

2nd DRAFT
WBP/PSP/bt
7/10/72

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:

Summary
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. PCB's were apparently first used commercially in the late 1920's. PCB's are chemical compounds with several very desirable qualities. They are very inert, substantially fire resistant and a non-conductor of electricity. As the properties of these new compounds became

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known, they were put to use in applications where they seemed to be ideally suited. Perhaps the first of these uses was as a dielectric fluid in transformers and capacitors. In ~~the~~ situations where ^{high voltage} ~~arcing of electricity~~ could occur, the fire resistant and insulating qualities of PCB's were highly desirable.

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

Insofar as handling of the material was concerned, PCB's are considered less toxic than many other chemicals in everyday use.

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

with some evidence that the tetrachloro and pentachloro also show ~~some degradation~~. *some of*

When questions first began to be raised about the effects of PCBS on the environment, Monsanto, in the light of ~~newly developed~~ *the developing* data, reviewed again the ~~products~~ and the applications in which ~~it was~~ *they were* used. While the environmental effect of PCB's was still in controversy, Monsanto began unilaterally to take steps intended to reduce the entry of PCB's into the environment. Acting on its own, Monsanto stopped the sale of PCB's for use in plasticizer applications such as paints, sealants and coatings. A program was initiated for reducing the sale of PCB's which provided that sales would be made only for use in applications where (a) the products ~~was~~ *were* necessary from the standpoint of the public interest, and (b) no acceptable alternates 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, ~~essentially~~ *virtually* all PCB's 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 ~~major~~ *significant* governmental regulations affecting PCB's.

We would now like to make specific comments concerning several of the proposed regulations.

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I. TEMPORARY FOOD TOLERANCES

FDA'S ? MC'S

7 | It is recognized that the current restrictions on the use of PCB's ^{should be} ~~virtually~~ eliminate the ~~unavoidable~~ contamination of foods ^{(assuming no}

During the interim in which the use control program becomes fully effective the establishment of temporary tolerances for a limited group of foods has merit.

Past incidences of high levels of PCB contamination in foods have been relatively few and have been attributed to an unusual single source and, in virtually every case, the source has been identified.

Under these conditions the ~~establishment~~ of 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 provided excellent protection to the consumer. Since the establishment of these guidelines ^{we are aware of which} no new information has been developed to support the need for lower tolerance levels. ^{we question} The ^{with 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 warranted and we respectfully urge that the levels be maintained as originally established.

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II. PROCESSING EQUIPMENT

Monsanto basically agrees with the objectives of the proposed regulations relating to the use of PCB's in heat transfer processing equipment. In 1971 we discontinued sales of PCB's to these applications and have recommended conversion to other available fluids. To the best of our knowledge all systems ^{utilized by former customers of Monsanto} in food or food-related applications have been converted. A copy of a bulletin provided to our customers to assist them in their conversion is attached. The food industry ^{in certain of its operations} requires high temperatures to properly process its products. To achieve the desired results the continued use of existing heat transfer systems must be assured to prevent serious industry-wide disruptions.

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Our experience with converted units indicates that, although great care is taken, some PCB's still remain in the system. The residual amount varies with such factors as the design of the system, the age of the system, and the operating temperature involved, therefore, no generalization can be made relating to the level of PCB's remaining in any given system. ~~except that that~~ _____ & we

The regulation as proposed prohibits the presence of any PCB's in a system. With the residual PCB's which will inevitably be present the industry will be prevented from continued use of its facilities and would not be able to achieve its desired processing results.

It becomes mandatory, therefore, that good judgement be exercised relating to the continued use of well run, properly managed systems

to avoid the alternative of a total shutdown. Serious, thorough studies must be undertaken to determine acceptable residual PCB levels in converted systems.

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III. FOOD PACKAGING MATERIAL

The proposed regulations contain a maximum tolerance level of five parts per million PCB's 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 PCB's in the various materials used in packaging must be developed. Second, it is necessary to determine the actual rate of migration of PCB's from each different 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 PCB's at all, while other materials which do contain PCB's prevent its 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.

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IV. CAPACITORS AND TRANSFORMERS

The importance of continuing the use of PCB's as a dielectric fluid in capacitors and transformers has been generally acknowledged. Recent reports supporting this use include the Interdepartmental Task Force on PCB's 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 hermetically 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 existence 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 demonstratable need.

Monsanto, therefore, 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.

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We recognize and appreciate the intention of the FDA to protect the American public from contaminated foods while not unnecessarily penalizing certain segments of the American public. We urge the FDA to move very carefully in establishing PCB tolerance levels in food since the only known instance in which persons were affected by ingested PCB's was the Japanese incident of 1968 in which PCB's in rice oil were ingested at extremely high levels (2,000 to 3,000 ppm), there is no known incident of human life being affected by ingested PCB's. We strongly urge that regulations not be promulgated established PCB levels in any medium other than food or food products. Food tolerance levels can and should be vigorously enforced, but PCB's used industrially in such a manner as to prevent its coming in contact with food should not be subjected to FDA regulation.

Respectfully submitted,

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