Monsanto

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July 14, 1972

Hearing Clerk
Department of Health,
Education and Welfare
Room 6-88
5600 Fishers Lane
Rockville, Maryland 28052

Re: Department of Health, Education and Welfare
Food and Drug Administration
21 CFR Parts, 3; 121; 122; 128
Polychlorinated Biphenyls, Notice of
Proposed Rule Making
Federal Register, Vol. 37, No. 54, pp. 5705-5707
Saturday, March 18, 1972

Gentlemen:

We have reviewed the Food and Drug Administration's proposed regulations relating to PCBs in food, animal feed, food and feed processing plants and packaging materials.

We agree with the Administration's intent to control the presence of PCBs in the nation's food supply and commit ourselves to continuing our activities directed toward this end. We endorse the recognition of the problem of unavoidable PCB residues in food and animal feeds. We support all appropriate action taken to prevent further introduction of additional PCBs into the environment. We equally support realistic action designed to minimize the unavoidable residues occurring from PCBs already present in the environment.

With respect to the rule making we have the following comments to offer:

1. The temporary tolerances for PCBs in milk and poultry should be maintained as originally established; 5.0 parts per million (fat basis) for milk and 5.0 parts per million edible portions for poultry.

2. Residual PCBs are present in converted heat transfer systems. Therefore, a regulation which specifies no PCBs in a system will create unnecessary hardships which are not warranted by the hazard to human health. Extensive studies should be conducted by the Administration to determine the realistic acceptable level which can be achieved, and the regulation should specify this level. The period for compliance, following the establishment of an acceptable level, should be of sufficient duration to assure its achievement.

3. More information should be developed concerning analytical methodology and migration rates before a PCB tolerance level is established for food packaging materials.

4. Provision should be made in the proposed regulation permitting the use of transformers and capacitors containing PCBs when installed in a manner which would prevent direct contact with the food or animal feed being processed.

5. These comments are premised upon the statement by the FDA that "...the current dietary level of PCBs is not considered an immediate hazard to the public health."

I. GENERAL DISCUSSION

Monsanto Company has been a manufacturer of various chemicals and other products since 1901. At the end of last year, Monsanto was the third largest chemical company in the United States. For many years we have supplied chemical products to almost every American industry, and, in fact, through our research departments have played a role in the development of technology in many industries.

On some occasions, a chemical compound with specific properties is developed to meet a need in a certain application. At other times, whether through innovative research or by happenstance, a chemical compound with unique properties is developed first and then applications are found for which the new compound is uniquely suited.

So it was in a sense with polychlorinated biphenyls. PCBs were apparently first used commercially in the late 1920's. PCBs are chemical compounds with several very desirable qualities. They are very inert, substantially fire resistant and non-conductors of electricity. As the properties of these new compounds became known, they were put to use in applications where they seemed to be ideally suited. Perhaps the first of the uses was as a dielectric fluid in transformers and capacitors. In situations where high voltage arcing could occur, the fire resistant and insulating qualities of PCBs were highly desirable.

Monsanto's production of PCBs began in the mid-1930's. As the desirability of PCBs gradually increased for many applications so did production of the material. Their fire resistant nature made them excellent choices for use as heat transfer fluids. Their inertness gave long lasting qualities to lubricants. When used as ingredients in coatings, they improved the waterproofing characteristics.

Insofar as handling of the material is concerned, PCBs are considered less toxic than many other chemicals in everyday use.

Recently questions have been raised concerning the effect of PCBs on the environment. The persistent nature of the products, while so desirable from the standpoint of many industrial applications, began to work against them. In the late 1960's, after sophisticated analytical procedures were developed which would determine minute quantities of PCBs, they were detected in the environment. It was later learned that PCBs could affect certain forms of marine, terrestrial and avian wildlife. Early evidence indicated that, like DDT, PCBs did not readily biodegrade in the environment. Recently it has been established that many PCBs are biodegradable, particularly the monochloro, dichloro and trichloro, with evidence that some of the tetrachloro and pentachloro also degrade.

When questions first began to be raised about the effects of PCBs on the environment, Monsanto, in the light of developing data, reviewed again the products and applications

in which they were used. While the environmental effect of PCBs was still in controversy, Monsanto began unilaterally to take steps intended to reduce the entry of PCBs into the environment. Acting on its own, Monsanto stopped the sale of PCBs for use in plasticizer applications such as paints, sealants and coatings. A program was initiated for reducing the sale of PCBs which provided that sales would be made only for use in applications where (a) the products were necessary from the standpoint of the public interest, and (b) no acceptable alternatives were available. Since sales as plasticizers had already been eliminated, the extended program further called for the termination of sales for use in hydraulic fluids and then the termination of sales for use in heat transfer fluids. Today, virtually all PCBs manufactured by Monsanto Company are used by the electrical industry for dielectric uses such as in transformers and capacitors; applications for which we understand there are, as yet, no satisfactory alternate products. The manufacturing and sales reduction program undertaken by Monsanto was completely unilateral and not because of any governmental requirement. The subject regulations being proposed by the FDA will be the first significant governmental regulations affecting PCBs.

II. TEMPORARY FOOD TOLERANCES

Monsanto's current program on the sale of PCBs should in time virtually eliminate the contamination of foods (assuming no other commercial sources are available). During the interim the establishment of temporary tolerances for the proposed limited group of foods has merit.

Past incidences of PCBs in foods, at levels considered to be unacceptable, have been relatively few, have been attributed to unusual single sources and, in virtually every case, the source has been identified. Additionally, we know of no facts that indicate that the action level guidelines established for milk in 1969 at 5.0 parts per million on a fat basis and for poultry in 1970 at 5.0 parts per million in edible portions have not provided adequate protection to the consumer. We, therefore,

conclude that the proposed temporary tolerances of 2.5 parts per million on a fat basis for milk and 5.0 parts per million on a fat basis for poultry do not appear to be justified and we respectfully urge that the levels be maintained as originally established.

III. PROCESSING EQUIPMENT

Monsanto basically agrees with the objectives of the proposed regulations relating to the use of PCBs in heat transfer systems in food, feed, and food packaging material plants. In 1971 we discontinued sales of PCBs to these applications and have recommended conversion to other available fluids. A copy of a bulletin available to our customers to assist them in their conversion is attached. You will note on page 12 our statement that heat transfer fluids are intended only for indirect heating purposes.

The food industry requires high temperatures in certain of its operations to properly process its products and to protect the consumer from the dangers of pathogenic microorganisms from products prepared in an unsatisfactory manner. The continued use of existing heat transfer systems must, therefore, be assured to prevent serious disruption to the nation's food distribution chain.

The regulation as proposed prohibits the presence of any PCBs in a system. Our limited experience with converted Monsanto Company units, which are not food related, indicates that, although considerable care is taken, some PCBs still remain in the system. The amount seems to vary with such factors as the design of the system, the age of the system, and the operating conditions involved. No generalization can be made relating to the levels of PCBs remaining in any given system even though our former PCB heat transfer customers have been cautioned to remove PCBs from their systems. Under such conditions, the regulation as proposed could deny the food industry the continued use of its facilities and would make more difficult the achievement of desired processing results.

Before promulgating this section of the regulations, we urge that extensive studies be conducted by the Administration to determine the acceptable residual level of PCBs which can be realistically achieved in well run, properly managed systems. Following the establishment of this level, reasonable time, which we feel is considerably longer than the 30 days proposed, should be permitted to provide the food industry an opportunity for its orderly achievement.

IV. FOOD PACKAGING MATERIAL

The proposed regulations contain a maximum tolerance level of five parts per million PCBs which would be allowed in food packaging material. The proposal of any standard for packaging materials at this time would appear to be ill-conceived. There are at least two areas in which more information must be developed before a reasonable PCB tolerance level can be established. First, accurate methodology for use in determining the exact levels of PCBs in the various materials used in packaging must be developed. Second, it is necessary to determine the actual rate of migration of PCBs from each packaging material into foods. Since the composition of various materials used in packaging foods varies to a considerable extent, this information must be developed with respect to a number of different materials. It may be that some materials contain no PCBs at all, while other materials which do contain PCBs prevent their migration into foods. In either case, a PCB tolerance level for the packaging material would appear to be unnecessary. In any event, more information should be developed concerning analytical methodology and actual migration rates before a PCB tolerance level is established for food packaging materials.

V. CAPACITORS AND TRANSFORMERS

The importance of continuing the use of PCBs as a dielectric fluid in capacitors and transformers has been generally acknowledged. Recent reports supporting this use include the Interdepartmental Task Force on PCBs report entitled

"Polychlorinated Biphenyls and the Environment" dated May, 1972 and the Food and Drug Administration's "Environmental Impact Statement - Notice of Proposed Rule Making - Polychlorinated Biphenyls" dated May 8, 1972.

In the food processing industry there are a number of applications of PCB-type electrical devices which cannot be adequately performed by substitutes. The hermatically sealed construction of capacitors and transformers, the very low failure rates, 0.1% to 0.2% per year, the exceedingly low failure rate which could lead to loss of fluid, approximately 0.01%, and the existance of lost electrical function, which would also occur on equipment failure signaling the operating personnel to take appropriate actions, are all characteristics which would tend to preclude food contamination. Banning of PCB-containing capacitors and transformers in factories engaged in food, animal feed, or food packaging materials would result in extensive rebuilding, relocating and re-equipping programs, all without demonstrable need.

Monsanto, therefore, does not believe that the use of PCB-containing capacitors and transformers in food plants should be arbitrarily denied and wholeheartedly supports the proposals relating to this rule making submitted for your consideration by the General Electric Company, the Aerovox Corporation and the Certified Ballast Manufacturers Association.

Our purpose in making these comments is to aid the Administration in developing realistic rules that will achieve the intended objectives without serious disruptions to the food industry and to the consumer. We believe the suggestions given above, if adopted, will serve this purpose and we respectfully urge that they be given serious consideration.

Respectfully submitted,

W. B. Papageorge
Manager
Environmental Protection

WBP/bt
Attachment

DSW 019834