DRAFT
PSP/pa
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OUTLINE OF COMMENTS TO FDA PROPOSED REGS CONCERNING PCB

I. DESCRIPTION OF MONSANTO.

A. Manufacturer of PCB materials for many years.

B. Has worked with other industries in developing applications.

C. Since PCB began to emerge as possible environmental problem in Spring of 1970, MC has taken a number of steps to protect the environment. Steps taken:

(1)

(2)

II. COMMENTS ON PROPOSED MILK STANDARD.

A. Refer to and draw parallel with DDT standard (if still at 0.2 ppm.).

B. Refer to shortage of information concerning PCBs' effect on humans of low intake levels.

C. Recommend continuation of present PCB tolerance level in milk: 0.2 ppm. in whole milk.

III. PCB USE IN FOOD PROCESSING EQUIPMENT.

A. Refer to Monsanto's sales reduction program, point out that PCB is now sold only for closed system dielectric uses and, therefore, no need exists to regulate use of PCB in food processing equipment.

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B. Point out that Toxic Substances Control Act has passed the U.S. Senate, is now being considered by the House of Representatives and will probably become law in the near future. This 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 should be developed and enforced by the EPA pursuant to the new Act.

C. Point out that while there is no question as to FDA authority to establish tolerance levels for any substance in foods, a question does exist as to the authority of the FDA to regulate materials used in equipment and elsewhere in situations where the materials will not come in contact with the food.

D. Cite problems which would be encountered in enforcing the proposed regs:

(i) PCB only fire resistant heat transfer fluid, thus possibly safest from fire hazard standpoint.

(ii) For this and other reasons, many operating plants, refineries, etc., including food processing plants, use PCB fluids in heat transfer system.

(iii) PCB, like many fluids, impregnates equipment in which used.

(iv) Since PCB heat transfer fluid no longer sold, users are changing or have changed to other fluids. Effectiveness of change varies. Zero PCB contact will never be reached. Average system after changeover will still have 5-10% PCB in fluid.

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(v) As time passes, and equipment is changed (pumps removed, etc.), non-PCB fluid will be added and PCB content in system will decrease.

E. Since heat transfer fluid never has contact with food, it should be immaterial what fluid is used. Important thing is that PCB content of foods not exceed established tolerance levels.

F. Every heat transfer fluid would be "harmful or deleterious" if eaten with food. No heat transfer fluid is developed with intention it be food additive. No one heat transfer fluid could qualify under proposed regs.

IV. FOOD PACKAGING MATERIAL.

A. Urge FDA to withhold this proposed regulation until tests are completed which show migration rates of PCB from food packaging material. PCB from packaging material is no problem so long as it does not contaminate food. Packaging industry should not be penalized unnecessarily. It may be that certain packaging materials prevent or allow migration at greater rates than others. If so, different tolerance levels should be provided for different materials.

VI. Urge FDA to move carefully when establishing PCB tolerance levels since, outside of the Japanese incident involving extremely high intake level, there is no known incidents of life being affected by ingested PCB. FDA should be particularly careful about establishing PCB levels in anything other than food.

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