Monsanto

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Hearing Clerk (HFA-305)
FOOD AND DRUG ADMINISTRATION
Room 4-62
5600 Fishers Lane
Rockville, Maryland 20857

Docket No. 80N-0128

Dear Sir:

Ref. FR 45, pp 30984, May 9, 1980
21 CFR Parts 109, 110, 225, 226, 500 and 509

I. Introduction

Monsanto Company is a broad-based manufacturer of industrial chemicals. Our product line includes many materials used as food and feed ingredients or additives and food- and feed-packaging materials. Manufacturing plants for these products include many multipurpose chemical complexes which contain facilities for manufacturing the products of concern in the proposed regulation in addition to many other industrial chemicals. In the United States, Monsanto has investments in 64 plants, employing approximately 40,000 workers.

The following comments are offered by Monsanto as part of its sincere desire to help in drafting and promoting regulations which offer a significant benefit-to-risk ratio in protecting food-, feed- and related packaging chemicals and materials. Monsanto's comments may be divided into four general areas as follows:

A. Proposed regulations are extremely broad and are not clearly defined.

B. Economic impact of the proposed regulations would be significant and burdensome.

C. Current regulations by FDA and EPA are adequate to accomplish the purpose.

D. Alternatives

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II. Comments on Breadth of Regulations and Definitions

The proposed regulations are extremely broad and vaguely defined as to the specific processes or portions of manufacturing plants and facilities that are included. For example, the proposed regulation proposes to prohibit PCB's in electrical transformers and capacitors "....used in or around FDA-regulated food, feed and food-packaging materials plants and storage facilities..."

In a multipurpose chemical manufacturing complex that encompasses up to several hundred acres of land within the plant's limits, many different chemical process units may be (and generally are) present. In addition, many service and support facilities are located within the plant site which include warehouses and storage facilities, utilities and power distribution facilities, etc., which may not be physically near or in any way associated with a process unit manufacturing a chemical product for food-, feed- or related packaging material use. As we understand the proposed rule, it does not apply to the total plant site, e.g., support facilities as well as the immediate process units manufacturing food-, feed- and related packaging materials. However, the definition of facilities must be clarified to more clearly delineate this point.

The definitions of several key words and phrases are extremely broad and vague as to be almost meaningless to one skilled in such manufacturing plants and their components. Clear, precise definitions are required for:

A. food- and feed-packaging materials plants

B. "in and around" such plants

Is a "plant" the total fenced site perimeter? Does it include all processes within the site whether or not the process involves food-, feed- or related packaging materials or is in close proximity to such a process unit?

Do the definitions "in and around" mean physically within a process unit or nearby, e.g., 10 yards or 50 yards from such a unit? How close is "around"? Many process units in a multipurpose complex are judged sufficiently isolated for other fire and safety purposes if separated by a "city street" width, e.g., ~50 feet, if sewer and other utilities, including vent and disposal systems, are separate and isolated.

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In summary, current proposed definitions of "plant" and "in and around a plant" are so broad and vague as to be of little value in establishing criteria for multipurpose chemical manufacturing plants.

III. Economic Impact and Risk/Benefits

The economic impact of the proposed regulation would be significantly high and extremely burdensome. Using the cost guidelines in the EPA proposed rule change (40 CFR Part 761) that was published in the FEDERAL REGISTER May 9, 1980, accompanying the FDA rule change under discussion, an estimate of the economic impact upon our company can be made.

The data is based upon information obtained from 31 chemical manufacturing plants that at some location within the total plant site manufacture chemical products for food-, feed- or related packaging materials. (The data does not include equipment in electrical power distribution substances which could add significantly to the cost.)

Total No.		Replacement Cost
Transformers 200 (88)*	@$44M** each	$ 8.8$\overline{M}$ (3.9\overline{M}$)
Capacitors 1259 (311)*	@$1M each	$ 1.3$\overline{M}$ ($ .3$\overline{M}$)
Total		10.1\overline{M}$ (4.2\overline{M}$)

*( ) Indicates units within 300 yards of food-, feed- or related packaging material manufacturing process unit.

The cost to Monsanto Company alone would exceed $10 million (based upon estimates using EPA guidelines) to remove PCB containing transformers "in and around" these "plants" if total removal were required.

**Although the economic impact is based upon the costs as defined, in order to obtain a ball park figure, we believe these costs to be significantly low and only a fraction of actual costs incurred. A very recent, November 19, 1980, cost estimate for storage and

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disposal of nine inactive transformers and contents containing 2,000 gallons of PCB fluid and occupying a space volume of 1,800 cubic feet is $195,000. Thus, costs for storage and disposal of contents and shell alone now average $22,000 per transformer; or, half the EPA guideline cost used which also includes cost of new unit, labor, depreciation, etc.

By comparison, a more reasonable approach to define finite limits indicates that significant cost reductions could occur. (Risk/benefits will be discussed later.) If a limit of 300 yards from an affected process unit is arbitrarily imposed (which still is unnecessarily restrictive), this cost could be reduced 60% to about $4.2 million. A more realistic and practical approach, e.g., imposing a limit of 10-25 yards (i.e., a street width) would result in even more savings. If a physical barrier exists between the process and the PCB item, the distance could be substantially less.

If any of the above limits were required by the amended rule the benefits and risks would still be extremely difficult to evaluate, even though cost estimates were made. In the three examples cited in the proposed FDA rule change (pp 30985 FR) two incidents involved equipment in storage. The third incident involving a leaky capacitor in a slaughterhouse did not specifically identify the location of the leaky capacitor. However, at least the two incidents involving storage of equipment could have been prevented had a minimum distance limit for prevention of locating PCB equipment near food/feed process units (including storage) been established.

This could have been accomplished by clear definitions of both "plant" (or process unit) and finite distances instead of the vague terminology "in and around." In both storage incidents a minimum distance would have sufficed to accomplish the purpose at little, if any, additional cost.

Thus, the benefits of proper storage to minimize risk of potential contact and contamination of foodstuffs could have been accomplished with a minimum of expense and wasted effort.

IV. Adequacy of Current Regulations

The proposed regulation by FDA is unnecessary in light of current regulations already promulgated by Federal regulatory agencies. Both FDA and EPA have regulations in place to deal with the overall problem of potential product and environmental contamination by PCB's.

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The major examples cited by FDA for needing the proposed regulation involved incidents where storage of PCB containing electrical equipment was involved. The present EPA regulations appear adequate for this purpose. They also provide for a reasonable phase-out of electrical equipment containing PCB's in an orderly fashion.

In addition, current facilities for proper disposal of PCB's and related equipment are not available. Removal of and storage of such equipment presents additional hazards and potential opportunities for contamination until such commercial facilities are readily available. Presently, only two such commercial facilities have even applied for permits and conducted tests for disposal of PCB's by incineration -- the method prescribed by existing regulations. Even when (and if) these facilities are approved, the backlog of PCB's and related equipment presently in storage for disposal could take several years.

V. Alternatives to Proposed Rule Changes

Several alternatives to the proposed rule changes are discussed briefly below ranked in order of preference.

A. Withdraw proposed changes and rely on existing regulations. This is the best course from an economic impact/risk-benefit perspective.

B. Implement proposed changes; however, including clear, specific definitions to reduce the breadth and remove the vagueness of the proposal as written. Specific definitions of "plant" or "process unit" covered by the regulation with definite physical distances instead of the vague terminology "in and around" would clearly define the areas of concern and lessen the economic impact of the proposed rule. As a result, a much more favorable benefit-risk evaluation, including better estimates of cost of compliance, could be made.

C. A modification of Alternative B. to allow exemptions for certain equipment which is physically isolated and contained. This modification would ensure that in event of a leak or rupture any material would be contained within the unit or structure. Such modifications could include requirements for diking and physical construction, e.g., concrete pads with dikes on the ground; enclosure or walls to separate units, e.g., power distribution substations, etc., EX P-1271 in specified distances, etc.

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Conclusion

The proposed rule is not warranted on the basis of the incidents cited in view of current regulations already in place. However, if such a rule is to be issued nonetheless, it should not be so broad and so vague as to impose a significantly high economic burden upon manufacturers, yet yielding little benefit and reduction of risk.

We trust that consideration of these comments and suggestions will enable better regulation to be drawn up for betterment of the country with government, industry and the general public working together to achieve this purpose.

Respectfully submitted,

MONSANTO COMPANY

By John H. Craddock, PhD
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