

CLIPPED BY
BACONS

The National Association of Printing Ink Manufacturers (NAPIM) has commissioned the National Printing Ink Research Institute (NPIRI) to prepare this brochure for the guidance of its members and their customers, the printers and converters, as well as other interested parties.

The members of NAPIM are dedicated to the betterment of their industry and the observance of the law. They intend to deliver printing inks that meet the requirements, not only of the application, but also of applicable government laws and regulations. In addition, they try through their association to ascertain what these requirements may be in the future, so as to be prepared to meet them with minimum delay, cost, and inconvenience.

The printing ink industry is a small but vital part of the graphic arts and communications industry, with annual sales of over \$600,000,000.

Department of
HEALTH, EDUCATION AND WELFARE
Food and Drug Administration
Washington 25, D. C.

Mr. Herbert Litwin
National Association of Printing Ink Makers
29 West 40th Street
New York, N. Y.

DEAR MR. LITTLE:

In response to your oral inquiry of this date restate as the reason under the Food Additives Amendment of printing ink for certain inserts in food packages, we are impressed on certain as follows:

We own of the opinion that printing into used in accordance with the principles of good manufacturing practice for human consumption is necessary dry granular feeds are not feed additive within the meaning of Section 201(g) of the Act in that there is no renovative representation of a significant magnitude of any of their constituents in the feed. Should, as my wife, information be brought to our attention that the composition of such ink be constituents foreign substances to such feed, we would of course reconsider the action.

000. Although small in size, this industry is complex and diversified, producing a large number of products with different formulations. It is estimated that one million new printing ink formulations are produced each year and another four-fifths million older-but still-useful formulations are kept on file. These different formulations use more than 2,000 different raw materials. Such a wide variety of products, each tailored to a specific application, can be produced only by a technically-sophisticated industry.

Printing inks serve the consumer in all aspects of his daily life: in the

The members of NAPII have an enviable record under normal circumstances, printed ink films do not cause harm or injury to the public. A discussion of this statement follows:

There are three ways in which substances can enter the body: 1 by ingestion; 2 by inhalation; 3 by contact. Any potential hazard from a printed ink film is almost certain to be by ingestion rather than by inhalation or contact. Although ingestion of printed matter is not a likely possibility, it should be pointed out

morning they identify his brand of toothpaste; in midday they establish his financial credibility in the form of printed currency and checks; in the evening they provide his entertainment in the form of reading material. Because this important contribution of printing inks often goes unrecognized or may even be taken for granted, the members of NAPIM are concerned that the products they offer for sale do not cause harm to the consumer or expose him to unnecessary risk.

that a small segment of the population suffers from pica, an abnormal craving for non-food items.

Early in 1973, a survey was conducted among the members of NAPIM to ascertain if any member company had knowledge of an instance in which an individual or the public suffered harm or injury because of the ingestion of printed matter. A "yes" or "no" declaration was requested for each of the following statements:

Regarding injury, harm or poisoning attributable to ingestion of printed matter.

1. I have personal knowledge of a case.
2. I have read about a case
3. I have heard of a case

Details were requested if any of the answers were "yes." The response to these statements was "no," unanimous for the first two and near-unanimous for the third (one respondent had heard of an alleged case of poisoning that occurred thirty years ago, another of alleged cases of allergy from handling printed matter; details were unavailable).

This result was supported by a literature search carried out by the Toxicology Information Program of the National Library of Medicine. This search turned up several investigations of the potential toxicity of printing inks and their ingredients, but no instance of harm, in-

March 11, 1955

FIGURE 1

(signed)
Einar T. Waldborg
Food and Drug Officer

jury, or poisoning attributable to ingestion of printed matter.

A subsequent survey of the voluminous literature on lead by NPIRI revealed only one case, reported in November 1973, in which ingestion of printed matter was suspected as contributing to an elevated blood level in a child afflicted with pica. Other non-food items implicated in the case were leaves, soil, and grass.

The members of NAPIM are determined to maintain this impressive record. They have expressed their determination by continued support of scientific research, by using good manufacturing and house-

edge and even less control over the final composition and use of his products.

For these reasons, NAPIM members cannot give blanket warranties or guarantees as to the conformance of their products with various laws and regulations, now can they accept responsibility for the use or misuse of their products.

NAPIM members are dedicated to observing the laws and regulations governing the use of their products and to cooperating with their customers to ensure that these products conform to the applicable laws and regulations.

stated in one of the letters (Figure 2). "The Food and Drug Administration has no authority . . . to approve specific products." Its only means of expressing approval is by promulgation of food additives regulations. Printing inks used in food packaging are not considered food additives; therefore, no regulation on this subject has been issued. Instead, the Food and Drug Administration has recommended that "printing inks (be used) on food packaging only under conditions where they are not food additives, that is, where no migration to food occurs" (Figure 3).

The Law and the Consumer

Prepared by the National Printing Ink Research
Institute for the National Association of
Printing Ink Manufacturers.

keeping practices, by establishing good communications with their customers and suppliers, and by trying to gain a better understanding of the subtle effects of the environment on the human body. This brochure is one result of NAPIM's concern and determination.

THE NAPIM POSITION

The members of NAPIM are in business to manufacture and sell printing inks. Each member company is eager to supply inks for specific applications in its area of specialization. However, NAPIM members are often asked to supply inks that meet the requirements, not only of the end use, but also of laws and regulations that do not apply to printing inks. In these cases, the printer or converter should not expect, nor should he be given the impression, that the inks supplied to him conform to these laws and regulations that do not apply to printing inks.

Moreover, ink formulations are often altered (intentionally or inadvertently) in the converting plant or even on the press. In these cases, the NAPIM member has little knowl-

THE LAWS THAT APPLY

Currently, there are three Federal laws that apply to the manufacture and use of printing inks:

1. The Food Additives Amendment (1958) of the Federal Food, Drug and Cosmetic Act (1938), as amended.

2. The U.S. Department of Agriculture Meat and Poultry Inspection Program Policy and Interpretation of Regulations.

3. The Federal Hazardous Substances Act (1960), as amended.

The Federal Food Additives Amendment to the Food, Drug, and Cosmetic Act. The Food Additives Amendment is concerned with additives to food and their effect on the human body. Its applicability to printing inks for food packages is outlined in a series of letters to NAPIM from the Food and Drug Administration (FDA), which are summarized below and reproduced in this text as Figures 1, 2, 3 and reprinted in the Appendix.

The term "FDA-approved inks" is incorrect, and its use is totally without foundation. *There are no FDA-approved inks.* As clearly

Printing inks formulated entirely from components that are "prior sanctioned," "generally recognized as safe," "color additives regulated for direct addition to food" or "food additives resulting from contact with containers or equipment and food additives otherwise affecting food" are not considered food additives unless the migration of ink components to the food is recognizable by observation or test. Moreover, printed films on coupon inserts in packages of ordinary dry granular foods are not considered food additives if there is no reasonable expectation of migration of ink components to the food.

The primary concern, however, is with food packaging inks other than those special cases described above. Due to certain performance requirements, many food packaging inks cannot be formulated entirely with "prior sanctioned" ingredients. Even in these cases, "the ink manufacturer should be very selective in choosing materials of very low toxicity" (Figure 3). Moreover, the printed ink film must *always* be separated from the food by a functional barrier that prevents migration of ink components to the food (Figure 2).

Therefore, ink films printed on the outside of a food package are not considered food additives provided the package serves as a functional

barrier between the ink and the food. If the printed ink film is applied to the inner food contact surface, it must be overcoated with a functional barrier film to prevent migration of ink components to the food.

The important requirement is that, with the exception of the dry granular foods case, the printed ink must always be separated from the food by a functional barrier. This functional barrier must prevent contact of the ink film with the food under *extra-ordinary* as well as ordinary conditions. Certain foods (e.g., candy, cake) soften in hot weather and adhere to the inner surface of the wrapper. Moreover, a person eating a candy bar or ice cream sucker may lick the food off the wrapper or even eat part of it. Therefore, it is especially important to formulate printing inks for these applications from ingredients of very low toxicity, even though there is a functional barrier between the ink film and the food that serves under ordinary conditions.

POLYCHLORINATED BIPHENYLS

The Food Additives Amendment of the Federal Food, Drug, and Cosmetic Act has also been applied to

limit the content of polychlorinated biphenyls (PCB's) in milk, dairy products, poultry, eggs, animal feed, fish and shellfish, infant and junior foods, and paper food packaging materials (Appendix 1).

Polychlorinated biphenyls are stable, heat-resistant, nonflammable chemicals that have been used industrially as electrical transformer and capacitance fluids, heat transfer fluids, hydraulic fluids, and plasticizers, as well as in the formulation of lubricants, coatings, and inks. Recently these compounds have been found to be a persistent and ubiquitous contaminant in the environment, causing contamination of certain foods. Also, they have been found in paper food-packaging materials made from both recycled and virgin pulp; in this case, their origin is not known.

Because of the persistence of these polychlorinated biphenyls and the difficulty in tracking down their origin, the Food and Drug Administration has issued temporary tolerances effective September 4, 1973. The temporary tolerance is 10 parts per million or 0.001 percent for paper food packaging materials intended for human food, finished animal feed, and any components of animal feed.

In the past, these compounds have been used as an ingredient of only a few specialty inks, and their prohibition presents few problems to the ink formulator. More important, however, is the possible contamination of printing inks by polychlorinated biphenyls of indeterminate origin, which can be resolved only by accurate chemical analysis.

U.S. Department of Agriculture Meat and Poultry Inspection Program and Interpretation of Regulations: The United States Department of Agriculture has jurisdiction over the packaging of meat and poultry in federally-inspected packing houses. The policy governing the use of various materials in these packaging applications is outlined in the "USDA APHIS Materials Evaluation and Acceptance" (Appendix 2).

This policy states that any material used in or on a container (for federally-inspected meat and poultry food products) must be considered a potential food additive. These materials must be examined for substances that are toxic or hazardous, or that could migrate to the food under the conditions of use. Materials found to be acceptable can be described as "accepted by APHIS.

FIGURE 2

S. 2. 2. 1

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Food and Drug Administration
Washington, D. C. 20205

May 25, 1973

National Association of Printing Ink Editors
20 West 40th Street
New York, N. Y. 10018

Attention: Mr. R. B. Leving

Dear Sir:

This letter is in response to your letter of May 1, requesting the above labeled requested Food and Drug Administration approvals of printing ink.

The Food and Drug Administration has no authority under the Food Additives Amendment of the Federal Food, Drug, and Cosmetic Act to approve specific substances. The only action we have of authority is to approve or disapprove the use of a substance in a food or drug.

We have had a number of requests in the subject of printing ink used on food packaging and we have advised requesters as follows:

1. It is our policy that printing ink applied to the outside surface of food packaging materials can be used without further approval of the Food and Drug Administration. The only action we have of authority is to approve or disapprove the use of a substance in a food or drug.
2. The printing ink for food contact must be of a type that is not known to be a potential hazard to health. In this case, printing ink must be of a type that is not known to be a potential hazard to health. In this case, printing ink must be of a type that is not known to be a potential hazard to health.
3. We have no authority to approve or disapprove the use of a substance in a food or drug.

4. We have no authority to approve or disapprove the use of a substance in a food or drug.

If you are of assistance in processing the food additive status of a printing ink, we will be pleased to do so up to the time we have received sufficient information to make a decision.

Sincerely yours,

Robert A. Smith
Deputy Assistant Secretary
Food and Drug Administration
Washington, D. C. 20205

S. 2. 2. 1

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Food and Drug Administration
Washington, D. C. 20205

May 25, 1973

Mr. Douglas S. Warner
National Association of Printing Ink Manufacturers
141 Congress Building
Flushing, New York 10335

Dear Mr. Warner:

This letter is in response to your letter of April 25, requesting your request on the printing of food and drug packaging materials.

My letter of May 15, 1973 should be changed slightly. The following points should be corrected. First, the ink manufacturer should be responsible for ensuring that the ink is of a type that is not known to be a potential hazard to health.

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USDA" in catalogs, brochures, and letters, but not in advertising.

Printing inks used in packaging of meat and poultry food products can be divided into three categories: 1. branding inks; 2. inks for insert labels; 3. inks for the outside of the immediate container.

Printing or branding inks that are applied directly to food may contain only water, ethanol, acetone, sugar, and FDA-certified food colors.

Printing inks for label inserts must conform to the Food Additives Amendment and may contain only FDA-certified food colors.

Package and label inks (and overprint varnishes) for the outside of the immediate container must be formulated from vehicles that conform to the Food Additives Amendment and pigments from that Regulation of FDA Provisional Lists of Food Colors, or from dyes and pigments accepted by the Scientific Services (USDA). Acceptable colorants include: the provisionally-listed color additives; titanium dioxide; carbon black made by the impingement process; iron oxides; phthalocyanine blue, ultramarine blue; calcium and magnesium lakes of FD&C dyes; and certain organic coloring materials. Specifically excluded are: lakes or pigments containing antimony, arsenic, cadmium, chromium, lead, mercury, and other toxic metals; fluorescent brighteners; known

carcinogens, mutagens and teratogens.

It is agreed among NAPIM members to identify inks that are acceptable for the outside of the immediate container as "meat and poultry" inks or "M&P" inks.

The USDA evaluation of proposed materials takes into account the conditions of use, i.e., the type of food (aqueous or fatty) and the temperatures to which the material will be exposed. The temperature categories include: 1. "below 150°F"—frozen food storage, room temperature storage, shrink tunnel treatments where the temperature of the food does not rise appreciably; 2. "below 250°F"—the foregoing plus boil-in-the-bag, heat sterilization, retorting, etc.; 3. "oven temperatures"—the foregoing plus roasting or cooking above 250°F.

The following information must be submitted for evaluation of a proposed material: 1. the brand name or manufacturer's code; 2. a description of the conditions of use; 3. a list of components or ingredients. Trade secrets and proprietary information are held in confidence and used only to evaluate the material.

Federal Hazardous Substances Act (1960) as Amended. The Hazardous Substances Act covers substances used in the household that are: toxic; corrosive; irritants; strong sensitizers; flammable or combustible;

generate pressure through decomposition, heat, or other means; cause substantial personal injury or illness during or as a proximate result of any customary foreseeable handling or use, including reasonably foreseeable ingestion by children. It is applicable only to materials shipped in interstate commerce.

Initially, the Act was administered by the Food and Drug Administration. As a result of the recent Consumer Product Safety Act, which will be discussed later, jurisdiction is now under the newly created Consumer Product Safety Commission.

A 1972 amendment (6) to the Federal Hazardous Substances Act specifically bans any paint or similar surface coating material intended for use in or around the household that contains more than 0.5 percent lead. Also banned is any toy or other article intended for use by children that bears any paint or similar surface-coating material containing more than 0.5 percent lead.

The Act also provides that the allowable lead content of household paints and paints for children's toys be lowered to 0.06 percent after December 31, 1973; however, at the time of writing, the Consumer Product Safety Commission has deferred the implementation of this new limit.

The applicability of the Federal Hazardous Substances Act to printing ink is outlined in a letter from HEW to NAPIM (Figure 4), which is summarized below.

Printing inks in general are not subject to regulation under the Act because they are not considered a paint or similar surface-coating material nor are they intended for use in the household.

Printed ink films applied to children's toys, however, are subject to regulation by the Act, i.e., their lead content must be less than 0.5 percent. The package in which the toy is sold is generally considered to be part of the toy unless it is obviously intended to be discarded (e.g., as is a cardboard header or display carton).

State and Local Regulations

The foregoing Federal laws may not be applicable in all communities

C O P I

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Food and Drug Administration
December 16, 1972

Address reply to:
Bureau of Product Safety
1001 Woodland Avenue
Washington, D.C. 20535

Mr. Charles B. Wilbur, Executive Director
National Association of Printing Ink Manufacturers
191 Eastman Boulevard
Brooklyn, New York 11201

Dear Mr. Wilbur:

This is in reference to your letter of December 11, 1972, requesting information to determine the printing inks of the order of March 11, 1972, containing certain lead-containing pigments and other printer surface-coating materials on certain household containers.

Since the printing inks you described are not intended or packaged to be used suitable for use in or around the household, they are not subject to the above regulation. In any event, printing inks would not be considered a paint or other similar surface-coating material.

They are other matter regulated and used by children are covered by the Federal Hazardous Substances Act if they bear or contain a hazardous substance. No regulation is necessary to implement these provisions of the Act. The packaging of a toy is generally considered to be part of the toy unless it is obviously intended to be discarded, as is a "cardboard header" or display carton.

I appreciate reporting the way of your Printing Ink Handbook and will issue it for future reference. It is not to be of any further use in this matter, please let us know.

Sincerely yours,

(signed)
Paul W. Sullivan
Special Agent in Charge
Division of Consumer
Bureau of Product Safety

FIGURE 4

**The
Chemist Distributors**

Subsidiaries of
Central Solvents & Chemicals Company

Atlanta (404) 448-7122
Atlanta Solvents & Chemical Company
Buffalo (716) 876-1871
Buffalo Solvents & Chemicals Corporation
Chicago (312) 594-7000
Central Solvents & Chemicals Company
Cincinnati (513) 242-7700
Amoco Solvents & Chemicals Company
Cleveland (216) 282-1100
Ohio Solvents & Chemicals Company
Dallas (214) 827-3450
Texas Solvents & Chemicals Company
Detroit (313) 941-4088
Western Eastern Solvents & Chemicals Company
Ph. Wayne (216) 748-5153
Hosler Solvents & Chemicals Corporation
Grand Rapids (616) 245-8111
Wolverine Solvents & Chemicals Company
Greenboro (810) 464-1161
Southern Solvents & Chemical Company
Houston (713) 875-5241
Texas Solvents & Chemicals Company
Indianapolis (317) 838-1381
Hosler Solvents & Chemicals Corporation
Kansas City (816) 241-5223
Missouri Solvents & Chemicals Company
Los Angeles (213) 775-2471
Central Solvents & Chemicals Co.
Louisville (502) 466-6111
Dixie Solvents & Chemicals Company
Milwaukee (414) 784-2488
Wisconsin Solvents & Chemicals Corporation
Minneapolis (612) 528-9238
Wisconsin Solvents & Chemicals Corporation
New Orleans (804) 537-4888
Southern Solvents & Chemicals Corporation
Pittsburgh (412) 623-2570
Allegheny Solvents & Chemicals Company
Portland, Ore. (503) 286-5821
Central Solvents & Chemicals Co.
St. Louis (314) 421-3488
Missouri Solvents & Chemicals Company
Salt Lake City (801) 282-0457
Central Solvents & Chemicals Co.
San Antonio (512) 523-0123
Texas Solvents & Chemicals Company
San Francisco (415) 471-5428
Central Solvents & Chemicals Co.
Seattle (206) 228-0088
Central Solvents & Chemicals Co.
Spokane (509) 325-4918
Central Solvents & Chemicals Co.
Toledo (419) 526-3771
Toledo Solvents & Chemicals Company
Toronto, Ontario (416) 748-1881
Western Solvents & Chemicals (Can.) Ltd.
Vancouver, B.C. (604) 528-1881
Western Solvents & Chemicals (Can.) Ltd.
Windsor, Ontario (519) 252-5776
Western Solvents & Chemicals (Can.) Ltd.

Provo-Quin S.A. de CV
Guadalajara, Jal., Mex. 12-18-00
Leon, Gto., Mex. 3-08-52
Mexico City, D. F. 567-01-55
Monterrey, N.L., Mex. 52-47-90
Puebla, Pue., Mex. 2-86-12
Tijuana, Baja, Mex. 3-36-73

THE SOLVENTS & CHEMICALS COMPANIES
7000 W. 71st. Street, Chicago, Illinois 60638

in the United States. For example, the USDA meat and poultry regulations are applicable only in federally-inspected packing houses, and the Federal Hazardous Substances Act applies only to items shipped in interstate commerce.

To ensure the protection of their residents, many states and municipalities have passed ordinances similar to the Federal laws. Others will pass such ordinances in the future. The provisions of many of these ordinances are identical to those of the Federal laws, but some differ significantly and thus should be checked locally.

LAWS THAT DO NOT APPLY

The following laws were enacted only recently and have not yet been fully implemented; however, at the time of writing, they are not considered to be applicable to printing inks.

Consumer Product Safety Act

The Consumer Product Safety Act of October 28, 1972, created an independent regulatory Consumer Product Safety Commission, effective December 19, 1972. The principal purpose of this Act is to protect the consumer from unreasonable risk of injury associated with consumer products.

The Commission is empowered to develop and impose safety standards for consumer products under its jurisdiction. Products for which no feasible standard can be developed may be banned as hazardous.

Also, the Act transfers to the Commission a number of other functions heretofore administered by other Federal agencies, among them the Federal Hazardous Substances Act heretofore administered by the Food and Drug Administration.

Aside from the provisions of the Federal Hazardous Substances Act, which are discussed in the foregoing section, this new Consumer Product Safety Act is not considered to be applicable to printing inks.

Federal Flammable Fabrics Act

At the time of writing, the Federal Flammable Fabrics Act is not considered to be applicable to printing inks; however, the inks used for

printing vinyl upholstery and textiles may possibly be construed as subject to this Act.

Federal Poison Prevention Act

At the time of writing, the Federal Poison Prevention Act is not considered to be applicable to printing inks.

GENERAL OBSERVATIONS ON PRINTING INKS

Printed ink films comprise only a small part of the total weight and volume of a printed sheet. Just how small this part is can be shown by calculating typical ink film thicknesses. Let us assume that the coverage of an ink is in the range 150-300,000 square inches per pound of ink and that the specific gravity of the ink is 1.2. Complete and uniform coverage of the substrate give an ink film thickness of only 2-4 microns (25,000 microns equal one inch). Just what proportion of the printed sheet this 2-4-micron-thick film would comprise depends upon the thickness of the sheet and the extent of ink coverage. For example, if the paper thickness were 5 mils and its porosity 50 percent, the ink film of 2-4 microns thickness completely covering its surface would amount to only 1.5-3.0 percent of its total volume and 0.75-1.5 percent of its total weight.

In many cases, however, the printed ink film covers only a small part of the surface, often 5 percent or less. A 2-4-micron-thick ink film covering 5 percent of the surface of the same paper sheet would amount to only 0.08-0.16 percent of the total volume and 0.04-0.08 percent of the total weight of the printed sheet. These very small proportions would be correspondingly smaller for thicker paper or paperboard substrates and correspondingly greater for greater coverages.

These very thin printed ink films usually are not subject to peeling or flaking (as are paint films which become embrittled with age). Therefore, it is unlikely that fragments of free ink films would be ingested by an individual. Instead, the ingestion of printed ink films usually requires the ingestion of the entire printed substrate. Such ingestion by adults

is unlikely, but must be considered as a possibility with children.

The more-than-2,000 different ingredients used in the formulation of printing inks include a wide variety of pigments, dyes, polymers, resins, solvents, catalysts, driers, antioxidants, and surfactants. Some of the pigments used are lead compounds. Although the effects of excess lead in the body are known to be harmful, these lead pigments can be used in printing inks, subject to the laws described in the foregoing section and employing good formulation practices, with negligible risk of harm to the public.

Some printers and converters have asked their ink suppliers for "lead-free" inks, and some ink makers have used this term in promoting their products. This usually means that the inks have been formulated with non-lead-based pigments. However, the term "lead-free" is a misnomer and a myth—"lead free" inks do not exist. Lead is all around us—in the food we eat, the air we breathe, the clothing we wear, as well as the newspaper or magazine we read. In most cases, the lead concentration is too small to be of concern.

The important point to consider with printing inks is the lead concentration in relation to the possibility of ingestion. For example, food containing 1,000 parts per million or 0.1 percent of a soluble lead compound would certainly cause lead poisoning if ingested in sufficient quantities over a prolonged period of time. In comparison, a magazine color page containing 1,000 parts per million of a sparingly-soluble lead pigment encapsulated in a polymer matrix would pose no hazard to the consumer, provided it were not ingested. Even if such a page were ingested, it would be unlikely to cause any harm, because there is considerable doubt whether sparingly-soluble lead compounds can be digested completely and absorbed by the body through the digestive tract. Even if the digestion were complete, the ingestion of a single sheet would be unlikely to introduce enough lead to cause harm. Lead poisoning results from the continual intake of lead at a rate greater than that of

elimination. It is extremely unlikely that such a buildup could arise from the ingestion of printed matter.

Well-worked-out analytical procedures are available for the determination of lead and other heavy metals in printing inks. The methods and instrumentation used depend upon the metal to be determined, the solubility of the metal compound, its concentration, and the accuracy and precision required. The application of these analytical methods to printing inks is unnecessary in most cases and can be justified only in special cases. Because of the very large number of ink formulations produced each year, the cost of analyzing each batch would amount to a prohibitive total, which must be passed on to the user. Therefore, such analyses should be carried out only when necessary.

NPIRI ANALYTICAL FACILITY

NAPIM has established at the National Printing Ink Research Institute (NPIRI) an analytical facility for the determination of lead, other heavy metals, and PCB's in printed matter and its constituents. This facility will carry out analyses on a service basis not only for NAPIM members, but also for their customers and suppliers. In addition, it will be used in the NPIRI research program to survey the content of lead in various forms of printed matter. For more information, please

Reprints of this article may be obtained from the National Association of Printing Ink Manufacturers, 101 Executive Blvd., Elmsford, N. Y. 10523. The telephone number is 914-892-4836. Prices are \$50¢ for members, \$1.00 for non-members. Prices in bulk on request.

contact the National Printing Ink Research Institute, Lehigh University, Bethlehem, Pennsylvania 1801- (telephone (215) 691-7000, ext. 220)

REFERENCES AND APPENDIX

Figure 1. Letter to NAPIM from Wulfsberg of FDA, 3-11-63.

Figure 2. Letter to NAPIM from Strand of FDA, 5-28-65.

Figure 3. Letter to NAPIM from Strand of FDA, 5-26-71.

Figure 4. Letter to NAPIM from Hallman of FDA, 12-19-72.

Appendix 1. Excerpt from Federal Register 38 (129) 18096-18103, July 6, 1973.

Appendix 2. USDA APHIS Materials Evaluation and Acceptance, 1973.

Appendix 3. Excerpt from Food Drug Cosmetic Law Reports.

GUIDELINES FOR THE INK MAKER

1. Know the laws and regulations that apply to printing inks and follow them.
2. Find out as much as possible about the ultimate use of the ink and be prepared to advise your customers accordingly.
3. Recognize the limits of control you have over the ink you deliver and the extent to which you can assume responsibility for its use or misuse.
4. Maintain good housekeeping practices to rigorously segregate the various ink ingredients.

GUIDELINES FOR THE INK USER

1. Know the laws and regulations that apply to printing inks and follow them (NAPIM is one of the best sources for such information).
2. Inform the ink maker of the application and its special requirements.
3. Recognize that ink making is a highly-specialized activity and that each different application requires an ink formulated especially for it.
4. Maintain good housekeeping practices to avoid the inadvertent mixing of inks.

Appendix 1

EXCERPT FROM FEDERAL REGISTER

Volume 38, Number 129, Friday, July 6, 1973

pages 18096-18013

Title 21—Food and Drugs

CHAPTER 1—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 Foods, Feeds, and Food-Packaging Materials

PART 3—STATEMENTS OF GENERAL POLICY OR INTERPRETATION

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

§ 3.98 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 Kancelor (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. Recycled fibers containing carbonless copy paper (contains 3 to 5 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. 6, 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 408 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 408 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 MATERIALS

3. A new Part 122 is added as follows:

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

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

(b) 10 parts per million in paper food-packaging materials 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.

(c) A compilation entitled "Analytical Methodology for Polychlorinated Biphenyls, February 1973" for determining compliance with the tolerance limits listed in this section is available from the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-28, 5600 Fishers Lane, Rockville, MD 20852.

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Appendix 2

MATERIALS EVALUATION & ACCEPTANCE

United States Department of Agriculture
Animal and Plant Health Inspection Service
Meat and Poultry Inspection Program
Scientific Services
Washington, D. C. 20250

Introduction. The safety of materials for packaging and handling of meat and poultry food products is part of the responsibility assigned to the Meat and Poultry Inspection Program by the Federal Meat Inspection Act as amended by the Wholesome Meat Act of 1967 and by the Poultry Products Inspection Act as amended by the Wholesome Poultry Products Act of 1968. Materials containing, contacting, or even closely approaching food products may be composed of substances some of which could migrate to the food by diffusion, dissolution, absorption, accidental abrasion, or other means of transfer. Therefore, the materials must be examined for substances which are toxic or hazardous or which could migrate in undesirable amounts under the actual conditions of use. When a material or container is found acceptable for the proposed use, a letter of acceptance is issued referring to it by brand name or code. The supplier or manufacturer should make this letter available to buyers and inspectors as needed.

Requirement. Three pieces of information must be supplied for our evaluation of an item or group of items:

1. Brand name or manufacturer's identifying mark.
2. Description of the conditions of use.
3. List of substances composing the material.

The list must identify all major and minor constituents by proper chemical name as it appears in the appropriate Food Additives Regulation, or by reference to previous acceptance. Trade secrets and proprietary information are held in confidence and used only to evaluate the material. Send the information to:

Mr. John W. Sloan
Chemistry Staff
Scientific Services, APHIS
U.S. Department of Agriculture
Washington, D.C. 20250
Telephone: (202) 447-7888

Immediate Containers for meat or poultry food product must be fabricated of only those materials in compliance with the Food Additives Regulations, particularly 21 CFR 121 Subparts B (Exemptions), E (Prior Sanctions) and F (Containers). It is important to note the type of food in direct contact (aqueous and fatty) as well as the temperatures to which the packaged food will be exposed. "Below 180 degrees Fahrenheit" includes frozen storage, room temperature storage and shrink tunnel treatment, where the temperature of the food product does not rise appreciably. "Below 250 degrees Fahrenheit" includes These plus boil-in-the-bag, heat sterilization, retorting, etc. "Oven temperatures" includes all these plus roasting or cooking above 250 degrees Fahrenheit. Plastic resin films

must comply with the appropriate Food Additives Regulation extractability requirements. Adhesives for laminating and fabricating must comply with 21 CFR 121.2588 and pressure-sensitive adhesives for band labels, etc., must comply with 21 CFR 121.2577.

Ink and colorants are evaluated according to their use. Branding Ink, for direct and prolonged contact with meat or poultry, is described in the Manual of Meat Inspection Procedures, Sections 316.10 and 316.11. It may contain only water, ethanol, acetone, sugar and FDA certified food colors. Inks for insert labels must comply with 21 CFR 121.2614 plus FDA certified food colors. Package and label inks (and overprint lacquer) for the outside of immediate containers must have a vehicle in compliance with 21 CFR 121.2614 and pigments chosen from that Regulation or from FDA Provisional Lists of Food Colors or from dyes and pigments accepted by Scientific Services. The following are specifically excluded: Lakes or pigments containing Antimony, Arsenic, Cadmium, Chromium, Lead, Mercury and other toxic metals, fluorescent brighteners; known carcinogens, mutagens and teratogens. Colorants for plastic films, tubes, containers, etc., are subject to the same restrictions. Dyes and pigments should always be identified by their 5-digit Colour Index number or structural formula.

Equipment Materials are evaluated on the basis of their chemical composition. Small equipment such as aprons, bags, cutting boards, gloves, pins, saws, timers, tools, twins, etc., is handled the same as immediate containers. Larger equipment such as conveyor belting, hoses, metals, metal coatings, pipes, plastics, rubbers, solders, etc., must have its chemical composition cleared and then be referred to Equipment Staff, Plant Facilities and Equipment Staff, Technical Services Staffs, APHIS. Paints and coatings applied to equipment, machinery or panels before installation are evaluated similarly to inks by this office.

Paints and coatings to be applied on site are evaluated by the Compounds Evaluation Laboratory, as are chemical compounds such as cleaners, sanitizers, boiler water treatment, pesticides, lubricants, etc. Send this information, with small sample, to:

Mr. Donald D. Derr
Chemistry Staff
Scientific Services, APHIS
U.S. Department of Agriculture
Building 308, ARC
Beltsville, Maryland 20705

Telephone: (301) 344-2888

General Considerations. This Agency (APHIS) has no authority to evaluate materials for use with foods other than federally inspected meat and poultry. Materials which meet our criteria are termed "acceptable" because the term "approved" might erroneously indicate a preference for one brand over another. The phrase "accepted by APHIS, USDA" may be used in brochures, catalogs and letters to customers where valid but is inappropriate for use in advertising.

Although basic materials are often evaluated, it is more useful to the meat or poultry inspector to have an acceptance on the finished item as it appears in the processing or packaging area. Thus a corrugated carton might be found acceptable provided all its components—liner board, corrugating medium, adhesives, wax coating, printing inks, etc.,—comply with the requirements. This may be simplified to an acceptable corrugated stock plus an acceptable ink system. Similarly, a transparent package may consist of

acceptable polyvinylchloride film (PVC, stabilizers, plasticizers, etc.) plus an acceptable ink system.

Manufacturers requesting acceptance of many similar items such as a system of inks or paints differing only in pigment, gloves of the same material but different style, cartons of the same composition but various sizes, film of the same resin blend but different gauge, should group them in a convenient way to facilitate the acceptance. Materials not specifically described here or in the Food Additives Regulations must be considered individually and regulated in a way most likely to guarantee the consumer complete protection against toxic or hazardous substances. If a material is found to contain an unacceptable substance, the correspondent will be so advised and allowed to make a substitution or withdraw the request. Once an evaluation has been made and materials found acceptable, one final criterion must be met. The material, when placed in actual use, must perform in a safe and satisfactory manner.

Appendix 3

EXCERPT FROM FOOD DRUG COSMETIC LAW REPORTS 8-7-72, pages 494-5

[¶ 9309] Banned hazardous substances

➡➡➡ Caution: Reg. § 191.9(a) reads as amended and (a)(7) reads as added, effective September 24, 1972. —CCH.

§ 191.9 (a) Under the authority of section 2(q)(1)(B) of the act, the Commissioner declares as banned hazardous substances the following articles because they possess such a degree or nature of hazard that adequate cautionary labeling cannot be written and the public health and safety can be served only by keeping such articles out of interstate commerce.

(6)(i) Any paint or other similar surface-coating material intended, or packaged in a form suitable, for use in or around the household that:

(a) Is shipped in interstate commerce after December 31, 1973, and contains lead compounds of which the lead content (calculated as the metal) is in excess of 0.06 percent of the total weight of the contained solids or dried paint film; or

(b) Is shipped in interstate commerce between December 31, 1972, and December 31, 1973, and contains lead compounds of which the lead content (calculated as the metal) is in excess of 0.5 percent of the total weight of the contained solids or dried paint film.

(ii) Any toy or other article intended for use by children that:

(a) Is shipped in interstate commerce after December 31, 1973, and bears any paint or other similar surface-coating material containing lead compounds of which the lead content (calculated as the metal) is in excess of 0.06 percent of the total weight of the contained solids or dried paint film; or

(b) Is shipped in interstate commerce between December 31, 1972, and December 31, 1973, and bears any paint or other similar surface-coating material containing lead compounds of which the lead content (calculated as the metal) is in excess of 0.5 percent of the total weight of the contained solids or dried paint film.