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R&S 113834

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HEATED BITTERNESS I hope the people are not lead by the lawyers to get satisfaction out of fighting? TRT

0000426

PREPARED DISCUSSION BY T. R. TORKELSON
FOR SOEH WORKING CONFERENCE ON OSHA PROPOSAL ON CARCINOGEN REGULATION - WASHINGTON, D.C. - JUNE 2, 1977

In the few minutes alloted, I don't intend to comment much on the legal implications of this standard. That will be left to the lawyers who can make each other miserable and lay off the scientist for a while. The circuitous (BOOTSTRAP) logic used to rephrase the 17 Principles of Carcinogenisis into this document hopefully will not stand legal tests just as they do not stand tests of scientific logic.

R&S 113835

I would rather direct your attention to some other considerations ~~that need to be discussed:~~

The first one is the obvious disregard for dose. Are we so naive as to believe that in practice all carcinogens are equally potent and the same controls will be needed for all? Can we ignore thresholds of response and changes in metabolism with dosage? How, for example, can we continue to operate breweries, distilleries, and pharmaceutical plants when no exposure to ethyl alcohol will be permitted for this acknowledged human (Category I) carcinogen. I presume we substitute other compounds. This is not meant to be facetious; ethanol is a documented human carcinogen and will require all the controls of Category I, although we all recognize or accept no practical carcinogenic hazard at low levels of exposure. Are we hypocritically going to ignore this proven human carcinogen as we do tobacco which so dominates the cancer

Who would make rebuttal decision on rebuttal. Not subject to review by court of appeals

EDUCATION IS NEGLECTED - Employee frustration supervision

problem in the U.S. that it makes occupational problems pale in comparison? Lung cancer, to a large extent due to tobacco, is the only form of cancer to show an increase in the U.S. according to the American Cancer Society. If OSHA is really concerned about cancer in the workplace, shouldn't there be a 200 page document restricting smoking to protect non-smokers. It is my understanding that this issue was raised at a recent NACOSH meeting. Apparently no legal opinion has yet been given on whether an employer can restrict smoking to protect his non-smoking employees under the general duty clause of OSHA.

This is not meant to suggest that excessive exposures to vinyl chloride, asbestos, arsenic, and other compounds have not caused cancer; obviously they require control and I certainly support proper regulations, as does all concerned industry. But it does indicate where society (and industry) might most effectively spend its resources if it is sincere about reducing cancer.

Second, the rigid simplistic frame work contemplated in the draft document removes all judgement and flexibility and precludes the use of future knowledge. OSHA must seriously consider other possible criteria such as measurement of the amount of DNA to which a material or its metabolite(s) are attached. Research in areas of immunology and hormonal regulation of natural defense mechanisms may also provide additional useful, measurable parameters in the future, but

the present proposal seemingly precludes use of future knowledge. It appears particularly inappropriate at this time to place so much emphasis on in vitro mutagenic tests. As stated by OSHA in the proposed rulemaking, methodology is rapidly developing in this field and to lock-in and for practical purposes render irreversible the relative role of in vitro testing at this time is not justified. I understand that as recently as two weeks ago, the Science Advisory Panel to the EPA noted that mutagenic studies are not at this time sufficiently developed to be standardized, and questioned their correlation to long term studies.

Third, Category I or II presumptions should not be raised by animal tests alone. Further tests should be performed to demonstrate: (1) that at least one of the species showing a positive result metabolizes the material as does man; (2) that the dose level at which a positive finding occurs is one which does not overwhelm the animals' ability to detoxify as demonstrated by metabolic and pharmacokinetic data; and, (3) that the dosage at which a positive finding occurs does not cause other significant adverse effects as judged by the most recent NCI criteria (growth, pathologic effects, etc.). The last two are particularly applicable to ethyl alcohol, just as they are to many of the other inappropriate animal studies at unrealistic dosages.

Fourth, with respect to human evidence of carcinogenicity, the proposal should take into account the principles of

dose/dependency in epidemiology studies. It must be recognized that epidemiology can never prove a cause and effect, at most it might show an association. However, when done properly and objectively retrospective epidemiological investigation can be a good and valuable tool and the results must not be ignored. Provision must be made, however, to avoid poorly designed and improperly conducted studies. Case report and inadequately controlled studies must particularly be avoided.

In regard to substitutes, it is well and good for someone to say "ban a material and use a substitute." Unfortunately, those who glibly make such statements are often unaware of what is entailed in finding a suitable and available substitute. Compositions must generally be tested for stability and functionality. Processing equipment, shipping containers, and users' processes must also be evaluated. In addition, before any substitution is made, extensive testing is necessary to insure that the substitute is safer than the original product. Such testing would generally include an evaluation of carcinogenic potential and other toxic potentialities, and such physical/chemical properties as reactivity and flammability. All this takes time, ranging from months to years. Thus, while it may be easy to say substitute, it may be difficult to accomplish. It must always be remembered that banning a product does more than just remove a cancer problem; it may also introduce other problems which in fact may be worse, or at least as serious, as the real or imagined risk for cancer.

Finally, I'd like to suggest that if generic regulation is to become realistic, then an additional Category IV should be established for substances that are not considered suspect carcinogens. Let's hope a few materials will be left for societies' use.

We all have learned a lot from the recent strong reaction of the public to the Delaney clause. What we are talking about here appears to be merely a take-off on the Delaney mentality. It is clear the public expects their regulators to be able to show some discretion and true understanding of all the facts. The public (and I might add, most employees) are not so naive as to believe that simplistic, all or nothing, laws are really the answer. They expect that as in any situation all information about a material is to be evaluated if it is to be given a fair shake. Let's not lock into law that which attempts to fully regulate an area which is still a very active area of research, and let's be careful not to lock out new methods, new information, and new insights into the causes, cures, and reductions in exposure to environmental carcinogens.

Berry

PRELIMINARY PROGRAM

SOEH

SOCIETY FOR OCCUPATIONAL AND ENVIRONMENTAL HEALTH

1714 Massachusetts Avenue, N.W., Washington DC 20036 (202) 785-8177

IMPLICATIONS OF THE OSHA PROPOSAL ON CARCINOGEN REGULATION

A WORKING CONFERENCE

June 2, 1977

Hotel Washington
Washington, D.C.

8:15 A.M. REGISTRATION

8:45 A.M. INTRODUCTORY REMARKS

Greetings from SOEH - Dr. Joseph Wagoner, SOEH President

Conference Overview - Mr. John C. Kolojeski
Conference Chairperson

9:00 A.M. THE OSHA PROPOSAL

- Mr. Grover C. Wrenn, Deputy Director, Directorate of Health Standards, OSHA

Discussants:

- [redacted] Director of the Toxicology Research Laboratory, Dow Chemical Corporation
- Dr. J. William Lloyd, Epidemiologist, United Steelworkers of America
- Dr. William J. Nicholson, Environmental Sciences Laboratory, Mt. Sinai School of Medicine

Open Discussion

10:45 A.M. IMPACT OF THE NATIONAL CANCER INSTITUTE AND ITS BIOASSAY PROGRAM ON THE OSHA POLICY

- Dr. Robert Squire, Associate Professor of Pathology and Comparative Medicine, Johns Hopkins University School of Medicine (former Acting Chief, NCI Carcinogenesis Bioassay Program)

Discussants:

- Dr. Umberto Saffiotti, Chief, Experimental Pathology Branch, Carcin genesis Program, NCI
- (To Be Confirmed)

Open Discussion

--over--

R&S 113841

SOEH

SOCIETY FOR OCCUPATIONAL AND ENVIRONMENTAL HEALTH

IMPLICATIONS OF THE OSHA PROPOSAL ON CARCINOGEN REGULATION

A WORKING CONFERENCE

June 2, 1977 — The Hotel Washington, Washington, D.C.

ADVANCE REGISTRATION

Name _____

Affiliation _____

Address _____

_____ Zip _____

Telephone Number _____

Advance registration is recommended since attendance is limited. The registration fee includes lunch.

Enclosed: / / $15.00 Registration fee for SOEH Members

/ / $45.00 Registration fee for non-members

/ / Please check if you wish a copy of the OSHA proposal sent to you prior to the conference. Copies must be sent on or before May 23. Otherwise, your copy will be available at the registration table at the conference.

Please mail this form with your check to:

SOEH
1714 Massachusetts Ave., NW
Washington, D.C. 20036
Tel: (202) 785-8177

No registration fees will be refunded after May 31, 1977.

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SOCIETY FOR OCCUPATIONAL AND ENVIRONMENTAL HEALTH
1714 Massachusetts Avenue, N.W., Washington DC 20036 (202) 785-8177

April 26, 1977

Dear SOEH Members:

The Society will hold a working conference on the implications of the proposed Occupational Safety and Health Administration policy on carcinogen regulation on June 2, 1977, at the Hotel Washington in Washington, D.C. In March you received a letter regarding the conference from Mr. John C. Kolojeski, Conference Chairperson, asking you to reserve the date on your calendars.

Enclosed are a preliminary program and a registration form. Since attendance will be limited, please return the registration form with your check as soon as possible. Also, if you wish to receive a copy of the draft proposal prior to the conference, we need to mail it before May 23, 1977.

The one-day conference will highlight the draft proposal itself, and also how it will interface with other federal agencies. Major presentations will be made on the impact of the National Cancer Institute and its bioassay program on the OSHA policy and on the interface between the Environmental Protection Agency authority on carcinogens and OSHA. Other governmental components, including the National Institute for Occupational Safety and Health, the National Institute for Environmental Health Sciences, the Council on Environmental Quality, the Commerce Department, the Government Accounting Office, the Office of Technology Assessment, and the Food and Drug Administration, are being asked to designate representatives to the conference to provide substantive comments from the floor on the ramifications of the policy from their perspectives. Open participation, questions, and comments will take precedence over formal presentations.

This conference will deal with significant policy decisions. Plan to attend.

Sincerely,

Sandy Zimmerman
Executive Director

Enclosures (2)

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SOEH Working Conference:
IMPLICATIONS OF THE OSHA PROPOSAL ON CARCINOGEN REGULATION

June 2, 1977

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A Memo From

DOW

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Milt Hunt DC
Jim Hansen DC

This is the information on the SOEH meeting.
Good luck with
Gary Robinson

T. R. Torkelson

R&S 113850

From the desk of...

DOW

Marguerite L. Leng

Jim Hanson C1751

6/14/77

T. R. Torkelson

Attached are two articles about the SOCH meeting, both of which take pot shots at your talk. The first one says you misstated case on mutation testing, possibly because they thought you were referring to the EPA Science Advisory Board rather than Science Advisory Panel. They are quite different. Both are meeting this week or next to further discuss mutagenicity testing as noted on attached meeting notices.

Keep the faith!

M.

R&S 113851

PESTICIDE & TOXIC CHEMICAL NEWS

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PESTICIDE ADVERTISING TRR which has been under consideration by the Federal Trade Commission may not be issued because FTC now thinks it already has enough authority to enforce against advertising abusers, according to an EPA official. A Commission official said no decision had been made on TRR issuance, but admitted that the option of not issuing it would be considered at a public meeting set for today, June 8. EPA-ers noted that FTC may be worried about the time and expense of preparing a final TRR and said that there is some feeling that the problem of false advertising has abated (See Nov. 17, Page 5).

EPA DENIAL of 100 p.p.m. tolerance petition for Captan on seed corn (See June 1, Page 2) could result in review by an NAS advisory committee. Some EPA officials expect an appeal to an NAS committee to be filed (See Nov. 3, Page 5 and Nov. 24, Page 5).

CAPTAN RPAR decision is expected to be made about Oct. 15 (See June 1, Page 2).

ETHYLENE OXIDE RPAR decision is expected this month (See May 18, Page 27). The RPAR, if issued, would be based on mutagenicity and/or oncogenicity, Edwin L. Johnson, Deputy Assistant Administrator for Pesticide Programs, EPA, has indicated.

MALEIC HYDRAZIDE RPAR notice is now scheduled to be issued June 24 (See May 25, Page 2).

PRONAMIDE RPAR rebuttal time extension to August 26 has been requested by Rohm and Haas, sole manufacturer of the technical grade product and the 50% wettable powder marketed under the name "Kerb- 50-W." The firm said EPA raised some points it had not considered of concern and noted that additional time was needed to evaluate the RPAR notice (See May 11, Page 11).

KEPONE CANCELLATION hearing parties who have yet to file formal objections and labeling have been given until June 17 to do so by EPA Administrative Law Judge Bernard D. Levinson (See Junel, Page 2).

TSCA TESTING Committee, when it submits its list of no more than 50 chemicals for which EPA should require tests under TSCA, also will list chemicals for which information appears to be sufficient to make further testing unnecessary. Whether such information justifies regulation will be up to EPA (See June 1, Page 14).

GENERIC STANDARDS FOR PESTICIDES are being discussed at OSHA (See June 1, Page 24).

MINOR USE TOLERANCES may be issued for RPAR candidates if RPAR criteria triggers are not relevant to petitioned tolerances (See June 1, Page 2), an EPA official said last week. These tolerance decisions will be made case-by-case, according to the agency official.

STATE REGISTRATIONS under Section 24(c) received to date by the Registration Division, OPP, EPA, total 850, according to OPP.

PESTICIDE & TOXIC CHEMICAL NEWS

R&S 113854

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6/8/77

DOW EXECUTIVE MISSTATES CASE ON MUTATION TESTING; EPA TO PROCEED

Despite allegations to the contrary made by a Dow Chemical Corp. executive at a meeting of the Society for Occupational and Environmental Health (SOEH), the Environmental Protection Agency's Science Advisory Board (SAB) has not determined that the state of the art of mutagenicity testing (See June 1, Page 2) is so primitive as to preclude use of mutagenicity data to support regulatory actions against pesticide chemicals.

The executive, Dr. T. R. Torkelson of Dow's medical department, told last week's SOEH symposium on a cancer proposal from the Occupational Safety & Health Administration (OSHA) that OSHA should not depend on mutation tests at all for purposes of defining a chemical as a Category I carcinogen. Such a definition would trigger issuance of an OSHA emergency temporary standard entailing monitoring for the chemical in workplaces where it's produced, used, or packaged, as well as medical surveillance of exposed workers, "good housekeeping" requirements and other steps (See May 25, Page 20).

Placement of a chemical into Category I could be "rebutted" in a rulemaking proceeding. If the rebuttal were unsuccessful, the rulemaking would determine what the "lowest feasible" exposure level is, and workplaces would have to reach it. It would become the OSHA permanent standard. In the rulemaking, OSHA also could say that there are suitable substitutes for the chemical and attempt to promulgate a permanent standard requiring zero exposure.

OSHA has proposed to allow a positive bioassay result in a single mammalian species to trigger Category I classification if the bioassay has been "replicated" by a test on the same or a different species, or, if there exists "multi-test evidence of mutagenicity."

Torkelson said EPA's SAB, two weeks prior to the June 2 SOEH meeting, had decided that mutagenicity testing "wasn't ready yet" for regulatory use, and, Torkelson said, it would be "inappropriate" for OSHA to use mutation data if EPA wasn't going to.

However, the SAB Environmental Health Advisory Committee met June 1 to discuss EPA's proposed mutagenicity testing requirements for pesticides (See April 13, Page 14 and May 18, Page 2) and indicated that, in fact, the types of tests which EPA has proposed are sufficiently validated to require them for pesticide registration actions.

Drake, Nelson, Wogan and Abrahamson Say Mutation Tests are Ready

At the June 1 SAB meeting, another Dow executive, Dr. V. K. Rowe, said EPA should not impose the mutagenicity battery because th tests which comprise it have not been validated and because their relevance to man is questionable.

Dr. John W. Drak , a member of the study group which helped EPA draft the Section 3 guidelines, disagreed, saying that EPA and the study group had chosen only the best validated tests out of a possible total of 30.

Dr. Norton Nelson, Chairman of the Environmental Health Advisory Committee, said that based on "a wide variety of studies in the animal kingdom, we do know that heritable mutations are a severe threat. The jump from that to the human population is, to my mind, miniscule."

His arguments on validity and relevance to man discarded, Rowe then maintained that SAB should advise EPA to delay adoption of the testing requirements until the Agency had better defined what would be a "statistically significant" result in each test and until EPA had spelled out how it would interpret "mixed results" from the component tests in the eight-test battery.

Dr. Gerald Wogan, Chairman of Drake's study group, said that nothing in the upcoming criteria document, which will address "mixed" results, will change the requirements which EPA has set forth.

On statistical significance, EPA's final guidelines will provide "more acceptable biometric wording" regarding what constitutes a significant finding in each test, according to EPA's Dr. Ruth Pertel, a principle author of the mutagenicity guidelines. This change comes about largely as a result of urgings from Dr. Lincoln E. Moses, professor of statistics at Stanford University and a member of SAB.

With respect to maintaining flexibility and not putting mutagenicity testing requirements "in bronze," Nelson said, "Sure things are in a major state of flux, but that state of flux is going to lead to alternative ways of doing very much the same kind of things we're doing now, but doing them in a more efficient way." The document will say that the battery shall be reviewed every three years for possible changes. Drake held that some of the eight test "could fall by the wayside" not because they're invalid, but because "a more rapid or less expensive test may come along."

In probably the most telling argument against bacterial tests not being relevant to man, Dr. Seymour Abrahamson gave some history on how, with respect to radiation, a human risk estimate per Roentgen per gene using the mouse as a model has turned out to be "almost identical" to the human risk estimate which can be computed by using Drosophila (bacteria).

Abrahamson said there is "good evidence" that man responds very closely to the mouse in terms of radiation sensitivity. He said the U. S. spent over $50 million establishing the mouse as an appropriate model when it turns out that bacteria would have been just as good an indicator.

He said the argument against the mutagenicity testing battery on economic grounds was untenable, since, by Abrahamson's calculations, the battery would cost no more than $45,000 per compound.

He said the most expensive test other than the mouse specific locus test (which is included among the 13 from which eight will be chosen because it's valid, despite its cost) is the Drosophila test, which would cost around $10,000 if the experimenter was trying to detect a doubling of the spontaneous mutation rate. Abrahamson said the Drosophila test could cost as little as $1,000 if the experimenter were looking for a more drastic response, such as a five-fold increase over the spontaneous rate. Abrahamson is based at the University of Wisconsin.

The Wogan-Drake study group will meet June 15 to discuss the criteria document which will describe how EPA will interpret "mixed" mutagenicity testing results.

R&S 113856

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USDI LABORATORY TO INPUT RPAR PROCESS WITH FISH, WILDLIFE EFFECTS DATA

Fish-Pesticide Research Laboratory (FPRL), U. S. Fish and Wildlife Service, Interior Department, under an intragency agreement with the Environmental Protection Agency, will provide data on the effects of pesticides on fish and wildlife for use in the risk assessment portion of the rebuttable presumption against registration (RPAR) process.

The agreement, signed June 2 by Edwin L. Johnson, Deputy Assistant Administrator for Pesticide Programs, EPA, stated that the FPRL, located in Columbia, Mo., would supply copies of published and notification of unpublished results of research on the effects of about 150 pesticides -- RPAR candidates and alternatives -- on fish and wildlife.

In the first month, the Laboratory would provide reprints and research results on about 60 pesticides, according to the agreement which has not yet been signed by the Fish and Wildlife Service. After the first month, the agreement noted, research results and reprints would be required on 10 to 20 compounds a month. The Laboratory would also supply negative responses, the agreement provided.

The agreement would expire Sept. 30, 1977. EPA would pay the Fish and Wildlife Service about $10,000 for supplying the effects data.

EPA will list and assign priorities to the pesticides for which the Laboratory will provide effects data.

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$5,850 CIVIL PENALTY AGREED TO BY THOMPSON-HAYWARD HEADS EPA ENFORCEMENT

An agreement signed by Thompson-Hayward Chemical Co. of Fayetteville, N. C., to pay a $5,850 civil penalty assessed by Environmental Protection Agency officials in Region IV highlighted recent pesticide enforcement activity.

that the "important thing is how much product (grams? volume?) is put on the plate to form colonies." He said that these data are critical to evaluate the potential environmental hazard of this product.

Correction: Notice of receipt of the new active ingredient registration application was published in the April 29 not April 30 Federal Register.

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OSHA CANCER PROPOSAL HIT; SEEN AS FAILING TO SPEED RULEMAKING

The as-yet unproposed regulation under which the Occupational Safety & Health Administration (OSHA) would regulate carcinogens and suspect carcinogens (See Feb. 16 Page 33) was ridiculed by a Dow Chemical Corp. executive last week at a public forum in Washington, D.C., as being an example of "bootstrap logic" which could leave industry with no chemicals left to work with.

At the same forum, which was sponsored by the Society for Occupational & Environmental Health (SOEH), labor union officials criticized the proposal for not mandating that employers pay for employee protective clothing and equipment and medical examinations which OSHA carcinogen regulations do and will require.

Jack Sheehan, Legislative Director of United Steelworkers of America and Chairman of the Policy Subgroup of the National Advisory Committee on Occupational Safety & Health (NACOSH), criticized the cancer proposal for not solving the problem of "rate retnetion" i.e. "mandatory relocation."

As explained by Anson Keller, co-author of the OSHA proposal, the rate retention/mandatory relocation dilemma pertains to an employer moving an employee to an area of a business operation where exposure to a regulated chemical is less. Such a change often results in a lower salary for the employee, since less hazardous work usually pays less.

In short, Keller said, an employee could work for a firm for 30 years, get cancer, and because of the detection, lose his high salary. The phenomenon could prove to be an incentive for employees to avoid the medical examinations which OSHA wants employers to perform and make available.

OSHA Administrator Elva Bingham is assembling an advisory group to study the problem.

Unionists such as Sheehan derided the document one moment and commended it the next. OSHA was commended for attempting to improve its performance in carcinogen regulation but was derided for not taking an even deeper plunge into labor-management relations. Grover Wrenn, a Deputy in OSHA's Health Standards Division, and defender of the proposal throughout the all-day symposium, said OSHA's health-protecting plunge was inadvertant and the extent of it was unforeseen, but Wrenn defended it as necessary.

The Dow executive, Dr. T. R. Torkelson (See Page 3) hit the proposal for what he called "an obvious disregard for dose" when using laboratory animal tests to determine whether a chemical is a carcinogen. Torkelson got support from Dr. Roy Albert, Chairman of the Environmental Protection Agency's Carcinogen Assessment Group (CAG) (See May 18, Page 31), who asked if it "makes sense" to not consider dose for purposes of classification.

According to the proposal, a substance could be classified as a Category I carcinogen if it has been shown "at any dose level to cause the formation of malignant or benign neoplasms, or a combination thereof, in (a) man, or (b) two mammalian test species, or (c) a single mammalian test species if those results have been replicated in another experiment or by multi-test evidence for mutagenicity, or (d) upon the basis of any other evidence that the Secretary (of Labor) finds sufficient."

A Category II classification would be triggered by "suggestive" evidence of carcinogenicity from a single experiment on a single mammalian species, regardless of dose.

Category I classification would prompt issuance by OSHA of an emergency temporary standard which would be followed in 60 days by a proposed permanent standard. The proposed permanent standard would embellish the emergency standard and impose medical surveillance, workplace monitoring and other "model" requirements which OSHA wants to impose "across the board" for all Category I chemicals.

Engineering controls would be proposed to bring exposure to the Category I chemical down to the "lowest feasible" level, and if OSHA believed that "suitable" substitutes were available, a "zero" exposure level could be set.

According to the proposal, issues at the hearing on the proposed permanent standard would be limited to:

> "(1) Whether the Secretary correctly classified the toxic material into Category I; (2) whether the Secretary was correct in his determination that the Category I classification should not be rebutted; (3) whether the Secretary correctly determined the lowest feasible occupational exposure, or whether there are suitable substitutes that are less hazardous to humans; (4) the appropriateness of the specific protective means of the proposed standard and (5) the environmental impact caused by such regulation."

Issues also would be limited in hearings on Category II classifications.

John Kolojeski, moderator of the conference and President of Clement Associates (See June 1, Page 14) said that the proposed limitation on issues, which is central to OSHA's effort to speed rulemaking, could be construed as an abridgement of due process, while Sheehan held that these very issues probably would be litigated every time OSHA proposed a standard. Therefore, Sheehan said, OSHA rulemaking is likely to remain largely a substanc -by-substance affair, characteriz d by delay.

These cancer principles are essentially the same as those which have stretched out EPA cancellation proceedings on heptachlor and chlordane (See June 1, Page 25).

Once such review is completed, Wrenn contended, rulemaking would go faster.

The speed argument appears to have been rebutted by Sheehan, but Kolojeski argued in favor of making the document a regulation as opposed to a policy because the document's publication as a policy would not carry with it the mandatory timetables under which OSHA would be forced to propose permanent standards and take other actions.

The document could be abandoned by the next Administration if it were simply a policy, Kolojeski said.

Sheehan, on the other hand, argued that Federal Register publication of the proposal as a regulation would bog down OSHA in rulemaking on it and prevent OSHA from taking action on known problem chemicals. As an alternative, Sheehan suggested testing the policy on some real problems.

Pointing to the recent OSHA activity on benzene (See June 1, Page 11), Wrenn denied that Federal Register publication of the proposal as a regulation would hamper OSHA in its efforts to deal with current problems..

As a remedy to industry delaying tactics, NCI's Schneiderman suggested that for any chemical tied up in litigation, all profits should be placed in a closed fund unavailable to the manufacturer.

Richard Boggs of the National Institute for Occupational Safety & Health (NIOSH) asked how OSHA would handle chemicals which are similar in structure to those placed in Category I or II. He also asked for better definitions of the terms "feasible" and "detectable."

As an indication of just how complicated these issues are and how deep emotions run, a labor union official, misconstruing remarks made by Torkelson, said Dow is interested in DNA research because the firm wants to create a "super race" of chemical workers who are immune to cancer.

Over 140 people from government, industry and academia attended the SOEH conference.

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HOUSE COMMITTEE WANTS EPA TO ALLOW MIREX FOR FIRE ANT ERADICATION

"In the hope that the Environmental Protection Agency will rescind its ruling on mirex" the House Appropriations Committee has reserved $4,460,000 for a fire ant eradication program, (See March 30, Page 33).

Category II classification would prompt no emergency standard and no engineering controls, but an exposure limit would be set, as would medical surveillance and other "model" requirements. Rather than engineering controls, housekeeping practices and personnel protective equipment and clothing would be prescribed for Category II chemicals. Keller explained that Category II is needed to "gear up" in case information becomes available indicating that the chemical belongs in Category I.

Torkelson maintained that imposition of such requirements without consideration of the dose used in the animal experiment(s) would be irresponsible in light of the possibility that human metabolism could eliminate the threat which the chemical may pose.

Dose in Backup Animal Studies "Irrelevant," Says OSHA's Wrenn

Wrenn, however, responded that does was "largely irrelevant," since OSHA does not consider a threshold level to exist for carcinogens.

Marshall Miller, a legal expert and a former Deputy Assistant Secretary of Labor for OSHA, said that potency i.e. dose would be factored into OSHA deliberations "subjectively" when OSHA, taking economics into account, sets its lowest "feasible"or "zero" exposure level.

Wrenn also was supported by Dr. Marvin Schneiderman of the National Cancer Institute (NCI), who said that "cancer is bad," regardless of potency.

Kolojeski said procedures set out in the OSHA proposal for rebutting both Category I and II classifications "take care" of Torkelson's concerns.

Justification for rebuttals on toxicological grounds are spelled out twice in the OSHA proposal, once for Category I chemicals and once for Category II. According to Section 1990.11 of the proposal, the Secretary of Labor may rebut the presumption of a Category I classification if he determines:

> "(a) that the alleged carcinogenic effect based on animal data clearly resulted from non-specific physical, rather than chemical induction, or (b) that the route of exposure was grossly inappropriate relative to the potential occupational routes of human exposure, or (c) that the animal or human studies submitted for review were only suggestive or not adequate to establish any conclusion with respect to the carcinogenicity or noncarcinogenicity of the toxic materials or (d) that for some other biological reason, the positive results in experimental mammals are not scientifically relevant to man."

Justifications are similar for a successful rebuttal of a Category II classification. A successful rebuttal places a chemical at least one category below the proposed one.

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CAG's Albert Raises Sticky Regulatory Issue

Just what constitutes "replication" of an animal test, however, is a particularly difficult issue, according to CAG Chairman Albert. At the SOEH meeting, Albert cited a "not uncommon" example he has run across at CAG where a pesticide now up for a rebuttable presumption against registration (RPAR) notice was found to produce tumors in a long-term study conducted by the Food and Drug Administration (FDA), but the tumors were found only at the lowest dose level, which is "strange in itself," Albert said. A long-term study by NCI was negative, Albert stated, as were two others. Another study on the same chemical, however, was found to be positive in one sex at one dose level, but the tumors which appeared in the dosed animals appeared later than spontaneous tumors observed in controls. Since tumors in dosed groups usually occur sooner than tumors in controls, this "replication" of an already "suspicious" FDA study is questionable, Albert said. Nevertheless, the finding could conceiveably trigger a Category I classification if the OSHA proposal is allowed to stand as is (Albert would not reveal the identity of the pesticide in question).

Albert asked if positive findings in two dose groups in the same experiment would constitute "replication," as suggested by Dr. David Clayson of the National Cancer Advisory Board. He also asked whether observation of a dose-response relationship could be considered "replication." No one answered his rhetorical questions.

Generally, Albert expressed fears that OSHA's "black and white" proposal would give too much power to scientists.

Squire Fears "Over interpretation" of "Suggestive" Bioassay Results

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Dr. Robert Squire, former Chief of the NCI Bioassay Program (See March 2, Page 22) and now at Johns Hopkins University and an Associate Scientist with Clement Associates, Inc., warned against linking "suggestive" NCI bioassay results to OSHA regulation under Category II. He said "overinterpretation of uncertain results has done more harm to toxicology than anything else." He held that NCI's research mission should be allowed to continue unencumbered by OSHA's regulatory mission.

With respect to Category I classification, Squire said "results in a single mammalian species supported by incriminating in vitro data would be most convincing if either both sexes or more than one dosage group were affected."

There was considerable discussion on whether OSHA should simply adopt the proposal as an administrative policy, once it has been revised or, as an alternative, whether OSHA should publish it as a proposed regulation and subject it to judicial review.

The argument for the latter procedur , as stated by Wrenn, would be that to spe OSHA rulemaking, judicial r vi w is needed on the basic regulatory principles which OSHA follows every time it proposes a rule on carcinog ns.

ment areas on the map. There are twenty-three counties where strychnine baits may be applied following establishment of the presence of rabid skunks near areas of human habitation;

4. Exposure of any bait station within a five (5) mile radius circle (to survey for presence of rabid or suppress rabid skunk populations) may not exceed thirty (30) days;

5. Each strychnine lard bait will contain approximately 0.012 grams of actual strychnine alkaloid. Each strychnine egg bait will contain approximately 0.035 grams of actual strychnine alkaloid;

6. The Applicant's personnel are responsible for preparing the strychnine baits, selecting bait stations, posting warning signs, securing premise entry agreements, checking bait stations periodically for kills, and retrieving all unconsumed baits at the termination of the control program;

7. A maximum of two strychnine lard or egg baits per setting will be placed in the following skunk habitats: skunk dens, holes, garbage dumps, road culverts, junk piles, and unoccupied buildings;

8. Strychnine-treated lard or egg baits will be placed only on those lands where premise entry agreements have been signed by the landowner, lessee, or administrator;

9. Warning signs will be posted at entries to all premises and other visible positions near locations where treated baits have been placed;

10. Each bait station will be checked as often as possible for kills, but, in any case, no less than once a week;

11. All retrieved or excess strychnine baits will be disposed of by burial at least 18 inches deep in an approved sanitary landfill. Containers to be destroyed will be handled in a similar manner;

12. Animals poisoned in the control program will be submitted for laboratory analysis for presence of rabies virus if possible. Otherwise, they will be buried on the premises to prevent possible secondary non-target species poisonings;

13. The Applicant must follow any more stringent requirements imposed by State law or regulation or applied by the State pesticide regulatory authority; and

14. The specific exemption expires on March 31, 1978.

Statutory authority: Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (86 Stat. 973; 89 Stat. 751; 7 U.S.C. 136(s) et seq.).

Dated: May 19, 1977.

JAMES M. CONLON,
Acting Deputy Assistant Administrator for Pesticide Programs.

[FR Doc.77-14950 Filed 5-25-77;8:45 am]

[FRL 734-1]

SCIENCE ADVISORY BOARD ENVIRONMENTAL HEALTH ADVISORY COMMITTEE STUDY GROUP ON MUTAGENICITY TESTING

Open Meeting

Notice is hereby given that a meeting of the Study Group on Mutagenicity Testing of the Science Advisory Board's Environmental Health Advisory Committee will be held at 9:00 a.m. on June 15, 1977, in Conference Room A (Room 1112), Crystal Mall Building No. 2, 1921 Jefferson Davis Highway, Arlington, Virginia.

The purpose of the meeting will be to continue the discussion of Agency approaches to the evaluation of test data relating to mutagenicity in the context of section 3, Registration of Pesticides, of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

The meeting will be open to the public. Any member of the public wishing to attend or submit a paper should contact the Secretariat, Science Advisory Board (A-101), U.S. Environmental Protection Agency, Washington, D.C. 20460, by c.o.b. June 10, 1977. Please call Ms. Barbara Robinson on (703) 557-7720.

Dated May 19, 1977.

LLOYD T. TAYLOR,
Acting Staff Director, Science Advisory Board.

[FR Doc.77-14948 Filed 5-25-77;8:45 am]

[OPP-42009B; FRL 733-7]

WASHINGTON

Extension of Contingent Approval of State Plan for Certification of Pesticide Applicators

In accordance with the provisions of section 4(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended (86 Stat. 973; 7 U.S.C. 136 et seq.) and 40 CFR Part 171 (39 FR 36445 (October 9, 1974) and 40 FR 11698 (March 12, 1975)), the Honorable Daniel J. Evans, Governor of the State of Washington, submitted a State Plan for Certification of Commercial and Private Applicators of Restricted Use Pesticides to the Environmental Protection Agency (EPA) for approval on a contingent basis, pending promulgation of implementing regulations. On January 7, 1976, the Regional Administrator, EPA Region, X, approved the plan on a contingent basis for a fifteen month period. Notice of the approval was published in the FEDERAL REGISTER on February 18, 1976 (41 FR 7449). Legal authority for the program is contained in the Washington Pesticide Control Act, Washington Pesticide Application Act, and Washington Regulations.

On April 7, 1977, the State of Washington requested an extension of the Washington contingent approval pending promulgation of the regulations as described in the State Plan. The Agency finds that there is good cause for approving the request, and has granted an extension until September 1, 1977.

Dated: May 16, 1977.

DONALD P. DUBOIS,
Regional Administrator, U.S. Environmental Protection Agency, Region X.

[FR Doc.77-14949 Filed 5-25-77;8:45 am]

[FRL 733-2 PP7G1883/T105]

N-CHLOROACETYL-N-(2,6-DIETHYLPHENYL)GLYCINE ETHYL ESTER

Establishment of Temporary Tolerances

Hercules, Inc., Wilmington, DE 19899, has submitted a pesticide petition (PP 7G1883) to the Environmental Protection Agency (EPA). This petition requests that temporary tolerances be established for combined residues of the herbicide *N*-chloroacetyl-*N*-(2,6-diethylphenyl) glycine ethyl ester and its major metabolites *N*-chloroacetyl-*N*-(2,6-diethylphenyl) glycine ethyl ester glutathione conjugate and *N*-chloroacetyl-*N*-(2,6-diethylphenyl) glycine ethyl ester cysteine conjugate in or on the raw agricultural commodities soybeans and soybean forage at 0.2 part per million (ppm) and sugar beet roots and tops at 0.05 ppm.

Establishment of these temporary tolerances will permit the marketing of the above raw agricultural commodities when treted in accordance with an experimental use permit that is being issued concurrently under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (86 Stat. 973, 89 Stat. 751; 7 U.S.C. 136(a) et seq.).

An evaluation of the scientific data reported and other relevant material has shown that the requested tolerances are adequate to cover residues resulting from the proposed experimental use, and it has been determined that the temporary tolerances will protect the public health. The temporary tolerances are established for the pesticide, therefore, with the following provisions:

1. The total amount of the pesticide to be used must not exceed the quantity authorized by the experimental use permit.

2. Hercules, Inc., must immediately notify the EPA of any findings from the experimental use that have a bearing on safety. The firm must also keep records of production, distribution, and performance and on request make the records available to any authorized officer or employee of the EPA or the Food and Drug Administration.

These temporary tolerances expire April 11, 1978. Residues not in excess of 0.2 ppm remaining in or on soybeans and soybean forage and 0.05 ppm in or on sugar beet roots and tops after this expiration date will not be considered actionable if the pesticide is legally applied during the term of and in accordance with the provisions of the experimental use permit and temporary tolerances. These temporary tolerances may be revoked if the experimental use permit is revoked or if any scientific data or experience with this pesticide indicates such revocation is necessary to protect the public health. Inquiries concerning this notice may be directed to Libby Zink, Registration Division (WH-567), Office of Pesticide Programs, Room 315,

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procedure (1% neutral buffered potassium iodide standardized with arsenious oxide) specified in Appendix D of 40 CFR Part 50, as amended on February 18, 1975 (40 FR 7042). This method is:

RFOA-0577-020, "Beckman Model 950A Ozone Analyzer," operated on a range of 0-0.5 ppm and with the "SLOW" (60 second) response time; with or without any of the following options:

Internal Ozone Generator
Computer Adaptor Kit.

This method is available from Beckman Instruments, Inc., Process Instruments Division, 2500 Harbor Boulevard, Fullerton, California 92634. A notice of receipt of application for this method, submitted by Beckman Instruments, Inc., appeared in the FEDERAL REGISTER, Volume 41, October 19, 1976, page 46019.

A test analyzer representative of the first method has been tested by the State of California Air Resources Board in accordance with the test procedures specified in 40 CFR Part 53. In addition, certain supplemental tests were also conducted by EPA. After reviewing the results of all these tests as well as other information submitted by the applicants, EPA has determined, in accordance with Part 53, that this method should be designated as an equivalent method. Similarly, a test analyzer representative of the second method has been tested by the applicant, also in accordance with the test procedures specified in Part 53. After reviewing the test results and information submitted, EPA has determined, in accordance with Part 53, that this method should be designated as a reference method. The information submitted by the applicants will be kept on file at the address shown below and will be available for inspection to the extent consistent with 40 CFR Part 2 (EPA's regulations implementing the Freedom of Information Act).

As reference and equivalent methods, these methods are acceptable for use by States and other control agencies for purposes of section 51.17(a) of 40 CFR Part 51 ("Requirements for Preparation, Adoption, and Submittal of Implementation Plans") as amended on February 18, 1975 (40 FR 7042). For such use, a method must be used in strict accordance with the operation or instruction manual provided with the method and subject to any limitations (e.g., operating range) specified in the applicable designation (see description of the methods above). Vendor modifications of a designated method used for purposes of § 51.17(a) are permitted only with prior approval of EPA, as provided in Part 53. Provisions concerning modification of such methods by users were promulgated on March 17, 1976 (FEDERAL REGISTER, Vol. 41, page 11255).

In general, each designation applies to any analyzer which is identical to the analyzer described in the designation. However, similar analyzers manufactured prior to the designation and bearing the same model number as the designated method are not necessarily identical to the analyzer described in the designation. In many cases, such analyzers may be upgraded (e.g., by minor modification or by substitution of new operation or instruction manual) so as to be identical to the designated method and thus achieve designated status at modest cost. The manufacturer should be consulted to determine the necessity and feasibility of such upgrading.

Part 53 requires that sellers of designated methods comply with certain conditions. These conditions are given in 40 CFR Part 53.9 and are summarized below:

(1) A copy of the approved operation or instruction manual must accompany the analyzer when it is delivered to the ultimate purchaser.

(2) The analyzer must not generate any unreasonable hazard to operators or to the environment.

(3) The analyzer must function within the limits of the performance specifications given in Table B-1 of Part 53 for at least 1 year after delivery when maintained and operated in accordance with the operation manual.

(4) Any analyzer offered for sale as a reference or equivalent method must bear a label or sticker indicating that it has been designated as a reference or equivalent method in accordance with Part 53.

(5) If such an analyzer has one or more selectable ranges, the label or sticker must be placed in close proximity to the range selector and indicate which range or ranges have been designated as reference or equivalent methods.

(6) An applicant who offers analyzers for sale as reference or equivalent methods is required to maintain a list of ultimate purchasers of such analyzers and to notify them within 30 days if a reference or equivalent method designation applicable to the analyzer has been cancelled or if adjustment of the analyzers is necessary under 40 CFR 53.11 (b) to avoid a cancellation.

(7) An applicant who modifies an analyzer previously designated as a reference or equivalent method is not permitted to sell the analyzer (as modified) as a reference or equivalent method (although he may choose to sell it without such representations), nor to attach a label or sticker to the analyzer (as modified) under the provisions described above, until he has received notice under 40 CFR 53.14(c) that the original designation or a new designation applies to the method as modified or until he has applied for and received notice of a new reference or equivalent method determination for the analyzer as modified.

Aside from occasional breakdowns or malfunctions, consistent or repeated non-compliance with any of these conditions should be reported to: Director, Environmental Monitoring and Support Laboratory, Department E (MD-76), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711.

Designation of these references and equivalent methods will provide assistance to the States in establishing and operating their air quality surveillance systems under 40 CFR 51.17(a). Additional information concerning this action may be obtained by writing to the address given above.

WILSON K. TALLEY,
Assistant Administrator for Research nad Development.

[FR Doc.77-15677 Filed 6-2-77;8:45 am]

[OPP-00053 FRL 741-1]

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT SCIENTIFIC ADVISORY PANEL

Meeting

AGENCY: Office of Pesticide Programs, Environmental Protection Agency (EPA).

ACTION: Notice of meeting.

SUMMARY: There will be a two-day meeting of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel from 9:30 a.m. to 4:30 p.m. daily on Monday, June 20, and Tuesday, June 21, 1977. The meeting will be held in Room 1112A, Crystal Mall, Building Number 2, 1921 Jefferson Davis Highway, Arlington, Virginia.

FOR FURTHER INFORMATION CONTACT:

Dr. H. Wade Fowler, Jr., Executive Secretary, FIFRA Scientific Advisory Panel, Office of Pesticide Programs (WH-567), Rm. E-315, EPA, 401 M St. SW., Washington D.C. 20460, telephone 202-755-4851.

SUPPLEMENTARY INFORMATION: In accordance with Section 25(d) of the amended FIFRA, the Scientific Advisory Panel will comment on the impact on health and the environment of regulatory actions under section 6(b) and 25(a) prior to implementation. The purpose of this meeting is to discuss the following topics:

(1) Continued review of the advanced draft of the subpart on Hazard Evaluation: Humans and Domestic Animals of the Guidelines for Registering Pesticides in the United States.

2. Continued review of the proposed regulations for classification of pesticides as required under Section 3(d) of FIFRA, amended. (Note: This will be discussed only if needed. The proposed document was reviewed on May 26-27, 1977).

3. The Agency may present background information on changes anticipated in its basic regulatory approach to pesticides. Such a presentation would involve a discussion of a generic-chemical-standards approach to regulation.

The meeting will be open to the public. Any member of the public wishing to attend or submit a paper should contact Dr. H. Wade Fowler, Jr., Executive Secretary, FIFRA Scientific Advisory Panel,

subcommittee and May 16 & 17

Office of Pesticide Programs (WH-567), Room E-315, EPA, 401 M St. SW., Washington D.C. 20460, telephone: 202-755-4851). Interested persons are permitted to file written statements before or after the meeting, and may upon advance notice to the Executive Secretary, present oral statements to the extent that time permits. Written or oral statemens will be taken into consideration by the Panel in formulating comments or in deciding to waive comments. Persons desirous of making oral statements must notify the Executive Secretary and submit four copies of a summary, no later than June 18, 1977.

Individuals who wish to file written statements are advised to submit ten copies of statements to the Executive Secretary in a timely manner to ensure appropriate consideration by the Panel.

Dated: June 1, 1977.

JAMES M. CONLON,
Deputy Assistant Administrator
for Pesticide Programs.

[FR Doc.77-15877 Filed 6-2-77;8:45 am]

FEDERAL COMMUNICATIONS COMMISSION

[Report No. 860]

COMMON CARRIER SERVICES INFORMATION

Applications Accepted for Filing

MAY 31, 1977.

The applications listed herein have been found, upon initial review, to be acceptable for filing. The Commission reserves the right to return any of these applications, if upon further examination, it is determined they are defective and not in conformance with the Commission's Rules and Regulations or its policies.

Final action will not be taken on any of these applications earlier than 31 days following the date of this notice, except for radio applications not requiring a 30-day notice period (See § 309(c) of the Communications Act), applications filed under Part 68, applications filed under Part 63 relative to small projects, or as otherwise noted. Unless specified to the contrary, comments or petitions may be filed concerning radio and Section 214 applications within 30 days of the date of this notice and within 20 days for Part 68 applications.

In order for an application filed under Part 21 of the Commission's Rules (Domestic Public Radio Services) to be considered mutually exclusive with any other such application appearing herein, it must be substantially complete and tendered for filing by whichever date is earlier: (a) The close of business one business day preceding the day on which the Commission takes action on the previously filed application; or (b) Within 60 days after the date of the public notice listing the first prior filed application (with which the subsequent application is in conflict) as having been accepted for filing. In common carrier radio services other than those listed under Part 21, the cut-off date for filing a mutually exclusive application is the close of business one business day preceding the day on which the previously filed application is designated for hearing. With limited exceptions, an application which is subsequently amended by a major change will be considered as a newly filed application for purposes of the cut-off rule. (See § 1.227(b)(3) and 21.30(b) of the Commission's Rules.)

FEDERAL COMMUNICATIONS COMMISSION,
VINCENT J. MULLINS,
Secretary.

APPLICATIONS ACCEPTED FOR FILING

DOMESTIC PUBLIC LAND MOBILE RADIO SERVICE

21380-CD-P-77 Mobile Radio System of Ventura, Inc. (KSV976), C.P. for additional facilities to operate on 152.24 MHz to be located at a new site described as location No. 3; At Red Mountain, Approx. 6.0 miles NW. of Ventura, California.

21381-CD-P-77 Calhoun City Telephone Company (KUS373), C.P. to change antenna system operating on 158.10 MHz located 0.4 mile east of Derma, Mississippi.

21382-CD-P-77 DPRS, Inc. t/a Zip-Call (KCD890), C.P. for additional facilities to operate on 43.58 MHz to be located at a new site described as location No. 23; On Alpine Road, ¼ mile *N.* of *Pitchburg, Massachusetts.*

21383-CD-P-(4)-77 Adirondack Mobile Telephone Co., Inc. (new), C.P. for a new 2-Way station to operate on 152.06 152.18 MHz at location No. 1 to be located at Beekman Court; and location No. 2 to operate on 152.06 152.18 MHz to be located at WGFM-FM Tower; Rand Hill, Plattsburgh, New York.

21384-CD-P-77 Marc Weber Tobias and Michael Charles Tobias d/b as MT Systems, Inc. (new), C.P. for a new 2-Way station to operation on 152.21 MHz to be located North of Rt. 34 at the SW. corner of Wessington Springs, South Dakota.

21385-CD-P-2-77 Mount View Communications (new), C.P. for a new station to operate on 152.09 (base) and 459.075 (Repeater) MHz to be located at Aqua Ramon Mountain, 5.1 miles NE. of South Fork; and 454.075 MHz (Control) at location No. 2 to be located 715 1st Avenue, Monte Vista, Colorado.

21386-CD-P-77 RCC of Virginia, Inc. (new), C.P. for a new 1-Way station to operate on 152.24 MHz to be located at Rt. 47, approximately 600 feet east of the western city limits, South Hill, Virginia.

21387-CD-P-77 Citizens Telephone Company, Inc. (new), C.P. for a new 2-Way station to operate on 152.75 MHz to be located Union Street, Vienna, Georgia.

21388-CD-P-77 Citizens Telephone Company, Inc. (new), C.P. for a new 1-Way station to operate on 152.84 MHz to be located at Bond and Washington Streets, Plains, Georgia.

21389-CD-P-77 Digital Paging Systems of Pittsburgh, Inc. (KWB370), C.P. to change antenna system operating on 152.24 MHz located 1715 Grandview Avenue, Pittsburgh, Pennsylvania.

21390-CD-P-77 R.C.S., Inc. (KRM971), C.P. for additional facilities to operate on 152.24 MHz to be located at a new site described as location No. 5; 922 North I Street, Lompoc, California.

21236-CD-P-77 Susquehanna Mobile Communications, Inc. (new), Resubmitted, C.P. for a new 1-Way station to operate on 152.24 MHz to be located at Holly Pike, Route 34, approximately 1.1 miles south of Carlisle, Pennsylvania.

21391-CD-P-(2)-77 Statesboro Telephone Company (KWA654), C.P. to change antenna system operating on 152.69 MHz; add 152.81 MHz to be located at 76 E. Grady St., Statesboro, Georgia.

21392-CD-P-(2)-77 Mobilfone Communications, Inc. (KKX714), C.P. to change antenna system and relocate facilities operating on 152.03 152.21 MHz from location No. 2 to a new site described as location No. 3 to be located 1.3 miles south of Intersection of Highway 2244 and Highway 360, approximately 3 miles west of Austin, Texas.

21393-CD-P-77 Jackson Mobilphone, Inc. (new), C.P. for a new 1-way station to operate on 152.24 MHz to be located on U.S. Highway 43, Intersection of No. 3, Jackson, Alabama.

21394-CD-P-77 Jackson Mobilephone, Inc. (new), C.P. for a new 2-way station to operate on 152.06 MHz to be located on Highway 43, Intersection of No. 3, Jackson, Alabama.

21395-CD-P-(3)-77 The Mountain State Telephone and Telegraph Company (KOK-345), C.P. to change antenna system and replace transmitter operating on 152.75 MHz; Add 152.54 MHz to be located at 3.0 miles west southwest of Pocatello, and Test facilities to operate on 157.80 MHz located at 455 West Lewis Street, Pocatello, Idaho.

21396-CD-P-(6)-77 South Central Bell Telephone Company (KIC343), C.P. to relocate facilities operating on 454.375, 454.-450, 454.475, 454.525, 454.600, 454.625 MHz to be located approximately 4 miles northeast of Pegram, Tennessee.

MAJOR AMENDMENT

21041-CD-P-(2)-77 E. F. Mitchell, Jr. d/b as Douglas Radio (KRM967), Amend base frequency 454.125 MHz to read 454.200 MHz. All other particulars are to remain the same as reported on PN No. 852 dated April 4, 1977.

INFORMATIVE

It appears that the following applications may be mutually exclusive and subject to the Commission's Rule regarding Ex Parte presentations by reason of economic competition or potential electrical interference.

CALIFORNIA

Tadlock's Radio Dispatch (KMA259) Bald Mountain, 0991-CD-P-1-77.

Silveradio Communications (New) Napa, 21292-CD-P-2-77.

RURAL RADIO SERVICE

60277-CR-P/L-77 Puerto Rico Communications Authority (new), C.P. and License for a new Rural Subscriber station to operate on 454.375, 454.400, 454.425, 454.450, 454.475, 454.500, 454.525, and 454.550 MHz to be located at Bo. Anones, Carr. 152 Ramal 813 Km 1.4, Naranjito, Puerto Rico.

60278-CR-P/L-77 Same as above located at Bo. Quebradilla Carr. 900 Km. 9.7, Yabucoa, Puerto Rico.

60279-CR-P/L-77 Same as above to be located at Bo. Quebrada Grande Carr. 902 Km. 4.4, San Lorenzo, Puerto Rico.

60276-CR-P/L-77 Same as above to be located at Bo. Tejas Guayabal Carr. 921 Km. 3.3, Humacao, Puerto Rico.

60280-CR-P/L-77 Same as above to be located at Bo. Aguacate Comunes Ramal 9904, (1 Km. de Carr. 902), Yabucoa, Puerto Rico.

60281-CR-P/L-77 Same as above to be located at Calle Pedro Marques Esq. William Font, Culebra, Puerto Rico.

cc J Hansen
LLGAC
2030

SOEH

SOCIETY FOR OCCUPATIONAL AND ENVIRONMENTAL HEALTH

1714 Massachusetts Avenue, N.W. Washington, D.C. 20036 (202) 785-8177

December 16, 1977

Dr. T. R. Torkelson
Corporate Medical Department
The Dow Chemical Company
Bennett Building
2030 Dow Center
Midland, Michigan 48640

R&S 113865

Dear Dr. Torkelson:

This letter is written in response to your inquiry of November 16, 1977.

There is neither a transcript nor a tape recording of proceedings of the SOEH working conference, "Implications of the OSHA Proposal on Carcinogen Regulation".

Sincerely,

Sandy Zimmerman
Executive Director

STOCK FORM C-4100
PRINTED IN U.S.A. R2-68

THE DOW CHEMICAL COMPANY

SUBJECT

JOB NO. | SHEET | FILE | BY | DATE

R&S 113866

Art October 66777

Science Adv Panel To EPA

Said Mutagenic tests are nonsense

Open meeting last week May 17&18 1977

Dave Davis MD Miami

coming

Recommended back with more specific recommendations

Not consulted with long term studies.

Check last agenda

Will Meet Tomorrow Bethesda

Holiday Inn

(301) 652-8000

Clear Goings Carcinogen Paper
MCA - position statement
VKJ

SOEH

SOCIETY FOR OCCUPATIONAL AND ENVIRONMENTAL HEALTH

1714 Massachusetts Avenue, N.W., Washington DC 20036 (202) 785-8177

TO: Discussants, SOEH Working Conference: Implications of the OSHA Proposal on Carcinogen Regulation

DATE: April 27, 1977

FROM: Sandy Zimmerman
Executive Director

SUBJECT: Additional Information for June 2 Conference

As promised, a copy of the draft OSHA proposal on carcinogen regulation is enclosed. We have also prepared and enclosed a Table of Contents for the proposal to facilitate easy reference to specific sections.

The preliminary program was mailed to all SOEH members on April 26, 1977. A copy is enclosed.

As soon as I receive copies of the presentations by the primary speakers, I will let you know. Please call if you have any questions.

Enclosures (2)

R&S 113867

TABLE OF CONTENTS

Regulation of Certain Toxic Materials

Identification, Classification and Regulation of Toxic Materials Posing a Potential Occupational Cancer Risk to Workers

by any toxic substances to which they are exposed in the workplace.

The bill would provide protection to employees so that they could not be discharged or discriminated against because they applied for compensation, participated in a claim proceeding, or participated in any other action to carry out the purposes of the Act.

Under the bill, victims of toxic substance pollution would be eligible for compensation, medical benefits, rehabilitation services, and other benefits for disability or death as claimed by the victim or the survivors of the victim and approved by the Administrative Board. The compensation would be equal to the victim's actual lost wages or equal to 100 percent of the statewide average weekly wage of the state in which the victim lives.

Brodhead's spokesman said this compensation system would not affect benefits paid to coal miners disabled by black lung, state workmen's compensation programs, or any other workmens' compensation program.

The spokesman explained that the congressman considers the bill he introduced to be a "discussion draft." He could not speculate what action the House might be inclined to take on the measure.

The bill was referred jointly to the House Commerce and Ways and Means Committees.

Carcinogens

SOCMA DIRECTOR CRITICIZES PROPOSED GENERIC CARCINOGEN RULE

NEW YORK — (By a Chemical Regulation Reporter staff correspondent) — A proposed generic policy for regulating carcinogens is an over-simplified approach and will result in "fill in the blank" standards, the executive director of the Synthetic Organic Chemical Manufacturers Association said October 18.

Ronald Lang told a press briefing that the proposal by the Occupational Safety and Health Administration represents the first regulatory effort to set a national cancer policy (Current Report, October 7, p. 1049). Other federal agencies already have expressed interest in the proposal, he said.

While the rule would provide a much easier way for OSHA to deal with substances with potential carcinogenic risk, Lang explained, he does not believe it is the correct approach. He said that OSHA's starting point will be the list of suspected carcinogens drawn up by the National Institute for Occupational Safety and Health. The proposal makes it possible for a substance to be categorized as a Class I carcinogen if in simple tests it causes tumors or shows signs of being mutagenic, Lang said. Once a substance has been so categorized, he noted, a mechanism is triggered for development of an emergency standard. If there is a substitute chemical available, exposure for the original substance is set at zero, which amounts to "an effective ban," he added.

According to Lang, OSHA Administrator Eula Bingham has said that the agency can halt the triggering mechanism if it feels such a move is warranted. Bingham has called these options "escape hatches," Lang said. However, he expressed doubt that once a substance has been linked with cancer Bingham would be able to say it would not be regulated. Public pressure would be too great, he said.

SOCMA has not yet determined what it will propose as an alternative, Lang said, but he stressed that the association believes there should be sound scientific evidence for regulatory action. It should take more than a benign tumor to have a substance labeled a carcinogen, he added.

He called "horrendous" the timetable OSHA has devised for comments and hearings on the proposal. Public hearings are scheduled for March 14, 1978, and the deadline for written comments is set for December 8. Lang said SOCMA would ask the agency for an extension.

Guidelines

EPA ADVISORS CRITICIZE PROPOSALS FOR MUTAGENICITY TESTING PROTOCOLS

Revised guidelines for mutagenicity testing came under fire from the Federal Insecticide, Fungicide, and Rodenticide Act Science Advisory Panel during an October 25-26 meeting at the Environmental Protection Agency.

According to a statement supported unanimously by the panel, although not formally adopted, there is a need for a more critical survey for mutational events and for a survey of those events capable of producing mutations in test systems.

The statement continues: "A more prudent course would require that mutagenicity assays be carried out on all new products. We would suggest that the selection of tests be chosen to maximize their reproducibility and that cross species responses be surveyed. We have reservations about the testing system that has been proposed" (Current Report, October 21, p. 1175).

"The document presents a protocol that is largely investigational rather than practical," the statement says, and adds "concern centers upon practicality of these test protocols for mutagens of different chemical structure, interlaboratory reproducibility, and ease of performance by available laboratory personnel. Unsolvable legal argument arising from this testing may obscure the intent of the program itself."

According to the statement, the panel agreed to establish a critical review committee, constituted of outside experts, to consult with the panel in evaluating the proposed tests and possibly suggest an alternative and more practical protocol.

The statement also says that the panel concurs with the conclusion reached at a mutagenesis meeting held last year in Great Britain that "Overall, the general feeling was that as yet no single test or panel of tests can accurately predict potential hazards to man."

During a presentation to the committee on the revised guidelines, John W. Drake, National Institute of Environmental Health Sciences, told the panel that tests for mutagenicity have to be able to assess mutagen specificity, should concentrate on heritability, should evoke a positive response, should have qualitative sensitivity, and should have to be validated.

Drake said that a battery of tests was selected because no single point-mutation test is available at this time for mammals and testers have to fall back on sub-mammalian subjects. If positive results occur in one mammalian test, the compound tested is a mutagen and a potential human mutagen, Drake said, but he added that in using sub-mammalian subjects, a minimum of two tests should be used.

Water Pollution

EARLY MOMENTUM SLOWS IN WATER ACT CONFERENCE

Congressional conferees attempting to amend the Federal Water Pollution Control Act are encountering delays in

~~LMC/HHS/TMS~~

From the desk of...

DOW

Marguerite L. Leng

T. R. Torkelson 6/14/77

Attached are two articles about the SOGH meeting, both of which take pot shots at your talk. The first one says you misstated case on mutation testing, possibly because they thought you were referring to the EPA Science Advisory Board rather than Science Advisory Panel. They are quite different. Both are meeting this week or next to further discuss mutagenicity testing as noted on attached meeting notices.

Keep the faith!

M.

R&S 113871

PESTICIDE & TOXIC CHEMICAL NEWS

Detailed coverage and in-depth analyses, every week, of key developments regarding the laws and regulations governing pesticides and toxic chemicals

$160 a year • Additional subscriptions $105

R&S 113872

Volume 5, Number 28 • June 8, 1977

Published Weekly by FOOD CHEMICAL NEWS, Inc., 420 Colorado Bldg., 1341 G St., N.W., Washington, D.C. 20005

STerling 3-7472

PESTICIDE ADVERTISING TRR which has been under consideration by the Federal Trade Commission may not be issued because FTC now thinks it already has enough authority to enforce against advertising abusers, according to an EPA official. A Commission official said no decision had been made on TRR issuance, but admitted that the option of not issuing it would be considered at a public meeting set for today, June 8. EPA-ers noted that FTC may be worried about the time and expense of preparing a final TRR and said that there is some feeling that the problem of false advertising has abated (See Nov. 17, Page 5).

EPA DENIAL of 100 p.p.m. tolerance petition for Captan on seed corn (See June 1, Page 2) could result in review by an NAS advisory committee. Some EPA officials expect an appeal to an NAS committee to be filed (See Nov. 3, Page 5 and Nov. 24, Page 5).

CAPTAN RPAR decision is expected to be made about Oct. 15 (See June 1, Page 2).

ETHYLENE OXIDE RPAR decision is expected this month (See May 18, Page 27). The RPAR, if issued, would be based on mutagenicity and/or oncogenicity, Edwin L. Johnson, Deputy Assistant Administrator for Pesticide Programs, EPA, has indicated.

MALEIC HYDRAZIDE RPAR notice is now scheduled to be issued June 24 (See May 25, Page 2).

PRONAMIDE RPAR rebuttal time extension to August 26 has been requested by Rohm and Haas, sole manufacturer of the technical grade product and the 50% wettable powder marketed under the name "Kerb- 50-W." The firm said EPA raised some points it had not considered of concern and noted that additional time was needed to evaluate the RPAR notice (See May 11, Page 11).

KEPONE CANCELLATION hearing parties who have yet to file formal objections and labeling have been given until June 17 to do so by EPA Administrative Law Judge Bernard D. Levinson (See Junel, Page 2).

TSCA TESTING Committee, when it submits its list of no more than 50 chemicals for which EPA should require tests under TSCA, also will list chemicals for which information appears to be sufficient to make further testing unnecessary. Whether such information justifies regulation will be up to EPA (See June 1, Page 14).

GENERIC STANDARDS FOR PESTICIDES are being discussed at OSHA (See June 1, Page 24).

MINOR USE TOLERANCES may be issued for RPAR candidates if RPAR criteria triggers are not relevant to petitioned tolerances (See June 1, Page 2), an EPA official said last week. These tolerance decisions will be made case-by-case, according to the agency official.

STATE REGISTRATIONS under Section 24(c) rec ived to date by the Registration Division, OPP, EPA, total 850, according to OPP.

PESTICIDE & TOXIC CHEMICAL NEWS

R&S 113874

Editors: CATHY COOPER, Gary Robinson, Gail Tapscott
Publisher: Louis Rothschild, Jr.
Managing Editor: Raymond Galant
Associate Editors: Ron Grandon, Natalie Pargas
Circulation Dept.: Director, Shirley Galant; Assistant Director, Alice Wilkes
Production Manager: Dorothy Hill

6/8/77

DOW EXECUTIVE MISSTATES CASE ON MUTATION TESTING; EPA TO PROCEED

Despite allegations to the contrary made by a Dow Chemical Company executive at a meeting of the Society for Occupational and Environmental Health (SOEH), the Environmental Protection Agency's Science Advisory Board (SAB) has not determined that the state of the art of mutagenicity testing (See June 1, Page 2) is so primitive as to preclude use of mutagenicity data to support regulatory actions against pesticide chemicals.

The executive, Dr. T. R. Torkelson of Dow's medical department, told last week's SOEH symposium on a cancer proposal from the Occupational Safety & Health Administration (OSHA) that OSHA should not depend on mutation tests at all for purposes of defining a chemical as a Category I carcinogen. Such a definition would trigger issuance of an OSHA emergency temporary standard entailing monitoring for the chemical in workplaces where it's produced, used, or packaged, as well as medical surveillance of exposed workers, "good housekeeping" requirements and other steps (See May 25, Page 20).

Placement of a chemical into Category I could be "rebutted" in a rulemaking proceeding. If the rebuttal were unsuccessful, the rulemaking would determine what the "lowest feasible" exposure level is, and workplaces would hav to reach it. It would become the OSHA permanent standard. In the rulemaking, OSHA also could say that there are suitable substitutes for the chemical and attempt to promulgate a permanent standard requiring zero exposure.

OSHA has proposed to allow a positive bioassay result in a single mammalian sp cies to trigger Category I classification if the bioassay has been "replicated" by a test on the same or a different species, or, if there exists "multi-test evidence of mutagenicity."

Torkelson said EPA's SAB, two weeks prior to the June 2 SOEH meeting, had decided that mutagenicity testing "wasn't ready yet" for regulatory use, and, Torkelson said, it would be "inappropriate" for OSHA to use mutation data if EPA wasn't going to.

However, the SAB Environmental Health Advisory Committee met June 1 to discuss EPA's proposed mutagenicity testing requirements for pesticides (See April 13, Page 14 and May 18, Page 2) and indicated that, in fact, the types of tests which EPA has proposed are sufficiently validated to require them for pesticide registration actions.

Drake, Nelson, Wogan and Abrahamson Say Mutation Tests are Ready

At the June 1 SAB me ting, another Dow ex cutive, Dr. V. K. Rowe, said EPA should not impose the mutagenicity battery because th tests which comprise it have not been validated and because their relevance to man is questionable.

Dr. John W. Drake, a member of the study group which helped EPA draft the Section 3 guidelines, disagreed, saying that EPA and the study group had chosen only the best validated tests out of a possible total of 30.

Dr. Norton Nelson, Chairman of the Environmental Health Advisory Committee, said that based on "a wide variety of studies in the animal kingdom, we do know that heritable mutations are a severe threat. The jump from that to the human population is, to my mind, miniscule."

His arguments on validity and relevance to man discarded, Rowe then maintained that SAB should advise EPA to delay adoption of the testing requirements until the Agency had better defined what would be a "statistically significant" result in each test and until EPA had spelled out how it would interpret "mixed results" from the component tests in the eight-test battery.

Dr. Gerald Wogan, Chairman of Drake's study group, said that nothing in the upcoming criteria document, which will address "mixed" results, will change the requirements which EPA has set forth.

On statistical significance, EPA's final guidelines will provide "more acceptable biometric wording" regarding what constitutes a significant finding in each test, according to EPA's Dr. Ruth Pertel, a principle author of the mutagenicity guidelines. This change comes about largely as a result of urgings from Dr. Lincoln E. Moses, professor of statistics at Stanford University and a member of SAB.

With respect to maintaining flexibility and not putting mutagenicity testing requirements "in bronze," Nelson said, "Sure things are in a major state of flux, but that state of flux is going to lead to alternative ways of doing very much the same kind of things we're doing now, but doing them in a more efficient way." The document will say that the battery shall be reviewed every three years for possible changes. Drake held that some of the eight test "could fall by the wayside" not because they're invalid, but because "a more rapid or less expensive test may come along."

In probably the most telling argument against bacterial tests not being relevant to man, Dr. Seymour Abrahamson gave some history on how, with respect to radiation, a human risk estimate per Roentgen per gene using the mouse as a model has turned out to be "almost identical" to the human risk estimate which can be computed by using Drosophila (bacteria).

Abrahamson said there is "good evidence" that man responds very closely to the mouse in terms of radiation sensitivity. He said the U. S. spent over $50 million establishing the mouse as an appropriate model when it turns out that bacteria would have been just as good an indicator.

He said the argument against the mutagenicity testing battery on economic grounds was untenable, since, by Abrahamson's calculations, the battery would cost no more than $45,000 per compound.

He said the most expensive test other than the mouse specific locus test (which is included among the 13 from which eight will be chosen because it's valid, despite its cost) is the Drosophila test, which would cost around $10,000 if the experimenter was trying to detect a doubling of the spontaneous mutation rate. Abrahamson said the Drosophila test could cost as little as $1,000 if the experimenter were looking for a more drastic response, such as a five-fold increase over the spontaneous rate. Abrahamson is based at the University of Wisconsin.

The Wogan-Drake study group will meet June 15 to discuss the criteria document which will describe how EPA will interpret "mixed" mutagenicity testing results.

R&S 113876

USDI LABORATORY TO INPUT RPAR PROCESS WITH FISH, WILDLIFE EFFECTS DATA

Fish-Pesticide Research Laboratory (FPRL), U. S. Fish and Wildlife Service, Interior Department, under an intragency agreement with the Environmental Protection Agency, will provide data on the effects of pesticides on fish and wildlife for use in the risk assessment portion of the rebuttable presumption against registration (RPAR) process.

The agreement, signed June 2 by Edwin L. Johnson, Deputy Assistant Administrator for Pesticide Programs, EPA, stated that the FPRL, located in Columbia, Mo., would supply copies of published and notification of unpublished results of research on the effects of about 150 pesticides -- RPAR candidates and alternatives -- on fish and wildlife.

In the first month, the Laboratory would provide reprints and research results on about 60 pesticides, according to the agreement which has not yet been signed by the Fish and Wildlife Service. After the first month, the agreement noted, research results and reprints would be required on 10 to 20 compounds a month. The Laboratory would also supply negative responses, the agreement provided.

The agreement would expire Sept. 30, 1977. EPA would pay the Fish and Wildlife Service about $10,000 for supplying the effects data.

EPA will list and assign priorities to the pesticides for which the Laboratory will provide effects data.

$5,850 CIVIL PENALTY AGREED TO BY THOMPSON-HAYWARD HEADS EPA ENFORCEMENT

An agreement signed by Thompson-Hayward Chemical Co. of Fayetteville, N. C., to pay a $5,850 civil penalty assessed by Environmental Protection Agency officials in Region IV highlighted recent pesticide enforcement activity.

that the "important thing is how much product (grams? volume?) is put on the plate to form colonies." He said that these data are critical to evaluate the potential environmental hazard of this product.

Correction: Notice of receipt of the new active ingredient registration application was published in the April 29 not April 30 Federal Register.

●

OSHA CANCER PROPOSAL HIT; SEEN AS FAILING TO SPEED RULEMAKING

The as-yet unproposed regulation under which the Occupational Safety & Health Administration (OSHA) would regulate carcinogens and suspect carcinogens (See Feb. 16 Page 33) was ridiculed by a Dow Chemical Corp. executive last week at a public forum in Washington, D.C., as being an example of "bootstrap logic" which could leave industry with no chemicals left to work with.

At the same forum, which was sponsored by the Society for Occupational & Environmental Health (SOEH), labor union officials criticized the proposal for not mandating that employers pay for employee protective clothing and equipment and medical xaminations which OSHA carcinogen regulations do and will require.

Jack Sheehan, Legislative Director of United Steelworkers of America and Chairman of the Policy Subgroup of the National Advisory Committee on Occupational Safety & Health (NACOSH), criticized the cancer proposal for not solving the problem of "rate retnetion" i.e. "mandatory relocation."

As explained by Anson Keller, co-author of the OSHA proposal, the rate retention/mandatory relocation dilemma pertains to an employer moving an employee to an area of a business operation where exposure to a regulated chemical is less. Such a change often results in a lower salary for the employee, since less hazardous work usually pays less.

In short, Keller said, an employee could work for a firm for 30 years, get cancer, and because of the detection, lose his high salary. The phenomenon could prove to be an incentive for employees to avoid the medical examinations which OSHA wants employers to perform and make available.

OSHA Administrator Elva Bingham is assembling an advisory group to study the problem.

Unionists such as Sheehan derided the document one moment and commended it the next. OSHA was commended for attempting to improve its performance in carcinogen r gulation but was derided for not taking an even deeper plunge into labor-management relations. Grover Wrenn, a Deputy in OSHA's Health Standards Division, and defender of the proposal throughout the all-day symposium, said OSHA's health-protecting plunge was inadvertant and th extent of it was unforeseen, but Wrenn defended it as n cessary.

The Dow executive, Dr. T. R. Torkelson (See Page 3) hit the proposal for what he called "an obvious disregard for dose" when using laboratory animal tests to determine whether a chemical is a carcinogen. Torkelson got support from Dr. Roy Albert, Chairman of the Environmental Protection Agency's Carcinogen Assessment Group (CAG) (See May 18, Page 31), who asked if it "makes sense" to not consid r dose for purposes of classification.

According to the proposal, a substance could be classified as a Category I carcinogen if it has been shown "at any dose level to cause the formation of malignant or benign neoplasms, or a combination thereof, in (a) man, or (b) two mammalian test species, or (c) a single mammalian test species if those results have been replicated in another experiment or by multi-test evidence for mutagenicity, or (d) upon the basis of any other evidence that the Secretary (of Labor) finds sufficient."

A Category II classification would be triggered by "suggestive" evidence of carcinogenicity from a single experiment on a single mammalian species, regardless of dose.

Category I classification would prompt issuance by OSHA of an emergency temporary standard which would be followed in 60 days by a proposed permanent standard. The proposed permanent standard would embellish the emergency standard and impose medical surveillance, workplace monitoring and other "model" r quire-ments which OSHA wants to impose "across the board" for all Category I chemicals.

Engineering controls would be proposed to bring exposure to the Category I chemical down to the "lowest feasible" level, and if OSHA believed that "suitable" substitutes were available, a "zero" exposure level could be set.

According to the proposal, issues at the hearing on the proposed permanent standard would be limited to:

> "(1) Whether the Secretary correctly classified the toxic material into Category I; (2) whether the Secretary was correct in his determination that the Category I classification should not be rebutted; (3) whether the Secretary correctly determined the lowest feasible occupational exposure, or whether there are suitable substitutes that are less hazardous to humans; (4) the appropriateness of the specific protective means of the proposed standard and (5) the environmental impact caused by such regulation."

Issues also would be limited in hearings on Category II classifications.

John Kolojeski, moderator of the conference and President of Clement Associates (See June 1, Page 14) said that the proposed limitation on issues, which is central to OSHA's effort to speed rulemaking, could be construed as an abridgement of due process, while Sheehan held that these very issu s probably would be litigated every time OSHA proposed a standard. Therefore, Sh ehan said, OSHA rulemaking is likely to remain largely a substance-by-substance affair, characterized by delay.

Category II classification would prompt no emergency standard and no engineering controls, but an exposure limit would be set, as would medical surveillance and other "model" requirements. Rather than engineering controls, housekeeping practices and personnel protective equipment and clothing would be prescribed for Category II chemicals. Keller explained that Category II is needed to "gear up" in case information becomes available indicating that the chemical belongs in Category I.

Torkelson maintained that imposition of such requirements without consideration of the dose used in the animal experiment(s) would be irresponsible in light of the possibility that human metabolism could eliminate the threat which the chemical may pose.

Dose in Backup Animal Studies "Irrelevant," Says OSHA's Wrenn

Wrenn, however, responded that does was "largely irrelevant," since OSHA does not consider a threshold level to exist for carcinogens.

Marshall Miller, a legal expert and a former Deputy Assistant Secretary of Labor for OSHA, said that potency i.e. dose would be factored into OSHA deliberations "subjectively" when OSHA, taking economics into account, sets its lowest "feasible"or "zero" exposure level.

Wrenn also was supported by Dr. Marvin Schneiderman of the National Cancer Institute (NCI), who said that "cancer is bad," regardless of potency.

Kolojeski said procedures set out in the OSHA proposal for rebutting both Category I and II classifications "take care" of Torkelson's concerns.

Justification for rebuttals on toxicological grounds are spelled out twice in the OSHA proposal, once for Category I chemicals and once for Category II. According to Section 1990.11 of the proposal, the Secretary of Labor may rebut the presumption of a Category I classification if he determines:

> "(a) that the alleged carcinogenic effect based on animal data clearly resulted from non-specific physical, rather than chemical induction, or (b) that the route of exposure was grossly inappropriate relative to the potential occupational routes of human exposure, or (c) that the animal or human studies submitted for review were only suggestive or not adequate to establish any conclusion with respect to the carcinogenicity or noncarcinogenicity of the toxic materials or (d) that for some other biological reason, the positive results in experimental mammals are not scientifically relevant to man."

Justifications are similar for a successful rebuttal of a Category II classification. A successful rebuttal places a chemical at least one category below the proposed one.

CAG's Albert Raises Sticky Regulatory Issue

Just what constitutes "replication" of an animal test, however, is a particularly difficult issue, according to CAG Chairman Albert. At the SOEH meeting, Albert cited a "not uncommon" example he has run across at CAG where a p sticide now up for a rebuttable presumption against registration (RPAR) notice was found to produce tumors in a long-term study conducted by the Food and Drug Administration (FDA), but the tumors were found only at the lowest dose level, which is "strange in itself," Albert said. A long-term study by NCI was negative, Albert stated, as were two others. Another study on the same chemical, however, was found to be positive in one sex at one dose level, but the tumors which appeared in the dosed animals appeared later than spontaneous tumors observed in controls. Since tumors in dosed groups usually occur sooner than tumors in controls, this "replication" of an already "suspicious" FDA study is questionable, Albert said. Nevertheless, the finding could conceiveably trigger a Category I classification if the OSHA proposal is allowed to stand as is (Albert would not reveal the identity of the pesticide in question).

Albert asked if positive findings in two dose groups in the same experiment would constitute "replication," as suggested by Dr. David Clayson of the National Cancer Advisory Board. He also asked whether observation of a dose-response relationship could be considered "replication." No one answered his rhetorical questions.

Generally, Albert expressed fears that OSHA's "black and white" proposal would give too much power to scientists.

Squire Fears "Over Interpretation" of "Suggestive" Bioassay Results

Dr. Robert Squire, former Chief of the NCI Bioassay Program (See March 2, Page 22) and now at Johns Hopkins University and an Associate Scientist with Clement Associates, Inc., warned against linking "suggestive" NCI bioassay results to OSHA regulation under Category II. He said "overinterpretation of uncertain results has done more harm to toxicology than anything else." He held that NCI's research mission should be allowed to continue unencumbered by OSHA's regulatory mission.

With respect to Category I classification, Squire said "results in a single mammalian species supported by incriminating in vitro data would be most convincing if either both sexes or more than one dosage group were affected."

There was considerable discussion on whether OSHA should simply adopt the proposal as an administrative policy, once it has been revised or, as an alternative, whether OSHA should publish it as a proposed regulation and subject it to judicial review.

The argument for the latter procedur , as stated by Wrenn, would be that to speed OSHA rulemaking, judicial review is needed on the basic regulatory principles which OSHA follows every time it proposes a rule on carcinogens.

These cancer principles are essentially the same as those which have stretched out EPA cancellation proceedings on heptachlor and chlordane (See June 1, Page 25).

Once such review is completed, Wrenn contended, rulemaking would go faster.

The speed argument appears to have been rebutted by Sheehan, but Kolojeski argued in favor of making the document a regulation as opposed to a policy because the document's publication as a policy would not carry with it the mandatory timetables under which OSHA would be forced to propose permanent standards and take other actions.

The document could be abandoned by the next Administration if it were simply a policy, Kolojeski said.

Sheehan, on the other hand, argued that Federal Register publication of the proposal as a regulation would bog down OSHA in rulemaking on it and prevent OSHA from taking action on known problem chemicals. As an alternative, Sheehan suggested testing the policy on some real problems.

Pointing to the recent OSHA activity on benzene (See June 1, Page 11), Wrenn deni d that Federal Register publication of the proposal as a regulation would hamper OSHA in its efforts to deal with current problems.

As a remedy to industry delaying tactics, NCI's Schneiderman suggested that for any chemical tied up in litigation, all profits should be placed in a closed fund unavailable to the manufacturer.

Richard Boggs of the National Institute for Occupational Safety & Health (NIOSH) asked how OSHA would handle chemicals which are similar in structure to those placed in Category I or II. He also asked for better definitions of the terms "feasible" and "detectable."

As an indication of just how complicated these issues are and how deep emotions run, a labor union official, misconstruing remarks made by Torkelson, said Dow is interested in DNA research because the firm wants to create a "super race" of chemical workers who are immune to cancer.

Over 140 people from government, industry and academia attended the SOEH conference.

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HOUSE COMMITTEE WANTS EPA TO ALLOW MIREX FOR FIRE ANT ERADICATION

"In the hope that the Environmental Protection Agency will rescind its ruling on mirex" the House Appropriations Committee has reserved $4,460,000 for a fire ant eradication program, (S e March 30, Page 33).

ment areas on the map. There are twenty-three counties where strychnine baits may be applied following establishment of the presence of rabid skunks near areas of human habitation;

4. Exposure of any bait station within a five (5) mile radius circle (to survey for presence of rabid or suppress rabid skunk populations) may not exceed thirty (30) days;

5. Each strychnine lard bait will contain approximately 0.012 grams of actual strychnine alkaloid. Each strychnine egg bait will contain approximately 0.035 grams of actual strychnine alkaloid;

6. The Applicant's personnel are responsible for preparing the strychnine baits, selecting bait stations, posting warning signs, securing premise entry agreements, checking bait stations periodically for kills, and retrieving all unconsumed baits at the termination of the control program;

7. A maximum of two strychnine lard or egg baits per setting will be placed in the following skunk habitats: skunk dens, holes, garbage dumps, road culverts, junk piles, and unoccupied buildings;

8. Strychnine-treated lard or egg baits will be placed only on those lands where premise entry agreements have been signed by the landowner, lessee, or administrator;

9. Warning signs will be posted at entries to all premises and other visible positions near locations where treated baits have been placed;

10. Each bait station will be checked as often as possible for kills, but, in any case, no less than once a week;

11. All retrieved or excess strychnine baits will be disposed of by burial at least 18 inches deep in an approved sanitary landfill. Containers to be destroyed will be handled in a similar manner;

12. Animals poisoned in the control program will be submitted for laboratory analysis for presence of rabies virus if possible. Otherwise, they will be buried on the premises to prevent possible secondary non-target species poisonings;

13. The Applicant must follow any more stringent requirements imposed by State law or regulation or applied by the State pesticide regulatory authority; and

14. The specific exemption expires on March 31, 1978.

Statutory authority: Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (86 Stat. 973; 89 Stat. 751; 7 U.S.C. 136(a) et seq.).

Dated: May 19, 1977.

JAMES M. CONLON,
Acting Deputy Assistant Administrator for Pesticide Programs.

[FR Doc.77-14950 Filed 5-25-77;8:45 am]

[FRL 734-1]

SCIENCE ADVISORY BOARD ENVIRONMENTAL HEALTH ADVISORY COMMITTEE STUDY GROUP ON MUTAGENICITY TESTING

Open Meeting

Notice is hereby given that a meeting of the Study Group on Mutagenicity Testing of the Science Advisory Board's Environmental Health Advisory Committee will be held at 9:00 a.m. on June 15, 1977, in Conference Room A (Room 1112), Crystal Mall Building No. 2, 1921 Jefferson Davis Highway, Arlington, Virginia.

The purpose of the meeting will be to continue the discussion of Agency approaches to the evaluation of test data relating to mutagenicity in the context of section 3, Registration of Pesticides, of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

The meeting will be open to the public. Any member of the public wishing to attend or submit a paper should contact the Secretariat, Science Advisory Board (A-101), U.S. Environmental Protection Agency, Washington, D.C. 20460, by c.o.b. June 10, 1977. Please call Ms. Barbara Robinson on (703) 557-7720.

Dated May 19, 1977.

LLOYD T. TAYLOR,
Acting Staff Director, Science Advisory Board.

[FR Doc.77-14948 Filed 5-25-77;8:45 am]

[OPP-42009B; FRL 733-7]

WASHINGTON

Extension of Contingent Approval of State Plan for Certification of Pesticide Applicators

In accordance with the provisions of section 4(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended (86 Stat. 973; 7 U.S.C. 136 et seq.) and 40 CFR Part 171 (39 FR 36445 (October 9, 1974) and 40 FR 11698 (March 12, 1975)), the Honorable Daniel J. Evans, Governor of the State of Washington, submitted a State Plan for Certification of Commercial and Private Applicators of Restricted Use Pesticides to the Environmental Protection Agency (EPA) for approval on a contingent basis, pending promulgation of implementing regulations. On January 7, 1976, the Regional Administrator, EPA Region, X, approved the plan on a contingent basis for a fifteen month period. Notice of the approval was published in the FEDERAL REGISTER on February 18, 1976 (41 FR 7449). Legal authority for the program is contained in the Washington Pesticide Control Act, Washington Pesticide Application Act, and Washington Regulations.

On April 7, 1977, the State of Washington requested an extension of the Washington contingent approval pending promulgation of the regulations as described in the State Plan. The Agency finds that there is good cause for approving the request, and has granted an extension until September 1, 1977.

Dated: May 16, 1977.

DONALD P. DUBOIS,
Regional Administrator, U.S. Environmental Protection Agency, Region X.

[FR Doc.77-14949 Filed 5-25-77;8:45 am]

[FRL 733-2 PP7G1883/T105]

N-CHLOROACETYL-N-(2,6-DIETHYLPHENYL)GLYCINE ETHYL ESTER

Establishment of Temporary Tolerances

Hercules, Inc., Wilmington, DE 19899, has submitted a pesticide petition (PP 7G1883) to the Environmental Protection Agency (EPA). This petition requests that temporary tolerances be established for combined residues of the herbicide *N*-chloroacetyl-*N*-(2,6-diethylphenyl) glycine ethyl ester and its major metabolites *N*-chloroacetyl-*N*-(2,6-diethylphenyl) glycine ethyl ester glutathione conjugate and *N*-chloroacetyl-*N*-(2,6-diethylphenyl) glycine ethyl ester cysteine conjugate in or on the raw agricultural commodities soybeans and soybean forage at 0.2 part per million (ppm) and sugar beet roots and tops at 0.05 ppm.

Establishment of these temporary tolerances will permit the marketing of the above raw agricultural commodities when treted in accordance with an experimental use permit that is being issued concurrently under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (86 Stat. 973, 89 Stat. 751; 7 U.S.C. 136(a) et seq.).

An evaluation of the scientific data reported and other relevant material has shown that the requested tolerances are adequate to cover residues resulting from the proposed experimental use, and it has been determined that the temporary tolerances will protect the public health. The temporary tolerances are established for the pesticide, therefore, with the following provisions:

1. The total amount of the pesticide to be used must not exceed the quantity authorized by the experimental use permit.

2. Hercules, Inc., must immediately notify the EPA of any findings from the experimental use that have a bearing on safety. The firm must also keep records of production, distribution, and performance and on request make the records available to any authorized officer or employee of the EPA or the Food and Drug Administration.

These temporary tolerances expire April 11, 1978. Residues not in excess of 0.2 ppm remaining in or on soybeans and soybean forage and 0.05 ppm in or on sugar beet roots and tops after this expiration date will not be considered actionable if the pesticide is legally applied during the term of and in accordance with the provisions of the experimental use permit and temporary tolerances. These temporary tolerances may be revoked if the experimental use permit is revoked or if any scientific data or experience with this pesticide indicates such revocation is necessary to protect the public health. Inquiries concerning this notice may be directed to Libby Zink, Registration Division (WH-567), Offic of Pesticide Programs, Room 315,

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procedure (1% neutral buffered potassium iodide standardized with arsenious oxide) specified in Appendix D of 40 CFR Part 50, as amended on February 18, 1975 (40 FR 7042). This method is:

RFOA-0577-020, "Beckman Model 950A Ozone Analyzer," operated on a range of 0-0.5 ppm and with the "SLOW" (60 second) response time; with or without any of the following options:

Internal Ozone Generator
Computer Adaptor Kit.

This method is available from Beckman Instruments, Inc., Process Instruments Division, 2500 Harbor Boulevard, Fullerton, California 92634. A notice of receipt of application for this method, submitted by Beckman Instruments, Inc., appeared in the FEDERAL REGISTER, Volume 41, October 19, 1976, page 46019.

A test analyzer representative of the first method has been tested by the State of California Air Resources Board in accordance with the test procedures specified in 40 CFR Part 53. In addition, certain supplemental tests were also conducted by EPA. After reviewing the results of all these tests as well as other information submitted by the applicants, EPA has determined, in accordance with Part 53, that this method should be designated as an equivalent method. Similarly, a test analyzer representative of the second method has been tested by the applicant, also in accordance with the test procedures specified in Part 53. After reviewing the test results and information submitted, EPA has determined, in accordance with Part 53, that this method should be designated as a reference method. The information submitted by the applicants will be kept on file at the address shown below and will be available for inspection to the extent consistent with 40 CFR Part 2 (EPA's regulations implementing the Freedom of Information Act).

As reference and equivalent methods, these methods are acceptable for use by States and other control agencies for purposes of section 51.17(a) of 40 CFR Part 51 ("Requirements for Preparation, Adoption, and Submittal of Implementation Plans") as amended on February 18, 1975 (40 FR 7042). For such use, a method must be used in strict accordance with the operation or instruction manual provided with the method and subject to any limitations (e.g., operating range) specified in the applicable designation (see description of the methods above). Vendor modifications of a designated method used for purposes of § 51.17(a) are permitted only with prior approval of EPA, as provided in Part 53. Provisions concerning modification of such methods by users were promulgated on March 17, 1976 (FEDERAL REGISTER, Vol. 41, page 11255).

In general, each designation applies to any analyzer which is identical to the analyzer described in the designation. However, similar analyzers manufactured prior to the designation and bearing the same model number as the designated method are not necessarily identical to the analyzer described in the designation. In many cases, such analyzers may be upgraded (e.g., by minor modification or by substitution of new operation or instruction manual) so as to be identical to the designated method and thus achieve designated status at modest cost. The manufacturer should be consulted to determine the necessity and feasibility of such upgrading.

Part 53 requires that sellers of designated methods comply with certain conditions. These conditions are given in 40 CFR Part 53.9 and are summarized below:

(1) A copy of the approved operation or instruction manual must accompany the analyzer when it is delivered to the ultimate purchaser.

(2) The analyzer must not generate any unreasonable hazard to operators or to the environment.

(3) The analyzer must function within the limits of the performance specifications given in Table B-1 of Part 53 for at least 1 year after delivery when maintained and operated in accordance with the operation manual.

(4) Any analyzer offered for sale as a reference or equivalent method must bear a label or sticker indicating that it has been designated as a reference or equivalent method in accordance with Part 53.

(5) If such an analyzer has one or more selectable ranges, the label or sticker must be placed in close proximity to the range selector and indicate which range or ranges have been designated as reference or equivalent methods.

(6) An applicant who offers analyzers for sale as reference or equivalent methods is required to maintain a list of ultimate purchasers of such analyzers and to notify them within 30 days if a reference or equivalent method designation applicable to the analyzer has been cancelled or if adjustment of the analyzers is necessary under 40 CFR 53.11 (b) to avoid a cancellation.

(7) An applicant who modifies an analyzer previously designated as a reference or equivalent method is not permitted to sell the analyzer (as modified) as a reference or equivalent method (although he may choose to sell it without such representations), nor to attach a label or sticker to the analyzer (as modified) under the provisions described above, until he has received notice under 40 CFR 53.14(c) that the original designation or a new designation applies to the method as modified or until he has applied for and received notice of a new reference or equivalent method determination for the analyzer as modified.

Aside from occasional breakdowns or malfunctions, consistent or repeated non-compliance with any of these conditions should be reported to: Director, Environmental Monitoring and Support Laboratory, Department E (MD-76), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711.

Designation of these references and equivalent methods will provide assistance to the States in establishing and operating their air quality surveillance systems under 40 CFR 51.17(a). Additional information concerning this action may be obtained by writing to the address given above.

WILSON K. TALLEY,
Assistant Administrator for Research nad Development.

[FR Doc.77-15677 Filed 6-2-77;8:45 am]

[OPP-00053 PRL 741-1]

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT SCIENTIFIC ADVISORY PANEL

Meeting

AGENCY: Office of Pesticide Programs, Environmental Protection Agency (EPA).

ACTION: Notice of meeting.

SUMMARY: There will be a two-day meeting of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel from 9:30 a.m. to 4:30 p.m. daily on Monday, June 20, and Tuesday, June 21, 1977. The meeting will be held in Room 1112A, Crystal Mall, Building Number 2, 1921 Jefferson Davis Highway, Arlington, Virginia.

FOR FURTHER INFORMATION CONTACT:

Dr. H. Wade Fowler, Jr., Executive Secretary, FIFRA Scientific Advisory Panel, Office of Pesticide Programs (WH-567), Rm. E-315, EPA, 401 M St. SW., Washington D.C. 20460, telephone 202-755-4851.

SUPPLEMENTARY INFORMATION: In accordance with Section 25(d) of the amended FIFRA, the Scientifi Advisory Panel will comment on the impact on health and the environment of regulatory actions under section 6(b) and 25(a) prior to implementation. The purpose of this meeting is to discuss the following topics:

1. Continued review of the advanced draft of the subpart on Hazard Evaluation: Humans and Domestic Animals of the Guidelines for Registering Pesticides in the United States.

2. Continued review of the proposed regulations for classification of pesticides as required under Section 3(d) of FIFRA, amended. (Note: This will be discussed only if needed. The proposed document was reviewed on May 26-27, 1977).

3. The Agency may present background information on changes anticipated in its basic regulatory approach to pesticides. Such a presentation would involve a discussion of a generic-chemical-standards approach to regulation.

The meeting will be open to the public. Any member of the public wishing to attend or submit a paper should contact Dr. H. Wade Fowler, Jr., Executive Secretary, FIFRA Scientific Advisory Panel,

May 16 '77

Office of Pesticide Programs (WH-567), Room E-315, EPA, 401 M St. SW., Washington D.C. 20460, telephone: 202-755-4851). Interested persons are permitted to file written statements before or after the meeting, and may upon advance notice to the Executive Secretary, present oral statements to the extent that time permits. Written or oral statemens will be taken into consideration by the Panel in formulating comments or in deciding to waive comments. Persons desirous of making oral statements must notify the Executive Secretary and submit four copies of a summary no later than June 18, 1977.

Individuals who wish to file written statements are advised to submit ten copies of statements to the Executive Secretary in a timely manner to ensure appropriate consideration by the Panel.

Dated: June 1, 1977.

JAMES M. CONLON,
Deputy Assistant Administrator
for Pesticide Programs.

[FR Doc.77-15877 Filed 6-2-77;8:45 am]

FEDERAL COMMUNICATIONS COMMISSION

[Report No. 860]

COMMON CARRIER SERVICES INFORMATION

Applications Accepted for Filing

MAY 31, 1977.

The applications listed herein have been found, upon initial review, to be acceptable for filing. The Commission reserves the right to return any of these applications, if upon further examination, it is determined they are defective and not in conformance with the Commission's Rules and Regulations or its policies.

Final action will not be taken on any of these applications earlier than 31 days following the date of this notice, except for radio applications not requiring a 30-day notice period (See § 309(c) of the Communications Act), applications filed under Part 68, applications filed under Part 63 relative to small projects, or as otherwise noted. Unless specified to the contrary, comments or petitions may be filed concerning radio and Section 214 applications within 30 days of the date of this notice and within 20 days for Part 68 applications.

In order for an application filed under Part 21 of the Commission's Rules (Domestic Public Radio Services) to be considered mutually exclusive with any other such application appearing herein, it must be substantially complete and tendered for filing by whichever date is earlier: (a) The close of business one business day preceding the day on which the Commission takes action on the previously filed application; or (b) Within 60 days after the date of the public notice listing the first prior filed application (with which the subsequent application is in conflict) as having been accepted for filing. In common carrier radio services other than those listed under Part 21, the cut-off date for filing a mutually exclusive application is the close of business one business day preceding the day on which the previously filed application is designated for hearing. With limited exceptions, an application which is subsequently amended by a major change will be considered as a newly filed application for purposes of the cut-off rule. (See § 1.227(b)(3) and 21.30(b) of the Commission's Rules.)

FEDERAL COMMUNICATIONS COMMISSION,
VINCENT J. MULLINS,
Secretary.

APPLICATIONS ACCEPTED FOR FILING

DOMESTIC PUBLIC LAND MOBILE RADIO SERVICE

21380-CD-P-77 Mobile Radio System of Ventura, Inc. (KSV976), C.P. for additional facilities to operate on 152.24 MHz to be located at a new site described as location No. 3: At Red Mountain, Approx. 6.0 miles NW. of Ventura, California.

21381-CD-P-77 Calhoun City Telephone Company (KUS373), C.P. to change antenna system operating on 158.10 MHz located 0.4 mile east of Derma, Mississippi.

21382-CD-P-77 DPRS, Inc. t/a Zip-Call (KCD890), C.P. for additional facilities to operate on 43.58 MHz to be located at a new site described as location No. 23; On Alpine Road, ¼ mile N. of Fitchburg, Massachusetts.

21383-CD-P-(4)-77 Adirondack Mobile Telephone Co., Inc. (new), C.P. for a new 2-Way station to operate on 152.06 152.18 MHz at location No. 1 to be located at Beekman Court; and location No. 2 to operate on 152.06 152.18 MHz to be located at WGFM-FM Tower; Rand Hill, Plattsburgh, New York.

21384-CD-P-77 Marc Weber Tobias and Michael Charles Tobias d/b as MT Systems, Inc. (new), C.P. for a new 2-Way station to operation on 152.21 MHz to be located North of Rt. 34 at the SW. corner of Wessington Springs, South Dakota.

21385-CD-P-2-77 Mount View Communications (new), C.P. for a new station to operate on 152.09 (base) and 459.075 (Repeater) MHz to be located at Aqua Ramon Mountain, 5.1 miles NE. of South Fork; and 454.075 MHz (Control) at location No. 2 to be located 715 1st Avenue, Monte Vista, Colorado.

21386-CD-P-77 RCC of Virginia, Inc. (new), C.P. for a new 1-Way station to operate on 152.24 MHz to be located at Rt. 47, approximately 600 feet east of the western city limits, South Hill, Virginia.

21387-CD-P-77 Citizens Telephone Company, Inc. (new), C.P. for a new 2-Way station to operate on 152.75 MHz to be located Union Street, Vienna, Georgia.

21388-CD-P-77 Citizens Telephone Company, Inc. (new), C.P. for a new 1-Way station to operate on 152.84 MHz to be located at Bond and Washington Streets, Plains, Georgia.

21389-CD-P-77 Digital Paging Systems of Pittsburgh, Inc. (KWB370), C.P. to change antenna system operating on 152.24 MHz located 1715 Grandview Avenue, Pittsburgh, Pennsylvania.

21390-CD-P-77 R.C.S., Inc. (KRM971), C.P. for additional facilities to operate on 152.24 MHz to be located at a new site described as location No. 5; 922 North I Street, Lompoc, California.

21236-CD-P-77 Susquehanna Mobile Communications, Inc. (new), Resubmitted. C.P. for a new 1-Way station to operate on 152.24 MHz to be located at Holly Pike, Route 34, approximately 1.1 miles south of Carlisle, Pennsylvania.

21391-CD-P-(2)-77 Statesboro Telepho e Company (KWA654), C.P. to change antenna system operating on 152.69 MHz; add 152.81 MHz to be located at 76 E. Grady St., Statesboro, Georgia.

21392-CD-P-(2)-77 Mobilfone Communications, Inc. (KKX714), C.P. to change antenna system and relocate facilities operating on 152.03 152.21 MHz from location No. 2 to a new site described as location No. 3 to be located 1.3 miles south of Intersection of Highway 2244 and Highway 360, approximately 3 miles west of Austin, Texas.

21393-CD-P-77 Jackson Mobilphone, Inc. (new), C.P. for a new 1-way station to operate on 152.24 MHz to be located on U.S. Highway 43, Intersection of No. 3, Jackson, Alabama.

21394-CD-P-77 Jackson Mobilephone, Inc. (new), C.P. for a new 2-way station to operate on 152.06 MHz to be located on Highway 43, Intersection of No. 3, Jackson, Alabama.

21395-CD-P-(3)-77 The Mountain State Telephone and Telegraph Company (KOK-345), C.P. to change antenna system and replace transmitter operating on 152.75 MHz; Add 152.54 MHz to be located at 3.0 miles west southwest of Pocatello, and Test facilities to operate on 157.80 MHz located at 455 West Lewis Street, Pocatello, Idaho.

21396-CD-P-(6)-77 South Central Bell Telephone Company (KIC343), C.P. to relocate facilities operating on 454.375, 454.450, 454.475, 454.525, 454.600, 464.625 MHz to be located approximately 4 miles northeast of Pegram, Tennessee.

MAJOR AMENDMENT

21011-CD-P-(2)-77 E. F. Mitchell, Jr. d, b as Douglas Radio (KIM967), Amend base frequency 454.125 MHz to read 454.200 MHz. All other particulars are to remain the same as reported on PN No. 852 dated April 4, 1977.

INFORMATIVE

It appears that the following applications may be mutually exclusive and subject to the Commission's Rule regarding Ex Parte presentations by reason of economic competition or potential electrical interference.

CALIFORNIA

Tadlock's Radio Dispatch (KMA259) Bald Mountain, 0091-CD-P-1-77.

Silverado Communications (New) Napa, 21202-CD-P-2-77.

RURAL RADIO SERVICE

60277-CR-P/L-77 Puerto Rico Communications Authority (new), C.P. and License for a new Rural Subscriber station to operate on 454.375, 454.400, 454.425, 454.450, 454.475, 454.500, 454.525, and 454.550 MHz to be located at Bo. Anones, Carr. 152 Ramal 813 Km 1.4, Naranjito, Puerto Rico.

60278-CR-P/L-77 Same as above located at Bo. Quebradilla Carr. 900 Km. 9.7, Yabucoa, Puerto Rico.

60279-CR-P/L-77 Same as above to be located at Bo. Quebrada Grande Carr. 902 Km. 4.4, San Lorenzo, Puerto Rico.

60276-CR-P/L-77 Same as above to be located at Bo. Tejas Guayabal Carr. 921 Km. 3.3, Humacao, Puerto Rico.

60280-CR-P/L-77 Same as above to be located at Bo. Aguacate Comunes Ramal 9004, (1 Km. de Carr. 902), Yabucoa, Puerto Rico.

60281-CR-P/L-77 Same as above to be located at Calle Pedro Marques Esq. William Font, Culebra, Puerto Rico.

that the "important thing is how much product (grams? volume?) is put on the plate to form colonies." He said that these data are critical to evaluate the potential environmental hazard of this product.

Correction: Notice of receipt of the new active ingredient registration application was published in the April 29 not April 30 Federal Register.

Blair Rowe RL SDM TT

OSHA CANCER PROPOSAL HIT; SEEN AS FAILING TO SPEED RULEMAKING

The as-yet unproposed regulation under which the Occupational Safety & Health Administration (OSHA) would regulate carcinogens and suspect carcinogens (See Feb. 16 Page 33) was ridiculed by a Dow Chemical Corp. executive last week at a public forum in Washington, D.C., as being an example of "bootstrap logic" which could leave industry with no chemicals left to work with.

R&S 113885

At the same forum, which was sponsored by the Society for Occupational & Environmental Health (SOEH), labor union officials criticized the proposal for not mandating that employers pay for employee protective clothing and equipment and medical examinations which OSHA carcinogen regulations do and will require.

Jack Sheehan, Legislative Director of United Steelworkers of America and Chairman of the Policy Subgroup of the National Advisory Committee on Occupational Safety & Health (NACOSH), criticized the cancer proposal for not solving the problem of "rate retnetion" i.e. "mandatory relocation."

As explained by Anson Keller, co-author of the OSHA proposal, the rate retention/mandatory relocation dilemma pertains to an employer moving an employee to an area of a business operation where exposure to a regulated chemical is less. Such a change often results in a lower salary for the employee, since less hazardous work usually pays less.

In short, Keller said, an employee could work for a firm for 30 years, get cancer, and because of the detection, lose his high salary. The phenomenon could prove to be an incentive for employees to avoid the medical examinations which OSHA wants employers to perform and make available.

OSHA Administrator Elva Bingham is assembling an advisory group to study the problem.

Unionists such as Sheehan derided the document one moment and commended it the next. OSHA was commended for attempting to improve its performance in carcinogen regulation but was derided for not taking an even deeper plunge into labor-management relations. Grover Wrenn, a Deputy in OSHA's Health Standards Division, and defender of the proposal throughout the all-day symposium, said OSHA's health-protecting plunge was inadvertant and the extent of it was unforeseen, but Wrenn defended it as necessary.

The Dow executive, Dr. T. R. Torkelson (See Page 3) hit the proposal for what he called "an obvious disregard for dose" when using laboratory animal tests to determine whether a chemical is a carcinogen. Torkelson got support from Dr. Roy Albert, Chairman of the Environmental Protection Agency's Carcinogen Assessment Group (CAG) (See May 18, Page 31), who asked if it "makes sense" to not consider dose for purposes of classification.

According to the proposal, a substance could be classified as a Category I carcinogen if it has been shown "at any dose level to cause the formation of malignant or benign neoplasms, or a combination thereof, in (a) man, or (b) two mammalian test species, or (c) a single mammalian test species if those results have been replicated in another experiment or by multi-test evidence for mutagenicity, or (d) upon the basis of any other evidence that the Secretary (of Labor) finds sufficient."

A Category II classification would be triggered by "suggestive" evidence of carcinogenicity from a single experiment on a single mammalian species, regardless of dose.

Category I classification would prompt issuance by OSHA of an emergency temporary standard which would be followed in 60 days by a proposed permanent standard. The proposed permanent standard would embellish the emergency standard and impose medical surveillance, workplace monitoring and other "model" requirements which OSHA wants to impose "across the board" for all Category I chemicals.

Engineering controls would be proposed to bring exposure to the Category I chemical down to the "lowest feasible" level, and if OSHA believed that "suitable" substitutes were available, a "zero" exposure level could be set.

According to the proposal, issues at the hearing on the proposed permanent standard would be limited to:

> "(1) Whether the Secretary correctly classified the toxic material into Category I; (2) whether the Secretary was correct in his determination that the Category I classification should not be rebutted; (3) whether the Secretary correctly determined the lowest feasible occupational exposure, or whether there are suitable substitutes that are less hazardous to humans; (4) the appropriateness of the specific protective means of the proposed standard and (5) the environmental impact caused by such regulation."

Issues also would be limited in hearings on Category II classifications.

John Kolojeski, moderator of the conference and President of Clement Associates (See June 1, Page 14) said that the proposed limitation on issues, which is central to OSHA's effort to speed rulemaking, could be construed as an abridgement of due process, while Sheehan held that these very issues probably would be litigated every time OSHA proposed a standard. Th refore, Sheehan said, OSHA rulemaking is likely to remain largely a substance-by-substance affair, characterized by delay.

Category II classification would prompt no emergency standard and no engineering controls, but an exposure limit would be set, as would medical surveillance and other "model" requirements. Rather than engineering controls, housekeeping practices and personnel protective equipment and clothing would be prescribed for Category II chemicals. Keller explained that Category II is needed to "gear up" in case information becomes available indicating that the chemical belongs in Category I.

Torkelson maintained that imposition of such requirements without consideration of th dose used in the animal experiment(s) would be irresponsible in light of the possibility that human metabolism could eliminate the threat which the chemical may pose.

Dose in Backup Animal Studies "Irrelevant," Says OSHA's Wrenn

Wrenn, however, responded that does was "largely irrelevant," since OSHA does not consider a threshold level to exist for carcinogens.

Marshall Miller, a legal expert and a former Deputy Assistant Secretary of Labor for OSHA, said that potency i.e. dose would be factored into OSHA deliberations "subjectively" when OSHA, taking economics into account, sets its lowest "feasible"or "zero" exposure level.

Wrenn also was supported by Dr. Marvin Schneiderman of the National Cancer Institute (NCI), who said that "cancer is bad," regardless of potency.

Kolojeski said procedures set out in the OSHA proposal for rebutting both Category I and II classifications "take care" of Torkelson's concerns.

Justification for rebuttals on toxicological grounds are spelled out twice in the OSHA proposal, once for Category I chemicals and once for Category II. According to Section 1990.11 of the proposal, the Secretary of Labor may rebut the presumption of a Category I classification if he determines:

> "(a) that the alleged carcinogenic effect based on animal data clearly resulted from non-specific physical, rather than chemical induction, or (b) that the route of exposure was grossly inappropriate relative to the potential occupational routes of human exposure, or (c) that the animal or human studies submitted for review were only suggestive or not adequate to establish any conclusion with respect to the carcinogenicity or noncarcinogenicity of the toxic materials or (d) that for some other biological reason, the positive results in experimental mammals are not scientifically relevant to man."

Justifications are similar for a successful rebuttal of a Category II classification. A successful rebuttal places a chemical at least one category below the proposed one.

CAG's Albert Raises Sticky Regulatory Issue

Just what constitutes "replication" of an animal test, however, is a particularly difficult issue, according to CAG Chairman Albert. At the SOEH meeting, Albert cited a "not uncommon" example he has run across at CAG where a pesticide now up for a rebuttable presumption against registration (RPAR) notice was found to produce tumors in a long-term study conducted by the Food and Drug Administration (FDA), but the tumors were found only at the lowest dose level, which is "strange in itself," Albert said. A long-term study by NCI was negative, Albert stated, as were two others. Another study on the same chemical, however, was found to b positive in one sex at one dose level, but the tumors which appeared in the dosed animals appeared later than spontaneous tumors observed in controls. Since tumors in dosed groups usually occur sooner than tumors in controls, this "replication" of an already "suspicious" FDA study is questionable, Albert said. Nevertheless, the finding could conceiveably trigger a Category I classification if the OSHA proposal is allowed to stand as is (Albert would not reveal the identity of the pesticide in question).

Albert asked if positive findings in two dose groups in the same experiment would constitute "replication," as suggested by Dr. David Clayson of the National Cancer Advisory Board. He also asked whether observation of a dose-response relationship could be considered "replication." No one answered his rhetorical questions.

Generally, Albert expressed fears that OSHA's "black and white" proposal would give too much power to scientists.

Squire Fears "Over interpretation" of "Suggestive" Bioassay Results

Dr. Robert Squire, former Chief of the NCI Bioassay Program (See March 2, Page 22) and now at Johns Hopkins University and an Associate Scientist with Clement Associates, Inc., warned against linking "suggestive" NCI bioassay results to OSHA regulation under Category II. He said "overinterpretation of uncertain results has done more harm to toxicology than anything else." He held that NCI's research mission should be allowed to continue unencumbered by OSHA's regulatory mission.

With respect to Category I classification, Squire said "results in a single mammalian species supported by incriminating in vitro data would be most convincing if either both sexes or more than one dosage group were affected."

There was considerable discussion on whether OSHA should simply adopt the proposal as an administrative policy, once it has been revised or, as an alternative, whether OSHA should publish it as a proposed regulation and subject it to judicial review.

The argument for th latter proc dur , as stated by Wrenn, would be that to speed OSHA rulemaking, judicial review is needed on the basic regulatory principles which OSHA follows v ry time it proposes a rule on carcinogens.

These cancer principles are essentially the same as those which have stretched out EPA cancellation proceedings on heptachlor and chlordane (See June 1, Page 25).

Once such review is completed, Wrenn contended, rulemaking would go faster.

The speed argument appears to have been rebutted by Sheehan, but Kolojeski argued in favor of making the document a regulation as opposed to a policy because the document's publication as a policy would not carry with it the mandatory timetables under which OSHA would be forced to propose permanent standards and take other actions.

The document could be abandoned by the next Administration if it were simply a policy, Kolojeski said.

Sheehan, on the other hand, argued that Federal Register publication of the proposal as a regulation would bog down OSHA in rulemaking on it and prevent OSHA from taking action on known problem chemicals. As an alternative, Sheehan suggested testing the policy on some real problems.

Pointing to the recent OSHA activity on benzene (See June 1, Page 11), Wrenn denied that Federal Register publication of the proposal as a regulation would hamper OSHA in its efforts to deal with current problems.

As a remedy to industry delaying tactics, NCI's Schneiderman suggested that for any chemical tied up in litigation, all profits should be placed in a closed fund unavailable to the manufacturer.

Richard Boggs of the National Institute for Occupational Safety & Health (NIOSH) asked how OSHA would handle chemicals which are similar in structure to those placed in Category I or II. He also asked for better definitions of the terms "feasible" and "detectable."

As an indication of just how complicated these issues are and how deep emotions run, a labor union official, misconstruing remarks made by Torkelson, said Dow is interested in DNA research because the firm wants to create a "super race" of chemical workers who are immune to cancer.

Over 140 people from government, industry and academia attended the SOEH conference.

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HOUSE COMMITTEE WANTS EPA TO ALLOW MIREX FOR FIRE ANT ERADICATION

"In the hope that the Environmental Protection Agency will rescind its ruling on mirex" the House Appropriations Committee has reserved $4,460,000 for a fire ant eradication program, (See March 30, Page 33).

PESTICIDE & TOXIC CHEMICAL NEWS

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DOW EXECUTIVE MISSTATES CASE ON MUTATION TESTING; EPA TO PROCEED

Despite allegations to the contrary made by a Dow Chemical Corp. executive at a meeting of the Society for Occupational and Environmental Health (SOEH), the Environmental Protection Agency's Science Advisory Board (SAB) has not determined that the state of the art of mutagenicity testing (See June 1, Page 2) is so primitive as to preclude use of mutagenicity data to support regulatory actions against pesticide chemicals.

The executive, Dr. T. R. Torkelson of Dow's medical department, told last week's SOEH symposium on a cancer proposal from the Occupational Safety & Health Administration (OSHA) that OSHA should not depend on mutation tests at all for purposes of defining a chemical as a Category I carcinogen. Such a definition would trigger issuance of an OSHA emergency temporary standard entailing monitoring for the chemical in workplaces where it's produced, used, or packaged, as w ll as medical surveillance of exposed workers, "good housekeeping" requirements and other steps (See May 25, Page 20).

Placement of a chemical into Category I could be "rebutted" in a rulemaking proceeding. If the rebuttal were unsuccessful, the rulemaking would determine what the "lowest feasible" exposure level is, and workplaces would have to reach it. It would become the OSHA permanent standard. In the rulemaking, OSHA also could say that there are suitable substitutes for the chemical and attempt to promulgate a permanent standard requiring zero exposure.

OSHA has proposed to allow a positive bioassay result in a single mammalian species to trigger Category I classification if the bioassay has been "replicated" by a test on the same or a different species, or, if there exists "multi-test evidence of mutagenicity."

Torkelson said EPA's SAB, two weeks prior to the June 2 SOEH meeting, had decided that mutagenicity testing "wasn't ready yet" for regulatory use, and, Torkelson said, it would be "inappropriate" for OSHA to use mutation data if EPA wasn't going to.

However, the SAB Environmental Health Advisory Committee met June 1 to discuss EPA's proposed mutagenicity testing requirements for pesticides (See April 13, Page 14 and May 18, Page 2) and indicated that, in fact, the types of tests which EPA has proposed are sufficiently validated to require them for pesticide registration actions.

Drake, Nelson, Wogan and Abrahamson Say Mutation Tests are Ready

At the June 1 SAB meeting, another Dow executiv , Dr. V. K. Rowe, said EPA should not impos the mutagenicity battery b caus the tests which compris it have not been validated and because their relevance to man is questionable.

Dr. John W. Drake, a member of the study group which helped EPA draft the Section 3 guidelines, disagreed, saying that EPA and the study group had chosen only the best validated tests out of a possible total of 30.

Dr. Norton Nelson, Chairman of the Environmental Health Advisory Committee, said that based on "a wide variety of studies in the animal kingdom, we do know that heritable mutations are a severe threat. The jump from that to the human population is, to my mind, miniscule."

His arguments on validity and relevance to man discarded, Rowe then maintained that SAB should advise EPA to delay adoption of the testing requirements until the Agency had better defined what would be a "statistically significant" result in each test and until EPA had spelled out how it would interpret "mixed results" from the component tests in the eight-test battery.

Dr. Gerald Wogan, Chairman of Drake's study group, said that nothing in the upcoming criteria document, which will address "mixed" results, will change the requirements which EPA has set forth.

On statistical significance, EPA's final guidelines will provide "more acceptable biometric wording" regarding what constitutes a significant finding in each test, according to EPA's Dr. Ruth Pertel, a principle author of the mutagenicity guidelines. This change comes about largely as a result of urgings from Dr. Lincoln E Moses, professor of statistics at Stanford University and a member of SAB.

With respect to maintaining flexibility and not putting mutagenicity testing requirements "in bronze," Nelson said, "Sure things are in a major state of flux, but that state of flux is going to lead to alternative ways of doing very much the same kind of things we're doing now, but doing them in a more efficient way." The document will say that the battery shall be reviewed every three years for possible changes. Drake held that some of the eight test "could fall by the wayside" not because they're invalid, but because "a more rapid or less expensive test may come along."

In probably the most telling argument against bacterial tests not being relevant to man, Dr. Seymour Abrahamson gave some history on how, with respect to radiation, a human risk estimate per Roentgen per gene using the mouse as a model has turned out to be "almost identical" to the human risk estimate which can be computed by using Drosophila (bacteria).

Abrahamson said there is "good evidence" that man responds very closely to the mouse in terms of radiation sensitivity. He said the U. S. spent over $50 million establishing the mouse as an appropriate model when it turns out that bacteria would have been just as good an indicator.

He said the argument against the mutagenicity testing battery on economic grounds was untenable, since, by Abrahamson's calculations, the battery would cost no more than $45,000 per compound.

He said the most expensive test other than the mouse specific locus test (which is included among the 13 from which eight will be chosen because it's valid, despite its cost) is the Drosophila test, which would cost around $10,000 if the experimenter was trying to detect a doubling of the spontaneous mutation rate. Abrahamson said the Drosophila test could cost as little as $1,000 if the experimenter were looking for a more drastic response, such as a five-fold increase over the spontaneous rate. Abrahamson is based at the University of Wisconsin.

The Wogan-Drake study group will meet June 15 to discuss the criteria document which will describe how EPA will interpret "mixed" mutagenicity testing results.

R&S 113892

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USDI LABORATORY TO INPUT RPAR PROCESS WITH FISH, WILDLIFE EFFECTS DATA

Fish-Pesticide Research Laboratory (FPRL), U. S. Fish and Wildlife Service, Interior Department, under an intragency agreement with the Environmental Protection Agency, will provide data on the effects of pesticides on fish and wildlife for use in the risk assessment portion of the rebuttable presumption against registration (RPAR) process.

The agreement, signed June 2 by Edwin L. Johnson, Deputy Assistant Administrator for Pesticide Programs, EPA, stated that the FPRL, located in Columbia, Mo., would supply copies of published and notification of unpublished results of research on the effects of about 150 pesticides -- RPAR candidates and alternatives -- on fish and wildlife.

In the first month, the Laboratory would provide reprints and research results on about 60 pesticides, according to the agreement which has not yet been signed by the Fish and Wildlife Service. After the first month, the agreement noted, research results and reprints would be required on 10 to 20 compounds a month. The Laboratory would also supply negative responses, the agreement provided.

The agreement would expire Sept. 30, 1977. EPA would pay the Fish and Wildlife Service about $10,000 for supplying the effects data.

EPA will list and assign priorities to the pesticides for which the Laboratory will provide effects data.

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$5,850 CIVIL PENALTY AGREED TO BY THOMPSON-HAYWARD HEADS EPA ENFORCEMENT

An agreement signed by Thompson-Hayward Chemical Co. of Fayetteville, N. C., to pay a $5,850 civil penalty assessed by Environmental Protection Agency officials in Region IV highlighted recent pesticide enforcement activity.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 18, 1977

SCHAFER
JERSEY
GEARING
McCOLLISTER
ROWE

Mr. T. R. Torkelson
Corporate Medical
The Dow Chemical Company
Bennett Building
2030 Dow Center
Midland, Michigan 48640

Dear Mr. Torkelson:

R&S 113893

Please be advised that formal minutes, per se, of the subcommittee meeting of the FIFRA Scientific Advisory Panel held on May 16-17, 1977 are not contemplated. We do plan to publish a topical outline and summary of the meeting, but it is our current policy to concentrate our limited secretariat resources on formal meetings. Due to our extremely heavy schedule for meetings and two unscheduled moves of our office (another one since you wrote), we are considerably behind in our minutes. However, I expect to be current again in about two weeks.

The Panel plans another subcommittee meeting in September on Subpart F of the Guidelines, entitled "Hazard Evaluation: Humans and Domestic Animals." Mutagenic Test requirements will be discussed at great length. Should you desire to attend, the meeting is currently planned for the period September 28 to 29, 1977 in Room 2117, Waterside Mall, EPA Headquarters, Washington, D.C. Approximately 15 days prior to the meeting we will issue an official notice in the Federal Register. The Panel is still evaluating the proposed mutagenic testing procedures, and it is premature at this stage to indicate the opinion of the Panel on this issue. Following the September meeting, the Panel will eventually conduct a formal review of Subpart F of the Guidelines. This is expected to take place prior to Christmas.

I hope that you will attend our meeting in September. This is the best way of keep current on the status of the Guidelines.

Thank you for your interest.

Harland W. Fowler Jr.

Harland Wade Fowler, Jr., Ph.D.
Executive Secretary
FIFRA Scientific Advisory Panel
1921 Jefferson Davis Highway
Room 803, CM#2
Arlington, Virginia

August 10, 1977

R&S 113894

To All Interested Parties

The Secretariat for the FIFRA Scientific Advisory Panel has been relocated in Room 803, Crystal Mall, Building No. 2, 1921 Jefferson Davis Highway, Arlington, Virginia.

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