a) reporting form, sources said.

The petition indicates the industry group is anxious to prevent future, and perhaps more burdensome, requirements from using one underlying basis for rulemaking for all chemicals involved.

This first response to the Section 8(a) rule came as a surprise to the agency since the proposed rules were not expected to be very controversial, an EPA staff member said. The selection or inclusion of certain chemicals, however, and the requirement to submit customer information, always were expected to raise some objections.

CMA's Requests

Besides asking for an individual justification for each chemical on the list, CMA asked the agency to explain the process for reviewing the chemicals. The group also asked EPA for its rationale for requiring the reporting, including a description of the scoring or selection progress.

CMA also wants the record for each chemical to include any information collected by the Interagency Testing Committee or by EPA in subsequent study of the chemical.

EPA said in its proposal that many of the chemicals were selected from ITC scoring lists.

The industry group argued that the five general criteria given by EPA in the proposal do not give sufficient indication of how the chemicals were chosen because the proposal does not spell out which criteria were applied to which chemicals.

Finally, CMA asked EPA to extend the comment period on the proposal until 60 days after all requested information is compiled and included in the public record.

Although EPA has not replied yet, any decision to compile such a detailed record could delay the rule indefinitely. CMA recognized this fact in its petition when it pointed out how long it would take a manufacturer to gather such material for even a limited number of the chemicals.

Dibromochloropropane

CANCELLATION PROCEEDINGS TO INCLUDE HEARINGS IN ARIZONA, CALIFORNIA, HAWAII

Portions of Environmental Protection Agency hearings to consider the cancellation of registrations of dibromochloropropane (DBCP) will be conducted in Los Angeles, Phoenix, and Honolulu, EPA Administrative Law Judge Gerald Harwood announced March 18.

Various participants had requested field hearings on the West Coast and elsewhere to accommodate local witnesses, including migrant workers, farmers, and agricultural experts (Current Report, March 7, p. 1871).

Harwood, who will preside at the hearings, said he may decide later to hold additional field hearings in other requested locations, such as Georgia, Florida, and Texas.

Harwood scheduled another prehearing conference for April 30 and set April 29 as the deadline for participants to exchange witness lists and exhibits.

2,4,5-T

CASE AGAINST HERBICIDES OVERWHELMING, JELLINEK SAYS AS HEARINGS GET UNDER WAY

The evidence that the phenoxy herbicides 2,4,5-T and Silvex pose a hazard to health is "overwhelming," according to Environmental Protection Agency Deputy Administrator for Pesticides and Toxic Substances Steven D. Jellinek.

Jellinek released a public statement March 14 to mark the beginning of the oral phase of the hearings on EPA's proposed cancellation of registrations of the herbicides.

The hearings, in Washington, D.C., are expected to continue for four days each week for one to two years. In the first days of the formal proceedings, which began March 14, herbicide supporters cross-examined EPA witnesses on the health risks of continued use of the herbicides.

In his statement, Jellinek summarized the agency position in saying, "What makes the 2,4,5-T evidence overwhelming is its volume. What makes it unprecedented is its quality."

Dow: '2,4,5-T Is Being Victimized'

Etcyl Blair, Dow Chemical Company vice president and director of health and environmental sciences, related his firm's disagreement with EPA.

In a March 14 public statement, Blair said EPA is seeking to ban 2,4,5-T out of "politically expedient" motives, even though the agency's scientific data have been discredited