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DRAFT
PSP/pa
6/30/72

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

Gentlemen:

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 roll 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 biphenyl. PCB was apparently first discovered in the 1920s. It was a chemical compound with several very desirable qualities. It was very inert, substantially fire resistant and a non-conductor of electricity. As the properties of this new compound became known, it was put to use in applications where it seemed to be

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ideally suited. Perhaps the first of these uses was as a dielectric fluid in transformers and capacitors. In a situation where arcing of electricity could occur, the fire resistant and insulating qualities of PCB were highly desirable.

As time passed, additional applications for PCB were found. Its fire resistant nature made it an excellent choice for use as a heat transfer fluid. Its inertness gave long lasting qualities to lubricants. When used as an ingredient in coatings, it improved the waterproof characteristics. Monsanto's production of PCB goes back, through an acquired company, to the early 1930s. As the desirability of PCB gradually increased for many applications so did production of the material. Insofar as handling of the material was concerned, PCB was considered less toxic than many other chemicals in every day use.

As is now well known, only recently have questions been raised concerning the effect of PCB on the environment. The persistent nature of the product, while so desirable from the standpoint of many industrial applications, began to work against it. In the late 1960s, ~~the chemical was found to be~~ PCB was detected in the environment and it was later learned that PCB could affect certain forms of marine and wildlife. It finally became recognized that, like DDT, ^{it is} PCB does not readily biodegrade in the environment. *Recently found -*

get from Hawaii

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When questions first began to be raised about the effects of PCB on the environment, Monsanto looked more closely at the product and the applications in which it was used. While the environmental effect of PCB was still in controversy, Monsanto began unilaterally to take steps intended to reduce the entry of PCB into the environment. Acting on its own, Monsanto stopped the sale of PCB for use in paints, sealants and coatings. A program was initiated for reducing the sale of PCB and providing that sales would be made only for use in applications where (a) the product was necessary from the standpoint of the public interest, and (b) no acceptable alternates were available. Since sales as plasticizers had already been eliminated, the program called for reduction of sales for use as a lubricant and then the reduction of heat transfer sales. Today, essentially all PCB manufactured by Monsanto Company is used by the electric industry in transformers and capacitors; an application for which we understand there is, as yet, no satisfactory alternate product. 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 governmental regulations affecting PCB.

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DDT
-4- *Peril*
Speak on 2.1.1

I. PROPOSED MILK STANDARD

Many, if not most, articles and studies concerning PCB have drawn parallels between PCB and DDT. Both products are relatively inert, both tend to persist in nature and they show similar characteristics on a gas chromatograph. Most comments have indicated that DDT and PCB are similar in toxicity. There is no evidence that PCB is more toxic than DDT. There would appear then to be no reason for establishing a lower tolerance level for PCB in milk and other foods than the tolerance level already established for DDT. The tolerance level for DDT in milk is 0.2 parts per million. On the basis of all available information concerning PCB and DDT, we respectfully urge that the tolerance level for PCB should be no lower than 0.2 parts per million in whole milk.

It should be noted that there is no known instance of persons being affected by PCB when ingested at low levels. In fact, the only known instance in which persons were affected by ingested PCB was the Japanese incident of 1968 in which PCB in rice oil was ingested at extremely high levels. The tolerance levels being proposed in the subject regulations are approximately 1/10,000th of the level which was ingested by those affected during the rice oil incident.

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II. FOOD PROCESSING EQUIPMENT

The proposed regulations provide in three places for the testing of heat exchange fluids in existing food handling equipment and, if any PCB is found in such fluid, for the replacement of the fluid within thirty days after the effective date of the regulations with a heat exchange fluid that does not contain PCB or any other harmful or deleterious substance. This is an unnecessary regulation and is unreasonable in that its enforcement would work a severe hardship on many food processing firms. These provisions are unnecessary because so far as we are aware, no food handler or processor in this country is purchasing PCB for use as a heat exchange fluid or for any other purpose in connection with food handling or processing. Sometime ago, Monsanto discontinued the sale of PCB for this application. The only possible source of PCB for such use would be imported from a foreign country or purchased from some other domestic manufacturer. We doubt very seriously whether any food handler or processor in light of present knowledge would make use of either of such sources.

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Some food handlers and processors did use PCB in the past. It was used because of the desirability of safe working conditions -- the fire resistant nature of PCB making it very desirable as a heat exchange fluid. All processing of PCB for use as a heat exchange fluid in food handling or processing plants have changed to another heat transfer fluid. It is technically impossible, however, to completely eliminate PCB from a heat exchange system regardless of the effort which may be made to do so. No amount

of flushing, cleaning or scrubbing can completely remove all PCB from an existing system. Therefore, systems which have been converted from PCB to some other heat transfer fluid will always have some small amount of PCB remaining within the system. As time passes and parts of the system are replaced (motors removed, etc.), new, completely PCB-free heat transfer fluids will be added to the system to replace that fluid lost when portions of the system have been replaced. Therefore, the PCB content of the heat exchange fluid within each system will continuously decrease, approaching, but never completely reaching, zero. We estimate that immediately after converting from PCB to another heat transfer fluid, an average heat transfer system would still contain 5% to 10% PCB. As previously pointed out, this level will decrease as time passes.

There has been only one well-publicized incident in which a PCB heat transfer fluid leaked into an animal feed ingredient. There is no known effect on human life as a result of this incident. We submit that this was a very exceptional incident and that particularly in today's climate of environmental and human health consciousness, such an incident will not be allowed to occur again by the country's food handlers and processors.

The proposed regulation states that the heat exchange fluid used by food processing or handling equipment must not contain

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PCB "or any other harmful or deleterious substance". To our knowledge, there is no heat transfer fluid available which can meet this criteria. No heat transfer fluid available today is designed to be used as a food additive. All have been designed for use as a heat exchange medium and all would be "harmful or deleterious" if ingested. An FDA regulation dictating the composition of a heat exchange fluid or lubricant which might be used in food handling equipment is unrealistic and unnecessary. Controls can and should be established to prevent the leakage of heat transfer fluids or any other foreign substance into food. The FDA's regulations, however, should be limited to controlling the levels of PCB and other foreign substances in food itself and should not be extended to controlling the composition of various fluids used in food handling and processing equipment.

Notice should be taken of the proposed Toxic Substances Control Act of 1972 which has been passed by the U.S. Senate and is now being considered by the House of Representatives. This Act will probably become law sometime in the near future and will enable the Administrator of the EPA to regulate the use of every chemical substance, including PCB. Any regulation of chemical substances apart from tolerance levels in food itself should be developed and enforced by the EPA pursuant to that Act.

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III. FOOD PACKAGING MATERIAL

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

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 go move very carefully in establishing PCB tolerance levels in

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food since, apart from the Japanese incident previously referred to, there is no known incident of human life being affected by ingested PCB. We strongly urge that regulations not be promulgated establishing PCB levels in any medium other than food or food products. Food tolerance levels can and should be vigorously enforced, but PCB used industrially in such a manner as to prevent its coming in contact with food should not be subjected to FDA regulation.

Respectfully submitted,

W. R. Corey

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