PREFACE

Spurred on in the late 1980s by fears of an impending “landfill crisis,” state legislators found a ready remedy in recycling laws. Prompted by these new state laws, local governments put in place over 7,000 curbside recycling programs that began collecting tons of bottles, cans, jars, newspapers, and whatnot. In short order, the legislative refrain moved from “Recycle now” to “We need markets.” Legislators moved to calibrate recycling supply and demand with a host of proposed regulations—recycled content mandates, manufacturer “take-back” requirements, government procurement preferences, and various subsidies. Whatever the reason, deregulation as a way to expand recycling markets was virtually ignored.

This is unfortunate. Shorn of all its ideological trappings, recycling is essentially a process of innovation. Like electricity, cars, and computers, new recycling technologies must overcome a lot of institutionalized barriers to change. Many obvious regulatory barriers have been removed, but many still remain. Sometimes, these barriers are subtly hidden, disguised as unnecessary procurement standards or superfluous safety regulations. Sometimes, they're unintended side effects of unrelated legislation. But regulatory barriers do exist, and their elimination or modification ought to be the starting place for trying to enhance recycling markets.

It's time for a change of paradigm. For years, environmental policy has been run on a philosophy of “environment good, industry bad.” But this philosophy can't adequately deal with the reality of recycling—which blends environment with industry. This policy series, “Recycling and Deregulation: Opportunities for Market Development,” will cover the following areas:

- The use of recycled materials in food packaging, and why FDA regulations and other laws, originally enacted to protect the public health, can inhibit recycling;
- The recycling of hazardous wastes, and why some hazardous waste regulations, instead of protecting the environment, discourage the safe reuse of hazardous products, like lead batteries and used oil;
- The transport of solid waste, and developments to watch out for that could limit the supply of recyclables by discouraging their transportation;
- The scrap tire management problem, and how some state efforts to prevent tires piling up in garbage dumps are counterproductive;
- Recycled building materials, and how building codes unnecessarily prohibit their use;
- How industry standards groups, which governments rely on in their procurement practices, can discourage the use of recycled materials in products like plastic lumber and drainage pipes; and
- How government procurement agencies and miscellaneous other government bureaus, through superfluous regulation, stifle the development of innovative recycling technologies.

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THE FDA vs. RECYCLING:
Has Food Packaging Law Gone Too Far?

by
Alexander Volokh

EXECUTIVE SUMMARY

Since 1958, the Food and Drug Administration (FDA) has regulated the components of food packaging as "indirect food additives." The FDA doesn't have any special regulations for food packaging made with recycled materials. This means that any recycled material can be used as long as it's "suitably pure."

But no one knows how pure "suitably pure" is. This is a problem for packagers who use recycled material. Recycled paper and plastic come from many different, unknown sources, and are more likely to contain "contaminants" than virgin materials. This doesn't mean they're necessarily unsafe, but it does mean they're less "pure." So a standard that's too strict discriminates against recycled packaging.

To clarify things, the FDA issues informal "non-objection letters" to let packagers know that particular recycled content applications are O.K. Non-objection letters aren't required by law, but many packagers who use recycled material consider them a must. In July 1995, the FDA finalized its "threshold of regulation policy," announcing that it would exempt some substances from regulation as food additives. To qualify, the substance musn't be carcinogenic, and should have an expected dietary concentration of less than 0.5 parts per billion. This policy is now being applied to non-objection letter requests. It has simplified the process, but because of the FDA's backlog, the process is still lengthy and expensive. Getting a non-objection letter can take half a year and cost hundreds of thousands of dollars.

The FDA continues to be too restrictive in its food packaging regulations, and discourages new packaging applications, especially recycled-content packaging. Every non-objection letter request now requires an environmental assessment, which will add an extra few months of delay. Also, the FDA uses conservative risk assessment methods. It assumes the worst for any chemical, regardless of whether any migration of contaminants between the packaging and the food has been detected. When many studies have been done on a chemical, FDA uses the most pessimistic one, and extrapolates the results to humans in the most conservative ways. The new policy may actually tighten FDA standards. And the FDA gives itself blanket permission to sidestep its rules.

The FDA should:

- adopt reasonable risk assessment methods;
- act less arbitrarily by encouraging procedural certainty; and
- cut down on the delays in issuing non-objection letters by adopting a pre-market notification system and/or by farming out its approval system to approved, independent, competing labs.

We don't want to force food into recycled packages—that might not be safe. But we shouldn't discourage safe and profitable recycling. No one knows what "proper levels" are for recycled plastics in food

packaging, but we do know that the more of a drag the FDA is, the longer it'll take recycled material use to grow to desired levels, whatever they are. Add to that the burden of misguided state regulations—like California's Proposition 65, which was designed to protect public health but which has unintended perverse effects—and it's small wonder that recycled materials aren't being used much in food packaging. Prop. 65 was adopted in 1986 by voter initiative and was intended to improve health by informing consumers of products with carcinogens and reproductive toxins. But it has unintended effects. Because Prop. 65 also uses conservative risk assessment, violations of Prop. 65 don't necessarily correspond to actual risks. This means manufacturers spend a lot of money testing their products for tiny quantities of chemicals, and then spend a lot of money reformulating their products to not contain these chemicals—but we don't get any safer.

Again, such a state of affairs threatens recycled materials, which are more likely to have low levels of "bad" chemicals. At first, FDA-approved products were exempt from Prop. 65, but this "safe harbor" for food and drugs was rescinded in 1994. Now, packagers can find that while the FDA says their products are safe, the state of California doesn't. Because recycled paperboard, for instance, tends to have more contaminants than virgin paperboard, Prop. 65 may impede the use of recycled paperboard packaging.

Protecting health is important, but health isn't served by exaggerating risk and arbitrarily enforcing regulations. There are many forms of recycling that make economic sense and don't require a government mandate. But they are being discouraged by superfluous health regulations that don't protect people's health. If food additive regulations are properly eased, both the food packaging industry and the environment will benefit.

> *"I hate a man who swallows [his food], affecting not to know what he is eating. I suspect his taste in other matters."*
>
> —Charles Lamb, "Grace before Meat," *Essays of Elia*

> *"Why it's the Uneeda Biscuit made the trouble.*
> *Uneeda, Uneeda, put the crackers in the package, in the package,*
> *The Uneeda Biscuit in an airtight, sanitary package,*
> *Made the cracker barrel obsolete, obsolete."*
> *"Obsolete, obsolete, obsolete."*
>
> —Meredith Willson, "Rock Island," *The Music Man*

Introduction: THE DILEMMA OF FOOD PACKAGING RECYCLING

Food is beautiful, and Americans want theirs pure, clean, and safe. The Food and Drug Administration (FDA) is charged with maintaining the safety of our food supply. This means not only checking that our sausages are safe, but also making sure that we don't get poisoned through our food packaging. The FDA regulates what sorts of chemicals can go into any kind of packaging that comes into contact with food.

And Americans like recycling too. But recycling and food packaging may not always go great together—at least not according to the FDA. This attitude actually has a good deal of truth to it. Recycled plastic really is more likely to contain "contaminants" than virgin plastic, and so the FDA has been cautious in its regulation of food packaging with recycled content.

Too cautious, perhaps. The FDA has a long-standing reputation for being overcautious. Embedded in its risk assessment methods, the careful observer will find layer upon layer of conservative assumptions. And food packaging companies know better than most people how expensive and slow dealing with the FDA really is. Add to that the burden of misguided state regulations—like California's Proposition 65, which was designed to protect public health but which has some unintended perverse effects—and it's small wonder that recycled plastics aren't being used much in food packaging.

In this paper, I will explain the basics of food packaging law, and how it applies to recycled materials. I will examine the built-in conservatism of the FDA's risk assessment methods, and suggest possible reforms

that would continue to protect human health and safety while not deterring recycling that makes sense. I'll end the paper with a discussion of California's Proposition 65.

I. FOOD PACKAGING AND FOOD ADDITIVES[1]

Since 1958, the Food, Drug, and Cosmetic Act[2] (FD&C Act)—enforced by the FDA—has mandated pre-market approval of all substances which meet the definition of food additive. A substance is a food additive if its intended use "results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food."[3] "Direct food additives" are additives that have an intended technical effect in the food.[4] And since components of food packaging can migrate into the packaged food, food packaging materials are considered "indirect food additives."

The main purpose of the FDA's food additive regulations is to make sure that no component of food will make the food dangerous to human health. The regulations set specifications to identify a proper quality of food-contact material (whether plastic, paper, glass or metal) and, when necessary, limit the conditions of the material's use. Also, all indirect food additives, including packaging materials, must be of a purity suitable for their intended use.[5]

A. The Use of Recycled Plastics

The FD&C Act doesn't mandate special regulatory review or additional FDA clearance of recycled materials for food packaging. Neither do the FDA's Food Additive Regulations. This is because the FDA regulates food-contact materials based on their composition, and based on the identity and amount of the material that may migrate to food—not based on their manufacturing process. Any recycled material can be used if it complies with current regulatory requirements.[6]

The trouble with recycled materials, though, is that the people who wrote the original regulations weren't really thinking of them. No one petitioned the FDA to establish special regulations.[7] Thus, the regulations assume that packaging is being made out of virgin materials, or out of materials that come from a controlled source (rather than recycled materials, which may come from thousands of unknown sources). The concept of "suitable purity" is never defined. For instance, the regulations officially allow recycled paper and paperboard as long as neither "bears or contains any poisonous or deleterious substance which is retained in the recovered pulp and that migrates to the food."[8] This is a very general statement and can be interpreted as requiring a zero tolerance for contaminants.[9] So far, there are no regulations—no formal ones, that is—for the use of recycled materials in food contact applications.[10]

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1 Many thanks to Jerry Heckman, general counsel of the Society of the Plastics Industry, and the folks at Keller & Heckman, without whom I would not have been able to write this paper.

2 21 U.S.C. § 321 *et seq.*

3 Patricia S. Schwartz, Ph.D., Food and Drug Administration, "An FDA Perspective of Regulations for Food Packaging," p. 1.

4 Schwartz, p. 1.

5 21 C.F.R. § 174.5.

6 George Misko, "Regulatory Update: Recycled Plastics *Can* Be Used in Food Packaging If Safety Is Assured," *The New Food and Drug Packaging*, Aug. 1994.

7 Schwartz, p. 6.

8 21 C.F.R. § 176.260.

9 Schwartz, p. 6.

10 Sandra L. Varner, Supervisory Consumer Safety Officer, Food and Drug Administration, "Recycled Content in Plastic Food Packaging: Safety Issues," presented at "Survival Tactics thru the '90s," Society of Plastics Engineers Recycling Conference, June 14–16, 1993, p. 144.

"Clearly," as an FDA official put it, "some clarification is called for."[11] To date, FDA regulation of recycled materials has been "a mixture of common sense, informal opinion letters, and some rulemaking where necessary."[12] These informal opinion letters are called "non-objection letters."[13]

B. Non-objection Letters: Who Needs Them?

In the past, developers of food packaging with recycled plastic content had little guidance as to what sort of data the FDA required; they would submit their best guess to the FDA and hope for a non-objection letter. Sometimes, the FDA would respond by asking for more information, and the whole procedure usually took several months.[14]

But in May 1992, the FDA issued an informal guidance document to help manufacturers in the application process.[15] Current rules require recycled materials to meet the same standards as virgin materials. The recycled material suppliers have to make sure that the material is suitably free of contamination from microorganisms and toxic substances that can migrate to food. "Suitably free" has meant different things at different times. In 1992, different sources were indicating different thresholds between 0.5 ppb (parts per billion) and 1 ppb, which is perhaps an indication of how fluid FDA policy was at the time.[16] In general, a recycling process is acceptable if the FDA testing procedures show that the resulting dietary concentration is less than 0.5 ppb of contaminants.

In reality, though, because of the conservatism of the FDA testing procedures, the actual dietary concentration is much, much lower. This is how the FDA simulates contact with toxic chemicals to figure out dietary concentrations: "Contact with toxic chemicals can be simulated by exposing plastic packaging to selected surrogate contaminants. The plastic can be contaminated either by filling containers with the model contaminants or soaking several kilograms of flaked or ground plastic in the selected contaminants (depending on the recycling process). After mixing thoroughly, the bottles or flakes are stored with the contaminants for two weeks at 40^{o} C with periodic agitation. After draining off the contaminants, the level of each contaminant in the polymer is determined.... *These approaches represent worst-case scenarios*, i.e., all material entering the recycling stream is assumed to be contaminated."[17] Also, the formula used to calculate the dietary concentration of the contaminant, given the concentration in the packaging, assumes that all of the contaminant migrates into the food—which, of course, won't happen.[18]

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11 Schwartz, p.6.

12 Alan M. Rulis, Food and Drug Administration, director of the Division of Food and Color Additives, "FDA's Current Thinking on Recycled Polymers for Food-Contact Use," presented at GMA 1991 Environmental Issues Conference on Solid Waste, Washington, D.C., May 1, 1991, p. 2.

13 The food packaging literature alternatively refers to "non-objection letters," "no objection letters," and "letters of no objection." One article referred to "LONOs." Stephen Barlas, "FDA plans to speed approval for PCR use," *Packaging World*, June 1995. They are the same.

14 Eric F. Greenberg, "FDA issues guidelines on using recycled plastic for food packages," *Packaging Digest*, June 1992, p. 22.

15 *Points to Consider for the Use of Recycled Plastics in Food Packaging: Chemistry Considerations*, Chemistry Review Branch, December 1992. Available from Indirect Additives Branch, HFS-216, Food and Drug Administration, 200 C St. SW, Washington, D.C. 20204.

16 Helen R. Thorsheim, Ph.D., gave 0.5 ppb as an acceptable risk, in "Recycled Plastic in Food Contact Applications: The View from the Food and Drug Administration," presented during the PRD RETEC on "Plastics Recycling: A Blueprint for Success," Portland, Oregon, Sept. 23–24, 1992. Greenberg (1992) gave a figure of 1 ppb. Varner gave a "suggested" figure of 0.5 ppb. Thorsheim and David J. Armstrong, in "Recycled plastics for food packaging," *Chemtech*, August 1993, p. 55, gave a range of 0.5 to 1 ppb (p. 56, citing E.J. Machuga, G.H. Pauli, and A.M. Rulis, *Food Control* 1992, 3, 180). See below for the discussion of the "threshold of regulation" for food additives, and how the threshold ended up tightening the standards for recycled plastics.

17 Thorsheim, pp. 10–11 (emphasis added); see also Thorsheim and Armstrong, p. 57, and Varner, p. 148. The protocol is abstracted from *Points to Consider*.

18 Thorsheim and Armstrong, p. 56.

If the materials in reuse are "substantially identical" to the corresponding virgin materials, they can avoid undergoing a pre-market review process.[19] This means that any company that can establish to its own satisfaction that a recycled material is suitable for use in food packaging applications doesn't "officially" need to get the FDA's permission.[20] But since the authors of the food additive regulations didn't foresee recycling, the FDA has to determine how much regulation is necessary with recycled content food packaging materials—and it hasn't done that yet. During this "transition period," given the uncertainties involved in using recycled materials, the FDA "encourages manufacturers to consult with the agency."[21] Coming from the FDA, this isn't just an invitation.

Some industry members have questioned whether all manufacturers of post-consumer recycled plastic used to package food need FDA approval; according to Floyd Flexon, director of recycling for Johnson Controls' plastic container division, "You'll even find people within FDA who say, `Yeah, you probably don't.'" But while the FDA recognizes that some companies have, based on their research, sold their products without FDA's O.K.—which is perfectly legal—it stresses that companies do so at their own risk. If the agency finds out and comes to a different conclusion than the company, it could take regulatory action against the substance as an unsafe food additive or against the company that makes the substance for introducing an adulterated food into interstate commerce.[22] And the whole question is often moot anyway, since large food companies usually refuse to buy packaging that isn't FDA-approved.[23]

Things are different, though, in California, since the passage of the Rigid Plastic Packaging Container Program.[24] According to the Program, starting January 1, 1995 (January 1, 1997 for food[25]), all rigid plastic packaging containers sold in California must either be made from at least 25 percent post-consumer material, be recycled at a certain rate, be reusable or refillable, or be source-reduced.[26] Container manufacturers who choose to use recycled content have to "diligently seek non-objection letters" from the FDA by January 1, 1996;[27] and if a container with 25 percent post-consumer material can't meet FDA regulations, it has to comply under one of the other options.[28] "Diligence," here, means that the container manufacturers' "best efforts and research data result in an expectation that the Food and Drug Administration will conclude that the proposed use of the specific package complies with applicable regulatory standards." Moreover, by January 1, 1995, food product manufacturers were to have asked container manufacturers in writing to seek FDA non-objection letters.[29] (Oregon has a similar

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19 (1991), p. 5. See also Thorsheim, p. 9.

20 Misko.

21 Rulis (1991), p. 5.

22 Food Additives; Threshold of Regulation for Substances Used in Food-Contact Articles, 58 Fed. Reg. 52,719 (Oct. 12, 1993), at 52,720. In general, the FDA takes this view any time plastics are used in a slightly different way. Certain plastics were approved by the FDA before the advent of microwave technology; microwaveable packaging is subjected to higher temperatures than conventional packaging, and migration of foreign substances is proportional to temperature. "The higher level of exposure could also mean that FDA would require additional toxicological studies to demonstrate the safety of the new use for the packaging material. The key word here is demonstrate. It is not sufficient that the manufacturer be convinced that the new higher temperature use of a regulated packaging material is safe. If the new use results in significantly higher migration so that additional toxicological data are required to demonstrate safety, then the burden is on the manufacturer to provide those data to FDA prior to marketing the packaging material for the new higher temperature use." Schwartz, p. 2.

23 Patrick McCreery, "FDA May Implement Approval Policy for Recycled-Content, Food-Contact Plastic," *Recycling Times*, vol. 6, no. 23, November 15, 1994, p. 1.

24 California Code of Regulations, Title 14, Division 7, Chapter 4, Article 3, §§ 17942–17949.

25 California Code of Regulations, Title 14, Division 7, Chapter 4, Article 3, § 17944.2(a)(6).

26 California Code of Regulations, Title 14, Division 7, Chapter 4, Article 3, § 17944.

27 California Code of Regulations, Title 14, Division 7, Chapter 4, Article 3, § 17948.5.

28 California Code of Regulations, Title 14, Division 7, Chapter 4, Article 3, § 17944.2(a)(1).

29 California Code of Regulations, Title 14, Division 7, Chapter 4, Article 3, § 17948.5(b).

law.[30]) Not all companies will choose to use recycled content; many may well find source reduction a cheaper option. But those companies that do want to use recycled content will have to get a non-objection letter or be squeezed into possibly more expensive alternatives.

So while non-objection letters may not be statutorily required outside of California, major consumer food-product companies would never risk using recycled content without one. They are a necessary precaution to avoid getting into trouble with the FDA. Companies want to assure their customers that their packaging materials are safe and comply with regulations. And, despite the FDA's protestations that non-objection letters do not offer liability protection,[31] many companies find such letters an advantage in court. In a personal-injury lawsuit, a court could look favorably on a company that had a non-objection letter or that had made a good-faith effort to get one, even though it wouldn't be legally binding on the FDA.[32]

C. Thresholds of Regulation

In October 1993, the FDA announced that it was considering adopting a "threshold of regulation" for food additives.[33] The rule became final in July 1995.[34] The FDA has already been following this rule informally for a few years. Under the threshold of regulation policy, the FDA is formally exempting certain substances from regulation as food additives. To qualify:

- The substance mustn't be carcinogenic, because the use of carcinogens as food additives is prohibited by the Delaney Clause.[35] If the substance isn't carcinogenic but has a carcinogenic impurity, then the impurity should have a TD_{50} value greater than 6.25 mg/kg bodyweight/day.[36] Moreover, there must be no reason to suspect, based on the substance's chemical composition, that it could be a carcinogen.

- The expected dietary concentration of the substance should be less than 0.5 ppb. If the substance is already being regulated as a *direct* food additive, then the amount of the substance that gets into food through the packaging should be no more than 1 percent of that substance's acceptable daily intake. (For example, if the acceptable daily intake of some chemical is 100 g, then no more than 1 g of that substance should get into the food through the packaging.)

- The substance must have no technical effect in or on the food.

- The use of the substance must not have a significant adverse impact on the environment.[37]

The threshold of regulation standards are the ones now being used to judge non-objection letter requests. Substances that fail these conditions can still be approved, but they need to go through the regular food

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30 Eric F. Greenberg, "The states of the environment," *Packaging Digest*, May 1994, vol. 31, no. 5, p. 18.

31 "FDA `approval' of recycled PET containers is not liability protection," *Washington Beverage Insight*, November 4, 1994, vol. 21, no. 31.

32 "FDA `approval' of recycled PET containers."

33 Food Additives; Threshold of Regulation for Substances Used in Food-Contact Articles, 58 Fed. Reg. 52,719 (Oct. 12, 1993) ("Food Additive Thresholds").

34 Food Additives; Threshold of Regulation for Substances Used in Food-Contact Articles; Final Rule, 60 Fed. Reg. 36,582 (July 17, 1995) ("Threshold Final Rule").

35 21 U.S.C. § 409(c)(3)(A).

36 Food Additive Thresholds, at 52,723. TD_{50} is a commonly used measurement of how carcinogenic a substance is. In animal tests, animals (for example, rats) are fed large doses of a substance until they all die. As the doses get higher and higher, more and more of the rats start dying of cancer. TD_{50} is the feeding dose at which 50 percent of test animals get cancer. A substance with a high TD_{50} is less carcinogenic than one with a low TD_{50}, because it would take larger doses of the first substance for 50 percent of the rats to get cancer.

37 Food Additive Thresholds, at 52,724.

additive process. Thresholds of regulation are needed because with advancing technology, instruments can detect smaller and smaller amounts of any substance. But just because they're there doesn't mean they're dangerous. Many scientists agree that below a certain level, the risks posed by a substance are negligible.[38]

D. Acceptable Uses of Recycled Materials

Recycled glass, aluminum, and steel have been safely used in contact with food for years; they're impermeable, and the high processing temperatures used during recycling prevent organic contamination in the final recycled product.[39]

Paper has to abide by more or less the same standards as plastic.[40] With paper, there's more of a concern with microbiological contamination; microbes are unlikely to survive in plastics, because of the high processing temperatures, but might in paper. Usually, recycled paper is acceptable as long as the foods aren't wet or fatty—spaghetti bags, for instance, are fine. Since this is difficult to guarantee, most paper destined for packaging isn't recycled. Folding cardboard boxes (the kind hamburgers can go into) have been used for a hundred years, and they've received a non-objection letter. McDonalds hamburger wraps, Tootsie roll wrappings, and flour bags, on the other hand, aren't made with recycled content. But paper *specifically* meant for food packaging is a small part of total paper production. Certain forms of packaging have no non-objection letters because they weren't meant to be used with food. A bag maker can make 100-percent recycled content bags, without intending that they be used for food—but there's nothing to stop a hamburger vendor from buying these bags and putting hamburgers and greasy fries into them. In the last four to five years, the FDA has come closer to allowing recycled paper in contact with fatty foods, but it hasn't done so yet.[41]

Most of the FDA's new activity concerns plastic. In addition to direct reuse (which the FDA approves of, as long as the containers are suitably cleaned[42]), the FDA distinguishes between three different kinds of recycling.

- Primary recycling is the reuse of “in-house scrap and trim resulting from the production process.”[43] This recycled content is fine, as long as the source of the trim can be controlled. If a producer uses his own trim, then there is a reasonable certainty of no contamination; if the trim comes from many sources, some testing may need to be done.[44]

- Secondary recycling takes place when the plastic is physically reprocessed by grinding, washing, pelletizing or flaking, and remelted to form new containers.[45] In general, the FDA is more likely to issue a non-objection letter when the contact between the packaging and the food occurs for a short time and at room temperatures, when the ratio of the food's mass to the container's surface area is large, when there is a barrier between the packaging and the food (another approved package, an eggshell, or the like), or when the food is expected to be washed before use.[46]

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38 Bruce N. Ames and Lois Swirsky Gold, “Chemical carcinogenesis: Too many rodent carcinogens,” *Proc. Natl. Acad. Sci. USA*, vol.87, p.7772, October 1990. *See also* Alexander Volokh, “Clinical Trials,” *Reason*, May 1995, p. 22.

39 Thorsheim, p. 9.

40 Recycled paper is regulated under 21 C.F.R. § 176.260.

41 Personal communication, Joe Moran, James River Corp.

42 Varner, p. 148.

43 Thorsheim, p. 9.

44 Thorsheim, p. 11.

45 Thorsheim, p. 9.

46 Thorsheim and Armstrong, p. 57.

These conditions, of course, are rather restrictive; it's usually hard to say how long a food will be in contact with its packaging or what temperatures it'll be kept at. As a result, the FDA has been more willing to approve recycled content in "shipping" packaging (for instance, crates and trays) than in consumer packaging (for instance, bottles). The FDA has approved grocery bags made from recycled plastics, and recycled polyethylene or polypropylene harvesting crates and meat containers.

In 1990, the FDA consented to the use of recycled polystyrene in egg cartons; since then, egg cartons have been marketed with up to 40 percent post-consumer material. In 1993, the FDA agreed to the use of recycled polystyrene in food-contact packaging applications like fruit and vegetable containers, food- service clamshells, and poultry and meat trays.[47]

The FDA first O.K.'d the use of secondary post-consumer PET (polyethylene terephthalate) in 1993, when it issued a non-objection letter to Continental PET Technologies for using recycled PET in cold-filled aqueous, acidic and low-alcohol foods and beverages like mustard, soft drinks, olives and vinegar.[48] Coca-Cola, in partnership with Hoechst Celanese, has also developed a 25-percent post-consumer recycled content plastic bottle which has been cleared by the FDA.[49] Today, fruit and vegetable packaging baskets can be made from recycled PET.[50] The FDA has also approved the use of "coextruded laminate," where the inner core of post-consumer recycled PET or polystyrene is surrounded by layers of virgin material. One mil (1/1000th of an inch) of virgin material is an acceptable barrier, as long as the contact lasts no longer than two weeks[51] and occurs at room temperature or lower.[52] And the FDA recently approved Johnson Controls' 25-percent post-consumer recycled PET for unrestricted food packaging use.[53]

None of these parameters are set in stone, though; since there are no formal guidelines, new food contact applications are judged on a case-by-case basis.

Unlike PET, HDPE (high density polyethylene), which is used in milk jugs and detergent bottles, is porous and highly absorbent. Because it's hard to get contaminants out of HDPE, recycled HDPE isn't safe for food use.[54] To date, no one has a non-objection letter for a container made with recycled HDPE.[55]

- Tertiary recycling is the chemical breaking down and regeneration of the polymer into "monomers" or "oligomers."[56] Tertiary recycling is, in general, safer than secondary recycling, because contaminants are more likely to be destroyed in the chemical process.[57] The FDA has approved three tertiary recycling processes for post-consumer PET.

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47 "Dolco Packaging leads industry effort with FDA," *Business Wire*, October 12, 1993.

48 "Market for recycled PET packaging expands," *Green MarketAlert*, August 1993, vol. 4, no. 8.

49 David Biddle, "Recycling for Profit: The New Green Business Frontier," *Harvard Business Review*, November 1993/December 1993, p. 145.

50 Judy Rice, "Produce packaging gets fresh," *Food Processing*, vol. 56, no. 2, p. 76.

51 Varner, p. 151.

52 Thorsheim, p. 11.

53 "Companies Advance Food-Grade Post-Consumer Recycled PET Processes," *GreenPackaging 2000*, October 1994, p. 2.

54 Bradford H. Allen and Barbara A. Blakistone, "Assessing reclamation processes for plastics recycling," National Food Processors Association, p. 7.

55 Personal communication, Tom Rattray, associate director of environmental quality, Procter & Gamble Co.

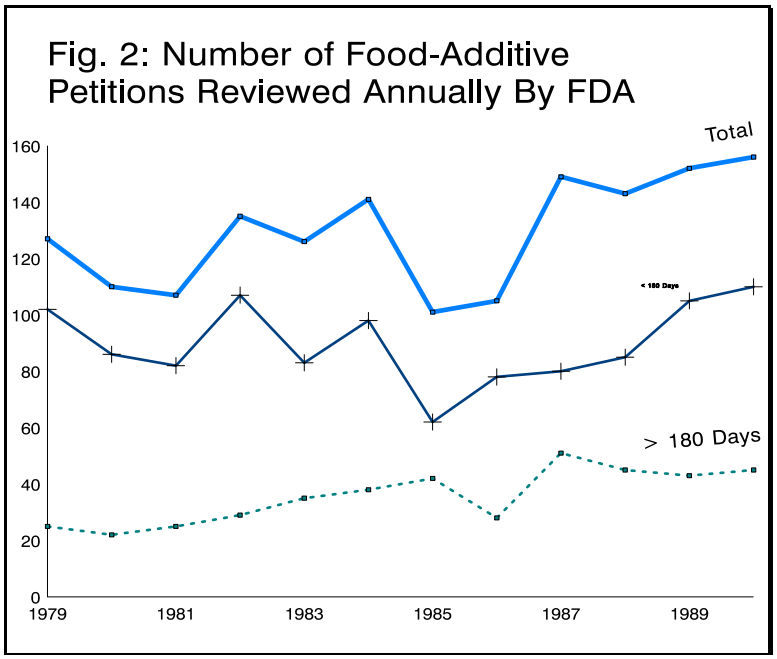
56 Thorsheim, p. 9.

57 Varner, p. 147.

E. The Food Additive Petition Backlog

The whole food packaging process is lengthy; preparing a new food additive petition, for instance, and seeing it through to approval, is a long and complicated process[58] (see Figure 1[59]). By law, if a petition is acceptable, the FDA must publish a final rule in the *Federal Register* within 180 days of receiving it.[60] But, as the FDA puts it, "rapid approval (or as we in the FDA would prefer to look at it, rapid decision making) for food additives today is not the reality many of us desire."[61] The 180 days are "FDA days"; like "basketball minutes," these are the days that the petition spends in the hands of the FDA rather than in the hands of the petitioner. Historically, the FDA has held on to a sizeable fraction of the petitions beyond 180 days (see Figure 2[62]). The total time between the receipt of an indirect food additive petition and the final rule is typically 1 to 2 years for a routine petition, and 3 to 4 years for a more complicated one[63] (see Figure 3[64]). A "threshold of regulation" determination usually takes about 6 to 8 months, and can take up to a year.

The FDA used to take a very long time to determine that uses of recycled plastics in food packaging were acceptable.[65] We have come a long way since then. But the situation is far from ideal. Even the informal non-objection letters have a significant backlog. At present—to the extent that the FDA insists that manufacturers seek non-objection letters, which aren't officially necessary—the FDA packaging "approval" process is a barrier to the use of recycled plastics.



The FDA's 1992 guidance document may have eliminated some of the guesswork from submitting applications, but the process is still quite lengthy. By some estimates, a typical non-objection letter takes at least six months to get through the system,[66] while the actual tests can be done in well under a month.[67] And the FDA can always ask for more tests. When the FDA approved Johnson Controls' 25-

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58 For details, see *Recommendations for chemistry data for indirect food additive petitions*, Food & Drug Administration, Center for Food Safety & Applied Nutrition, Office of Pre-Market Approval, Chemistry Review Branch, September 1988 (Version 1.2; March 1993).

59 Alan M. Rulis, director of the Division of Food and Color Additives, Food and Drug Administration, *The Food Additive Petition Process: An FDA View*, presented at the National Meeting of the Calorie Control Council, La Jolla, Calif., November 9, 1992, transparency #4.

60 Rulis, *Food Additive Petition Process* (1992), p. 4.

61 Rulis, *Food Additive Petition Process* (1992), p. 9.

62 Rulis, *Food Additive Petition Process* (1992), transparency #15.

63 Rulis, *Food Additive Petition Process* (1992), p. 4.

64 Rulis, *Food Additive Petition Process* (1992), transparency #16.

65 Personal communication, Tom Rattray.

66 Personal communication, Bob McDaniel, Coca-Cola.

67 Personal communication, Jerry Heckman.

percent post-consumer recycled PET, the non-objection letter came after almost two years of FDA-requested tests. ("A little longer than I expected," says Flexon.[68] "The time involved and the cost involved were incredible."[69]) Some companies aren't so lucky. Packaging Corporation of America (PCA) of Northbrook, Ill., waited a year for its non-objection letter, and by the time the letter arrived, the company had reallocated its new product-development funds and so its recycled polystyrene product was shelved. The FDA's slow response "put the brakes on that project," explains Lynn Carter, an attorney at PCA.[70]

The testing involved in getting a non-objection letter can get to be expensive; the entire process can easily cost hundreds of thousands of dollars. This includes labor costs at the packaging company itself, as well as the (substantial) cost of an appropriately credentialed lab to do two years' worth of testing.[71]

One test of one piece of plastic for contaminants can cost about $1,000, and one non-objection letter can require as many as 50 such tests. For example, if a company makes a plastic bag, it would send a bag to be tested in the laboratory. If the lab found, for instance, petrochemical residues, those residues could have come from the original plastic, from the trucks, from the heating system, or any of a number of places. Figuring out where the contaminants come from, and then fixing the problem, can require many extra tests, and take up a lot of time and money. Much of the work is done by Ph.D. polymer chemists, whose meters run fairly fast.[72] One estimate puts the cost of getting a non-objection letter at $100,000 to $150,000 a year, which includes $60,000 to $80,000 a year just for the analytic testing.[73]

Each new process, new use or new additive requires another non-objection letter. A "new use" happens whenever the same package is used with different foods (fatty foods are more worrisome than non-fatty foods), at different temperatures (high temperatures are more worrisome than low temperatures), or for different periods of time (long periods of contact are more worrisome than short periods).[74] Since many processes are proprietary, a non-objection letter granted for one company isn't an approval for the same package made by another company. Not all of this money is purely spent on regulatory compliance; a good deal of this testing would be done anyway, even in the absence of the FDA. Exactly how much is spent just to meet FDA requirements depends on how overly conservative the FDA's standards are. The entire backlog period, however, is "wasted" time.

The Center for Food Safety and Applied Nutrition (CFSAN) doesn't expect much growth in resources in the 1990s.[75] One proposed solution to the backlog problem has been a system of "user fees" similar to the system already in place for drug applications[76]—applicants would pay a fee, which would go to increase CFSAN staff and reduce review times. A system of user fees could well include fees for non-objection letters as well as for new food additive petitions. It is unclear, however, whether user fees would solve the problem. First, the FDA has a reputation for being overly conservative in its risk assessments.[77]

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68 Barlas.

69 Quoted in McCreery.

70 Barlas.

71 Personal communication, Floyd Flexon.

72 Personal communication, Tom Rattray.

73 Personal communication, Frank Vincent, James River.

74 Personal communication, Brad Allen, National Food Processors' Association.

75 Rulis, *Food Additive Petition Process* (1992), p. 7.

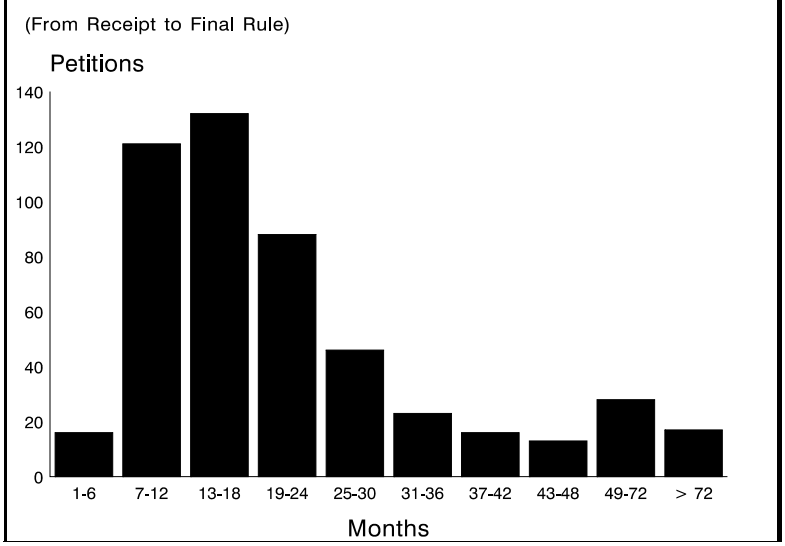
76 Rulis, *Food Additive Petition Process* (1992), p. 9.

77 For a general discussion of agencies' inherent conservatism, see Sam Kazman, "Death by Regulation," *Regulation*, Fall 1991, p. 18. For a discussion of the problems behind the FDA's risk assessment, see Sam Kazman, "Deadly Overcaution: FDA's Drug Approval Process," *Journal of Regulation and Social Costs*, vol. 1, no. 1, September 1990, p. 35. For a discussion of FDA user fees, see Alexander Volokh, "Leaving Us To Our Own Devices," *RT: The Journal of Respiratory Care Practitioners*, Dec. 1994/Jan. 1995, p. 69. (The last two articles deal with pharmaceuticals and medical devices, but the reasoning is general.)

If it increased its staff, it is possible that it would simply revise its standards of "reasonableness" upward and spend more time on each application. (This has already been observed, for instance, in the medical-device industry.[78]) Second, even if review times went down, they would only go down for those who could afford the applications. Those who could not would be shut out of the process. It's unclear how many people would be shut out, but previous user-fee proposals have been rather stiff.[79]

Backlog comes from having too few resources to handle the work that one is doing. To deal with the backlog problem in earnest, then, the FDA has to answer a larger question: how much of the problem is too few resources and how much of it is too much work? If the FDA is being too conservative on recycled food packaging, for instance, it should revise its standards appropriately, and the backlog will shrink or even disappear.

Fig. 3: Number of Indirect Food-Additive Petitions



F. A Problem of Overcaution?

So is the FDA being too conservative on food packaging?

As a general rule, it makes sense that recycled material should be more suspect than virgin material; recycled material usually comes from many sources, and, as the saying goes, "You don't know where it's been." Or what's been in it. Recycled plastics are less "pure" than virgin plastics, because they may contain trace amounts of the original contents of the package, or whatever the previous consumer happened to store in the container—pesticides, gasoline, rat poison, and so on.

From a safety standpoint, though, purity is not an interesting characteristic. What matters is how much of the contaminant actually gets into the food. A 20-mil thick PET bottle, for instance, could have 215 ppb of contaminants, but based on the density of the plastic, the surface-to-volume ratio of the bottle, and other factors, the FDA calculates that the dietary concentration would be only 0.5 ppb[80]—a 430-fold decrease.

So a performance-based standard, using real-world assumptions and relying on dietary concentrations, would protect the public health better than a purity standard which relies on concentrations in the packaging material. It could be, though, that even the current performance standards are overconservative. This is particularly important for recycled materials; an overconservative standard hits recycled materials harder than it hits virgin materials and could shut recycled materials out of the market altogether without improving safety.

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78 According to Peter Barton Hutt, FDA's chief counsel from 1971 to 1975, "there are two theories on the relationship between FDA work output and FDA staff numbers. The first theory holds that if you double the number of reviewers, you cut the average review time in half. The second theory is that if you double the number of reviewers, you double the review time. He observed that the bulk of evidence supports the latter theory." Paraphrased in Wayne K. Barlow, "Will user fees end the medical device regulatory nightmare?", address to the Medical Marketing Association, Orange County Chapter (Costa Mesa, Calif., Sept. 21, 1994) and Los Angeles Chapter (Culver City, Calif., Sept. 27, 1994), p. 3.

79 The Prescription Drug User Fee Act of 1992 provided for a fee of $100,000 for each application (rising to $233,000 after five years), an annual fee of $50,000 (rising to $138,000), and an annual fee of $6,000 for each product already on the market (rising to $14,000). See Herbert Burkholz, *The FDA Follies* (Basic Books: New York, 1994). The Medical Device User Fee Act of 1994 (which did not pass) provided for medical device user fees of $3,200 for run-of-the-mill devices and $52,000 for risky devices. Bear in mind that fees aren't comparable between industries, because they are determined, in part, by how much companies in that industry can pay.

80 Thorsheim and Armstrong, p. 56. The same calculation, scaled up by a factor of two, is present in Thorsheim, p. 10.

Based on the response to the "threshold of regulation" rule by the plastics industry, it is reasonable to conclude that the rule will lead to a greater variety of plastics, both virgin and recycled, in food packaging. Jerry Heckman of the Society of the Plastics Industry has called the proposal "unusually satisfying."[81] In certain ways, though, the proposal doesn't go far enough. The FDA could, for instance, exempt components of adhesives, if there's a functional barrier between the adhesive and the food. It could exempt packaging for dry foods. It could forgo regulation of rubber articles for repeated use. And it could eliminate regulation if the temperature levels of exposure are low enough.[82]

There's another problem. Under the new, finalized threshold of regulation policy, an environmental assessment has to be done before a non-objection letter is issued.[83] If the review goes well, the FDA issues a "Finding Of No Significant Impact" (FONSI). Otherwise, the FDA conducts a full-blown "Environmental Impact Statement" (EIS). EISs take a very long time; for instance, the FDA has spent seven years not completing an EIS on polyvinyl chloride (PVC) bottles. Fortunately, the FDA has only had to conduct an EIS twice in the last 30 years.[84] But even the less rigorous environmental assessments take time—about three to six months. Now that they're required, they could double the time required to get a non-objection letter.

And the proposal is also conservative in other ways:

- First, the standard is independent of whether any migration has been detected. If no migration is detected, then the FDA assumes the worst and declares that the amount of migration is, by definition, equal to the detection limit of the analytical method.[85] For instance, if a method is used that can't detect concentrations below 50 ppb, and if no migration is found, then the FDA assumes that migration is 50 ppb. If the food is more than 1 percent of the diet, the estimated dietary concentration is assumed to be above 0.5 ppb and doesn't get a threshold of regulation exemption.[86]

- Second, the FDA's exemption only applies to certain substances; the FDA's hands are tied when it comes to carcinogens. Under the Delaney Clause, no substance can be used as a food additive if it has been shown to cause cancer in at least one species of laboratory animal. (This isn't literally true. Under the FDA's constituents policy, if an indirect additive isn't itself carcinogenic, but has a carcinogenic constituent, it *can* be considered under the threshold of regulation. If an indirect additive is itself carcinogenic, though, it's a no-no.) But there are several problems with the Delaney Clause.

  Relying on animal tests may be a bad idea. Standard rodent carcinogen tests were developed back when diseases were poorly understood and public policy was extremely cautious. But we have better analytical procedures now, and we can evaluate dose levels at which pathological effects occur more realistically.[87] According to one study, out of 392 chemicals tested in both rats and mice, 226 were carcinogens in at least one test, but 96 were positive in the mouse and negative in the rat, or vice versa.[88] Since rats and mice are nearly identical genetically, and

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81 Eric F. Greenberg, "FDA at threshold of new approval approach," *Packaging Digest*, vol. 30, no. 13, December 1993, p. 12.

82 The advice to the FDA comes from Jerry Heckman, quoted in Greenberg (1993).

83 Threshold Final Rule, at 36,594, amending 21 C.F.R. § 25.22(a)(10).

84 Barlas.

85 Food Additive Thresholds, at 52,724.

86 Food Additive Thresholds, at 52,721.

87 Philip H. Abelson, "Testing for Carcinogens with Rodents," *Science*, September 21, 1990, vol. 249, no. 4975, p. 1357.

88 Bruce N. Ames, Renae Magaw and Lois Swirsky Gold, "Ranking Possible Carcinogenic Hazards," *Science*, vol.236, April 17, 1987, p. 275.

physiologically closer to each other than either are to humans, this suggests that extrapolations from mice or rats to humans are correct less than half the time. (One implication of this flaw is that such experiments may lead to the approval of some chemicals that are dangerous to humans but not to rats.[89]) The International Agency for Research on Cancer lists only 26 chemicals or groups of chemicals as showing definite evidence of human carcinogenicity.[90]

To the Delaney Clause, dose is irrelevant. The clause was passed in 1958, when very few carcinogens were known and when analytical methods were less capable of finding minute quantities of a chemical. Since then, many common substances have been found to be carcinogenic, and the Delaney Clause prohibits their use—regardless of how little there is. The FDA readily admits that "the likelihood of a substance posing a health hazard depends on its dietary concentration and on its toxic potency."[91] But it's prohibited from reaching the same conclusion for carcinogens. Ultimately, repealing the Delaney Clause is something only Congress can do.

The law applies to food additives, and not to natural chemicals already present in the food. But carcinogens occur naturally in most commonly eaten foods, like apples, pears, carrots, potatoes, lettuce, mushrooms, parsley, basil, celery, cola, wine, beer, mustard, peanut butter, bread, and lima beans. Carcinogens are also produced every time we bake bread, brown meat, or allow an apple slice to become brown.[92] Moreover, the cancer risks from pesticides in food and from additives in our diet are generally trivial compared to the quantities of natural carcinogens we routinely consume;[93] for instance, the amount of carcinogenic pesticides the average American eats in a day is one twentieth of the amount of natural carcinogens in one cup of coffee.[94]

- Third, when figuring out acceptable levels of a chemical, the FDA assumes that it will one day be found to be a carcinogen.[95]

- Fourth, the FDA assumes a linear relationship between the dose of a chemical and its carcinogenic response when calculating acceptable values of TD_{50}.[96] This means that eating half as much of the chemical carries half the risk. It also means that if you assume that animal tests are valid for humans (and so a TD_{50} is the dose that corresponds to a one-in-two risk), then to get a one-in-a-million risk, all you have to do is divide the TD_{50} by 500,000. For example, if half the rats die when you feed them 500 ppm (500,000 ppb) of some chemical, then the one-in-a-million risk for humans is 1 ppb.

  But the linear dose-response relationship is not a realistic assumption. In the animal cancer tests from which the TD_{50} values are derived, animals are fed the maximum tolerated dose (MTD) of various chemicals; researchers do this to detect a carcinogenic effect more easily. But feeding

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89 Ronald D. Utt, "The Divergence Between the Perceived and Real Risks of Pesticide Use," *Journal of Regulation and Social Costs*, January 1991, p. 81, at p. 89.

90 Lester B. Lave, Fanny K. Ennever, Herbert S. Rosenkranz, and Gilbert S. Omenn, "Information Value of Rodent Bioassay," *Nature*, vol. 336, December 15, 1988, p. 631.

91 Food Additive Thresholds, at 52,721.

92 Richard L. Stroup and John C. Goodman, "Making the World Less Safe: The Unhealthy Trend in Health, Safety and Environmental Regulation," *Journal of Regulation and Social Costs*, January 1991, p. 5, at p. 18.

93 Stroup and Goodman, p. 19.

94 Bruce N. Ames, Testimony before the California Assembly Committee on Water, Parks, and Wildlife, October 1, 1986. Cited in Stroup and Goodman, p. 19.

95 Alan M. Rulis, "Threshold of Regulation: Options for Handling Minimal Risk Situations," in *Food Safety Assessment*, ed. J.W. Finley, S.F. Robinson, and D.J. Armstrong, American Chemical Society Symposium Series 484, 1992, p.132, at p.138.

96 Food Additive Thresholds, at 52,723.

animals the MTD stimulates cell division, which itself increases the incidence of cancer. This means that when the animals get cancer, it may be because the dose was high, not because the chemical was toxic. In fact, below a certain dose, there is no extra cell division, so we should expect the animals' carcinogenic response to fall off sharply, not linearly. Assuming a linear dose-response relationship ends up seriously overestimating the actual risk. Without knowing the mechanism of carcinogenesis, the fact that a chemical is a carcinogen at the MTD in rodents gives us no information about low-dose risk to humans.[97]

- Fifth, the FDA assumes a worst-case scenario when checking whether carcinogens posed a risk at 0.5 ppb. When many studies have been done on the same chemical, the carcinogenic potency chosen is "the most sensitive species/sex/organ combination."[98]

- Sixth, the threshold of regulation policy may in fact *tighten* FDA requirements for indirect additives. ("Somewhat paradoxically," says Alan Rulis of the FDA, who notes that it might also temporarily increase the agency's workload.) Before the policy, the only toxicological requirements for indirect additives with a dietary exposure under 50 ppb were a rodent-feeding study and a literature search (to find published studies on the substances' effects). A threshold level of 0.5 ppb would focus regulatory attention on exposures far below 50 ppb. People who are now using indirect additives in applications with dietary exposures of 10, 5, or 2 ppb or lower because, under the previous regulatory framework, they've assumed that they were O.K., would have to find out whether they qualified for an exemption.[99]

- Seventh, the choice of 0.5 ppb as a threshold has no apparent justification. Let's assume that animal tests and linear extrapolation are valid. The potencies of known carcinogens are shown in curve 1 in Figure 4,[100] and linear extrapolation gets us to curve 2.[101] The peak of distribution 2 happens at approximately 1 ppb. This means that about half of known carcinogens present a risk greater than 10^{-6} at 1 ppb.[102] Assuming that about one in five untested chemicals are carcinogens,[103] 10 percent of untested chemicals would present a risk greater than 10^{-6} at 1 ppb.

  Alan Rulis, the FDA officer who wrote the *Federal Register* notice on thresholds, and who also wrote some of the scientific articles which the notice was based on, was cautious about what this meant. "Recall," he wrote, "that these `risks' are conjectural and not actuarial in any sense. They are upper-bound estimates derived from a highly conservative linear extrapolation of data from animal studies. Furthermore, it has been presumed that the chemical in question is in fact a carcinogen."[104] He concluded that 0.5 ppb may represent a "reasonable balance between

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97 Ames and Gold, "Environmental Pollution and Cancer: Some Misconceptions," *Phantom Risk: Scientific Inference and the Law*, K.R. Foster, D.E. Bernstein, and P.W. Huber, eds. (Cambridge, Mass.: MIT Press, 1993), p. 153, at pp. 156–157. *See also* Ames and Gold, "Too many rodent carcinogens: Mitogenesis increases mutagenesis," *Science*, vol. 249, 1990, p. 970. Some scientists, of course, dispute the Ames theory, but this is not the place to resolve this long-standing controversy.

98 Food Additive Thresholds, at 52,722.

99 Rulis, "Threshold of Regulation" (1992), p. 134.

100 Alan M. Rulis, "Establishing a Threshold of Regulation," in *Risk Assessment in Setting National Priorities*, ed. James J. Bonin and Donald E. Stevenson (Plenum Publishing Corp., 1989), p. 271, Figure 1.

101 The TD_{50} is the dose that corresponds to a one-in-two (0.5, or 5×10^{-1}) risk. One in a million (0.000001, or 10^{-6}) is 2×10^{-6} times 0.5, so we get curve #4 by multiplying curve #3 by 2×10^{-6}. Because the horizontal axis measures $-\log_{10}$ of the effect level, multiplying the curve by 2×10^{-6} means moving it to the right by $-\log_{10}(2\times10^{-6}) = \log_{10}(500{,}000) = 5+\log_{10}(5) \approx 5.7$.

102 See Figure 5. Rulis, *Food Additive Petition Process* (1992), figure 2.

103 This is the assumed probability used in Rulis, "Threshold of Regulation" (1992), p. 136. Elsewhere, Rulis uses "one in perhaps three to five." *Ibid.*, p. 138.

104 Rulis, "Threshold of Regulation" (1992), p. 138.

necessary conservatism and practical utility"[105]—it's lower than 1 ppb, but higher than 1 ppt (part per trillion), the level necessary to provide almost total protection. Why 0.5 ppb is a better compromise than 0.99 ppb, 0.9 ppb, 0.1 ppb, or 0.01 ppb (10 ppt) is never explained.

The $\$6.4\times10^4$ question, of course, is: Where do you set the threshold? It is one which the FDA may not be able to answer, and one which criteria like "reasonable certainty" of no harm serve only to obscure. Numbers like 0.5 ppb and 1 percent of acceptable daily intake are nice, round numbers; they are also totally arbitrary.[106] The difficulty of finding the right number is no excuse for accepting a random one.

- And finally, to deal with possible unknown contaminants in the recycled plastic supply, the agency announces that "it is impossible to foresee all of the safety issues that may be revealed by scientific information not presently available. Therefore... FDA is reserving the right to decline to grant an exemption in any case where available information suggests that the proposed use of the substance may pose a public health risk."[107] The FDA is, in effect, giving itself blanket permission to sidestep its own rules whenever it feels that it isn't being conservative enough.

G. The Implications of Conservatism

The main problem with conservative risk *assessment* is that it makes rational risk *management* impossible. We can tolerate high risks, or we can be risk averse, but with risk assessment methodologies that systematically exaggerate risk, we can never even know what the true risks of food packaging are. The FDA may think it's giving us a one-in-a-million risk of cancer, but this isn't quite true. What we're getting is a one-in-a-million *calculated* risk of cancer. The true risk is much lower. How much? No one knows. Suppose, now, that we were willing to tolerate a one-in-a-million *true* risk of cancer. What *calculated* risk does that correspond to? No one knows that either.

As it happens, conservative risk assessment is a fact of life in regulatory agencies, a relic of earlier days when less was known about diseases (and cancer in particular), and when exaggeration may have been necessary to compensate for scientific ignorance. Today, any one of these levels of conservatism may be justifiable, but all of them together are not. We don't know how much risk is being exaggerated, but we do know that before the Food Additive Amendments, there was never any dramatic health-threatening incident like thalidomide in food packaging. No government or responsible authority in the United States had ever raised any serious concerns about the safety of food packaging.[108] Since the Amendments,

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[105] Rulis, "Threshold of Regulation" (1992), p. 138. The Food Additive Thresholds notice is confusing on the rationale for choosing 0.5 ppb, because it dealt with the issues in a different order. Thresholds Final Rule, at 36,582. The FDA reviewed a study by the Society of Plastics Industries, which advocated a threshold of 1 ppb, and then decided to propose "a somewhat lower level." Food Additive Thresholds, at 57,721. The agency analyzed 18,000 oral feeding studies on a wide variety of substances in rats and mice, and found that no acute toxic effects occurred below 1000 ppb. The agency also considered the effects of chronic exposure to 220 different chemical substances; only five pesticides showed toxic effects below 1000 ppb, and none of these five showed any toxic effects below 100 ppb. "To provide an adequate safety margin, however, the dietary concentration chosen as a level that presents no regulatory concern should be well below 1000 ppb. Therefore, FDA is proposing in § 170.39(a)(2)(i) to establish a dietary concentration of 0.5 ppb as the threshold of regulation for substances used in food-contact articles. A 0.5 ppb threshold is 2,000 times lower than the dietary concentration at which the vast majority of studied compounds are likely to cause noncarcinogenic toxic effects and 200 times lower than the chronic exposure level at which potent pesticides induce toxic effects. FDA believes that these safety margins, which are larger than the 100-fold safety factor that is typically used in applying animal experimentation data to humans (21 C.F.R. § 170.22), support a conclusion that substances consumed in dietary concentrations at or below 0.5 ppb are not of regulatory concern." *Ibid.*, at 52,722. The notice then goes on to consider possible carcinogenic effects, and concludes that 0.5 ppb provides adequate protection against that risk — giving the impression that 0.5 ppb was chosen because of the 2,000-fold safety margin. In fact, though, 0.5 ppb was chosen because of carcinogenicity concerns. The 2,000-fold safety margin was coincidental.

[106] For a discussion of how policy decisions come to be made based on convenient round numbers for no apparent reason, see Kathryn A. Kelly and Nanette C. Cardon, "The Myth of 10^{-6} as a Definition of Acceptable Risk," *EPA Watch*, vol. 3, no. 17, p. 4.

[107] Food Additive Thresholds, at 52,724.

[108] Jerome H. Heckman, *Is It Time to Look for a New Approach to Harmonization?*, prepared for presentation at the

there hasn't been a single FDA case aimed at condemning or seizing food because of hazardous packaging material.[109] The FDA itself has noted that unlike direct food and color additives, indirect additives migrate to food in such "minuscule amounts" that they're "of extremely low or no toxicological concern in terms of food safety."[110]

What are the consequences of this sort of conservatism? Here are some numbers on the consumption, recycling, and use in food packaging of selected plastics. I've selected PET, polystyrene and polypropylene because they're the plastics that are recycled the most into food packaging. Table 1 shows the total amount of each plastic sold in the United States, and the percentage used in food packaging. Since there are no good food-packaging numbers, I've given a rather broad range.

Table 2 presents the recycled amounts of each plastic, and the approximate percentages of each plastic that go into food packaging.

Table 1: U.S. Domestic Packaging Consumption (millions of pounds)

Plastic	Total 1994	Food Packaging Absolute	Percent
PET	2869[a]	1870[b]	65%
PS	5527[c]	1360[d]	25%
PP	9140[e]	1323[f]	14%

[a] "Polyethylene terephthalate: Pattern of consumption," p. 66.

[b] This number was derived using the total PET numbers in different categories from "Polyethylene terephthalate: Pattern of consumption," and also using the percentages of each category used in food from Franklin Associates, Prairie Village, Kansas. One caveat: the PET numbers are from 1994; the percentages used in food are from 1990.

[c] "Polystyrene (PS): Major markets," p. 65.

[d] Personal communication, Polystyrene Packaging Council.

[e] "Polypropylene (PP): Major markets," p. 65.

[f] This number was derived using the total polypropylene numbers in different categories from "Polypropylene (PP): Major markets," and also using the percentages of each category used in food from Franklin Associates. A caveat: the percentages used in food are from 1990, and are based on categories from *Modern Plastics*, January 1992. Some of these categories no longer exist in the January 1995 numbers. For these categories, I used the 1991 values and extrapolated them to expected 1994 values.

Source: *Modern Plastics*, January 1995, unless otherwise noted.

We certainly wouldn't want to force food into packages with recycled content—that might not be safe. But it's important not to discourage safe recycling that makes sense economically. Getting an accurate sense of how much impact regulatory changes will have is difficult, if not impossible. But we can note a few things. First, the overall recycled PET numbers indicate that there's plenty of growth possible. In 1991, the Center for Plastics Recycling Research at Rutgers University estimated that the quality and cost of recycled PET was so good that the recycled PET market could grow from 150 million pounds in 1987 to 600 million pounds in 1993.[111] In 1993, the Center's expectations weren't realized, since the recycled PET market was only 450 million pounds strong.[112] So we still have a ways to go.

Second, the food-packaging numbers also indicate that there's a lot of growth possible. A hefty percentage of virgin plastics go into food packaging, while the recycled food-packaging percentages are a good deal lower (see Tables 1 and 2). Of course, no one knows what "proper levels" are for the use of recycled plastics in food packaging. But we do know that the more of a drag the FDA is, the longer it'll take recycled plastics markets to grow to desired levels, whatever they are.

ICI/PIRA International "Plastics for Packaging Food" Symposium in Washington, D.C., June 21 & 22, 1995, p. 2.

109 Statement of Jerome H. Heckman of the Society of the Plastics Industry, in *Need for Modifying the Food Additive Regulatory Process*, Hearings before the Subcommittee on Human Resources and Intergovernmental Relations, Committee on Government Reform and Oversight, U.S. House of Representatives, June 29, 1995, p. 2.

110 Food and Drug Administration, *Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food*, 1982, p. 5, NTIS #PB83-170696.

111 Robert A. Bennett, "Market Research on Plastics Recycling," Technical Report #31, Center for Plastics Recycling Research, Rutgers University.

112 "Post-consumer recyclate: Pattern of consumption," *Modern Plastics*, January 1995, p. 67.

Table 2: U.S. Domestic Use of Recycled Plastics in Food Packaging (Millions of Pounds)

Plastic	Recycled Total[b]	Recycled Percent[c]	Recycled Packaging[a] Absolute	Percent
PET	475	17.0%	20–60[d]	4–13%
PS	45	0.8%	NA[e]	NA
PP	<75[f]	<0.8%	NA[g]	NA

[a] Amount of recycled plastic used in food packaging. "Post-consumer recyclate: Pattern of consumption," p.67.

[b] "Post-consumer recyclate: Pattern of consumption."

[c] Recycled total as a percent of 1994 total (from Table 1).

[d] Low-end estimate contains primarily repolymerized (tertiary recycled) food bottles. High-end estimate also contains "sheet." Categories "fibers," "non-food bottles," "strapping," "alloys, compounds," "export," and "all other" (non-bottle-grade) weren't counted.

[e] Because of the limited approved uses of recycled polystyrene in food packaging, this number is widely estimated to be very small—way smaller than 10%. Actual statistics are hard to come by. The *Modern Plastics* numbers for foam packaging give us an upper bound of 16 (36%), but this vastly overestimates the true amount.

[f] This is the amount of "other resins" in "Post-consumer recyclate: Pattern of consumption."

[g] Because of the limited approved uses of recycled polypropylene in food packaging, this number is widely estimated to be very small—way smaller than 10%. Actual statistics are hard to come by.

Source: *Modern Plastics*, January 1995.

And finally, it's reasonable to expect that at least some of the growth in the use of recycled plastic will come from food packaging. Overall, plastic food packaging is 17 percent of total plastic packaging, which is itself 30 percent of total plastics sales[113]—non-trivial percentages when we're talking about very large waste flows.

H. Three Ways Out

- The first thing the FDA should do is adopt reasonable risk assessment methods. Repealing the Delaney Clause would be an important first step, and would make the FDA approval process far less of a problem.[114] The current methodology overstates risk. Yet, overcaution is wasteful, and overcaution in food packaging discriminates more heavily against recycled packaging *without giving added protection to the public*.

- Second, the FDA should act less arbitrarily. The whole point of regulation is to make government more predictable and rule-bound. However, one of the main disad-vantages of current FDA practice is uncertainty and arbitrariness. When the FDA sets a standard but then ignores it (as above, when the FDA gave itself blanket permission to bypass the regulatory system it had laid out), the element of certainty is lost. Any reform needs an added element of procedural certainty.

- And third, the FDA should cut down on the delays in issuing non-objection letters. There are a number of ways of doing this.

  One way is to adopt a pre-market notification system. Instead of asking the FDA whether a particular use is O.K. and waiting for the agency to answer, packagers should be able to submit their data with a pre-market notification. If the FDA doesn't answer in a certain time (say, 90 days), the packager should be able to market his product. This would put a limit on how much time the FDA can take looking at applications. It would also require new legislation.

  Or the FDA could accept the results of testing by approved, independent labs. An example of such a certification program is the FDA's French program for soft cheese, by which the FDA has agreed not to detain soft cheese if the French government goes through certain inspection steps.[115] Under this program, only those plants certified by the French government to be following good manufacturing practices are permitted to export soft-ripened cheese to the United States. The

[113] Society of the Plastics Industry, Committee on Resin Statistics (CRS), annual major markets survey, as compiled by Ernst & Young. Numbers are for 1994.

[114] "FDA dance delays progress," *Plastics News*, July 3, 1995, viewpoint, p. 12.

[115] Personal communication, Shellee Davis, Office of Plant and Dairy Foods and Beverages, Center for Food Safety and Applied Nutrition, Food and Drug Administration.

program was initiated in 1974 and expanded to include goat cheese in January 1987.[116] Allowing independent lab certification would reduce the backlog of applications for non-objection letters, because companies willing to pay more could have the tests conducted without the administrative delay characteristic of the FDA.

II. THE TROUBLE WITH PROP. 65

A. What is Prop. 65?

California's Safe Drinking Water and Toxic Enforcement Act was enacted by voter initiative in November 1986 and is commonly known as Proposition 65.[117] Prop. 65, the most sweeping chemical regulatory law ever enacted by a state government, was designed to improve human health and the environment by informing consumers of products that contain carcinogens and reproductive toxins. The Proposition provides for the listing of chemicals if they are "known" to cause cancer or reproductive harm.[118] Recently, Cal/EPA's health hazard office considered a sweeping plan to expand Prop. 65 to "postnatal" ailments.[119] Twenty months after the listing of a chemical, it bans the discharge of that chemical into water.[120] It also requires warnings for individuals who are exposed to these chemicals, whether environmentally, in the workplace, or, most significantly, in consumer products.[121] For consumer products, the warnings read: "WARNING: This product contains a chemical known to the State of California to cause cancer" and "WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm."[122] The Proposition recognizes that the California warning requirement doesn't apply where federal law "governs warning in a manner that preempts state authority,"[123] though there's no similar federal preemption for the discharge prohibition.[124]

The proposition mandates that the governor of California publish a list of offending chemicals. What gets on the list, and how it gets there, has been a subject of great controversy. In 1988, a coalition of environmental and labor groups, including the Environmental Defense Fund, the Natural Resources Defense Council, the Sierra Club, and the AFL-CIO filed a suit demanding that the EPA be recognized as an "authoritative body" regarding the carcinogenicity of chemicals and that all EPA-designated carcinogens be added to the Prop. 65 list.[125] This lawsuit never went to court; the state negotiated with the petitioners and issued a regulation that established certain agencies as authoritative for the purposes of the list of offending chemicals: IARC, National Toxicology Program (NTC), the EPA, the FDA, and so on.[126] The list of chemicals includes such common chemicals as benzene (present in gasoline), arsenic

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116 FDA Import Alert, "Automatic Detention and/or Examination of Imported Soft Cheese," May 13, 1987.

117 Cal. Health and Safety Code §§ 25249.5-25249.13.

118 Cal. Health and Safety Code § 25249.5.

119 "OEHHA eyes sweeping Prop. 65 expansion for child development effects," *Inside Cal/EPA*, vol. 6, no. 20, May 19, 1995, p. 1.

120 Jerome H. Heckman, "California Proposition 65: A Federal Supremacy and States Rights Conflict in the Health and Safety Arena," n.5. (A previous version of this paper was presented at the Food and Drug Law Institute's seminar "The Regulatory Impact of California's Proposition 65 on the Marketing of Foods, Drugs, Cosmetics, and Medical Devices," Washington, D.C., September 9, 1987.)

121 Cal. Health and Safety Code § 25249.6.

122 Cal. Admin. Code Tit. 22, R. 12601 (1988).

123 Cal. Health and Safety Code 25249.10(a).

124 Heckman (1987), n.5.

125 Jerome H. Heckman, "Proposition 65—A Legal Viewpoint: Reflections on the Political Science of How Not to Do It," presented at the American Industrial Hygiene Association's Toxicology Symposium, Williamsburg, Virginia, August 18, 1988, at p. 10.

126 Personal communication, David Roe, Environmental Defense Fund.

(used in pesticides), lead, and alcohol. In 1988, 216 substances were listed as carcinogens and 15 as reproductive toxins; by 1991, these numbers had grown to 369 and 111.[127] There are over 500 listed chemicals now.[128]

The rules for the listing of chemicals continue to change.[129] Carcinogen-listing agencies have come under fire for being too eager to list carcinogens, since it doesn't hurt them to list a substance wrongly or based on speculative evidence.[130] Certainly, listing decisions are heavily influenced by political considerations.[131]

Public employees are required to notify the news media when they discover violations of Prop. 65, and are subject to criminal penalties if they don't. Private citizens who successfully sue violators are entitled to collect 25 percent of the fines imposed.[132] In citizen lawsuits, all the plaintiff has to do is assert that a listed chemical is present in a product; everything else is up to the defendant.[133] There are no penalties for unnecessary warnings. As a result, Prop. 65 has been well enforced. One result of Prop. 65, in fact, has been a proliferation of unnecessary warnings.[134]

But violations of Prop. 65 don't necessarily correspond to actual risks. For carcinogens, a violation happens when:

- someone is exposed to a chemical, and
- they would have been at significant risk if the same exposure were maintained for their entire lives.

"Significant risk," incidentally, is not defined (though Cal/EPA seems to have defined it to mean one chance in 100,000).[135] In the case of reproductive toxins, Prop. 65 recognizes that there exists a threshold dose below which the chemical is harmless. This dose is called the NOEL, or "no observable effect level."[136] A violation of Prop. 65 happens if:

- someone is exposed to a reproductive toxin, and
- the exposure is greater than 0.1 percent[137] of the NOEL.[138]

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127 Stroup and Goodman, p. 13. A list of 29 substances was published on February 27, 1987. On July 1, 34 were added. Another 20 were added on October 1, and 91 on January 1, 1988. On April 1, 45 were added. Seven were added on July 1. And so on. Heckman (1988), Prop. 65 Chronology in "Proposition 65—A Legal Viewpoint," p. 4.

128 Richard A. Lovett, "Proposition 65 comes of age," *California Journal*, November 1994, p. 25.

129 *See* "Prop. 65 Revisions," *Inside Cal/EPA*, February 17, 1995, p. 3.

130 "Heckman attacks carcinogen listings," *Food Chemical News*, vol. 35, no. 54, March 7, 1994.

131 *See*, for instance, Paul Jacobs, "Judge orders 201 more toxics listed; rejects Deukmejian's limited view of chemicals that cause cancer, defects," *Los Angeles Times*, April 25, 1987, part 1, p. 1.

132 Stroup and Goodman, p.13. *See also* Richard C. Paddock, "New breed of bounty hunter to hit polluters," *Los Angeles Times*, February 14, 1988, part 1, p. 1.

133 Heckman (1988), p. 12.

134 Michael deCourcy Hinds, "As Warning Labels Multiply, Messages Are Often Ignored," *New York Times*, March 5, 1988. *See also* "Houses With Warning Labels," *Sacramento Bee*, July 25, 1988. Cited in Stroup and Goodman.

135 Lovett, p. 26.

136 Heckman (1988), p. 3.

137 Another "arbitrary and unscientific" number. Heckman (1988), p. 7.

138 Stroup and Goodman, p. 13.

Even though carcinogens are regulated at a risk level of 10^{-5}—often less stringent than the EPA, which can regulate at a risk level of 10^{-6}—Prop. 65 calculates threshold levels differently than the EPA, so the Prop. 65 10^{-5} level can actually be lower than the EPA 10^{-6} level. Also, there are some chemicals that the EPA doesn't regulate at all (for example, many consumer products, like tobacco products or components of nail polish, which fall under the jurisdiction of other agencies), or only regulates at a lower level (like dioxin, which is regulated at a 10^{-6} risk level for inhalation pathways but at a level greater than 10^{-4} for dietary intake[139]). This means that maximum allowable levels of Prop. 65 substances can be much lower than EPA levels, even though the EPA is officially less tolerant of risk.

Manufacturers have to spend a lot of money testing their products for minute quantities of hundreds of chemicals, and reformulating their products if there's some possibility they might be in violation. If a manufacturer makes a mistake and his product violates Prop. 65, he can be subject to stiff fines. Every violation can cost up to $2,500 in addition to any existing penalties.[140] Illegally disposing of hazardous waste carries a fine of $5,000 to $100,000 for each day of violation, unless the violation "caused great bodily injury or caused a substantial probability that death could result," in which case the penalties increase to imprisonment and fines of up to $250,000 per day for each day of violation.[141] Also, products in violation of Prop. 65, though they may pose minimal risks to consumers, are at a market disadvantage because of their scary warning labels.

Prop. 65 distorts people's risk perception by concentrating on carcinogens and reproductive toxins to the exclusion of all other risks.[142] Also, the proliferation of warning labels dilutes the value of warnings in general, by making it difficult for consumers to tell the difference between large risks, small risks, and nonexistent risks.[143]

B. The Food and Drug Safe Harbor

Prop. 65 was enacted with the best of intentions, but reality is tricky. Food packaging recyclers' problems with Prop. 65 may dwarf their problems with the FDA. Prop. 65 didn't bother the food packaging industry until recently. At first, despite fierce protests of Prop. 65 proponents, all products approved by the FDA (and by a few other agencies, like USDA and OSHA[144]) came to be presumed safe and therefore exempt from Prop. 65's labeling requirements.[145] The only exceptions were for products that contained chemicals for which the state of California had come up with a "no significant risk level" (NSRL). As more and more chemicals were given NSRLs, the exemption became more and more curtailed, but it still remained in force.[146] The exemption, started in 1988, was called the "food and drug safe harbor."

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139 *See* Curtis C. Travis, Holly A. Hattemer-Frey, and Ellen Silbergeld, "Dioxin, dioxin everywhere," *Environmental Science & Technology*, vol. 23, no. 9, 1989, p. 1061.

140 Cal. Health and Safety Code § 25249.7.

141 Cal. Health and Safety Code § 25189.5 (as amended by Prop. 65). Richard J. Denney Jr., "California's Proposition 65: Coming Soon To Your Neighborhood," *Toxics Law Reporter*, December 17, 1986, p. 791.

142 Stroup and Goodman, pp.15–16.

143 "Overambitious information efforts may outstrip decision-making capabilities." Richard J. Zeckhauser and W. Kip Viscusi, "Risk within reason," *Science*, vol. 248, no. 4955, May 4, 1990, p. 559. *See also* W. Kip Viscusi, "Predicting the Effects of Food Cancer Risk Warnings on Consumers," *Food Drug Cosmetic Law Journal*, vol. 43, 1988, p. 288. *See also* David W. Stewart and Ingrid M. Martin, "Intended and Unintended Consequences of Warning Messages: A Review and Synthesis of Empirical Research," *Journal of Public Policy & Marketing*, vol. 13, no. 1, Spring 1994, p. 1.

144 Personal communication, Joe Moran. Heckman (1988), p. 8.

145 Heckman (1988), p. 6.

146 "SPI questions FDA's new advisory opinion policy," *Food Chemical News*, December 7, 1992, vol. 34, no. 41.

The "safe harbor" regulation, or "12713" (named after Article 7, Section 12713 of the California Health and Welfare Agency's emergency regulations) essentially confers "no significant risk" status on anything which is:

- the subject of a specific FDA regulation or tolerance;
- generally recognized as safe (GRAS);
- prior-sanctioned; or
- not reasonably expected to become a component of food.[147]

In May 1988, the Environmental Defense Fund, the Natural Resources Defense Council, and the Sierra Club, among others, sued the state of California, calling the exemption "blatantly illegal" and a "massive loophole."[148] This case went through elaborate litigation. In late 1988, a state trial judge enjoined the government from keeping the exemption on the books, but this decision was appealed.[149] The food and drug exemption was again voided by a Superior Court judge in March 1990. But the ruling was appealed by the Grocery Manufacturers of America.[150] In 1992, the state settled to get rid of the exemption; the safe harbor went out of effect in 1994.

Now, officially, no food package (or drug or cosmetic) can contain a chemical on the Prop. 65 list in quantities above the NSRL—even if the NSRL hasn't been set yet. In July 1993, NSRLs had been established for about 220 carcinogens, but over 200 chemicals still had no NSRL.[151] Prop. 65 sets forth ways to calculate NSRLs, so if no NSRL has been set, someone can calculate one and sue a company for exceeding it. In cases where no NSRL is set, a company has to do its own calculation and hope that no one else will come up with a different number. Of course, carcinogens are already illegal—in any quantity—under the Delaney Clause. So why do food packagers care about carcinogens? Because not everything on the Prop. 65 carcinogen list is a carcinogen. For instance, the Prop. 65 list incorporates the IARC list, which contains some "possible carcinogens." By including the IARC list, Prop. 65 treats these *possible* carcinogens as if they were *actual* carcinogens. The Delaney Clause doesn't regulate possible carcinogens, and so for these, Prop. 65 actually makes a difference.

The rescission of the food and drug safe harbor changes the rules of the game for food packagers. For packages that contain "possible carcinogens" from the IARC list, FDA approval isn't enough anymore; now, they have to make sure that their package contains less than the NSRL of that chemical. And for those chemicals that still have no NSRL, the packagers may know that their products are safe—since the FDA told them so—but they can't say that they pose "no significant risk" according to California's definition.[152]

This could severely curtail the use of recycled paperboard packaging. Prop. 65 has been called one of the most serious issues affecting packaging manufacturers who use recycled content.[153] Recycled paperboard tends to have more contaminants than virgin paperboard, and the nature and amounts of these contaminants are hard to determine, since wastepaper comes from many different places. Moreover, the burden is on the manufacturer to prove that his material doesn't violate Prop. 65, and it is a

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147 Heckman (1988), slide #5. *See* "SPI urges retention of Prop. 65 `safe harbor' provision," *Food Chemical News*, vol.35, no. 20, July 12, 1993.

148 Heckman (1988), p. 10.

149 Personal communication, David Roe.

150 Richard C. Paddock, "Ruling could lead to cancer warnings on more products," *Los Angeles Times*, March 3, 1990, p. A31.

151 "SPI urges retention."

152 Heckman (1988), p. 5.

153 Personal communication, Joe Moran.

heavy one.[154] The packaging user needs to be able to determine the Prop. 65 status of his products' packaging without doing expensive and sometimes impossible analyses, and without demanding an unlimited guarantee which no reliable packaging supplier will be willing to provide.[155] The costs to the packaging industry of figuring out whether their recycled paperboard violates Prop. 65 has been estimated in the hundreds of thousands of dollars, and this doesn't include the market disadvantage of having to put warning labels on recycled paperboard if it is indeed in violation.[156] Packaging manufacturers will tend to use virgin paper instead of recycled paper when they can to avoid these costs.[157]

Such dire scenarios have been predicted in the past; many of them haven't occurred because people realized in time just how dire the scenario was going to be. Vitamin A can cause birth defects in large doses, but is essential for health at lower doses. The “good” dose, though, is greater than 0.1 percent of the NOEL. This means that officially, vitamin A would have to have a Prop. 65 warning. Ethyl alcohol can cause birth defects, but fresh-baked bread, orange juice, and vanilla ice cream contain more than 0.1 percent of the smallest harmful dose of alcohol. To avoid warnings on these products, Cal/EPA has used “creative listing.” The listing of vitamin A has been qualified; it now only applies to exposures above a specified, harmful dose. Ethyl alcohol is only listed as “ethanol in alcoholic beverages.” But such amendments have rarely been made, and on a case-by-case basis, because the initiative was based on an intrinsic distrust of government agencies.[158]

The solution to the Prop. 65 problem is simple. Prop. 65 should be repealed or substantially revised, or recycled products should be exempted from it. Actually getting rid of Prop. 65, though, is a trickier matter. Prop. 65 could be invalidated by the courts. For instance, it has been argued that Prop. 65 is inconsistent with Congress' objectives under the FD&C Act because it usurps the FDA's role in regulating foods, drugs, and cosmetics and their packaging. Some say that Prop. 65's warning requirements are invalid because Congress intended the FD&C Act to be a comprehensive regulatory scheme, and because the warnings apply to nationally merchandised products that don't need warnings in other states, which unconstitutionally burdens interstate commerce.[159] It has also been argued that just saying that something contains a carcinogen, with no information about the basis for considering the chemical a carcinogen or about its carcinogenic potency, is misleading and may constitute misbranding of a product within the meaning of the FD&C Act.[160] But a resolution by the courts doesn't seem likely.

In California, all changes to a voter-approved initiative have to be approved by the voters as well, unless the proposition itself allows for legislative amendment. Prop. 65 can be clarified in two ways:[161]

- One or more agencies are allowed to “adopt and modify regulations, standards, and permits as necessary to conform with and implement the provisions of this chapter and to further its purposes.” This sort of quasi-legislative action would be subject to the California Administrative Procedure Act[162] and judicial review.[163] The only problem is that the listing of chemicals,

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154 Personal communication, Jack Lewis.

155 Heckman (1988), p. 6.

156 Personal communication, Joe Moran.

157 Personal communication, Frank Vincent.

158 Lovett, pp. 26–27.

159 Heckman (1987), p. 18.

160 §§ 201(n) and 403(a). Heckman (1987), n.12.

161 Denney, p. 793.

162 Cal. Government Code §§ 11346 *et seq.*

163 Cal. Code of Civil Procedure § 1085.

according to the proposition, isn't a regulation within the meaning of the Administrative Procedure Act.[164] This means that courts can't strike down specific listing decisions.

- The Legislature can adopt amendments; the proposition states that "to further its purposes this initiative may be amended by statute, passed in each house by a two-thirds vote."[165]

The key phrase, of course, is "to further its purposes." Therefore, Prop. 65 will be difficult to amend or rescind through the legislative process.

Health protection is important, and that's why we have health and environmental agencies and regulations. But the FDA and Prop. 65 pursue this goal by exaggerating risk, and their policies are often implemented arbitrarily. The unintended consequence is that recycling is discouraged.

ABOUT THE AUTHOR

Alexander Volokh is assistant policy analyst at the Reason Foundation specializing in environmental risk assessment. Volokh's expertise includes risks posed by synthetic pesticides and other man-made chemicals, hazardous waste policy, solid waste management, regulatory barriers to the use of recycled materials, the valuation of natural resources, and medical device regulation.

[164] Cal. Health and Safety Code § 25249.8(e).

[165] Prop. 65, § 7.