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Monsanto

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

Dear Sir:

Re: Docket No. OPTS-62032
Proposed Rule - Polychlorinated Biphenyls (PCBs); Exclusions, Exemptions and Use Authorizations (48 FR 55076)

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

General Comments

Monsanto Company generally supports the proposed rule and believes that it will resolve remaining issues concerning inadvertently generated and recycled PCBs. In addition, Monsanto supports the proposed use authorizations for PCBs in hydraulic and heat transfer systems, including EPA's consideration to amend its proposal for heat transfer systems to set a 100 ppm limit.

As a participant in developing the "consensus rule" proposal last April by the Chemical Manufacturers Association (CMA), the Environmental Defense Fund (EDF), and the Natural Resources Defense Council (NRDC), Monsanto believes that the proposed rule is fully consistent with Congressional intent in Section 6(e) of the Toxic Substances Control Act and is fully supportable by available scientific and economic data and places tight, practicable cost effective limitations and controls on inadvertent PCB releases and certain other uses that assure no unreasonable risks will be posed to health and the environment.

While fully supporting the proposed rule, Monsanto Company does not agree with certain deviations by EPA in several aspects of the consensus pro-

posal and also questions the validity and value of the untried, unproven, non-peer reviewed methodologies employed by EPA in attempting to perform pseudo scientific risk assessment evaluations as background documents in support of the proposed rule making. Specific items are discussed in detail below.

However, Monsanto Company fully supports the inclusion of recycled PCBs in the proposed rule in order to insure that manufacturing operations having products containing inadvertent PCB contamination due to recycle operations receive fair and equitable regulatory treatment as other inadvertently PCB contaminated products.

Specific Issues

Monsanto Company submits the following comments relevant to specific issues.

I. Deviations From Consensus Proposal

Monsanto disagrees with EPA deviations from the recommendations of the consensus proposal in the following areas:

- Lower 5 ppm concentration limits for certain consumer products, specifically, deodorant bars and soaps and plastic building materials and products.
- Deletion of the "upset provision" providing for an affirmative defense in enforcement actions.

1. Consumer Products

EPA's singling out of the two consumer product categories (1) deodorant bars and soaps, and (2) plastic building materials and products is arbitrary and capricious and totally unnecessary. EPA states that they are not aware of any evidence that PCBs are found in soaps or plastic building materials and states (1) "In fact, PCBs are only hypothesized to occur in soaps and may not be present" (emphasis added), and (2) "Evidence suggests that PCBs are present in plastic only as a contaminant in pigments at a maximum weight percent of plastic of less than 2 ppm..." (emphasis added).

Singling out of such products on a purely arbitrary and whimsical basis serves no useful purpose in protecting the consumer or the environment. Furthermore, EPA's explanation of the basis of their justification merely serves to confuse the general public and leads to a general loss of credibility. Such arbitrary classification can also cause unjust and irreparable harm to businesses that rely on these product sales and could result in severe financial losses from such allegations due to customers' unfounded fears.

Finally, use of EPA's pseudo scientific risk assessment evaluations at worst case exposure scenarios are totally unrealistic and meaningless and detract from the Agency's scientific credibility. This will be discussed in detail later.

2. Upset Provision

EPA rejected and deleted the "upset provision" recommended by the consensus proposal on the basis that "high levels of releases ...should not be excluded from regulations."

Obviously EPA did not fully understand the provisions of the consensus proposal upset provision which was modeled after the similar provision in Clean Water Act NPDES regulations. That provision was intended to provide safeguards and prevent misunderstandings for both industry and the Agency and the constituency they represent. The proposed upset provision required notification of an upset within 72 hours of occurrence. It did not "exclude" from regulation "high levels" of releases nor did it excuse any factors within the control of the generators. It was solely applicable to an "exceptional incident in which there is unintentional and temporary non-compliance" because of factors beyond the control of the generator. The provision only provided an affirmative defense in an enforcement action for unintentional and temporary non-compliance provided detailed notification was given to EPA within 72 hours. As a result of the provision EPA would be quickly notified of any upset and would be informed and able to insure future compliance with all regulations at such sites. Thus the upset provision would have served to call out any sudden high releases to EPA's attention and would have encouraged more vigilant surveillance of inadvertent generation activity.

Since precedent for use of such upset provisons has been established by EPA in other environmental regulations and it offers significant benefits to both the EPA and industry at essentially no cost, Monsanto Company urges EPA to reconsider the consensus proposal upset provision for incorporation into the final rule.

II. Risk Assessment Evaluation Methodologies & Assumptions

Monsanto and others have maintained for many years, based upon evaluation of the best available scientific data on animals, humans and the environment, that EPA has grossly over-estimated the toxic potential of PCBs. Major differences in interpretation of findings of PCB health effects, especially related to carcinogenicity studies in animals and human health effects (epidemiology) studies, have been published as a part of this and other PCB rulemakings by both industry groups, including Monsanto, and the Agency, and will not be reiterated here. We will focus our comments on the recent methodologies used by the Agency in this rulemaking to estimate risk and exposure assessments.

In the consensus proposal of April, 1983, the parties - CMA, EDF and NRDC - although having different views on the toxicology of PCBs, believed that their recommendation would assure an absence of unreasonable risk of injury to the health or environment based upon evaluation of all available scientific information.

Although peer-reviewed scientific methodologies have not been developed to provide accurate unequivocal quantitative risk and hazard assessments that could be placed on a numerical scale, the parties belief and recommendation was based upon the best scientific judgments available to all parties.

EPA, however, in a zealous attempt to resolve the inadvertent generation rulemaking to a simple numerical choice, conducted a new round of risk assessment and exposure assessment using the talents of certain in-house scientists and consultants. The result of the latest numerical risk and exposure assessments by EPA is confusion, contradiction and credulity that totally strain the bounds of scientific credibility.

Although EPA uses the documents to arrive at the same point to support the consensus proposal and states, "Based on the risk assessment for carcinogenicity as well as information on reproductive/developmental effects, environmental effects and costs, EPA has determined that the manufacture, processing, distribution in commerce, and use of PCBs below the limits proposed in the consensus proposal would not present an unreasonable risk of injury to human health or the environment (48 FR 55079)," because of the poor factual scientific basis these documents should be withdrawn from the rulemaking proposal and be reevaluated. (Emphasis added.)

The documents generally fail to rely on factual information and generally accepted scientific principles and concepts. In all cases the documents rely on and compound worst case assumptions which cause the numerical estimates to vary by factors of 1,000,000 or more in many calculations. EPA recognizes these shortcomings and points out in several discussions of human health risks that "The actual exposure level will be significantly lower than the estimated exposure; therefore the actual risk will be lower than the worst case estimate presented in the quantitative risk assessment" (48 FR 55081-55085). Again, such pseudo scientific calculations and methodologies merely serve to confuse the public and strain the credibility of the Agency.

A detailed critique and review of the scientific aspects of the carcinogenicity and reproductive health effects risk assessments was conducted for Monsanto by independent consultants in toxicology having expertise in evaluation of PCB health effects and is attached as Appendix I.

However, the most critical review of the validity and utility of the EPA risk assessment documents comes from the EPA HERD scientists/authors themselves who state in their opening paragraph of the executive summary of the Carcinogenic Risk Assessment: "This document presents the HERD risk assessment for carcinogenicity of PCBs and summarizes the results of four previous PCB risk assessments

for cancer conducted by FDA, OTA, and CAG/EPA, and OTS. Unfortunately, no consolidated assessment can be developed from these sources because of the different units and different techniques used, the results from these various risk assessments are not directly comparable, though they are consistent."

The most serious flaws with these documents are that they don't conform in style and/or content to that recommended by the National Academy of Sciences (1983) which have been accepted by other EPA officials and working groups including the Administrator and the Carcinogen Assessment Group. In addition, the documents obviously suffer from lack of outside scientific peer review.

Monsanto Company recommends that the carcinogenicity and reproductive health effect risk assessment documents and generic exposure scenario documents be withdrawn as part of this rulemaking as being unnecessary and of little scientific value.

III. Listing Of "Organic Chemical Product Classes Potentially Containing Inadvertently Generated PCBs"

EPA's mere listing of "Organic Chemical Product Classes Potentially Containing Inadvertently Generated PCBs" (48 FR 55080) is misleading in certain aspects and has already caused considerable confusion and misunderstanding.

Certain chemical process classes and subsequently product classes have been mistakenly identified in EPA's support documents on lists of processes and products that could lead to significant inadvertent generation of PCBs. The listing as published is scientifically incorrect because it is not the fact that the class of chemical product or process exists that give rise to the implication that inadvertent PCB contamination is a possibility. The possibility of contamination occurs because the process of manufacture involves the use of several key ingredients all of which are necessary to cause the alleged inadvertent PCB contamination. These key ingredients are (1) hydrocarbon sources, and (2) active chlorine sources as has been pointed out previously in this rulemaking by others, including EPA consultants.

Thus the allegation that a certain compound or process can be contaminated by inadvertent PCBs is incorrect unless it is stated specifically and succinctly that the route to this product or the process itself involves all of the key ingredients.

For example, "diphenyl oxide" and "linear alkyl benzenes" are classified by EPA as part of "seventy chemical processes (that) were determined to have a high potential for PCB generation."

EPA compounded the problem by employing the downstream uses of these products to develop further "worst case" generic exposure scenarios, i.e., linear alkyl benzenes are used in the manufacture of detergents, a consumer product again.

Significant quantities of both biphenyl oxide and linear alkyl benzene, both in excess of about 30% of total U.S. production, are produced annually in the U.S. by chemical routes which involve absolutely no chlorine. Thus the necessary and sufficient conditions for inadvertent PCB generation requiring both hydrocarbon sources and active chlorine are not fulfilled. However, the casual reader of this information and these listings who is not technically sophisticated and trained in chemistry would not understand that these chemicals should not be listed as alleged PCB contaminated products/processes because it is scientifically impossible.

Such a casual listing and allegation has the potential to cause irreparable harm to businesses due to loss of sales due to consumer/purchaser misunderstanding and fears. EPA should clarify the listing and explicitly state the minimum conditions necessary for alleging possible PCB contamination by inadvertent generation.

IV. Heat Transfer Use Authorization

EPA has proposed a use authorization for PCBs in heat transfer systems in a manner other than totally enclosed at a concentration level of less than 50 ppm.

The Agency stated that they are also considering the option of raising the standard to the 100 ppm concentration level.

The regulatory impact analysis conducted by the Agency indicates that the total quantity of PCBs controlled if the standard were relaxed would vary by only about 4,000 pounds from that of the lower proposed 50 ppm level. However, the cost saving per pound of PCB removed would be substantial, changing from $18,000 to only $300 per pound.

From verbal contacts with many owners of heat transfer systems that once contained concentrated PCB materials, Monsanto has learned that design, construction, and operating characteristics of some equipment make difficult, if not a practical impossibility, to achieve the 50 ppm level or lower. The old heat exchanger pipes/systems can have many turns, twists and recesses where small quantities of resinous and sludge-like materials caused by localized heat stress can build up and coat the internal surfaces of the heat exchangers. After multiple drainings and flushings (as many as eight) use of the systems with fresh heat transfer fluid have a hydrocarbon-like base at elevated temperatures, leads to some dissolving of these solid materials leading to a gradual increase in levels greater than 50 ppm.

Because heat transfer systems generally operate at elevated temperatures they are designed to operate at some positive pressure and are thus sealed. Leakage, if any, is minimal and usually occurs at pumps or similar locations where they can be collected and controlled.

In its generic exposure assessment, EPA assumed worse-case situations that are totally unrealistic in the workplace as they pointed out themselves.

Monsanto Company urges EPA to carefully reconsider the proposed heat transfer use authorization standard taking into account cost/benefit and probably overstated risk assumptions and propose the 100 ppm standard in the final rule.

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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Product and Environmental
Safety Director

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