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To: Dave Penney

From: Joe Ledvina

Date: August 2, 1991

Subject: **Basic Resin Doctrine**

Dave,

Enclosed is information on the Basic Resin Doctrine that we use to justify Vista PVC as FDA allowed. The three documents include an article by Jerry Heckman with a section on the Basic Resin Doctrine. The second attachment is correspondence from Keller and Heckman on the Doctrine. Attached to it is supporting documentation. Finally, I've included a proposed rulemaking from FDA that was intended to get approval for use of PVC in liquor bottles. There were several adverse comments on the proposal and EPA decided to require an Environmental Impact Statement before proceeding further. I'm not sure where the EIS stands, but the proposal is still on hold.

I included the proposal because it has a lot of specifics on PVC allowed applications. As you can see, the Basic Resin Doctrine is nowhere to be seen in the Federal Register. Keller and Heckman admit it is informal. It is my understanding that all the PVC producers supplying the FDA market rely on the Doctrine.

I'm interested in your thoughts on this.

Joe Ledvina

Joe Ledvina

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MANAGING EDITOR

Margaret Cahill Deegan
1701 K Street, N.W.
Suite 904
Washington, D.C. 20006

EDITOR EMERITUS: Frank T. Dierson, Esq.

FOOD DRUG COSMETIC LAW JOURNAL 42, 38–49 (1987)

Fathoming Food Packaging Regulation: A Guide to Independent Industry Action

JEROME H. HECKMAN, ESQ.*

When trying to chart a course through the laws of food packaging, many in the industry feel as if they have sailed into a blank space on the map, the kind anciently marked, "Here There Be Dragons." They are daunted by the prospect of venturing out alone upon these seemingly uncharted waters. Bewildered by an inscrutable agency that will not tell them plainly which food-packaging materials require government approval and which do not, packaging materials manufacturers persuade themselves that the only safe course is to seek the Food and Drug Administration's (FDA) imprimatur before marketing or using new food packaging. So they file a food additive petition with FDA and then they wait: often they wait a year, sometimes four years. Sometimes manufacturers are still waiting after ten years[1]—waiting for FDA to clear products which may not have needed approval at all, waiting because their "maps" of food packaging regulation did not point out the many situations where it is unnecessary and, in fact, ill-advised to approach the agency. For this reason, leading attorneys in the field have long

* Jerome H. Heckman is the senior partner in the Washington, D.C. law firm of Keller and Heckman. He is also General Counsel of the Society of the Plastics Industry, Inc., and a member of the *Journal's* Editorial Advisory Board. This article was prepared for publication in the *Journal*.

[1] *See, e.g.*, Food Chem. News, Jan. 14, 1985, at 4. The following table tracks FDA's indirect food additive petition record over the last nine years.

Pending Petitions for Indirect Food Additives 1977–1985

Year (as of Dec. 31)	Pending petitions filed	Total petitions pending	Time pending							
			Less than 6 mos.	More than 6 mos.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr. or more
1985	34	75	18	16	9	11	9	3	3	6
1984	33	84	15	18	21	11	5	4	2	8
1983	46	89	25	21	17	6	3	2	1	14
1982	47	85	29	18	12	9	2	1	6	8
1981	33	78	26	7	20	3	1	8	7	6
1980	36	68	12	24	7	3	9	8	4	1
1979	17	47	12	5	5	10	9	5	1	0
1978	13	46	4	9	12	10	9	1	0	1
1977	20	47	18	2	13	12	1	0	1	0

These statistics are derived from articles in Food Chem. News (Jan. 6, 1986, at 3; Jan. 7, 1985, at 3; Jan. 9, 1984, at 3; Feb. 2, 1981, at 3; Jan. 14, 1980, at 5; Jan. 15, 1979, at 4; and Jan. 16, 1978, at 4–5), FCN/PTCN ANNUAL YEARBOOK '82, at 26–34, and ANNUAL CHEMICAL NEWS REGULATORY UPDATE 1983, at 26–34.

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FOOD DRUG COSMETIC LAW JOURNAL 42, iii–iv (1987)

Reports to the Reader

Peter Barton Hutt, Development of Federal Law Regulating Slack Fill and Deceptive Packaging of Food, Drugs, and Cosmetics. *Food Drug Cosmetic Law Journal* 42, 1–37 (1987).

Foods, drugs and cosmetics are covered by slack fill and deceptive packaging laws. This article discusses the development of these laws, over a seventy-year period, and examines their interpretation and application. The author finds that most of the regulatory action taken by the Food and Drug Administration (FDA), and all of the litigated cases, involved slack fill of the immediate product container. Deceptive packaging, on the other hand, involved little regulatory action and no litigation. Furthermore, the author points out that FDA lost all of the slack fill cases that it pursued to litigation. In addition to the Federal Food, Drug, and Cosmetic Act (FD&C Act), the author also discusses the statutory authority given to FDA under the Federal Fair Packaging and Labeling Act (FPLA) and concludes, despite the litigation losses, that the FD&C Act and the FPLA are potent statutory weapons that FDA can use in the future against misleading packaging.

Jerome H. Heckman, Fathoming Food Packaging Regulation: A Guide to Independent Industry Action. *Food Drug Cosmetic Law Journal* 42, 38–49 (1987).

Food packaging regulation by the Food and Drug Administration (FDA) is a very beclouded area, complicated in part because much of the law is not officially recorded or codified conveniently. As a result, manufacturers often assume erroneously that the FDA's imprimatur is required prior to the use of any new packaging material or chemical component of a package or utensil. They frequently file food additive petitions with the Agency and wait long periods of time—as much as ten years—for a clearance by way of a Food Additive Regulation, when it may not be necessary or even desirable to seek FDA approval. The purpose of this article is to discuss the relevant law, place it in perspective for the marketer, and provide a guide to seven exemplary situations in which a packaging material may be marketed without going through the burdensome petition process.

Stephen H. McNamara, FDA Regulation of Food Substances Produced by New Techniques of Biotechnology. *Food Drug Cosmetic Law Journal* 42, 50–64 (1987).

This article reviews the regulatory requirements that apply to the introduction into commerce of a substance that is newly produced by techniques of modern biotechnology for human food use. The article includes review of pertinent statements published by the White House Office of Science and Technology Policy in 1984, 1985 and 1986, and statements of policy issued by the Food and Drug Administration (FDA) in 1984 and 1986. Other pertinent precedents are also included. To regulate food products that are produced by modern biotechnology, FDA has stated that it intends to apply existing requirements of law and related procedures concerning added poisonous or deleterious substances, food additives and generally recognized as safe (GRAS) substances. The Agency does not intend to establish new requirements or procedures specifically for food products that are developed with new techniques of biotechnology. Agency statements suggest that a new food additive regulation or a new GRAS affirmation regulation may be required for a food substance that is produced by new techniques of modern biotechnology. However, the author takes the position that at least some of these substances may qualify as GRAS without need for approval by regulation, or may come within the scope of existing GRAS or food additive regulations, in which case additional agency approval prior to marketing should not be required.

Daniel D. Jones and Albert E. Cunningham, The Use and Labeling of Animal Proteins in Meat Food Products. *Food Drug Cosmetic Law Journal* 42, 65–82 (1987).

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advised against seeking the agency's sanction when marketing can be accomplished legally without it.

Peter Barton Hutt, a highly respected fellow member of the food and drug law bar, and a former General Counsel of FDA, thus advised in 1969 that:

> [I]t is the primary and initial responsibility of the manufacturer of a product to determine the proper classification of his product, and to make certain that it meets all applicable legal requirements. It is in no instance necessary, and in most instances inadvisable, to ask the Food and Drug Administration for its opinion on the proper jurisdiction over the product. . . . [It] will probably seize upon any opportunity to state that the product should be handled as a [food additive]. It is therefore usually preferable for the manufacturer to exercise the obligation of proper classification given to him by the statute, rather than abdicating that responsibility to the Government.[2]

The goal of this article is to provide a guide to proper classification, *i.e.*, independent industry action, by calling attention to seven escape hatches from the FDA petition process which, taken together, constitute a most important part of the real law of food packaging. To a large extent, this body of law has not heretofore been gathered together or officially recorded. Yet it is firmly rooted in long-standing FDA policies and in some cases in the language of the Federal Food, Drug, and Cosmetic Act (FD&C Act) itself,[3] the source of FDA's authority over food packaging materials.

I. DEFINITION OF A FOOD ADDITIVE

The starting point for any discussion of the legal requirements for marketing food packaging materials is the definition of a food additive. FDA has authority over food packaging materials to the extent they are encompassed by the definition of a "food additive" under the FD&C Act.[4] Section 201(s) of the Act defines a food additive as:

> any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in . . . packing. . . . packaging. . . . or holding food . . .).

The definition specifically excludes substances that are (1) not reasonably expected to become a "component" of food;[5] (2) generally recognized as safe (GRAS) among experts qualified by scientific training and experience to evaluate their safety;[6] or (3) "prior sanctioned."[7]

Thus, under the definition, the term "food additive" includes not only substances directly added to food, but also substances, such as some packaging ma-

[2] Address by P. B. Hutt, Proper Classification of Products Under the Federal Food, Drug, and Cosmetic Act, presented at the Annual Convention of the Federal Bar Ass'n, Miami, Florida (Sept. 4, 1969). This paper dealt with cosmetics and drugs for the most part. With Mr. Hutt's permission, the bracketed [food additive] has been substituted for the word "drug."

[3] FD&C Act § 201–902 (1985), 21 U.S.C. § 301–392 (1982).

[4] FD&C Act § 201(s), 21 U.S.C. § 321(s).

[5] *Id.*

[6] *Id.*

[7] FD&C Act § 201(s)(4), 21 U.S.C. § 321(s)(4). A "prior-sanctioned" substance is one permitted or

terials, that contact and are reasonably expected to migrate into food, unless those substances are GRAS or prior-sanctioned. If a substance that is reasonably expected to become a component of food is not GRAS or prior-sanctioned, the statute provides that its use for food-contact applications must be authorized by a food additive regulation issued by FDA in response to a food additive petition.[8] As will be discussed below, however, "no migration," GRAS and prior sanction escape clauses are not the only saviors that make filing a food additive petition unnecessary. In addition, food additive petitions are not required for housewares, substances covered by the mixture doctrine, packaging materials separated from food by a functional barrier, and processing aids used to make a duly regulated polymer.

II. NO-MIGRATION DETERMINATIONS

No-migration is the most significant escape clause, for it provides the most used premise for self-determination that a food packaging material need not be subjected to FDA's onerous processes. Even as things stand today, no-migration is a potent and durable regulatory principle with a long history within the FDA folklore that is as much a part of the law as the codified principles.

Based on this exclusion, manufacturers are free to market food packaging materials without prior FDA review when there is a sound basis for concluding that any food contact substance not otherwise excluded or regulated is not a food additive because it is not reasonably expected to become a component of food under the conditions of its intended use.[9] A solid basis for adopting a "no migration—no food additive problem" position exists when properly designed and conducted extraction studies show no migration to food.

A key question has been what constitutes no migration, *i.e.*, must there literally be no migration or is an insignificant amount of migration permissible? This question received considerable attention in the case of *Monsanto v. Kennedy*.[10]

Monsanto arose from FDA's 1977 decision to ban the use of acrylonitrile/styrene (AN/S) copolymer in the fabrication of beverage containers on the basis that the substance was an unsafe food additive.[11] At issue was whether any unreacted AN monomer was reasonably expected to become a component of food. The evidence at the hearing clearly established that no AN monomer could be detected in test solvents designed to simulate food. The sensitivity of the analytical method was a state-of-the-art 10 parts per billion (ppb). Nonetheless, the Commissioner ruled that AN/S used in beverage containers is a food additive

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approved by FDA or the U.S. Dep't of Agriculture (USDA) prior to 1958, usually in response to an informal inquiry. These informal approvals attained official status with the enactment of the Food Additives Amendment of 1958.

[8] FD&C Act § 409(a), 21 U.S.C. § 348(a).

[9] *See* letter from Thomas W. Brown, FDA, to the author (Aug. 21, 1970); letter from the author to Thomas W. Brown, FDA (July 23, 1970); address by L.L. Ramsey, FDA, The Food Additive Problem of Plastics Used in Food Packaging, presented at the National Technical Conference of the Society of Plastics Engineers (Nov. 1969).

[10] 613 F.2d 947 (D.C. Cir. 1979).

[11] Acrylonitrile Copolymers Used to Fabricate Beverage Containers, Final Decision, 42 Fed. Reg. 48,528–44 (1977).

under section 201(s) of the FD&C Act based on the theoretical conclusion that some unpolymerized AN monomer will always migrate from the walls of the container into the beverage. Citing a lack of data demonstrating the safety of AN/S, the Commissioner determined that the agency would not authorize its use in the manufacture of beverage containers. Monsanto and several other manufacturers filed petitions for review of the agency's action, noting in particular the theoretical and *de minimis* nature of the AN migration projected by FDA.

The U.S. Court of Appeals for the District of Columbia Circuit held that migration occurs within the meaning of the FD&C Act only if a substance's "presence in food can be predicted on the basis of a meaningful projection from reliable data."[12] The court rejected FDA's contention that mere contact between food and its container made the container a food additive. Instead, the court stated that:

> Congress did not intend that the component requirement of a "food additive" would be satisfied by . . . a mere finding of any contact whatever with food. . . . For the component element of the definition to be satisfied, Congress must have intended the Commissioner to determine with a fair degree of confidence that a substance migrates into food in more than insignificant amounts.[13]

The court thus held that FDA has the discretion to determine that substances that migrate to food in very small amounts are not food additives.

Since 1979 FDA has cited *Monsanto* as support for decisions that go so far as to permit putative carcinogenic substances to remain on the market where the substances have been found to present insignificant risks to health. This was most recently evidenced by FDA's decision to continue to permit the use of methylene chloride for decaffeinating coffee on the basis that "the risk from the use of methylene chloride in decaffeinating coffee (no greater than 1 in 1 million) is so small as to be effectively no risk."[14]

FDA's use of the *de minimis* concept for substances it has characterized as carcinogens should reassure industry that the agency tacitly approves of no-migration determinations since it follows easily that any minute, undetected quantities of toxicologically innocuous indirect additives migrating to food must certainly be considered *de minimis*. Of course, manufacturers should not have to take silence as consent.

What has again become obvious to industry and to many at FDA is the idea that there should be explicit rulings evidencing a practical threshold of regulation. In other words, the agency should acknowledge the propriety of the use, without prior promulgation of food additive regulations, of substances that show no detectable migration above a certain safe level. In fact, FDA is now considering ways to implement this concept.[15] Ideally, the agency should also officially sanc-

[12] 613 F.2d at 955.

[13] *Id.* at 948.

[14] 50 Fed. Reg. 51,551 (1985). A new appeal of the Commissioner's methylene chloride decision was recently filed by several consumer groups. Public Citizen v. Bowen, C.A. No. 86-1540 (D.D.C. filed June 4, 1986).

[15] *See* letter from Dr. Sanford Miller, FDA, Dir. of the Center for Food Safety and Nutrition, to the author (Jan. 29, 1986). In his letter, Dr. Miller agreed that "there ought to be some conditions under

tion the no-migration exclusion by issuing routine letter opinions concurring in the non-additive status of substances not reasonably expected to become components of food. There is strong precedent for such a policy. Ironically, an early advocate of this approach was the agency itself.

In the early 1960s, it was the agency's practice to determine whether a packaging material presented a food additive problem when it first received a petition. FDA often found that new materials could properly be used in contact with food without a food additive regulation when migration was not detected using extraction tests sensitive to 1 or 2 parts per million (ppm).[16]

During the same era, Arthur Checchi, the agency's chief spokesman, gave talks advising the packaging world to do simple extraction studies and "tell us what you see. . . . [I]f we're satisfied you have no significant food migration (1 or 2 ppm) problem, we'll tell you you're home free."[17]

Then, in 1968, in response to widespread industry criticisms offered at the National Conference on Indirect Additives, FDA circulated a draft proposal. Simply put, this so-called "Ramsey proposal"[18] said that most substances migrating to food in quantities no higher than 50 ppb are not food additives. It would have applied a 50 ppb threshold of regulation to all substances, save those known to pose special toxicological concern, such as heavy metals and known carcinogens. Although never formally adopted, the standards used in the Ramsey proposal were deemed scientifically acceptable.[19]

In the absence of FDA's concurrence as to whether migration occurs in *de minimis* amounts, industry can take some comfort from the fact that FDA has the

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which FDA would be willing to say that a component of a food contact material would not require regulation as a food additive."

[16] *See, e.g.*, letter from J. Kenneth Kirk, FDA, to Eastman Chemical Products, Inc. (Apr. 14, 1961); *Monsanto*, FDA Docket No. 7GN-0070, Ex. M-79, Appendix at A-348; withdrawal of notice of filing, 26 Fed. Reg. 3438 (1961). *See also* W.B. Rankin, *Incidental Food Additives*, 14 FOOD DRUG COSM. L.J. 768 (1959) (quantity of migrating component may be so small that by definition it is not a food additive).

[17] Address by A. Checchi, FDA, Food Packaging Under the Food Additives Amendment—What Needs to be Done, 2, 3, presented at the 14th Annual Paper and Plastics Conference, Chicago, Ill. (Sept. 22, 1959):

> Once the extraction studies are completed, you will find yourself confronted with one of two possibilities. There may be no expected migration of any substance to food. If so, you're home free. The packaging material you have tested is not subject to the Amendment, except in the unlikely event that it otherwise affects the characteristics of the food contained in it.

See also A. Checchi, *Developments Under the National Pure Food Law Affecting the Packaging Industry*, 14 FOOD DRUG COSM. L.J. 527 (1959); J.K. Kirk, *Food Additive Developments*, 15 FOOD DRUG COSM., L.J. 755 (1960).

[18] The proposal is named for Mr. Lessel L. Ramsey, then Ass't Dir. of Regulatory Programs in FDA's Bureau of Science, who provided the details of the idea in a speech before the Society of Plastics Engineers the following year. Ramsey, *supra* note 9, at 5–6.

[19] Since the advancing of the Ramsey proposal in 1968, many in the packaging industry have used 50 ppb as a benchmark for "no reasonable expectation" of migration except in situations where exposures are apt to be high, as in the case of soft drink bottles. In this latter type of situation, 10 ppb is commonly used. What the "benchmark" really means is that industry will equate "no migration" to no detectability with a validated method sensitive to 50 or 10 ppb, as the case may be. As the Ramsey

burden of proving that a substance is a food additive. In a 1974 statement from the Office of the General Counsel, the agency acknowledged that the legal determination that a substance is a food additive must be based on more than migration *per se*.

> Finally, if any court action is brought, we [FDA] have the burden of proving two things: first, that the ingredient may reasonably be expected to become a component of the food, and, second, that the amount of migration involved is not generally recognized as safe. We would need expert testimony on both issues. The fact that extreme conditions produced extraction would not, in my opinion, be sufficient evidence in and of itself to justify a food additive conclusion. We would be required to put on evidence of experts showing that the extraction studies are reasonably related to actual use conditions and, thus, that the results can be extrapolated to normal use. We would also be required to show that the amount that might reasonably be expected to migrate is not generally recognized as safe and, thus, is a food additive.[20]

III. FUNCTIONAL BARRIER DOCTRINE

A subset of the "no-migration" exclusion is what we have come to call the functional barrier doctrine. If a substance is not part of the food contact surface of a package and is separated from the food by a barrier that does not permit migration of the substance to food, the substance may not be expected to become a component of food and does not fall within the definition of a food additive subject to FDA review. This functional barrier doctrine, already a well-established, though unpublished, FDA position,[21] received judicial confirmation in the 1975 case of *Natick Paperboard v. Weinberger*.[22]

Natick dealt with the issue of whether paper and paperboard containing high levels of polychlorinated biphenyl (PCB) contaminants were impermissible food additives. In 1973, Natick Paperboard and Crown Paperboard, two manufacturers of paper food-packaging material, brought an action in district court for injunctive and declaratory relief against an FDA proposal to seize paper food-packaging materials containing more than 10 ppm of PCB's.[23] On remand, after originally denying relief on the basis of lack of jurisdiction,[24] the district court granted summary judgment for FDA declaring that the agency had authority under the FD&C Act to recommend seizure of such paper packaging as adulterated food.[25]

Although the court of appeals affirmed the district court's decision, it made an important distinction regarding the food additive status of substances separated from food by a functional barrier. In relevant part, the court stated that if "the food placed in or to be placed in the paper container is or will be insulated from

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proposal dictates, these "rules of thumb" do not apply to known carcinogens, economic poisons or substances whose chronic toxicity levels are below 40 ppm in the diet. As to such substances, complicated risk assessment techniques must be employed to develop an "acceptable daily intake," against which an "estimated daily intake" can be measured.

[20] Memorandum from P.B. Hutt, FDA General Counsel, to S.D. Fine (Oct. 31, 1974); *Monsanto*, FDA Docket No. 76N-0070, Ex. M-70, Appendix at A-344-45.

[21] *See, e.g.*, letter from Frederick A. Cassidy, FDA, to the author (June 9, 1965).

[22] 525 F.2d 1103 (1st Cir. 1975), *cert. denied*, 429 U.S. 819 (1976).

[23] 367 F. Supp. 885 (D. Mass. 1973).

[24] 498 F.2d 125 (1st Cir. 1974).

[25] 389 F. Supp. 794, 798 (D. Mass. 1975).

PCB migration by a barrier impermeable to such migration, so that contamination cannot reasonably be expected to occur, the paperboard would not be a food additive . . . under the Act."[26] In other words, substances separated from food by a functional barrier are not food additives.

This approach often helps in determining the regulatory status of interior layers of laminates, outer layers of packages, and external printing inks. The only significant question for a food packager with respect to non-contact substances or layers is whether a true barrier exists; this question may be resolved by considering the package structure, the exposure conditions anticipated for the package, or, where necessary, by conducting appropriate extraction tests.

IV. GRAS SUBSTANCES

GRAS substances, as noted above, are also excluded from the regulatory impact of the food additive definition.[27] A producer may market any substance generally recognized as safe by qualified experts without FDA approval or notification.

In light of the FD&C Act's silence on the question of procedures for determining whether a substance should be classified as GRAS and the admitted incompleteness of FDA's official list of GRAS substances,[28] it is the initial responsibility of the manufacturer to determine whether a substance he manufactures is GRAS for any specific intended use. The GRAS status of a substance often turns on how it is being used and in what quantity. It is a popular misconception that a substance must be generally regarded as safe in all possible contexts in order to be deemed GRAS. The true key to GRAS status is the amount of the substance being used. As the *Monsanto* court noted, a substance may be considered GRAS in concentrations below a certain threshold even though it is not GRAS in higher concentrations.[29]

A manufacturer may make an independent GRAS determination through reliance on qualified experts and the scientific literature.[30] Obviously, should FDA consider a manufacturer's GRAS determination incorrect, the agency can take appropriate regulatory action; however, the burden is then on FDA to prove that the substance is not GRAS. A manufacturer who wishes to receive FDA's confirmation of an independent GRAS determination may file a GRAS Affirmation Petition and have his product placed on FDA's published GRAS list. Since the filing of a GRAS Affirmation Petition implies a good faith assertion by the petitioner

[26] 525 F.2d at 1107–08.

[27] FD&C Act § 201(s), 21 U.S.C. § 321(s).

[28] FDA's list of GRAS substances is set forth at 21 C.F.R. pts. 182, 184, 186 (1985). The agency acknowledges that this list is by no means exhaustive:

> The food ingredients listed as GRAS in Part 182 of this chapter or affirmed as GRAS in Part 184 or § 186.1 of this chapter do not include all substances that are generally recognized as safe for their intended use in food. Because of the large number of substances . . . , it is impractical to list all such substances that are GRAS.

21 C.F.R. § 170.30(d) (1985).

[29] 613 F.2d at 856.

[30] 21 C.F.R. § 170.30 (1985).

that the substance in question is in fact GRAS, and FDA's acceptance of the petition amounts to a prima facie finding that GRAS status is probable, the substance may be marketed while the petition is pending.[31] Substances affirmed as GRAS as "direct additives" (i.e., substances directly added to food) are also GRAS as "indirect additives" (i.e., additives used in packaging materials that indirectly become components of food), provided any applicable limitations on use are met.[32]

V. PRIOR-SANCTIONED SUBSTANCES

The prior-sanctioned exclusion, like that for GRAS substances, is drawn directly from the FD&C Act. Substances sanctioned by an FDA or USDA letter or memorandum issued prior to 1958 are not food additives.[33] A manufacturer may use any material prior-sanctioned for its intended application without further FDA clearance. As in the case of GRAS substances, there are many more prior-sanctioned substances than are listed in FDA's regulations or files.

The prior-sanctioned status of a substance is a question of fact depending solely on the existence of an appropriate pre-1958 letter. However, this does not mean FDA is powerless to control prior-sanctioned substances. The agency has attempted to limit the scope of the exclusion by consistently construing prior sanctions as narrowly as possible.[34] Though FDA is precluded from regulating a prior-sanctioned substance as a food additive, the agency can prohibit or set conditions on the use of any substance which it has proof is adulterating food.[35] Proof, however, is the critical word, for in a case of alleged adulteration, the government must prove that the amount of the substance getting into food is such that the food may be injurious to health within the meaning of section 402(a)(1) of the FD&C Act.

VI. HOUSEWARES EXEMPTION

The housewares exemption holds that substances sold for use in housewares such as dinnerware or eating utensils need no FDA clearance. This exclusion flows from the legislative history of the 1958 Amendment to the FD&C Act.[36]

The genesis of this exemption was a conversation between the author, as counsel for The Society of the Plastics Industry, Inc. (SPI), and Curt Borchardt, then counsel to the House Subcommittee on Health and Science, during Sub-

[31] This right is supported by the preamble to FDA's 1972 proposed GRAS regulation, 37 Fed. Reg. 6207 (1972), and a June 25, 1985 letter to the author of this article from Richard J. Ronk, Deputy Dir. of FDA's Center for Food Safety and Applied Nutrition. Mr. Ronk's letter stated that FDA would not take regulatory action against a direct food additive which was the subject of a pending GRAS affirmation petition. Other agency statements support this view as well.

[32] 21 C.F.R. § 184.1(a) (1985).

[33] FD&C Act § 201(s)(4), 21 U.S.C. § 321(s)(4).

[34] For example, FDA deemed that a food substance consisting in part of buffalo meat, sodium nitrate, and sodium nitrite did not conform to a prior sanction for meat food products under the Federal Meat Inspection Act because the Act's definition of such products did not specifically mention buffalo meat. United States v. Articles of Food . . . Buffalo Jerky, 456 F. Supp. 207, 209 (D. Neb. 1978), *aff'd sub nom.* United States v. Nielsen (8th Cir. 1979), *cert. denied*, 444 U.S. 832 (1979).

[35] 21 C.F.R. pt. 181 (1985).

[36] 104 CONG. REC. 17,418 (1958).

committee hearings on the Food Additives Amendment. Mr. Borchardt was asked whether the inclusion in the definition of a food additive of articles that are intended to "hold" food meant FDA would regulate melamine dinnerware and eating utensils. He replied that the Subcommittee did not intend to regulate nonsensically, and invited the author to draft a question and answer statement on housewares to be read into the legislative history. The statement subsequently placed in the legislative history by the Chairman of the Subcommittee, the Honorable John Bell Williams, read as follows:

> I have been asked since the Committee reported the bill what is meant by a substance "holding" food, as mentioned in the bill. An example of what is meant by this would be a plastic film or paper wrapper which surrounds a package of food. *This bill is not intended, for example, to give the Food and Drug Administration authority to regulate the use of components in dinnerware or ordinary eating utensils.*[37]

FDA has written many letters affirming this exclusion. With the exception of one point in the mid-1970s when it proposed to abolish the housewares exemption,[38] FDA's position has been and remains that it will not require Food Additives Amendment-type clearance of materials used to manufacture empty containers, utensils or appliances sold to the consumer for home use.[39]

VII. MIXTURE DOCTRINE

The mixture doctrine permits a manufacturer to physically blend two different polymers or substances if both are cleared by FDA for their intended use.[40] Such blends require no further FDA approval provided each individual substance in the mixture complies with any limitation in its respective regulation. For example, assume that polymer A is approved for use in packaging carbonated beverages. If polymer B is cleared for the same use, a blend of polymers A and B is also considered approved so long as each individual substance complies with any limitation in its respective regulation. If combining A and B results in a reaction forming a new substance "C," then C would need to be cleared, as appropriate.

VIII. BASIC POLYMER DOCTRINE

When FDA was granted authority to regulate what would become known as "indirect food additives" in 1958, regulations establishing conditions for the safe

[37] *Id.* (emphasis added).

[38] 39 Fed. Reg. 13,285 (1974).

[39] *See* letter from Joseph P. Hile, FDA Assoc. Dir. for Regulatory Affairs, to H.S. Dennenberg (Oct. 23, 1979); letter from Karen J. Skinner, FDA (Sept. 14, 1977). A 1958 FDA Food Law Institute Question and Answer Session discussion of housewares confirms FDA's contemporaneous understanding that preclearance of housewares was not included in the authority granted it in 1958. *See* FDA, *Answers to Questions Submitted at Washington Conference on November 24–25, 1958, to Discuss Food-Additives Amendment*, 14 FOOD DRUG COSM. L.J. 5, 13 (1959).

[40] Letter from William F. Randolph, FDA (Aug. 23, 1963); Address by W.F. Randolph, FDA, The Regulatory Control of Plastic Food-Packaging Materials in the United States, presented at the World Health Organization 5th Annual Seminar on Food and Drug Control for Central America and Panama, Managua, Nicaragua (May 1969); E.B. Detwiler, FDA, *Synthetic Polymers and the Federal Food, Drug, and Cosmetic Act*, SPE JOURNAL 61 (Jan. 1965).

use of polymers in contact with food were among the first to be promulgated. These original polymer regulations were designed to focus on what might migrate from the polymer into food. They regulated the polymer as a whole, not the complex variations in the polymerization process, which, for a given plastic, might involve the use of an extremely small amount of any one of a myriad variety of catalysts, reaction control agents, and other essential processing aids. At some point in the development of the polymer regulations, it must have been recognized that any attempt to regulate every phase of polymer production would be a herculean task that could never result in any kind of sensible regulation. Accordingly, FDA framed the earliest polymer regulations to put limits on what it anticipated might be significant migrants and did not in any way attempt to govern manufacturing processes, catalysts or reaction control agents.

Such was the state of polymer regulation in 1966 when an FDA panel speaking before an industry gathering further delineated the scope and intent of FDA's polymer regulations. At a question and answer session during a meeting of the Society of the Plastics Industry's Food Packaging Materials Committee, Assistant Director for Regulatory Programs Ramsey and Dr. Joseph McLaughlin of the Bureau of Science's Division of Toxicological Evaluation were asked: "What is a basic polymer?" In other words, what exactly does FDA mean when it issues a food additive regulation for a "basic polymer"? Dr. McLaughlin's response was described in a letter[41] to the SPI Food Packaging Materials Committee that is now part of the folklore as the first articulation of what has come to be known as the basic polymer doctrine:

> Commenting on a question as to what FDA means by its use of the terms "basic" or "base polymer" in various food additive regulations, Dr. McLaughlin explained that FDA presently considers the basic polymer to be the total polymer (without adjuvant type ingredients such as plasticizers) as it comes out of the polymerization process. He noted that if it is impossible to make the polymer without crosslinking agents, catalysts, anti-oxidants, or other necessary adjuvants, the basic polymer definition is intended to include such essential components employed at the polymerization stage.[42]

This basic polymer doctrine received further confirmation in 1968 at the FDA-sponsored National Conference on Indirect Food Additives, when, in response to a question, Mr. Ramsey made the following statement about how FDA regulates what goes into the manufacture of polymers:

> There are exceptions . . . with regard to the handling of certain substances that we really didn't regard as food additives, such as the catalysts, and the plastics industry is well aware of that. They use catalysts certainly by the dozens, if not by the hundreds.
>
> And there are no catalysts listed in the regulations unless the petitioner actually insisted that catalysts be put there.[43]

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[41] Dr. McLaughlin confirmed his statement regarding the definition of a "basic polymer" after the meeting. The letter from the author to the Food Packaging Materials Committee (Dec. 28, 1966) was shown to Messrs. Ramsey and McLaughlin before being mailed for any editorial revisions or comments they cared to make.

[42] *See* letter from the author to Food Packaging Materials Committee members (Dec. 28, 1966).

[43] PROCEEDINGS OF NATIONAL CONFERENCE ON INDIRECT FOOD ADDITIVES 202–03 (Feb. 12, 1968). Mr. Ramsey's final observation about catalysts being listed based on a petitioner's insistence confuses the issue. Petitioners have occasionally tried to steal a march on the competition by getting

What Mr. Ramsey said about catalysts applies with equal force to other "basic polymer" components such as reaction control agents and surfactants. The principle is the same, namely, that where a substance is used in only a small quantity and either becomes part of the resin during polymerization or is washed from the resin at the conclusion of polymerization, its potential for significant migration is minimal. In other words, there is no reasonable expectation of migration and therefore the substance is not considered a food additive.

Beyond reliance on the lack of likelihood that the *de minimis* presence of components like catalyst residues will ever cause a significant adulteration problem, FDA honors the basic polymer stance because of the inherent safeguards provided by the incidental additives good manufacturing practices regulation.[44] Under that regulation, it is a manufacturer's responsibility to make certain that any indirect food additive, or article made therefrom, is made in compliance with the adulteration provisions of the FD&C Act.[45] Whether it be a surfactant, a catalyst, or a reaction control agent, the manufacturer has an obligation to make sure any raw material he employs or food contact product he makes is suitable for its intended use.

FDA's reliance on good manufacturing practices to deal with any potential problems posed by polymerization agents is sound. It is also, perhaps, a tacit acknowledgment of the limits of generic food additive regulation. There simply is no way in which generic regulations can be framed to foresee every possibility. The only alternative to the good manufacturing practices approach would be a comprehensive licensing system which compelled case-by-case consideration of every particular of polymer production by each company. FDA has always rejected the individual licensing approach as impractical and administratively undesirable. From 1958 to this day FDA has consistently adhered to the philosophy that a food additive regulation "[is] a rule for all to follow, not a license to a single manufacturer."[46]

What this lesson in the philosophical history of polymer regulation means to industry is the following. As long as a polymer is listed in a regulation or is GRAS or prior-sanctioned and is manufactured in accordance with good manufacturing practices, the polymer is covered by that regulation or exclusion even though different manufacturers may make it by different processes.[47]

Thus, catalysts, chain transfer agents, surfactants and other substances essen-

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FDA to include their particular catalyst or manufacturing process in the regulation for a new polymer. FDA's willingness to do so says more about the agency's general "more regulation is better" philosophy than it does about the regulatory status of catalysts or the viability of the basic polymer doctrine.

[44] 21 C.F.R. § 174.5.

[45] FD&C Act § 402, 21 U.S.C. § 342.

[46] *Food Additives: Hearings Before Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 85th Cong., 2d Sess. 447 (1958) (statement of George P. Larrick, Comm'r of Food and Drugs); *see also id.* at 424–27, 436 (statement of Elliot L. Richardson, Ass't Sec'y for Legislation, Dep't of Health, Education and Welfare).

[47] Letter from Gerad L. McCowin, FDA, to the author (Nov. 15, 1985); letter from John L. Herrman, FDA, to Paul Garvin (Apr. 25, 1980); letter from Richard C. Kraska, FDA, to James T. Elfstrum (Apr. 3, 1980); PROCEEDINGS OF NATIONAL CONFERENCE, *supra* note 43, at 202–03.

tial to polymerization used in accordance with good manufacturing practices are considered part of the basic polymer and are implicitly cleared when the basic polymer is sanctioned. The basic polymer doctrine, however, does not apply to substances not essential to the polymerization reaction. Stabilizers, antioxidants, pigments, lubricants, and other adjuvants added after polymerization require specific clearance like other additives.

The regulation of polymers based on good manufacturing practices may not be absolutely foolproof, but it has long been recognized as the only reasonable approach. Going all the way back to the drafting of the Food Additives Amendment in 1958, there has been an awareness that any other conceivable regulatory method would enmesh FDA and the packaging world in complexities that would confound all indirect food additive regulation.

IX. CONCLUSION

The aim of this article is to fill in some of the blank spaces on the map of food packaging regulation and show that these waters are not always quite so perilous. A packaging materials manufacturer has many options to consider before turning to FDA for advice or approval. The agency's murky food additive policy need not inspire a "when-in-doubt, file-a-petition" attitude. Such reassurance is purchased at too high a price. A food packaging manufacturer often files a food additive petition because he would rather be safe than sorry. But by the time he emerges from the petition ordeal, he will certainly be sorry and may not be one whit more safe. A process statutorily limited to 180 days habitually takes far longer—approximately half of all food additive petitions take more than a year.[48] For manufacturers who need prompt food additive status assurance, the food additive petition is, at best, a poor solution, one which often leads to a long spell in the doldrums.

Fortunately, as we have seen, there are legitimate alternatives to the food additive petition in many cases. These alternatives are not legalistic loopholes, but rather practical refinements of the regulatory scheme entirely in keeping with the spirit of the FD&C Act and the protection of public health. They are grounded in the history of the agency itself. In the face of FDA's often shown unwillingness to do so, these exclusions help clarify what is and is not a food additive. These seven exclusions, and the "no-migration" concept in particular, represent common sense and reason in a regulatory area where obscurity, confusion, and excess have too long held sway. When charting a course through the food packaging laws, industry should recall that it has rights as well as obligations.

[48] One of the most egregious cases was the handling of Monsanto's food-additive petition to use the previously discussed acrylonitrile copolymer as a packaging material in its Cycle-Safe soft drink bottle. Despite the 1979 court decision in that case establishing the *de minimis* concept and remanding the case for agency reconsideration, the bottle was not cleared until 1984—more than 7½ years after Monsanto first sought clearance. Although the bottle was once considered to be a highly competitive material, it now has only a limited chance of being used for soft drinks in the United States because the market for these containers was satisfied during the intervening time by other materials.