Monsanto

FROM (NAME & LOCATION) W. H. Slowikowski - B2SD

DATE May 6, 1976

SUBJECT RECENT EPA (PCB) LETTERS TO PYDRAUL, THERMINOL CUSTOMERS

REFERENCE

TO R. S. Bevacqua - 1550
C. L. Clay - 1070
G. F. Fague - 1550
A. A. Johnson - 1010
J. C. Larkin - G4NN
D. L. Mellon - 1010
J. S. Pullman - 1010
J. J. Roder - G4NN
K. S. Rosenberg - 1460
C. F. Seger - 1010
J. E. Spinks - 1010

cc D. R. Bishop - B1NB
T. H. Bottini - B2CA
R. L. Koch - B2SD
M. E. Marshall - B2SD
C. Paton - B2SK
R. G. Pier - B2SK
R. G. Potter - B2SB
D. L. Sliney - B2SB
J. C. Weber - B2SB

The Federal Environmental Pollution Agency is in the process of identifying and quantifying possible sources of PCBs entering the environment. This program is part of an overall plan to assess the nature and the extent of possible adverse effects resulting from the presence of PCB compounds in the environment. We obviously have information which could aid this program. Monsanto, in fact, was directed by the Federal Environmental Pollution Agency to supply a listing of all past purchasers of PCB containing materials as well as amounts purchased. The EPA also has a list of PCB containing products and the percent by weight of PCBs in each product. (See attached.)

We now have been informed that all customers who used PCB containing Therminol® and Pydraul® fluids since 1971 (other than those contained in sealed systems, such as transformers and capacitors, obtained in finished form from another facility and used without breaking the seal) may receive a letter from the EPA asking the customer to provide detailed information with respect to the facilities which used PCBs, tradename of the PCB product used, percent by weight and amount of each PCB compound used, sold, discarded, reclaimed, etc., etc. Some customers have already received these letters. (This ought to be a small list since Therminol discontinued on 12/15/71 and Pydraul PCTs in June of 1972.) However, this has led to a plethora of requests to MIC for information and assistance in responding to the EPA.

The Product Group will continue to relay all such inquiries to the appropriate salesmen. The salesmen are requested to adhere to the following guidelines when contacted by their customers:

- The EPA letters have been addressed to specific accounts and include the amount of PCB (in pounds) as well as the PCB containing products used by that account. Therefore, the data contained in these letters are as accurate as any we could provide. The information contained in these letters was no doubt generated from the reports extracted from Monsanto. If the customer requires more information, he should request this information from the EPA.

- With respect to verifying usage, locations, disposal, etc., the customer should check his own records. It is the customer being asked to account for the use of this product and not Monsanto. We have already done so. If the customer hasn't any records, then he should consult with his own environmental engineering department and/or the local EPA office for direction. It is no offense, as far as we understand it, to tell EPA that they did not maintain records of PCB-containing products.

- The letter asks for results of any sampling the customer may have done to measure PCBs in air or waste-water discharge streams. With respect to this, it's important that our policy on PCB sampling is adhered to. Since late 1971 Monsanto has referred customers requiring PCB sampling analysis to laboratories who claim competence in this area. Monsanto does not undertake this service. Laboratory lists were furnished in SIB #60 (11-19-71) and SIB #193 (10-7-75). (Copies of both these SIBs are attached.) In actual fact, the credibility of PCB figures provided by Monsanto for its customers could easily be suspect. Also, given our position as the sole U.S. source of PCBs, it is conceivable that we could be obligated to inform the EPA of any knowledge of PCBs in the environment. Should this occur, it would be necessary to reveal the information we had as a result of analyzing customer samples for PCBs. Independent laboratories therefore must be consulted.

- If asked what Monsanto recommends in terms of future action on the part of the customer, please remind him that there has been a variety of regulations (federal, state and local) concerning PCBs and PCTs, both passed into law and being discussed for future laws. PCB legislation takes a different form in each state. Monsanto has no expertise in this area as the action to be taken depends upon the specific circumstances involved with the customer's use of the PCB products, location, and plant operations. The customer's own environmental engineering office, the local EPA office, and outside consulting firms can provide much more detailed information on this matter. As a point for discussion, one consulting firm has recommended that "if PCBs were purchased, grab samples of water discharges should be collected and analyzed. If these analyses show PCB levels at or above the prescribed level, the firm should initiate a program to define the extent of contamination of your facility and means of reducing or eliminating discharge of PCBs." (Please note that effluent regulations and water purity standards do not deal solely with PCBs, other chemicals can be - and often are - involved. Pollution abatement is going to be a way of life whatever products industry uses.)

- Some customers may try to make this issue one in which Monsanto bears responsibility. We do not accept this argument. On August 3, 1973 we sent all our Pydraul customers the attached letter which asks them to inspect their facilities to insure compliance with new regulations. You may wish to remind them of this and send them a copy if they claim that Monsanto did not alert them to potential problems. Prior to this we sent a series of eight letters beginning in February 1970 which kept them abreast of the PCB situation. Please remind them that the current Pydraul line, i.e. Pydraul 230C, 312C, 320C, 540C, MC, 10E, 29E LT, 30E, 50E, 65E, 90E and 115E, does <u>not</u> contain PCBs.

I trust the above will provide you with sufficient information to deal with these customer inquiries. It looks as if this PCB issue will be around for sometime. We intend to keep abreast of the situation and inform the field sales as any new developments occur. In the meantime, let's keep our responses

to the customers as pleasant, yet direct as possible. This situation bears close scrutiny at major accounts where potential drain and refill alternatives are to be considered in reducing the PCB level.

Thank you for your cooperation in this matter.

W. H. Slowikowski

/pep
Attachments

POLYCHLORINATED BIPHENYL AND POLYCHLORINATED TERPHENYL PRODUCTS

MONSANTO INDUSTRIAL CHEMICALS COMPANY

1971 - 1975

PCB: polychlorinated biphenyl
PCT: polychlorinated terphenyl

Hydraulics/Lubricants	% PCB or PCT
Pydraul AC-A	53.5% (PCT)
Pydraul AC-A Winter Grade	14.0% (PCT)
Pydraul A-200	100.0% (PCB)
Pydraul A-200B	30.0% (PCT)
Pydraul F-9A	39.5% (PCT)
Pydraul 135	46.0% (PCB)
Pydraul 135A	27.8% (PCT)
Pydraul 150	23.0% (PCB)
Pydraul 150A	14.8% (PCT)
Pydraul 230	57.7% (PCB)
Pydraul 230A	29.3% (PCT)
Pydraul 312	47.3% (PCB)
Pydraul 312A	31.1% (PCT)
Pydraul 540A	38.8% (PCB) 15.7% (PCT)
Pydraul 540B	42.0% (PCT)
Pydraul 625A	60.0% (PCT)
Santovac 1	100.0% (PCB)
Santovac 2	100.0% (PCB)
Turbinol 153	87.9% (PCB)

Heat Transfer Fluids	% PCB or PCT
Therminol FR-0	80.0% (PCB)
Therminol FR-0 Low Temperature	50.0% (PCB)
Therminol FR-1	100.0% (PCB)
Therminol FR-2	100.0% (PCB)
Therminol FR-3	100.0% (PCB)

MONS 028949

FILE COPY

Monsanto

MONSANTO INDUSTRIAL CHEMICALS CO.
800 N. Lindbergh Boulevard
St. Louis, Missouri 63166
Phone: (314) 694-1000

August 3, 1973

Dear Sir:

In February, 1971 we announced the reformulation of our Pydraul^{R} industrial fluids to eliminate the use of polychlorinated biphenyls (PCBs) as components of these fluids. Since then we have reviewed our formulations and taken further steps to remove all chlorinated compounds from our Pydraul^{R} fluids. Pydraul^{R} fluids containing chlorinated materials have not been sold since mid-1972.

Recently the Food and Drug Administration published in the Federal Register (Vol. 38, No. 129, pgs. 18096-18104, July 6, 1973) a final rule-making order regulating the sources by which polychlorinated biphenyls (PCBs) may contaminate animal feed, food, and food-packaging materials during manufacturing, handling and storage, and limiting the levels of PCBs that may be present in animal feed, food, and food packaging materials as a result of unavoidable, environmental contamination. Attached is a copy for your use.

Because you may have purchased Pydraul^{R} fluid prior to our changeover activities in mid-1972 which may have contained PCBs, you may wish to review your procedures and inspect your facilities at this time to insure that your operations are in compliance with the new regulation. To assist you in any investigations you may care to conduct, I have attached a list identifying the Pydraul^{R} fluids which contained chlorinated ingredients and those which do not.

Proper disposal of chlorinated materials requires high temperature incineration. Monsanto has installed a facility at its Sauget, Illinois plant and has made this service available to its customers. Information relating to this service is attached to help you should you decide to dispose of such materials in this manner.

MONS 028950

Our current line of Pydraul^{R} fluids which do not contain chlorinated materials do not require this method of disposal.

I hope this information is useful to you. If I can be of further service please let me know.

Sincerely,

Cumming Paton
Product Manager
Fluids

/pep
Enclosures

PYDRAUL® FLUIDS WHICH CONTAINED CHLORINATED INGREDIENTS

Pydraul® 90	Pydraul® 540B
Pydraul® 135	Pydraul® 625
Pydraul® 135A	Pydraul® 625A
Pydraul® 150	Pydraul® AC
Pydraul® 150A	Pydraul® AC-A
Pydraul® 230	Pydraul® AC-A Winter Grade
Pydraul® 230A	Pydraul® AC Winter Grade
Pydraul® 280	Pydraul® A-200
Pydraul® 312	Pydraul® A-200A
Pydraul® 312A	Pydraul® A-200B
Pydraul® 540	Pydraul® F-9
Pydraul® 540A	Pydraul® F-9A

CURRENT PYDRAUL® FLUIDS (DO NOT CONTAIN CHLORINATED INGREDIENTS)

Pydraul® 10E (formerly Pydraul® 60)	
Pydraul® 29E LT	
Pydraul® 30E	
Pydraul® 50E	Pydraul® 230C
Pydraul® 65E	Pydraul® 312C
Pydraul® 90E	Pydraul® 540C
Pydraul® 115E	Pydraul® MC (formerly MCS 1330)

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PART II

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

POLYCHLORINATED BIPHENYLS

Contamination of Animal Feeds, Foods, and Food Packaging Materials and Availability of Supplement to Environmental Statement on Rulemaking

MONS 028953

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER A—GENERAL

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

POLYCHLORINATED BIPHENYLS (PCB's)

Contamination of Animal Feeds, Foods, and Food-Packaging Materials

In the FEDERAL REGISTER of March 18, 1972 (37 FR 5705) a notice of proposed rule making was published limiting the sources by which polychlorinated biphenyls (PCB's) may contaminate animal food, food, and food-packaging materials during manufacturing, handling, and storage, and limiting the levels of PCB's that may be present in animal feed, food, and food-packaging materials as a result of unavoidable, environmental contamination. The notice provided for the filing of comments within 60 days after the date of publication and this was extended to July 16, 1972 by a notice published May 18, 1972 (37 FR 10003).

In response to the notice, ninety-three comments were received from members of industry, trade associations, consumer groups and individual consumers.

The following is a summary of the provisions contained in the notice and the comments on these provisions received by the Food and Drug Administration:

1. *Sections 3.93, 128.4, and 135.113.* The notice included provisions which would prohibit the use of PCB-containing materials and equipment in animal feed, in food, and in food-packaging material manufacturing, handling and storage establishments, in order to preclude direct, accidental PCB contamination of animal feed, food, and food-packaging materials.

a. One comment suggests that since most industrial chemicals can be interpreted to be "harmful or deleterious", the phrase should be deleted as a criterion for PCB replacement. The Commissioner concurs with deleting the phrase "harmful or deleterious". The toxicity and other characteristics of fluids selected as PCB replacements must be adequately determined so that the least potentially hazardous replacement is used. In making this determination with respect to a given fluid, consideration should be given to (1) its toxicity; (2) the maximum quantity that could be spilled onto a given quantity of food before it would be noticed, taking into account its color and odor; (3) possible signaling devices in the equipment to indicate a loss of fluid, etc.; and (4) its environmental stability and tendency to survive and be concentrated through the food chain. The judgment as to whether a replacement fluid is sufficiently nonhazardous is to be made on an individual installation and operation basis. Accordingly, the appropriate amendments have been made in § 135.113(b)(3) (21 CFR 135.113(b)(3)), § 3.93(b)(2) (21 CFR 3.93(b)(2)), and § 128.4(b)(2) (21 CFR 128.4(b)(2)).

b. One comment argues that electrical capacitors and transformers should be exempt from the requirement that new equipment and existing equipment in establishments engaged in the processing of animal feed, human food, or packaging materials shall not contain PCB's, since no known substitute is available which offers the proper balance of characteristics (e.g., fire safety and design efficiency). In support of the comment, it is stated that both capacitors and transformers are constructed in sealed metal cases and are not normally installed in equipment or located in such a manner as to be in direct contact with the material being processed. The Commissioner of Food and Drugs agrees that there should be an exemption for the safe use of PCB's in electrical capacitors and transformers. The final order has been amended in § 135.113(c), § 3.93(c) and § 128.4(b)(3), to provide an exemption for electrical capacitors and transformers.

c. One comment contends that an effective date of 90 days following publication of the final order should be established since this time period would be required for the modification of existing plant equipment to accommodate PCB replacements. The Commissioner concludes that there is no justification for extending the effective date and the final order establishes an effective date of 30 days from the date of publication in the FEDERAL REGISTER.

d. One comment contends that with the replacement of PCB formulated heat exchange fluids with non-PCB fluids, some level of PCB residue is likely to remain in certain equipment. Therefore, the comment continues, the Food and Drug Administration should initiate studies for the purpose of establishing a finite allowable residual level. While it is true that some residue of PCB may remain in certain equipment, if the change is made in a reasonable manner and in good faith there should not be significant concentrations of PCB remaining. Without additional data it is not possible to set any specific limit for PCB concentration in the equipment fluids. Furthermore, the Commissioner has determined that no reasons exists for FDA to initiate studies to determine the extent of residual levels of PCB's in heat exchangers or to specify by regulations finite tolerances for such residual material at this time.

2. *Section 121.2546.* The notice included an amendment to the existing food additive regulations (21 CFR 121.2546) so as to exclude from use in food-packaging materials pulp from reclaimed fibers containing poisonous and deleterious substances which may migrate to the packaged food.

a. One comment contends that the language of the amendment is incomplete since it does not establish a limit or tolerance for poisonous or deleterious substances, such as PCB's, which may ultimately be found in the packaged food product. The Commissioner disagrees because the purpose of § 121.2546 is to regulate the use of reclaimed fibers containing poisonous or deleterious substances for use in the manufacture of food-packaging materials and, to the extent necessary, to prevent contamination of the packaged food product with these substances. Therefore, the regulation precludes the necessity of establishing tolerances for the packaged food product. The Commissioner agrees, however, the clarification of the amendment is needed in order to be consistent with regulations which permit the presence of what could otherwise be regarded as poisonous or deleterious substances at levels that have been proved to be safe in food-packaging materials. Therefore, the order is amended in § 121.2546 by adding the phrase "except as provided in regulations promulgated under Sections 406 and 409 of the Federal Food, Drug, and Cosmetic Act."

3. *Part 122.* The notice included the proposal to establish temporary tolerances under Section 406 of the Federal Food, Drug, and Cosmetic Act for unavoidable PCB residues in animal feed, certain foods and food-packaging materials as a result of environmental contamination.

a. One comment recommends that a zero tolerance for PCB's in foods and feeds should be established. The Commissioner rejects this recommendation. Animal feeds, certain foods, and paper food-packaging materials contain PCB's which, under present conditions of environmental contamination, are unavoidable. Current toxicological information does not support the necessity of establishing zero tolerances for these articles in order to protect public health since human exposure to dietary sources of PCB's is usually sporadic, non-systematic, and occasional. The "finite" temporary tolerances being established will provide the assurance that significant PCB levels are not contained in food and that human exposure to PCB's from dietary sources will be maintained at safe and minimal levels. Zero tolerances, therefore, are unwarranted and would unnecessarily deprive the consumer of a portion of his food supply and disrupt the Nation's food distribution system because a portion of fish, poultry, eggs, and milk and packaging used for food would be violative.

b. A consumer group's comment recommended lowering the PCB tolerances for human foods by a factor 5–10; while another comment recommended that the temporary tolerances should be based on toxicological data which would allow a level that is deemed safe rather than allow a level that can be reasonably achieved. The Commissioner disagrees with both recommendations. Section 406 of the act, which is the authority for establishing the temporary tolerances for PCB's, states that where the addition of a poisonous or deleterious substance to food cannot be avoided the Secretary shall promulgate regulations "limiting the quantity therein or thereon to such extent as he finds necessary for the protection of the public health", and also specifically states that the Secretary in setting such a tolerance shall take into account the extent to which use of the substance "cannot be avoided". The fact

MONS 028954

that the tolerances are termed "temporary" is recognition that, in the future, there should be less PCB contamination which "cannot be avoided" and the Commissioner is authorized to reduce the tolerance levels accordingly. The temporary tolerance levels are based on an analysis of animal and human toxicological data and data on the occurrence of PCB's in the food supply as follows:

(1) *Animal toxicological data.* Data from long-term animal studies are available to show that the no-effect level in rats and dogs (for PCB's with 42, 54, and 60 percent chlorination) is 10 parts per million (ppm). Employing a 100 to 1 safety factor, the "no-effect" level for man would be 2.5 microgram (mcg)/kilogram (kg) body weight/day based on data drived from dogs, or 3 mcg/kg body-weight/day from rats. Therefore, based on long-term animal studies, the allowable level of PCB ingestion in man would be approximately 175 mcg/day for a 70 kg individual.

(2) *Human toxicological data.* Human intoxication with Kanachlor 400, a PCB manufactured in Japan with 48 percent chlorine was noted when a heat exchanger leaked fluid into rice oil and was consumed by Japanese families in 1968. About 1,000 people were eventually affected. Typical clinical findings included chloracne and increased pigmentation, visual impairment due to hypersecretion of the Meibomian glands, and systemic gastrointestinal symptoms that included abdominal pain and disturbances in liver function. A few babies were born with decreased birth weights and skin discoloration which slowly regressed as the children grew in size, although the growth rate of males appeared to be somewhat slower than normal. Adult patients had protracted clinical disease with very slow regression of symptoms and signs, suggesting slow metabolism and excretion of this PCB in humans, probably involving a long biological half-life. Exposure levels to the oil were calculated to approximate, on the average, 15,000 mg per day. The oil itself was reportedly contaminated at a level of about 2,000 ppm. This level was derived from the known organic chlorine content of rice oil related to the known organic chlorine content of Kanachlor 400. The average total dose of PCB's causing an effect in the Japanese was reported to be 2,000 mg. The human data published by Karatsune, et al., Fukuoka Acta. Med. 23:117 (1971) established that the lowest level of PCB that produced an effect in man (using a 50 kg man) was 500 mg consumed over a period of 50 days at a rate of approximately 200 mcg/kg body weight/day. The effect level was based on overt symptoms rather than sensitive biochemical tests that might have demonstrated some effects at even lower levels. Employing a safety factor of 10 to 1 to go from an effect level in man to a permissible no-effect level in man allows for an ingestion of 20 mcg/kg body weight/day; or 1.4 mg/day for a 70 kg man based on a total period of exposure of 50 days (equivalent to the Japanese incident). Since PCB's probably have a long biological half-life in man, an alternative toxicological analysis of the human data may be based on the assumption that ingested PCB's would continue to accumulate in tissues for a long period of time. Since 2,000 mg was reported to be the average total dose causing an effect in the Japanese, it is possible that 200 mg total dosage PCB's (applying a safety factor of 10 to 1 as above) may be tolerated over a much more protracted period of time without overt adverse effect if daily exposure is held to minimal levels. It would take 22 months of daily ingestion of 300 mcg of PCB's to arrive at a total ingestion of 200 mg. This would permit ingestion of 4 mcg/kg/day as derived from a 70 kg man. Since the lowest total dose producing an effect in man was 500 mg, a similar analysis leads to an allowable protracted ingestion of 1 mcg/kg/day as derived from a 70 kg man.

(3) *Dietary sources of PCB's.* The results of FDA total diet studies for fiscal years 1970–1972 show that quantitatively measurable residues of PCB's are equivalent to an intake of approximately 0.06 mcg/kg/body weight/day (or 4.2 mcg/day for a 70 kg man). Because of the sensitivity of the analytical methods used, PCB's may be present at levels too low to be detected. If lower levels could be measured, the dietary intake of PCB's from the total diet studies would probably show an increase. It should be recognized, however, that in rare instances some people could have more systematic exposures to PCB's in foods than those expected by eating a moderately well balanced diet such as represented by the total diet samples. Hence, there is a need for minimizing potential human exposures. The total diet studies indicate that PCB's most frequently occur in the food composite consisting of meat, fish and poultry (experience has shown that most of the PCB residues in this composite are in fish and, to a lesser extent, poultry) and in the food composite consisting of grain and cereal products (experience has shown most of the PCB residues in this composite are derived from paper packaging materials). FDA's food surveillance activities have shown that PCB's also occur in dairy products, eggs, and packaged foods, in addition to packaged cereal products.

(4) *Temporary tolerances for PCB's.* Using the human toxicological data described above, FDA concludes that for the short term, based on the lowest total dose producing an effect and estimated biological half-life of PCB's, current levels of PCB's in the diet represent no immediate hazard. This is also true for the average total dose causing an effect in the Japanese for long-term exposure. However, based on the most sensitive "Japanese patient" (i.e., lowest total dose producing an effect), the possibility of potential long-term hazards necessitates reduction of the levels of PCB's in food as soon as possible. In the interim, temporary tolerances are necessary to limit human exposure to those foods that may contain PCB's resulting from environmental contamination, which as a practical matter are presently unavoidable. Those foods, for which temporary tolerances are being established, include milk and dairy products, poultry, eggs, fish, and infant and junior food. Infants and young children consume a greater amount of food per kilogram of body weight and thereby have a proportionately greater exposure than do adults. A separate temporary tolerance for infant and junior food, therefore, reflects the possibility that undesirable exposures could result if combinations of certain PCB-contaminated foods comprise a major portion of this age group's diet. In order to minimize the overall dietary intake of PCB's, individual sources of PCB contamination must also be appropriately minimized. PCB's have been shown to occur in packaged food as a result of the PCB contamination of paper food-packaging materials. Limitations on the levels of PCB's in paper food-packaging materials are, therefore, necessary to minimize the amount of PCB's which may migrate to the packaged food. Since PCB's can be transmitted to and concentrated in edible portions of food-producing animals ingesting PCB-contaminated feed, animal feed represents another source of PCB's in the food supply. Limitations on the levels of PCB's in animal feeds and animal feed components are necessary, therefore, to minimize the frequency and magnitude of PCB residues in foods of animal origin.

The Commissioner concludes that the temporary tolerances being established will protect the public health from PCB's in food, but cautions that the temporary tolerances are not to be construed as "guidelines" permitting the consumption of foods containing these amounts of PCB's on a regular and consistent basis. Further, the temporary tolerances will be lowered as experience indicates that lower levels can be attained.

c. One comment recommends that FDA issue warnings to pregnant women who breast feed their babies to restrict their intake of fish to species that have been thoroughly monitored by FDA and found to be uniformly within the temporary tolerance. The basis for this recommendation is that consumption of PCB-containing fish and, for that matter other foods, may result in transfer and storage of PCB residues in human milk which in turn, the comment contends, would present a hazard to breast fed babies. The Commissioner concludes that such a warning is not warranted. On the basis of available, but limited monitoring data, most of which is unpublished, it appears that PCB levels in human milk would generally be less than approximately 0.05 ppm (whole product basis). Analysis of available toxicological data involving multigeneration reproduction studies in rat indicates that this level presents no immediate hazard to infants. Furthermore, this level is substantially less than the level of PCB's FDA will permit in the milk of dairy cows. The temporary tolerance being established for milk is 2.5 ppm (fat basis), which is

MONS 028955

equivalent to 0.1 ppm (whole product basis). Therefore, a public warning as recommended is not supported by the scientific facts available at this time.

d. One comment recommends clarification of the term "PCB's" so as to distinguish between PCB-compounds of different chemical composition. The basis for this comment is the fact that PCB's are mixtures of chlorinated biphenyl compounds. Each component of the PCB mixture is a specific chemical compound having the basic biphenyl moiety and one to ten chlorine atoms. There are 209 different chlorinated biphenyl compounds. Each component of manufactured and sold in the United States under the registered trade name of Aroclor, followed by a four digit number (i.e., 1242; 1248; 1254; etc.). The term Aroclor signifies that the product consists of chlorinated biphenyls, chlorinated terphenyls, or a mixture of these compounds. The first two digits of the numerical part of the trade name indicate the molecular type (1200 signifies chlorinated biphenyl), while the last two digits give the weight percent of chlorine (42 signifies 42 percent chlorine). Since the physical and chemical properties of each Aroclor vary, the analytical behavior of each Aroclor will also vary. For PCB residue analysis, it is customary to determine the amount of PCB residue found by comparing the residue to a known quantity of the Aroclor it most nearly matches when separated into multicomponents on a gas chromatograph. Therefore, the Commissioner agrees that clarification of the term "PCB" is necessary for the analysis of food, animal feed and paper food-packaging materials for PCB residues. The compilation of FDA analytical methods to be used for enforcing the PCB tolerance that is available upon request contains instructions regarding this aspect of the recommendation. The Commissioner does not agree, however, that the tolerances for PCB's should distinguish between PCB-compounds of different chemical composition because toxicological data do not support the need to establish separate tolerances for each Aroclor. Therefore, the temporary tolerances will apply to the term "PCB" irrespective of which Aroclor or mixture of Aroclor is present as the contaminant.

4. *Section 122.10(a)(1) and (2).* The notice included the proposal to establish a temporary tolerance for PCB's in milk and dairy products at 2.5 ppm (fat basis).

a. One comment recommends that since FDA's previous action level for PCB's in milk and dairy products, which was set at 55 ppm (fat basis), was stated as adequate for protecting public health, the temporary tolerance for milk and dairy products should be kept at the same level. The Commissioner concludes that there is no justification for raising the proposed tolerance from 2.5 ppm to 5 ppm in the fat of milk and dairy products. The 2.5 ppm temporary tolerance takes into account current toxicological data and the level of PCB residues that is presently considered unavoidable. A recent FDA survey revealed that only one sample of milk in 520 tested contained more than 2.5 ppm PCB in the fat, i.e., 0.2 percent of the total samples. Evidence also indicates that higher levels may be generally attributed to avoidable sources of contamination, such as the use of PCB coatings in diary farm silos which caused PCB contamination of silage for diary cows with subsequent transmission of PCB's to the milk of these cows.

b. One comment recommends the PCB tolerance be expressed on an "as is" basis because the fat content of dairy products varies and these foods are consumed "as is". The Commissioner rejects this recommendation. The butterfat is generally considered the most valuable constituent of milk. PCB's are fat soluble, and in the manufacture of various dairy products from milk, remain at a nearly constant concentration in the fat. The fat basis tolerance is therefore necessary to govern the level of PCB's in such products in preparing some other type of food. For example, butter (about 80 percent fat) made from milk containing levels of PCB's below tolerance would also be acceptable since the PCB concentration in the fat would be unchanged.

5. *Section 122.10(a)(3).* The notice included a proposal to establish a temporary tolerance for PCB's in poultry at 5.0 ppm (fat basis).

a. One comment recommends that since FDA's previous action level for PCB's in poultry, which was set at 5 ppm on the edible tissue, was stated as adequate for protecting public health, the temporary tolerance should be kept at that same level. The Commissioner rejects this recommendation. PCB contamination of poultry at levels in excess of the temporary tolerance being established has been attributed to the use of animal feed contaminated with PCB's as a result of industrial accidents, e.g., leakage of PCB's onto feed components. The Commissioner concludes that there is no justification for establishing a tolerance level that accounts for avoidable sources of contamination. The temporary tolerance of 5 ppm (fat basis) takes into account that this level of PCB is generally unavoidable because some poultry feeds contain unavoidable PCB residues that will transfer to and concentrate in the fat of poultry. Furthermore, current toxicological data supports this tolerance level.

b. One comment recommends that the tolerance for poultry be expressed on an "as is basis" since this would more closely relate to the total PCB intake from this food than would a tolerance established for poultry on a "fat basis". In response, the Commissioner finds that although the dietary intake of PCB's resulting from contaminated poultry was considered on an "as is" basis (whole tissue) in the development of the temporary tolerance level, expressing the temporary tolerance on a fat basis is preferred since PCB's are fat soluble and fat derived from poultry can be used as a separate food (e.g., soups, gravies, etc.). The fat basis tolerance, therefore, provides the assurance that poultry contains acceptable levels of PCB's, irrespective of whether the whole tissue is consumed or the fat is consumed as a separate food.

6. *Section 122.10(a)(5) and (6).* The notice included the proposal to establish temporary tolerances for PCB's in finished animal feeds at 0.5 ppm and animal feed components (including fishmeal) at 5 ppm.

a. One comment recommends that the term "finished animal feed" be changed to "complete animal feed" since some finished feeds are further mixed with grains, by-products of grains, and other feed ingredients of plant origin before feeding. The Commissioner agrees that certain finished animal feeds such as feed concentrates, premixes, and supplements, often contain high levels of PCB's because they consist of a high percentage of animal-derived ingredients. At time of use, however, these articles are mixed with plant-derived ingredients which are not expected to contain PCB's. Thus, the final ration for the animal would not contain excessive levels of PCB's. The Commissioner concludes that for purposes of the PCB tolerance for animal feeds, clarification of the term "finished animal feed" is needed rather than a change in terminology. Therefore, the order is amended in § 122.10(a)(5) (21 CFR 122.10) so that the temporary tolerance for PCB's is applicable to finished animal feeds, except feed concentrates, supplements, and premixes.

b. One comment recommends a PCB tolerance of 1.0 ppm be established for animal feed components which are not of animal or marine origin. Since there has been no reported finding of PCB's (other than that which may be due to avoidable contamination during processing, handling, or storage) in animal feed components such as grains and by-products of grains, the Commissioner concludes there is no need at this time to establish a separate tolerance for PCB's in this category of animal feed component.

c. One comment recommends that the term "animal feed components" be qualified by the expression "including fishmeal and concentrates, premixes, and supplements". The Commissioner agrees with this recommendation and the order is amended in § 122.10(a)(6) so that the temporary tolerance for PCB's is applicable to animal feed components of animal origin (including fishmeal and other marine by-products) and animal feed concentrates, premixes and supplements.

d. The Commissioner finds that although there was no comment to change the proposed tolerance levels of 0.5 ppm for finished animal feeds and 5 ppm for animal feed components, current information indicates a lowering of these tolerance levels is warranted for the following reasons:

(1) Data from FDA conducted feeding studies show that the proposed temporary tolerance 0.5 ppm for finished animal feeds is incompatible with the temporary tolerances for poultry. While leghorn hens exposed to a diet containing 0.5 ppm PCB's (Aroclor 1254) for 8 weeks

MONS 028956

contained residues in excess of 5 ppm (fat basis) in the muscle (breast and thigh), dissectable fat, and liver of these animals. At a 0.2 ppm feeding level, the concentration of the PCB tissue residues in poultry was less than 5 ppm (fat basis). Data further indicate that continuous feeding of Aroclor 1254 at 0.5 ppm from day three to day forty-three post initial egg production can result in PCB residues only slightly less than 0.5 ppm in the eggs.

(2) Data from FDA surveillance programs and from industry reports indicate that PCB levels in finished animal feeds and in animal feed components are generally substantially less than the proposed tolerance limits. (a) Last year FDA conducted a survey of finished animal feeds for PCB's. The survey consisted of 1274 sample examinations representing various categories of animal feeds. The results show that 4.4 percent of the samples contained PCB residues. The highest reported level was 0.6 ppm PCB in feed intended for beef cattle. The average level for all samples tested was less than 0.1 ppm and the average level of the 56 samples that contained reportable levels of PCB's was less than 0.2 ppm. About 1 percent of the samples exceeded 0.2 ppm. (b) Animal feed components of animal and marine origin are expected to contain PCB's as a result of environmental contamination. During the past year, 32 samples of imported fishmeal were examined by FDA for PCB's. The results show that about 37 percent of the samples contained PCB residues. The highest level reported was 0.47 ppm. In addition, 153 fishmeal samples of domestic origin were examined during this period. The results show that about 48 percent of the samples contained PCB residues. The highest level reported was 2.1 ppm and the average was less than 1 ppm. (c) In the fall of 1971, industry conducted a survey of the PCB levels in rendered animal by-products used for feed ingredients such as hydrolyzed feather meal; meat and bone meal; fats and greases; and poultry by-product meal. The results of this survey which were published in "Feedstuffs," issue of July 3, 1972, show that of the 438 samples tested, the highest level of PCB found was 1.6 ppm in fat and greases. The average PCB level for the samples tested was less than 1 ppm. Other data that the FDA has received on the levels of PCB's in rendered animal by-products essentially confirms the results of this industry survey. Therefore, on the basis of the above, the Commissioner concludes that available evidence requires and justifies a reduction in the PCB tolerances for animal feeds and animal feed components. The order is thus amended in § 122.10(a) (5) and (6) to establish temporary tolerances for PCB's in finished feeds at 0.2 ppm and in animal feed components at 2 ppm.

e. One comment recommends that a tolerance of 5 ppm be established for PCB's in pet food. The Commissioner agrees in part with the comment. The proposal to establish a tolerance for animal feed was directed toward food-producing animals because the transmission of PCB's to the edible portion of animals ingesting PCB contaminated feed constitutes a potential hazard to human health. Further, the comment makes a reasonable recommendation since some pets may be able to safely consume levels of PCB's higher than 0.5 ppm. However, on the basis of available toxicological information, there is insufficient data for FDA to establish a tolerance for PCB's in feed for all types of pets and for other non-food producing animals. For this reason, studies will be initiated to obtain this information and, if warranted, FDA will issue a proposal to limit the level of PCB's in this category of finished animal feed. In the interim, the order is amended so that the temporary tolerance in § 122.10(a) (5) is applicable to only food-producing animals.

7. *Section 122.10(a) (7)*. The notice included the proposal to establish a temporary tolerance for PCB's in fish (edible portion) at 5 ppm.

a. One comment recommends that a temporary tolerance be established for shellfish. The Commissioner agrees with this recommendation because shellfish also have been found to contain PCB's as a result of unavoidable, environmental contamination and it is also in the interest of public health to limit the level of PCB's in this food. Therefore, § 122.10 (a) (7) is amended to include shellfish under the temporary tolerance of 5 ppm.

8. *Section 122.10(a) (8)*. The notice included the proposal to establish a temporary tolerance for PCB's in infant and junior foods at 0.1 ppm.

a. One comment states that the level proposed cannot be achieved because of trace quantities of PCB's in certain foods and in paper food-packaging materials. The Commissioner concurs with this statement because information indicates that this level of PCB's cannot be avoided and that current analytical methodology is insufficient to enforce a tolerance of 0.1 ppm. Therefore, the final order is amended by revising the temporary tolerance for PCB's in infant and junior foods to 0.2 ppm.

9. *Section 122.10(a) (9)*. The notice included the proposal to establish a temporary tolerance for PCB's in food-packaging materials at 5 ppm.

a. One comment recommends that plastic and other non-paper food-packaging material be exempt from the temporary tolerance. The Commissioner agrees with this recommendation because there is no evidence to indicate that PCB's occur in plastic or other non-paper food-packaging materials as a result of unavoidable contamination. For this reason, no basis exists for establishing a tolerance under Section 406 of the Federal Food, Drug, and Cosmetic Act for these articles. Therefore, the wording of § 122.10(a) (9) is revised to apply only to paper food-packaging materials. This exemption means that no PCB's whatever may be present, either as a result of purposeful addition or industrial accidents, in plastic and other non-paper food-packaging materials. The provisions in the Statement of General Policy or Interpretation under Part 3, which prohibits the use of PCB-containing equipment and materials, are applicable to those establishments engaged in the manufacture, handling, and storage of plastic and other non-paper food-packaging materials.

b. One comment contends that no authority exists under Section 406 of the Federal Food, Drug, and Cosmetic Act for the establishment of temporary tolerances for PCB's in food-packaging materials. The Commissioner concludes that the establishment of temporary tolerances for PCB's in food-packaging material is consistent with the language and purpose of Sections 402(a) (2) (A) and 406 of the Federal Food, Drug, and Cosmetic Act.

c. One comment recommends the temporary tolerance be applied to the packaged food, rather than the food-packaging material. The Commissioner rejects this recommendation for the following reasons:

(1) Since the transfer of PCB's from packaging material to the food is dependent on time and conditions of exposure, tolerances based solely on the food would not provide adequate protection to the consumer. A packaged food analyzed at the time of packaging may be entirely free of PCB's, but by the time it reaches the consumer and is finally consumed it may have accumulated considerable quantities of PCB's if the packaging material is contaminated. A tolerance system in which analytical findings are so dependent on many variables such as time of sampling would not be reasonable or adequate. (2) In order to achieve compliance with a tolerance for packaged food, the level of PCB in the packaging has to be taken into account and limited to preclude the potential transfer of quantities of PCB's to the food that would cause the food to exceed its tolerance level. The fact that the level of PCB in packaged food is related to the level of PCB in its packaging, in effect, necessitate tolerance for both the food and its packaging. This would represent an obvious redundancy. (3) Establishing a tolerance for packaged food would be inconsistent with the intent and meaning of section 406 of the Federal Food, Drug, and Cosmetic Act. The packaged food does not contain unavoidable PCB residues. The principal source of the PCB contamination of packaged food is the paper food-packaging material, which contain the unavoidable contamination. As such, the tolerance should deal with this article. Therefore, this source of food contamination should be limited so as to minimize the levels of PCB's that may migrate to the packaged food. (4) Failure to limit the level of PCB's in food-packaging materials would perpetuate the use of a known, avoidable source of PCB contamination of food.

d. One comment received from industry and related trade associations argues that the temporary tolerance for PCB's in food-packaging materials should be deleted or postponed until: (1) quality control test procedures and adequate analytical methods are developed to regulate production and insure compliance,

MONS 028957

and (2) migration rates are established to take into account barrier effects, type of food, and package weight to food weight ratio. In response, the Commissioner finds that: (1) Although a trade association submitted data which they claimed indicates a lack of reliability in analyses of paperboard material, the data failed to show that uniform test methods were employed by the participating laboratories or that these tests were performed by laboratories with demonstrated capabilities in trace residue analysis. Further, an interlaboratory study conducted under the auspices of another trade association using FDA analytical methodology, supports the conclusion that current methodology is adequately sensitive and reproducible from laboratory to laboratory in order to insure compliance with the tolerance. (2) It is recognized that migration rates (actual level of PCB in food resulting from the use of contaminated packaging) are affected by factors such as barriers, type of food, package weight to food weight ratio, and time and conditions of exposure. Since FDA's primary concern is not the fact that paper food-packaging materials contain PCB's, but the fact that PCB's can migrate to the food from the packaging, the use of barriers which prevent migration is an acceptable alternative to limiting the PCB content of paper food-packaging material. For this reason, the final order is amended in § 122.10(a)(0) to exempt paper food-packaging materials from compliance with the temporary tolerance if the paper food-packaging material is separated from the food by a functional barrier impermeable to PCB migration. Metal cans and glass bottles are obvious examples of what constitutes a functional barrier impermeable to PCB migration. Data from industry sponsored studies have shown that materials such as polyvinylidene coated paper and glassine can, to varying degrees, prevent or reduce PCB migration under test conditions which would favor migration. FDA would not object to the use of flexible materials and other materials as barriers provided there is no evidence of migration of PCB's to the food. At this time, however, there is insufficient information for FDA to list as part of the regulation those materials that are considered functional barriers. The other factors mentioned above which affect migration rates may also be important considerations and should be thoroughly studied. In the interim, the temporary tolerance for paper food-packaging materials and the exemption to this temporary tolerance are considered necessary to assure the consumer that packaged food is not being contaminated with PCB's to an avoidable degree.

e. One comment states that the establishment of temporary tolerance for PCB in paper food-packaging materials is unwarranted for public health reasons because available scientific evidence shows that Aroclor 1242 (predominant PCB found in paper) is not persistent and cumulative, and thus will not present a chronic toxicity problem. Although data indicates that some components of Aroclor 1242 are metabolized in biological systems more rapidly than the higher chlorinated Aroclors, there is no information available which describes the composition, toxicity, and fate of the metabolic products. The absence of Aroclor 1242 residues in human and other animal tissue and in the environment is not a sound basis from which to argue that no hazard exists from the ingestion of Aroclor 1242. The possibility exists that Aroclor 1242 is converted to alteration products which may be more toxic than the original compounds, but which are not detectable by current analytical methods. Further, available data from chronic feeding studies with rats and dogs fail to substantiate claims that Aroclor 1242 does not represent a toxic substance or that it differs in toxicity from the higher Aroclors. The Commissioner concludes that the temporary tolerance for paper food-packaging materials will apply to the tem "PCB" irrespective of which Aroclor is present as the contaminant.

f. Several manufacturers and trade associations recommended that the temporary tolerance for PCB's in food-packaging materials be modified so that the tolerance is expressed as "0.265 mcg/square centimeter in that portion of the package from which migration to the food can reasonably be expected", rather than using "parts per million" terminology. The Commissioner believes that this would not be a practical alternative because: (1) Expressing the tolerance for the weight of PCB residues in terms of unit area of packaging material rather than unit weight of packaging material assumes that PCB's are uniformly distributed throughout the food package and that any area of the packaging material selected for PCB analysis would be representative of the entire package. It is generally recognized that this assumption is not valid. (2) The migration of PCB from package material to food is considered to be chiefly a vapor phase phenomenon which is related to the concentration of PCB's in the packaging material. It is therefore not possible to ascertain which portion of the package would be expected to contribute to the PCB contamination of the packaged food. For these reasons, it is necessary to take into account the paper food-packaging material in its entirety as a potential source for the PCB contamination of the packaged food. Therefore, expressing the tolerance in terms of weight of PCB's per weight of packaging material as "parts per million" is a practical means to measure the "average" PCB level in the packaging.

g. One comment recommends that FDA include in the final regulation PCB analytical procedures employed by FDA in determining the extent of compliance with the established temporary tolerance for paper food-packaging materials. The Commissioner concurs in part with this recommendation and FDA will provide upon request the analytical methods to be used for enforcing the temporary tolerances for PCB's in paper food-packaging materials and the other articles for which tolerances are established in § 122.10(a). Omitting the methodology from the regulation will permit easier adoption of improved procedures as they are developed while having the analytical methods readily available to all interested parties.

h. One comment states that the temporary tolerance for PCB's for paper food-packaging materials will be detrimental to solid waste disposal programs, increase food packaging costs and result in an insufficient supply of packaging materials due to limitations of raw materials, and thus will significantly affect the quality of the human environment. The underlying basis for this statement is the fact that PCB's may occur in recycled paper because of the inclusion of some types of carbonless copy paper containing 3–5 percent PCB's into wastepaper stocks used in the manufacture of recycled paper. The comment contends that the temporary tolerance will have an adverse effect on the recycled paper industry and thus will cause the above environmental consequences. In response, FDA prepared in accordance with the National Environmental Policy Act of 1969 an environmental impact statement on the proposed rule making. FDA issued a Draft Environmental Impact Statement on May 11, 1972, a Final Environmental Impact Statement on December 21, 1972, and a Supplement to the Final Environmental Impact Statement (published concurrently with this order). In these statements, FDA asserted that information on the toxicity of PCB's necessitates limiting the levels of PCB's currently present in certain foods as a result of environmental contamination, as well as levels of PCB's in certain unavoidable sources of food contamination, i.e., PCB contaminated paper foodpackaging materials. FDA also asserted that the public health benefits derived from the rule making would outweigh any benefits that might be derived from industry-recommended alternative courses of action. These alternatives, which were considered and rejected by FDA as ineffective consumer protection measures, included: (1) The alternative of not regulating the PCB content of food-packaging materials; (2) The alternative of exempting Aroclor 1242 from the regulation; and (3) The alternative of regulating the packaged food rather than the packaging. FDA concluded in the statements that the rule making would have a significant, beneficial effect on the quality of the human environment. FDA did, however, re-evaluate the proposed level of 5 ppm as the temporary tolerance for PCB's in paper food-packaging materials. Data from the FDA survey of PCB's in foods and food packaging showed that the food portion of the samples with 5–10 ppm in paper food packaging contained the same range of PCB levels (0.1–0.6 ppm) as the food portion of the samples with 0–5 ppm in paper packaging. Samples with more than 10 ppm in the packaging contained higher levels in the food, ranging up to 3.7 ppm. The Commissioner concluded that this was the only acceptable alternative available and stated in the Final Environmental Impact Statement that the temporary tolerance for PCB's in paper

MONS 028958

food-packaging materials would be changed to 10 ppm. (This order amends § 122.10(a)(9) to reflect this change.) Data provided by industry shows that levels of PCB's in paper food-packaging materials have diminished during the past year to the point that 93 percent or more of this material will contain 10 ppm or less PCB's. Therefore, FDA concluded that the temporary tolerance of 10 ppm and the exemption to this tolerance for paper food-packaging materials separated from the packaged food by a functional barrier will protect the public, while minimizing or negating the impact of the rule making on recycling programs. Furthermore, FDA indicated in the Supplement to the Final Environmental Impact Statement that it will explore with other federal agencies measures for eliminating PCB-containing carbonless copy paper from existing inventories. If feasible, this action would reduce the primary source of PCB's found in paper food-packaging materials permitting FDA to reduce the temporary tolerance, and eventually to eliminate the need for regulating this unavoidable source of PCB's in food.

Accordingly, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 402(a), 406, 409, 701, 52 Stat. 1046 as amended, 1049, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948, 72 Stat. 1784–1788 as amended; 21 U.S.C. 342(a), 346, 348, 371) and under authority delegated to the Commissioner (21 CFR 2.120) Parts 3, 121, 128, and 135 are amended and a new Part 122 is added, as follows:

PART 3—STATEMENTS OF GENERAL POLICY OR INTERPRETATION

1. The following new section is added to Part 3:

§ 3.93 Use of polychlorinated biphenyls (PCB's) in establishments manufacturing food-packaging materials.

(a) Polychlorinated biphenyls (PCB's) represent a class of toxic industrial chemicals manufactured and sold under a variety of trade names, including: Aroclor (United States); Phenoclor (France); Colphen (Germany); and Kanaclor (Japan). PCB's are highly stable, heat resistant, and non-flammable chemicals. Industrial uses of PCB's include, or did include in the past, their use as electrical transformer and capacitor fluids, heat transfer fluids, hydraulic fluids, and plasticizers, and in formulations of lubricants, coatings, and inks. Their unique physical and chemical properties and widespread, uncontrolled industrial applications have caused PCB's to be a persistent and ubiquitous contaminant in the environment, causing the contamination of certain foods. In addition, incidents have occurred in which PCB's have directly contaminated animal feeds as a result of industrial accidents (leakage or spillage of PCB fluids from plant equipment). These accidents in turn caused the contamination of food products intended for human consumption (meat, milk and eggs). Investigations by the Food and Drug Administration have revealed that a significant percentage of paper food-packaging material contains PCB's which can migrate to the packaged food. The origin of PCB's in such material is not fully understood. Reclaimed fibers containing carbonless copy paper (contains 3 to 6 percent PCB's) have been identified as a primary source of PCB's in paper products. Some virgin paper products have also been found to contain PCB's, the source of which is generally attributed to direct contamination from industrial accidents from the use of PCB-containing equipment and machinery in food packaging manufacturing establishments. Since PCB's are toxic chemicals, the PCB contamination of food-packaging materials as a result of industrial accidents, which can cause the PCB contamination of food, represents a hazard to public health. It is therefore necessary to place certain restrictions on the industrial uses of PCB's in establishments manufacturing food-packaging materials.

(b) The following special provisions are necessary to preclude the accidental PCB contamination of food-packaging materials:

(1) New equipment or machinery for manufacturing food-packaging materials shall not contain or use PCB's.

(2) On or before August 6, 1973, the management of establishments manufacturing food-packaging materials shall:

(i) Have the heat exchange fluid used in existing equipment for manufacturing food-packaging materials sampled and tested to determine whether it contains PCB's or verify the absence of PCB's in such formulations by other appropriate means. On or before Sept. 4, 1973, any such fluid formulated with PCB's must to the fullest extent possible commensurate with current good manufacturing practices be replaced with a heat exchange fluid that does not contain PCB's.

(ii) Eliminate to the fullest extent possible commensurate with current good manufacturing practices from the establishment any other PCB-containing equipment, machinery and materials wherever there is a reasonable expectation that such articles could cause food-packaging materials to become contaminated with PCB's either as a result of normal use or as a result of accident, breakage, or other mishap.

(iii) The toxicity and other characteristics of fluids selected as PCB replacements must be adequately determined so that the least potentially hazardous replacement is used. In making this determination with respect to a given fluid, consideration should be given to (a) its toxicity; (b) the maximum quantity that could be spilled onto a given quantity of food before it would be noticed, taking into account its color and odor; (c) possible signaling devices in the equipment to indicate a loss of fluid, etc.; and (d) its environmental stability and tendency to survive and be concentrated through the food chain. The judgment as to whether a replacement fluid is sufficiently non-hazardous is to be made on an individual installation and operation basis.

(c) The provisions of this section do not apply to electrical transformers and condensers containing PCB's in sealed containers.

PART 121—FOOD ADDITIVES

2. In Part 121, § 121.2546(b) is amended by revising subparagraphs (1) and (2), as follows:

§ 121.2546 Pulp from reclaimed fiber.

* * * * *

(b) * * *

(1) Industrial waste from the manufacture of paper and paperboard products excluding that which bears or contains any poisonous or deleterious substance which is retained in the recovered pulp and that migrates to the food, except as provided in regulations promulgated under sections 406 and 409 of the Federal Food, Drug, and Cosmetic Act.

(2) Salvage from used paper and paperboard excluding that which (i) bears or contains any poisonous or deleterious substance which is retained in the recovered pulp and that migrates to the food, except as provided in regulations promulgated under sections 406 and 409 of the act or (ii) has been used for shipping or handling any such substance.

* * * * *

PART 122—UNAVOIDABLE CONTAMINANTS IN FOOD AND FOOD-PACKAGING MATERIAL

3. A new Part 122 is added as follows:

Subpart A—Definitions and Procedural and Interpretive Regulations

Sec.
122.1 Definitions and interpretations.
122.2—122.9 [Reserved]

Subpart B—Industrial Contaminants in Food and Food-Packaging Material

122.10 Temporary tolerances for polychlorinated biphenyls (PCB's).

AUTHORITY: Secs. 402(a), 406, 409, 701, 52 Stat. 1046 as amended, 1049, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948, 72 Stat. 1785–1788 as amended; 21 U.S.C. 342(a), 346, 348, 371.

Subpart A—Definitions and Procedural and Interpretive Regulations

§ 122.1 Definitions and interpretations.

(a) The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act shall be applicable to such terms when used in this part.

(b) Unavoidable natural, environmental, or industrial contaminants include any poisonous or deleterious substance added to any food where such substance cannot be avoided by good manufacturing practice.

Subpart B—Industrial Contaminants in Food and Food-Packaging Material

§ 122.10 Temporary tolerances for polychlorinated biphenyls (PCB's).

(a) Polychlorinated biphenyls (PCB's) are toxic, industrial chemicals. Because of their widespread, uncontrolled industrial applications, PCB's have become a persistent and ubiquitous contaminant in

MONS 028959

the environment. As a result, certain foods and animal feeds, principally those of animal and marine origin, contain PCB's as unavoidable, environmental contaminants. PCB's are transmitted to the food portion (meat, milk, and eggs) of food producing animals ingesting PCB contaminated animal feed. In addition, a significant percentage of paper food-packaging materials contain PCB's which may migrate to the packaged food. The source of PCB's in paper food-packaging materials is primarily of certain types of carbonless copy paper (containing 3 to 5 percent PCB's) in waste paper stocks used for manufacturing recycled paper. Therefore, temporary tolerances for residues of PCB's as unavoidable environmental or industrial contaminants are established for a sufficient period of time following the effective date of this paragraph to permit the elimination of such contaminants at the earliest practicable time. For the purposes of this paragraph, the term "polychlorinated biphenyls (PCB's)" is applicable to mixtures of chlorinated biphenyl compounds, irrespective of which mixture of PCB's is present as the residue. The temporary tolerances for residues of PCB's are as follows:

(1) 2.5 parts per million in milk (fat basis).

(2) 2.5 parts per million in manufactured dairy products (fat basis).

(3) 5 parts per million in poultry (fat basis).

(4) 0.5 parts per million in eggs.

(5) 0.2 parts per million in finished animal feed for food-producing animals (except the following finished animal feeds: feed concentrates, feed supplements, and feed premixes).

(6) 2 parts per million in animal feed components of animal origin, including fishmeal and other by-products of marine origin and in finished animal feed concentrates, supplements, and premixes intended for food producing animals.

(7) 5 parts per million in fish and shellfish (edible portion). The edible portion of fish excludes head, scales, viscera, and inedible bones.

(8) 0.2 parts per million in infant and junior foods.

(9) 10 parts per million in paper food-packaging material intended for or used with human food, finished animal feed and any components intended for animal feeds. The tolerance shall not apply to paper food-packaging material separated from the food therein by a functional barrier which is impermeable to migration of PCB's.

(b) A compilation entitled "Analytical Methodology for Polychlorinated Biphenyls, February 1973" for determining compliance with the tolerances established in this section is available from the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, MD 20852.

PART 128—HUMAN FOODS; CURRENT GOOD MANUFACTURING PRACTICE (SANITATION) IN MANUFACTURE, PROCESSING, PACKING OR HOLDING

4. In Part 128 by revising § 128.4 to read as follows:

§ 128.4 Equipment and utensils.

(a) *General.* All plant equipment and utensils should be (1) suitable for their intended use, (2) so designed and of such material and workmanship as to be adequately cleanable, and (3) properly maintained. The design, construction, and use of such equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces.

(b) *Use of polychlorinated biphenyls in food plants.* Polychlorinated biphenyls (PCB's) represent a class of toxic industrial chemicals manufactured and sold under a variety of trade names, including: Aroclor (United States); Phenoclor (France); Colphen (Germany); and Kanaclor (Japan). PCB's are highly stable, heat resistant, and non-flammable chemicals. Industrial uses of PCB's include, or did include in the past, their use as electrical transformer and capacitor fluids, heat transfer fluids, hydraulic fluids, and plasticizers, and in formulations of lubricants, coatings, and inks. Their unique physical and chemical properties and widespread, uncontrolled industrial applications have caused PCB's to be a persistent and ubiquitous contaminant in the environment and causing the contamination of certain foods. In addition, incidents have occurred in which PCB's have directly contaminated animal feeds as a result of industrial accidents (leakage or spillage of PCB fluids from plant equipment). These accidents in turn cause the contamination of food intended for human consumption (meat, milk, and eggs). Since PCB's are toxic chemicals, the PCB contamination of food as a result of these accidents represents a hazard to human health. It is therefore necessary to place certain restrictions on the industrial uses of PCB's in the production, handling, and storage of food. The following special provisions are necessary to preclude accidental PCB contamination of food:

(1) New equipment, utensils, and machinery for handling or processing food in or around a food plant shall not contain PCB's.

(2) On or before September 4, 1973, the management of food plants shall:

(i) Have the heat exchange fluid used in existing equipment or machinery for handling or processing food sampled and tested to determine whether it contains PCB's, or verify the absence of PCB's in such formulations by other appropriate means. On or before Sept. 4, 1973, any such fluid formulated with PCB's must be replaced with a heat exchange fluid that does not contain PCB's.

(ii) Eliminate from the food plant any PCB-containing food-contact surfaces of equipment or utensils and any PCB-containing lubricants for equipment or machinery that is used for handling or processing food.

(iii) Eliminate from the food plant any other PCB-containing materials wherever there is a reasonable expectation that such materials could cause food to become contaminated with PCB's either as a result of normal use or as a result of accident, breakage, or other mishap.

(iv) The toxicity and other characteristics of fluids selected as PCB replacements must be adequately determined so that the least potentially hazardous replacement is used. In making this determination with respect to a given fluid, consideration should be given to (*a*) its toxicity; (*b*) the maximum quantity that could be spilled onto a given quantity of food before it would be noticed, taking into account its color and odor; (*c*) possible signaling devices in the equipment to indicate a loss of fluid, etc.; and (*d*) its environmental stability and tendency to survive and be concentrated through the food chain. The judgment as to whether a replacement fluid is sufficiently non-hazardous is to be made on an individual installation and operation basis.

(3) For the purposes of this section, the provisions do not apply to electrical transformers and condensers containing PCB's in sealed containers.

PART 135—NEW ANIMAL DRUGS

5. The following new section is added to Part 135, Subpart B:

§ 135.113 Use of polychlorinated biphenyls (PCB's) in the production, handling, and storage, of animal feed.

(a) Polychlorinated biphenyls (PCB's) represent a class of toxic industrial chemicals manufactured and sold under a variety of trade names, including: Aroclor (United States); Phenoclor (France); Colphen (Germany); and Kanaclor (Japan). PCB's are highly stable, heat resistant, and nonflammable chemicals. Industrial uses of PCB's include, or did include in the past, their use as electrical transformer and capacitor fluids, heat transfer fluids, hydraulic fluids, plasticizers, and in formulations of lubricants, coatings, and inks. Their unique physical and chemical properties and widespread, uncontrolled industrial applications have caused PCB's to be a persistent and ubiquitous contaminant in the environment, causing the contamination of certain foods. In addition, incidents have occurred in which PCB's have directly contaminated animal feeds as a result of industrial accidents (leakage or spillage of PCB fluids from plant equipment). These accidents in turn cause the contamination of food intended for human consumption, (meat, milk, and eggs). Investigations by the Food and Drug Administration have revealed that heat exchange fluids for certain pasteurization equipment used in processing animal feed contain PCB's. Although heat exchange fluids in such equipment are considered to be in "closed systems", leakage has occurred that resulted in direct contamination of animal feed with PCB's and subsequently resulted in the transfer of PCB's to human food produced by animals consuming the contaminated feed. The use of PCB-containing coatings on the inner walls of silos has resulted in the contamination of silage which has in turn caused PCB

MONS 028960

residues in the milk of dairy cows consuming the contaminated silage. Since PCB's are toxic chemicals, the PCB contamination of food as a result of these and other incidents represent a hazard to public health. It is therefore necessary to place certain restrictions on the industrial uses of PCB's in the production, handling, and storage of animal feed.

(b) The following special provisions are necessary to preclude accidental PCB contamination of animal feed:

(1) Coatings or paints for use on the contact surfaces of feed storage areas may not contain PCB's or any other harmful or deleterious substances likely to contaminate feed.

(2) New equipment or machinery for handling or processing feed in or around an establishment producing animal feed shall not contain PCB's.

(3) On or before Sept. 4, 1973, the management of establishments producing animal feed shall:

(i) Have the heat exchange fluid used in existing equipment or machinery for handling and processing feed sampled and tested to determine whether it contains PCB's, or verify the absence of PCB's in such formulations by other appropriate means. On or before Sept. 4, 1973, any such fluid formulated with PCB's must to the fullest extent possible commensurate with current good manufacturing practices, be replaced with a heat exchange fluid that does not contain PCB's.

(ii) Eliminate to the fullest extent possible commensurate with current good manufacturing practices from the animal feed producing establishment any PCB-containing lubricants for equipment or machinery used for handling or processing animal feed.

(iii) Eliminate to the fullest extent possible commensurate with current good manufacturing practices from the animal feed producing establishment any other PCB-containing materials, whenever there is a reasonable expectation that such materials could cause animal feed to become contaminated with PCB's either as a result of normal use or as a result of accident, breakage, or other mishap.

(iv) The toxicity and other characteristics of fluids selected as PCB replacements must be adequately determined so that the least potentially hazardous replacement should be used. In making this determination with respect to a given fluid, consideration should be given to (a) its toxicity; (b) the maximum quantity that could be spilled onto a given quantity of food before it would be noticed, taking into account its color and odor; (c) possible signaling devices in the equipment to indicate a loss of fluid, etc.; (d) and its environmental stability and tendency to survive and be concentrated through the food chain. The judgment as to whether a replacement fluid is sufficiently non-hazardous is to be made on an individual installation and operation basis.

(c) For the purpose of this section, the provisions do not apply to electrical transformers and condensers containing PCB's in sealed containers.

(d) For the purpose of this section, the term "animal feed" includes all articles used for food or drink for animals other than man.

Any person who will be adversely affected by the provisions of §§ 121.2546 and 122.10 of the foregoing order may at any time on or before August 6, 1973 file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, MD 20852, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order, specify with particularity the provisions of the order deemed objectionable, and state the grounds for the objections. If a hearing is requested, the objections shall states the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Objections may be accompanied by a memorandum or brief in support thereof. Six copies of all documents shall be filed. Received objections may be seen in the above office during working hours, Monday through Friday.

Effective date. This order will become effective for foods, feeds, and paper food-packaging materials initially shipped in commerce after Sept. 4 1973 except as to any provisions of §§ 121.2546 and 122.10 that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be announced in the FEDERAL REGISTER. In the event § 122.10 is stayed by valid objections, pending a final regulation the Food and Drug Administration will enforce the levels stated in § 122.10 by seizing pursuant to sections 301 and 304 of the Act any food, feed, or paper food-packaging material shipped in commerce containing higher than the specified level of PCB's as adulterated in violation of section 402 of the Act.

(Secs. 402(a), 406, 409, 701, 52 Stat. 1046 as amended, 1049, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948, 72 Stat. 1785-1788 as amended; 21 U.S.C. 342(a), 346, 348, 371)

Dated: June 21, 1973.

SHERWIN GARDNER,
Acting Commissioner of Food and Drugs.

[FR Doc.73-13849 Filed 7-5-73;8:45 am]

MONS 028961

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

POLYCHLORINATED BIPHENYLS

Availability of Supplement To Final Environmental Impact Statement

The Commissioner of Food and Drugs published a notice in the FEDERAL REGISTER of December 21, 1972 (37 FR 28201) announcing that a statement entitled "Final Environmental Impact Statement—Rule Making on Polychlorinated Biphenyls" had been issued by the Food and Drug Administration.

Notice is hereby given that a statement entitled "Supplement to the Final Environmental Impact Statement—Rule Making on Polychlorinated Biphenyls" has been issued by the Food and Drug Administration. Copies of the supplement are available from the Office of the Assistant Commissioner for Public Affairs, Room 15B-42, or the Office of the Hearing Clerk, Room 6-88, 5600 Fishers Lane, Rockville, MD 20852.

This notice is issued pursuant to provisions of the National Environmental Policy Act of 1969, Public Law 91-190 (sec. 102(2)(c), 83 Stat. 853; 42 U.S.C. 4332), and under authority delegated to the Commissioner (21 CFR 2.120).

Dated: June 21, 1973.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.73-13548 Filed 7-5-73;8:45 am]

MONS 028962

FLUIDS

THERMINOL PYDRAUL SANTOVAC SANTOSOL SKYDROL TURBINOL COOLANOL

This information is prepared for internal use only and should be used with discretion, since it has not been completely evaluated for such considerations as toxicity and patent conflict, except as specifically stated.

Sales Information Bulletin No.

DATE: November 19, 1971

SUBJECT: ANALYTICAL LABORATORIES FOR PCB

Several customers have asked us for the names of laboratories who can successfully identify PCBs by analytical methods. Here is a list prepared by Bill Papageorge:

Woodson-Tenent Laboratories
345 Adams Avenue
P.O. Box 2135
Memphis, Tennessee 38102
Attention: Mr. J. Laubscher

Battelle Memorial Institute
Columbus Laboratories
505 King Avenue
Columbus, Ohio 43201
Attention: Mr. G. W. Kinzer

Monsanto Research Corporation
Dayton Laboratory
1515 Nicholas Road
Dayton, Ohio 45407
Attention: Dr. A. D. Snyder

WARF Institute, Inc.
(Wisconsin Alumni Research Foudation Institute)
P.O. Box 2037
Madison, Wisconsin 53701
Attention: Dr. Francis Coon

Analytical Bio-Chemistry Laboratories, Inc.
Interstate 70 East
P.O. Box 1097
Columbia, Missouri 65201
Attention: Mr. James P. Ussuary

These names should be passed on to interested customers.

Cumming Paton

MONS 028963

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FLUIDS

THERMINOL SKYDROL PYDRAUL SANTOSOL TURBINOL SANTOVAC COOLANOL



This information is prepared for internal use only and should be used with discretion, since it has not been completely evaluated for such considerations as toxicity and patent conflict, except as specifically stated.

Sales Information Bulletin No. #193

DATE: October 7, 1975

SUBJECT: ANALYTICAL LABORATORIES FOR PCB

SIB #60 gave a list of laboratories equipped to assist our customers with PCB analyses. This SIB up-dates that previous list.

Analytical Bio-Chemistry Laboratories, Inc.
Interstate 70 East
P. O. Box 1097
Columbia, Missouri 65201
(314) 474-8579

Carus Chemical Corporation
1375 Eighth Street
LaSalle, Illinois 61301
(815)223-1500

Gollob Analytical Service Corporation
47 Industrial Road
Berkeley Heights, N. J. 07922
(201) 464-3331

Limnetics, Inc. (Subsidiary of Carus Corp.)
6132 West Fond du Lac Avenue
Milwaukee, Wisconsin 53218
(414) 461-9500

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New England Analytical Testing Laboratory
2 Shady Oak Lane
Netick, Mass. 01760
(617) 873-8469

WARF Institute, Inc.
(Wisconsin Alumni Research Foundation)
P. O. Box 2037
Madison, Wisconsin 53701
(608) 241-4471

Woodson-Tenent Laboratories
345 Adams Avenue
P. O. Box 2135
Memphis, Tennessee 38102
(901) 525-6333.

David Wood

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