

Monsanto

FROM
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SUBJECT New PCB Regulations -
PCBs Inadvertently Manufactured

REFERENCE

TO : C. F. Callis - G5WA
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The new regulation covering inadvertently manufactured PCBs was proposed by EPA in the December 8 Federal Register. A 60 day comment period regarding the proposed rule and support documents closes February 6, 1984.

The new regulation is substantially based upon the "consensus rule" jointly proposed to the Agency earlier this year by environmentalist and industry groups, including EDF, NRDC and CMA. Industry per se and Monsanto generally support the rule.

Although the rule has several onerous provisions related to sampling, record-keeping and certification by an officer (or agent) of the company, the rule generally sustains and provides exclusions for products in commerce containing inadvertently generated PCBs up to 50 ppm level excursions at an annual average of less than 25 ppm.

From an industry standpoint the problem with the proposed rule is not the rule itself but the support documents and pseudo scientific methodology used by the agency to justify the rule. The agency support is based upon new "methodology" for conducting health effect risk assessments in the areas of carcinogenicity and reproductive effects as well as estimating environmental risks and hazards and calculating various worst case exposure scenarios.

A key concern is that these pseudo scientific techniques if unchallenged will establish precedents that spill over into other significant areas of regulatory concern such as Superfund, RCRA, TSCA PMN's, etc.

Several major problems arise in commenting on the proposed rule:

1. Relatively short 60 day comment period (over the holidays) dictated by D.C. Circuit Court timetable.
2. Large volume of scientific documents to review and critique.
3. Defining a strategy to support the proposed regulation yet challenge the poor science techniques employed by the agency in the support documents.

The CMA PCB Special Projects Group (PCB Group), along with other CMA committees, has developed a plan to deal with Issue #3. The PCB Group will develop comments demonstrating support for the rule but emphasizing the reasoning of the "consensus proposal" task force. We are endeavoring to get EDF and NRDC to file joint comments in this area. The CMA PCB Group will broadly oppose the use of the agency health and environmental risk assessments based upon the questionable science and methodology. Independent consultants having expertise in risk assessment methodology have been retained by the CMA PCB Group.

In addition, several other CMA committees, including CRAC, EMC, along with AIHC, will focus efforts upon broadly challenging the EPA pseudo scientific methods and will use forums other than this new rule to challenge the risk assessment documents based upon improper use of scientific principles and data. This issue may be raised with the new Assistant Administrator, Dr. Jack Moore.

Due to the large volume of technical material in the support documents the CMA PCB Group nor myself is able to handle the exposure assessment scenarios in the comment time frame. These scenarios review about 200 chemical processes that could conceivably generate inadvertent PCBs and evaluate various exposures for 20 different occupational settings as well as environmental releases to air, water and waste and also some consumer uses. Among the occupational settings considered are spray painting, pesticide spraying, removal of still bottoms from process equipment, maintenance of various process equipment, etc. One major concern of these occupational scenario reviews is that EPA may attempt to preempt OSHA and establish more stringent workplace exposure rules for PCB contaminated processes.

Because of the short time fuse and the rapidly approaching holidays, I propose to meet with representatives of the four operating companies as soon as possible to discuss these process/occupational and product exposure scenarios and ask each operating company to scan the documents (three inches thick) to identify concerns to their operations.

Once concerns are identified we will develop a plan to prepare Monsanto comments for the record to challenge fallacious assumptions and principles that lead to EPA conclusions resulting in unnecessarily low and restrictive control levels.

Please nominate representatives (one or two) for your operating unit to participate in these discussions and to develop appropriate comments. (One representative should be knowledgeable in the details of your operating unit's product and process chemistry.)

I will convene a meeting December 20 or 21 to review this information and get started identifying Monsanto Company areas needing review and comment. Our target for a first draft of Monsanto comments for internal review should be about January 18.

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In addition I will be happy to prepare a discussion of these proposed PCB regulations for a future DEO meeting if you desire to summarize the requirements for obtaining and keeping the exclusion to manufacture products containing PCBs above 2 ppm.

JHC /dg

J. H. Craddock

/dg

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