

Monsanto

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Document Control Officer (TS-793)
Office of Pesticides and Toxic Substances
U.S. ENVIRONMENTAL PROTECTION AGENCY
Room E-409
401 "M" Street, Northwest
Washington, DC 20480

Dear Sir:

Re Proposed Rule - Polychlorinated Biphenyls
(PCB's); Manufacture, Processing, Distribution
and Use in Closed and Controlled Waste
Manufacturing Processes (47 FR 24976)

Monsanto Company, a broad-based manufacturer of chemicals,
welcomes the opportunity to comment on the proposed rule
indicated.

General Comments

A review of the history of the adoption of the Toxic Substances Control Act in general, and Section 6(e) in particular, leads clearly to the conclusion that Congress intended Section 6(e) to apply only to PCB which was intentionally manufactured for sale as commercial PCB. (The second paragraph of footnote 37 in *EDF vs. EPA*, decided October 30, 1980, is unfortunate. After laying a basis for concluding that the legislation did not deal with incidental manufacture of PCB, the Court went on to reach a confusing conclusion. If this question were to be directly brought before a court today, it is likely that a judicial determination would be obtained that Section 6(e) does not apply to incidental manufacture of PCB.) Since PCB is no longer being intentionally manufactured for commercial use, no regulations are now necessary relating to the manufacture of PCB. However, in the interest of avoiding further litigation, Monsanto would not oppose an EPA regulation dealing with the incidental manufacture of PCB's provided that such regulation applied only to materials having a PCB content in excess of 50 ppm.

July 8, 1982

Specific Issues

Monsanto Company submits the following comments relevant to the summary issues as requested by EPA (FR 47, p 24986, June 8, 1982).

1. The CMA data survey represents a significant demonstration that the total quantity of incidental PCB's generated by the bulk of chemical manufacturers producing chlorinated organic chemicals and/or using chlorinated solvents is less than about 14,000 pounds per year. Of these incidental PCB's produced by chemical manufacturers, less than five percent (about 700 pounds per year or less) is contained in products that could theoretically result in an ultimate release to the environment.

These levels are de minimus in the context of (1) PCB's already accessible in the environment estimated by the National Academy of Sciences to be in the range up to 150 million pounds, (2) PCB's estimated by EPA to be environmentally released annually from leaks in totally enclosed electrical transformers and capacitors at a level in excess of 450,000 pounds per year (FR 27, p 17426ff, April 22, 1982), (3) PCB's estimated by EPA at 162 million pounds which are contained in small capacitors each containing less than three pounds of dielectric fluid such as used in household appliances, fluorescent light ballasts and industrial equipment. These PCB's are disposed of literally by dumping in sanitary landfills and municipal trash dumps and are unregulated as PCB's per se by EPA.

2. EPA's approach of excluding closed and controlled waste processes is appropriate in that these processes pose de minimus risks and that the benefits of these processes significantly outweigh the risks.
3. EPA's approach to specifying criteria for analysis of PCB's in various media is unwarranted in that use of performance standards would be more suitable and practicable. The types of PCB's and matrices encountered will vary significantly with each process and stream. No one routine analysis will suffice to resolve these questions. In addition, the proposed analytical method and cut-off limits, e.g., quantifiability, as defined, are overly burdensome and costly to achieve.

An evaluation of risk of exposure to PCB's based upon a review of the total published literature relating to health and toxicity of PCB's would indicate that there is no basis to establish a regulatory cut-off at any PCB

July 8, 1982

level below 50 ppm and hence the need for the extremely complex and costly analytical instrumentation and analytical protocols is not necessary to protect health or the environment and would be prohibitively costly.

4. A numerical regulatory cut-off based upon a true risk/benefit analysis using potential exposure data, exposure data published in epidemiology studies of worker exposure along with health and toxicity effects would be more meaningful and definitive than a cut-off based upon a moving target of improving analytical methodology, whether or not it is defined as limits of quantification or limits of detection. Analytical techniques will improve as science improves, thus continually shifting the regulation's target and its associated costs and other burdens.
 5. The proposed rule to require controlled wastes to be sent to facilities capable of handling PCB wastes is totally inappropriate. It will increase significantly the costs associated with such waste disposal and put a severe strain on current disposal capabilities for destroying more concentrated (>500 ppm) PCB's. Costs for disposal and handling of "controlled wastes" as PCB wastes could increase by a factor of six to ten fold.
 6. A self-certification program in the absence of a reasonable numerical regulatory cut-off would be meaningless. Professional scientists would not be willing to sign such a certification knowing the uncertainties of the accuracy and precision of the analytical methods that would vary from process matrix to matrix and from lab to lab and sample to sample. The end result would be an unworkable administrative morass.
- It would be even more unreasonable to require a Corporate officer, who may have little if any of the necessary analytical scientist background and training, to make such a valid certification.
7. The use of theoretical analysis in lieu of actual monitoring of such low levels of PCB's as are non-quantifiable by GC/EIMS is totally inappropriate and unworkable.

Although EPA's theoretical analysis basis has not yet been defined, from a purely scientific basis the chances of incidental PCB generation in a given process or stream are not predictable from any known scientific laws or principles. (If such were the case, university and industry scientists could save billions of dollars annually by theoretically predicting various chemical reactions, yields, effects of operating parameters,

July 8, 1982

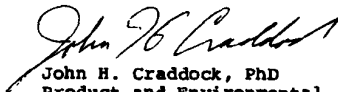
etc., rather than conducting actual research programs experimentally.

8. We strongly recommend that no analyses or other actions be required with respect to products containing less than 50 ppm PCB. Manufacturing of such products should not be required to maintain any records for PCB purposes. Any trace PCB contamination would simply be looked upon in the same manner as any other trace contamination. Government record retention requirements are already resulting in substantial costs throughout the country in maintenance of excessive files. The proposed PCB regulation should not result in an increase in this already enormous burden.

The costs and economic impact of various parameters in this exclusion policy are not adequately defined in the EPA proposal and support document. This question is better answered by referral to the comments submitted to this proposed rulemaking by the Chemical Manufacturers Association.

As a CMA member, Monsanto contributed data and technical expertise to the comments submitted by CMA for the industry. Furthermore, to the same extent as if they were fully and completely set out herein, Monsanto Company supports and adopts the comments submitted on this subject by the Chemical Manufacturers Association.

Respectfully submitted,



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