DRAFT REGULATORY ANALYSIS

Amendment To Current Good Manufacturing Practice
Regulations Relating To Poisonous and Deleterious Substances
in Food, Feed, and Food Packaging Material Plants

(PCBs in Transformers)

INTRODUCTION

There have been a number of incidents in which the use or disposal of polychlorinated biphenyls (PCBs) have resulted in contamination of food in the United States. At least two of these incidents were the result of PCBs leaking from damaged spare transformers and contaminating feed for poultry and livestock. The contaminated feed resulted in PCBs being carried into human food.

Animal studies show a definite association between low-level PCB exposure and potentially more serious subchronic and chronic toxicities, including adverse reproductive effects, liver damage, and tumor production.

The Food and Drug Administration (FDA) is proposing to amend several regulations under the Federal Food, Drug, and Cosmetic Act to prohibit or limit the use of PCBs in sealed electrical transformers and capacitors used or stored in, or around, food, feed, and food-packaging materials plants or storage facilities, even though the PCBs are in sealed containers. FDA is also proposing that certain raw material used for human foods be examined to ensure that they comply with FDA tolerances for PCBs and other poisonous or deleterious substances. The U.S. Department of Agriculture's Food Safety and Quality Service (FSQS) also intends to propose similar regulations prohibiting PCB-containing equipment in federally inspected meat, poultry, and egg product plants. The Environmental Protection Agency is proposing related regulations to prohibit the use of PCB items in facilities manufacturing fertilizers or agricultural pesticides.

FDA, pursuant to Executive Order 12044 on Improving Government Regulations and interim HEW guidelines, has considered the economic impact of the above proposal. Based on this assessment, it has been determined that a draft regulatory analysis, which is described in Executive Order 12044, section 3 (b)(2), is required.

Requirement for Regulatory Analyses

Executive Order 12044, section 3(a)(1), specifies various criteria governing the preparation of regulatory analysis. Agency heads must ensure that regulatory analyses are performed for all regulations which will result in an annual effect on the economy of $100 million or more. A preliminary analysis of this proposal indicates that it will probably exceed this threshold, even though a reliable estimate of economic costs cannot be made without additional data. The evaluation supporting this determination follows.

ANALYSIS

This proposal permits an FDA-regulated food, feed, and food-packaging establishment either to replace PCB-containing transformers and capacitors with non-PCB equivalents or to drain the PCB-containing fluid from transformers and refill them with a fluid containing not more that 50 ppm PCB. In both situations, it is presumed that all capacitors must be replaced since retrofilling of capacitor fluid is not believed to be feasible. The economic consequences of this proposal are discussed in

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two parts. The first part presents estimated unit costs for replacing or refilling transformers and replacing capacitors. The second part discusses the aggregate consequences of these unit costs for the affected industries.

Unit Cost Estimates

A contract study prepared for EPA[1] developed initial estimates of the costs of replacing/refilling transformers and capacitors. The contractor's estimate for the average costs of replacing PCB equipment are shown in the following table:

1. "ADDITIONAL REGULATION OF POLYCHLORINATED BIPHENYLS (PCBs) IN FOOD-RELATED INDUSTRIES", prepared for the Office of Pesticides and Toxic Substances, Environmental Protection Agency, by Putnam, Hayes and Bartlett, Inc. A copy of the final report on this study will be placed in the record of this rulemaking.

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AVERAGE COSTS FOR PCB EQUIPMENT REPLACEMENT
(1979 $/Unit)

EQUIPMENT	EQUIPMENT OWNER: FOOD ESTABLISHMENT	EQUIPMENT OWNER: UTILITY
TRANSFORMERS		
Removal and Installation	$13,000	$13,000
Purchase of New Unit	19,000	19,000
Disposal of PCB Unit and Liquid	10,992[a]	8,478[b]
Administrative Time and Miscellaneous	600	600
TOTAL	$43,592	$41,087
CAPACITORS		
Removal and Installation	$ 400	$ 400
Purchase of New Unit	589	1,691
Disposal of PCB Unit	19[c]	29[c]
Administrative Time and Miscellaneous	160	160
TOTAL	$ 1,168	$ 2,280

a. Range from $10,029 to $11,955.
b. Range from $7,529 to $9,445.
c. Methods and costs of disposing of PCBs have not been established. Currently, high temperature incineration is believed to be the only safe and effective way of disposing of PCBs. The EPA has not yet published the results of recent test burns of PCBs nor has the agency approved any incinerators for PCB disposal.

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The contractor reduced these out-of-pocket costs by investment tax credit and income tax deductions to an average after-tax cost for food establishments of $35,060 per transformer and $984 per capacitor. Comparable statistics for utility-owned equipment were $33,707 and $1,980.

The contractor also considered the average costs of retrofilling transformers containing PCB fluids.

AVERAGE COSTS FOR PCB TRANSFORMER RETROFILL
VIA CONTRACTOR
(1979 $/Unit)

	EQUIPMENT OWNER	
	FOOD ESTABLISHMENT	UTILITY
Silicone		
Initial Drain, Flush, Refill, Fluid Disposal	$10,000	$ 8,000
Filtering/Flushes	5,000	4,000
Administrative Time/Miscellaneous	800	800
TOTAL	$15,800	$12,800
Hydrocarbon		
Initial Drain, Flush, Refill, Fluid Disposal	$ 8,750	$ 7,000
Filtering/Flushes	3,533	3,533
Administrative Time/Miscellaneous	800	800
TOTAL	$13,083	$11,333

An average cost of the silicone and hydrocarbon retrofill alternative was used to calculate the after-tax, out-of-pocket costs of $7,798 for food establishments and $6,516 for utilities. These cost estimates presumed reduction of PCB concentrations within the transformer to less than 500 ppm. The contract estimate does not include any additional flushes or filtering of the transformer fluid necessary to reduce PCB concentration to the presumed 50 ppm level.

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Aggregate Industry Costs

This proposal, if implemented, has the potential to affect all establishments using PCB-containing equipment where there exists the possibility of contaminating the food supply. Approximately 76,000 food establishments are known to FDA including approximately 34,000 food manufacturers and 24,000 food warehouses. Additionally, there are an unknown number of food and feed packaging materials establishments. It is known that not all these establishments use PCB-containing equipment, but their proportions are not known. That is, there are no reliable estimates of the number of potentially affected establishments that own or use utility owned transformers or capacitors. Neither are there reliable estimates of the proportion of such equipment that may be PCB-free. Nor of the proportion of such equipment that may be used or stored in such a way that it is not "in or around" a plant or facility within the meaning of FDA's proposal.

The previously mentioned contract study did try to estimate the number of transformers and capacitors used by food manufacturers. It did so by assuming that the national inventory of transformers and capacitors (estimated as of 1976) would be allocated among SIC codes proportional to each SIC code's rate of growth in electricity use between the years 1947-1976. This theoretical relationship predicted 3,165 transformers and 81,634 capacitors in food manufacturing establishments subject to FDA regulation (SIC codes in the 2000 series less meat, poultry, and egg establishments in the 201 series). It made no estimates of equipment in food packaging or food storage establishments.

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A recent survey by the Department of Agriculture of transformer and capacitor use in meat, poultry, and egg establishments has produced some preliminary data alternative to the contract model. The FSQS survey found about three times as many plant-owned transformers in the meat, poultry, and egg packing and processing industries as the contract model predicted, but less than two percent of the predicted number of capacitors. This variability suggests that none of the data now available are sufficiently accurate for estimating industry-wide costs of FDA's proposal. It does appear likely, however, that the total cost for replacing transformers will exceed $100 million. The FSQS survey did confirm the contract model's prediction that only a small minority of potentially affected establishments would have transformers or capacitors. FSQS, thus far, has found that less than 20 percent of establishments have such equipment, and that many of those that do are likely to have multiple units.

Thus, while the data obtained from these surveys are not sufficient for a reliable estimate of transformer and capacitor use in the industries subject to this regulation, it seems likely that transformers and capacitors will be concentrated in a comparatively few large establishments.

Because more complete data are required to assess a total economic impact, FDA, EPA, and USDA, have contracted for a more extensive survey of the affected industries. The results of this survey will not be available until after publication of this proposal.

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FDA has also deferred estimation of the costs of the part of this proposal requiring examination of certain raw materials for PCB contamination. Such costs are anticipated to be small compared to the costs of the FDA-proposed restrictions on PCB-containing electrical equipment. Costs of examinations, as well as the results of more thorough industry surveys will, of course, be carefully considered in the final regulation and its final regulatory analysis.

ALTERNATIVES

The agency considered several alternatives before developing its proposal:

(1) Do Nothing

The agency concluded that the continued use of PCB-contaminated electrical equipment poses unreasonable risk of injury to human health. It is difficult to measure the potential harm, but the recent contamination incidents demonstrate the extent to which large numbers of people can be exposed to PCB health risks because of a single contamination.

(2) Complete Ban

A complete ban on equipment containing any level of PCBs in food, feed, and packaging plants, i.e., a "zero" level in electrical fluids, would be unnecessarily restrictive. This approach would not allow the retrofilling of transformers where it is the less expensive option. Furthermore, the increased margin of a safety may not be justified by the significantly higher costs.

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(3) Inspection Program

This alternative, requiring regularly scheduled inspection of PCB-containing equipment, in lieu of replacing such equipment, was estimated by the previously mentioned EPA contract. A daily inspection program based on a 15-minute inspection for transformers and a 5-minute inspection for capacitors was estimated to cost $1,825 per year per transformer, and $608 per year per capacitor. While these costs are lower than replacement or retrofilling equipment, they must be endured for the life of the equipment and, consequently, this option has a higher net present value. Also, there is no assurance that an inspection program, however rigorous, can prevent contamination experienced in recent incidents, e.g., fire.

(4) Restrict PCBs in New Equipment Only

This alternative would mean that PCB-containing equipment would be replaced at the going obsolescence rate for transformers and capacitors. This would extend the danger of PCB contamination in foods over many years, since the life of a transformer can exceed 40 years.

Variations on this option could phase out PCB-containing equipment over periods of time shorter than the remaining life of existing equipment. This would reduce the immediate economic impact of the proposal. It may also ensure that the demand for replacement transformers and capacitors would be more easily met by the electrical manufacturing industry. This alternative

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would not provide any action to eliminate a potential public health hazard in the interim, and thus does not meet the essential requirement for timely protection against future contamination incidents.

(5) Installation of Protective Devices Against Leaks and Spills

This alternative would require the installation of dikes, catch basins, signaling devices, or similar systems to prevent PCBs leaked or spilled from transformers or capacitors from contaminating foods, feeds, and food packaging materials. At this time the FDA does not have cost data on this alternative and hopes to obtain such information through a contracted survey and also through the comments submitted in response to this proposal. This alternative was not considered at this time because of lack of information on the effectiveness or cost of any protective system.

(6) Restrict the Use of PCB-Containing Equipment in Animal Feed and Feed Ingredient Facilities Only

The recently reported incidents of direct PCB contamination of foods, feeds, and packaging material (where the PCB source was known to have been from transformers or capacitors) have originated in facilities manufacturing and/or storing animal feeds or ingredients.

Therefore, this alternative would remove the most recently experienced problem sources and result in no costs to the remainder of the food and food packaging industry.

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This option was not considered a suitable alternative because there is insufficient evidence to warrant limiting this proposal to the animal feed industries. The potential for leaking PCBs exists in the human food industry as well, and direct human food PCB contamination would present a much greater health hazard since there would be no PCB dilution as in the feed processing chain.

FDA expects to obtain additional insight into the feasibility and costs of the proposed action as well as the alternatives described above. Much essential information is expected from the contract efforts. Results of contract studies will be made available as a part of this rulemaking. FDA solicits any comments that may provide additional data or ideas helpful in developing a final regulatory analysis.

FDA may update this draft analysis before preparation of the final analysis if more definitive data becomes available in the interim.

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