DELAYS IN THE FDA'S FOOD ADDITIVE PETITION PROCESS AND GRAS AFFIRMATION PROCESS

HEARINGS

BEFORE THE

SUBCOMMITTEE ON HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS

OF THE

COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT HOUSE OF REPRESENTATIVES

ONE HUNDRED FOURTH CONGRESS

FIRST SESSION

JUNE 22 AND 29, 1995

Printed for the use of the Committee on Government Reform and Oversight

U.S. GOVERNMENT PRINTING OFFICE

20-081 CC WASHINGTON : 1995

For sale by the U.S. Government Printing Office
Superintendent of Documents, Congressional Sales Office, Washington, DC 20402
ISBN 0-16-047796-4

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DELAYS IN THE FDA'S FOOD ADDITIVE PETITION PROCESS AND GRAS AFFIRMATION PROCESS

THURSDAY, JUNE 22, 1995

U.S. HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HUMAN RESOURCES AND
INTERGOVERNMENTAL RELATIONS,
COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:30 a.m., in room 2247, Rayburn House Office Building, the Honorable Christopher Shays (chairman of the subcommittee) presiding.

Present: Representatives Shays, Davis, and Towns.

Also present: Representative McIntosh.

Staff present: Lawrence J. Halloran, staff director and counsel; Thomas M. Costa, clerk; Anne Marie Finley, professional staff; Ronald Stroman, minority deputy staff director; Cheryl Phelps, minority professional staff member; Elisabeth Campbell, minority staff assistant; and Kevin Davis, minority professional staff member.

Mr. SHAYS. I would like to call this hearing to order.

The purpose of today's oversight hearing is to examine the causes and effects of lengthy delays in the Food and Drug Administration's review of food additive petitions. We will continue these hearings, as well, on June 29. These are the first oversight hearings on the FDA's management of this process since the food additive amendments to the Federal Food, Drug and Cosmetic Act were adopted in 1958.

I want to make it just as clear what our purpose is not. Oversight isn't a game of "Gotcha." FDA-bashing is not a sport I care to play. We want our oversight to be thoughtful and constructive, asking the questions that need to be asked and evaluating the answers with the help of experts and other interested witnesses. So this hearing will examine the reasons for delays and, more importantly, the adverse impact on food technology research and consumer nutrition benefits caused by a review process at times unwilling or unable to yield a decision.

In this instance, our oversight approach has borne fruit, and I commend the FDA for its openness and cooperation with us in this inquiry.

On May 2, the FDA informed the subcommittee that 295 food petitions were under review, some of which were filed in the 1970's. The oldest pending food additive petition was filed on March 26,

1971. This situation persists despite a statutory requirement that the agency review and act on food additive petitions not more than 180 days after the date of filing of the petition.

Obviously, the statutory deadline has been interpreted out of existence by the FDA, and I am eager to learn how the agency plans to restore accountability to the process for determining the safety of food additives. The agency will present such a plan to reduce the backlog of pending petitions in its testimony today. Although long overdue—that's quite an understatement—this commitment to address the problem is very welcome.

This week the FDA approved long-pending petitions affirming that certain enzymes are "Generally Recognized As Safe." Those applications were filed on August 31, 1972. With this action, the agency appears ready to concede that good science and a healthy respect for public safety should not require 23 years of review to affirm that substances used in foods throughout the world are safe. That is a giant step in the right direction.

This positive agency response illustrates the importance of the congressional oversight process. Sometimes a hard look can do as much good as a new law.

The goal is certain and timely decisionmaking on the safety of food additives. The FDA statutory charge is to determine the safety of food additives, applying the best science available. The standard is not at issue; rather, it is the process of applying the standard that our witnesses have been asked to address. The potential benefits of this technology, both in terms of public health and economic vitality, are too great to permit regulatory torpor to jeopardize food research and innovation.

Finally, I must express some deep concern over the unwillingness of food companies to step forward and describe their experiences in the food additive review process. While understandable to a degree, the reluctance of petitioners to speak openly about their problems at the FDA denies the subcommittee important firsthand evidence. It also tends to confirm the impression that the FDA can be a vengeful regulatory master, inflicting punishment through delays in its processes. Objective performance should insulate the agency from that criticism. Hopefully, a more predictable review timetable will also embolden corporate petitioners so that we will have the full benefit of their views in the future. I might say, parenthetically, that this committee will not be reluctant to subpoena those reluctant witnesses in the future.

Still, we are fortunate to have witnesses here today who bring broad experience and technical expertise in the matter of food additive safety review. I want to welcome our distinguished witnesses, and I look forward to their testimony.

We have four panels. It's going to be a fairly long morning and afternoon. I apologize to everyone for the delay in beginning this hearing. We had a vote earlier. Here I am making excuses for delays already, and I'm going to be talking to the FDA. Give me a break.

Mr. Towns, my good friend and colleague, you have the floor.

Mr. TOWNS. Thank you very much, Mr. Chairman. Let me begin by thanking you for paying special attention to this problem. I look

forward to working with you to see if we can bring about some solutions.

It is clear that this agency is sorely in need of congressional oversight to carry out its mission. I hope we can help establish a foundation upon which the Congress, FDA, and industry can bring about the needed reforms to expedite the petition process for food additives, and most importantly, ensure food safety, and at the same time protect the consumer.

Much to the credit of the FDA, the American food supply is among the safest in the world, and the food additives amendment has played a vital role in ensuring this safety. However, there is still room for improvement.

Much has changed since the enactment of the food additives amendment almost 30 years ago. New technologies have produced better packaging that decreased the likelihood of harm from indirect additives, and better science has enabled us to more effectively assess the safety of food.

With these advances, the FDA has increasingly requested that more information be included in a food additive petition. As a result, petitions have gotten longer, but the agency has devoted few additional resources to review petitions. It has been estimated that food regulation accounts for approximately 70 percent of the FDA's workload.

I have a chart over there. I don't think you can see it from here.

Mr. SHAYS. Let there be no doubt.

Mr. TOWNS. The point is that, in 1994, only 25 percent of the agency's resources were devoted to food regulation. In 1992 and 1993, a small percentage of resources were allocated to food regulation, 28 percent and 27 percent, respectively, although it is 70 percent of FDA's workload. There seems to be something wrong with those kinds of numbers, and I think that is something we need to talk about, as well, Mr. Chairman.

As a result, there are currently 295 food additive petitions that are pending at the agency, some of which have been pending since 1970. This, quite frankly, is unacceptable and particularly troubling in light of the statutory requirements to review and act on a petition within 180 days. I think we can say that is long overdue and that the timeframe, of course, is way, way overdue.

In assessing the delays in the petition review process, I believe that it is equally important to recognize the role of industry in contributing to the situation. The review process entails mutual obligation on the part of the FDA and industry. Everybody must cooperate. To that end, it is important that industry submit petitions with credible scientific data and sufficient information to support approval.

As we begin these hearings, I look forward, Mr. Chairman, to hearing the witnesses, and also finding out why this tremendous delay has to take place. In addition, I anticipate working cooperatively with you, the FDA, and industry to expedite the petition process and ensure that America's food supply still remains the safest in the world.

On that note, Mr. Chairman, I yield back the balance of my time.

Mr. SHAYS. I thank the gentleman.

We have been joined, as well, by Mr. Davis from Virginia.

I don't know if you would like to make an opening statement.

Mr. DAVIS. I have no statement at this time.

Mr. SHAYS. It's nice to have you here. Thank you for being here.

I would like, at this time, to just ask for two unanimous consents. I ask unanimous consent that all members of the subcommittee be permitted to place an opening statement in the record and that the record remain open for 3 days for that purpose. Without objection, so ordered.

I also ask unanimous consent that our witnesses be permitted to include their statements in the record, as well. Without objection, so ordered.

If I could, I would like to call on the first panel to come, and if they would remain standing. We have Linda Suydam, Acting Deputy Commissioner for Operations, Food and Drug Administration; accompanied by Dr. Fred Shank, Director, Center for Food Safety and Applied Nutrition; accompanied by Dr. Alan Rulis, Acting Director, Office of Premarket Review, FDA; also joined by Margaret Jane Porter, FDA general counsel, and Catherine Copp, FDA associate chief counsel for foods.

I'm sorry. We have four chairs, but it would be nice to swear in all of our witnesses in case we hear testimony from all five.

[Witnesses sworn.]

Mr. SHAYS. For the record, I would like to note that all five have answered in the affirmative.

We have a statement from one individual, and then we will proceed to ask questions.

Ms. Suydam, nice to have you here. I understand you will be giving a statement.

STATEMENT OF LINDA A. SUYDAM, ACTING DEPUTY COMMISSIONER FOR OPERATIONS, FOOD AND DRUG ADMINISTRATION; ACCOMPANIED BY DR. FRED SHANK, DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION; DR. ALAN RULIS, ACTING DIRECTOR, OFFICE OF PREMARKET REVIEW; MARGARET JANE PORTER, GENERAL COUNSEL; AND CATHERINE COPP, ASSOCIATE CHIEF COUNSEL FOR FOODS

Ms. SUYDAM. Thank you, Mr. Chairman. I am pleased to be here today to provide information about the Food and Drug Administration's regulation of food additives.

As my written statement explains, I intend to highlight three things this morning: why the agency reviews the safety of substances added to the food supply in the manner that it does; concerns that have been raised regarding the existing process; and to provide an overview of the comprehensive plan that we have devised to improve management of the overall program, reduce the inventory of pending petitions, and improve the timeliness and predictability of agency decisions.

FDA's primary mission is to ensure that the food supply is safe for the 280 million American consumers. Clearly, we have achieved this goal. The American food supply is one of the safest and most abundant in the world. The American public expects its food, including any additives used in food, to be safe, regardless of who consumes the food, or the quantity consumed, or for what length of time.

The requirement that chemical substances used as food additives be proven to be safe before they can be introduced into the food supply is a critical link in the food safety chain.

Approval of a food additive poses unique safety considerations for the agency. Unlike drugs, which are ingested for their significant therapeutic benefit, food additives are eaten by everyone and, by definition, are not supposed to provide any pharmacological effect. As such, they do not provide direct benefits that justify exposing consumers to risk.

When FDA approves use of a food additive, that approval is generic. It permits anyone to manufacture or use the additive, in conformance with the chemical's identity, specifications, and conditions of use. Unlike drugs or medical devices, a food additive regulation is not a product license limited to a single sponsor or manufacturer. Therefore, a food additive petition must contain information adequate to demonstrate that this additive is safe under each condition of use permitted.

It was the clear intent of Congress in its drafting of the food additives amendment that safety was to be the only consideration when deciding whether to authorize use of a food additive.

The legislative history of the 1958 amendments defines the standard by which FDA is to measure the safety of additives. Congress stated that safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not and cannot require proof beyond any possible doubt that no harm will result under any conceivable circumstance.

The newly enacted law was a milestone in that it required safety testing for chemicals used in foods prior to their use and placed the burden for conducting the testing squarely on the industry. FDA's review of an additive is a scientific inquiry to determine, with reasonable certainty, that no harm will result from the proposed use of that additive.

The credibility of FDA's review is very valuable to food manufacturers. They can be secure in the knowledge that FDA evaluated ingredients in their products, and in the packages in which they are sold, and determined that they will not be harmful to the public. FDA stands behind these manufacturers and supports the safety of their products. Furthermore, the credibility of the safety of the U.S. food supply and the safety of FDA-permitted food ingredients is a boon to domestic food producers who engage in global trade.

While our primary mission is to ensure the safety of the food supply, FDA acknowledges that it needs to improve upon its other and very important obligation; that is, to review and render decisions on proposed new food additives expeditiously. The food industry is entitled to timely and predictable decisions on food additive petitions.

We are committed to improving the review process without jeopardizing food safety or the integrity and credibility of the process. As a result, we have developed a comprehensive plan that addresses improvements to the management of the program, uses new approaches for the review of petitions, and that we believe will reduce the numbers of pending petitions and ensure timely review of new submissions.

Some of the elements have been underway for some time; some are just beginning. This plan is a thoughtful but practical attempt to reach a goal of timely, predictable decisions for food additive petitioners. We believe that it will in the long run, and when viewed as a whole, achieve significant improvement.

For the plan to be successful, however, depends also, in part, on the food industry. Presently, many petitions, when submitted, have shortcomings in the data needed to support a decision to approve the additive, or during our review the data are found to be of poor quality.

Because of the competitive nature of the marketplace, the industry has been reluctant to have the agency formally deny product petitions. Consistent with this preference, FDA's policy has been to work very closely with each petitioner to develop data, including additional scientific studies, if necessary, to resolve safety questions that arise, rather than simply to deny petitions that lack adequate supporting data.

This cooperative process for improving the quality or completeness of a petition added to the review time, but more importantly, it also improved the likelihood that an additive would ultimately be approved. The industry has the responsibility to ensure that petitions are of adequate quality so as not to impede the timeliness of an agency decision.

Before I describe the discrete elements of our plan, I would like to mention priorities regarding resources in the agency as a whole. Part of the difficulty of addressing program needs in a time of limited and dwindling resources has meant that the agency has had to make some hard choices regarding internal priorities.

As a result, we have committed significant resources to review the safety and effectiveness of drugs and medical devices. Not only do such products have some associated risks, but they also confer clear health benefits to the public. With management changes and additional resources in both the drug and device programs, we have been able to improve our performance markedly. By applying some of the lessons that we have learned from these programs to the food additive process, we hope that we can achieve similar results.

I would like now to take a few moments to more fully explain some of the elements of the plan. In November 1992, the Center for Food Safety and Applied Nutrition was reorganized, placing most of the petition review process under one central line management. This provides for more effective and efficient oversight of the process and allows for a more uniform alignment of priorities.

We have also established a regulatory and science policy board to resolve difficult scientific issues and to set policy for nonroutine petitions and other food ingredient related issues. And we intend to increase significantly our consultation with the food advisory committee, especially for help in resolving complex scientific issues.

FDA believes that the expenditure of resources for review of a particular petition should be commensurate with the risk posed by that substance. Even though many indirect additives are likely to pose relatively little risk to consumers, FDA has had to expend a large amount of resources reviewing these petitions.

As a result, to address petitions for low-risk, indirect additives, what we have done is implemented a "threshold of regulation" ap-

proach for indirect additives, which establishes a process for determining when the likelihood or extent of migration to food of a noncarcinogenic substance used in packaging is so trivial as to not require regulation of the substance as a food additive.

We have been implementing this policy on a limited basis for some time, and in fiscal year 1994, we issued 46 letters for substances that otherwise would have been the subject of food additive petitions. Today, I am pleased to be able to tell you that the final regulations implementing the threshold of regulation policy will be completed soon and published in the Federal Register in the near future.

Also, as part of President Clinton's and Vice President Gore's National Performance Review, FDA is also proposing to replace the current regulatory process for reviewing the GRAS status of ingredients with a simple notification procedure.

Another major problem that has contributed significantly to FDA's lengthy review time is the sizable inventory of pending petitions. To reduce this backlog, the agency is committing research scientists from CFSAN and other centers to perform technical reviews of studies in backlogged pending petitions.

Since almost 150 of the approximately 290 petitions are for indirect additives, and the testing requirements for these are generally straightforward ones for which the agency has well-developed guidelines, we, as a part of this program, expect to award a contract for independent, third-party scientific review of many indirect additive petitions.

The purpose of this review will be to evaluate the overall strength of the evidence offered by the petitioner to support a safety determination. Upon receipt of the results of the review, FDA will render the final safety decision and prepare the administrative documents to approve the petition or inform the petitioner of the reasons why the petition is not approvable.

To expedite completion of the pending direct food additives and of the more complex indirect additives, we also intend to award a contract for review of specific types of studies, such as classical, standard toxicity studies, that are routinely submitted in support of both direct and indirect additive petitions.

We believe that these programs will assist us in reducing substantially the number of pending petitions, which will in turn improve our efficiency in reaching decisions in a much more timely way on petitions of all types. With a reduced backlog, and together with full implementation of the other initiatives in our plan, we are prepared to establish performance goals for the review of food additive petitions.

In considering the performance goals that we might set, we have categorized petitions into one of three tiers, based on length, complexity, and novelty of issues presented. Tier I petitions would include routine petitions of several classes; that is, many indirect additive petitions or subsequent approvals for already approved additives where new issues have not arisen. For these petitions, our goal is to issue an agency response within 90 days of receipt of the submission.

Tier II includes petitions that do not pose novel scientific or regulatory issues but which contain more data than a petition that

would meet the criteria for tier I. For these petitions, our goal is to issue an agency response within 180 days of receipt of submission.

Tier III includes petitions for additives that present difficult or novel scientific or regulatory and policy issues, or either have wide exposure, such as an artificial sweetener, or high exposure, such as an additive used as a macro ingredient. Petitions for such additives generally contain very numerous and/or very complex safety studies. For these petitions, our goal is to issue an agency response within 360 days of submission.

Because it will take some time to reduce the backlog of pending petitions and institute other management improvements, we propose to phase in our accomplishment of these goals over 3 years. We believe that full implementation of this program will respond to industry's major concerns about the process. Decisions will be reached in a more timely manner and with much greater predictability for petitioners.

The agency is keenly aware that the food additive process takes too long. We have outlined and already begun to implement our comprehensive plan to remedy the situation. We are willing to work with the committee and to consider other approaches that might further improve the efficiency of this program.

We strongly urge, however, that the zeal to speed up the process not be allowed to override the credibility and integrity of that process nor to undermine the confidence in the safety of the American food supply. American consumers and the food industry would be ill-served if food safety is sacrificed simply because of a desire for speedy review.

Consumers expect safety, and industry relies upon FDA's careful scientific decisions regarding the safety of food ingredients. We do not want either of these to be compromised.

Mr. Chairman, I have some documents that I would like to submit for the record, in addition to my testimony, and I would be happy to answer any questions you or other members of the committee may have.

[The prepared statement of Ms. Suydam follows:]

PREPARED STATEMENT OF LINDA A. SUYDAM, INTERIM DEPUTY COMMISSIONER FOR OPERATIONS, FOOD AND DRUG ADMINISTRATION

Mr. Chairman:

I am pleased to be here today to provide information about the Food and Drug Administration's (FDA) regulation of food additives. Under the Federal Food, Drug, and Cosmetic Act (the Act), FDA is responsible for evaluating the safety and approving the use of food additives and color additives. In addition, FDA currently reviews petitions to affirm that substances used in food are generally recognized as safe (GRAS).

This statement addresses why the Agency reviews the safety of chemicals added to the food supply in the manner it does and identifies concerns that have been raised regarding the existing review process. It then outlines the comprehensive plan that FDA has devised to improve management of the overall program, reduce the inventory of pending petitions, and improve the timeliness and predictability of Agency decisions.

I. OVERVIEW

FDA's primary mission is to ensure that the food supply is safe for 280 million American consumers. Clearly, we have achieved this goal: the American food supply is one of the safest and most abundant in the world. The American public fully expects its food—including any substances added to food—to be safe, regardless of who

consumes the food, the quantity consumed, or the period of time over which it is consumed. The requirement that chemical substances used as food additives be shown to be safe before they can be introduced into the food supply is a critical link in the food safety chain.

Approval of a food additive poses unique safety considerations for the Agency. Unlike drugs which are ingested for the significant therapeutic benefit they are intended to confer on the patient, food additives are eaten by everyone and, by definition, are not supposed to produce any pharmacological effect. They do not provide direct benefits that justify exposing consumers to risk. This is true even for food additives, such as artificial sweeteners, that may have a beneficial effect on the American diet. Even in the case of an artificial sweetener, for example, there are already safe and effective alternatives available to reduce caloric intake for anyone motivated to do so.

Other factors also contribute to the unique safety concerns related to food additives. A food additive potentially will be consumed by everyone in the population, including pregnant women, children, and the elderly. In addition, food additives are going to be consumed by healthy individuals and may be consumed for an entire lifetime.

Finally, when FDA approves use of a food additive, that approval is generic—it permits anyone to manufacture or use the additive (consistent with any existing patent protection), in conformance with the substance's identity, specifications, and conditions of use. Unlike drugs or medical devices, a food additive regulation is not a product license limited to a single sponsor or manufacturer. Therefore, a food additive petition must contain information adequate to demonstrate that the additive is safe under each and every condition of use to be permitted and to identify issues that would require restrictions to ensure safety.

Food ingredients can be classified into four groups: 1) food additives; 2) color additives; 3) ingredients for which either FDA or the U.S. Department of Agriculture specifically authorized use prior to 1958, the so-called, "Prior Sanctioned Substances;" and 4) GRAS substances, that is, substances that are agreed upon as safe by the general scientific community on the basis of scientific evidence or that were marketed prior to 1958 and are considered GRAS because of a long history of safe use. Only food and color additives require premarket approval. Our focus today is on food additives,[1] of which there are two types: those intentionally added to foods (direct additives) and those that can be expected to become components of food unintentionally because of their use (indirect additives). This latter category includes components of food packaging materials which may migrate into the food. Food additives vary greatly in composition and may be consumed, in the aggregate, in amounts exceeding millions of pounds per year.

The Food Additives Amendment of 1958 and the Color Additive Amendments of 1960 require that chemicals that are going to be used in food are safe. The 1958 law was a milestone in that it required safety testing for chemicals used in foods prior to their use, and placed the burden for conducting that testing squarely on the industry. It was the clear intent of Congress in its drafting of the Food Additives Amendment to the Act that safety was to be the only consideration in the decision whether to authorize use of a food additive. The legislative history of the 1958 amendments defined the standard by which FDA is to measure the safety of additives. Congress stated that:

> Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance.

The Color Additive Amendments contain the identical safety standard.

FDA's review of an additive is not an attempt to determine the absolute harmlessness of any chemical substance, nor an attempt to establish that no harm will result under any conceivable circumstance. Rather, it is a scientific inquiry to determine, with reasonable certainty, that no harm will result from the proposed use of an additive. The statute requires that the Agency perform a thorough, careful review that will allow us credibly to support and defend our evaluation that the use of an additive will be safe.

The credibility of FDA's review is very valuable for food manufacturers. They can be secure in the knowledge that FDA evaluated ingredients in their products and in the packages in which they are sold, and determined that these materials will not be harmful to the public. FDA stands behind these manufacturers and supports

[1] Unless otherwise noted, the term "food additive" in this statement applies to color additives also.

the safety of their products. Furthermore, the credibility of the safety of the U.S. food supply and the safety of FDA permitted food ingredients is a boon to domestic food producers who engage in global trade.

As we stated at the outset, FDA's primary mission is to ensure the safety of the food supply. With that mission comes the very important obligation to review and render decisions on proposed new food additives expeditiously, and we acknowledge that we need to improve our performance in this regard. The U.S. food industry is entitled to timely and predictable decisions on food additive petitions. We are committed to improving the review process in order to provide those decisions, and to do this in a way that will not jeopardize food safety or the independence, integrity and credibility of the review process.

We have taken, therefore, a close look at our process for reviewing petitions and have developed a comprehensive plan to improve the efficiency and overall functioning of the food additive review program. We will describe the plan in greater detail later in the testimony, but in essence, it addresses improvements to the management of the program and new approaches for the review of petitions that we believe will reduce the numbers of pending petitions and ensure timely review of new submissions.

The major elements of the plan include:

- reorganization of FDA's Center for Food Safety and Applied Nutrition (CFSAN) to place petition review resources under one central manager;
- development and issuance of a "Threshold of Regulation" approach for indirect additives that meet specific criteria;
- performance goals to review petitions within defined time periods;
- reform of the GRAS regulatory process;
- additional Agency resources to reduce the inventory of pending petitions; and
- use of external scientific expertise to expedite the review of pending petitions;
- elimination or reduction of requirements for environmental assessments for many petitions; and
- expanded programs to help petitioners submit complete, sufficient submissions.

This plan represents our thoughtful—but practical—attempt to reach a goal of timely, predictable decisions on food additive petitions. We believe that implementation of this comprehensive plan as a whole will, in the long run, result in significant, long-term improvement. We have begun implementation of several components and already have seen positive results.

For the plan to be fully successful, however, we will need the cooperation and assistance of the food industry. Presently, many petitions, when submitted, have shortcomings in the data needed to support a decision to approve the additive. Similarly, during FDA's review, the data in a petition too often are found to be of poor quality or inadequate. An example of this is when the data do not answer the particular questions that a study was designed to address.

In the past, because of the competitive nature of the marketplace, the industry has been reluctant to have the Agency formally deny product petitions. Consistent with industry's preference, FDA's traditional policy for food additives has been to work very closely with each petitioner to develop data, including additional scientific studies if necessary, to resolve safety questions that arise. We do this instead of simply denying those petitions that lack adequate supporting data. The point is that while this cooperative process to correct deficiencies in a petition added to the review time, it also added significantly to the likelihood that an additive ultimately would be approved.

In short, we acknowledge that FDA can improve the process for reviewing petitions for food ingredients, and we affirm our commitment to providing industry with timely decisions. Nevertheless, we also must call upon the industry to ensure that the petitions submitted to the Agency are of adequate quality so as not to impede the timeliness of a final decision.

I would like to add one final note regarding resources in the Agency as a whole. Part of the difficulty of addressing program needs in a time of limited and dwindling resources has meant that the Agency had to make some hard choices regarding its internal priorities. Historically, FDA has committed significant resources to review the safety and effectiveness of drugs and medical devices. Although such products have some associated risks, they confer clear benefits to the health of the public. With management changes and additional resources in both the drugs and device programs, we have been able to improve our performance markedly. By applying some of the lessons we have learned in those two programs to the food additive process, we believe that we can achieve similar results.

II. THE AGENCY'S PLAN

FDA is committed to decreasing the time to a decision, and to reducing the pending inventory of active petitions, every bit as much as petitioners are. Our efforts to do so, however, must not compromise the safety of products entering the marketplace and must be fair to all petitioners. Indeed, FDA already has implemented changes to speed and improve the petition review process. A brief description of our comprehensive plan follows:

A. MANAGEMENT REFORMS

1. CFSAN Reorganization

In November 1992, CFSAN was reorganized, placing most petition review resources under one central line management. Prior to this time, the former Division of Food and Color Additives had to coordinate review of chemistry and toxicology data with other offices under different directors. These other directors were responsible for programs other than petition review. Under the reorganized structure, the direct line authority of the Director of the Office of Premarket Approval over most personnel reviewing petitions provides for more effective and efficient oversight of the process and allows for more uniform alignment of priorities.

2. Special Focus Team for Complex Scientific Issues

To assist in the review of petitions that present complex scientific or regulatory issues, FDA organized a Regulatory and Science Policy Board, composed of the senior management of the Office of Premarket Approval and other senior scientists from CFSAN or other parts of the Agency as needed. The board acts to resolve difficult scientific issues and to set policy for non-routine petitions and other food ingredient-related issues.

3. Increased Use of Other Scientists

CFSAN is increasing its direct use in the petition review process of both non-federal scientists and research scientists from other Centers and agencies when CFSAN scientists lack specific expertise. Such scientists provide in-depth reviews and reports for the development of regulations and serve as consultants for the premarket review process in CFSAN. For example, to resolve novel questions raised in the review of petitions to evaluate the use of fat substitutes, CFSAN requested assistance from clinical nutritionists at the U.S. Department of Agriculture (Beltsville), and from reviewers from FDA's Center for Veterinary Medicine to evaluate special animal studies in swine.

The Agency also intends to increase significantly consultation with the Food Advisory Committee, especially for help in resolving complex scientific issues, such as those posed by novel food ingredients. For example, the Agency sought advice from the Committee regarding FDA's approach to regulating products developed using biotechnology.

4. Contract with the Federation of American Societies for Experimental Biology (FASEB)

FDA has been criticized as being too conservative in making safety determinations and as requiring more testing than is necessary or appropriate. FDA has asked FASEB, under an existing contract, to consider these issues.

A vexing issue for the Agency today is deciding how to reach a safety decision for food ingredients for which tests using traditional animal models may not be appropriate. For example, consumer interest in nutritionally modified diets has led to new food ingredients used in high amounts that replace or supplement common food components, principally, sugar or fat. In such situations, FDA has made safety judgments on a case-by-case basis, using criteria that it believed would be accepted by the community of food safety experts. FDA believes that some of its decisions have been delayed because of a lack of general agreement on the testing that is appropriate when traditional approaches may not resolve safety questions definitively. To address this, FDA also has asked FASEB to institute a study to make recommendations on, among other things, criteria that the scientific community would agree justify the use of alternative models to ensure the safety of food ingredients.

B. REDUCING THE PENDING INVENTORY OF PETITIONS

1. Increase Petition Review Staff

A problem that contributes significantly to FDA's lengthy review time is the sizable inventory of pending petitions. Indeed, because of the queue of assignments on a particular reviewer's desk, it may take a long time before work on a newly submit-

ted petition can begin. Studies from petitions submitted previously are "ahead" of the new petition and fairness to petitioners dictates that they be reviewed first.

To reduce the backlog of pending petitions, the Agency is committing resources for the food additive process from other offices in CFSAN and other Centers, such as, the National Center for Toxicological Research. For example, research scientists may perform technical reviews of studies in pending petitions. We will make available no fewer than 22 FTE's from other programs over the next 6–12 months for this effort.

2. Contracts

Almost 150 of the approximately 290 pending petitions are for indirect additives (components of food packaging or other articles that come in contact with food). Generally, the testing requirements for many of these substances are standard and straightforward for which the Agency has well developed guidelines for the industry. Therefore, we expect to award a contract for independent third-party scientific review of some indirect additive petitions. Upon receipt of the results of the review, FDA will render the final safety decision and prepare the documents to approve the petition or, in the case that the petition is not approvable, to inform the petitioner of the reasons why.

Similarly, for many direct food ingredients, there are often thousands of pages of data from studies carried out to assess the toxicity of the compound in animals. In order to expedite completion of the review of the pending direct food additive petitions and of the more complex pending indirect additive petitions, FDA will award a contract for review of specific types of studies—such as classical, standard toxicity studies, routinely submitted in support of both direct and indirect additive petitions. We believe that this will greatly speed our notification to a petitioner that the data in the petition support approval, or why the data do not support such a finding.

These programs should assist us in reducing substantially the number of pending petitions. This, in turn, will improve our timeliness in reaching decisions on petitions of all types.

C. NEW APPROACHES TO PETITION REVIEW

The Agency believes that the expenditure of resources for review of a particular petition should be commensurate with the risk posed by the substance. To address petitions for low-risk situations, we have done the following:

1. "Threshold of Regulation" Policy

Because of their low dietary exposure, many indirect additives are likely to pose relatively little risk to consumers. Because of the large number of petitions submitted for indirect food additives, however, FDA has had to expend a large amount of resources reviewing these petitions.

FDA has implemented a "Threshold of Regulation" approach for indirect additives. In October 1993, FDA proposed this policy, which establishes a process for determining when the likelihood or extent of migration to food of a noncarcinogenic substance used in packaging is so trivial as not to require regulation of the substance as a food additive. Under this process, information about the proposed use of a noncarcinogenic substance that results in a dietary concentration that does not exceed the threshold would undergo an abbreviated review by FDA, as opposed to the extensive review and formal issuance of a regulation normally required for food additives.

We have been implementing this policy on a limited basis, and in FY 1994, we issued 46 letters for substances that might otherwise have been the subject of food additive petitions. The final regulations implementing the Threshold of Regulation policy will be completed and published in the Federal Register soon.

2. Reinvention of GRAS Regulatory Process

Unlike a food additive, a substance that is "generally recognized as safe" by qualified experts may be used lawfully in the absence of any FDA action. In part because of this distinction, and as part of President Clinton's and Vice President Gore's National Performance Review, FDA is proposing to replace the current regulatory process for reviewing the GRAS status of ingredients with a simple notification procedure. Under this process, FDA will have a brief period of time—60 to 90 days—to object to an independent GRAS determination reflected in a notification.

3. Expanding Criteria for Exclusion from a Requirement to Prepare Environmental Assessments

Under the National Performance Review, we also are proposing to eliminate or reduce requirements for environmental assessments for many routine petitions.

4. Policy for Food Biotechnology Products

We created a process whereby the developer of a food product utilizing biotechnology (many such products present low risk) consults the Agency early on to discuss the product and identify potential safety and regulatory issues. This process allows the Agency to use its resources effectively to remain abreast of developments in the food biotechnology field and identify those cases in which premarket review and approval may be warranted. To date, the Agency has concluded the consultation process on approximately a dozen products.

D. PERFORMANCE GOALS

One of the industry's greatest concerns is that the Agency takes too long to inform petitioners that the information in a petition supports approval, or that the data are inadequate and clarification or more data are needed. A key lesson of the prescription drug user fee program has been the utility of establishing performance goals in managing the product review process. We believe the establishment of such goals for the food additive petition review process will serve to fulfill the Agency's commitment to timely and predictable decisionmaking over the long term. We are announcing that we will be establishing performance goals for the review of food additive petitions. Such goals can only become operative, however, once the backlog of pending petitions is reduced substantially and the other management review process improvements are implemented fully.

In considering the performance goals that we might set, we have classified petitions into one of three "tiers" based on length, complexity, or novelty of issues presented. These proposed response time goals will apply to new petitions received following full implementation of the comprehensive plan.

- TIER I petitions would include "routine" petitions of several classes: e.g., many indirect additive petitions, or subsequent approvals for an already approved additive where new issues do not arise. For these petitions, our goal is to issue an Agency response—that the submission is adequate, or provide a complete description of why it is not adequate—within 90 days of receipt of the submission.
- TIER II includes petitions that do not pose novel scientific or regulatory issues, but which contain more data than a petition that would meet the criteria for Tier I. For these petitions, our goal is to issue an Agency response within 180 days of receipt of submission.
- TIER III includes petitions for additives that present difficult or novel scientific or regulatory and policy issues or either have wide exposure (such as an artificial sweetener) or high exposure (such as an additive used as a macro-ingredient). Petitions for such additives generally contain very numerous and/or very complex safety studies. For these petitions, our goal is to issue an Agency response within 360 days of submission.

We propose to phase in our accomplishment of these goals over three years, beginning one year after initiation of the contracts to reduce the backlog. For example, our goal is to act on 70 percent of new Tier I petitions within 90 days in the first year, 60 percent of new Tier II petitions within 180 days in the first year, and likewise, 50 percent of new Tier III petitions within the 360 day goal. A complete list of our goals is as follows:

TIER I—70% year 1; 80% year 2; 90% year 3
TIER II—60% year 1; 75% year 2; 90% year 3
TIER III—50% year 1; 65% year 2; 80% year 3

We believe that full implementation of this program will respond to industry's major concern about the process: Decisions will be reached in a more timely manner, and with much greater predictability for petitioners.

There is still much to be done, but once our plan has been completely phased in, we believe we will see additional speed and efficiency in our review process, while simultaneously preserving the integrity, credibility, and science base of that review, and, importantly, continuing to protect the public health.

E. WORKING WITH INDUSTRY

1. Petitioners Workshops

FDA has well-established guidelines for petitioners, for example, preparing chemistry data to measure migration of packaging materials, or information needed to determine exposure scenarios, etc. We also are exploring other ways to educate petitioners regarding development of petitions that are complete and sufficient. For example, we are planning a "Food Additive Petition Workshop" in conjunction with CFSAN's National Center for Food Safety and Technology in Chicago to be held in the fall; if successful, we will hold additional workshops.

2. Industry Proposals

FDA is interested also in the "Industry Initiative for Food Additive Petitions," which has been proposed by Pfizer, Inc., together with a group of other food and food ingredient companies. The proposal aims to improve the quality of the data submitted to the Agency, thereby facilitating and potentially reducing FDA's review time. We believe elements of this proposal could be helpful both for FDA and for industry. We look forward to working with the industry to identify elements that will improve the process and simultaneously preserve the credibility and integrity of that process in keeping with the existing safety standard upon which the American public and the industry rely.

III. CONCLUSION

Mr. Chairman, the Agency is keenly aware that the food additive, color additive, and GRAS affirmation petition processes take too long. We have outlined and already begun to implement our comprehensive plan to remedy the situation. We are willing to work with the Committee and to consider other approaches that might further improve the efficiency of this program.

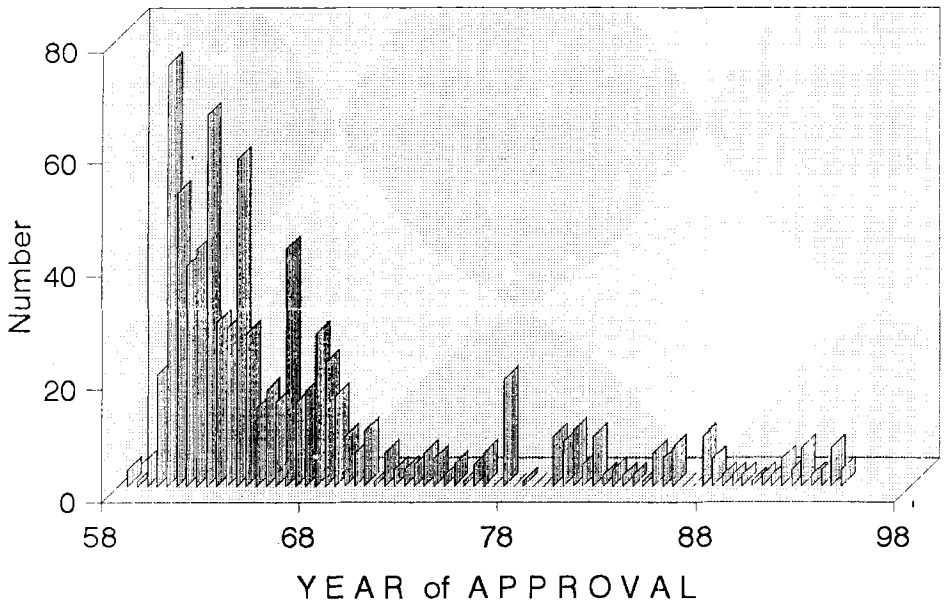
We strongly urge, however, that the zeal to speed up the process not be allowed to override the credibility and integrity of that process, nor to undermine consumers' confidence in the safety of the American food supply. American consumers and the food industry would be ill served if food safety is sacrificed simply because of a desire for a speedy review of petitions. Consumers expect safety and industry relies upon FDA's careful scientific decisions regarding the safety of food ingredients. We do not want either of those to be compromised.

I would be happy to answer any questions you or other members of the Committee may have.

[NOTE.—To reduce publication costs, the subcommittee has omitted from the record, a list of all pending food petitions. A copy of the list may be found in the subcommittee files.]

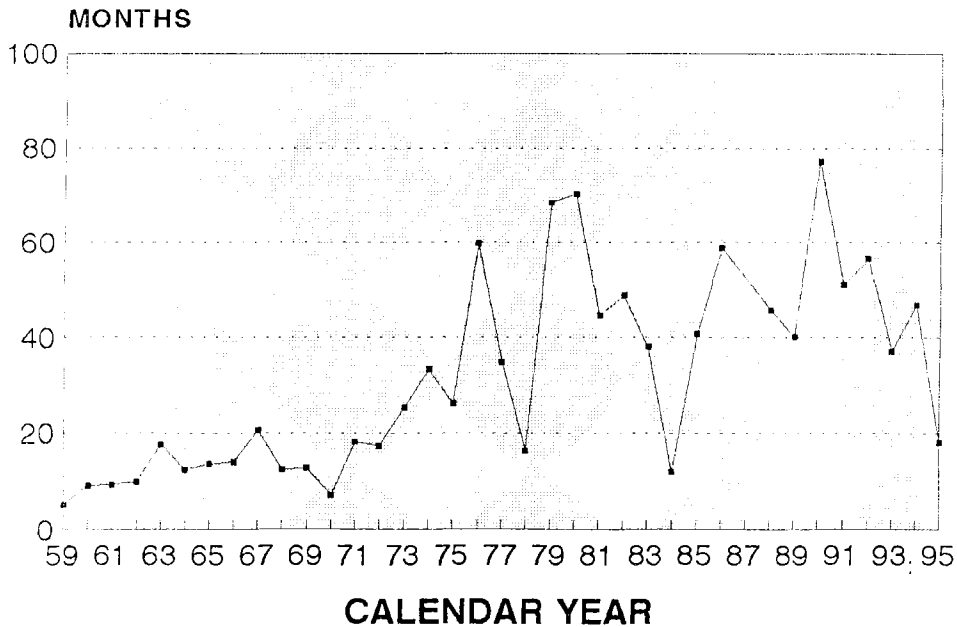
DIRECT FOOD ADDITIVES

All Approvals since 1958



AVERAGE TIME TO APPROVAL (MONTHS)

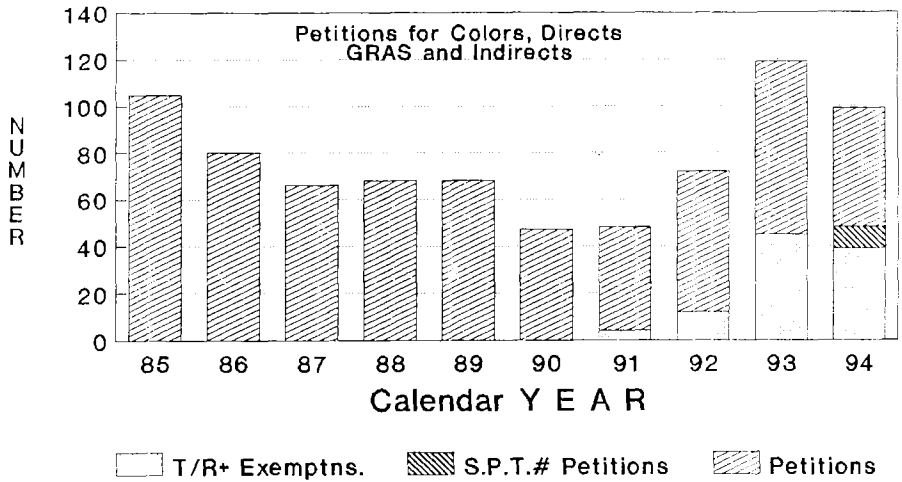
ALL DIRECT ADDITIVE USES EVER APPROVED



By Yearly Regulation Cohort

CFSAN Office of Premarket Approval

Total* Petition Actions



* Approvals, Drops, Withdrawals, Denials
\+ Approval Ltrs. issued under T/R Policy
\# Special Project Team Ind. Addv. Petns.

1993: 39 Approvs.; 35 Termins.
1994: 46 Approvs.; 14 Termins.

Mr. SHAYS. I thank you. We will put into the record anything you would like us to add.

I am going to be asking Mr. Towns to do the first series of questions. But I do want to say that your warning at the end sounds almost a little disingenuous to me, in the sense that we're not talking about, you know, the difference in speeding up something 2 or 3 months. We're talking about extraordinarily long delays. I mean, there's nothing to do with safety that has resulted in these long delays. It is simply a bureaucratic system.

One of the questions I am going to ask you to touch on is where in your testimony you are asking us to lengthen the time of the review period. Could you refer me, in your testimony, to where you are suggesting we lengthen the 180 days?

Ms. SUYDAM. In the testimony, I talk about the three-tiered system. Under the three-tiered system, we are talking about, for those complex food additive petitions—of the most complex—that we would take 360 days to review.

Mr. SHAYS. So only in the most complex would you need 360 days, and in all others you will achieve your 180 days.

Ms. SUYDAM. Right.

Mr. SHAYS. I just don't believe it. I mean, I don't. And we will get into that.

Mr. TOWNS. Thank you very much, Mr. Chairman.

You testified that sometimes the petition process may be delayed because of insufficient data provided to FDA by the petitioner.

Ms. SUYDAM. Yes.

Mr. TOWNS. To what extent is the problem of delay associated with industry's failure to submit complete petitions or to reply in a timely fashion to FDA's requests for additional information?

Ms. SUYDAM. That's a very difficult question to answer, because I think that it depends on the situation with each petition. Some are definitely the result of industry. I can't tell you an exact percentage. Perhaps Dr. Rulis might be able to give you a better guess about what the percentage might be.

Mr. TOWNS. Fine. Dr. Rulis.

Mr. RULIS. Yes. Thank you.

I think it is important to keep in mind that there is a wide range of types of petitions. For the fairly simple petitions that are usually associated with packaging materials, very often we find that the petitions are quite adequate, and we find that our times for reviewing those petitions are at the lower end of our spectrum.

However, I think it is important to point out that for complex petitions, ones that relate to, for example, artificial sweeteners, or fat substitutes, or ingredients that will be ingested in large quantities, relatively speaking, on the order of millions of pounds disappearing annually into the U.S. food supply, for those kinds of petitions, often there are lots of studies, sometimes tens of thousands of pages of toxicological data.

In those instances, it is almost always the case that there are substantive questions that our scientists have when they review those studies. They determine, for example, that the tables don't make sense or the columns don't add up. And they go through the data carefully to establish that. So when they find those kinds of

situations arising, they will go back to the petitioner and ask for clarification. That does, in fact, lengthen the time of review.

Mr. TOWNS. How can FDA provide better guidance to companies so that their petitions contain the necessary information?

Ms. SUYDAM. I think there are a number of elements in our comprehensive plan that specifically address that issue. We are talking about having additional workshops for petitioners. We do provide guidance. We are talking about supporting an industry proposal that would help petitioners prior to their submission of the petition to the FDA.

Mr. TOWNS. Let me just say what I think is a real problem. I think the chairman hit on it. We want to openly and honestly go after this problem and bring about some solutions.

When I look at the fact that you have 70 percent of the workload and 27 percent of the money, I think that's a problem. And I think that when we talk about moving things along, it's going to be very difficult, even in this new structure that you are talking about, in this new arrangement, unless we do something about the shifting of the money.

I don't see how you can be expected to do 70 percent of the work with 27 percent of the money. I think that it has to affect people in industry. And I think we have to be open and honest about this if we're really going to deal with it. When you have things pending for 20 years, that seems to be a long time.

Ms. SUYDAM. I think we understand and recognize your concern. I think that we also are concerned about the length of time. We also are concerned about the resources that have been added to this program—or the resources that the program has had over the last few years. This has been a very difficult time, in terms of resources for the agency, and we have had situations where we have had new programs added that have taken resources from the agency.

I think that what we are saying is that the comprehensive plan, which includes an infusion of resources to get rid of the backlog through a contracting out process, that with that infusion of resources, one-time resources, we will then be able to handle the incoming workload within the timeframes that I described.

Mr. TOWNS. Let me just say this, too. I also feel a little uncomfortable with what you are proposing, that if you are now going to look at the pending applications and you are going to work with them, what happens to the new applications? If you are just going to now take your resources and focus——

Ms. SUYDAM. No. I think the contracts that we are talking about awarding are for the backlog, for the pending applications. What that will then do is free up the reviewers who are currently working on backlog. What often happens is that the delay is the result of the incredible queue that sits on one reviewer's desk, or on many reviewers' desks. We need to get rid of the backlog so that we can start fresh in this program.

Also, I do have a chart with me that shows you review times of direct additives, if I could. I think it will show you that review times have been going down. We have been making progress. I think that it's fairly significant that there was a peak in review times, as you can see.

The initial review times we have charted since 1959, and there was a peak in 1990, but since that time the review times have been coming down. We are focusing on this issue, and we are working to make this better.

Mr. SHAYS. Would the gentleman yield just for a second?

Mr. TOWNS. Yes. I would be delighted to yield to the chairman.

Mr. SHAYS. This won't be off his time. We have a lot of time on this witness.

I'm looking at months over to the left.

Ms. SUYDAM. Yes.

Mr. SHAYS. And I'm thinking, the law requires for you to do it in how many months?

Ms. SUYDAM. Six.

Mr. SHAYS. Six months. The number between zero and 20 practically—I mean, none of them seem to happen—this is the average time?

Ms. SUYDAM. This is the average time.

Mr. SHAYS. I mean, it's an astounding chart, because none of it is within the law.

Ms. SUYDAM. And you can see that it goes back to 1959.

Mr. SHAYS. The one thing I haven't said is that this is a Republican or Democratic problem, nor have I said it is a unique problem. Obviously, if it goes back to 1970, it's not your fault that in 1978 it wasn't done, or 1972. That's not the issue that we will get into.

I'm just wondering if the gentleman would mind——

Mr. TOWNS. I'm delighted to yield.

Mr. SHAYS. Would you go through each chart with us? And then we will just continue with the questioning.

Mr. TOWNS. Sure. I think that's a good way to do it.

Mr. SHAYS. The first chart basically shows that in the average we don't meet the law.

Ms. SUYDAM. Yes.

Mr. SHAYS. Not even close to it. And that it fluctuates significantly.

Ms. SUYDAM. Yes. Yes, that's correct.

Mr. SHAYS. Anything else you want us to know?

Ms. SUYDAM. One thing is that the review time, the trend, has been coming down since 1990. That shows progress.

Mr. SHAYS. That's a very good point.

Ms. SUYDAM. Thank you. I think the other point that we wanted to make from this chart, this is the number of direct food additive approvals since 1958.

Mr. SHAYS. Could I interrupt you a second? Could you just go back to that chart?

Ms. SUYDAM. Sure.

Mr. SHAYS. Because it does raise—I mean, it's worse than the stock market in the worst of days.

Ms. SUYDAM. Yes.

Mr. SHAYS. It's like at the start of each decade we start to go down. 1980, I mean, there's this gigantic drop to 1985. And then there's, in 1989, a significant——

Ms. SUYDAM. Part of that is the problem of using average. When you have an outlier—for example, if we approve something that

we've had in-house for 20 years, then it skews your average. That's why, sometimes, average is not in fact the best.

Mr. SHAYS. Do you have the median?

Ms. SUYDAM. I don't have the median, but we can do that.

Mr. SHAYS. OK. Thank you. I'm sorry.

Ms. SUYDAM. I think that was good, because that's a very important area, Mr. Chairman.

Mr. SHAYS. Could she go through those charts; do you mind?

Mr. TOWNS. Not at all.

Mr. SHAYS. Would you continue to go through those charts? I'm sorry. I have a way of interrupting.

Mr. TOWNS. I would be delighted to yield.

Mr. SHAYS. Do you want to explain again, Ms. Suydam?

Ms. SUYDAM. I think what you will see on this is—there has been criticism that there have been no new approvals since 1988, or there have been few. And we are not saying that there have been a tremendous number, but what you will see is the bulk of food additives were approved in the decade between 1958 and 1968, which was right after the amendments were passed.

What we have had since then is a lessening of the number of approvals, but I think what you also see, from 1988 to the current year, is a fairly stable number. I mean, it fluctuates somewhat, but it is still a fairly stable number. The process has not completely shut down. It is not what we want it to be, but it has not completely shut down.

And this chart shows, since 1985, the number of petitions that have been approved since that year. And that includes colors, directs, GRAS, and indirects, all actions from the Office of Premarket Approval. You will see that there are significant numbers of actions that have taken place, that those actions run between the 80 and 100 mark in the last 4 years.

Mr. TOWNS. Actually—let me make sure I understand this—the number of pendings have gone up, but the amount of approvals have gone down?

Ms. SUYDAM. Actually, the number of pendings have stayed fairly stable for some time.

Mr. RULIS. That's right.

Ms. SUYDAM. The number of approvals—I think actions are fairly constant also. You will see we had a peak in 1993 where that number has gone up, and it is now down a little bit for 1994.

Mr. TOWNS. I'm trying to make certain I understand this backlog.

Ms. SUYDAM. This chart does not include the backlog.

Mr. TOWNS. Yes, that's what I'm saying. That's the question I want to ask you.

Ms. SUYDAM. That's right. It does not include the backlog.

Mr. TOWNS. That's the reason why I'm asking.

Ms. SUYDAM. The number of pending petitions has been fairly constant for the last few years. What that means is, the number that have come in and the number that have gone out has been fairly close to equal.

Mr. TOWNS. OK. You referred to the reform initiative, which I'm happy to hear about, but what additional costs, if any, are likely to be associated with it?

Ms. SUYDAM. Well, we are adding $7 million to the program to do the review of indirects through the contracting process and to do the review of some direct studies through a contracting process, to eliminate or substantially reduce the backlog.

Mr. TOWNS. Will legislation be needed in order to carry out your reform initiatives?

Ms. SUYDAM. No. What we have chosen to do is to focus on those things that we can do within our own control, that we have control over at this particular time.

Mr. TOWNS. Some of the petitions have been pending for 20 years. What assurance can you provide this committee and the petitioners that the FDA's recommendations will reduce the petition backlog? How can you assure us that that will happen?

Ms. SUYDAM. Well, what we have done is put together a comprehensive plan that we think will address the issues that are now precluding us from reducing the backlog. That is, we don't have enough staff to handle all of the petitions that are currently in the backlog.

This contracting process that would allow us to go out for third-party review of some of the indirects, of some of the studies related to the directs, will provide us with the relief that we need, that would provide us then with staff to be able to handle the complex petitions and to handle the remaining issues that are in the Office of Premarket Approval.

Dr. Rulis may have some additional thoughts.

Mr. RULIS. Yes.

Mr. TOWNS. Could I just ask one quick thing before you go into that?

Mr. RULIS. Sure.

Mr. TOWNS. Maybe you can respond to this in your answer, because the chairman has been very generous with the time, and I thank him for that.

What would the backlog be——

Mr. SHAYS. Please remember that, if you are ever chairman again. [Laughter.]

Mr. TOWNS. Thank you. I certainly will. I would be delighted to remember that.

Mr. SHAYS. I think long term.

Mr. TOWNS. After implementing these reforms, what do you consider the backlog will be? I know you can't tell me exactly, but the point is, you can speculate given that you've been around now for quite some time, Dr. Rulis.

Mr. RULIS. Let me take a moment, if it's OK with you, to spend just a second to talk about backlog, because I think it's a term that we use without defining it very well. Let me also preface by saying we agree there is a backlog; we agree it's too big, and our job—and with the comprehensive plan we're putting forward—is to get it way down. We would expect a very substantial decrease in the size of that backlog within a year after those contracts are in place.

But if I might, I think it's important for us to realize that the backlog, as we talk about it, is, in fact, the active inventory of petitions. So if we receive five petitions in the mail today, they would go onto the "backlog." They would become part of the "backlog," as we refer to it; they would become part of our active inventory.

I think it's also of some value to point out that the way in which we have done business—and this may speak to the question of the 180 days, and it probably deserves a certain amount of teasing out here—the way in which we have tried to do business over the years is to work with petitioners in such a way as to reach closure in a favorable way for them, and that means sending them information about where we are having problems and asking them to supplement the petition where they can.

Oftentimes petitions are back with the petitioner for substantial work. In that period of time, the public, and everyone else, sees the petition as under review at FDA, but, in fact, the petitioner may be doing something substantial to supplement the petition.

During that whole time, it's part of the "backlog;" it's part of the active inventory. We have been reluctant to deny petitions that are in that status, and we've never really done it. So we've kept the petitions on the books in order to eventually reach closure with them in a favorable way with the petitioner.

So if you look at the figure of 295, for example—and I've just handed out some tables for you to orient the numbers with respect to one another—you will see there are two boxes, the upper one and the lower one. The 295 of the current active inventory needs to be seen in the context of all of the direct additive and indirect additive petitions that have been received since, let's say, 1958, over on the upper right, or, if you would like, since the charts we've shown show a breakpoint in 1970, since 1970.

Total receipts, about 4,800. Decisions made on those receipts, 4,500. Two hundred ninety-five is the current active inventory. Now, in the lower box, the 295, of those, 84 petitions are currently awaiting petitioner action; that is, something of substance has been identified that requires the petition to be supplemented. It could be a new study; it could be a clarification on some data.

Nineteen of the 295 are "not filed." We carry them in our inventory, but we haven't formally filed them in the Federal Register, for a number of possible reasons, usually trivial. So that results in an actual current active inventory of 192.

As a matter of practice, we have counted our 180-day clock from the time when we have in our possession a petition that is, as we term it, "complete;" that is, a petition that has been supplemented appropriately so that we now can consider it approvable. Before that we may have a petition, and it's not approvable in its present form.

Years ago we used to call that "reject status." That's a rather pejorative term. We have since moved away from using that terminology. We basically inform petitioners that the petition is not approvable in its present form but we want to work with them.

Of those petitions that we currently have that are complete and in our lap for final action, 77 are there, have been there for more than 180 days. So for the purposes of discussing the backlog, I think it might be useful, at least, to have this particular chart to put it into perspective.

[The tables referred to follow:]

Additive-Related Petition Data 1958–1995

I. Synopsis of Petition Activity *

Type of Action	Period of 1970–1995	Period of 1958–1995
Direct Petitions Received	676	1334
Indirect Petitions Received	1451	3474
Total Receipts	2127	4808
Decisions Made	1832	4513
Current Active Inventory (see II. below)	295	295

* Includes FAP, CAP, GRP; data approximate and obtained from FDA's "SIREN" database.

II. Current Petition Inventory *

Status	Number
Total Inventory	295
Awaiting Petitioner Action	84
Not Filed	19
In Review at FDA (Current Active Inventory)	192
Number of complete petitions in review at FDA over 180 days	77

* As of April 18, 1995; includes FAP,CAP,GRP and Citizen petitions; data approximate and obtained from FDA's "MATS" database.

Food and Color Additive and GRAS Affirmation Petitions Completed 1984–1995 *

[Calendar year]

	84	85	86	87	88	89	90	91	92	93	94	95
Food Additive Petitions												
Receipts	72	65	73	78	68	65	49	53	43	48	35	7
Final Actions	52	85	62	52	55	55	42	33	48	54	44	9
Approvals	30	57	49	38	40	43	30	23	34	33	37	5
Color Additive Petitions												
Receipts	8	7	11	4	4	3	10	6	3	1	2	1
Final Actions	6	7	12	4	7	1	6	4	1	7	9	1
Listings	4	5	9	4	4	1	5	0	1	5	7	1
GRAS Affirmation Petitions												
Receipts	7	13	19	8	11	12	10	14	11	5	7	2
Final Actions	14	13	6	10	6	6	9	1	13	12	6	0
Affirmations	11	9	6	5	5	2	2	0	5	1	1	0

* 1995 figures are through 4/19/95

Mr. TOWNS. Well, thank you very much, Dr. Rulis, but I must admit that I'm sitting here, and I want to stretch the backlog to the point where all of a sudden now we're just giving rejections rather than to really analyze it and look at it in a very serious kind of way, but that is a real problem. I just think that when you look at 20 years, that's a long, long time.

Mr. Chairman, I yield back.

Mr. SHAYS. I thank the gentleman.

Are there one or two other charts that are behind there?

Ms. SUYDAM. No, those are the charts.

Mr. SHAYS. I'm trying to get a handle on just some basic law. We ultimately have to make recommendations to the full committee and to the Congress, and obviously to the FDA, on where we see the problem and what we would like to see done. The first thing I have to get beyond is just what the law is. So help me understand the law.

It's Section 38 of the Food Additives text, and it's a phrase that says, "The order required by paragraph—" da, da, da, da—"of this subsection shall be issued within 90 days after the date of the filing of the petition, except the Secretary may (prior to such 90th day) by written notice to the petitioner extend such 90-day period to such time (not more than 180 days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition."

What does the law require you to do? Not what you do, because you don't abide by the law and haven't been for years, but what is the law? Then let's work backwards from there.

Ms. PORTER. Mr. Chairman, the law requires us to do a number of things. The law requires us to evaluate petitions for food additive approval to ensure that the additive is safe, within the meaning of the statute, before the agency can act on a petition for approval.

Mr. SHAYS. Right.

Ms. PORTER. The law also requires a rather complicated procedural process that must be followed in order to ensure that the regulation, once issued, is, in fact, legally defensible. The law also requires the agency to do all of that within 180 days.

Mr. SHAYS. OK.

Ms. PORTER. Let me just say——

Mr. SHAYS. So the 180 days is just ridiculous.

Ms. PORTER. That is certainly my view.

Mr. SHAYS. OK. Well, one of the purposes for this hearing is to understand the law, and my problem is that when I read tier I, I read tier II, and I read tier III, it says, "for these petitions our goal is to issue an agency response," and then "within 90 days." Tier II, "for these petitions our goal is to issue an agency response within 180 days from receipt of submission." Tier III, "our goal to issue an agency response within 360 days of submission."

I mean, goals are important. I just want to know what the law is, and then I want to know how we can make the law logical. I mean, I feel like we have a speed limit telling people they can't drive more than 15 miles an hour, and everyone is driving 70 miles an hour, because the law is so absurd. Then we allow them to drive at 70, and we don't abide by the law. So what's the point?

It just seems to me that the petitioners need protection. The American people, obviously, need protection. And then you all should be coming to us to say, we want to abide by the law, and the law doesn't make sense, and this is what we need to abide by the law and to fulfill our mandate. I'm not getting that yet. I'm getting a goal. A goal is important, but the law is important too.

So have you all given any thought as to what you want the law to read? Because, candidly, even your goal of 360 days, it may not be possible. And then there needs to be, it seems to me, a logical process.

Now, I'm not putting all the focus on the FDA. I understand that it's conceivable that petitioners simply don't want to know, and they don't want to acknowledge—someone working for the petitioner doesn't want to acknowledge that it may be the company's fault or they don't have a product, and doesn't want to tell his CEO that they are dead in the water. But it seems to me it's almost like

a little game between the FDA and the petitioners, but in the process a lot of other people get hurt.

So you can respond to this: I need to know what "goal" means, and I need to know what the law means. What do you want the law to do?

Ms. SUYDAM. Mr. Chairman, we have this similar kind of timeframe in other laws that the agency is responsible for. And the reason we went to——

Mr. SHAYS. I don't understand what you just said to me.

Ms. SUYDAM. For example, in drugs and devices, we have a 180-day timeframe for the review of new drugs and new medical devices.

Mr. SHAYS. And it doesn't mean anything.

Ms. SUYDAM. No, it does mean something. It is, in fact——

Mr. SHAYS. Let me back up a second. Do you think the 180 days, as it relates to food additives, means something?

Ms. SUYDAM. I think, clearly, Congress had an intent when they put that in the law in 1958.

Mr. SHAYS. I know. I just want to know if the law means anything.

Ms. SUYDAM. We think it's a target, and we try to meet that target. I think that's clearly——

Mr. SHAYS. No, it's the law.

Ms. SUYDAM. It is the law.

Mr. TOWNS. Would the gentleman yield?

Mr. SHAYS. I would be happy to yield.

Mr. TOWNS. That's the reason I raised the question with you, would legislative remedies be necessary. Because the goal is not even in compliance with the law, and that's the point the chairman is making. That's the reason I raised that question with you. And you're saying, no, you don't need that. What I'm saying is, your plan is in violation of the law.

Ms. PORTER. Mr. Chairman, if I might. The issue of the statute specifying timeframes for review and agency decision is an issue that the agency has addressed for dozens of years in various programs. As Ms. Suydam indicated, it applies in other programs, as well, notably drug and device approvals, and the agency has from time to time been sued in that program, not generally in this one, because for a particular application the approval time hasn't been met.

The courts have usually, when faced with that situation, acknowledged that the 180-day timeframe wasn't met in a particular case, but found that, given the structure of the statute, there really wasn't a basis for the courts to substitute their judgment as to how the agency ought to manage its programs.

Let me just say, Mr. Chairman, that whatever timeframe ought to be specified, either in the agency's performance plans or in the statute, is a subject that obviously we would be prepared to have further discussion on in an appropriate forum.

Mr. SHAYS. Wait, wait, wait. Slow down. No, this is an appropriate forum to talk about this.

Mr. TOWNS. Yes.

Mr. SHAYS. I don't understand what you mean by "an appropriate forum." The whole purpose of this hearing, or a good part

of this hearing, is to talk about the fact that you have a requirement of 180 days that is not being met. We're trying to understand that, and we're trying to understand how the agency is dealing with it.

I have learned more from the responses in the last 2 minutes than I ever imagined to learn, and it tells me a great deal about your mentality and how you view this. Basically, the law is meaningless. It is a goal. So I guess, for me, I should be happy that what has been passed through Congress and signed by the President is a goal from your standpoint. For me, it's the law.

What I get a sense of is, from the lack of having a fixed deadline, all other problems follow. And it gives you extraordinary opportunity to do whatever the hell you want. Because once you assume that the 180 days is not a requirement, then 3 years isn't a requirement, 5 years isn't a requirement. I'm trying to think of where the protection is for the petitioner and for the public as well.

So I would like you to supply us with those particular cases, and we will talk about those cases sometime else.

Ms. PORTER. Of course. We will be prepared to do that.

Mr. SHAYS. Are you done in a second here, or do you want the floor? I would just like to go back.

Mr. TOWNS. No, you can go ahead, Mr. Chairman.

Mr. SHAYS. So what I'm sensing—you see, when I asked you where you were recommending that we make a change in the law, and you were saying, "Well, it's on page 18," I don't see that as a recommendation. I see that as saying, in spite of the law being 180 days, you're going to have a 90, a 180, and a 360 days, and it's going to be a goal.

I can tell you that we're on a totally different wavelength. If you came to me and said—and obviously there have to be escape clauses, but they have to be fairly well defined—if you came to me and said that, subject to a point where the petitioner has everything in order, once it's in order, it's 180 days, that may be the logical way to go.

The first point I make to you is that these goals don't cut it for me, and I don't think for the ranking member of the committee, and we need to know what, specifically, you want to recommend as a change in the law for you to do your job and to do it fairly. I just think that's going to be one recommendation that we're going to want to make.

Candidly, what is kind of flooring me right now, this seems so basic to me that it's almost pointless to proceed. I mean, you have given us a suggestion of how you want to deal with the backlog and how you want to function in the future. And I'm thinking that you don't have a law that really works; you just have a practice that has been followed well before your time, that you have continued.

What commitment can the FDA make to act on the results of the third-party reviews?

Ms. SUYDAM. We believe that the third-party reviews will give us the information we need to make timely decisions, once we have the review from the third party. We are committed to moving forward with that as quickly as possible.

Mr. SHAYS. When we look at what was approved from 1958 to 1960, say, gigantic approvals in the 1950's, and 1960's as well, and

then a gigantic drop. It is being suggested by one of our witnesses that science and technology have been able to provide us with a tremendous number of concerns about the potential hazards of food additives but not provided us with an easy solution as to the answers. That's testimony that we're going to hear in the second panel.

Could you comment on that?

Ms. SUYDAM. I think, certainly, the issues that we are facing are extremely complex and have become more complex as they have moved forward from the 1960's. I think that we are aware that the complexity of those issues requires us to look at those in new and different ways. That's what we have been trying to do and tried to do in the proposals that we have put forward.

Mr. SHAYS. Mr. Towns' chart that you see up front, how would that look 3 years from now, given your review of this process in an effort to try to speed up the review process?

Ms. SUYDAM. Well, we are committed in the agency to meet the President's streamlining plan. As a result, we will be taking reductions in our FTE ceiling from now through 1999. As a result, there will be a reduction in the foods program, as there will be in other programs.

There is also an unintended consequence of the Prescription Drug User Fee Act, which allowed user fees to be used as an additive to the FDA's appropriated budget. The unintended consequence is that the prescription user fee program, the base for that program must be protected, which means that it must be maintained at fiscal year 1992 levels. As a result, the other parts of the agency's programs have to take cuts to make up for that large program being protected.

Mr. SHAYS. If the ranking member doesn't have any questions, we have three other panels. I want to just say, though, your counsel has just raised a gigantic question in the mind of this committee that this 180 days that exists for food additives review also exists in other parts of the FDA, and that basically the FDA views these as goals rather than legal requirements. So we're going to be taking a good look at other aspects and requirements on the FDA.

It is not the intent of this committee to say to anyone who works in the government, in the kind of job that you have, that this is your fault, and "How dare you have allowed this to happen?" Because, clearly, this has existed for a long time. But where I start to have a problem with government officials is when they don't tell us what we need to do here to make the system work. Resources, you have made a point of, but there is a whole lot more to this.

I come down to a general feeling that there is almost—I mean this in a more gentle way than it sounds—a conspiracy between the industry and the FDA, in some cases, not to move forward, because the petitioners don't have their act together, or they fear your decision, or, candidly, that the FDA just simply doesn't want to make a decision.

My sense is—and maybe it will change over time—that we have the ability to put a lot of fear in people's minds, in terms of, is this a problem or is that a problem, without the ability to come to some conclusions. What I fear about that is that there may be new products that we're simply being deprived of.

So this is really the first of, I think, a number of visits that we're going to have. I would be happy if you have a question or a comment you want to make.

Ms. SUYDAM. Mr. Chairman, I believe we are committed to making decisions. I think what has hindered that decisionmaking in the past is this incredible backlog of applications. What we were trying to put forward today was a practical plan that we thought would work, to improve the process. It had a number of elements, including performance goals that are being used as a management tool, as well as new and innovative ways of looking at the backlog.

We think we are committed to making decisions. I don't want to leave here with you having the thought that that is not the case.

Mr. SHAYS. Well, I think it's important that I acknowledge that we did ask you to give us an outline of how you wanted to approach a problem that you have had for a long time. We appreciate that. I don't want to underestimate the value of that.

But in this process you have opened up another element, which I never thought was the issue, and that is that, I guess, if the speed limit says 15, and it's not logical, and you drive at 60, after a while the speed limit doesn't mean anything. I want the law to be more reflective of reality.

Because I think once you get beyond that—I'm sorry to talk so long, but I'm just trying to explain to you—I think what the end result of this is, is that you have carte blanche to do anything. Because once you pass a law and once it's so unrealistic, then you can do whatever the hell you want, and then the court says it's not a realistic law, and that's not what should be.

Do you have any other comment that you want to make?

Mr. TOWNS. Yes, one other thing. You talked about new drug applications and what took place in 1992.

Ms. SUYDAM. Yes.

Mr. TOWNS. I understand that, as a result of that, their backlog now is down tremendously; is that true?

Ms. SUYDAM. Yes, that's correct. There has been a significant reduction in the backlog. And the performance goals that were established as part of the prescription drug user fee program, which was that, for fiscal year 1994, 55 percent of the products would be reviewed within a year, those performance goals have been met. Those were agreed upon as part of the Prescription Drug User Fee Act.

Mr. TOWNS. I understand the industry people are very happy with that.

Ms. SUYDAM. Yes.

Mr. TOWNS. While you're thinking and being creative, why don't you look at some of those kinds of proposals?

Ms. SUYDAM. Well, a user fee program is difficult in the food additive area because a manufacturer is not given a product license as one is in the drug and devices area. But we are open to considering a whole variety of options.

Mr. TOWNS. That's what I'm saying, at least something to bring you in compliance with the law. There must be some way that you can do that; if not, then you need to come to us and ask for legislation.

Mr. SHAYS. With that in mind—if the gentleman would yield——

Mr. TOWNS. Sure.

Mr. SHAYS. I'm going to make a formal request that you come back to this committee with suggested changes in the law that you think will enable you to perform your job as you perceive it. Could I ask how long you think that would take? Do you want to consult with someone?

Ms. PORTER. Mr. Chairman, as you know, legislation is proposed by the administration through a policy development and clearance process. We will, obviously, take your concerns back and have further discussions in the Department.

Mr. SHAYS. That is a lawyer's answer to a question.

Ms. PORTER. I am a lawyer; that's right.

Mr. SHAYS. That really makes me angry. I mean, that could take 6 months; it could take a year; it could take 3 months. I would like to know what is fair—I'm trying to be fair to you all. I'm trying to be courteous, as well, and not bash the FDA. But that's really an unacceptable answer.

Can you give me a relatively decent idea, within a few weeks, of when you could come and suggest to us a change in the law that you would be comfortable with? If you want to consult with somebody that's fine, but I would like some kind of idea.

Ms. SUYDAM. We can provide you with some program information about what might be necessary, but, as our counsel has said, we are part of the Department and part of the Administration, and we do have to go through those——

Mr. SHAYS. I've never once blamed the administration for this problem. I would like to request that within a month you come back to us with suggested changes in the law and that we will have a hearing to examine those suggested changes.

Ms. SUYDAM. Fine.

Mr. SHAYS. I thank you very much.

Mr. McIntosh, did you want to ask a question of this witness?

We need to—I'm delighted to have the gentleman—just explain that we have three other panels. I'm happy to give you time.

Mr. MCINTOSH. I understand. If I could just make a couple of brief remarks and then put the longer one in the record, Mr. Chairman, that would be great.

Let me, first of all, commend you for holding this hearing and for looking into this. I think you're doing a tremendous job. I think your staff, Ms. Finley, has done a great job of preparing us for this. And I think the full committee will be well served by your work in this area.

I noticed, as I was looking through the materials, that the problem here is very similar to one that we encountered when I was looking at it at the Competitiveness Council on delay in drug approvals, that new technology and new products just simply are not getting out into the marketplace. I think it is unconscionable. The American public is not well served when delay is used as a tactic in these things.

So let me just say there are a couple of other questions that I would also, perhaps, have them do in writing, one of which is, should we consider doing this whole function in a different agency, the Department of Agriculture or some other agency, if it simply can't be fixed at FDA?

Today, what I was wondering is if it would be possible for Ms. Suydam to tell us how many direct food additives have been approved by FDA in the last 25 years?

Ms. SUYDAM. That number is difficult to come by, because we did not keep track of approvals, as such, in our computer system. I can tell you that we approved 42 direct food additives since July 1988, when we have hard numbers to keep track of.

Mr. MCINTOSH. And how many applications have you had during that time?

Ms. SUYDAM. I don't know the exact number of applications. I don't know if Dr. Rulis has it.

Mr. MCINTOSH. Were those 42 new direct food additives?

Ms. SUYDAM. Well, it's hard to tell exactly which—I don't have a list of all of them, but there were at least 8 that were of significance, of those 42 direct food additives.

Mr. MCINTOSH. The information in the briefing I had was that there were approximately 100 applications each year; is that roughly the order of magnitude?

Ms. SUYDAM. Not of directs.

Mr. RULIS. It includes indirects.

Ms. SUYDAM. It would include indirects.

Mr. MCINTOSH. That would include indirects?

Ms. SUYDAM. Yes.

Mr. MCINTOSH. Do you know roughly what percentage tends to be direct versus indirect?

Mr. RULIS. Seventy-five, 80 percent.

Ms. SUYDAM. Yes, about 75 percent are the indirects.

Mr. MCINTOSH. So maybe 25 a year during that time, of which there are 8 significant new ones and 42 total that you know about.

Ms. SUYDAM. Yes.

Mr. MCINTOSH. That seems like an awfully low percentage to me. How many of those approvals have occurred since Mr. Kessler was appointed as commissioner—or Dr. Kessler? Excuse me.

Ms. SUYDAM. Dr. Kessler, that would be since 1990, and I'm not sure exactly how many of those were approved. I don't have the data by that cut, but we will provide that for you for the record.

Mr. MCINTOSH. If you could find that for us, I think that would be helpful.

I am tremendously concerned—and I won't engage in a lot of other questions but perhaps ask if you could submit answers in writing to them later—that the agency has really systematically slowed down the approval of these additives, that the public would be greatly benefited by them, and that we need to take steps fairly quickly.

So I want to second the chairman's request for your input in legislative fixes and assure you that I will support his efforts to move forward in that area, either with or without your suggestions. So I would take the opportunity that he is giving you to make those.

That's all I would say.

Mr. SHAYS. I thank the gentleman. I thank our witnesses.

Our next panel is Dr. Sanford Miller, University of Texas Health Science Center; Dr. Richard Hall, chairman, Food Forum, National Academy of Sciences; and Al Clausi, Institute of Food Technologists.

If all three gentlemen would remain standing, I will swear you in, so you don't have to sit down and stand up.

[Witnesses sworn.]

Mr. SHAYS. For the record, all three gentlemen have responded in the affirmative.

I thank you for your patience. You obviously know we have a number of witnesses that will follow you, and I would encourage you to focus on the high points of your testimony. Your entire testimony will be submitted for the record. It's very nice to have all of you here today.

We will go in this order: Dr. Miller, Dr. Hall, and Al Clausi, in that order.

STATEMENT OF SANFORD A. MILLER, UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER; RICHARD L. HALL, CHAIRMAN, FOOD FORUM, NATIONAL ACADEMY OF SCIENCES; AND AL S. CLAUSI, INSTITUTE OF FOOD TECHNOLOGISTS

Mr. MILLER. Thank you, Mr. Chairman.

My name is Sanford A. Miller. I am currently dean of the Graduate School of Biomedical Sciences at the University of Texas Health Science Center in San Antonio. Prior to my appointment as dean, I served as Director of the Center for Food Safety and Applied Nutrition at the FDA and its predecessor, the Bureau of Foods, and before that I served for 20 years as professor of nutritional biochemistry at the Massachusetts Institute of Technology in Cambridge, MA.

My testimony today is my own opinion, and I do not represent either the University of Texas or MIT or, for that matter, the FDA.

Mr. Chairman, the problem of evaluating food safety has always been a difficult one for the scientific community and certainly for the Center for Food Safety. Scientists at the Center work at the very limits of contemporary science. This is not a new problem; it goes back to the very origins of the Center, back in 1906.

Moreover, as modern biology provides deeper insights into the mechanisms by which life is regulated and maintained, the issues to which the evaluators at the Center for Food Safety must address themselves have increased enormously. As in the peeling of an onion, each layer reveals new areas of concern, resulting in protocols for safety determinations that have often become so complex and so enormous that they take many, many years to accomplish and are extremely expensive.

These circumstances alone would result in increasing the time necessary for evaluating the complex petitions for approvals of really new materials. When you add the fact that, after the last two decades, the Center has suffered from substantial reductions in personnel, then you realize how difficult it has become for the Center to provide the appropriate resources to meet reasonable time schedules for evaluation of food additive and GRAS petitions.

For example, in 1978, the number of FTEs in the Center for Food Safety approximated 1,000. By 1994, this number had reduced to 830—these are nontargeted FTEs—a 20 percent reduction in the size of the Center. This occurred at a time when not only the process of safety evaluation had become more complex but the Center, by legislative mandate, had received several new responsibilities.

The consequences of such changes have already been described by yourself and Mr. Towns in earlier discussions. The fact that the time for pending petitions continues to increase to, on the average, over 60 months in 1994, from as little as 30 months in 1983, is simply a reflection of the fact that the Center has neither the resources nor is it able to apply additional resources to deal with this problem at this time.

I was pleased to hear the previous testimony that the agency has come up with a plan that will, at least in the short term, provide some additional help to deal with this problem.

Now, obviously, one of the solutions to this problem is to substantially increase the resources of the Center. In today's world, unfortunately, it is highly improbable that this will take place. In my view, then, there are two areas that need to be examined very closely in order to resolve these questions.

First is the long-term question of the organization of food safety activities within the Federal Government. I will not say more about that, because this has been covered by this committee on previous occasions, but really deserves further review.

The second area is the immediate issue concerning the approval and evaluation of new food additives and GRAS petitions. I would suggest that the agency needs bold and imaginative action to leverage its resources and incorporate in its evaluation process the scientific expertise of the entire scientific community.

To do so without conflict, however, will require some careful thought about the model used. You have already heard the agency indicate that they were prepared to provide some extramural reviews of the existing backlog. I would argue this should apply to the entire system.

I would propose, however, that any model be matched against a set of criteria which would ensure that the outcome will not be challengeable on the basis of conflict of interest or lack of transparency. I have listed several criteria against which such a proposed model could be judged, as part of my formal statement.

First and foremost, the model must be credible, with no perception of conflict. It must also recognize that the FDA's mandated responsibility is to oversee the review process and to assure the safety of the food supply. That is first, primary, and foremost in any discussion about these issues.

I must say, parenthetically, there is a tendency on the part of some people to believe that the responsibility for assuring food safety, and the decision for assuring food safety, can be delegated to some outside group. I disagree with that. I think the credibility of the process will only be maintained if it remains within the FDA.

Now, for the Center to fulfill these roles, additional support is required to assure the availability of quality scientists to credibly provide oversight of these activities. Ultimately, the process must provide for the public the belief that this new approach to food safety will result in a safer food supply and also a process that will maintain public confidence because it is transparent.

In addition, any such model must assure that decisions will be made within reasonable times. That is absolutely certain. Because, at the moment, the basic conflict that exists is that the period of

time for review, as you already pointed out, tends to be variable, varying from time to time.

Mr. Chairman, for the Center for Food Safety and Applied Nutrition, the agency having principal responsibilities for ensuring the safety of the food supply, these are difficult times. Not only have their tasks become more complex, requiring more highly trained and competent scientists, but the political, social, economic, and cultural pressures on the decision process have increased enormously.

I realize that this is a time when great fiscal concerns exist, but reducing overall government budgets does not mean reducing government budgets in every area. There are some areas, such as food safety, in which the investment of resources could result in long-term savings, in terms of better health and a better food supply.

These resources must be provided in the context of a new framework for evaluating food safety and innovation in ways in which we organize our food safety issues within the Federal Government. I would submit, Mr. Chairman, the issue is not only legislation to try and assure that decisions are made within an appropriate time period, but legislation that also allows the agency even greater freedom in utilizing all of the scientific community to help make its decisions.

Mr. Chairman, thank you for giving me this opportunity to provide my views. I, of course, am prepared to answer any questions.

[The prepared statement of Mr. Miller follows:]

PREPARED STATEMENT OF SANFORD A. MILLER, UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER

Thank you, Mr. Chairman. My name is Sanford A. Miller. I am currently Dean of the Graduate School of Biomedical Sciences at the University of Texas Health Science Center in San Antonio, Texas. Prior to my appointment as Dean, I served as Director of the Center for Food Safety and Applied Nutrition at the FDA and its predecessor, The Bureau of Foods. Before that, I served for 20 years as Professor of Nutritional Biochemistry at the Massachusetts Institute of Technology in Cambridge, Mass.

I am pleased to have this opportunity to discuss with you and the Committee the problems faced by the Center for Food Safety and the Food and Drug Administration in fulfilling their role as not only protectors of the food supply but also as gate keeper in the introduction of innovations for the expansion and improvement in the quality of the food supply.

Mr. Chairman, I think it is fair to say, to quote our Chinese colleagues, that we live in interesting times, particularly for those regulatory agencies concerned with assuring the safety of the food supply. Indeed, in view of the economic and social revolution taking place in the Country and in Congress we might say we are rapidly approaching perilous times for these agencies. The curious, paradoxical fact is that as available resources are decreasing, their responsibilities are increasing.

The problem of evaluating safety has always been a difficult one for the scientific community and the Center for Food Safety. Scientists at the Center work at the very limits of contemporary science. This is not a new problem. It goes back to the very origins of the Center. In 1906, appearing before the House Committee on Interstate and Foreign Commerce, Dr. Harvey Wiley noted that determining the physiological effects of chemicals on human subjects was not as easy or as straight forward as with animals. Concerning the use of borax as a preservative, the following discussion took place between Congressman James D. Mann and Dr. Wiley.

> Mr. MANN: Does your report show that, in your opinion, the use of Borax has a deleterious effect upon the organs of the body?
>
> Dr. WILEY: Of course, you understand, Mr. Mann, the tests that we have made are not the same as those made upon animals fed for pharmacological experiments because after a given time the animals are killed and the or-

gans are examined and changes in the cells are studied with the microscope. We were precluded from doing that.

Mr. MANN: Is that your conclusion?

Dr. WILEY: My conclusion is that the cells must have been injured, but have no demonstration of it because I would not kill the young men and examine the kidneys.

This colloquy between the Congressman and Dr. Wiley compressed into a brief moment the still accurate picture of the problems faced by the Center for Food Safety and other regulatory agencies in assuring the safety of the food supply. Moreover, as modern biology provides deeper insights into the mechanisms by which life is regulated and maintained, the issues to which the evaluators at the Center for Food Safety must address themselves have increased enormously. As in the peeling of an onion, each layer reveals new areas of concern, resulting in protocols for safety determinations that have become so complex and so enormous that they take many many years to accomplish and are extremely expensive.

These circumstances alone would result in increasing the time necessary for evaluating the complex petitions for approval of new materials. When you add the fact that, for the last two decades, the Center has suffered from substantial reductions in personnel then you realize how difficult it has become for the Center to provide the appropriate resources to meet reasonable time schedules for evaluation of food additive and GRAS petitions. For example, in 1978 the number of FTE's in the Center for Food Safety approximated 1,000. By 1994 this number had been reduced to 830, a 20% reduction in the size of the Center. This occurred at a time when not only the process of safety evaluation had become more complex but the Center, by legislative mandate, had received several new responsibilities. Between 1988–1994, seven additional regulatory responsibilities were legislatively added to FDA's responsibilities. Even in this case the agency estimated that there was a need for some 280 additional FTE's plus operational funds to cover these new responsibilities. What they actually received was about 82 FTE's specifically targeted for these new responsibilities. As a matter of interest, compare this to Drugs and Biologics where, in the same period of time, these centers received additional personnel such that their total resource increased by some 50%. Without arguing the relative importance to the National health of drugs and food, let it suffice to say that food is at least as important and should have received the same attention to need as did drugs and biologics.

What happens when a regulatory agency with the responsibilities such as those of the Center for Food Safety is underfunded and overly-committed? Not surprisingly substantial changes occur in the behavior of the scientists in the Center. Most significant, is the suppression of the responsibility to act as a gate keeper not as a barrier to the introduction of new technologies. In other words, they no longer recognize that being a gate keeper implies opening gates as well as closing them. Consequently, confidence in the regulatory scientists at the Center becomes reduced, while complaints and criticism increase. The result is an agency that is unwilling to use judgment and unwilling to support innovation. In other words, an organization that tends to say no when faced with the need for judgment because it is difficult to get into trouble by saying no. More importantly, the Center has difficulty in reaching decisions of any kind, a practice that very often is worse than saying no. There also is a tendency to concentrate on less important issues and, perhaps most damaging of all, this behavior encourages increasing importance of nonscientific issues in reaching decisions concerning the safety of food.

I submit that the Center for Food Safety and Applied Nutrition is in exactly that position now. The Center clearly has difficulty in reaching decisions and in particular those decisions that require judgment. It is never possible to have all the data we believe we need to make safety evaluations. Nevertheless, a confident, well supported group of scientists should be willing to make judgments based upon their experience and confidence in their competence.

The outcome of this attitude best indicated by looking at the number of food additive approvals over the past decade. In 1982 something over twenty petitions were pending in the Center. By 1994 this increased to almost fifty. Equally important the number of orders issued during this period averaged less than 10. Even more telling is the fact that, in the same decade, the time required for the Center to reach a conclusion on those petitions for which orders were finally issued had increased from 20 months to 40 months. For pending petitions, the time for consideration increased from about 30 months in 1983 to over 60 months in 1994.

Clearly this is a situation that cannot continue. The agency's inability to reach decisions on their pending petitions has resulted in nearly a complete stasis in innovation in the food industry. The food industry is not well known for its willingness

to take risks in introducing new products. Everybody wants to be number two. When, to that reluctance for risk taking, is added the recognition that new technologies will have to undergo extremely long periods of review without decision by the agency, the result is an industry which tends to repeat past technologies rather than developing new ones. From this point of view reaching no decision is more daunting than the fear of a "no" decision.

Obviously one of the solutions to this problem is to increase the resources of the Center, an option that would require adding as many as 200–300 additional personnel for the Center for the sole purpose of doing evaluations. In today's world however, it is highly improbable that this will take place. Even if it were possible, this would not necessarily be the best option.

In my view there are two areas that need to be examined very closely in order to resolve these questions. First is the long-term question of the organization of food safety activities within the Federal Government. Over the past several decades, several distinguished committees reviewed the organization of food safety activities in the Federal establishment. Each committee produced a report. Each committee's report was gratefully received and then very little happened. Today I believe, during this period of great turmoil in the nature and safety of the food supply, there is opportunity in the midst of conflict to really examine the most efficient and effective organization to assure the safety of the food supply and at the same time assuring that the food supply remains innovative and aggressive. This is particularly important in today's world where food has become a global commodity, a situation in which our producers and processors have to compete on the world market.

I suggest therefore that one of the things that Congress and the Administration should consider is the appointment of very high level, distinguished commission consisting of members appointed by the President and by the Congress from within and without the Government. Alternatively, this responsibility might be delegated to the Food and Nutrition Board of the Institute of Medicine in the National Academy of Science. This committee would be charged to review all existing food safety programs within the Federal Government and to consider new structures, including the placement of all food safety activities within a single agency located either in an existing department or in an independent agency concerned with issues of food safety. Finally, the Committee should be charged to review the economic implications of such changes and to determine if resources could be saved by such an organizational change.

The second area is the immediate issue concerning the approval and evaluation of new food additives and GRAS petitions. I would suggest that the Agency needs bold and imaginative action to leverage its resources and incorporate in its evaluation process the scientific expertise of the entire scientific community in the United States. To do so without conflict, however, will require some careful thought about the model to be used. Later on in this hearing several such models will be presented. I would propose, however, that any model be matched against a set of criteria which would ensure that the outcome will not be challengeable on the basis of conflict of interest or lack of transparency. In table 1, I have listed several criteria against which proposed model could be judged. First and foremost the model must be credible with no perception of conflict. It must also recognize the FDA's mandated responsibility to oversee the review process and assure the safety of the food supply. There is a tendency to believe that the responsibility for assuring food safety can be delegated to some outside group. I disagree with that point of view. Under the provisions of the Food, Drug, and Cosmetic Act, the FDA, as delegated by the Secretary, has the ultimate responsibility. Therefore, if the Center is to effectively operate within such a model, several conditions must be met. First, the Center must continue to assure the credibility of the date submitted. Second, it must have the responsibility to select the appropriate extramural review group. Third, the Center must establish criteria for selection of the members of such groups. Fourth, it must, in consultation with the petitioner, develop the questions submitted for review by the Extramural Committee.

For the Center to fulfill these roles, additional support is required to assure the availability of quality scientists to credibly provide oversight of these activities. Ultimately, the process must provide for the public the belief that this new approach to food safety will not only result in a safer food supply but is a process that will maintain public confidence because it is transparent.

A model that meets these criteria is outlined in Table 2. Each component has specifically defined tasks and must perform according to strict timetables. If for example FDA does not issue a regulation or a report defending an opposing view within the prescribed time, then an assumption of approval is made.

Mr. Chairman, as I said earlier the current environment may be described as perilous. The responsibility for assuring the safety and the health of the American peo-

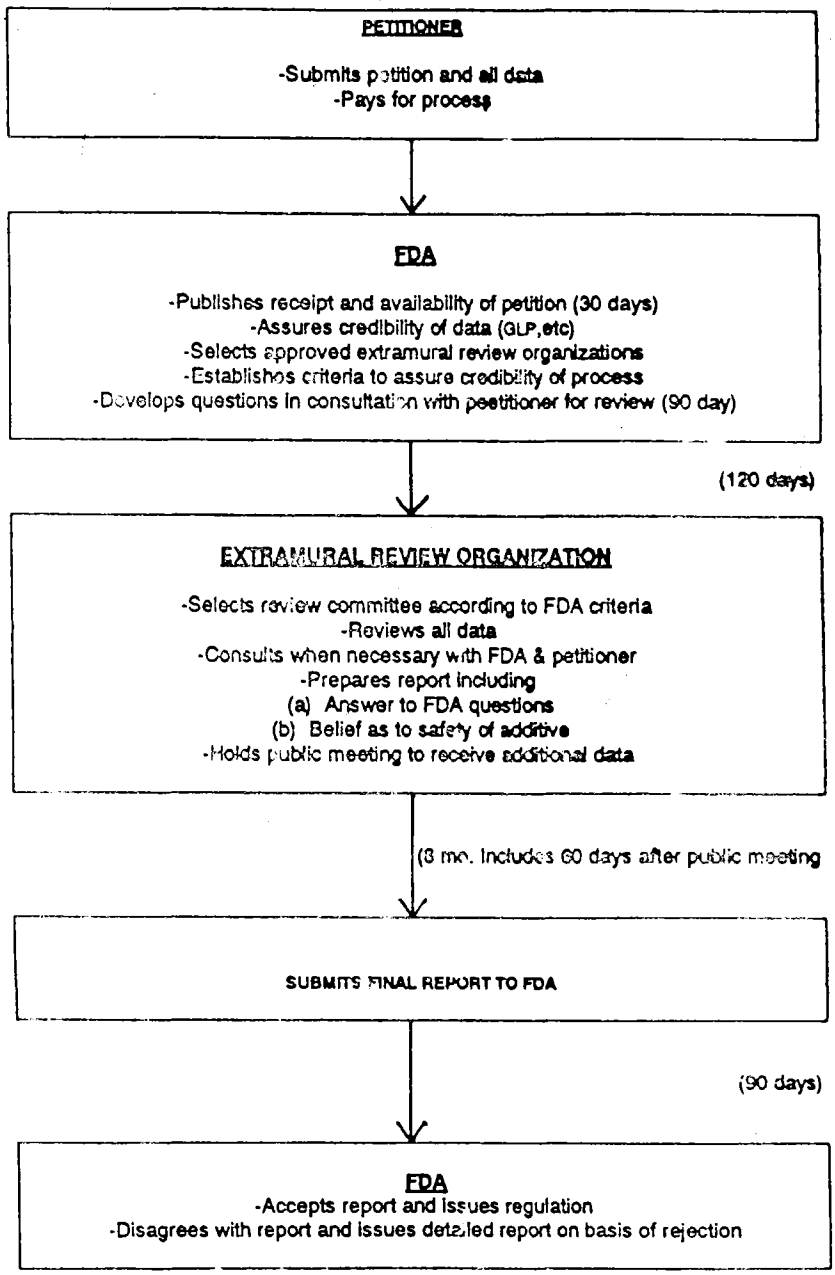
ple has become more difficult as science becomes more complex and the American public enjoys a longer and better life. They want that to continue. Food is unquestionably the most important component in the environment that contributes to the desire of the American people to remain healthy and functional. For the Center for Food Safety and Applied Nutrition, the agency having the principle responsibility of ensuring the safety of the food supply, these are difficult times. Not only have their tasks become more complex requiring more highly trained and competent scientists but the political, social, economic and culture pressures on the decision process have increased enormously. I realize that this is the time when great fiscal concerns exist. But reducing overall Government budgets does not mean reducing Government budgets in every area. There are some areas, such as food safety, in which the investment of resources could result in long-term savings in terms of better health and a better food supply. But these resources must be provided in the context of a new framework for evaluating food safety and innovation in ways in which we organize our food safety issues within the Federal Government. On the other hand, we might be successful in reducing the budget of these programs. But that victory will be pyrhhic in the sense that the American people will suffer in the end. Mr. Chairman, thank you for giving me this opportunity to provide my views on this subject and I am prepared to respond to any questions that you might have.

TABLE 1—CRITERIA FOR EXTRAMURAL REVIEW

- Must be credible with no perception of conflict
- Must assure sound, state-of-the-art science
- Must recognize FDA's responsibility to assure soundness of the review process and safety of the food supply.
- Must include additional support for FDA to assure a quality science base.
- Must assure decisions in reasonable time periods.
- Must be based on non-FDA funding with no possibility of actual or apparent petitioner influence.
- Must not result in apparent or actual reduction in safety standards
- Must be transparent
- In summary; it must be credible.

TABLE 2

PROPOSED SCHEMATIC FOR EXTRAMURAL REVIEW



Mr. SHAYS. Thank you, Dr. Miller. We look forward to asking you questions in a second.

Dr. Hall.

Mr. HALL. Thank you and good morning.

Mr. SHAYS. Dr. Hall, I'm going to suggest you bring the mike down a little bit further, because then it will pick up your voice better.

Mr. HALL. All right. Is that better?

Mr. SHAYS. That's better.

Mr. HALL. Thank you.

My name is Richard Hall. In 1988, I retired as vice president, science and technology, of McCormick & Co., and have since worked part-time as a consultant and on various pro bono activities. I have been fortunate in having had many opportunities to work with and observe the Food and Drug Administration in other than my company duties.

I appreciate the opportunity to comment on the food additive approval process and the background of events that not only affect it but, in my view, virtually determine it. All of these comments are strictly my own. I am not representing the academy or any other organization in any way.

I am not an FDA-basher. I have great respect for its mission and for many of its people. We need and must have a strong and effective FDA for the public health and for honesty and fair dealing. Any effort to improve its operations must squarely face its problems, and these problems continue to grow as our food supply and public expectations change.

Dealing effectively with food additives requires both careful attention to the public health and an openness to innovation that, properly screened, itself serves the public health. With respect to food additives and related topics, the most significant factor in shaping our attitudes and actions of the past 40 years has been the phenomenal progress in toxicology and even more in analytical chemistry.

We are now aware of the presence of low levels of substances that may imply a possible hazard, often remote or simply theoretical, that 20 or 40 years ago we simply were blissfully unaware of. Reducing the largest hazards in the food supply, the microbiological and nutritional ones, is critically important to continuing to improve our health.

Many of the efforts aimed at trace residues of pesticides and environmental contaminants have long since passed the point of diminishing returns. This misapplication of effort, however, has simply responded to widespread misperceptions of relative risk, inverted misperceptions that incorrectly see the risks from pesticide residues, additives, and environmental contaminants as far larger and more deserving of attention than the actually much larger microbiological and nutritional one. Reluctance to accept new substances is one consequence.

Thus, the problems the agency faces start with continually increasing awareness of possible risk, because awareness is relatively easy, cheap, and quick, and the media are always helpful. Regrettably, our skills in evaluating risks lag far behind our skills in detecting them. Effective evaluation is often slow, uncertain, and

highly demanding of expert judgment. Many in the public would like a certainty that biology can never provide.

The process called quantitative risk assessment has been eagerly adopted by regulators, by no means just in the FDA, in part, I regret, because it provides a misleading certainty that simply isn't there. It is also a retreat from exercising judgment and is both a result of and a contributor to our risk aversiveness.

Other problems include a base of science and technology that doubles about every 7 years. FDA has broader responsibilities than those of the industry it regulates, and it has less resources. Low-priority responsibilities are part of the problem, such as the Tea Board and the packaging component regulations you have already heard mentioned. The need to respond to hidden agendas is a third factor, objections framed as safety concerns but actually motivated by economic, social, or political factors. BST was an example.

The explosion in critical fields such as toxicology has left the FDA with wholly inadequate access to really top-level expertise, expertise essential to wise judgments and, ironically, available to the industry, the regulated industry. The agency has some highly able and motivated people. They are the ones you tend to see. But they are too few, and they are very thinly spread. In general, it has a competent but very cautious staff.

Much of the Food and Drug Act works, or has been ingeniously interpreted to work, very well. There are two failed portions: the Delaney clause and the food additive approval process. The Delaney clause should be replaced by a risk-based approach.

The food additive approval process, in my view, should be modified to insert third-party—highly expert, independent third-party—evaluation into the process and to require FDA action, based on that evaluation, within a reasonable time, either in the form of a regulation permitting and defining safe use in accord with the third-party evaluation or rejection of the third-party evaluation based on explicitly stated, substantial, countervailing considerations, and with recourse to judicial appeal.

Bureaucratic caution is normal and very much alive. Add to it the problems I have listed, and we confront a situation I believe only statutory change can effectively alter. The agency also needs to make even more use of external experts in other ways but without giving up, in any sense, its ultimate responsibility for the conclusion.

My written testimony makes several suggestions. One is for the still wider use of expert external ad hoc groups for the lower priority, less difficult, or less controversial issues. There are many of these, far more than most of us know, and they are doing useful and excellent work. The satisfactory operation of the GRAS process is only one of numerous examples that touch many aspects of the agency's food operations.

These steps won't bring the millennium, but I think they will move us in the right direction. I, too, will be happy to respond to any questions.

[The prepared statement of Mr. Hall follows:]

PREPARED STATEMENT OF RICHARD L. HALL, CHAIRMAN, FOOD FORUM, NATIONAL ACADEMY OF SCIENCES

My name is Richard L. Hall. My undergraduate and graduate education—long ago—were in chemistry, and particularly in the chemistry of natural products. My working career after graduate school was entirely with McCormick & Company, Inc., from which I retired in 1988 as a director and as Vice-President—Science and Technology, after nearly 38 years of employment. For nearly all of that period, other than management responsibilities, most of my professional involvement was in the fields of food technology and toxicology. In the past five years I have had no consulting or other relationship—other than a friendly one—with McCormick. I have served as a consultant, on a gradually declining time basis, to the Flavor and Extract Manufacturers' Association (FEMA), and as an active participant in the International Food Biotechnology Council. The latter involvement ended in 1992, and currently about 15% of my time is spent with the FEMA. Essentially all of my other activities are pro bono. All of the views I may express here today are strictly my own, I am not representing any organization or activity in any way. Fortunately McCormick has been an employer with a long history of encouraging constructive public involvement by its people, and those multiple involvements gave me, over time, many opportunities to observe and work with the FDA.

You will not find these remarks to be those of an "FDA basher." I have great respect for its mission and for many of the people in the agency. Any attempt to improve the FDA's operations should start from knowledge of its mission, history, problems, and resources. In breadth and directness of impact, it is one of our three or four most important public health agencies, and that is its primary role. When, in the past, the FDA has had the resources to pursue economic fraud and enforce label integrity, it has been an ethical food company's best assurance of a level playing field. Unfortunately, that role has greatly diminished. Other responsibilities I shall mention later have preempted it because they have grown much faster than FDA's resources.

Several major problems confront the agency, and almost all of these continue to grow as our food supply and public expectations change. FDA is responsible for the safety and proper labeling of all foods in interstate commerce except meat and poultry. Our food supply has grown enormously, not in weight or caloric content, but in the number of items and in diversity of source and processing. Only by field work—and accident—does FDA know where food processing plants are located. The extent of processing continues to increase, as does the number of meals eaten away from home—both of which increase the agency's task.

Due partly to the progress of toxicology, but even more to the phenomenal advances in analytical chemistry, we are now aware of possible hazards, often remote or simply theoretical, of which, 20 or 40 years ago, we were blissfully unaware. Our efforts to reduce the larger and more direct hazards, chiefly although not exclusively, the microbiological and nutritional ones, have well served the public health. Many other efforts, particularly those aimed at trace residues of pesticides and environmental contaminants, have long since passed the point of diminishing returns. That misapplication of effort has been consistent with widespread public perceptions of risks, but not at all consistent with the available data. We need to recall and implement the principle of commensurate effort—that the effort to reduce or eliminate a risk should be commensurate with the size of the risk.

Also, in my view, those of us who deplore the agency's virtual standstill in approvals for new ingredients need to recall that for most of the last 40 years—certainly until the saccharin controversy—FDA correctly read public and Congressional sentiment as being unwilling to tolerate any perceived safety questions about substances in the food supply. That, of course is unrealistic. The FD & C Act does not define safety, but prohibits the addition to food of ". . . any poisonous or deleterious substance which may render it [the food] injurious to health . . ." (U.S.C.A. 342 (a)(1)). The definition of "safe" and "safety" in the CFR makes even more explicitly clear that there is no absolute safety. "Safe" or "safety" is the ". . . . reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. It is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance." (CFR 170.3 (i))

Unfortunately this practical recognition that there is no absolute safety became lost in later public discussion, a succession of widely trumpeted alarms, and ultimately, in the enforcement itself. The common slogans were, "If there's smoke, there's fire." and, "When in doubt, toss it out." In wave after wave of that, the FDA went too far, and read essentially all judgement out of the regulatory process.

We need to pursue this history a bit further. In the seven years that followed the passage of the Food Additives Amendment, the FDA performed an enormous effort in dealing successfully and realistically with the backlog of substances then in use. Toxicology in those days was a small and little-known specialty. There were very few toxicologists in industry FDA staff, including Dr. Arnold Lehman, the Director of Toxicology, and others such as Dr. Garth Fitzhugh, were few in number, but they had wisdom, experience, and high stature in the field. They made judgements which, with amazingly few exceptions, have not been upset by later data.

In the past 30 years, due largely to the progress in toxicology and analytical chemistry already mentioned, our perception of risks has virtually exploded. The field of toxicology has grown enormously. FDA personnel simply cannot dominate or lead the field. A number of large firms have more toxicologists than FDA, and the firms can afford the best.

Beyond these trends, the public today is simply much more risk-aversive. The kind of well informed, wise, but informal and unstructured regulatory judgements of 35 years ago are no longer as possible or acceptable as they were then. In my view, in large part because of these pressures, a new basis of regulatory judgement has emerged and been welcomed by the current generation of regulatory decision-makers. This basis is inaccurately labeled "quantitative risk assessment," or "QRA." A detailed examination of QRA is much beyond the scope of these comments. In short, it consists of using data from animal studies, conducted at high levels to be sure of finding an effect, if there is one. One then uses a mathematical assumption to extrapolate downward from the high levels fed animals to the typically very low levels to which humans are exposed. One also assumes that humans will respond as do the animals. Then, using data on worst case human exposure, or more often, assumptions about worst case exposure, the risk to humans is calculated. Because of the multiple, combined, conservative assumptions, this should be called an "upper bound risk estimate." That more careful term is usually lost, the conservatisms immediately forgotten or never explained, and the result called simply, "the risk." It then takes on a numerical firmness and reality that is wholly without justification, but which forms the basis of its regulatory appeal. At its best, it is an informed upper-bound guesstimate, and can be useful, at least in comparing the risks of alternatives about which similar assumptions can justifiably be made. In practice, it often ignores what is known about metabolism, mechanisms, and exposure, and becomes the refuge of the biologically bankrupt. I mention it here in this detail because it is another way in which we have abandoned judgement, in favor of an extreme, nonjudgmental process that promotes inaction.

The body of scientific literature doubles about every seven years. This includes the literature on products, processes, ingredients, analytical methods, microbiological, nutritional, and toxicological advances, and risk analysis. To be effective, FDA must have some way to keep up with at least what is most important—another obviously increasing task. The industries the FDA regulates keep up, although with a struggle, because their individual responsibilities are narrower, and they are free to expand as far and fast as economic opportunity and profitability permit. No regulatory agency can accommodate such increases internally, FDA will need to make wider use of external resources.

Much of the Food and Drug Act works, or has been ingeniously interpreted to work, reasonably well. There are, however, two notable exceptions to this statement: provisions for food additive approvals, and the Delaney Clause.

Provisions for food additive approvals are, by any standard, a near total failure. Such approvals often are badly delayed even when they simply involve new uses for an already approved additive. When they involve something entirely new the pace becomes glacial. Approximately five new chemical entities have been approved since the saccharin watershed in 1980. Now it is difficult to conceive of any circumstances in which a well-advised firm would file a food additive petition. This paralysis avoids the theoretical risks from carefully tested and evaluated new food additives, but it also prevents the improvements in safety, health, economy, acceptability, and convenience that such new ingredients bring. The entire public is the loser.

The Delaney clause has long been outdated by the progress of analytical chemistry, which now permits us to find traces of almost anything in virtually everything, and by advances, still far from complete, in our understanding of the mechanisms of chemical carcinogenesis. This growing understanding of mechanisms, often based on considerations such as dose-dependent metabolism and secondary mechanisms, makes it increasingly clear that the simplistic, black and white absoluteness of the Delaney clause is inconsistent with all other food safety provisions of the Act. It is past time to replace it with a risk-based approach.

By comparison, GRAS status is alive and well. GRAS, as this sub-committee well knows, is the acronym for ". . . generally recognized, among experts qualified by

training and experience to judge its safety, as having been adequately shown to be safe under the intended conditions of use." Both FDA and private GRAS have been and are being widely used. Although the FDA has successfully moved against a few products improperly termed "GRAS," there have been, to my knowledge, no instances involving the application of scientific review in establishing GRAS status that later required regulatory action by the FDA. Two possible exceptions to that statement were cyclamate and saccharin. These substances were originally FDA GRAS. In the light of new data, FDA removed them from the GRAS list, and made them food additives, thus subjecting them to the Delaney clause. In my view, then and now, both actions by the agency were mistakes. It would have been better to have first made a careful, broadly-based effort to reassess GRAS status. Had this been done, I suspect GRAS status would have survived, and that would have been far more appropriate. I hope that the Congress will not feel compelled to try to fix something that isn't broken.

As this committee is well aware, Congress from time to time assigns FDA broader responsibilities, as in the partially mislabeled Nutrition Labeling and Education Act.

There is another external problem which the agency does not invite, but which the public dumps on it. With few exceptions, the decisions the agency is authorized by statute to make on foods deal only with safety and the accuracy of label information. The agency cannot lawfully consider whether or not a product is "needed" or is "unnecessary," is economically justified or unjustified, or is socially desirable or undesirable. I am not arguing that FDA should make these judgements. In fact, the agency can sometimes let these issues enter into its decision, but only if no one cares. The key point here is that these "trans-science" issues often deeply concern many segments of the public, and they tend to be highly controversial. There is no clear forum in which they can be aired, much less decided. As a result, alleged safety issues are often raised, as with BST, when the actual issue is not safety, but something else.

Finally, of course, the agency faces these growing complexities and responsibilities at a time when most of us recognize the need to deal effectively with deficit reduction.

The next set of problems might be called "internal," although most have external causes or components. The first is priorities. FDA has been assigned, by Congress, or in some cases, has assumed, too many low priority tasks. My favorite example is the Tea Board, a congressionally mandated group of industry tea tasters who taste test imported teas. The thousands of packaging constituents covered by regulation are another example, in that case imposed by a short-sighted industry that saw commercial advantage in an FDA endorsement for every constituent, no matter how insignificant. That was encouraged by an FDA General Counsel who was quoted as saying that if you had to run an extraction study on a plastic to see if a constituent was there, then "it might have become a component of food" and was therefore a food additive. Thus, the guilt for this unproductive overload is liberally spread. Again, the principle of commensurate effort should be invoked.

The next category of problems are resources. I will not comment on physical facilities and overall funding—you will have others far better informed on those matters. The most important resource is people, and the agency's people problems can be ameliorated, but never wholly solved. It is impossible to retain in-house the level and variety of experience the FDA needs. This requires more effective access to outside expertise. Fortunately, the agency has a minority of really able and highly motivated people, among them a number I am honored to regard as professional colleagues and friends. Unfortunately, they are spread far too thinly. In my perception, the primary motivation of the majority of middle level people—in an agency a former Bureau head described as "run by the sergeants"—is caution. The most important thing to do is not to make a mistake. It is far safer to delay, usually by asking more questions, than to make a decision. Your committee needs to consider the impact of that attitude in a climate characterized by more products, increasing scientific knowledge, more public awareness of and aversion to risks, and our enormously enhanced ability to detect risks, not matched by our corresponding ability to measure and evaluate them accurately.

In my view, part, but only a part of this problem, is due to the fact that our Civil Service system usually cannot bring to bear the set of incentives, pressures, and disciplines that enhance productivity in industry and academia. The National Institutes of Health, a jewel in our federal crown, is an exception to this statement. That is because much of the NIH's success lies in encouraging an "academic" atmosphere, with all that implies in terms of peer pressure, professional recognition and "perks," and, let us face it, a snobbish appeal that suggests that research is a more prestigious calling than regulation.

In fact, the Agency has long made much use of external expertise. Most of this takes the form of specialized ad hoc groups, dealing with a particular set of issues. Some of these groups such as the Association of Official Analytical Chemists (AOAC) are semi-official, drawing personnel from federal and state agencies, but from industry and universities as well. Others, such as the Federation of American Societies for Experimental Biology (FASEB), which performed many GRAS reviews for the FDA, work by contract. The Food Chemicals Codex Committee, which, not surprisingly, produces the Food Chemicals Codex (FCC), also works by contract, in that case through the National Academy of Sciences. Still others work without direct federal agency input, but publish their results and make them available to the FDA. Among these are the Society of the Plastics Industry, which establishes threshold limit values for packaging materials, or the Flavor and Extract Manufacturers' Association (FEMA), which uses an expert panel, independent of the industry, to establish a GRAS list of flavoring ingredients.

There are at least two common characteristics of all of these groups that explain their usefulness and their success. First, all involve a depth of specialized knowledge and level of expertise in a particular set of issues that the FDA could not possibly maintain in-house. Secondly, all deal with issues that are critically important, and which must be disposed of effectively, but they are not perceived as posing high levels of risk, and they are not highly visible and controversial. That observation begins to suggest how a reassessment of priorities and wider access to outside expertise could materially assist the agency. FDA should, in fact, be complemented for having made the use it has of such mechanisms, and it should be strongly encouraged—even required—to expand that approach in appropriate ways.

FDA can and does bring in consultants as temporary government employees. That is helpful, but it lacks the interactive process involving outside experts which is often the most productive and necessary aspect of their use. The use of two or more such consultants invokes the Federal Advisory Committee Act, well intended to avoid conflicts of interest, but stultifying in actual effect.

In summary, the problems the agency faces include:

- continually increasing awareness of possible risks, because awareness is easy, cheap, and quick, and the media are always helpful,
- difficulty in evaluating risks because effective evaluation is often slow, uncertain, expensive, and highly demanding of expertise, and many in the public would like a certainty that science can never provide,
- as one consequence, much greater public risk-aversiveness,
- a rapid and continually increasing base of science and technology, additional responsibilities, often not of high priority, added by Congress, industry, or the agency itself,
- "hidden agendas"—economic, socially, and politically motivated objections only nominally based on safety,
- inadequate access to really top-level expertise,
- some, but too few, highly able and motivated people. In general, a competent but extremely cautious staff.
- crippling resource constraints, and the imminent need for still greater economies.

This list of pressures and problems virtually assures agency inaction in those cases in which the agency is the sole decision-maker on a novel product. Nothing less than statutory change can alter this.

To help FDA more effectively confront its problems, and particularly the problem, on new materials, of reaching regulatory decisions that are both prompt and fully protective of the public health, there are several steps the Congress should consider:

1. Encourage and assist the FDA to sort out, with outside advice, those issues which must be addressed internally, as by food additive petitions, from those that pose lower levels of risk, or are less complex or controversial, and which can be handled better by external ad hoc groups. These external groups may operate with or without agency participation, but without any abdication of the agency's ultimate authority, and with the agency explicitly able to intervene if new data or changed circumstances so dictate. The conclusions of such external processes must, of course, be publicly available and open to public criticism, as in fact they are at present. Use the principle of commensurate effort to husband the agency's limited resources for the issues that really demand full agency involvement. This would simply recognize and extend what often happens now. Along the way, abolish the Tea Board and any similar anachronisms. Anachronistic laws breed anachronistic procedures and attitudes.

I do not think it will ever be possible to draw hard and fast boundaries between the high-risk, or high-visibility issues concerning food ingredients that are best served by a modified food additive petition, and those lower in risk, visibility or com-

plexity, for which, in general, GRAS status is much more appropriate. I tend to think that our experience with GRAS has now been such that, if privately obtained, fully expert advice suggests that GRAS status is appropriate, that is the better way to go. In that case, the sorting process is done for the FDA, unless the FDA chooses to object.

2. Equip the agency to make broader and more effective use of the highest levels of outside expertise. Among the options are:

a. Adequately funded, one-year fellowships for outstanding academic scholars and research personnel in new, rapidly moving areas relevant to the agency's mission.

b. Careful, selective modification of the Federal Advisory Committee Act to remove the impediments to participation by the specifically most relevant and expert consultants, so that the most useful experts can be convened as needed.

c. Implementation of the current Pfizer proposal, or something closely similar, so as to provide the agency with the very best outside advice on those issues, which because of questions of risk, or controversiality, must receive full in-house review. This fits well with needed statutory reform, discussed later.

3. Revise the FD & C Act in two respects:

a. Modify the Delaney clause to permit risk-based decision making.

b. Revise the food additive petition process to——

—invoke highly expert third party review and evaluation, and if that evaluation results in a judgement of safety under the conditions of proposed use,

—require the Secretary to issue a regulation permitting such use, or to refuse to do so only on the basis of explicitly stated, substantially supported countervailing considerations.

This is essentially the current industry proposal. The Pfizer proposal, mentioned earlier, easily becomes part of this. These will not bring the millennium, but they should move us in the right direction.

Our human food preferences evolved early in human history. As nomadic hunters and gatherers, we exercised a great deal, out of necessity, not to stay healthy. We had to spend at least 3500 calories per day to obtain a barely adequate diet. A preference for high fat, calorie-dense foods was a survival advantage. Thomas Hobbes' comment that, in a state of nature, the life of man was ". . . nasty, brutish, and short" has only been confirmed by modern research.

Since those days, only ten thousand years ago, our food preferences have not had time to change, but our lives and lifestyles have changed a great deal. The bad news is that most of us in this room will die of some chronic disease of the later years. The good news is that, in sharp contrast to our ancestors, we will live long enough to get it. Along with our genetic make-up, our diets clearly have an important role—not yet understood in detail—in the cause and development of chronic diseases. As we continue to learn more, we must adjust our diets to our needs—not merely to live longer, but to live better, fully functional lives. Those adjustments will require modified foods. Some of that modification will come through genetic change in food plants and animals, some through processing, some by new ingredients. The most exciting and promising areas of research in diet and health are at the interface of nutrition, biochemistry, and toxicology. This is precisely the area that presents the most difficult judgements for the FDA. We need to have a truly effective system for assuring not only the safety of these new foods and the validity of the information about them, but also for assuring their availability, as our knowledge grows.

Mr. SHAYS. Thank you for your elegant statement here. It's nice to know—we have a little bit of a disagreement, but you two are such gentlemen that you will probably say you don't disagree.

Mr. Clausi.

Mr. CLAUSI. Thank you, Mr. Chairman.

I am Al Clausi. I am the immediate past president of the Institute of Food Technologists. Founded in 1939, IFT is a nonprofit scientific society of 28,000 members, all of whom work in food science technology and related professions in academia, industry, and government.

I am retired from General Foods Corp. where, in 1987, I was a senior vice president and chief research officer for General Foods worldwide. Currently, I serve as a consultant and technical advisor in food product research and development.

I am pleased to present my testimony at this hearing on behalf of IFT. I ask that my written comments be included in the formal record, and I will try to summarize briefly because of time constraints.

Mr. SHAYS. Let me just tell you the task, and you all have a vested interest in this one. We have a series of votes that started, and we have 15 minutes to get there. My sense is that we are going to be gone for a little bit of time. I think it might be helpful to all of you to be able to conclude with your testimony to ask you questions. So we're going to ask you to get right into it and summarize, and then we will get to some questions.

Mr. CLAUSI. All right, sir. I will do that.

Mr. SHAYS. You have a little bit of time. We've heard some thoughtful statements here, so feel free to make your key points to us.

Mr. CLAUSI. I was going to spend a little time on the future, because we have had problems in the past.

Mr. SHAYS. Let's talk about the future.

Mr. CLAUSI. I'm much more concerned about the future.

Mr. SHAYS. Let's talk about it.

Mr. CLAUSI. A society that is looking to foods for health and well-being, a science that seems to be moving in the direction of identifying more and more useful, healthful components of food, as well as those elements that could be minimized, such as excessive fat in the diet, in order to accomplish all of this, in order to satisfy the consumers, we have a need for healthful ingredients, for new technologies, additives, if you will, that will facilitate the technology to bring these new products to the consumer's table.

We, therefore, feel that we need an improved food additive approval system. We support providing FDA with the adequate human and financial resources that they need to review food additive petitions and GRAS review petitions. At the same time, we believe that they must be reviewed more expeditiously than is currently the custom, to ensure that innovation is not stifled and that the introduction of new, useful, and safe ingredients is not hindered.

While saying this, IFT believes that it is critical that the thoroughness and the integrity of the scientific review process be preserved in any efforts to streamline the safety review process. To this end, IFT supports the application of sound scientific toxicology principles in safety evaluation and in the review of petitions for new food ingredients and GRAS affirmation of substances.

We support the use of third-party scientific review panels to enhance the agency's review of food additives and to assist in the process. We believe, however, that these panels should focus on the adequacy of the scientific data to assure safety but should be comprised of scientists with pertinent expertise from all sectors: industry, academia, and government, wherever possible.

As a multidisciplinary scientific society, with thousands of members working in food science and technology, including renowned toxicologists, biochemists, et cetera, IFT offers its services in helping to provide the resources and the talent needed for such an activity.

In sum, Mr. Chairman, we feel that new ingredients and technologies are the key to new food innovations. They always have been, and they always will be. We have gone through a trough over the past 15 or 20 years, but the future is bright, and we need to break through that bottleneck. IFT supports sound food science and safety principles in the evaluation of new food ingredients and technologies.

Back in 1982, a nonprofit group called the Food Safety Council recommended such principles, and I will leave their report with the committee to review.

Mr. SHAYS. I thank you.

Mr. CLAUSI. Finally, IFT believes that this process must be done more expeditiously, and to that end we offer our support in the way of providing resources to aid the agency.

Thank you.

[The prepared statement of Mr. Clausi follows:]

PREPARED STATEMENT OF AL S. CLAUSI, INSTITUTE OF FOOD TECHNOLOGISTS

Good morning. I am Al Clausi, immediate past president of the Institute of Food Technologists (IFT). I am pleased to present testimony at this hearing on behalf of IFT. Founded in 1939, IFT is the scientific society of 28,000 members working throughout the food system in food science, technology, and related professions in academia, industry, and government. I am retired from General Foods Corporation where in 1987 I was Senior Vice President and Chief Research Officer for General Foods Worldwide. Currently I serve as a consultant and technical advisor in food product research and development.

Demography and lifestyles of U.S. consumers have changed dramatically during the past few decades. The population has increased; the average age of the population has increased; there are more families with both parents working outside the home, and, food preferences have changed (Smith, 1993). At the same time significant advances have been made in food science and technology and in understanding of the complex relationships between diet and health. Partly as a result, demand for foods that meet specific health and dietary needs has soared. Food science and technology is enabling response to consumers' dietary needs with an array of custom-designed foods. These foods are crucially dependent upon innovative ingredients and technology, including additives.

Food additives are particularly useful in creating an array of appealing, convenient foods. Food additives are also an important component of food preservation, i.e. in inhibiting microbiological spoilage and reducing the risk of foodborne illness; preventing chemical, physical, and enzymatic deterioration; and in conserving nutritive value.

Growth of microorganisms is affected by, among other factors, the moisture content, acidity, nutrients, and antimicrobial constituents of foods and by the temperature, relative humidity, and atmospheric gas composition of the storage environment (Jay, 1992). Food additives are effective in altering certain food properties to either favor growth of desirable microorganisms or inhibit growth of undesirable or pathogenic microorganisms. Because bacteria, yeasts, and molds differ in their growth requirements and sensitivity to food properties and environmental conditions, controlling them in different types of foods is a challenge requiring an array of technologies including food additives. Salt and sugar, for example, are used in some foods to reduce moisture that undesirable or pathogenic microorganisms would otherwise use for their growth. Lactic and acetic acids may be added to increase the acidity of foods to inhibit growth of bacteria and yeasts.

To enhance nutritional value, restore nutrients lost through processing, and prevent nutritional deficiency diseases, some foods such as bread and milk are fortified with vitamins and minerals. Once associated mainly with nutritional deficiency diseases, the issue of nutrient fortification for positive health benefits is particularly germane in conjunction with the recent science linking insufficiency of folic acid with neural tube (birth) defects.

Other additives, aspartame, acesulfame K, gums, simplesse, maltodextrins, and polydextrose, to name a few examples, are important sugar and fat substitutes that have greatly expanded the variety of fat- and calorie-reduced foods available to those striving to make healthful food choices.

The Food and Drug Administration (FDA) lists nearly 3,000 substances in its book "Everything Added to Food in the United States" (FDA, 1993). Although many additives and GRAS substances are available, further innovation in food technologies and ingredients are needed to enable food scientists and technologists to make additional advances toward improving human health. Further development of sugar and fat substitutes and ingredients for functional food that provide specific health benefits will enhance the ability of foods not only to meet nutrition needs but also to contribute positively to health and well being. Availability of new food additives will be increasingly useful as food scientists and technologists further modify traditional foods to meet specific dietary needs and preferences. As alternative ingredients and additives are developed and as foods are redesigned, the technologies that are necessary must be available, including food additives, to assure sensory appeal, quality, and microbiological stability and safety.

As new food and color additives and potential GRAS substances are developed, they are subjected to extensive toxicological testing, safety assessment, and regulatory data review to meet the safety requirements of the U.S. Food, Drug and Cosmetic Act and the 1958 and 1960 Food and Color Additives Amendments. These procedures are time-consuming and costly to both private and public sectors.

Many factors complicate safety review and risk assessment of food additives. For example, tremendous advances in analytical chemistry during the past few decades now enable the detection of substances at a level as low as 10^{-18}. The ability to detect substances in foods at increasingly infinitesimal levels complicates interpretation of data and risk assessment. Other limitations we face in conducting safety assessments include extrapolation to lower doses commonly encountered from dose-response data obtained using the Maximum Tolerated Dose (MTD, the highest dose that will not kill the animal) in assessing toxicity and carcinogenicity, and extrapolation to humans of test results obtained in animal studies (CAST, 1992; Taylor and Sumner, 1990). It is important to make a distinction between toxicity and hazard and to recognize that zero risk or absolute safety in any area, including food, is unattainable. A substance may be toxic at some dose, but may not be hazardous at commonly used doses or typical dietary levels (IFT, 1988). Modern concepts of safety and risk assessment must be incorporated in the expeditious review of food additives (Food Safety Council, 1982).

IFT appreciates the challenges the Food and Drug Administration faces in dealing with new food additive petitions. IFT supports the development and implementation of an improved food additive review system that provides FDA adequate human and financial resources to conduct reviews of new food additives and GRAS petitions. IFT believes that petitions for new food additives and GRAS substances, however, must be reviewed more expeditiously than is currently the custom, to ensure that innovation is not stifled and the introduction of new, useful, and safe ingredients is not hindered.

IFT believes that it is critical that the thoroughness and integrity of the scientific review process be preserved in efforts to streamline the safety review process. IFT firmly supports the application of sound scientific principles in the safety evaluation and review of petitions for new food ingredients and GRAS affirmation of substances.

IFT appreciates the value of third-party scientific review panels in enhancing the agency's review of food additives. IFT supports the use of such safety review panels to enhance the agency's review of substances as long as the panels focus primarily on assessing the adequacy of the scientific data to assure safety and are comprised of scientists with pertinent expertise. Such panels should include expertise from industry, academia, and government wherever possible. As a multidisciplinary scientific society with thousands of members working in food science and technology, IFT includes esteemed toxicologists, biochemists, and other scientists in disciplines pertinent to safety evaluation. IFT would be pleased to identify for the agency or any review boards members with technical expertise pertinent to food additive and GRAS review.

In summary, new ingredients and technologies are the key to new food innovations. IFT supports sound food safety principles in the evaluation of new food ingredients and technologies. IFT believes, however, that regulatory food safety review must be done expeditiously to ensure that innovation is not stifled and the introduction of new, useful, and safe ingredients is not hindered.

Mr. SHAYS. We're going to be working with the FDA to try to get them to, one, get at the backlog, and also establish a more logical process and time requirements for the future. My biggest concern is that there is an attitude that evolves in any organization that

basically no longer feels it has to abide by a law and then basically can invent its own process and write its own law, in effect.

Your comment, Dr. Miller, your concern that you wouldn't want them to abrogate their responsibility, and you, Dr. Hall, saying that they could utilize outside resources, as well. I think it's a matter of degrees, Dr. Miller. I would be happy to have both of you comment, or all three of you. I mean, I don't know how they are going to get at this without using some outside resources.

Mr. MILLER. I would absolutely agree, Mr. Chairman. I have great sympathy for the agency's approach to the problem, trying to keep as much of it in-house as possible, but with the current resources and the direction it's going, I don't believe they are going to meet even their performance standards. They must somehow or other, use an outside approach.

Mr. SHAYS. So you do concur that they will have to, but you express some concern about that.

Mr. MILLER. Right.

Mr. SHAYS. And that's basically your point.

Mr. HALL. That's basically my view, as well. Indeed, Mr. Chairman, I mentioned in my written testimony a number of examples, and that's a small fraction of those, in which they now use outside resources. They ought to be complimented for doing that and encouraged to use much more.

Mr. SHAYS. It seems to me your point, Dr. Hall, that our analytical abilities are such that our perception of risk has virtually exploded and is at the very center of this problem. We are so aware of the risks and not quite certain of what those risks really mean. I'm not sure what the solution to that is.

Mr. Clausi, is there a solution to that challenge?

Mr. CLAUSI. May I suggest, Mr. Chairman, that it is true we can find almost anything in anything today, as a result of our scientific capability. We have to separate hazard from risk. We have to recognize that there may be materials that may represent a hazard at one level but are no risk as used in practice.

Mr. SHAYS. I'm sure that we're going to be getting into this issue, because it's just at the center, and our committee will be involved more with that.

I would like the ranking member to ask some questions in the 3 minutes he has before a vote.

Mr. MILLER. May I just make one comment about that, Mr. Chairman, for the record.

Mr. SHAYS. Yes, sir.

Mr. MILLER. I think the answer to your question is a question of judgment. That's what makes the difference. You get judgment from people who have confidence in their own competence and they are confident in their ability to defend that competence. That's part of the problem in what is happening now, that we're not getting it.

Mr. SHAYS. Mr. Towns.

Mr. TOWNS. Thank you very much, Mr. Chairman.

Let me also thank all of you for your testimony. I think you have been extremely helpful.

Dr. Hall, you said something, I think, that I would like for you to just elaborate on a little bit more.

Mr. HALL. Sure.

Mr. TOWNS. In your testimony, if I understood you clearly, you said that we should get rid of the Delaney clause?

Mr. HALL. No.

Mr. TOWNS. No?

Mr. HALL. I said it should be replaced by a risk-based approach.

Mr. TOWNS. What is that risk-based approach you are talking about?

Mr. HALL. One way would be to specify, in general terms, because I don't think—it's a rapidly moving field that Congress shouldn't micromanage—but to replace, in general terms, with a statement that says that the agency should establish a level of acceptable risk, below which there is no hazard to humans through consumption, under intended use or normal use, and that the general safety provisions of the act and those that explicitly now totally exclude carcinogens should be reinterpreted to meet that negligible risk standard.

In effect, it implements the idea of a negligible risk, because, as Mr. Clausi said, we can now find traces of everything in anything. So there's risk there, but it's way, way out, and we need to have some way of recognizing that. That's what I meant by "risk-based."

Mr. TOWNS. Thank you very much.

Thank you very much, Mr. Chairman.

Mr. SHAYS. Gentlemen, we're going to thank you for your testimony.

You're going to make your plane, Dr. Miller.

Mr. MILLER. Thank you.

Mr. SHAYS. We really appreciate all of your testimony. It is unfortunate we don't have a little bit more time, but I think it makes sense to go on to the next panel. Thank you very much for coming, and please be in touch with us in terms of any recommendations you would like to make, specifically as it relates to changes in the law to make the law more realistic, as well as how we deal with the issue of risk. I thank you.

For the next panel that is going to appear before this committee, we're going to allow you to get some lunch. If you could be back in 25 minutes, I think we will be back. I just need to tell you there was a little bit of contest and discussion about a misvote and whether the Speaker should have seen someone wanting to register a vote. So I can't determine whether there won't be some procedural statements made on the floor that will keep us longer.

We will recess until approximately 12:30.

[Recess.]

Mr. SHAYS. I would like to call the hearing to order and to invite Dr. Stephen Ziller, Grocery Manufacturers of America; Dr. Rhona Applebaum, National Food Processors Association; and Mr. Robert Gelardi, Calorie Control Council.

If you all would stand, I will administer the oath.

[Witnesses sworn.]

Mr. SHAYS. For the record, I would like to note that all three witnesses have responded in the affirmative.

Thank you for your patience and your adjusting to our schedule. We will go in the order in which I called you before: Dr. Ziller, Dr. Applebaum, and then Mr. Gelardi.

We will start with you, Doctor.

STATEMENT OF STEPHEN A. ZILLER, GROCERY MANUFACTURERS OF AMERICA, INC.; RHONA S. APPLEBAUM, NATIONAL FOOD PROCESSORS ASSOCIATION; AND ROBERT C. GELARDI, CALORIE CONTROL COUNCIL

Mr. ZILLER. Thank you, Mr. Chairman.

I am Dr. Steve Ziller, vice president of scientific and technical affairs for the Grocery Manufacturers of America. GMA strongly urges that substantial change be made in the food additive approval process to meet current and future consumer needs. GMA's members include a number of companies who have submitted some of the major direct food additive petitions, many of which are still pending before the Food and Drug Administration after too many years of review.

We strongly applaud this oversight committee's action to take a close look at the food additive approval process. After 35 years, it is due for a major overhaul. The current program resembles a Model T, when the world is moving at Concorde speeds. Businesses that operate this way would be out of business.

Before I begin specific comments, let me state a few general principles. First, both the food ingredient manufacturers and food companies who use these in their most valued assets, their brands, demand that their products continue to be the safest in the world. These comments are made with that prerequisite.

Second, the food industry believes that FDA's participation in food additive approvals adds important credibility and assurance for consumers, and we favor this. Third, the problems with the current food additive approval system are not due to a single reason but result from multiple causes. Fourth, the current global competitiveness and trade reality demand that all parts of industry and government continually improve in their efficiency and effectiveness.

The fundamental causes of the breakdown of the food additive approval process are, one, a lack of clear mission; two, a steadily declining priority over the years; and three, the increasing lack of incentive and ability of the agency to make a final, positive decision on a petition against the statutory criteria. Congress should give the agency more specific direction on the importance of food additive approvals in its mission, since it relates to U.S. competitiveness and leadership in nutrition, safety, and food technology worldwide.

A second cause for the breakdown of the food additive approval process is a steadily decreasing priority. The general trend for food approvals over the last 12 years has been increased pending petitions and decreased approvals. Several of the major petitions still pending were submitted about 8 years ago.

Over the last 12 years, policy decisions were made on priorities which robbed FDA of foods staff. Congress needs to provide direction to Food and Drug on the need for higher priority for food additive approval within the resources they have. In the future, FDA will have to leverage external sources more effectively, as it will not be possible to maintain all the needed expertise in-house.

A third major problem with the current food additive approval process is both a growing inability to bring closure to the final deci-

sion and the replacement of sound scientific judgment with an infinite series of "what if" questions that delay the need for a decision.

There seems to be a preoccupation with fear of change or an obsession with an impossible standard of zero risk, when the actual statutory standard is reasonable certainty of no harm. This problem is very fundamental and must be addressed by bringing the best science and the best scientists together to determine decisive action steps for resolution.

The inherent delays resulting from this inability to make final decisions is beginning to turn off major food companies from investing in new additives and technologies. The system of approval is now so unpredictable and uncertain that businesses cannot make reasonable estimates of either the cost of developing a new ingredient or the timing of related investments to commercialize it.

Based on usual nutrition and health yardsticks, FDA should be much more supportive of many new food additives which can provide benefits such as lower calories, fat, and saturated fat. The secondary impact on expected reduction in risk of chronic disease is very important to consumers and society, both from a health and an economic standpoint.

One GMA member company has provided the following estimates of reduction in the incidence and cost of chronic disease associated with lower dietary saturated fat intake by the use of a fat substitute. Depending on the assumptions, savings of up to $25 billion in health care costs and 112,000 fewer deaths, over a 20-year period, have been estimated by experts in these types of calculations.

Mr. Chairman, I am not here to debate the precise accuracy of these estimates. Even if they are one-tenth of those figures, they still amount to large numbers, which we believe should encourage Food and Drug to speed up approvals of these types of ingredients that can have healthful advantages. The negative impact of not doing this is the unavailability to consumers of these beneficial ingredients.

Finally, the details of the consensus food industry legislative proposal will be given by others later in this hearing. I do want to briefly summarize a few key elements. FDA should be the quarterback for the review and approval process. FDA should approve and provide final regulations for direct food additives.

Third parties listed by FDA as meeting agreed criteria may be selected by the petitioner to receive the petition from Food and Drug, in order to provide additional resources to FDA in their review. This would include nationally renowned scientists in critical subject areas.

The third party will have authority to make the primary safety judgment and to conduct a public hearing to receive input prior to completing the report for the Food and Drug Administration. The petitioner will pay the third party for their effort. Appropriate time limits should be established for the third party and FDA, and these should be strictly upheld.

Thank you for the opportunity to testify today. I will be happy to answer any questions you may have.

[The prepared statement of Mr. Ziller follows:]

PREPARED STATEMENT OF STEPHEN A. ZILLER, PH.D., VICE PRESIDENT, SCIENTIFIC AND TECHNICAL AFFAIRS, GROCERY MANUFACTURERS OF AMERICA, INC.

Mr. Chairman, I am Dr. Steve Ziller, Vice President, Scientific and Technical Affairs, for the Grocery Manufacturers of America, Inc. (GMA). GMA is the national trade association representing companies which manufacture and market branded grocery products that comprise 85% of the volume of food and grocery items sold in the United States. Member company annual sales exceed $360 billion.

While virtually every GMA member company and their consumers have benefited from the increase in food quality, nutrition, safety, and availability made possible by food additives already approved or affirmed as safe by the Food and Drug Administration over the years, we strongly urge that substantial change be made in the food additive approval process to meet current and future consumer needs. GMA's members include a number of companies who have submitted some of the major direct food additive petitions, many of which are still pending before the Food and Drug Administration after too many years of review.

We strongly applaud this oversight subcommittee's action to take a close look at whether the way the food additive approval process is working today 1) is still consistent with the Congressional intent when provisions were passed legislatively in 1958, 2) whether it is working as effectively as it can in the current environment, and 3) what changes would help make it most efficient for the future. Few processes that define such a very important interaction between government and industry can be expected to survive for over 35 years without a significant overhaul, both by regulatory and legislative means.

Mr. Chairman, I have had extensive experiences in working on important food ingredient approvals by FDA, both from the point of view of the petitioner, for example in the case of Olestra (a complete fat substitute), and as part of a food processor wanting to use a new food ingredient, for example in the case of an artificial sweetener. In my current position at GMA I have discussed the major problems with a number of companies with pending petitions for ingredients which have the capability of providing consumers a better and broader choice of foods to fit their individual nutrition and dietary needs. My comments are based on this background.

Before I begin specific comments, let me state a few general principles. First, both the food ingredient manufacturers and the food companies who use these in their most valued assets, i.e. their brands, demand that their products continue to be the safest in the world. These comments are made with that prerequisite. Secondly, the food industry believes that the FDA's participation in food additive approvals adds important credibility and assurance for consumers and we favor this. Third, the problems with the current food additive approval system are not due to a single reason but result from multiple causes. Fourth, the current global competitiveness and trade reality demands that all parts of industry and government continually improve their efficiency and effectiveness. For the food industry this includes expectation of a government that will support new technology and approval of new food ingredients.

While it is easy to say that the first and only cause of the breakdown of the FDA food additive approval process is reduced resources, I contend that this is more of a symptom and not a root cause. The fundamental causes are lack of a clear mission, a steadily decline in priority over the years, and the increasing lack of incentive and ability of the agency to make a final positive decision on a petition against the statutory criteria.

One of the recommendations of the Edwards Commission review of FDA and its operations was for FDA to develop a mission statement that included a strong statement for new product approvals. There was some disappointment in the industry when this important role was relegated to a secondary and debatable status for food additives, "Be a positive force in making safe and effective products available to the consumer . . ." Of course, words on a piece of paper do not make things happen; however, they can give some clue as to the agency's lack of commitment to this area. Congress should give the agency more specific direction on this matter in the future as this relates to US competitiveness and leadership in nutrition, safety, and food technology worldwide.

A second cause for breakdown in the food additive approval process is a steadily decreasing priority. The general trend for food additive approvals over the last 12 years has been increased pending petitions and decreased approvals. For the direct food additives and irradiation petitions the numbers pending over the last 5 years has been about 50 and those approved each year have been less than 10. For the same group the pending petitions are averaging about 5 years to approval. Several of the major petitions still pending were submitted about 8 years ago.

We get a hint of the contributing factors by looking at the Center for Food Safety and Nutrition (CFSAN) staffing versus drugs and biologics. CFSAN staffing has remained essentially constant for the last 12 years (ranging from about 800 to 900) while that for drugs and biologics increased steadily from 1357 to 2253. Policy decisions were made on priorities which robbed the FDA CFSAN staff. Congress needs to provide direction to FDA on the need for higher priority for this effort within the resources they have. In the future, FDA will also have to leverage external resources more effectively as it will not be possible to maintain all needed expertise in-house.

A third major problem with the current food additive approval process is a growing inability to bring closure to the final decision and the replacement of sound scientific judgment with an infinite series of "what if" questions that delay the need for a decision. There seems to be a preoccupation by technical reviewers and the legal staff with fear of change and an obsession with an impossible standard of "zero risk" when the actual statutory standard is "reasonable certainty of no harm". This contributes to many associated problems such as no clear guidance on what the petitioner must do to satisfy the reviewers in advance of submission and further confusion after reviews are begun. This problem is very fundamental and must be addressed by bringing the best science and the best scientists together to determine decisive action steps to bring resolution. Importantly, the legal community must provide clearer guidance and support for final decisions. The inherent delays resulting from this inability to make final decisions is beginning to turn off major food companies from investing in new additives and technology. The system of approvals is now so unpredictable and uncertain that businesses cannot make even reasonable calculations about the costs of developing a new ingredient and the timing of related investments to commercialize it. Seven or eight years and a page full of new questions will kill all major new product development in the current world economy.

I will provide one example to illustrate that the long US timing delays are not necessary. Sucralose is still waiting for US approval since its submission February 9, 1987. Yet similar submissions in Canada and Australia have already been approved (9/91 and 10/93 respectively). These are well respected developed countries with food supplies as safe as the US. We should be able to do much better.

There should be much more commitment to approvals by FDA to be consistent with their other efforts to support a more nutritious and safe food supply. The same type of nutrition and public health yardstick should be used to justify increased FDA effort in promptly approving important new ingredients which can provide benefits such as lower calories, fat, and saturated fat. The secondary impact on expected reduction in risk of chronic disease is very important to consumers and society in general.

Based on an eight gram per day reduction in saturated fat, optimistic assumptions provide for a $24 billion per year health care saving and two million fewer patients developing heart disease. One GMA member company has provided the following estimates of reduction in the incidence and costs of chronic disease associated with lower dietary saturated fat intake by use of a fat substitute only in the snacks and crackers food categories. Using a conservative "cost-of-illness" approach targeted at high risk groups for coronary heart disease produced estimated savings of $2 billion over 10 years based on state of the art calculations. Extending the benefits to the entire population and including reduction in cancer risk would provide a $4 billion saving over 20 years in direct medical costs and lost wages and 14,600 fewer deaths. Broader use of the fat substitute beyond snacks and crackers could provide savings of $25 billion in health care costs and 112,400 fewer deaths over 20 years.

Mr. Chairman, I am not here to have a debate about the precise accuracy of these estimates. That can be done in another forum. However, I think the point is that important food additives with this magnitude of benefits should be encouraged with a speedy review and decision. The negative impact of their unavailability to consumers must be carefully considered in justifying continuing delay in approval.

Finally, the elements to the solution need to address all the critical elements of the underlying problems with the current system. Congress must make its position known to FDA about the importance of food additive approvals to the health and economy of Americans. There must be a positive and supportive attitude by FDA. While the details of the consensus industry legislative proposal will be provided later, let me summarize several key areas. FDA should be the "quarterback" for the review and approval process FDA should approve and provide final regulations for direct food additives. Third parties listed by FDA as meeting agreed criteria may be selected by the petitioner to receive the petition from FDA in order to provide additional resources to FDA for review (including nationally renowned scientists in critical subject areas). The third party will have authority to make the primary safe-

ty judgment and to conduct a public hearing to receive input prior to completing the report to FDA. The petitioner will pay the third party for their effort. Appropriate time limits should be established for third party and FDA review and these should be strictly upheld.

Thank you for the opportunity to testify today. I would be happy to answer any questions you may have.

AGENCY OVERVIEW—FDA'S MISSION

The Food and Drug Administration is a team of dedicated professionals working to protect, promote and enhance the health of the American people. FDA is responsible for ensuring that:

—Foods are safe, wholesome and sanitary; human and veterinary drugs, biological products, and medical devices are safe and effective; cosmetics are safe; and electronic products that emit radiation are safe.

—Regulated products are honestly, accurately and informatively represented.

—These products are in compliance with the law and FDA regulations; noncompliance is identified and corrected; and any unsafe or unlawful products are removed from the marketplace.

We strive to:

—Enforce FDA laws and regulations, using all appropriate legal means.

—Base regulatory decisions on a strong scientific and analytical base and the law; and understand, conduct and apply excellent science and research.

—Be a positive force in making safe and effective products available to the consumer, and focus special attention on rare and life-threatening diseases.

—Provide clear standards of compliance to regulated industry, and advise industry on how to meet those standards.

—Identify and effectively address critical public health problems arising from use of FDA-regulated products.

—Increase FDA's effectiveness through collaboration and cooperation with state and local governments; domestic, foreign and international agencies; industry; and academia.

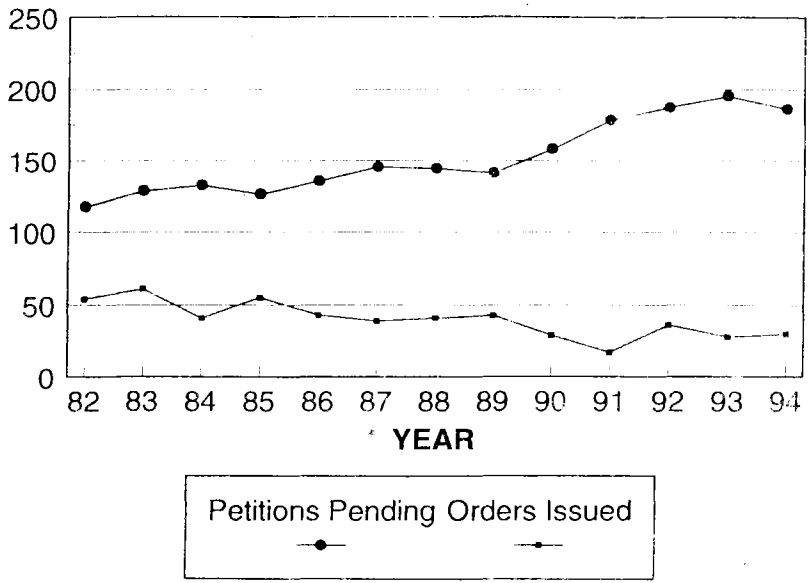
—Assist the media, consumer groups, and health professionals in providing accurate, current information about regulated products to the public.

—Work consistently toward effective and efficient application of resources to our responsibilities.

—Provide superior public service by developing, maintaining and supporting a high-quality, diverse work force.

—Be honest, fair and accountable in all of our actions and decisions.

FDA FOOD ADDITIVE APPROVAL TRENDS
1982-1994

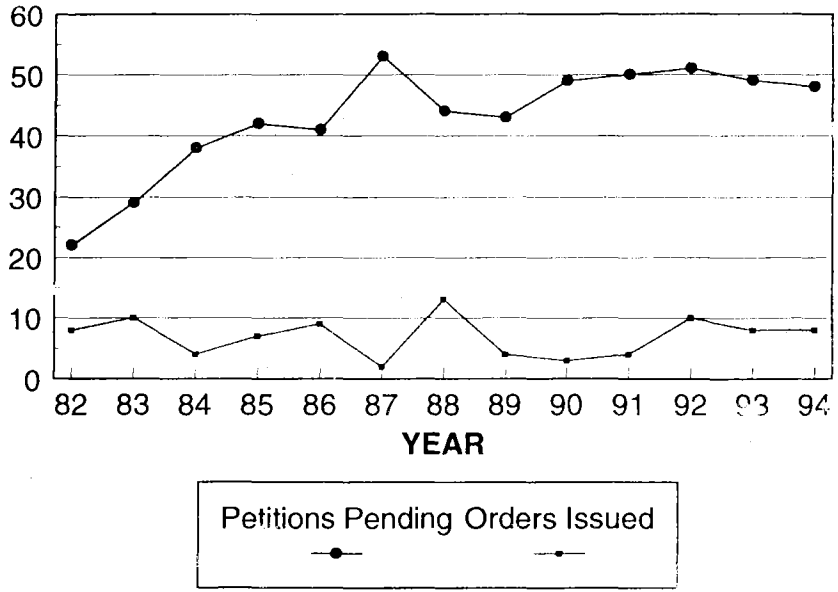


Does not include FDA-generated proposals; includes all indirect additive, direct additive, veterinary, and irradiation petitions.

Source: Food Chemical News

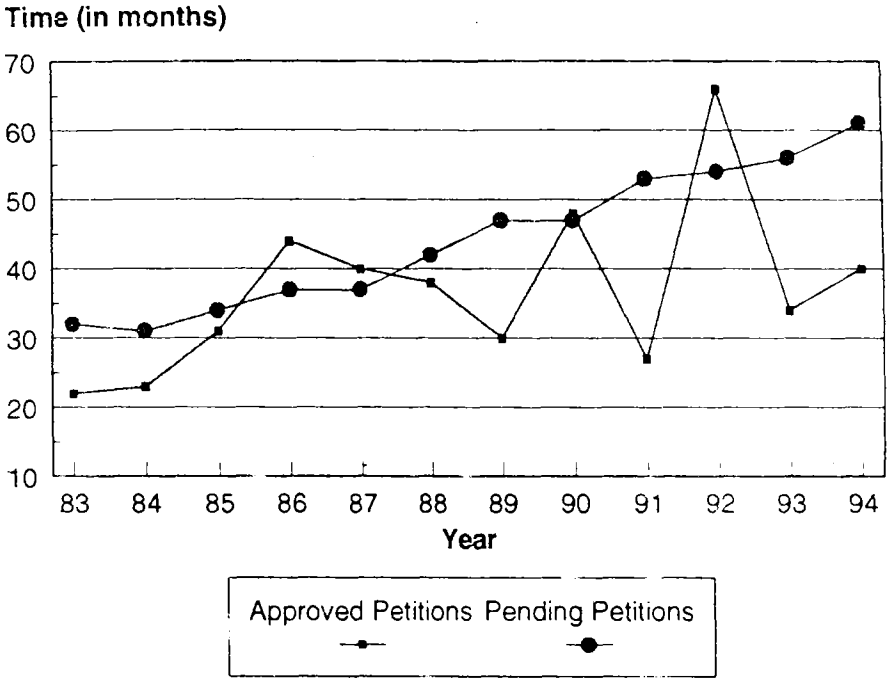
FDA FOOD ADDITIVE APPROVAL TRENDS
1982-1994

Direct Additive and Irradiation Petitions Only



FDA Food Additive Petitions 1983 - 1994

Average Time Pending
Direct Additives and Irradiation Petitions Only

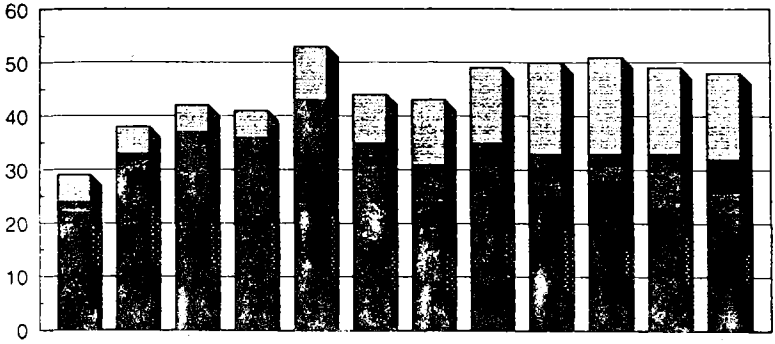


- For Approved Petitions, time from initial filing to approval
- For Pending Petitions, time from initial filing to end of year

FDA Food Additive Approvals Pending 1983 - 1994

In months - Direct Additives and Irradiation Petitions Only

Approvals Pending (total)

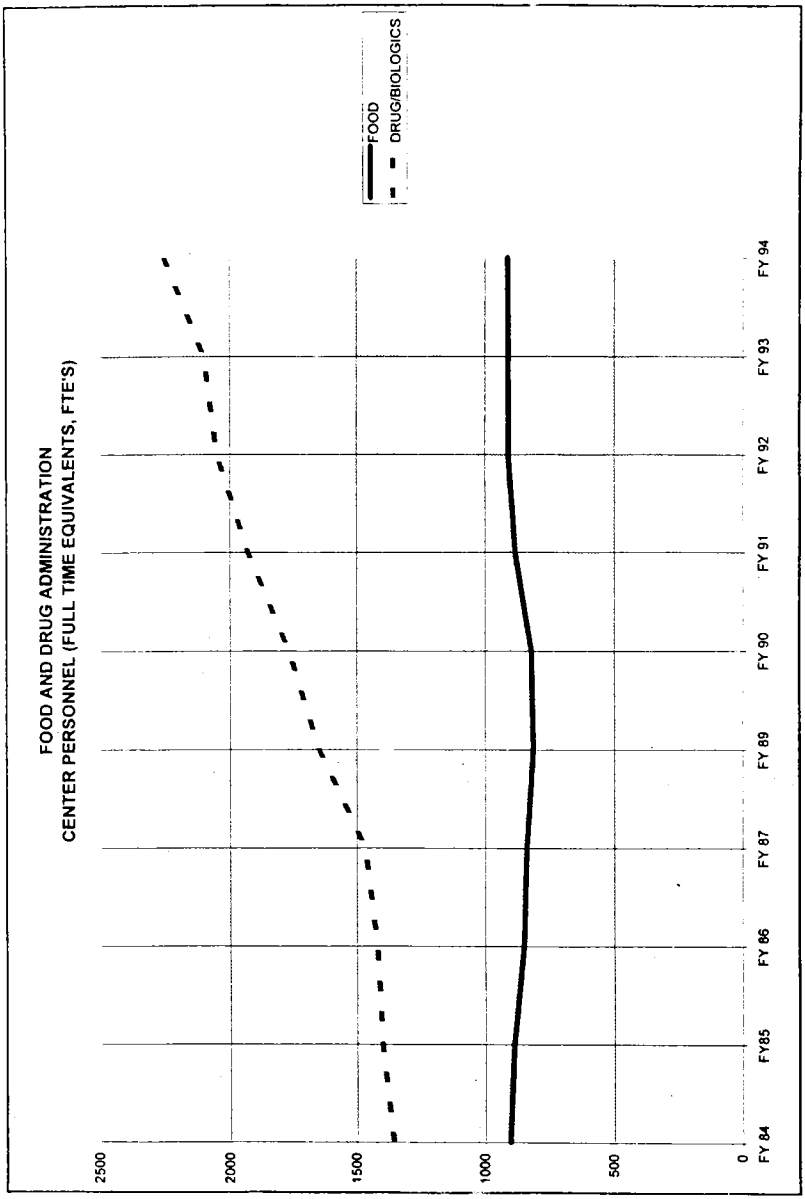


Year	83	84	85	86	87	88	89	90	91	92	93	94
1-12 mos	13	13	13	12	11	8	7	13	8	11	9	10
13-24 mos	7	11	8	9	12	9	8	6	12	5	10	6
25-36 mos	2	6	8	5	10	7	9	6	5	12	4	6
37-48 mos	1	2	6	5	5	7	4	6	3	3	7	4
49-60 mos	1	1	2	5	5	4	3	4	5	2	3	6
61+ mos	5	5	5	5	10	9	12	14	17	18	16	16

Food and Drug Administration

Center Personnel (Full Time Equivalents, FTE'S)

Fiscal Year	Food	Drugs/Biologics
FY 84	905	1357
FY 85	889	1401
FY 86	850	1419
FY 87	839	1467
FY 89	815	1648
FY 90	821	1768
FY 91	884	1929
FY 92	909	2051
FY 93	909	2101
FY 94	912	2253


FOOD AND DRUG ADMINISTRATION
CENTER PERSONNEL (FULL TIME EQUIVALENTS, FTE'S)
FOOD
DRUG/BIOLOGICS
2500
2000
1500
1000
500
0
FY 84
FY85
FY 86
FY 87
FY 89
FY 90
FY 91
FY 92
FY 93
FY 94

FACILITATING INNOVATION IN THE FOOD INDUSTRY—MAKING THE FDA REVIEW PROCESS FOR FOOD INGREDIENTS WORK

THE PROBLEM

Consumers in the United States enjoy the world's most varied, wholesome, and affordable food supply. Innovations in food processing and technology and in food packaging technology—the development of fat and sugar substitutes and new fiber sources, for example, as well as new types of packaging such as aseptic juice packages—enable food companies to develop and offer consumers increased food choices, including foods that have fewer calories, less fat, or more fiber, as well as enhanced convenience. Extraordinary delays in the FDA approval processes for new food ingredients impede much needed and desirable innovation in the food industry.

Since 1958, new food ingredients which qualify as "food additives" have been required to have FDA approval before marketing. Food additives include both those ingredients added directly to food to achieve a physical or technical function (sugar substitutes and antioxidants, for example-so-called "direct" food additives) and those substances that are used in food packaging or other food contact situations which may become part of the food through contact with it (so-called "indirect" food additives). Approximately seventy-five percent of the food additive petitions submitted to FDA are for indirect food additives.

Under the law, FDA has 180 days to review a food additive petition and to take action on it. Few, if any, food additive petitions are acted upon in the statutorily-prescribed time period. Rather, FDA action on a typical food additive petition, if it occurs at all, takes 4–6 years and, in some cases, twice as long as that. Increasingly, as the graphs attached to this paper show, food additive petitions remain in "pending" status in perpetuity. For example, in 1982, there were about twenty petitions pending for direct food additives; by 1994, the number had grown to nearly fifty. With the exception of 1988, FDA took action on fewer than ten petitions in each of the years in question. In five of the years in question, FDA acted on fewer than five petitions. If one looks at all pending petitions (direct and indirect), the numbers are equally distressing: there are nearly 200 petitions pending while only about half that number were pending in 1982. The trend on petitions acted on is decidedly downward with about twenty-five actions per year on average whereas fifty or more petitions were acted on in 1982 and 1983.

There are numerous reasons why the food ingredient review processes are not working. Most observers believe that FDA reviewers have become unduly cautious and conservative and thus unable to conclude that a particular substance under review is safe. This caution is frequently exhibited in requests that reviewers make for more studies and data that have little, if any, relevance to the determination of safety for a food ingredient. A considerable part of the problem with the current system derives from the allocation of resources within the food ingredient review divisions of FDA-far too many resources are devoted to indirect additive review and far too few resources are devoted to the review of significant new ingredients. Of course, on occasion, petitioners also contribute to delays through submissions that are inadequate and because of the complexity of issues sometimes presented in petitions.

It is also apparent that FDA has perceived there to be no substantial harm to the public from its dysfunctional food ingredient processes and it therefore has invested no significant effort in repairing a broken process. FDA's perception is, of course, incorrect. By taking so long to act on petitions, if it acts at all, FDA depresses investment in new food ingredients and technologies which then deprives consumers of the benefits that these new ingredients and technologies can offer.

Reforming the FDA food ingredient review process does not mean eliminating FDA review or lowering the standards that help to provide consumers with a safe and wholesome food supply. Rather, reform means developing a system and processes that rely on sound science, helping to establish appropriate priorities, and requiring decisions in reasonable time periods. The proposals described below meet these criteria.

SOME SOLUTIONS

Solving the problems with the food ingredient review processes at FDA requires amendments to the food additive portions of the Federal Food, Drug, and Cosmetic Act to provide for a simplified procedure for indirects and to mandate the use of external scientific reviews for directs, when the petitioner requests that form of review and is willing to pay for the external review. These two relatively simple changes have the potential to improve dramatically the efficiency of the food addi-

tive review processes while maintaining the high level of consumer protection that the food industry and its consumers expect.

For direct human food and color additives (color additives are nothing more than food additives whose function in food is to impart color), a new system of "third party review" should be established. Under this system, FDA would enter into agreements with at least three independent organizations which are qualified to review the data contained in food additive petitions which demonstrate the safety and functionality of the additive. If the petitioner requests this form of review, it would designate which of the independent review organizations it wishes to conduct the review. FDA and the independent organization would review the data under appropriate but strict time periods. The FDA, the independent reviewing organization, and the petitioner would freely communicate with each other during the review. FDA would publish a notice of the filing of the petition within 30 days of receipt and thereafter the safety and functionality data in the petition would be available to the public (except for confidential commercial information and trade secrets). The time periods for the review begin with the publication of the notice of filing.

After a suitable period of review (six months, perhaps) during which time FDA and the independent review organization would be required to raise all potential issues with the petitioner (so that the petitioner can respond and so that the review process is not simply an endless series of questions posed to the petitioner without closure ever being reached), the independent review organization would convene a public meeting to receive scientific testimony about the safety and functionality of the additive. FDA, the petitioner, and the public would participate in this meeting.

Within sixty days of the conclusion of the public meeting, the independent review organization would present to FDA a report and recommendation on the petition, concluding either that the additive had been shown to be safe (safety meaning a reasonable certainty of no harm from use of the additive under its intended conditions of use) or that safety has not been demonstrated. If the report concludes that safety has been demonstrated, a presumption of approvability will be created. The petitioner and the public will, of course, have access to the report. At the request of the petitioner, the time period for the report will be suspended (to allow, for example, analysis of existing data or the generation of additional data to respond to issues that have been raised during the review).

After receipt of the report, FDA will have ninety days to act on the recommendation by either accepting it and issuing a regulation to allow the use of the additive or by rejecting it and advising the petitioner in detail of the basis of the rejection. If FDA failed to take either action within the specified time period, it would be deemed to have accepted the report of the independent review organization and would have sixty days to issue a regulation to authorize the use of the additive.

The presumption of approvability arising from a favorable report of the independent review organization would be rebuttable by FDA only if it concluded that there existed substantial evidence to demonstrate that the additive had not been shown to be safe.

The costs of the review by the independent review organization would be borne entirely by petitioners who have requested this form of review. FDA would annually set forth the anticipated fees associated with the independent review (the actual fees incurred in a specific case would, of course, depend on the scope and complexity of the review required of a particular petition). Payment for the review would go directly from the petitioner to the independent review organization. FDA's contracts with the independent review organization would set forth the payment schedule for the petitioner (one-third initial payment, one-third at the conclusion of the public meeting, and one-third after delivery of the report and recommendations, for example). In addition, those contracts would provide for a refund of the petitioner's fee if the independent review organization failed to perform its tasks under the contract or failed to meet the timeframes for completion of those tasks.

For petitions pending at the time that this new process is instituted, the petitioner should have the option of withdrawing the petition and resubmitting it under the new procedures or to have the petition continue to be reviewed under the existing procedures.

This process would enhance the efficiency of the process and bring some order and certainty to a process that is now anything but orderly and certain. Petitions would be reviewed in reasonable time periods because the independent review organizations would be contractually obligated to do so (and would respond as the private sector typically does—if more reviewers are needed to complete the reviews on time, more will be hired) and because real statutory time periods would be established under the law with teeth to enforce them. Consumer protection would be maintained because the standards for decisions on additives would remain rigorous.

The solution for indirects is simple. Indirect additives which are not, by definition, added directly to food and which rarely become a component of food in scientifically-meaningful quantities, do not require extensive food additive petitions nor elaborate FDA review. It simply makes no sense to burden the regulatory process with hundreds of petitions for indirects and for FDA to devote substantial resources to the review of this category of substances. Consumer protection can be maintained at equivalent levels by substituting a notification procedure for the current one.

Under the proposed process for indirects, a notification would be submitted to FDA at least ninety days before the "food contact substance" was intended to be used. The notification would combine the identity of the substance, its intended use, and data and information to show either that the substance was not reasonably expected to become a component of food or that the substance is safe (the identical safety standard for direct human food and color additives). The notification would take effect in ninety days and use of the substance therefore allowed, unless FDA concluded that there existed substantial evidence to show either: (1) that the substance is reasonably expected to become a component of food, if that contention was the basis for a notification; or, (2) that the substance was not safe (again, the same standard as would apply to the rejection of a favorable report from an independent review organization for a direct additive). The notification would be confidential during the ninety day period, but would, except for trade secrets and confidential commercial information, be made public after ninety days. FDA would maintain a list of food contact substances which are the subject of effective notifications.

The term "food contact substance" would be defined as a subset of "food additive." Existing food additive regulations would be unaffected; likewise, the categories of GRAS and prior sanction would continue to exist for food contact substances.

This simple notification system would facilitate the use of indirect additives and thus new or improved food packaging, while also ensuring that these substances are safe. FDA would continue to be made aware of new food contact substances and the basis for the manufacturer's conclusion that the substance is safe. Finally, FDA would have ample time and authority to prevent the use of a new food contact substance if it concluded that it was appropriate to do so.

Attachments

DIRECT HUMAN FOOD AND COLOR ADDITIVE PETITION REVIEW

(a) Amend section 409(b)(2) by adding at the end thereof the following:

"(F) for a direct human food additive, a request for third party consideration under subsections (j) - (o) of this section and the identity of the independent review organization to review the petition."

(b) Amend section 409(b)(5) to read as follows:

"(5) Notice of the regulation proposed by the petitioner, including the name and intended use of the additive, and a designation for third party consideration, if any, shall be published in general terms by the Secretary within thirty days after filing."

(c) Amend section 409(b) by adding at the end thereof the following:

"(6) Upon request of the petitioner set forth in the petition for a direct human food additive, the Secretary shall designate a petition for third party consideration and such petition shall be subject to the procedures set forth in subsections (j) - (o) of this section"

(d) Amend section 409 by adding at the end thereof the following new subsections:

THIRD PARTY CONSIDERATION

"(j)(1) Upon the publication of a notice of filing of a petition which contains a designation of third party consideration, the Secretary shall promptly place on public display in a location maintained for the examination of public documents a complete copy of the data and information contained in the petition which relate to the safety and functionality of the additive, except for data and information which are trade secrets or confidential commercial information.

"(2) Upon publication of a notice of filing of a petition which contains a designation of third party consideration, the Secretary shall promptly provide a complete copy of the data and information contained in the petition which relate to the safety and functionality of the additive to an independent review organization with which the Secretary has entered into an agreement under subsection (o). If the petitioner has designated a specific independent review organization to conduct the review, the Secretary shall refer the safety and functionality data and information to that organization. If the petitioner has not designated a specific organization to review the petition, the Secretary shall determine which organization shall conduct the review.

"(3) The Secretary and the independent review organization shall review the petition for a period not to exceed six months from the notice of filing. During the re-

view period, the Secretary and the independent review organization may communicate with each other or with the petitioner in person or in writing; a complete record of all such communications and the petitioner's responses shall be maintained by the Secretary. Within the six month period provided for review of the petition, the Secretary and the independent review organization shall advise the petitioner in writing of all issues relevant to the evaluation of the petition. In evaluating a petition under this subsection, neither the Secretary nor the independent review organization may consider any data or information which is not filed with the Secretary within six months of the notice of filing or presented at the public meeting under subsection (k), unless such data and information were provided by the petitioner.

PUBLIC MEETING

"(k) Within sixty days of the completion of the review period under subsection (j)(3), the Secretary and the independent review organization shall convene a public meeting to consider the petition. The petitioner shall have the right to appear and to present testimony and to respond to questions. Members of the public shall also have the right to appear and present testimony concerning the safety and functionality of the additive. A verbatim record of the hearing shall be maintained. The meeting shall be chaired by a representative of the independent review organization.

RECOMMENDATION

"(l)(1) Within sixty days of the completion of the public meeting under subsection (k), the independent review organization shall provide to the Secretary a report and recommendations, together with a statement of the reasons or basis for the recommendations. The independent review organization shall recommend that the petition be approved if a fair evaluation of the data and information before it establishes that the proposed use of the additive under the conditions of use to be specified in the regulation will be safe within the meaning of section 201(u). The Secretary shall promptly provide a copy of the report and recommendations to the petitioner and shall promptly place a copy on public display in a location maintained by the Secretary for the examination of public documents, except that trade secret and confidential commercial data and information shall not be disclosed.

"(2) Upon request of the petitioner, the independent review organization shall defer submission of the report and recommendations provided for under subsection (1) for such period of time as the petitioner requests.

"(3) A report and recommendation from the independent review organization that concludes that an additive has been demonstrated to be safe shall create a presumption of approvability.

ACTION ON THE RECOMMENDATION

"(m)(1) Within ninety days of receipt of a report and recommendations under section (l), the Secretary shall either——

"(A) issue a regulation providing for the use of the additive under the conditions of use found by the independent review organization to be safe; or

"(B) reject the report and recommendations on the ground that there is substantial evidence to demonstrate that the additive has not been shown to be safe under the intended conditions of use. The decision of the Secretary to reject the report and recommendations of the independent review organization shall set forth the evidence on which the Secretary relies and the basis and rationale for the decision. A copy of the Secretary's decision under this subsection shall promptly be provided to the petitioner and independent review organization and placed on public display in a location maintained by the Secretary for the examination of public documents.

"(2) If the Secretary fails to take action under paragraph (1) within the required ninety days, the report and recommendations of the independent review organization shall be deemed to be the decision of the Secretary and the Secretary shall, within sixty days, issue a regulation providing for the use of the additive under the conditions of use found by the independent review organization to be safe.

JUDICIAL REVIEW

"(n) Upon issuance of a regulation under section (m)(1)(A), a rejection under section (m)(1)(B), or the failure of the Secretary to act within ninety days of receipt of a report and recommendation under section (l), any person who will be adversely affected by the decision of the Secretary, and without regard to the provisions of

subsection (f) of this section, may obtain judicial review in accordance with subsection (g) of this section.

INDEPENDENT REVIEW ORGANIZATION

"(o)(1) The Secretary shall enter into an agreement with at least three organizations qualified to evaluate petitions seeking approval for the use of food and color additives to review such petitions and to make reports and recommendations on them. In assessing the qualifications of any such organization, the Secretary shall consider, among other relevant factors——

"(A) the scientific and technical capabilities of the organization and the persons employed by it;

"(B) the experience of the organization in evaluating petitions or similar applications for approval, or data of the type typically contained in petitions;

"(C) the ability of the organization to protect the confidentiality of trade secret and confidential commercial information;

"(D) the ability of the organization to undertake balanced and objective reviews of petitions and to be free of bias; and,

"(E) the ability of the organization to undertake competent and timely reviews of petitions.

"(2) The agreement between the Secretary and an independent review organization shall require the organization to conduct its reviews in accordance with the provisions of section 409 and regulations issued by the Secretary to implement that section. In performing its responsibilities under an agreement with the Secretary, such organization shall not be subject to the provisions of the Federal Advisory Committee Act, 5 U.S.C. App. 2.

"(3) The Secretary shall publish annually the fee schedule in effect for each independent review organization for the review of petitions in the twelve-month period succeeding the notice. The Secretary shall also prescribe appropriate terms for payment by the petitioner to the independent review organization, including terms to ensure that the independent review organization completes the tasks required under this section within the time periods set forth and that payments by the petitioner are contingent on timely completion of those tasks."

(e) Amend section 721 by adding a new subsection (9) to read as follows:

"(g) Notwithstanding any provision to the contrary in this section or any other provision of this Act, any person may file with the Secretary a petition seeking the issuance of a regulation authorizing the use of a color in or on a food, drug, device or cosmetic which petition requests designation for third party consideration under section 409 (b)(2)(F). Upon the acceptance for filing of any such petition, the provisions for third party consideration in section 409 (j)- (o) shall apply."

FOOD CONTACT SUBSTANCES

(a) Amend section 409(a) by deleting "or" at the end of paragraph (1) and the period at the end of paragraph (2); insert a semicolon at the end of paragraph (2), followed by "or," and insert the following new paragraph (3):

"(3) in the case of a food contact substance as defined in subsection (p)(4), there is in effect, and it and its use or intended use are in conformity with, a notification submitted under subsection (p) of this section."

(b) Amend the concluding paragraph of section 409(a) to read as follows:

"While such a regulation relating to a food additive, or, in the case of a food contact substance, a notification, is in effect, a food shall not, by reason of bearing or containing such an additive or food contact substance in accordance with the regulation or notification, be considered adulterated within the meaning of clause (1) of section 402(a)."

(c) Amend section 409 by adding at the end thereof the following new subsection (p):

"(p)(1) At least 90 days before being introduced or delivered for introduction into interstate commerce, the manufacturer of a food contact substance shall notify the Secretary of the identity and intended use of the substance and provide the Secretary with information to establish either that the substance is not reasonably expected to become a component of food, if the manufacturer has elected to file a notification in such circumstance, or that the risk of the use of the substance under the intended conditions of use is negligible or insignificant.

"(2) A notification submitted under this paragraph shall become effective after ninety days unless the Secretary concludes that there is substantial evidence to demonstrate either that the food contact substance is reasonably expected to become a component of food, if that was the basis of the notification, or that the risks of the food contact substance under the intended conditions of use are not negligible

or insignificant, in which case the Secretary shall promptly notify in writing the person who submitted the notification of such conclusion and the basis for it. The decision of the Secretary to deny effectiveness to a notification shall constitute final agency action subject to judicial review.

"(3) The Secretary shall keep confidential any information provided in a notification under paragraph (1) for 90 days following receipt. After the expiration of 90 days, the Secretary shall place the information on public display, except for matters in the notification which are trade secrets or confidential commercial information.

"(4) For purposes of this section and section 402, the term "food contact substance" means any substance intended for use as a component of materials used in commercially manufacturing, packing, packaging, transporting or holding food or other substances used in commercial food contact surfaces if such substance may reasonably be expected to result, directly or indirectly, in its becoming a component of food, and is not intended to have any physical or other technical effect in such food."

Mr. SHAYS. Dr. Ziller, thank you.

Dr. Applebaum.

Ms. APPLEBAUM. Thank you. Good afternoon.

Mr. SHAYS. Good afternoon.

Ms. APPLEBAUM. My name is Rhona Applebaum, and I serve as executive vice president for scientific and regulatory affairs for the National Food Processors Association. NFPA is the voice of the $400-billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters, and consumer affairs. NFPA appreciates the opportunity to present testimony this afternoon.

The lack of efficiency in the food additive approval process runs counter to one of the principal goals of the Nutrition Labeling and Education Act, which was to improve the dietary habits and thus the public health of Americans. There is no incentive to develop new products, since new products are kept hostage by the current FDA food additive approval process.

In view of these concerns, NFPA sought to enlist one or more of its members who could elaborate on their companies' experiences with the failure of the food additive approval process. We were extremely disappointed to find that companies declined our request, save for one, because they were concerned that their public criticism of FDA would adversely affect their chances for approval of a food additive petition or otherwise prejudice them in their dealings with FDA.

Mr. SHAYS. Let me just be clear on this. You sought to help this committee by providing someone to testify. You found no one willing to testify based on concern that it would adversely affect them whenever they had to go before the FDA.

Ms. APPLEBAUM. One of our companies will be testifying.

Mr. SHAYS. So you were able to find one, but you received a lot of rejections.

Ms. APPLEBAUM. Yes. The near unanimity among food companies that we talked with demonstrates an industry perception of FDA that is difficult to reconcile with a responsible and responsive government.

NFPA is in full agreement with the universally stated view that the FDA food additive approval process is now in a total state of disrepair and is in need of major overhaul, so that new food additives will be developed by industry and evaluated by FDA on a timely basis.

The cause of the breakdown in the food additive approval process is undoubtedly complex. Many will point to inadequate agency resources and inadequate staffing as a contributing factor. NFPA shares this view. We would like to focus, however, on two other factors that have contributed significantly to the agency's apparent inability to manage the approval process effectively.

First, the statute and the system are set up in such a way that FDA has virtually no incentives to make affirmative determinations on particular food additive petitions. These circumstances have developed a positive incentive to do nothing.

The repercussions of such regulatory inactivity are far-reaching. Agency inaction impacts jobs, as companies question the wisdom of multimillion-dollar expenditures for research and development, if the gains from such ventures will not see the light of day for 6 to 10 years on average, if at all.

And what of the line extensions for products which would have used these new ingredients? I know of one company in particular who expended significant resources for a new product line because they thought the additive, a fat substitute, which was in the approval process pipeline, would be approved.

After years of delay, the additive finally was approved, but the company was unable to wait that long and had to absorb major losses both in actual cost and anticipated revenue. Further, jobs were lost, and the consumer, who would have benefited from this product in the context of their total diet, suffered the biggest loss of all.

Another worrisome example is FDA's inaction to date on a request by the Secretary of Agriculture, sent in early 1994, for expedited agency review of a petition for approval of irradiation of red meat. Irradiation of red meat can effectively combat organisms that cause food-borne disease illness, such as Salmonella and E. Coli. It has been over 1½ years, and FDA has not approved irradiation of meat, even though it has already approved irradiation for a number of other foods.

A second important contributing factor to the breakdown of the food additive approval process is the absence of time lines that compel agency action within prescribed periods. We cannot imagine that the breakdown of the food additive approval process has been a deliberate long-term strategy of the FDA, but the agency's allocation of resources and the demands of more immediate and obvious issues have apparently relegated the food additive approval process to a lower priority.

NFPA and a broad segment of food industry trade associations are committed to the view that without amendments to the act that establish an effective forcing mechanism, there can be no real prospect for substantial improvement in the food additive approval process.

For these reasons, NFPA endorses the draft statutory language that has been proposed by a large number of food trade associations for reform of the food additive approval process. Key features of this proposal include allowing responsible scientific expertise outside the FDA to play an important role in achieving significant improvement in the food additive approval process and prescribing a 90-day time line for action by the agency once the record has

been assembled and favorably acted upon by the scientific body. Other witnesses at next week's hearing will discuss this proposal in greater detail.

I would like to take this opportunity to address briefly several other food law reforms that we hope will be considered by Congress in this session. More detailed information on these three issues is contained in our written testimony.

First, problems created by the Delaney clause are closely related to the need to improve the food additive approval process. There can be no more important FDA reform than a congressional determination that food substances should not be prohibited where the substance has been shown to present, at most, a negligible or insignificant risk to human health.

Second, is the need for an amendment to the health claims provisions of the Nutrition Labeling and Education Act; specifically, to remove that act's total ban on unapproved health claims on foods.

Third, NFPA urges Congress to amend the FD&C Act to ensure uniformity. There should be just one set of regulatory requirements for products that are widely distributed throughout the country.

In closing, NFPA does not want food safety compromised. We want our food supply to remain safe, affordable, and abundant, but we also want to increase the variety of foods in our food supply. FDA's inertia has constrained technological innovation, which in turn has had an adverse effect on new product research and development and, thus, U.S. commerce. The American consumer has also been affected from these delays, since the direct consequence has been a lack of new and varied food products which can contribute to a healthful diet.

Once again, I thank the subcommittee for this opportunity to address these extremely important issues, and I will answer any questions you have later.

[The prepared statement of Ms. Applebaum follows:]

PREPARED STATEMENT OF RHONA S. APPLEBAUM, PH.D., EXECUTIVE VICE PRESIDENT, SCIENTIFIC AND REGULATORY AFFAIRS, NATIONAL FOOD PROCESSORS ASSOCIATION

Good morning. My name is Dr. Rhona Applebaum and I serve as the Executive Vice President for Scientific and Regulatory Affairs for the National Food Processors Association (NFPA). NFPA is the voice of the $400 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters and consumer affairs. We represent over 400 food manufacturers who produce processed and packaged foods, drinks, and juices. NFPA appreciates the invitation of Chairman Shays to present testimony at this hearing on FDA's food additive approval process, and the impact it has had on food technology research, product development, domestic and international commerce, and most importantly public health.

I am obliged to bring to your attention an issue that quite frankly has caused us a great deal of concern. The difficulties with—and indeed the failure of—FDA's food additive approval process are widely acknowledged throughout the food industry, particularly by those companies that have experienced first hand the delays and inefficiencies of that process. These concerns are shared throughout the food industry, since these delays and inefficiencies have had an adverse impact on not only the development of new food ingredients but also on the research and development into new food products which require these new ingredients. Consequently there has a dearth of new products with added health benefits marketed.

This inability to respond to the need of the American public for a more healthful diet that does not sacrifice taste, economy and convenience runs counter to one of the principal goals of the Nutrition Labeling and Education Act of 1990, which was to improve the dietary habits, and thus the public health, of Americans. FDA wished to improve the nutrient profile of the food supply by creating incentives for

the food industry to engineer their products with less fat and more fiber. In fact, it was Commissioner Kessler himself who articulated this hoped-for result. Yet, how can new and more healthful products be introduced into the market place, when the necessary building blocks for these new products are kept hostage by the current morass which is FDA's food additive approval process?

In view of these industry concerns, NFPA sought to enlist one or more of its members to provide a scientifically knowledgeable witness who could elaborate on their company's experience with the failure of the food additive approval process. We were extremely disappointed to find that companies declined our request, save for one, because they were concerned that their public criticism of FDA would adversely affect their chances for approval of a food additive petitions or otherwise prejudice them in their dealings with FDA. This widespread and matter-of-fact reaction by the managements of major American food companies is, in our view, cause for considerable concern.

We do not know whether these companies can cite actual experiences that might justify their apprehensions as to the possibility that FDA decisions would be further delayed or otherwise affected by publicly expressed criticism of the agency. But the near unanimity among the companies that we talked to demonstrates an industry perception of FDA that is difficult to reconcile with a responsible and responsive government.

NFPA's own experience with FDA has in general been candid and straightforward. We make every effort to be constructive in our criticism of the agency and in our objections to particular policies, practices or statutory interpretations. We have no evidence, indeed no suspicion, that FDA ever has responded to NFPA's criticism in an inappropriate or extra-legal fashion. Companies may believe, however, that whereas government retaliation against an industry segment or a trade association is unlikely, the situation may be different when FDA is dealing with specific products and particular companies.

In short, we have no hard evidence that FDA may react to public criticism by delaying action on or otherwise adversely affecting a company petition. But the fact of such apprehension on the part of many companies almost certainly has the effect of limiting public debate, and of keeping the most knowledgeable and experienced companies on the sidelines.

NFPA is in full agreement with the universally stated view that the FDA food additive approval process is now in a total state of disrepair, and is in need of a major overhaul so that new food additives will be developed by industry and approved by FDA on a timely basis. As far as I know, there is no room for legitimate debate on this issue. The question is not whether a new food additive approval process is needed, but what form that process should take.

In the most immediate sense, the food industry's involvement in the food additive approval process is necessarily product- and company-specific. Failure of the FDA to handle any particular food additive petition expeditiously most directly concerns the company involved. When the entire process has collapsed of its own weight, however, it is the entire food industry, and indeed the consuming public, that loses out.

The cause of the breakdown in the food additive approval process is undoubtedly complex and attributable to a number of factors. Many will point to inadequate agency resources and inadequate staffing as contributing factors. NFPA shares that view. We would like to focus on two other factors that have contributed significantly to the Agency's apparent inability—or perhaps unwillingness—to manage the approval process effectively.

First, the statute and the system are set up in such a way that FDA has virtually no incentive to make favorable determinations on particular food additive petitions. The requirement that FDA place its stamp of approval on a food additive before it may be used apparently is perceived as exposing the Agency to criticism, or worse, if an actual or perceived safety question is raised after the substance has been approved. Affirmative action gives rise to no benefits for FDA; negative action, or perpetual delay, insulates the Agency from charges of favoring industry and inadequately protecting the public.

In our view, these circumstances have created an incentive for FDA to do nothing. Many would believe that the worst that can happen from Agency inaction is that a particular company will be unable to reap the benefits of its research and development of a new food substance. This, however, is naive, because in actuality the repercussions of such regulatory inactivity are far reaching.

Agency inaction impacts jobs, as companies question the wisdom of multi-million dollar expenditures for research and development if the gains from such ventures will not see the light of day for 6 to 10 years, on average, if at all. And what of the line extensions for products that would have used these new ingredients? I know

of one company in particular that expended significant resources for a new product line because they thought the additive, which was in the approval process pipeline, would be approved. After years of delay, the additive finally was approved, but the company was unable to wait that long, and had to absorb their major losses, both in actual costs and anticipated revenue. But more importantly, jobs were lost, and the consumer, for which this nutritionally improved product would have benefited, also lost. This loss was the biggest of all, since the potential benefit to public health can not be regained.

Another worrisome example is FDA's inaction to-date on a request by the Secretary of Agriculture, sent early in 1994, for expedited Agency review of a petition for approval of irradiation of red meat. Irradiation, a proven food safety technology which can be of significant value in reducing or eliminating microbiological contamination of foods, must receive a food additive approval for any foods on which it is to be used. The Secretary of Agriculture stated his support for use of irradiation on red meat to combat organisms that cause foodborne illness, substantially reducing human risk from disease caused by organisms such as Salmonella and E. Coli and noting that more than 35 countries have approved irradiation as a safe food technology. And yet, nearly a year and a half later, FDA has not approved irradiation of red meat, even though it has already approved irradiation for a number of other foods, regardless of the potential public health impact of such a delay.

The point must be made that the negative action or perpetual delay, practiced by the Agency, can not be justified by simply their "erring on the side of safety." Their inability to act in a timely and expeditious manner has an impact on American innovation, commerce and, most importantly, public health. The current process can no longer be accepted, and rationalized with a "so what, one less company getting rich off of a new additive" attitude. The adverse impact of not obtaining timely FDA approvals is not that simple; the consequences are much farther reaching.

In short, the status quo of inaction, postponement, requests for even more data or more tests and Agency reluctance to make a decision is perceived as harming no one but a few companies wishing to reap a competitive advantage by exploiting a food technology breakthrough. This, as we have discussed, is not the case. Consequently, the time has arrived when the status quo is no longer acceptable and must be understood as unduly constraining the development of new food additives that can yield immeasurable benefits to the public.

A second important contributing factor to the breakdown of the food additive approval process is the absence of time lines that compel agency action within prescribed periods. As long as the default position is no action whatever, it is easy to see why any day-to-day decisionmaking within the Agency can be easily postponed and put off, rather than addressed and resolved.

We cannot imagine that the breakdown of the food additive approval process has been a deliberate long-term strategy of the FDA. But the Agency's resource allocation decisions and the demands of more immediate and obvious issues have apparently relegated the food additives process to a lower priority, where the absence of any statutory compulsion to act within prescribed time parameters has made it possible for FDA to focus on other matters that it regarded as more pressing or of greater concern.

In the light of these circumstances, NFPA believes it is essential that Congress, FDA, the food industry and other interested parties work together to reach agreement on action-forcing measures that will provide the Agency with very real incentives to reach decisions. Discussion and debate concerning how such improvements can best be achieved will of course be useful, as these hearings demonstrate, but it is hoped that the issues can be addressed on a cooperative, rather than on an adversarial basis.

NFPA and a broad segment of food industry trade associations are committed to the view that without amendments to the Act that establish an effective forcing mechanism, there can be no real prospect for substantial improvement in the food additive approval process. We acknowledge that reform of that process conceivably could be achieved without statutory amendment through rigorous and sweeping changes in FDA's policies and practices. We are satisfied, however, that it is too much to expect that FDA has the will and the resources necessary to bring about the degree of reform that is required.

NFPA and other interested associations have considered various non-statutory options for food additive reform. One suggested approach was to seek a Congressional directive that FDA must solicit public comments and develop its own proposals for reform, with final changes in its regulations to become effective within a year. But ultimately we concluded that even with that degree of prodding by Congress, it seemed quite unlikely that true reform could be achieved. In the absence of any perceived incentive for FDA to work toward timely approval of particular additives,

new time lines and deadlines prescribed by FDA itself in revised procedural regulations—without express statutory requirements—would almost certainly yield to other demands on the Agency's resources. We have no reason to expect that new resolve by FDA to mend its ways, in response to current public concerns about its performance, will be sustained over the longer term that is necessary for achievement of real action.

Another suggested approach is the establishment of a third-party scientific body, funded by industry contributions and substantial fees, that would review and consider petitions, and then pass along its conclusions for evaluation by FDA. Our concern is that such an approach, without amendment of the Act to establish action-forcing decisions and to give some presumptive weight to the outside body's conclusions, would do little more than impose an extra-bureaucratic burden and cost on petitioners, without any assurance that FDA would credit those conclusions and take final action within a reasonable time.

For these reasons, NFPA endorses the draft statutory language that has been proposed by a large number of food trade associations for reform of the food additive approval process. We understand that other food industry witnesses will address this proposal in greater detail but its principal features are worth emphasizing at this stage.

A major feature of this proposal is that responsible scientific expertise, outside of the FDA, can be relied upon to play an important role in achieving significant improvement in the food additive approval process. These outside bodies would provide knowledge and substantial scientific input into the evaluation of new food additives, and contribute significantly to the establishment of a record on safety and related issues that can materially reduce the resources that have to be expended by FDA on any particular application.

A second and equally important feature of the proposal is that time lines are prescribed for action by the agency once the record has been assembled and favorably acted upon by the scientific body. FDA would have 90 days to act on the recommendation of the independent review organization by either accepting it and issuing a regulation to allow use of the additive, or by rejecting it and advising the petitioner in detail of the basis for the rejection. A favorable report by the review organization would establish a presumption of approval, which would be rebuttable by FDA if FDA concluded that there existed substantial evidence to demonstrate that the risks of the additive under its intended conditions of use were not negligible or insignificant. If FDA failed to act within the 90 days, it would be deemed to have accepted the report and recommendations, and it would then proceed as if it had affirmatively accepted that additive.

The costs of the review by the independent review organization would be borne entirely by petitioners who requested this form of review.

Attached to this statement is a description of the food industry's proposal for food additive reform. I will leave it to other food industry witnesses to spell out the details and elaborate further on this proposal.

We understand that these hearings are intended to address the need for reform in FDA's food additive approval process. I would like to take this opportunity, however, to address briefly several other food law reforms that we hope will be considered by Congress in this session.

Closely related to the need to improve the food additive approval process is the necessity of assuring that process will be based upon sound scientific judgment. It is by now widely accepted that the Delaney clauses in the food additive, color additives and animal drug provisions of the Federal Food, Drug, and Cosmetic Act prevent the agency from relying upon sound science, and instead impose a non-scientific, zero-risk policy for evaluation of new additives. It is not clear at this stage what legislative vehicle may be best suited for achieving Delaney clause reform. In our view, however, there can be no more important FDA reform than a Congressional determination that food substances may not be prohibited on the basis of safety where the substance has been shown to present at most a negligible or insignificant risk to human health.

Another reform that will be sought by NFPA and others in this session is amendment of the health claims provisions of the Nutrition Labeling and Education Act (NLEA) to remove that Act's total ban on unapproved health claims on food labels. We are gratified that the FDA has responded favorably to an NFPA petition for modification of the agency's health claims regulations so that companies will be encouraged to make accurate, fully substantiated claims concerning the relationship between a sound diet and good health. In responding to our petition, however, FDA stated that it could not—under the statute as it is presently written—establish any procedures for authorization of health claims that have not been explicitly approved by the agency.

The NFPA petition set forth the basis for our conviction that the statutory requirement of prior approval of health claims by FDA not only prevents the dissemination of valuable diet and health information to consumers, but also is squarely at odds with the Supreme Court's decisions on the commercial free speech rights of manufacturers and distributors. Our legislative proposal for elimination of the total prohibition of unapproved health claims is consistent, we believe, with the broader theme of FDA reform that permits reliance on third-party, objective science as an alternative to bureaucratic prior approval.

Our proposal would leave in place the present system for pre-approval of health claims, but it would provide an alternative route under which a company could choose to make a health claim on its label without going through the elaborate and burdensome FDA prior approval process. Under this approach, a health claim will be presumed to be authorized if it is based on and consistent with the findings of an authoritative scientific body of the United States responsible for public health protection, or the findings of an objective panel of experts qualified by scientific training and experience to evaluate scientific evidence concerning the relationship between a food substance and a disease. In order to qualify a claim in this manner, the company must submit to FDA the data and information upon which it relies before putting a food labeled with the claim on the market. FDA will thus be on notice of the company's plans and can take whatever action it deems appropriate.

Finally, NFPA urges that Congress amend the Act to assure that there will be one set of regulatory standards applicable to the manufacture and sale of food products throughout the United States. We will urge that Congress build upon the uniformity provisions embodied in the NLEA by extending federal preemption to the adulteration and other labeling provisions of the Act. We believe that states can play a vitally important role in monitoring the manufacture and distribution of foods, but there should be just one set of regulatory requirements for products that are widely distributed throughout the country.

Once again, let me thank the Subcommittee for this opportunity to appear before it today to address these extremely important issues.

NATIONAL FOOD PROCESSORS ASSOCIATION—THIRD PARTY CONSIDERATION FOR DIRECT HUMAN FOOD AND COLOR ADDITIVES

A new process would be created for the consideration of direct human food and color additive petitions for which the petitioner has chosen "third party consideration." Third party consideration would be granted as a matter of right by the Secretary. Direct human food and color additives for which third party consideration is granted would undergo a six-month review period after the notice of filing by both FDA and an independent review organization under contract to FDA. After the petition is filed, the safety and functionality data in the petition would be provided to the review organization and be placed on file in the Dockets Management Branch. All communications between FDA, the review organization and the petitioner would also be placed on public display. The amendment would require that FDA and the review organization advise the petitioner in writing of all issues pertinent to the evaluation of the petition within the six-month review period.

Within sixty days of the conclusion of the review period, the review organization and the FDA would convene a public meeting to discuss the petition with the petitioner and interested members of the public. Under the amendment, comments from the public could be considered in the review process only if received during the period beginning with the notice of filing and concluding with the public meeting. The review organization would have sixty days after the public meeting to provide FDA with a report and recommendations on the petition. The review organization would be required to recommend approval if a fair evaluation of the data before it demonstrates that the additive is safe within the meaning of section 201(u). A recommendation for approval by the review organization would create a "presumption of approvability."

FDA would be required to provide the petitioner with a copy of the report and recommendations and to place a copy on public display. FDA would have ninety days after receipt of the report and recommendations to issue either a regulation authorizing the use of the additive under the conditions of use found to be safe by the review organization or to decline to issue the regulation. In order to rebut the presumption of approvability (and to decline to issue the regulation), FDA would have to conclude that there is substantial evidence to demonstrate that the risks of the additive under the intended conditions of use are not insignificant. The FDA would be required to set forth in writing the evidence on which it relies and the basis and rationale for the decision. The decision would be provided to the petitioner and review organization and placed on public display.

Judicial review would be available after FDA acts, whether by issuance of a regulation or by a decision to reject the report and recommendations of the review organization. There would be no opportunity for objections and requests for administrative hearings.

FDA would be required to enter into an agreement with an independent review organization to conduct the third party reviews provided for under the amendment. The amendment would specify criteria for the selection of the review organization. Petitioners would be required to provide funds to the review organization for the review of petitions (within thirty days of filing). The Secretary would publish annually a fee schedule.

The amendment would also provide that the procedures for third party consideration of food additive petitions also apply to color additive petitions.

Mr. SHAYS. Thank you for your statement. They are extremely important, and I appreciate all of our witnesses today.

Mr. Gelardi.

Mr. GELARDI. Thank you, Mr. Chairman.

I am Robert Gelardi, executive vice president of the Calorie Control Council. The council is an international association which has for almost 30 years represented the low-calorie, reduced-fat, and light food and beverage industry. We currently have over 60 members, including manufacturers of products reduced in calories or fat, as well as companies which make ingredients for these products; that is, manufacturers of low- and reduced-calorie sweeteners, fat replacers, and low-calorie bulking agents.

Many of the food additive and GRAS petitions before the FDA are of primary importance, not only to our member companies, but to the American public. The products these petitions make possible could specifically assist Americans in meeting dietary goals and guidelines of health and medical groups, and of the government, inside and outside the United States.

For example, the U.S. Surgeon General's Report on Nutrition and Health stated, "The public would benefit from increased availability of foods and food products low in calories, total fat, saturated fat, and sugars." Many of the important petitions that have been pending for more than 5 years include these products. FDA appears to have little incentive for approving or, in the case of GRAS petitions, for affirming petitions.

The perception, unfortunately, of many of those outside FDA with an interest in the food additive and GRAS affirmation processes is that the FDA processes are open-ended, prone to inaction and lengthy delays, as you have heard today, and without sufficient administrative accountability.

In December 1993, the Calorie Control Council submitted comments to FDA, providing specific suggestions on how to improve the food additive and GRAS processes. These comments, with only slight modification, were submitted to FDA in February of this year as a citizen petition, because even though we had heard that progress was going to be made, we had not received any specific indication of action.

In the petition, the Calorie Control Council specifically proposes that administrative accountability be increased in the food additive process, urges that comments or submissions on a pending food additive petition filed by a third party, after the 60-day comment period, be deferred to the post-decision period unless they present previously unavailable, valid scientific results that demonstrably relate to serious health concerns.

We urge and in the petition identify that greater clarity is needed in review criteria for evaluating the safety of substances added to food.

The petition urges a more interactive process between the FDA and the petitioner, without formally stopping and starting the review clock, which causes many of the delays and the time line that you saw earlier; urges FDA to establish an abbreviated process for approving additional uses of an already approved food additive, which sometimes goes for 5 or more years; requests that FDA clarify their schedule for submission of and the agency's response to comments submitted after publication of the filing of a notice of a food additive petition; and, importantly, urges that steps be taken to conserve and enhance FDA's scientific expertise and human resources.

We will take advantage of the chairman's notation to provide and have provided a copy of the petition for the record.

Furthermore, we believe that incentives and encouragement should be provided to those at FDA who make positive and sometimes difficult decisions. As was stated by the GMA representative recently, we feel that it is extremely important to give encouragement to those within the agency and to set up procedures that will enable positive decisions to be made.

Additionally, the FDA's Office of General Counsel reviews should be restructured to facilitate timely action. Many times, the Office of General Counsel has delayed actions and repeatedly reviewed food additive petitions.

Although many stumbling blocks exist to progress within the agency, there are external ones as well. Some of those have been commented on. For example, the Delaney clause frequently hinders progress, and many scientific advances have occurred since the clause was enacted in 1958. It does not currently represent either good science or good regulation.

FDA's Center for Food Safety and Applied Nutrition has many diligent staffers, as was exemplified by recent accomplishments on food labeling. They should be encouraged—and we believe you will and have—by Congress to support the U.S. food industry, which provides the safest, most abundant food supply in the world.

As was noted earlier, industry needs that support to compete effectively in the global marketplace and to also meet the ever-increasing demand by Americans for more good-tasting products. The Council has, on numerous occasions, offered to assist FDA. We hope this committee's work will aid the agency in fulfilling its important mission.

[The prepared statement of Mr. Gelardi follows:]

PREPARED STATEMENT OF ROBERT C. GELARDI, EXECUTIVE VICE PRESIDENT, CALORIE CONTROL COUNCIL

I am Robert Gelardi, Executive Vice President of the Calorie Control Council. The Calorie Control Council is an international association which has for almost 30 years represented the low-calorie, reduced fat, and light food and beverage industry. We currently have over 60 members, including manufacturers of products reduced in calories or fat as well as companies which make ingredients for these products (i.e., manufacturers of low and reduced calorie sweeteners, fat replacers and low-calorie bulking agents). Many of the food additive and Generally Recognized As Safe (GRAS) petitions before the U.S. Food and Drug Administration are of primary importance to both our member companies and the American public. The products

these petitions make possible could specifically assist Americans in meeting dietary guidelines and recommendations of health/medical groups. For example, the U.S. Surgeon General's Report on Nutrition and Health stated that "The public would benefit from increased availability of foods and food products low in calories, total fat, saturated fat, . . .and sugars." Many of the important petitions have been pending for more than five years. FDA appears to have little incentive for approving or, in the case of GRAS petitions, affirming petitions.

The perception of many of those outside FDA, with an interest in the food additive and GRAS affirmation processes, is that the FDA processes are open ended, prone to inaction and lengthy delays, and without sufficient administrative accountability. In December, 1993, the Calorie Control Council submitted comments to FDA providing specific suggestions on how the food additive and GRAS affirmation processes might be improved. These comments with only slight modifications were submitted to FDA in February of this year as a citizen petition.

In the petition, the Calorie Control Council specifically: (1) proposes administrative accountability in the food additive review process; (2) urges that comments or submissions on a pending food additive petition filed by a third party after the 60-day comment period, be deferred to the post decision period unless they present previously unavailable valid scientific results that demonstrably relate to serious health concerns; (3) urges greater clarity in review criteria for evaluating the safety of substances added to food; (4) urges a more interactive review process between the FDA reviewers and petitioner—without formally stopping and starting the review clock; (5) urges FDA to establish an abbreviated process for approving additional uses of an already approved food additive; (6) requests that FDA clarify the schedule for submission of, and the agency's response to, comments submitted after publication of a notice of filing of a food additive petition; and, (7) importantly, urges that steps be taken to conserve and enhance FDA's scientific expertise and human resources. (A copy of the petition is provided for the record.)

Furthermore, incentives and encouragement should be provided to those at FDA who make positive and sometimes difficult decisions. Additionally, FDA's Office of General Counsel reviews should be restructured to facilitate timely action.

Although many stumbling blocks to progress exist within current agency procedures, there are external ones as well. For example, the antiquated Delaney Clause frequently hinders progress. Many scientific advancements have occurred since the Clause was enacted, and it does not currently represent either good science or good regulation.

FDA's Center for Food Safety and Applied Nutrition has many diligent staffers as exemplified by their recent accomplishments on food labeling. They should be encouraged by Congress to support the U.S. food industry, which provides the safest, most abundant food supply in the world. Industry needs that support to compete effectively in the global marketplace and to meet the ever-increasing demand by Americans for more good-tasting products reduced in calories and fat. The Calorie Control Council has on numerous occasions offered to assist the Food and Drug Administration in any way it can, and we hope this Committee's work will aid the agency in fulfilling its important mission to serve the American people.

CITIZEN PETITION

The Calorie Control Council (the "Council") submits this petition under section 409 of the Federal Food, Drug and Cosmetic Act (FD&C Act) to request that the Commissioner of the Food and Drug Administration amend certain sections of the Code of Federal Regulations, Title 21, and establish specific regulatory guidelines (1) to improve the food additive approval process and (2) to expedite and give greater certainty to the Generally Recognized as Safe (GRAS) affirmation process.

The Council is an international association of manufacturers of low-calorie and reduced fat foods and beverages, including the manufacturers and users of a variety of alternative sweeteners, fat replacers and low-calorie bulking agents. A significant number of the direct food additive petitions and GRAS petitions pending before FDA are for products of particular interest to members of the Council. Many of these products could specifically assist Americans in meeting dietary guidelines and recommendations of health/medical groups. For example, the Surgeon General's Report on Nutrition and Health stated that "The public would benefit from increased availability of foods and food products low in calories, total fat, saturated fat, . . . and sugars."

This petition is divided into three parts, addressing (1) the food additive approval process; (2) the GRAS affirmation process and (3) FDA's 1993 Staff Manual Guide.

I. FOOD ADDITIVE APPROVALS

A. ACTION REQUESTED

This petition requests that regulations be amended to expedite and give greater certainty to the food additive approval process:

1. § 171.1(c). Amend the Food Additive Petition form:

(a) by replacing the first sentence inside the parenthesis in Paragraph E with the following:

"(A petition may be regarded as incomplete unless it includes full reports of adequate tests whose procedures take into account the guidelines contained within the Organization for Economic Cooperation and Development's (OECD) "Guidelines For Testing of Chemicals" or the Agency's "Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food," commonly referred to as the "Redbook," in effect at the time of the initiation of the tests; petitions submitted prior to the issuance of any edition of the "Guidelines" or "Redbook" must contain tests reasonably applicable to show whether or not the food additive is safe for its intended use . . .)"

(b) by replacing the third sentence under Paragraph G with the following:

"A supplemental petition must be submitted for any change beyond the variations provided for in the regulation issued on the basis of the original petition unless data in the possession of the petitioner or other marketer of the food additive, and made available to the Agency upon request, show that daily usage of the additive from all known uses will not exceed safe daily intake levels publicly adopted by the Commissioner or recognized international authorities (e.g., the Joint FAO/WHO Expert Committee on Food Additives)."

2. § 171.1(i)(2). Insert before the final sentence:

"Upon publication of the notice, the Commissioner will place on public display at the Dockets Management Branch (or some other publicly accessible location specified in the notice) a copy of the petition to the extent available for public disclosure in accordance with § 171.1(h)(1)."

3. § 171.1(i)(3). Add a new paragraph (3) as follows:

"(3) The notice of filing in the Federal Register will allow a period of 60 days during which any interested person may review the petition and/or file comments with the Dockets Management Branch. Copies of all comments received shall be made available for examination in the Dockets Management Branch's office."

4. § 171.100. Amend this section:

(a) by adding the following at the end of subsection (a):

"The regulation will be published in the Federal Register not more than 30 days after the completion of the review process, as provided in subsection (b) of this section."

(b) by adding the following at the end of subsection (b):

"The Commissioner, with the agreement of the petitioner, may extend the review period for up to two additional 180-day periods (for a total of 540 days); if the petitioner does not concur, the petition will be deemed withdrawn without prejudice rather than denied. Each written request for extension to the petitioner will include a status report describing the point of review of each section of the petition and an explanation for the delay; it is contemplated that the sections of the petition will be reviewed in parallel unless the petitioner is given notice of the need for another form of review. If for some exceptional reason the review cannot be completed within 540 days, the Commissioner will provide the petitioner with a detailed explanation and place the petition on a priority review."

"Except as provided in § 171.100(c), the Commissioner will not delay issuance of an order acting on a food additive petition for the purpose of considering or responding to comments received more than 60 days after the filing of the petition. Any comments received after this time will be deferred for consideration and treated as objections under § 171.110."

(c) by adding the following new subsection (c):

"(c) The Commissioner may at any time entertain and consider new data which reasonably support the conclusion that serious adverse health consequences are associated with the proposed use of a food additive. Any person desiring to submit such new data more than 60 days after the filing of a food additive petition shall:

(1) demonstrate that the data were not available at an earlier date;

(2) demonstrate that the data relate to the identical substance that is the subject of the proposed food additive petition;

(3) identify, where applicable, the laboratory which conducted the studies and certify that the data are the product of studies performed in compliance with the good laboratory practices regulations set forth in Part 58 of this chapter; and

(4) certify that the data are not being submitted in bad faith or interposed for any improper purpose such as unjustifiably delaying the approval of a food additive petition."

B. STATEMENT OF GROUNDS

The perception of many of those outside FDA with an interest in the food additive process is that the process is open ended, prone to inaction and lengthy delays, and without sufficient administrative accountability. Thus, the current system discourages the submission of food additive petitions to FDA.

That has two potentially deleterious effects. First, innovative and potentially important new food ingredients never make it into the U.S. food supply because manufacturers cannot rationally plan for their approval and use. Many of these substances may assist in achieving healthier diets by substituting for fat or otherwise eliminating calories, so that delays in their approval, or decisions not to pursue the material, have costs to the public health as well as the petitioner.

The second problem relates to the process itself. When companies utilize the food additive process, they recognize that it will take many years and millions of dollars to develop the necessary data and proceed with the petition. Discussions are commonly held with FDA to assure that information provided in the petition meets FDA's requirements and needs. However, once the petition is submitted to FDA, there is little way to know how long the review will take, whether it is under active review, who is responsible for the review of various sections, who is coordinating the review, and whether there are administrative milestones to be met within the statutory time frame—no progress reports are offered during the review process.

Experiences reported to the Council, and our own experience with the cyclamate petition, are that petitions are routinely handled by several consumer safety officers (CSO) and may be in the hands of a number of review teams before approval, without centralized tracking or expectation of completion. Part of the problem is that CSO's and reviewers leave the agency before completion of the review or even major phases. This leads to re-review, which is costly in time, money and resources for both FDA and industry.

Another problem is the current method of handling outside comments. At the present time, whenever new nonpetitioner submissions are made, FDA feels impelled to place a hold on the approval process until the data are reviewed, and that review is incorporated into the overall petition process. If, as is sometimes the case, there are persons interested in slowing a petition review for asserted public interest or competitive reasons, the careful timing of their submissions can hold up a review numerous times just short of approval, while either new or even repetitive submissions are combed and responded to.

Finally, and most importantly, there does not appear to be a sufficient commitment on the part of FDA to decision making, particularly for innovative substances, or ones that appear controversial, whether for historical reasons, as in the case of cyclamate, or due to outside criticisms. We recognize FDA's difficulty in making decisions that may be criticized but this should not prevent FDA's making appropriate decisions.

A related perception is that FDA applies a double standard to petitioner and nonpetitioner submissions, where the petitioner properly is held to high standards of data integrity and scientific review, while nonpetitioner submissions are accorded a full review without hard data, or peer review, and when indeed they often are no more than opinion.

We also are concerned that reviewing scientists appear to operate in isolation, without any opportunity for interaction with the petitioner to clarify data or other elements of the submission. Often issues presented as requiring a restarting of the review clock could have quickly been resolved (with proper documentation) without awaiting the collection of major points to resolve. We are concerned, additionally, about the opposite problem; that of repeated restarting of the review clock on the pretext of missing trivial data where the result is simply to avoid decision making.

The proposals we make are designed to address all of these issues. FIRST, we propose administrative accountability in the food additive review process. Guidelines should detail how the process is conducted, the units responsible for scientific and administrative review, and the internal milestones of the review process; regulations should fix maximum review periods, and public accountability for the status of the review and any extraordinary delays; and they should be adhered to. More detailed guidelines and regulations should not only increase petitioners and other interested parties' understanding of the approval process but should also facilitate FDA's accomplishing the job at hand.

SECOND, we urge that nonpetitioner submissions on a petitioned food additive outside the 60-day comment period be deferred to the post-decision period unless they present previously unavailable data of petition quality that demonstrably relate to serious health concerns. This should expedite the approval process by allowing FDA to proceed with the review without justifying decisions before they are even finalized. Removing interruptions, interference and controversy from the process should increase the continuity and fairness of the review.

THIRD, we urge greater clarity in review criteria for evaluating the safety of substances added to food. Guidelines can be helpful here as well, as the "Redbook" has been since its first publication. While the "Redbook" (for which a draft revision is now being circulated for informal comment) represents a structured approach to toxicological review, it should not be literally applied on a retroactive basis to studies conducted before its creation, just as "good laboratory practices" in their current form cannot have a literal application to earlier studies.

FOURTH, we urge a more interactive review process. Reviewers should be able to seek clarification of minor points and petitioners should be able to respond without formal stopping and restarting of the review clock. Moreover, there should also be comprehensive assessments at regular intervals that will provide both a management tool for FDA and an assurance of progress for the petitioner. We commend FDA for FDA's Management Assignment Tracking System (MATS) referred to in FDA's "Management programs policies and procedures—policies, authority, and procedures for food and color additive petitions and GRAS affirmation petitions," known as the Staff Manual Guide (SMG), and encourage it to be used for both internal FDA management and periodic updates to the petitioner.

FIFTH, we urge FDA to establish an abbreviated process for approving additional uses of an approved food additive. Once the Commissioner has set an acceptable daily intake (ADI) based on a complete data package, industry should be able to rely on that figure in developing new uses for additives without going through the entire review process. Adoption of an abbreviated process could assist with FDA's announcement that it "wants to increase the effectiveness and efficiency of the review process," and to "clear work from the pending inventory of active petitions as quickly as the petitioners desire . . . consistent with upholding the standard of safety."[1]

SIXTH, we support the June 1992 citizen petition submitted by Covington & Burling on behalf of McNeil Specialty Products Company requesting that FDA clarify the schedule for submission of, and for the agency's response to, comments submitted after the publication of a notice of filing of a food additive petition. The Council's petition reiterates a number of McNeil's requests and we urge the Commissioner to expedite the review of both the McNeil and Council petitions and to take appropriate action to implement requests therein.

FINALLY, we urge that steps be taken to conserve and enhance FDA's scientific expertise and human resources. They are the key to timely, rational, competent, and reliable reviews. FDA should assure that adequate training is undertaken, and that positions are classified and graded in a way that is competitive with other scientific positions throughout government, in particular with EPA, USDA, OSHA, and similar agencies having scientific review components that compete for the same talent pool.

II. GRAS AFFIRMATION PROCESS

A. ACTION REQUESTED

This petition requests that the Commissioner revise 21CFR 170.35(b)(4) and 170.35(c)(7) as follows:

1. § 170.35(b)(4). Amend this section by:

(a) inserting in the second sentence, "within 90 days of the filing date" after "publish."

(b) adding the following at the end:

"If the Commissioner determines that additional time is needed to study and investigate the petition he may by written notice to the petitioner extend the 90-day period for no more than three successive 180-day periods (for a total of 630 days). Each written notice of extension shall include a status report and an explanation for the delay. If for some exceptional reason the review cannot be completed in 630 days, the Commissioner will provide the petitioner with a detailed explanation for the delay and place the petition on priority review."

2. § 170.35(c)(7). Add the following new paragraph (7):

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[1] A. Rulis and L. Tarantino, The Food Additive Petition Process: Recent Data, 48 Food and Drug L.J., 137, 141 (1993).

"(7) A petition that establishes that the safety of the substance has been carefully reviewed by an acceptable independent expert scientific body that has made public its findings of the conditions of use under which the substance is safe will presumptively be considered to provide convincing evidence that the substance is GRAS and will be afforded priority review status. The Commissioner advises that the Federation of American Societies for Experimental Biology (FASEB), the Flavor and Extract Manufacturers' Association (FEMA), and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) are acceptable independent scientific bodies; the Commissioner will provide an opinion on the acceptability of other bodies upon request."

B. STATEMENT OF GROUNDS

The perception of many of those outside FDA with an interest in the GRAS affirmation review process is that the process is open ended, not an FDA priority and, therefore, prone to inaction and lengthy delays.

There is a great deal of pressure for companies to utilize the self-GRAS determination route, thereby limiting interaction with FDA and possible confrontational situations where the agency lacks the background information to evaluate the self-GRAS decision. There is a clear legal basis that FDA affirmation of the GRAS status of a substance is not required prior to marketing:

"GRAS affirmation petitions are filed to gain FDA's concurrence in the sponsor's independent determination that the substance is GRAS. . . . Upon receipt of a GRAS petition, FDA conducts a preliminary review to verify that the petition contains the required information. If the petition is complete, FDA accepts it for filing and publishes a notice to that effect in the Federal Register. At this stage, FDA stresses that it has made no determination of the substance's GRAS status and, as a strictly legal matter, the substance's status is the same as that of any substance whose sponsor has made an independent GRAS determination: the sponsor is free to market it subject to the risk that FDA will object and halt its marketing on the ground, that it is an unapproved food additive."[2]

However, these concepts are not well understood by many companies considering the use of a substance pending FDA affirmation. In part because it is an easy substitute for making hard decisions, many food producers are unwilling to purchase ingredients for which the supplier cannot point to a Federal Register citation documenting FDA's acceptance of the ingredient as GRAS. FDA's abandonment of less formal assurances of the acceptability of ingredients (including interim letters during the GRAS affirmation review process to the effect that the agency has no basis to disagree with the petitioner and thus was not in a position to take regulatory action where the substance was used) has only increased the tension between the delays in the affirmation process and the lack of certainty in self-affirmation.

The second problem relates to the process itself. Companies make a major commitment in time, money and resources to develop a GRAS affirmation petition, whether based on a documented history of use, or publicly available scientific studies. In either case, discussions are commonly held with FDA to assure that information provided in the petition meets FDA's requirements and needs. However, once the petition is submitted to FDA, there is little way to know how long the review will take, whether it is under active review, who is responsible for the review of various sections, who is coordinating the review, and whether there are administrative milestones to be met within the statutory time frame—no progress reports are offered related to the extent toward approval decision.

Experiences reported to the Council are that petitions are routinely reassigned to several different consumer safety officers (CSO) and may be in the hands of a number of review teams before approval, without centralized tracking or expectation of completion. Part of the problem is that CSO's and reviewers leave the agency before completion of the full review or even major phases of the review. This leads to rereview, which is costly in time, money and resources for both FDA and industry.

There does not appear to be a commitment on the part of FDA to decision making. For example, several long pending GRAS petitions recently were further delayed when FDA changed its policy to now require that information substantiating GRAS self affirmation claims be published. Petitions should be evaluated on the basis of policy at the time of submission and not be subject to policy changes effective after that date. Furthermore, if petitions were acted upon expeditiously, the chance of policy changes between the filing date and the approval date would be minimized.

[2] M.R. Taylor, Food Safety Regulation, Food and Drug Law, 182, 200, Food and Drug Law Institute publisher, 1991.

In addition, reviewing scientists appear to operate in isolation, without any opportunity for interaction with the petitioner to clarify data or other information in elements of the submission. Often issues currently requiring a restarting of the review clock, could quickly be resolved (with proper documentation) without awaiting the collection of major points to resolve if time restraints are instituted for GRAS petitions as requested. We are aware of the opposite problem as well: that of repeated restarting of the review clock on the pretext of missing trivial data, where the result is simply to delay decision making.

The proposals we make are designed to address all of these issues. FIRST, we propose administrative accountability in the GRAS affirmation review process. Guidelines should detail how the process is conducted, the units responsible for scientific and administrative review, and the internal milestones of the review process. Regulations should establish maximum review periods, and require public accountability for the status of the review and any extraordinary delays.

SECOND, we urge a more interactive review process. Reviewers should be able to seek clarification of minor points, and petitioners should be able to respond as questions arise. Moreover, there should also be comprehensive assessments at regular intervals that will provide both a management tool for FDA and an assurance of progress for the petitioner.

We are pleased to see that FDA has developed "Management programs policies and procedures—policies, authority, and procedures for food and color additive petitions and GRAS affirmation petitions," known as the Staff Manual Guide (SMG), thereby establishing internal guidelines as described above. This document, however, does not reflect any accountability to the petitioner for internal FDA delays. The Management Assignment Tracking System (MATS) referred to in the SMG, however, could be used for both internal FDA management and providing periodic updates to the petitioner.

THIRD, we urge more extensive reliance and acceptance of external reviews and comprehensive evaluations. For example, if JECFA or FASEB has conducted a comprehensive evaluation of a substance and determined an ADI for its intended conditions of use or FEMA's Expert Panel has examined a flavoring substance and published background data and usage levels relevant to safety, it should be possible to treat such reviews, with their public or international critiques, as presumptive evidence of GRAS status. This is consistent with 21 CFR § 170.30, which calls for "general recognition of safety . . . based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances directly . . . added to food." Similarly, when the Commissioner or a group such as JECFA has set an ADI based on a complete data package, industry should be able to rely on that figure in developing new uses for the additive without going through the entire review process.

AGAIN, we urge that steps be taken to conserve and enhance FDA's scientific expertise and human resources. They are the keys to timely, rational, competent, and reliable reviews. FDA should assure that adequate training is undertaken, and that positions are classified and graded in a way that is competitive with other scientific positions throughout government, in particular with EPA, USDA, OSHA, and similar agencies having scientific review components that compete for the same talent pool.

III. FDA'S APRIL 1993 STAFF MANUAL GUIDE

The Council is pleased to learn that a group of senior staffers from the Center for Food Safety and Applied Nutrition has been convened to study methods to improve the food safety evaluation portion of the food additive petition process. Hopefully, the study group can initiate changes to dispel the perception of many outside FDA that the food additive and GRAS affirmation review processes are open ended and prone to inaction and lack sufficient decision making and administrative accountability.

The Council also is pleased to see that the Food and Drug Administration has developed a Staff Manual Guide (SMG). "Management Programs Policies and Procedures—Policies, Authority, and Procedures for Food and Color Additive Petitions and GRAS Affirmation Petitions." The Council believes the SMG should facilitate FDA staff, petitioners and other interested parties in better understanding the review processes. The Council, therefore, provides the following comments on the SMG in the hope of further expediting the food additive and GRAS affirmation processes.

The Council suggests that the SMG:

1. Incorporate a description of the administrative and scientific criteria used in the review, including those for determining whether evidence is "convincing," and

how foreign data (including that of common use in food in support of GRAS affirmation petitions) are handled;

2. Establish the normal timing or process milestones to measure and monitor the completion of the review process;

3. Establish criteria and process for seeking review of some or all of the petition by non-FDA experts;

4. Specify that a meeting with the petitioner should be routinely scheduled within 90 days of filing to evaluate the status of the review and identify any additional information or data needed to complete the review;

5. Be revised in Section III 19(a) to limit submission of information by or on behalf of only the petitioner. (CFR § 171.6 currently describes a substantive amendment in terms of additional information provided by the petitioner. Submissions by other persons should not reset the review clock. Submissions by other persons should be held and reviewed as objecting after the publication of an approval.)

Overall, we urge a more interactive review process. Reviewers should be able to seek clarification of minor points, and petitioners should be able to respond without formal stopping and restarting of the review clock. Moreover, there also should be comprehensive assessments at regular intervals that would serve both as a management tool for FDA and as an assurance of progress for the petitioner. The SMG could be used for both internal FDA management and to provide periodic updates to the petitioner.

The Council recognizes the immense responsibilities of the FDA and its limited resources but is greatly concerned about the inactivity in the petition review area. The Council would be pleased to work with FDA in minimizing its difficulties in this important area.

IV. ENVIRONMENTAL IMPACT

This petition is entitled to a categorical exclusion from the requirement to prepare an environmental assessment under 21 CFR § 25.24(a)(8) because positive action on this petition would result in the revision of procedural regulations or guidelines applicable to the submission of applications for product approval.

V. CERTIFICATION

The undersigned certify that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

LYN O'BRIEN NABORS
Executive Director
ROBERT C. GELARDI
Executive Vice President

Mr. SHAYS. I thank all three who have testified right now.

I would like to just ask a question: Is there any representative from—I'm not going to ask them to come and testify—I just want to know if there is any representative from the FDA here present now.

Good. Thank you. If you would stay afterward, I would love to just touch base with you on what you are hearing now and in the next testimony. After the hearing, not under oath, just to dialog. So I would welcome anyone from the FDA to stay afterward.

I got kind of hung up with Ms. Suydam, in terms of what was a goal and what is a law, and my sense that, by simply having a law that is not realistically being followed, then we have nothing, because it's totally ignored. So it does give them, as all three of you said, almost a license to do what they choose.

You heard their recommendation on how they would deal with their problem, the 90 days, the 180 days, and the 360 days. Do you have any comment on that recommendation on their part? You are all looking at me with a blank face.

Mr. ZILLER. I think if they could deliver that, there would be little debate here. I think that, in fact, knowing the complexity of some of those petitions, that, in fact, it will take longer than those times that they are saying there. The issue is, how do we determine what is an appropriate way to express that in legislation, so that they can always abide by the law?

Mr. SHAYS. OK.

Ms. APPLEBAUM. I will go a little bit further to say that if there is no type of hammer involved, I think what you will likely see and what we will likely have to live with is the fact that they will look at these dates simply as goals, trying to attain these goals. And if they don't meet those goals, so what? So I think there has to be some type of—either they do it or they don't.

Mr. GELARDI. I would applaud what they are trying to do and what they are saying as a goal, but I do believe that legislation or specific implementation of regulations that would assure that there would only be limited exceptions, and that they be identified in advance, would be very helpful.

Mr. SHAYS. What I am struck with is that either side could be responsible for the delay. It seems to me that there have to be trigger mechanisms along the way. I don't have the knowledge or expertise to know where you would hit these different target points.

Obviously, when the application is complete—and let's just say FDA has asked for a response, and the response comes in, and they are satisfied now that they have the answer and now will evaluate the answer—then there should be a trigger mechanism along the way.

I mean, in other words, once the applicant has said, "You have everything that we're going to give you, and we're going to sink or swim on this," then it seems to me there should be truly a deadline. I guess my problem is knowing when you start the clock.

Mr. GELARDI. Mr. Chairman, if I may, one of the most frustrating aspects of going through an additive petition is that you believe you have all of the questions presented, the petitioner believes all of the questions have been presented, and they find out 3 years, 5 years, 8 years, 10 years later that there is an additional question. And even after 10 or 12 years, there still is not closure on what the questions are.

Mr. SHAYS. That's beyond absurdity. I'm just talking when we get down to a year or so. I know where you are coming from. I honestly believe that some of that is going to change. I can tell you that this committee, along with others in Congress, are going to be providing an outside hammer. What would we do to provide a hammer within the structure?

Ms. APPLEBAUM. Within FDA itself?

Mr. SHAYS. Yes.

Ms. APPLEBAUM. One of the recommendations will be that upon receipt of all the scientific information that is required to fulfill the needs for the approval process, that the FDA has 90 days to respond, respond either affirmatively or request, in some way, more information, or deny. But if they don't, then there is going to be, if you will, a tacit approval based on the outside experts that this additive is safe and will have the full use as if it had received from FDA——

Mr. SHAYS. What I'm struck with is, there would have to be some escape clause sometimes, because you could have a particular point where you have a lot of applications at one time and not as many at others. I get the gist of what you are saying.

You were mentioning—I think you, maybe, Dr. Ziller, or Dr. Applebaum—about the outside review and the actual payment. I think it was you, Dr. Ziller, who was saying that the payment would be made to the third party. In the State of Connecticut we have an expedited process where the applicant pays for that expedited process. It's not dealing with drugs; it deals with, actually, corporations, in the secretary of state's office.

But the point I would make is, it would strike me that the payment would have to be made to the FDA, and the FDA would make that payment. In other words, I guess I don't like the idea that the person making the review is getting paid by the petitioner.

Mr. ZILLER. Right. The proposal itself basically would have Food and Drug actually having the contract with a number of third parties. But the intention is that the money would be "for effort" basis to the review group, and the check can surely go through FDA's hands, provided a service charge is not excised during the process.

Mr. SHAYS. You both alluded to this and, in one case, spoke to it directly, the different causes. One, it strikes me, is an attitude that has to be changed, not just a resource. I mean, if this was a resource problem—that's part of it. You were making the point that the lack of resources is expressed as an attitude, as well. But it strikes me that there has to be a whole change in mind-set.

What do you think would be the most dramatic way to change the mind-set?

Ms. APPLEBAUM. One of the suggestions that we would have is to establish, in some form or another, a priority setting within FDA. Right now, there doesn't appear to be a priority setting as it relates to the food additive approval process. It comes in. In 180 days you get a letter. And then 6, 8, 10 years later your food additive might see the light of day; it may not.

Mr. SHAYS. See, I don't understand when you say that, to me, I have to believe in my heart of hearts that any petitioner who had to wait 10 years somehow wanted that to happen. I don't believe that—because I would think a petitioner would be making so much noise, once it got beyond 2 years or 3 years. Maybe you could explain this to me, because it just boggles my mind to think that there would be a passive petitioner after 2 or 3 years.

Ms. APPLEBAUM. I don't think, Mr. Chairman, it's necessarily a passive petitioner, but what you attempt to do is, you try to work within the system that you have, without going to the last resort, which constitutes legislative action. And you——

Mr. SHAYS. I could see after—sorry to interrupt—just so you know what is in my mind. I can see how someone could complain after 2 or 3 years and say, "Well, maybe I've got to be reasonable. They have so much to do." But after 10 years, it strikes me that there's no way you can defend it, any which way.

Ms. APPLEBAUM. You can't defend it. You can't defend it. And there's a lot of frustration on the part of companies. When you submit a petition and you call up and you ask what the status of your petition is, and the reason for the delay has been, there's been a

change in the person who was responsible for your petition, so it had gone to somebody else. So then you give them the necessary time to review all the information, to answer their questions. You call up again, and something else has occurred.

There is a problem within the agency, a mind-set, a management style, call it what you will, in terms of taking something and following it through to the end. By changing the leadership or changing the principal person during the important discussion periods does not add to expediting the approval process.

Mr. SHAYS. I'm going to go vote. But I would love to ask this question for the record, and my counsel is here, as well as the ranking member. If you could just explain, there must have been a number of cases where petitioners sued after 180 days. Are you saying to me that someone, after 7 years or 8 years, simply doesn't have the ability to succeed in a suit?

I'm leaving the answer, but I would like to make sure that—one, have there been suits, and what is the outcome, and why are suits discouraged, et cetera? With all due respect, I would like my counsel to be able to follow up on that question.

You are in charge, Mr. Towns.

Mr. TOWNS. Sure.

Ms. APPLEBAUM. We will have to provide you with information for the record in regard to how many suits there have been and what the suits have involved. But speaking from past experiences, a suit is something you don't necessarily want to take on. I mean, it's very important, but I don't think it's necessarily one of the triggers you want to constantly enact, in terms of bringing a lawsuit against the Food and Drug Administration.

[The information referred to follows:]

We are unaware of any.

Mr. ZILLER. If I could add to that, as time goes on and you're talking those kinds of years, you can also get a tremendous increase in the toxicology understandings. I think, in most cases, a judgment on safety is a difficult one, because there's always an evolving science going on in the toxicological areas. New tests with lower sensitivities are developed.

So if you push the system in the lawsuits against Food and Drug, they could well come back and say, "Well, while that may have been OK when you submitted it, things have changed. Now there are some new tests you need to do," and throw you back into another recycle. It's a very expensive and time-consuming test, then even after that they may have more questions, more tests, and so forth.

So, in general, a lawsuit approach has not been used very frequently. I don't know anybody, in my own experience. I'm sure there have been several, because they were referred to earlier in the morning. I think what we need to do is look at what's right and try to fix the system for the future.

Mr. HALLORAN. Well, you would only need to win one to set some kind of a benchmark. That was the point of the question, both to the FDA and here, is that the industry itself—if the system is as broken as it appears, there are obvious and extreme cases when the delay is so unconscionable that a court would have to say, "It's

just stuck on somebody's desk. The agency had an obligation to act."

If you lose these lawsuits, you're at the status quo. The agency is—you are at its mercy. If you win one, you have a benchmark. Again, it's like getting industry people to testify. You're not willing to help yourselves here. The motivation for the Congress to do it is a little bit diminished, I think.

Mr. TOWNS. Thank you very much.

Let me begin by first asking—you know, I was hoping that this would be the beginning of a dialog between this committee of Congress and the industry, and of course FDA, to sort of bring about a kind of working dialog, to see what we might do to bring about positive reform.

Dr. Applebaum, after listening to you, I'm not sure that that could happen, based on the fact that there is this feeling of intimidation that might prevent some folks from coming and sort of openly discussing these matters with us, to bring about the kind of change that is needed desperately, based on your comment, in terms of retribution, I'm referring to.

Ms. APPLEBAUM. Again, we have no specific examples for why the companies are apprehensive to come forward. However, we do not believe that in any way their not coming forward should prevent the FDA food additive approval process from being reformed to benefit everyone. Just because there is this, again, an apprehension to testify does not mean that they themselves do not believe the system is broken. They do.

There is this reluctance. We don't understand the reluctance. We're disappointed in the reluctance. But at the same time, that should in no way prevent or preclude the subcommittee from considering further legislative action to institute FDA reform in the food additive approval process.

Mr. TOWNS. Let me ask this, then: Do you think that forcing rigid compliance with the 180-day period will compromise food safety in any way?

Dr. Ziller, Dr. Applebaum, Mr. Gelardi.

Ms. APPLEBAUM. No, I do not. And if there are questions concerning the information that is contained in the petition, then within that time period there is adequate time for them to meet with the petitioners to get all questions of safety resolved.

Mr. TOWNS. Dr. Ziller.

Mr. ZILLER. I think the exact number of days and how you define it and what the peg point is, when it starts, and so forth, are still up for further discussion.

But surely it is in the industry proposals—the consensus proposal has it—they put most of the burden of the lengthy review of the actual data onto the third party. Food and Drug can participate in that process. Then by the time that they come and provide that report to Food and Drug, I think 180 days, or some other similarly defined point, is fine.

Now, you know, there's a real question, in the end, whether, in practice, you've accomplished your objective, because you can put whatever hammer you want into the FDA side of the decision, but in the end, if FDA has to publish a regulation because they didn't exactly agree with the third-party conclusion, they didn't have

enough to formally reject it, so they say, "We're publishing this regulation because Congress said we had to." There's a question of whether the food manufacturer is actually going to put that ingredient in their product.

So you have all those things to consider. It's not simple. You can't design a system that is such a perfect hammer that it helps without offering some problems. But in the end, we think that a hammer is necessary. If Food and Drug can deliver in the way they were promising this morning, I don't think they should have any trouble with a time limit like that, if most of the time-consuming review of the toxicology has been done by the third party.

Mr. TOWNS. Thank you, Dr. Ziller.

Mr. Gelardi.

Mr. GELARDI. There needs to be a congruence of reality and the law, as well as the interpretation of the law. The law may provide for certain extensions of time beyond the initial period. I think it is important, as Congress looks at what the law does and where we are, that the timeframe for realistic review and the opportunity for exceptions, on a very limited basis, be provided.

Mr. TOWNS. Let me put it this way: What do you recommend that we do, as Members? Just switch seats for a moment. You're a member. Tell me, what do you think we should do?

Mr. GELARDI. First, I would simply comment that having this hearing has helped. The proposal that was presented by FDA to you today did not exist before the committee called this hearing. So the FDA has focused its attention on the problem. Additionally, as the two other witnesses on this panel have identified, the industry does have proposed reform legislation that we believe should be seriously considered by the Congress and hopefully enacted.

We also, as the Calorie Control Council, have made suggestions to the agency in the form of a petition that we would like to see either enacted through regulation or through legislation.

Mr. TOWNS. Dr. Applebaum.

Ms. APPLEBAUM. Well, again, there has to be something, I believe, based on FDA's testimony today, where they don't view the law as being the law. There's a problem when 180 days in which they have to fulfill a responsibility comes and goes, and there is nothing done to either force them to make a decision or to have the petitioner in this regard be given any type of benefit.

I think something has to be done legislatively. I think, at this point in time, FDA has neither the resources nor the willingness to do something constructively without some type of legislative interaction.

Mr. TOWNS. Thank you very much, Dr. Applebaum.

Dr. Ziller.

Mr. ZILLER. I think that the industry proposal—and, in fact, it comes with even some proposed legislative language—is what we would suggest this committee take a look at and recommend, as far as what Congress could do to help.

Mr. TOWNS. I think I read somewhere, in terms of drugs, where there is $25 million—in terms of every application. Do we have any idea of how much is lost, in terms of an application when it's filed? Would you know? I know, in terms of drugs, we have numbers on that. But in terms of an application of this type, would you have

any idea as to the kind of loss that takes place during the waiting period?

Ms. APPLEBAUM. Specific numbers, at this time, no, but we can provide them for the record.

[The information referred to follows:]

The average cost for a food additive application typically ranges between $15 million and $25 million. However, there have been applications whose total costs have exceeded $200 million.

Mr. TOWNS. I would appreciate that.

Major corporations have a tremendous advantage over most small businesses, because major corporations have greater resources to endure delays in the petition process. What efforts have been undertaken to address the concerns over delays as it specifically relates to small businesses? Has any work been done in that area, in terms of the process moving forward when a small business is involved?

Ms. APPLEBAUM. In our testimony, we mention that all business is impacted by this broken process at FDA, the reason being, maybe the small business doesn't have the R&D, per se, to develop that new food ingredient, but they do have the capacity to do research and development on utilizing that new ingredient to produce new products, to extend a particular line, and a variety of other products that that particular small company might be able to utilize.

So we are here representing small companies because they are at a disadvantage right now, because they are waiting for these new food additives to be approved, in order to not only extend their own product lines, but to benefit their consumers by providing a variety of products to fill their needs and lifestyles.

Mr. TOWNS. Dr. Ziller, your proposal for third-party petition review would reduce the role of the FDA in the petition review process, as I understand it. The concern that I have with your proposal is that it places the burden of disproving safety on the FDA. This proposal seems very similar to the system that Congress abandoned with passage of the food additive amendment in 1958.

Would enactment of such a proposal undermine the safety and protections brought about by the food additive amendment?

Mr. ZILLER. Not at all. I think one of the problems we have right now is that you don't have a system that has as ready access—I think, as Sandy Miller may have referred to earlier, on the second panel—to the world class scientists you may need to address certain specific issues.

The third-party system of the type that we are recommending would envision a third-party group assessing what scientific needs are there, who the experts are, bring them together, and have them make the decisions. This is not envisioned to be some minor closet group.

Second, part of the proposal is that there would be no group that would be used that would not be under contract to Food and Drug, having met the criteria for an independent third-party review group.

Finally, Food and Drug is envisioned to be interactive, part of it, and able to provide some questions to the third party to work with the petitioner. So it's not like they are not involved. It's just that

they do it much like they did in the past, in the GRAS review, where they were provided information on safety of ingredients.

Prestigious groups like FASEB, which will be testifying later, next week, to this committee, have reviewed food ingredients and provide finished toxicological reports, which Food and Drug then reviewed for concurrence. And they have seldom disagreed with the judgment of a collection of some of the best scientists who can address specific areas.

So no, not at all. I think safety would very likely be enhanced.

Mr. TOWNS. Don't think for a moment that I disagree with your idea, but I just want to ask a couple more questions about it. How would we ensure the independence of such a group of third parties? How could we ensure that they have the kind of independence to be able to make the decisions without any kind of influence of any sort?

Mr. ZILLER. Well, I think there are a number of models that are used for those kinds of conflicts. I think the person, even if he was a world-famous—maybe the most knowledgeable person about a given issue, if he had done one of the pivotal studies in the petition, obviously, would not be allowed.

On the other hand, I think, if there is proper disclosure, that other renowned scientists can provide extremely useful assistance in working with the rest of the group in the third party, and Food and Drug, to come to the conclusions that they will have to make.

Mr. TOWNS. Let me ask you this. Here again, don't let my questions make you think for a moment that I'm not interested in it. I like this. Where do you think the opposition would come from, if we move forward with such a proposal?

Mr. ZILLER. Well, I think Food and Drug will perceive it as the loss of some sort of hands-on, day-to-day capability of controlling the system. I think the people who don't want additives, virtually of any type, any way, will see this as moving decisions away from a group that they think they have greater political power over.

I think the industry supports it, and I think that it's a good thing, and I think it builds on some successful models of the past that dealt with other food ingredients.

Mr. TOWNS. I agree with you. I think that something of this type or model would have to be put in place for them to meet the 180 days. I mean, I don't see, under the present structure, that they would be able to do it. I think we have to look at doing something, so this makes a lot of sense.

Mr. ZILLER. You know, it's envisioned as something that would have some central secretariat body that has full-time employees and then those people would contract with other experts, depending upon what the subject of the petition was about.

Mr. TOWNS. Let me thank all three of you for your testimony. The chairman is back now, so I yield.

Mr. Chairman, I yield back to you.

Mr. SHAYS. Are you all set?

Mr. TOWNS. I'm all set, yes. Thank you.

Mr. SHAYS. The only other question that I would want to ask is, the difference between a large and small business—and you all represent both—in terms of their approach and their mentality on how to deal with this issue. I would make an assumption that a larger

business can deal with it better than a smaller business, in terms of the delay. Wrong assumption?

Mr. ZILLER. You're talking about small business from the point of view of being a petitioner or a user of products?

Mr. SHAYS. Yes, a petitioner. I'm sorry. A petitioner who is a large operation has the ability, financially, to deal with the delays. Who tends to be the most impatient? See, what I've come to the conclusion is, nobody is very impatient with the FDA. They might complain about them, but they don't seem to care enough to take a suit and confront them.

What I'm trying to understand is, who is benefiting, and who is losing. Competition being what it is, if somebody has a good product, and they know the FDA is taking a long time on another product, then they are the beneficiary. Some of your own people benefit from the delay, because you don't get the better product on the market. That's one thing I'm thinking of.

I'm thinking of this—I'm concerned because I've seen it in other areas of government where there's a complaint about a product, and you find out it was the competition. And sometimes the competition is able to delay the product from getting to the market.

So I'm asking—you get a sense of where I'm coming from here. Let me just come first with the small/large. Do you think that the small business benefits more by delay than the big one, or the big one more than the small? Or maybe you don't think it matters?

Ms. APPLEBAUM. I don't think anyone benefits from the delays.

Mr. SHAYS. Nobody?

Ms. APPLEBAUM. No one benefits from the delays.

Mr. SHAYS. OK. You're a small business. You've had this product on the market for a number of years. You've got pretty exclusive market share. You benefit because your competition can't get to the marketplace. So, I mean, that's silly. I mean, somebody does benefit.

Isn't that true, in that instance?

Ms. APPLEBAUM. These products are extending—these food additives are expanding, if you will, the variety of products out there.

Mr. SHAYS. You're talking about the consumer. But grant me this point, I mean, there are some businesses that will therefore not have competition; correct?

Mr. GELARDI. Mr. Chairman, if I may add a word?

Mr. SHAYS. Yes. I think the consumer loses. I want to put on the record, the consumer loses from this. That's the issue about which I'm asking.

Mr. GELARDI. Mr. Chairman, that's one of the things that's in our petition. It's a recognition that there are sometimes a limited number of people or organizations that will benefit from the delay. That's why we say that unfounded comments on scientific information that are thrown into the process should not be used to delay the approval process.

I don't want to speak for Dr Applebaum, but I think she was talking in the generic sense, that there is such a vast majority of people who benefit and so few that benefit from the delay, that shouldn't interfere. That's one of the reasons we had that specific suggestion.

Mr. SHAYS. The whole issue of a third party making comment, can they do it anonymously?

Mr. GELARDI. They do it through the use of another third party. For example, they will utilize a law firm.

Mr. SHAYS. And the law firm can present the complaint and never——

Mr. GELARDI. They can present the data without identifying who their client is.

Mr. SHAYS. Lawyer-client privilege.

Ms. GELARDI. Yes.

Mr. SHAYS. Well, one of the things I'm going to do is—and my staff will make sure I do this—I'm just going to sit down with the FDA and have them go through the whole process with me. I would welcome the ranking member, Mr. Towns, to do the same. Because I just need to be clear. I just think there are so many areas of abuse that can take place in this process and obviously have.

Anything you want to say at the end, before we get to our final panel? Any other comment you would want to make?

Mr. GELARDI. Mr. Chairman, I made a comment earlier, in your absence, and I do think it's worth repeating, and that is that the mere convening of this hearing has, I think, focused attention on something that is long overdue and is of real benefit to the American people. We are pleased to see that. I hope that, working with the FDA, all of us can help them to do a better job for all of us.

Mr. SHAYS. I thank you for saying that. I do think it will be beneficial. For me, though, it's beyond my comprehension about the whole mind-set of people waiting 10 years. So I'm not sure if it's all sinking in yet. I thank you all.

I would like to call our last panel. The last panel has obviously been the most patient, I'm assuming, for waiting.

This is Dr. Stephen Saunders from Frito-Lay, the one private industry that has come forward. So for that I am extremely grateful. Dr. Wayne Callaway, George Washington School of Medicine, and Dr. Michael Davidson, Chicago Center for Clinical Research.

I appreciate all three of you for waiting. Do you have any planes to catch or anything? You've already missed them?

Would you raise your right hands.

[Witnesses sworn.]

Mr. SHAYS. For the record, all three acknowledged in the affirmative.

We will go in the order in which I called you: Saunders, Callaway, and then Davidson.

Dr. Saunders, thank you for coming.

STATEMENT OF DR. D. STEPHEN SAUNDERS, FRITO-LAY, INC.; DR. C. WAYNE CALLAWAY, GEORGE WASHINGTON UNIVERSITY MEDICAL CENTER; AND DR. MICHAEL H. DAVIDSON, CHICAGO CENTER FOR CLINICAL RESEARCH

Dr. SAUNDERS. Good afternoon, Mr. Chairman.

Mr. SHAYS. I'm just going to say it again. Maybe you don't want me to give you this much attention, but you are a valuable resource. I want to say, I don't think you have anything to fear by coming before this committee. I feel very comfortable that the FDA would treat you and your company with all the respect it deserves.

Dr. SAUNDERS. Thank you, Mr. Chairman. We are honored to be here, and we are pleased that you would take the time to hear our views.

As I said, good afternoon. My name is Steve Saunders, and I am manager of food safety at Frito-Lay. You have my written comments which I would like to just summarize for you now.

As you know, Frito-Lay is the Nation's leading manufacturer of quality snacks, such as Lays, Ruffles, and Doritos, a favorite of former politicians everywhere. At Frito-Lay, Mr. Chairman, we have a motto, which is, "Find a better way." What we mean by that is, we're constantly seeking to improve every aspect of our business, from production to distribution to product development.

In the area of new product development, we have succeeded in greatly reducing development time while introducing record numbers of new products into the marketplace. Mr. Chairman, virtually every food company in this Nation would like to do the same thing. As a result, the consumer has a wide variety of foods from which to choose. All too often, however, these choices are in spite of rather than because of the regulatory process.

The subcommittee has asked for some examples of regulatory delays which have impeded the introduction of new products. The best examples I can provide you deal with packaging. Now, Mr. Chairman, the snack food industry is one of the largest users of flexible packaging in this country. So any improvements we make in this area can translate into immediate environmental benefits.

We have made good progress at Frito-Lay in source reduction and in recycling of scrap plastic into usable materials. Together these efforts account for savings of about 20 million pounds each year. These are reductions in materials which would have otherwise ended up as waste. We have achieved these results largely by applying innovative engineering techniques to existing, already approved packaging materials.

I would like to say to you that we have achieved additional benefits by using newer, more innovative materials. This has not been the case. In a specific example, we are currently awaiting approval for use in snack foods of a packaging material that has already been approved for other food uses. This material offers the benefits of improved freshness and reduced waste in the environment. We estimate an additional 2 million to 4 million pounds would be saved with this material.

Approval of this material for snack foods has been under consideration now for 18 months. Now, keep in mind, it has already been reviewed once. They spent 3 years in the review of the original petition, and one would assume that any significant issues had been identified and resolved during this previous review. So it's difficult for us to imagine why we need a second review period of this length. In fact, it has taken longer to consider these new data than it took to actually conduct the studies.

In another example, a supplier has proposed to alter the proportion of individual components that are used to make a food contact plastic. Now, the individual components in the basic plastic have already been approved and have been used for years in food packaging. This relatively simple request has also been under consideration for more than 2 years. So even a trivial change such as this

gets bogged down in the regulatory process, and the consumer is denied the benefit of new materials.

I want to stress, as have other panelists, that I'm not coming here today to criticize the FDA. But I would like to explore with the subcommittee ways in which the process can be improved. From my own experience, the scientists at FDA are dedicated, competent professionals, and I think they genuinely do care about what they do.

From my view, I think the difficulty is that there is an institutional reluctance to make decisions. So I think that one of the questions we have here today is, what can we do to help speed up and improve the decisionmaking process?

Absolutely, I do not advocate a reduction in safety. We enjoy the safest and most abundant food supply in the world, and nobody wants to change that. But I do think it's time to consider whether our resources are focused properly. Because of the relative lack of hazard for most of these compounds, the resource- and time-intensive data reviews that currently constitute the regulatory process simply are not warranted.

One credible suggestion for improving this process involves the use of independent expert review panels, and we have heard other people talk about them. These panels would be approved by and operated under the guidance of FDA. This proposal would allow the FDA to better focus its resources and should speed up the decisionmaking process. In my written comments I gave you two precedents involving the EPA in the pesticides program and also the FAA in licensing of new pilots, in terms of using private organizations as part of the regulatory process.

Another suggestion for improving this process has been proposed for indirect food additives. Now, the idea here is to use default assumptions and presume that a new packaging material is safe. This is basically an extension of the threshold of regulation concept which you heard about this morning, which was a bold and innovative proposal announced by the FDA 2 years ago. I think the FDA should be encouraged to finalize this policy and even consider extending it further.

I commend this committee for its interest in helping the FDA find a better way for its food additive review process. I urge you to move forward with reforms that will streamline the regulatory process. Consumers will benefit from new products, and resources will be used more wisely.

Thank you for your time. I will be happy to answer any questions.

[The prepared statement of Dr. Saunders follows:]

PREPARED STATEMENT OF D. STEPHEN SAUNDERS, PH.D., TECHNICAL MANAGER FOR FOOD SAFETY, FRITO-LAY, INC.

Good Morning Mr. Chairman, and members of the Subcommittee. I am Dr. Stephen Saunders, Technical Manager of Food Safety for Frito-Lay, Inc. We are the nation's leading manufacturer and distributor of quality snack food products, including Lays• and Ruffles• brand potato chips, Doritos• brand tortilla chips, Fritos• brand corn chips, and numerous other brand name products. An operating division of PepsiCo, Frito-Lay employs more than 30,000 people nationwide. We have 42 manufacturing plants in 26 states, and sales and distribution centers throughout the country. Thank you for this opportunity to comment on the impact of the regulatory process on product innovation in the food industry.

At Frito-Lay, our motto is "Find A Better Way". We are constantly seeking to improve, through innovation and the use of new technologies, all aspects of our business, from production to distribution to product development. Not only have we reduced the amount of time necessary to introduce new products into the marketplace, but we have also offered more choices to our customers.

Virtually every food company in the United States tries to duplicate this process. A trip down the aisles of any grocery store presents the consumer with an amazing array of choices. Unfortunately, this amazing diversity of choices is not the result of a partnership between industry and the federal regulatory process. In fact, these choices are often in spite of, rather than a result of, the regulatory process.

The Subcommittee has asked for examples of delays which have impeded the introduction of new products. The best examples I can provide are in the areas of packaging. The snack food industry is one of the largest users of flexible packaging in this country. Therefore, any improvements our industry makes in terms of source or waste reduction translates into immediate environmental benefits. At Frito-Lay, we are continually searching for new packaging materials which provide fresh chips for consumers and reduce waste or have other environmental benefits, such as improved recyclability. By applying innovative engineering techniques to our flexible packaging, we have reduced the volume of packaging used for our products. This translates into a source reduction of about 15 million pounds per year. In addition, we are currently recycling about 6 million pounds of scrap packaging material each year. In both cases, these are reductions in the amount of packaging materials which would have otherwise ended up as waste.

We have achieved these reductions largely by applying innovative engineering techniques to existing, already approved packaging materials. I would like to be able to say that we have achieved additional environmental benefits through the introduction of new, more innovative packaging materials. This is not the case.

Research, development and testing of a new packaging material, including toxicology and safety assessments, represents a tremendous investment of resources, and generally takes several years before a petition is presented to FDA. And then, on average, it takes another two years for the FDA to approve this new material for food use. In some cases, it has taken much longer. Speaking as a toxicologist, this seems like an inordinately long time for consideration of materials that are inert and essentially non-toxic. Our knowledge base in toxicology has expanded dramatically over the past 40 years. In my view, we have made good progress in terms of identifying the types of compounds that pose a potential hazard for man. Yet, apparently the FDA doesn't take advantage of the strides that have been made in toxicology, particularly predictive toxicology. Nor, in my view, does the FDA give sufficient credence to its own wealth of experience in the review of new packaging materials that are, as I said, essentially inert and non-toxic.

For example, we are currently awaiting approval for use in snack foods of a packaging material that has already been approved for other food uses. This material offers the benefits of superior barrier protection and improved recyclability, which translates into improved freshness for the consumer and reduced waste into the environment. Approval of the use of this material for snack foods has now been under consideration at the FDA for 18 months. FDA is currently reviewing a submission which consists of two toxicology studies and the required migration data for snack foods. Keep in mind that this material has already been considered once by the FDA (3 years were spent in consideration of the original petition), and one would assume that all significant issues had been identified and resolved during the previous review. Therefore, the only new issues to consider would be those which were raised by the new data. Since these data failed to show any toxic effects or other concerns, it is difficult to imagine the need for a review period of this length. In fact, it has taken longer for the FDA to consider these data than it took to actually conduct the studies.

In another example, a supplier has proposed to alter the proportion of individual components that exist in a food contact polymer. The individual components and the basic polymer have already been approved for use in food by the FDA. Our supplier intends merely to alter the relative proportions of the individual components of this polymer. This relatively simple request has also been under consideration at the FDA for more than two years. Again, there were no toxicity or other issues to consider, and the individual components have been in use in packaging materials for years. Even a trivial change such as this gets bogged down in the regulatory process and the consumer is denied the benefit of new materials.

I would like to stress that my purpose in coming here today is not to criticize the professionals at FDA, but rather to explore with the Subcommittee ways in which the process can be improved. In my experience, the scientists at FDA are dedicated, competent individuals who seem to genuinely care about what they do. The dif-

ficulty seems to be, at least in part, an institutional reluctance to arrive at decisions. I suspect that a large part of this problem is that there are relatively few incentives for making decisions. I think that one of the questions before the Subcommittee today is: "What can be done to improve and speed up the decision-making process at FDA?"

Certainly, I do not advocate a reduction in safety. The United States today enjoys the safest and most abundant food supply in the world. Any plan which compromises on safety would be unacceptable. However, I do think that it is time to consider whether our resources are focused properly with respect to food additives and the food supply. In my view, the relative lack of demonstrable hazard for the vast majority of these compounds does not merit the resource and time-intensive data reviews that currently constitute the regulatory process.

One credible suggestion for improving the process involves the use of independent, expert review panels. These panels would be approved and operate under guidelines and criteria established by the FDA. This proposal has merit in that it would allow the FDA to focus its resources more effectively, and would speed up the decision making process.

There are precedents for this type of approach in the Federal regulatory process. The EPA pesticides program has made extensive use of outside contractors to conduct reviews of pesticide data submissions. These reviews are prepared by the contractor according to guidelines established by the EPA, and then reviewed by the EPA for accuracy. This allows the EPA to maximize its resources without sacrificing safety. In another example, the FAA makes use of private citizens who have been certified by the FAA as Designated Pilot Examiners (DPEs) when licensing new private pilots. An applicant for a pilot's license then has the freedom to chose a DPE for examination. The DPE follows an established syllabus for conducting the test, and scores the applicant according to criteria established by the FAA. I believe that a similar approach could be adapted for use in the food additive area.

Another practical suggestion for improving the process has been advanced in the area of indirect additives. This suggestion is to use default assumptions, and presume that a new packaging material is safe unless the FDA determines, within a short review period, that this presumption is not warranted. This is basically an extension of the Threshold of Regulation proposal (FR6 58, 195, 52719–52729, October 12, 1993), which was a bold and innovative proposal announced by the FDA two years ago. The FDA should be encouraged to finalize this proposed policy, and to consider extending it further.

I commend this Subcommittee for its interest in helping FDA "Find A Better Way" for its food additive review process. I urge you to move forward immediately adopting reforms that will streamline the regulatory process. Consumers will benefit from the introduction of more new products into the marketplace, and resources will be used more efficiently. Thank you for holding this hearing. I'll be happy to answer any questions.

Mr. SHAYS. Thank you for being here.

Dr. Callaway.

Dr. CALLAWAY. Mr. Chairman, Mr. Towns, thank you for inviting me to participate. I would echo a lot of the things that have been said already in regard to my respect for my colleagues at the FDA and the tough job that they have.

As you have indicated, my name is Wayne Callaway. I am a physician. I practice medicine in Washington, DC, and I am on the clinical faculty of the George Washington University Medical School. I am an endocrinologist and also board certified in clinical nutrition.

In the last decade and a half, I have spent part of my career serving on committees and as an advisor to various agencies, including USDA and FDA and NIH, and have been involved in a number of the reports which have to do with dietary recommendations, including the development of the Dietary Guidelines for Americans in 1980, its revision in 1990, the Surgeon General's Report on Nutrition and Health, and so forth.

I have also served as a consultant to various trade and food organizations which have been involved in some of the issues that we

are talking about. However, obviously, my testimony here today reflects my own opinions and not those of any of these organizations.

Mr. SHAYS. You said all of that in one breath. Unbelievable. [Laughter.]

Dr. CALLAWAY. I'm partly Irish.

As you well know, for more than 30 years, public health authorities have been recommending dietary changes as one means of reducing premature death and the risk of various chronic conditions, especially heart disease, obesity, some types of cancer, high blood pressure, and so forth.

Although we argue vehemently over the details, I think there is a strong consensus about certain basic principles; namely, eat a variety of foods, including at least five servings of fruits and vegetables a day, and avoid excessive intakes of dietary fat and sugars and salt and alcohol.

There have been several reports which have addressed the issue of how best to implement these dietary recommendations. Consistently these reports call for the development of new foods which are lower in fat and sodium and so forth.

The challenge has been to provide such foods in a manner that is acceptable—but if it's not eaten, it doesn't do any good—or even preferred by consumers. To do this requires consideration of cost, convenience, and especially taste. The technological tools that are now available offer us a lot more opportunities than we had 30 years ago, particularly in the critical issue of taste.

As a physician, I have learned that you can't expect long-term changes in behavior with short-term, sudden, extreme types of recommendations. To make something stick, requires incremental changes, long term. We are more likely to succeed if we make the food supply, if you will, more "user-friendly."

In changing the eating habits of the general population, I think the newer food technologies hold a great deal of promise. It is increasingly possible to provide foods that look, smell, feel, and taste like traditional foods, but which are lower in fat, sodium, sugar, and any other specific nutrient that we may be concerned about.

Such products, when available, add to consumer choices. None of these products, in and of itself, is going to solve any public health nutrition problem. However, they will increase our success in promoting more healthful diets for the American population. Our next witness will talk about some of the numbers on this.

Topping the list are fat substitutes. I won't go into the technical details, but, as some of you know, some of the fat substitutes are protein-based, some are carbohydrate-based; some are lipid-based. Some of them involve ingredients that have been out there for a long time and easily qualify for GRAS classification.

Others have required extensive research and documentation to establish their physical chemical properties, their potential for toxicity, their potential nutritional impact when consumed as food additives. Thus, some of these products have required little or no regulatory approval, while others have taken many years to compile the required data, and are still not available for the American consumer. It is my opinion that much could be done to reduce the regulatory delays that currently impede the development of new and potentially beneficial products.

Earlier the representatives from FDA noted that in the traditional classification of food versus drugs, drugs do something beneficial, and foods are what we eat. But we are moving into an era where, at least in terms of chronic disease, there are potential benefits from the new additives that we are talking about. This is just not the indirect additives or coloring; these are things that have a strong potential for benefit.

I would offer just a few comments on the FDA. It seems to me that there are several issues. There is lack of sufficient internal expertise in regulatory agencies. Nobody can be an expert in all things. It's unrealistic to expect the FDA or any other regulatory agency to have all the expertise they need. To evaluate the scientific base we need true experts.

Second, I personally think there has been inadequate direction from the top folks, in terms of defining the timetables and giving support to the technical staff when they need it, especially when they come under fire.

I think we have failed—and this is an issue that hasn't been brought up enough today—I think we have failed to distinguish clearly what studies need to be done to document safety of a new product, versus studies that would be interesting but not necessary, versus studies that are being done, in my opinion, simply to address speculative issues brought up by "consumer advocates" and others, including competitors, and by those who seem to oppose all forms of technological advance.

I put "consumer advocates" in quotes, because I think the best consumer advocates are the people who have been trained in science and health and medicine, and who have spent their careers in this field. No committee I have ever been on has had anyone I could identify who wanted to compromise public health.

I mean, all of us are committed to public safety. We have our reputations at stake. To divide the world into scientists and consumer advocates distorts the picture. We have a lot of good consumer advocates, as I say, who are well trained and who have spent their careers in science.

Expert panels put together by NIH or the National Academy of Sciences have to face peer review. In science you have to publish original data, and have that data evaluated. You are subject to the criticism of your colleagues.

In contrast consumer advocates and public interest groups go directly to the media—entertainment media and news media—and don't have to face peer review. So we are dealing with different levels, if you will, of expertise or certainty in evaluating these very difficult scientific issues.

The exploitation of consumer fears and the excessively cautious reactions from both regulatory agencies and the food companies—and I think we see this today—the failure of many food companies to appear before your hearings is an example of that—has led to some things—and the chairman brought this up—about who is penalized.

My personal opinion is that the small company has little chance to compete when new products, particularly big ones, are encumbered by large delays, large costs, and the cost of many, many studies which are not really scientifically indicated.

So I don't know data on this, but my personal opinion is, that what we have done is narrow the field to the really large companies which, ironically, is just the opposite of what some of the consumer groups would say that they are for, the little guy. But I think we are really favoring the big guy in this thing.

Mr. SHAYS. That's probably accurate.

Dr. CALLAWAY. I beg your pardon.

Mr. SHAYS. My intuition seems more willing to accept that, your comment.

Dr. CALLAWAY. In the consulting work I do, the small companies just don't have the resources to hang in there long term. They may develop something, but then they have to sell out. They just can't bring it to market.

I would conclude with a few ideas for improving the situation. In the age in which we live, it's common that people who have technical expertise in one area forget their expertise is not transferable. So when we are dealing with narrowly technical issues, it's critical to have people who have expertise in that area.

Generalists serve a role, but I would urge greater participation of small, ad hoc committees to review specific technical details as soon as they come up and not late in the game, to speed this process along. I think some of the formal advisory panels and committees that exist right now are a bit too cumbersome to deal with these types of technical issues. So anything we can do to get small, ad hoc groups to hit the issue early on and to resolve the scientific aspects of it would really speed the process.

Issues raised by consumer groups and political activists or corporate competitors have to be dealt with fairly and factually, but they shouldn't delay the review process simply because of fears of adverse media coverage. Resources are limited. It's imperative that we avoid recommending costly, scientifically unjustified studies simply to allay all fears that may be raised.

We should be more aggressive, however, in educating the public as to the nature of safety. That's a perennial problem that everyone has tried to deal with, including the National Academy of Sciences. But instead of capitulating on this, we need to take the initiative and get out and educate as to how science is evaluated and what risk is all about.

I can well empathize with my colleagues at FDA. None of us wants to be called on the carpet or criticized in the Post for having missed some detail or for some apparent conflict of interest. In this regard, it is imperative that the heads of regulatory agencies provide clear directives and timetables, and then back up their technical people when they are subjected to undue criticism. You have to know that you're being supported in order to get beyond this problem.

In summary, newer technologies can add to the choices available to consumers who wish to follow the dietary guidelines to improve their health. Such products should be subject to careful review in order to assure their safety for long-term consumption. However, the current system is too costly, too lengthy, and too influenced by emotionally charged issues.

The delays we experience not only increase the cost of developing new products, but they also increase the cost to the consumer, not just in the grocery store, but in terms of impaired consumer health.

Thank you for listening to these remarks.

[The prepared statement of Dr. Callaway follows:]

PREPARED STATEMENT OF C. WAYNE CALLAWAY, M.D., F.A.C.E., ASSOCIATE CLINICAL PROFESSOR, GEORGE WASHINGTON UNIVERSITY MEDICAL CENTER

My name is Wayne Callaway. I am a physician in private practice in Washington, D.C. I am trained and board certified in Internal Medicine, Endocrinology and Metabolism, and Clinical Nutrition. In addition, I am Associate Clinical Professor at George Washington University.

During the past 15 years, I have served in numerous advisory positions with the U.S. Department of Agriculture (USDA), the Department of Health and Human Services (DHHS), the National Institutes of Health, the Food and Drug Administration, the Federal Trade Commission, the National Academy of Sciences, and other governmental, scientific and health organizations.

I was intimately involved in the development of the First Edition of the Dietary Guidelines for Americans, published jointly by USDA and DHHS, in 1980, and I was a member of the Dietary Guidelines Advisory Committee, which recommended revisions for the 3rd Edition in 1990. I was also a Senior Editorial Advisor to the DHHS Nutrition Policy Board for The Surgeon General's Report on Nutrition and Health (1988) and was Senior Science Consultant to the Food and Nutrition Board of the National Academy of Sciences during development of its report, Diet and Health: Implications for Reducing Chronic Disease Risk (1989), and the most recent edition (10th) of the Recommended Dietary Allowances (1990). I have also served as a consultant to various trade organizations and corporations involved in the production, processing, and delivery of food to the American public. My testimony today, however, reflects my own personal views and not those of any of the agencies or organizations for which I have served as a consultant.

For more than 30 year, public health authorities have recommended dietary changes as a means of reducing the risks of premature death and of various chronic conditions, especially heart disease, high blood pressure, high blood cholesterol, obesity, and some forms of cancer. Although we may differ on the details, all of us agree on the major principles:

- Stay physically active
- Eat a variety of foods, including at least five servings a day of fruits and vegetables
- Avoid excessive intakes of dietary fats, sugars, salt, and alcohol

We may differ as to whether there should be quantitative targets, what those quantitative levels should be, what priorities should be given to each of these recommendations, and whether there should be targeted recommendations for different segments of the population. However, practically no one disagrees with the overall principles.

Several reports have addressed how best to implement dietary recommendations. Consistently, these reports call for increasing the number of lower fat, lower sugar, and lower sodium foods and food products available to the consumer, especially for those of us who already have chronic conditions which would benefit from dietary modification. The challenge has been to provide such foods in a manner that is acceptable—even preferred—by consumers. To do so, requires considerations of costs, convenience, and, especially, taste.

The Designing Foods report, from the Board on Agriculture, National Research Council/National Academy of Sciences, explored options available in producing foods from animal sources. These include changes in breeding practices, feeding practices, processing, and even genetic engineering. Similar issues are involved in the development of foods from plant sources. The technological tools available at this point in time are quite impressive. However, the issue of taste continues to play a critical role in the acceptance of such foods by many consumers.

As a practicing physician, I strongly believe that sudden, extreme attempts to change eating and activity behaviors are rarely successful long term. We now know a lot about the underlying biological and psychological factors which predispose to failure when people dramatically restrict their total food intake or specific nutrients, such as dietary fats. Our colleagues in behavioral medicine have shown that step-by-step, incremental changes, designed to allow the person to develop a set of behaviors that he or she can live with, are more likely to succeed long term. "No pain, no gain!" and "Just Say No!" are not useful concepts when it comes to changing day-

to-day habits. Mark Twain observed that it was fool hearted to attempt to throw habits out the window; they needed to be "coaxed downstairs, one step at a time."

This coming together of health concerns with a greater appreciation of the factors that are involved in sustaining long-term healthful behavioral changes gives newer food technologies a special role. It is increasingly possible to provide foods that look, smell, feel, and taste like traditional foods, but which are lower in fat, sugar, sodium, or any other specific ingredient that a consumer might benefit by limiting. Such products, when available, will add to consumer choices. None, in and of itself, will "solve" any single national public health problem. However, in the aggregate, they will increase our success in promoting more healthful diets for the American population.

Topping the list are products known as fat replacers. These include carbohydrate-based products, such as dextrins, modified starches, polydextrose, pectins, and gums; protein-based products, such as lecithin, gelatin, and microparticulated proteins; and lipid-based products, such as sucrose polyesters, propoxylated glycerol, and structural triglycerides. Some of these products meet the standards for generally regarded as safe (GRAS) classification. Others have required extensive research and documentation to establish their physiochemical properties, their potential for toxicity, and their potential nutritional impact when consumed as food additives. Thus, some of these products have required little or no regulatory approval, while others have taken many years to compile the required data, and are still not available for the American consumer.

It is my opinion, as both a practicing physician and as one who has played an active role in the evolution of dietary recommendations for the general public, much could be done to reduce the regulatory delays that currently impede the development of new, potentially beneficial products.

Among the problems which I have experienced or observed are the following:

- lack of sufficient internal expertise in regulatory agencies;
- cumbersome regulations regarding the use of external consultants and advisory panels;
- inadequate direction from senior regulatory officials to their technical staffs;
- failure to distinguish clearly what studies need to be done to document safety of a new product versus studies that would be interesting, but not essential to safety evaluation versus studies that are being done simply to address speculative issues brought up by "consumer advocates" and by those who seem to oppose all types of technological advance.

When I put the words, "consumer advocates" in quotation marks, I do so not to denigrate such individuals or organizations. Rather, I wish to emphasize that those of us who have been professionally trained in science, medicine and public health, and who have spent our professional lives in these areas, are, with rare exception, the strongest consumer advocates that we have. Among the many panels and advisory committees with which I have been affiliated, I cannot think of anyone who would willingly compromise consumer health or safety. As I have said, we may differ over the details, and, indeed, argue quite forcefully for our own viewpoints. However, all of us share the goal of providing the best synthesis of current scientific data and the best health recommendations based on such analysis, as we can. After all, we and our families are also consumers. And none of us wishes to compromise our professional reputations, our integrity, and our own sense of self-worth by recommending anything that was not consistent with our current understanding of the scientific data.

The difference, however, between expert panels brought together by the National Academy of Sciences or the National Institutes of Health, on the one hand, and organizations led by individuals with little or no scientific background, founded by the leader, and largely run as "closed shops," is that the latter organizations are not subjected to peer review. They are not called upon to present original data, to defend the methods by which those data were obtained, to defend the conclusions that they have drawn from such data, to present their discussion of those conclusions within the context of the broader, published scientific literature, or to be willing to modify their conclusions in the face of newer data as it becomes available. Instead, such groups go directly to the news/entertainment media or to legislative bodies, city councils, school boards, and other political groups, with a rhetorical message, unencumbered by the constraints of scientific deliberations. Even when the advocates have advanced degrees, including Ph.D.s, it is rare that the training and professional expertise is relevant to the issues that they are addressing.

Unfortunately, because of the media exposure that such organizations can obtain, it is my opinion that both regulatory agencies and major components of the food industry have chosen to deal gingerly with the often spurious issues these groups raise. The result is that regulatory agencies become excessively cautious, resulting

in inordinate delays in the review process for foods or food additives derived from new technologies. And, the companies involved in developing new technologies and adapting them to our food supply frequently undertake lengthy, costly, and largely irrelevant studies—presumably, because they concluded that it is less risky in the long-run to do the studies, even though their own outside scientific advisors assure them that such studies are either unnecessary or, in some cases, without scientifically rationale.

The exploitation of consumer fears and the excessively cautious reactions from both regulatory agencies and food companies have brought us to a position where only very large companies can compete. It is too expensive for smaller or moderate size companies to withstand the costs and the delays involved in addressing spurious health and safety issues that have little scientific basis. Thus, consumer advocates are actually fostering the trend for greater consolidation of technical knowledge, resources, and power in large organizations, just the opposite of what these groups would have us believe.

When I was younger, I would probably have been bold in suggestions specific steps that should be taken to correct the issues that I am addressing. However, like the regulatory agencies and the food companies, as I get older, I get a bit more cautious! Nevertheless, I would like to submit a few ideas for your consideration. I believe strongly that it is extremely important to assure the safety of our food supply. However, I think that we can improve on our ability to assure safety, while still streamlining and accelerating the review process.

We live in an age, as predicted by the Spanish writer, Ortega y Gassett, where people trained in narrow areas of knowledge fail to recognize that their "expertise" is not necessarily transferable. In dealing with scientific issues, we should require that scientific data be reviewed by scientists who have acknowledged expertise related to the specific issues being reviewed. A Ph.D. or M.D., by itself, does not qualify any of us to be an expert on subjects in which we have not received formal training, or in which we have not demonstrated superior knowledge, either through publication of original research or cogent synthesis of existing research data in peer review journals. (Being board certified and having published in endocrinology and clinical nutrition in no way qualifies me to render a scientific opinion on an issue involving neurosurgery!) My point is that in the review of scientific data, we must rely on people who have legitimate, acknowledged expertise. There are but limited roles for "generalists" and no role for "advocates" at this stage of the process.

From a practical point of view, it is not feasible for regulatory agencies to have sufficient expertise in-house to address all technical issues that arise. Instead, I would urge more liberal use of ad hoc expert panels, to address specific technical issues, in an expeditious manner, when such issues become identified in the review process.

Issues raised by consumer groups, "political activists," or corporate competitors, should be dealt with fairly and factually, but they should not delay the review process simply because of fears of adverse media coverage.

Resources are always limited; today is no exception. Thus, we should avoid recommending costly, scientifically unjustified studies simply to allay the apprehensions of consumer advocates. Nevertheless, we must make sure that all relevant studies are performed and that the data are both accurate and convincing with regard to any product that is approved for consumer use.

Having worked at NIH and DHHS myself, I can well empathize with the caution my colleagues in regulatory agencies exhibit. I suspect one's worst nightmare is to be singled out in the Washington Post as having overlooked some critical piece of data or as having an apparent conflict of interest—especially when there is no substantive evidence that either situation has occurred. We all know, once the damage is done, it is rarely repaired. Therefore, for the technical folks to do their job well, with minimal anxiety and with appropriate dispatch, it is imperative that the heads of regulatory agencies and their immediate subordinates, provide clear, unambiguous directives for the review process, and consistent support in backing the process when it is exposed to unwarranted criticism.

In summary, newer technologies can add to the choices available to consumers who wish to follow the recommendations of the Dietary Guidelines for Americans in order to reduce their risks of heart disease, obesity, and some types of cancer, or who wish to improve their management of chronic conditions such as diabetes mellitus, hypertension, or hyperlipidemias—to name only a few. Such products should be subjected to careful review of their chemical, toxicological, nutritional, health, and environmental effects, in order to assure their safety for long-term human consumption. However, the current system is too costly, too lengthy, and too much influenced by emotionally-charged issues, promoted by self-appointed "consumer advocates," resulting in delays. Such delays increase the costs and finan-

cial risks involved in developing such products, dampen further innovation, place smaller companies at a competitive disadvantage, and ultimately cost consumers more—both at the grocery store and in terms of personal health.

I wish you success in your efforts to improve upon this important aspect of public regulatory activity. Thank you for inviting me to share these ideas with you.

Mr. SHAYS. I thank you very much.

Dr. Davidson.

Dr. DAVIDSON. Thank you, Mr. Chairman, Mr. Towns.

I am Michael Davidson, the medical director at the Chicago Center for Clinical Research, and assistant professor at Rush Presbyterian—St. Luke's Medical Center, located in Chicago, IL. I am here to speak to you on the subject of food additives from three different perspectives: the perspective of a medical researcher, a cardiologist, and as a son whose father died of coronary artery disease.

As an objective medical researcher, I have conducted many trials investigating the safety of synthetic fats as part of the food additive petition process.

As a clinical cardiologist with a subspecialty in preventive medicine, I witness daily the frustration of my patients with coronary heart disease who, despite their best efforts, are unable to lose weight or lower blood cholesterol levels adequately within a diet program.

Last, from an emotional perspective, my own father died of a sudden heart attack at the age of 47. His only risk factor for heart disease was his high fat diet.

The American population is addicted to a high fat diet. Our high incidence of heart disease, diabetes, cancer, and obesity are greater than any other country and a direct result of our high fat addiction. Total fat intake per capita in the United States has not changed in more than 30 years, despite our scientific advancements in food research and education.

The food industry has offered low fat alternatives and substitutions but with limited success in patient compliance. The most famous example I can recall is the McDonald's McLean Deluxe, launched with considerable enthusiasm, but has been largely an economic failure. Most consumers refuse to sacrifice taste for perceived health benefits. It is naive to believe that significant fat reduction can be achieved in our diet without modifying foods to satisfy both taste and convenience.

Preventive medicine is the hallmark feature of many health care reform programs. The following points support disease prevention through dietary food additives. No. 1, reducing saturated fat by 8 grams a day will save as much as $24 billion a year in the treatment of chronic diseases, and 2 million fewer Americans would have heart disease.

No. 2, using a conservative cost of illness approach, just a 1 percent reduction in fat intake by utilizing fat substitutes would reduce the incidence of heart disease by 32,000, with a cost savings of $4 billion. Increasing that to 3 percent would increase the savings to $13 billion.

No. 3, fat reduction in limited foods, such as savory snacks and crackers, by using fat substitutes, could result in 23,000 fewer cancer cases and 7,500 fewer cancer deaths by the year 2015.

Point No. 4, approximately one-third of the U.S. population have elevated cholesterol levels that require dietary therapy, and about

7 percent to 10 percent require drug therapy. Drug therapy costs alone are $4 billion to $5 billion.

The harmful effects of dietary fat are well documented, and, therefore, evaluation of synthetic fats for approval as a food additive should consider not only safety but should be approved rapidly because of potential health benefits.

As a physician, I am constantly evaluating risks versus benefits for the treatment of disease in my patients. The FDA uses the same process to evaluate new drug approvals and expedites the approvals of breakthrough drugs that offer significant medical advances. Food additives should receive the same type evaluation on the basis of comparative risks, and expedited reviews should be considered for those food additives that enhance healthy dietary objectives.

From my experience, the food industry in the United States is very willing and able to invest considerable funding and resources in the research and clinical development of food additives that offer potential health benefits. To accomplish this mission, the United States needs a cooperative regulatory environment that provides incentives rather than disincentives to improve our diets, which will ultimately improve the health care that this Nation significantly needs.

I appreciate the opportunity to present my views and look forward to answering any questions you may have. Thank you.

[The prepared statement of Dr. Davidson follows:]

PREPARED STATEMENT OF MICHAEL H. DAVIDSON, M.D., F.A.C.C., MEDICAL DIRECTOR, CHICAGO CENTER FOR CLINICAL RESEARCH

Mr. Chairman, Members of the Subcommittee, I am Michael H. Davidson, M.D., the Medical Director at the Chicago Center for Clinical Research and Assistant Professor at Rush-Presbyterian St.-Luke's Medical Center, located in Chicago, Illinois. On behalf of the Chicago Center for Clinical Research, I appreciate the opportunity to appear before you today regarding "The Effects of Regulatory Delays on Food Technology Research and Consumer Nutrition Benefits."

I am here to speak to you on the subject of food additives from three different perspectives; the perspective of a medical researcher, a cardiologist and as a son, whose father died of coronary artery disease.

As an objective medical researcher, I have conducted many trials investigating the safety of synthetic fats as part of the Food Additive Petition process. As a clinical cardiologist with a subspeciality in preventive medicine, I witness daily the frustration of my patients with coronary heart disease, who despite their best efforts, are unable to lose weight or lower blood cholesterol levels adequately within a diet program. Lastly, from an emotional perspective, my own father died in of a sudden heart attack at the age of 47. His only risk factor for heart disease was his high fat diet.

The American population is addicted to a high fat diet. Our high incidence of heart disease, diabetes, cancer and obesity are greater than that of any other country, and a direct result of our fat addiction. Total fat intake per capita, in the United States, has not changed in more than 30 years, despite our scientific advancements in food research and education. The food industry has offered low-fat alternatives and substitutions, but with limited success in patient compliance. The most famous example of this fact is McDonald's McLean Deluxe, launched with considerable enthusiasm, but has been an economic failure. Most consumers refuse to sacrifice taste for perceived health benefits. It is naive to believe that significant fat reduction can be achieved in our diet without modifying foods to satisfy both taste and convenience.

Preventive medicine is the hallmark feature of many health care reform programs. The following points support disease prevention through dietary food additives:

1) Reducing saturated fat by eight grams a day will save as much as $24 billion a year in the treatment of chronic diseases and two million fewer Americans would have heart disease (M. Jacobson CSP1).

Using a conservative "cost of illness" approach, a one percent reduction in fat intake by utilizing fat substitutes would reduce the incidence of heart disease by 32,000 with a cost savings of $4 billion. (Oster and Thompson, 1995 In Print).

	1% Point Reduction	3% Point Reduction
Incidence	32,000	99,700
Cost Savings	$4 billion	$13 billion

3) The fat reduction in savory snacks and crackers by using fat substitutes could result in 23,700 fewer cancer cases and 7,500 fewer cancer deaths by the year 2015 (Levin 1995).

4) Approximately one third of the United States population have elevated cholesterol levels that require dietary therapy, and about seven to ten percent require drug therapy. Drug therapy costs $4 to $5 billion a year for the treatment of hypercholesterolemia.

The harmful effects of dietary fats is well documented and therefore, evaluation of a synthetic fats for approval as a food additive should not only consider safety, but should be approved rapidly because of potential health benefits. As a physician, I am constantly evaluating risks vs. benefits for the treatment of disease in my patients. The FDA uses this same process to evaluate new drug approvals and expedites the approval of breakthrough drugs that offer significant medical advances. Food additives should receive the same evaluation on the basis of comparative risks and expedited approvals should be considered for those food additives that enhance healthy dietary objectives.

The food industry in the United States is willing and able to invest considerable funding resources into the research and clinical development of food additives that offer potential health benefits. To accomplish this mission the United States needs a cooperative regulatory environment that provides incentives rather than disincentives to improve our diets which will ultimately improve the health care that this nation significantly needs.

I appreciate the opportunity to present my views and look forward to answering any questions you may have.

Thank you.

Mr. SHAYS. Thank you, Dr. Davidson.

All of you have raised in my mind a question. Foods that have additives, and so on, that have been certified and are in use today, if they had to go under the same process, is it likely that some of them might not pass the test?

Dr. CALLAWAY. I think that you have a witness coming up at your next hearing, Dr. Fisher, who could probably answer that question quite well.

Mr. SHAYS. So give me the short version. I mean, is there an argument that some wouldn't?

Dr. CALLAWAY. There's an argument that some wouldn't. I don't know how strong the evidence is.

Mr. SHAYS. That they wouldn't be able to go through the process, given new science and so on?

Dr. CALLAWAY. Right.

Mr. SHAYS. But you raise another point.

Dr. CALLAWAY. That has been applied to caffeine, for example.

Mr. SHAYS. Pardon me.

Dr. CALLAWAY. That argument has been made about caffeine.

Mr. SHAYS. You have to understand, you live with this; I don't. So that's probably just common knowledge as an example, but for me, I hadn't thought about it, but that would be an obvious one.

The other thing that I'm struck with is the test isn't this additive compared to its alternative; it's this compared to whether it's totally and completely safe, without risk.

I mean, one of the points you are raising—you know, it's like slapping me in the face—is that there may be alternatives to what we do today, and those alternatives would be far better, even though they might not pass an FDA test.

Dr. DAVIDSON. That's the important point. The FDA made this point this morning, that they don't evaluate benefits of food additives; they just evaluate safety.

Mr. SHAYS. Right.

Dr. DAVIDSON. So when they are deciding to approve something, they ignore, basically, potential benefits. That's how they view it. Now, not to say they don't somehow consider it in the overall process, but, as it stands right now, there is no benefit consideration allowed in the approval process.

The recommendation is that at least priority be given to those food additives that do have health benefits, that they receive expedited approvals, or reviews.

Mr. SHAYS. Dr. Saunders, just give me a quick version of the process where you and your company decide to go before the FDA. What basically happens?

Dr. SAUNDERS. Well, I guess each case is an individual one. Let's say, for example, with a packaging material, we identify——

Mr. SHAYS. Can you talk a little louder?

Dr. SAUNDERS. I'm sorry. Let's say, in the case of a packaging material, we have a new idea, or a concept, or through working with a supplier we have an idea of a new approach that would provide a fresher product, or something.

Mr. SHAYS. OK.

Dr. SAUNDERS. Generally speaking, we would work with a supplier, the manufacturer of the film, in this case, where they would conduct whatever studies were required, and so forth, and they file the petitions. Then the clock starts, as you pointed out. So it's not a complicated process. It's not rocket science. These studies are well-defined. We've been doing them for years.

In my comments to you I pointed out that not only do we have 40 years or more of toxicology knowledge now, since these laws were passed, but the FDA has a whole wealth of experience in dealing with a lot of these compounds. So I think we just need to do a better job of applying our knowledge.

Mr. SHAYS. Is there a lot of interaction between the FDA and your office? I mean, are there constant phone calls? Is there a process that says you're not allowed to contact certain people?

Dr. SAUNDERS. I mean, I think they have an open-door policy. You can talk to them. There's always the question of whether the manufacturer is influencing the process unduly somehow, or whatever.

You know, one of the questions you have had today is, why don't people sue the FDA, or why do they put up with these delays? I think that people have kind of danced around, but we're brave enough to be here. I'm going to tell you what the reason is, or so I've been told anyway.

There are two things: One, it's a serious business to file a lawsuit. It's expensive, and so forth. And filing a lawsuit against the government is, you know, doubly a scary business. OK. But the other reason is, if you push for an answer, the answer is likely to be no. OK.

Mr. SHAYS. Gotcha.

Dr. SAUNDERS. So no answer is better than an answer that is no. I think that's a big part of it.

Mr. SHAYS. In other words, until they are ready to give you an answer, if you ask for one, it's simply not going to be a yes.

Dr. SAUNDERS. I mean, I think that's a—in working with our suppliers, that is very much a fear.

The other question is, with this 180-day clock, why don't we complain after 180 days? Well, the one way that they can avoid the 180 days is to come back and ask you for more data. So the manufacturers don't want to have to go spend more money.

Mr. SHAYS. But the clock doesn't start over again.

Dr. SAUNDERS. But they always have the option of finding a problem and then saying——

Mr. SHAYS. No, I understand. OK. Your point is that they can—if you complain about the 180 days, they can say, well, it's on your shoulder. Then you answer that, and if you complain again, they could ask you another question.

Dr. SAUNDERS. Right. It was alluded to here. I think a lot of the problem is, as I said, a reluctance to make a decision, spending an inordinate amount of time worrying about risks that are at best trivial. You've heard that from other people here, as well. I would say the risks are almost metaphysical, some of them.

Mr. SHAYS. I think that's true.

I yield to the gentleman.

Mr. TOWNS. Let me thank all three of you for your testimony.

Dr. Saunders, I really appreciate your shedding some light on this situation, because I was becoming very concerned about the fact that companies would not come forward. I think that in order to do something about this situation, to really fix it, that we must have dialog.

The fact that they were a little concerned about talking, I found that to be very, very disturbing, when FDA is saying they would like to fix the problems, and of course we are saying we would like to fix the problems, and I know that those companies out there would love for the problem to be resolved. But when you have just two doing the talking, sometimes that could become problematic.

I really think you have been very, very helpful in that regard. Let me just raise one question with you. As you are aware, the FDA has implemented the threshold of regulation policy, which abbreviates FDA's review of indirect additives that have little likelihood of causing any harm. I mean, it's almost a fact that it won't occur.

Packaging materials are an indirect additive. In your testimony you mentioned Frito-Lay's continual search for new and improved packaging materials. How has the threshold of regulation policy affected your company's ability to improve the packaging? Could you be specific in terms of how this has occurred?

Dr. SAUNDERS. We haven't yet come up with something that's going to slip underneath the bar of this regulation yet. Let me be very clear. I think this is a good idea that they had. I mean, it was a bold step forward. But at this point, the bar is quite low, and you have to have certain special conditions to be able to slip through that particular "loophole," so to speak. That's not a good word. But in any case——

Mr. TOWNS. I understand what you said.

Dr. SAUNDERS. I would like to see them extend this policy and raise the bar a little bit so that more materials could make it through. I mean, after all, we're dealing with plastics. We've been using these things for a lot of years. I think, in toxicology, we know quite well now what types of compounds can pose a hazard for man.

So I can't give you a specific example at this time, but I do very much endorse that concept.

Mr. TOWNS. Right. Thank you.

Dr. Callaway, you mentioned in your testimony that regulatory delays have impeded the introduction of food additives that would promote, as you put it, healthful diets. That, to me, is very, very important. How significantly have delays impacted the introduction of such products?

Dr. CALLAWAY. My impression as an outsider, because I'm not in the industry, is that a number of corporations have slowed down their own work in developing products like that because of the delays they have seen in the products that have already been submitted for—or the petitions have been submitted.

To my knowledge, there are few fat substitutes on the market which meet the taste test, and I think that problem can be solved with some of the technologies that are already available but have not been approved. So I think there has been a chilling or a dampening effect on companies developing products or bringing the products they already have to a further state because they have been waiting and waiting and waiting to see this field open up.

In all fairness, this is a brand new concept. We haven't had to deal with macronutrient food additives before. So it's a new playing field, and this may be a unique phenomenon. Once it's solved, it may not be as much of a problem again. But it really has dampened the innovation, I think.

Mr. TOWNS. Well, you know, when we look at where we are, in terms of health, and we know what fats will do, I think that should encourage us to try to move along as quickly as possible. That's what really bothers me, the fact that—when I hear some of these stories—20 years and 10 years and 10 years, and they tell me 3 or 4 years is nothing.

Dr. CALLAWAY. It's a generation for some of these products.

Mr. TOWNS. Yes.

Dr. CALLAWAY. And I think another thing, at least I've observed, is that the companies involved in making these products have legitimately restrained from implying health claims. And it's people like Dr. Davidson and myself who are in the trenches, if you will, who come out and say, "Look, there are health benefits here. Let's put the clothes back on the emperor. There's something here that's going to benefit some of us, if we can get these products approved."

Mr. TOWNS. Let me just thank all three of you—you, too, Dr. Davidson—for your testimony. I really appreciate the information that you have given us.

Mr. Chairman, we have a lot of work to do. And I also appreciate the fact that—as it was said earlier—the fact that you are having this hearing has started the process. If that's the case, then I'm really very pleased about that, as well.

Again, I thank all of you for your testimony.

Mr. SHAYS. I thank the gentleman.

I want to say again for the record that the FDA has been very, very cooperative with us, and we appreciate it, and we think that we can work together to help them move forward. I evidently sent a slight tidal wave by saying I wanted to speak to FDA people. My purpose for mentioning it was, one, to know if the FDA cared enough to stay to hear what you all had to say, and the panel before you, and the panel before them, and they did. So it was really, one, to gauge that interest. So I thank FDA representatives for being here.

I realize that talking to a Member of Congress, you have to be approved, not by us, but by the FDA. I just want to pass on some messages, so I look forward to a discussion with FDA people after this hearing.

Thank you, gentlemen, for being here. I appreciate it.

This hearing is adjourned.

[Whereupon, at 2:05 p.m., the subcommittee was adjourned, subject to the call of the Chair.]

DELAYS IN THE FDA'S FOOD ADDITIVE PETITION PROCESS AND GRAS AFFIRMATION PROCESS

THURSDAY, JUNE 29, 1995

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HUMAN RESOURCES AND
INTERGOVERNMENTAL RELATIONS,
COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:10 p.m., in room 2247 Rayburn House Office Building, the Honorable Mark E. Souder presiding.

Present: Representatives Souder, Towns.

Staff present: Lawrence J. Halloran, staff director and counsel; Anne Marie Finley, professional staff; Thomas M. Costa, clerk; and Kevin Davis, minority professional staff.

Mr. SOUDER. I call this hearing to order. I am going to read Mr. Shays' statement for the record, describing the hearing.

This hearing is a continuation of last week's oversight hearing into the causes and effects of lengthy delays in the Food and Drug Administration's review of food additive petitions. The subcommittee determined that the agency has a backlog of 295 food additive petitions, some of which have been pending at the agency since the 1970's.

As a result of this regulatory backlog, food companies have abandoned research into promising food additives. This, in turn, has affected the public health by preventing development of foods with new ingredients that could have significant health benefits.

Last week in testimony, the FDA presented their plan to jump start a system that is all but stalled for over 20 years. The plan provides a road map for reducing the backlog over a 3-year period. However, the FDA was unable to reconcile either its past performance or its future plans with the statutory requirement that the Secretary act on food petitions not more than 180 days after the date of filing of the petition.

In the intervening week Mr. Towns and Mr. Shays wrote to Secretary Shalala and requested that the Department of Health and Human Services articulate in a month's time a legislative proposal to assure the FDA's compliance with a reasonable deadline in which to approve or disapprove food additive petitions. They also requested that the department provide technical assistance to the subcommittee in the evaluation of other proposals to improve the food additive pre-market review process.

Today, we will focus on those proposals for reform, particularly the food industry's plans to improve the process. Central to this discussion is the role of the third party scientific analysis in the review of food additive petitions.

The relationship between the FDA and outside review bodies must be carefully defined. Determining the difference between the delegation of authority and the abdication of responsibility can be a subtle measurement involving complex science and one's perception of acceptable risk. Using outside scientific review also raises questions about the degree to which the FDA should be required to abide by third party findings and the burden of proof borne by each party at each stage of the process.

We appreciate the willingness of today's witnesses to share their expertise and proposals for reform of the food additive regulatory process.

I also have a brief statement I would like to put into the record, and I ask our distinguished ranking member, Mr. Towns, if he has a statement.

[The prepared statement of Hon. Mark Souder follows:]

PREPARED STATEMENT OF HON. MARK E. SOUDER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF INDIANA

On behalf of our subcommittee chairman, Congressman Chris Shays, I would like to thank everyone for joining us today for our second round of hearings on the FDA process for reviewing food additive petitions. Again, the purpose of these hearings is to help the subcommittee determine the causes and effects of the lengthy delays that many petitioners have experienced and to help the subcommittee look for common-sense solutions to expedite this process.

Last week we heard from officials of the Food and Drug Administration, including Linda Suydam, the Acting Deputy Commissioner for Operations. Joining us today will be witnesses from the private sector and from research institutions to tell us their views on the process and their constructive criticisms. I welcome all of you here and look forward to our discussion.

Mr. TOWNS. Thank you very much. Today begins the second day of testimony in what has already been a tremendously informative and productive hearing. Last Thursday we heard testimony by the FDA that brought to light the crisis that exists in the administration of the petition and review process. We learned, for example, that the FDA is not in compliance with the food additives amendment and, in fact, may not be able to comply with the statute.

The FDA has roughly 6 months to review and act on a petition; however, the average review time for direct additives petitions approved in 1995 is 20 months. As recently as 1990, the average review time of these petitions was almost 80 months.

How can we encourage new product innovation in light of these circumstances? It is very difficult. How can we promote improvement in the quality of food available to consumers, because the review process is so lengthy the number of pending petitions has mushroomed such that there is currently a backlog of 295 petitions, some of which date back more than 20 years.

As we hasten to find solutions to the problems with the petition review process, we should be mindful that the process always requires the cooperation and support of industry. Industry must provide the FDA with credible scientific data and must respond promptly to FDA's requests for additional information. Of the 295

petitions currently pending before the FDA, 84 are awaiting action by the petitioners before they can be reviewed by the agency.

Reforming the petition review process will be a cooperative effort that will involve the input of FDA, and will need the input of the industry, trade associations, and also consumer groups.

Testimony like Thursday raised a concern that one such group, industry, may fear reprisal for criticizing the FDA. I trust the integrity of the FDA officials that such fears are unfounded and I sure hope so and, most importantly, remain unrealized. We cannot afford to have the views of any group suppressed in our efforts to reform.

I am confident that the subcommittee can work with the interested parties to craft a solution that expedites the petition review process and insures the safety of America's food supply. I look forward to working with the committee, working with industry, and working with the FDA and working with consumers to be able to come up with something that we know that will work.

So, Mr. Chairman, on that note, I look forward to hearing from these witnesses and I yield back the balance of my time.

Mr. SOUDER. Thank you. For the record, I note that a quorum is present. I also ask unanimous consent that all members of the subcommittee be permitted to place any opening statements in the record, and the record will remain open for 3 days for that purpose.

Without objection, so ordered.

I also ask unanimous consent that our witnesses be permitted to include their written statements in the record. Without objection, that is so ordered.

The first panel—and I will read your name and group in the order of testimony. First is Kenneth Fisher from the Federation of American Societies for Experimental Biology; second is Stuart Pape on behalf of the National Soft Drink Association; third is Jerome Heckman from the Society of the Plastics Industry; and fourth is Donald Farley from Pfizer, Inc.

Would you all rise so we can give the oath.

[Witnesses sworn.]

Mr. SOUDER. Note for the record that all witnesses answered in the affirmative.

So, Mr. Fisher, if you would like to begin.

STATEMENT OF KENNETH FISHER, FEDERATION OF AMERICAN SOCIETIES FOR EXPERIMENTAL BIOLOGY; STUART PAPE, NATIONAL SOFT DRINK ASSOCIATION; JEROME HECKMAN, SOCIETY OF THE PLASTICS INDUSTRY; AND, DONALD FARLEY, PFIZER, INC.

Mr. FISHER. Thank you. Mr. Chairman and Mr. Towns, my name is Kenneth Fisher. I am the former director of the Life Sciences Research Office of the Federation of American Societies for Experimental Biology and a member of the American Institute of Nutrition. My testimony today is on the experience of FASEB in conducting the review of the generally recognized as safe (GRAS) food ingredients from 1972 to 1982.

FASEB organized a select committee on GRAS substances (SCOGS) in March 1972, for the purpose of assisting FASEB in providing FDA with evaluations of scientific information on the

safety of GRAS substances. The framework and operational flow of the GRAS evaluation process is appended to the statement which has been submitted.

Of the 468 substances considered during the 10 years, 422 were direct food ingredients and 46 were indirect packaging material components. The time for the review of any one substance during that period ranged from 6 months to 42 months, depending upon the extent and complexity of the information available.

Starting with a monograph or, in the case of a food additive petition, it would be analogous. This is different from other studies which FASEB has conducted for FDA, such as the current study for FDA on adverse reactions to monosodium glutamate, which is not a safety review.

Several aspects of the operations of the select committee during the 10 years contributed to the successful completion of the effort. There are several noted in the statement, but I would like to mention the ones that I consider most critical.

First, the members of the committee and the LSRO staff had a clear understanding that their role was to examine scientific data and information and that their reports were but one aspect of FDA's GRAS affirmation process.

Second, the meetings of the select committee were conducted in the total absence of the adversarial process.

Third, FASEB sought and received from FDA complete freedom to appoint members to the select committee and the staff based on FASEB policies and procedures without interference or approval.

Fourth, FASEB and FDA agreed and never deviated from, the concept of the clear separation of scientific evaluation process from the subsequent regulatory decisionmaking.

In summary, the 10 years of effort in reviewing the 468 GRAS substances for FDA did establish a framework for scientific evaluation process whose success, in my opinion, has been unequaled. It was successful because it insured the gathering of all relevant scientific data; it minimized bias of conclusions; it was conducted independently by a third party that acknowledged their role was to assist, but not replace, the responsible Federal agency; and, it also insured that a permanent record of the evaluated data and scientific conclusions were made available as a public resource.

Based on this experience in regard to the GRAS review process, the following questions and observations appear pertinent. Is there a precedent for third party review of food additive petitions? Yes, the mechanism developed by FASEB was used successfully by FDA from 1972 to 1982 and they used it again in 1984; furthermore, the mechanism has been used by industry since 1989.

Since the FASEB mechanism has focused on GRAS substances, how could it be used for food additive petition review? The process and procedures for evaluating GRAS substances are amenable to food additive petition review with minor modifications which all parties could agree upon.

Why has FDA not used FASEB or some other third party to do food additive petition review since 1982? In my opinion, the resources made available to the Center for Food Safety and Applied Nutrition within FDA have not been adequate; thus, they have had to make choice in priorities, and food additive petitions have had

a lower priority for other things such as regulations related to the NLEA.

Has science in the process of scientific evaluation been a major contributor to delays in the food additive petition process? I'll give a typical scientific answer: yes and no. Yes, in the sense that science is more complex and there are more data; no, in the sense that the regulatory process within CFSAN has, with increasing frequency, been more controlled by external needs than the process of scientific evaluation.

What would be required to have a third party review of food additive petitions by an organization, third party organization such as FASEB? First, they would require the resources to contract with one or more of these third party organizations; second, a willingness within the agency and the department to accept a structured extramural review; third, an open dialog by all interested parties to develop a set of guidelines for third party reviews; fourth, a recognition by all interested parties that the third party doing the scientific review is an independent scientific body evaluating safety and, as such, it is not involved in the legal and regulatory aspects of the food additive petition approval process; and fifth, a mechanism for getting the third party review into the public domain prior to FDA's final regulatory decision.

It would appear that these requirements might be met either with or without modification of regulations, or perhaps modification of the law. It appears to me that several things would not be necessary in the process if this process that was developed could be used in the future for food additive petitions. First, there would be no need for amendments to the food safety laws; and second, there would be very limited need for changes in the FDA food additive petition review process.

Mr. Chairman, that completes my testimony. I again thank you and the subcommittee on behalf of FASEB and AIN for having held this hearing and for inviting me to make a statement. I will be pleased to answer any questions that you might have.

[The prepared statement of Mr. Fisher follows:]

PREPARED STATEMENT OF KENNETH D. FISHER, PH.D., FORMER DIRECTOR, LIFE SCIENCES RESEARCH OFFICE, FEDERATION OF AMERICAN SOCIETIES FOR EXPERIMENTAL BIOLOGY

Mr. Chairman and members of the Subcommittee:

My name is Kenneth D. Fisher. I am the former Director of the Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology (FASEB), a position I held from 1977 to 1994. I have been a member of the scientific staff of the LSRO since 1968, and currently hold the position of Senior Scientific Consultant. In addition, I am a member of the American Institute of Nutrition (AIN), a constituent society of FASEB. FASEB and AIN are aware that I am presenting this testimony today on the experience of the LSRO/FASEB in conducting the review of Generally Recognized as Safe (GRAS) substances from 1972 to 1982. The factual aspects of the GRAS review are taken from documents published by FASEB that are noted in the references; however, the comments and recommendations concerning the current and future needs for expedited food addition petition review are my synthesis of experience from 24 years of working with the Food and Drug Administration (FDA), academia, industry, and consumers on food ingredient safety.

As you are aware, FASEB is an organization of nine scientific societies with a membership of 42,000 biomedical research scientists. The society members conduct research in the life sciences, and teach at major universities, research institutes, and government laboratories throughout the nation and world. The LSRO was es-

tablished in 1962 as a unit of FASEB to analyze specific problems in biology and medicine confronting research administrators in the public and private sectors. The Office furnishes expert evaluation of scientific issues through a unique mechanism involving ad hoc review of study topics by qualified scientists who are actively engaged in research. The majority of consultants participating in LSRO studies are members of the nine FASEB societies.

Documented reports are prepared that provide scientific and technological assessment of the subject. Each study report is peer-reviewed by an independent internal FASEB committee for clarity, objectivity, and scientific integrity. Where appropriate, reports include new research opportunities, specific recommendations, a comprehensive literature review,and reflect the knowledge and experience of the scientists who participate in the study and those of the LSRO staff. Emphasis is placed on developing a documentable factual basis, free of conflict of interest, for subsequent administrative decisions by the study sponsors. Each study is conducted on an ad hoc basis. That is, when the study report is transmitted to the sponsor, LSRO/FASEB considers the project completed. Nevertheless, the reports of each study are published in scientific journals or are made available publicly.

THE GRAS REVIEW

In March 1972, FASEB, through its LSRO, organized the Select Committee on GRAS Substances (SCOGS), a group of recognized scientists with expertise in biochemistry, nutrition, physiology, toxicology, food safety and pharmacology for the purpose of assisting FASEB in providing FDA with evaluations of scientific information on the presence or absence of adverse health effects associated with GRAS substances other than flavors, spices, and essential oils. The Select Committee, as with all LSRO/FASEB expert groups, was to advise FASEB, who in turn, transmitted evaluation reports to FDA. The framework and operational flow of the GRAS evaluation process is outlined in the figure appended to this testimony.

Monographs of the scientific literature, estimates of consumption, as well as special tests of mutagenicity and teratogenicity were prepared under contract with FDA by several organizations. These were supplied to LSRO/FASEB and formed the basis of the evaluations made by SCOGS. For completeness, LSRO staff checked monographs and other data provided for accuracy and completeness. Where deficient, supplemental materials were added by LSRO staff.

Monographs and other data were in the public domain and the open files of LSRO and the FDA. To further supplement the available information and data on each of the 468 substances, LSRO/FASEB announced in the Federal Register an opportunity for the public to submit additional information and data, either in writing or orally at a public meeting. Public hearings were held as requested, and the SCOGS utilized the submitted materials in reaching their conclusions on each GRAS substance.

In March 1982, the SCOGS completed its work. During the ten year period, the Select Committee prepared 141 reports and several supplemental reports on 468 GRAS and prior-sanctioned food ingredients. Of the 468 substances considered, 422 were direct food ingredients and 46 were indirect packaging material components. The LSRO/FASEB and the Select Committee, with the concurrence of FDA, devised five conclusion statements for their scientific opinions. These are noted in the table appended to this testimony.

Several aspects of the Select Committee's operations and activities contributed to the successful completion of the ten year effort. Some are major, others minor; some relate to administration and management, some are scientific; others clearly relate to human factors and the tenor of the times. All in all, they are important facets of the GRAS review experience.

In regard to the Select Committee itself:

- its members each had an acknowledged reputation for scientific knowledge and integrity;
- its members represented the multidisciplinary mix necessary to evaluate a multiplicity of health effects of food ingredients;
- its members (as consultants to FASEB) and the LSRO staff (as FASEB employees) had a clear understanding that their role was to examine scientific data and information and that their reports were but one aspect of FDA's GRAS reaffirmation process.
- its members recognized the need to seek outside expertise when required;
- its meetings were conducted with total absence of the adversarial process;
- its meetings were open and/or closed sessions depending on the meeting purpose;

- it established procedures to collect data from all sources, thus supplementing the scientific literature reviews provided by FDA; and,
- it consisted of a unique mix of individuals with remarkable perseverance, motivation, and dedication to reasoned scientific judgment.

In regard to LSRO and FASEB:

- it sought and received from FDA, complete freedom to appoint members of SCOGS and LSRO scientific staff based on FASEB policies and procedures, without interference or approval;
- it instituted and maintained a posture with respect to freedom from conflict of interest for both SCOGS members and LSRO staff that was subject to three levels of internal FASEB review;
- it made provision for adequate support staff for managerial and administrative activities in its contract with FDA;
- it made provision for adequate scientific staff who provided continuity in evaluating specific substances, who were accepted by the Select Committee members as partners in the review process, but who maintained a total separation from development of the SCOGS's scientific conclusions on each substance; and,
- it instituted a procedure for a higher level of internal review that focused on scientific objectivity and clarity of writing and completeness of the reports.

In regard to the contractual relationship with FDA:

- LSRO sought and FDA recognized a need for adequate time to collect, digest, and evaluate a large body of scientific data;
- LSRO built a continuing relationship with the FDA scientific staff that was grounded in mutual respect and regard for the boundaries of an external organization (FASEB) making evaluations on scientific data and a Federal agency that had a responsibility to reach regulatory decisions on the basis of a broad array of factors, of which science was but one.
- LSRO/FASEB and FDA agreed, and never deviated from the concept of clear separation of the scientific evaluation process from the subsequent regulatory decision making.

One aspect of the GRAS review process deserves additional mention. That is, the early decision to have a limited number of alternative conclusions that could be applied to a majority of the substances being evaluated. Based in part on discussions with FDA staff, the Select Committee adopted the five statements noted in the appendix table and used these for almost all of the 468 substance reviews.

There are several distinct advantages in proceeding in this manner. First, the SCOGS acknowledged their responsibility to decide which conclusion best fit the available information on a substance. They recognized the temporal nature of their decisions and the possibility that subsequent new information might require revisiting the SCOGS conclusions. In addition, the Select Committee avoided the tendency of cautious scientists to always require high-quality or complete data, and in the absence of such, to "write around" and reach no useful conclusions. Second, in developing reaffirmation decisions and in considering modifications to regulations, FDA experienced less difficulty in interpreting the SCOGS conclusions. Third, the repetitive use of a limited number of alternative conclusions provided the scientific community, industry, and the general public with a relatively concise indication of the Select Committee's evaluation of available scientific evidence of hazard or safety.

In summary, the ten years of effort of LSRO/FASEB in reviewing 468 GRAS substances for the FDA did establish a framework for a scientific evaluation process whose success is as yet unequalled because:

- it was conducted during a period when LSRO/FASEB staff sought and FDA administrators provided, adequate time for the evaluation process;
- it maximized the opportunity to ensure the gathering of all relevant scientific data;
- it minimized the possibilities for subconscious and indirect biasing of conclusions;
- it was conducted independently by a third party that acknowledged their role was to assist, not replace the responsible Federal agency; and,
- it ensured that a permanent record of the evaluated data and scientific conclusions were made a public resource.

FOOD INGREDIENT REVIEWS—1982 TO 1995

The concept of peer review and organization of expert panels evaluating scientific issues is very much a continuing activity of LSRO/FASEB. Since 1982, the LSRO has continued to provide FDA, as well as other Federal agencies, with review and assessment of scientific issues and questions. In regard to use of the procedures developed for the GRAS review, several studies are of interest. In 1984, in response

to public concerns over sulfiting agents, FDA asked LSRO/FASEB to reconvene the SCOGS to readdress the safety of these food ingredients. Using SCOGS members as a nucleus with additional expertise on allergenicity, a report was prepared on safety of sulfiting agents which FDA used in modifying regulated uses of the several sulfiting agents.

Since 1982, the lessons learned in the GRAS review process have been used in developing reports to FDA on trans-fatty acids, sugar alcohols, dietary fiber, estimation of exposure to substances in the food supply, evaluation of medical food safety, and safety of amino acids used as dietary supplements.

In addition, the GRAS review process has been used to prepare several reports for industry on appropriateness of GRAS status for new food ingredients. These reports for private sector sponsors deviate from SCOGS reports in several ways. First, because the ingredient is not yet in the foods, an estimated exposure must be calculated. Second, there are no experiential data on absence of adverse health effects to consider. And third, they conclude the scientific data and information is consistent or not consistent with GRAS affirmation. That is, the decision of GRAS approval is left to FDA if and when the sponsor files a GRAS affirmation petition with the LSRO/FASEB report on safety evaluation attached. LSRO/FASEB continues to maintain the capability to perform such food ingredient reviews upon request.

APPLICATION OF THE GRAS REVIEW PROCESS TO FOOD ADDITIVE PETITIONS

The central questions that this Subcommittee is addressing are the causes, effects, and possible solutions to the apparent delays in FDA's process of reviewing food additive petitions. You have heard testimony in regard to problems and the consequences of delays identified by industry, ongoing efforts of FDA to address the delays, and you will hear of two proposals for modifying the procedures to involve third party review of food additive petitions.

Based on the experience of the LSRO/FASEB since 1962 and specifically in regard to the GRAS review process instituted in 1972, the following questions and observations are pertinent.

1) Is there a precedent for third party review of food additive petitions?

Yes, an external mechanism has been developed by FASEB; it was used successfully by FDA from 1972 to 1982 and again in 1984; and, it has been used by industry since 1989 on a limited basis.

2) Since the FASEB mechanism has focused on GRAS substances, how could it be used for food additive petition review?

The process and procedures for evaluating GRAS substances are quite amenable to food additive petition review with minor modifications. First the petition itself could constitute the monographic database for review. Second, estimation of human exposures would need to be calculated and confirmed. Third, a procedure for handling proprietary information would need to be developed. While not an issue with GRAS substances, it would be needed in the case of food additives. Resolution of this matter for LSRO/FASEB would be relatively easy by modification of agreed-upon procedures.

3) Why has FDA not used LSRO/FASEB or some other third party to do food additive petition reviews since 1982?

LSRO/FASEB has continued to be under contract with FDA since 1982. However, most studies have been on key areas or basic scientific issues in nutrition and food safety. These apparently have had a higher priority than food ingredient reviews. Nevertheless, it is obvious that the resources made available to the Center for Food Safety and Applied Nutrition (CFSAN) within FDA have not been adequate and continue to be inadequate to their burgeoning workload. For example, during the development of regulations to implement the Nutrition Labeling and Education Act, the CFSAN scientific staff was almost totally assigned to that one year effort. They completed the task in the time required by Congress, but other duties fell by the wayside because inadequate additional resources were made available.

4) Has science and the process of scientific evaluation been a major contribution to delays in food additive petition review?

Yes and no. Yes, in the sense that science is more complex. Our analytical capabilities and our experimental procedures have advanced significantly. Smaller and smaller quantities of substances can be detected. More and more minute perturbations of metabolism can be identified. No, in the sense that while there are more data to evaluate, science is but one part of the process of food additive approval. The regulatory process with increasing frequency must accommodate legal challenges, reinterpretation of regulations, politics, lack of adequate Agency resources and environmental impacts.

5) What would be required to have third party review of food additive petitions by an organization such as LSRO/FASEB?

Several things would be needed:

First, the resources within CFSAN to contract with one or more third party organizations to conduct the reviews. The institution of petitioner fees seems a logical method of covering costs of third party reviews. Whether fees are paid directly to the third party or via FDA needs further consideration. There are precedents for both.

Second, a willingness on the part of FDA and the petitioner to accept certain criteria for extramural review such as those prepared by Dr. Sanford Miller in his testimony on June 22nd. They are essentially, derived from the GRAS review experience that Dr. Miller was a part of for most of the ten years.

Third, an open dialogue by all interested parties to develop a set of guidelines for interaction among the third party reviewers, FDA, the petitioners, and the public that would be incorporated into the contracts with third parties.

Fourth, a clear and concise contractual workscope that indicated the third party was responsible for only scientific data evaluation and not regulatory decision-making. In my view, it is important that the third party contractor should not be bound by the provisions of the Federal Advisory Committee Act.

Fifth, a recognition by all interested parties; that is, Congress, HHS, FDA, industry and advocacy groups, that the third party is an independent scientific body evaluating safety. Food law and regulations are complex (in the view of some, too complex); and the third party organization should not be involved in the legal and regulatory aspects of the food additive petition approval process.

Sixth, a mechanism for getting the third party review in the public domain prior to FDA's final regulatory decision.

But several things would not be necessary in such a process:

First, no new amendments to the food safety laws;

Second, no or very limited need for changes in FDA food additive petition review processes or food safety regulations.

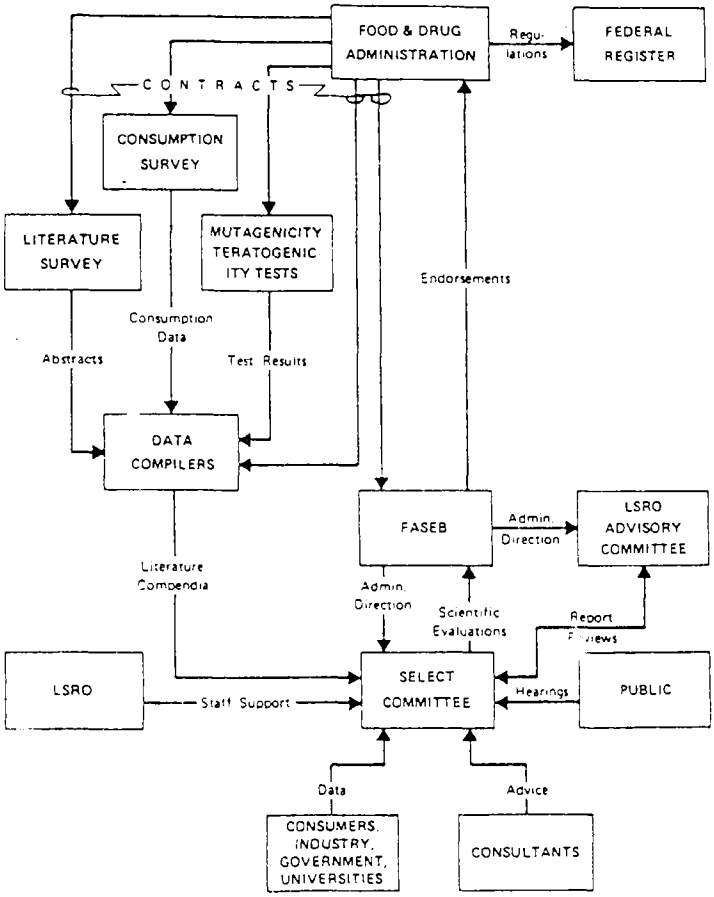
Mr. Chairman, that completes my testimony and I again thank you and the Subcommittee on behalf of the FASEB and AIN for having the hearing on this important issue in food safety, and for inviting me to make a statement. I will be pleased to answer the Subcommittee's questions.

APPENDED TABLE 1—CONCLUSIONS OF THE SELECT COMMITTEE ON 468 GRAS SUBSTANCES

1. No evidence of adverse health effects—continue as GRAS.
2. No evidence of adverse health effects, but additional data necessary if increased or new uses are contemplated—continue as GRAS with limitations on use.
3. No evidence of adverse health effects, but uncertainties exist—issue an interim food additive regulation requiring that testing be undertaken, but continue GRAS status until such tests are completed and evaluated.
4. Evidence is insufficient to determine if reported adverse health effects are not deleterious—require safe conditions of use be established.
5. Inadequate data on biological studies precludes evaluation—invite submission of data or, if none received, rescind GRAS status.

Of the 468 substances evaluated, the Select Committee concluded:

339 (72%) were No. 1
69 (15%) were No. 2
21 (5%) were No. 3
5 (1%) were No. 4
34 (7%) were No. 5



APPENDED FIGURE 1. FRAMEWORK AND OPERATIONAL FLOW IN THE LSRO/FASEB GRAS SUBSTANCE EVALUATION PROCESS.

Mr. SOUDER. Thank you very much. Mr. Pape.

Mr. PAPE. Thank you, Mr. Chairman. I am pleased to appear before this committee on behalf of the National Soft Drink Association to describe a realistic proposal for reform of the current food additive approval framework. The mechanism for food additive review in this country is broken. This situation is to the detriment of the American public and the food industry and deserves to be addressed by the Congress.

Previous witnesses have well-documented the adverse effects of the current system on innovation in food technology and, as a nation, we cannot afford to allow this situation to continue, particularly when a remedy to the problem is at hand.

There are numerous reasons for the problem. Most observers believe that FDA reviewers have become unduly cautious and conservative and, thus, unable to conclude that a particular substance under review is safe. Science in food additive review has become a tool to avoid answering important questions, rather than a foundation for making judgments as to safety.

In addition, far too many resources are devoted to indirect additive review and far too few resources are devoted to the review of significant new food ingredients.

It is also apparent that FDA perceives there to be no substantial harm to the public from the failures in the food ingredient review process and it, therefore, has invested no significant effort in repairing a broken process. FDA's perception is, of course, incorrect.

As a result of this inattention, there has been little creative debate over the proper role of FDA in review of food additives. Some have rashly suggested eliminating FDA's role entirely, or at least its role as a gatekeeper; however, achieving rational reform in food ingredient regulation does not mean eliminating FDA review or lowering the standards that help to provide consumers with a safe and wholesome food supply. Food processors and customers need to know that one governmental body, accountable to the Congress and the public, has passed upon the safety of ingredients. Thus, although serious problems must be addressed, the Federal Government must be the ultimate arbiter of the safety of food ingredients.

Reforming the food additive review process does not require massive changes to the law. No big fix is needed. The reform proposal developed by a broad-based group of food industry representatives will foster the development and timely review of new food additives while protecting the integrity of approvals. The proposal is not one to privatize the decisionmaking.

Reform means using the scientific resources of outside organizations to enhance the agency's ability to get the job done without significantly increasing Federal expenditures. It means bringing some finality to the process of additive review. It means deadlines for actions that are appropriate and real, and not merely advisory. It means a system that relies on sound science, establishes appropriate priorities, facilitates public participation, and requires credible decisions in reasonable time periods.

The proposal I will discuss today meets these criteria. Solving these problems requires a few discrete amendments to the law. A simplified notification procedure should be established for indirects and the use of external scientific reviews for the direct food addi-

tives. These two relatively simple changes have the potential to improve dramatically the efficiency of the process while maintaining a high level of consumer protection.

For direct human food and color additives, a new system of third party review should be established. This chart here illustrates how this system would work. Under the system, FDA would enter into agreements with at least three independent organizations which are qualified to review food additive safety data. FDA and the independent organization would review the data under appropriate but strict time periods. The FDA, the independent organization and the petitioner would freely communicate with each other during the review.

After a suitable yet finite period of review and interaction between the parties, 6 to 12 months perhaps, the independent organization would convene a public meeting to receive scientific testimony about the safety of the additive. This public meeting is critical to facilitating timely public participation in the food additive review process.

Within 60 days of the conclusion of the public meeting, the independent organization would present to FDA a detailed and publicly available report and recommendation concluding either that the additive had been shown to be safe or that safety had not been demonstrated. If the report concludes that safety has been demonstrated, a presumption of approvability will be created.

After receipt of the report, FDA would have 90 days to review the recommendation and either accept it and issue a regulation to allow the use of the additive, or reject it and so advise the petitioner of the reason. If FDA failed to take either action within the specified time period, it would be deemed to have accepted the report.

The presumption of approvability arising from a favorable report of the independent organization would be rebuttable by FDA only if it concluded that there existed substantial evidence to demonstrate that the additive has not been shown to be safe. Contrary to some suggestions, this is not a radical reversal of the burden of proving that the additive is safe. The petitioner would continue to bear the burden of demonstrating safety. The costs of the review by the independent organization would be borne entirely by petitioners who have requested this form of review.

This framework would enhance the efficiency of the process and bring some order and certainty to a process that is now anything but orderly and certain. Petitions would be reviewed in reasonable time periods because the independent organizations would be contractually obligated to do so and, presumably, would respond as the private sector typically does—if more or specialized reviewers are needed, they would be hired—and because real statutory time periods would be established under the law with teeth to enforce them.

Consumer protection would be maintained because the standards for decisions on additives would remain rigorous. FDA's role would remain central and critical. Its hand would remain firmly on the gate to the market. The solution for indirect additives is simple and my colleague, Jerry Heckman, will discuss the matter.

Overall, this industry proposal represents an achievable alternative to the currently dysfunctional food additive review process.

The resources and expertise of outside review organizations would be brought into the process. The credibility and integrity of FDA's food additive approval would be maintained.

Consumers and food processors would have access to these important new products in a timely fashion and would feel confident that they are safe to use. Food ingredient producers could depend on the certainty and timing of the process in making decisions as to investments in new ingredients.

And, overall, the public would get what we deserve: a food additive review function that fosters innovation, approves safe products that improve our foods, and one that protects us from ingredients that are not safe.

Thank you for the opportunity to provide this statement. I would be happy to address any aspect of the proposal I have described today.

[The prepared statement of Mr. Pape follows:]

PREPARED STATEMENT OF STUART M. PAPE, ON BEHALF OF THE NATIONAL SOFT DRINK ASSOCIATION

Good afternoon. My name is Stuart M. Pape. I am a partner with the Washington, D.C. law firm of Patton Boggs, L.L.P. and I appear before the Committee today on behalf of the National Soft Drink Association ("NSDA"). NSDA is the national trade association of the United States soft drink industry. NSDA's members manufacture, bottle, and distribute approximately 95 percent of all soft drinks consumed annually in the United States.

I am pleased to appear before you today to describe a realistic proposal for reform of the current food additive approval framework which has been developed by a broad array of food industry trade associations, including the Grocery Manufacturers of America, the National Food Processors Association, and the National Soft Drink Association, as well as many companies which are involved in the food additive process.

In my 20 years of practicing food and drug law, I have had extensive experience with the food additive process, both from within the Food and Drug Administration as FDA Associate Chief Counsel for Food and Executive Assistant to the Commissioner, and in private practice representing numerous clients in food additive matters. I have seen first hand the efforts of the staff and leadership of the food additive review function of FDA's Center for Food Safety and Applied Nutrition, and there can be no doubt that those professionals are attempting to do their job with the resources available and within the present framework. However, there are serious limits to what can be done within what is currently a flawed system.

THE BREAKDOWN OF THE FOOD ADDITIVE REVIEW PROCESS

Unfortunately, the mechanism for food additive review in this country is broken. This situation is to the detriment of the American public and the food industry, and deserves to be addressed by the Congress. Innovations in food technology, including new food ingredients, new aids for food processing, and new packaging, enable food companies to develop and offer consumers increased food choices. These choices include foods that offer fewer calories, less fat, or more fiber, as well as enhanced convenience. Examples include the development of fat and sugar substitutes, new fiber sources, and new types of packaging such as aseptic juice packages. Extraordinary delays in the FDA approval processes for new food ingredients seriously impede this much needed and desirable innovation in the food industry. As a nation, we cannot afford to allow this situation to continue, particularly when a remedy to the problem is at hand.

However, before I get to solutions, let me briefly describe the food additive approval framework and how and why the current problem developed. Since 1958, new food ingredients which qualify as "food additives" have been required to have FDA approval before marketing. Food additives include both those ingredients added directly to food to achieve a physical or technical function (sugar substitutes and antioxidants, for example—so-called "direct" food additives) and those substances that are used in food packaging or other food contact situations which may become part of the food through contact with it (so-called "indirect" food additives). Approxi-

mately seventy-five percent of the food additive petitions submitted to FDA are for indirect food additives.

Under the law, FDA has 180 days to review a food additive petition and to take action on it. Few, if any, food additive petitions are acted upon in the statutorily-prescribed time period, although, to be fair, 180 days is an inadequate time for the review of many food additive petitions. Rather, FDA action on a typical food additive petition, if it occurs at all, takes 4–6 years and, in some cases, twice as long as that.[1] Increasingly, as the graphs attached to this statement show, food additive petitions remain in "pending" status in perpetuity. For example, in 1982, there were about twenty petitions pending for direct food additives; by 1994, the number had grown to nearly fifty. With the exception of 1988, FDA took action on fewer than ten petitions in each of the years in question. In five of the years in question, FDA acted on fewer than five petitions. If one looks at all pending petitions (direct and indirect), the numbers are equally distressing: there are nearly 300 petitions pending while less than half that number were pending in 1982. The trend on petitions acted on is decidedly downward with about twenty-five actions per year on average whereas fifty or more petitions were acted on in 1982 and 1983.

WHY DID THE BREAKDOWN OCCUR?

There are numerous reasons why the food ingredient review processes are not working. Most observers believe that FDA reviewers have become unduly cautious and conservative and thus unable to conclude that a particular substance under review is safe. This caution is frequently exhibited in requests that reviewers make for more studies and data that have little, if any, relevance to the determination of safety for a food ingredient. Science in food additive review has become a tool to avoid answering important questions rather than a foundation for making judgments as to safety. It is significantly easier to make no decision at all and keep asking questions of petitioners rather than make a scientific judgment. To a large extent, this caution derives from an excessive fear of being criticized—criticized by consumer groups and the Congress.

A considerable part of the problem with the current system derives from the allocation of resources within the food ingredient review divisions of FDA. Far too many resources are devoted to indirect additive review and far too few resources are devoted to the review of significant new ingredients.

Of course, on occasion, petitioners also contribute to delays through submissions that are inadequate and because of the complexity of issues sometimes presented in petitions. However, these petition-related issues have always existed, and there is no reason to believe that they have grown in magnitude so as to significantly contribute to the dysfunctional nature of FDA's food additive review process.

It is also apparent that FDA officials have perceived there to be no substantial harm to the public from the failures in the food ingredient review processes and the agency therefore has invested no significant effort in repairing a broken process.

Indeed, this view was articulated as recently as last week when the agency testified that:

> Unlike drugs . . . [food additives] do not provide direct benefits that justify exposing consumers to risk. This is true even for food additives, such as artificial sweeteners, that may have a beneficial effect on the American diet. Even in the case of an artificial sweetener, for example, there are already safe and effective alternatives available to reduce caloric intake for anyone motivated to do so.[2]

FDA's perception that food additives do not provide direct benefits is, of course, incorrect. In the case of sugar substitutes, for example, some additives possess desirable functional properties—the capability to be used in baked goods and long shelf-life products, for example—that others do not possess. The availability of multiple sugar substitutes would provide substantial benefits to consumers.

Further, by taking so long to act on petitions, if it acts at all, FDA depresses investment in new food ingredients and technologies which then deprives consumers of the benefits that these new ingredients and technologies can offer. Indeed, few companies that have watched the delay and uncertainty in the current process would be willing to submit a food additive petition no matter what benefits their

[1] Attached to this testimony are several charts which illustrate the problems in the review of food additive and generally recognized as safe petitions.

[2] Testimony of Linda A. Suydam, Interim Deputy Commissioner for Operations, Food and Drug Administration before the Subcommittee on Human Resources and Intergovernmental Relations, Committee on Government Reform and Oversight, U.S. House of Representatives, June 22, 1995 at 2.

products might have. Simply put, the benefit of a functioning food additive review process is there, and must be valued by the agency.

Moreover, public attention does not tend to focus on the food additive review process. As the esteemed former FDA chief counsel Richard Merrill recently stated, there is " no Act-Up for food additives" no "vocal constituency for the benefits of new food technologies" as there is for new drugs and medical devices. Indeed, to my knowledge, in the 37 years since the passage of the Food Additives Amendment in 1958, this is the first Congressional hearing that has critically reexamined the process for food additive approval.

WHAT IS FDA'S PROPER ROLE IN REVIEWING FOOD ADDITIVES?

As a result of this inattention, there has been little creative debate over the proper role of FDA in review of food additives. Some have rashly suggested eliminating FDA's role entirely, or at least its role as the ultimate gatekeeper for the marketing of food additives. However, achieving rational reform in food ingredient regulation does not mean eliminating FDA review or lowering the standards that help to provide consumers with a safe and wholesome food supply. FDA's role is essential to the credibility of the process for consumers and the customers of food ingredient suppliers. Eliminating or unduly minimizing FDA's role in the process would result in confusion and a lack of accountability. Food processors and customers need to know that one governmental body, accountable to the Congress and the public, has passed upon the safety of ingredients.

Ensuring the safety of the food supply, including the safety of new food additives, is a fundamental governmental function that cannot credibly or efficiently be delegated in its entirety to the private sector. As a distinguished member of the Food and Drug bar has documented, the role of our government in ensuring the safety of our food supply, including what is added to food, is deeply rooted in the history of our country. Indeed, the important role of government in regulating what is added to foods was well recognized even in colonial days. For example, in 1668, the Massachusetts Bay Colony enacted a law that banned the used of a food ingredient known as "Turtooda's Salt, which leaves Spots upon the Fish, by reason of Shells and Trash in it."[3] As our country grew, and commerce increased, the importance of the Federal government in ensuring consistent and credible review of new food ingredients only intensified. This role is not properly characterized as a monopoly—it is a legitimate function of the public sector that should foster commerce and free enterprise without detriment to the public. Thus, although serious problems must be addressed, the Federal government must be the ultimate arbiter of the safety of food ingredients.

A PROPOSAL TO REMEDY THE FOOD ADDITIVE REVIEW PROBLEM

Reforming the food additive review process does not require massive changes to the law—no "big fix" is needed. Rather, a series of responsible and measured changes will result in a process that works for the food industry and for consumers. From that starting point, we have developed a reform proposal that we believe will foster the development and timely review of new food additives while protecting the integrity of approvals.[4] Such reform does not mean a notification process that essentially privatizes decision-making. Those who have criticized our proposal as a "privatizing" proposal are way off base. Reform means using the resources of outside organizations to enhance the agency's ability to get the job done without significantly increasing Federal expenditures. It means bringing some finality to the process of additive review. It means deadlines for action that are appropriate and real and not merely "advisory." It means a system that relies on sound science, establishes appropriate priorities, facilitates public participation, and requires credible decisions in reasonable time periods. The proposal I will discuss today meets these criteria. I suggest that other proposals, including that offered by my friends at Pfizer, do not meet these criteria and will not, therefore, solve the problems with the existing system.

Solving the problems with the food ingredient review processes at FDA requires amendments to the food additive portions of the Federal Food, Drug, and Cosmetic Act to provide for a simplified notification procedure for indirects—a procedure that

[3] Hutt, P.B., and Hutt, II, P.B., A History of Government Regulation of Adulteration and Misbranding of Food, 39 Food Drug Cosm. L. J. 2 (1984), citing The General Laws and Liberties of the Massachusetts Colony 54 (1672 ed.).

[4] Attached to this testimony is a detailed description of this proposal, a flow chart that illustrates how it would work, and legislative language to amend the Federal Food, Drug, and Cosmetic Act to implement the proposal.

will better harmonize the regulatory requirements with the issues presented—and to mandate the use of external scientific reviews for directs, when the petitioner requests that form of review and is willing to pay for the external review. These two relatively simple changes have the potential to improve dramatically the efficiency of the food additive review processes while maintaining the high level of consumer protection that the food industry and its consumers expect.

For direct human food and color additives (color additives are nothing more than food additives whose function in food is to impart color), a new system of "third party review" should be established. Under this system, FDA would enter into agreements with at least three independent organizations which are qualified to review the data contained in food additive petitions which demonstrate the safety and functionality of the additive. If the petitioner requests this form of review, it could designate which of the independent review organizations it wishes to conduct the review. FDA and the independent organization would review the data under appropriate but strict time periods. The FDA, the independent reviewing organization, and the petitioner would freely communicate with each other during the review. FDA would publish a notice of the filing of the petition within 30 days of receipt and thereafter the safety and functionality data in the petition would be available to the public (except for confidential commercial information and trade secrets). The time periods for the review begin with the publication of the notice of filing.

After a suitable period of review (six to twelve months, perhaps) during which time FDA and the independent review organization would be required to raise all potential issues with the petitioner (so that the petitioner can respond and so that the review process is not simply an endless series of questions posed to the petitioner without closure ever being reached), the independent review organization would convene a public meeting to receive scientific testimony about the safety and functionality of the additive. FDA, the petitioner, and the public would participate in this meeting. This public meeting and the enhanced access of the public to the safety and functionality data in a petition are critical steps to facilitating timely public participation in the food additive review process.

Within sixty days of the conclusion of the public meeting, the independent review organization would present to FDA a report and recommendation on the petition, concluding either that the additive had been shown to be safe (safety meaning a reasonable certainty of no harm from use of the additive under its intended conditions of use—the identical safety standard in use since 1958) or that safety has not been demonstrated. If the report concludes that safety has been demonstrated, a presumption of approvability will be created. The petitioner and the public will, of course, have access to the report. At the request of the petitioner, the time period for the report will be suspended (to allow, for example, analysis of existing data or the generation of additional data to respond to issues that have been raised during the review).

After receipt of the report, FDA will have ninety days to act on the recommendation by either accepting it and issuing a regulation to allow the use of the additive or by rejecting it and advising the petitioner in detail of the basis of the rejection. If FDA failed to take either action within the specified time period, it would be deemed to have accepted the report of the independent review organization and would have sixty days to issue a regulation to authorize the use of the additive.

The presumption of approvability arising from a favorable report of the independent review organization would be rebuttable by FDA only if it concluded that there existed substantial evidence to demonstrate that the additive had not been shown to be safe. Contrary to some suggestions, this is not a radical reversal of the burden proving that the additive is safe. The petitioner would bear that burden as it does now. However, once the independent review organization has concluded that safety has been demonstrated, FDA should not be able to frustrate the purpose of independent review and prevent the approval of the additive merely by identifying some question or issue that is unresolved. The conclusions of the independent review should determine the outcome unless there is a substantial basis for the conclusion that safety has not been demonstrated.

It has also been suggested that by requiring FDA to rebut the presumption of approvability with substantial evidence to demonstrate that safety has not been shown, somehow the safety of the food supply would be impaired and the agency's role trivialized to that of a paper pusher. Nothing could be further from the truth. As Dr. Sanford Miller and others have testified, FDA's role under the proposed scheme remains important and central, albeit different from what it now is. There is also ample justification for the "substantial evidence" requirement. Indeed, in its review of petitions to affirm the generally recognized as safe ("GRAS") status of food ingredients—where FDA would acknowledge virtually all GRAS petitioners begin marketing of the GRAS substance without FDA action on the GRAS petition—FDA

employs the equivalent of the "substantial evidence" requirement. That is, FDA does not challenge the marketing of a food ingredient on the basis of the petitioner's conclusion that the substance is GRAS, even where FDA has under review a GRAS affirmation petition, unless the agency possesses the equivalent of substantial evidence to demonstrate that the substance is not GRAS. The only novelty in our proposal is to apply a similar concept to food additives.

The costs of the review by the independent review organization would be borne entirely by petitioners who have requested this form of review. FDA would annually set forth the anticipated fees associated with the independent review (the actual fees incurred in a specific case would, of course, depend on the scope and complexity of the review required of a particular petition). Payment for the review would go directly from the petitioner to the independent review organization. FDA's contracts with the independent review organization would set forth the payment schedule for the petitioner (one-third initial payment, one-third at the conclusion of the public meeting, and one-third after delivery of the report and recommendations, for example). In addition, those contracts would provide for a refund of the petitioner's fee if the independent review organization failed to perform its tasks under the contract or failed to meet the timeframes for completion of those tasks.

For petitions pending at the time that this new process is instituted, the petitioner would have the option of withdrawing the petition and resubmitting it under the new procedures or to have the petition continue to be reviewed under the existing procedures.

This framework would enhance the efficiency of the process and bring some order and certainty to a process that is now anything but orderly and certain. Petitions would be reviewed in reasonable time periods because the independent review organizations would be contractually obligated to do so (and would respond as the private sector typically does—if more reviewers are needed to complete the reviews on time, more will be hired) and because real statutory time periods would be established under the law with teeth to enforce them. Consumer protection would be maintained because the standards for decisions on additives would remain rigorous. FDA's role would remain central and critical—its hand would remain firmly on the gate to the market.

The solution for indirect additives is simple and my colleague, Jerry Heckman, will discuss the problems of indirects in detail. I will briefly summarize our proposal.

Indirect additives which are not, by definition, added directly to food and which rarely become a component of food in scientifically meaningful quantities, do not require extensive petitions nor elaborate FDA review. It simply makes no sense to burden the regulatory process with hundreds of petitions for indirects and for FDA to devote substantial resources to the review of this category of substances. Consumer protection can be maintained at equivalent levels by substituting a notification procedure for the current one.

Under the proposed process for indirects, a notification would be submitted to FDA at least ninety days before the "food contact substance" was intended to be used. The notification would contain the identity of the substance, its intended use, and data and information to show either that the substance was not reasonably expected to become a component of food or that the substance is safe (the identical safety standard for direct human food and color additives). The notification would take effect in ninety days and use of the substance therefore allowed, unless FDA concluded that there existed substantial evidence to show either: (1) that the substance is reasonably expected to become a component of food, if that contention was the basis for a notification; or, (2) that the substance was not safe (again, the same standard as would apply to the rejection of a favorable report from an independent review organization for a direct additive). The notification would be confidential during the ninety day period, but would, except for trade secrets and confidential commercial information, be made public after ninety days. FDA would maintain a list of food contact substances which are the subject of effective notifications.

The term "food contact substance" would be defined as a subset of "food additive." Existing food additive regulations would be unaffected; likewise, the categories of GRAS and prior sanction would continue to exist for food contact substances.

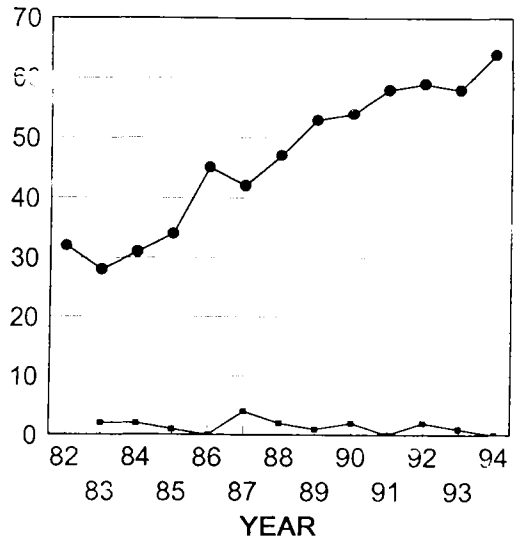
This simple notification system would facilitate the use of indirect additives and thus new or improved food packaging, while also ensuring that these substances are safe. FDA would continue to be made aware of new food contact substances and the basis for the manufacturer's conclusion that the substance is safe. Finally, FDA would have ample time and authority to prevent the use of a new food contact substance if it concluded that it was appropriate to do so. This notification system would consume considerably fewer resources than the current approach.

CONCLUSION

We believe this proposal represents an achievable alternative to the currently dysfunctional food additive review process. Although the resources and scientific knowledge of outside review organizations would be brought into the process, thereby bringing this country's best scientific minds to the review process, the credibility and integrity of FDA's food additive approval would be maintained. Consumers and food processors would have access to these important new products in a timely fashion, and would feel confident that they are safe to use. Food ingredient producers could depend upon the certainty and timing of the process in making decisions as to investments in new ingredients. Overall, the public would get what they deserve—a food additive review function that fosters innovation, approves safe products that improve their foods, and protects them from ingredients that are unsafe.

Thank you for the opportunity to provide this statement. I would be happy to address any aspect of the proposal I have described today.

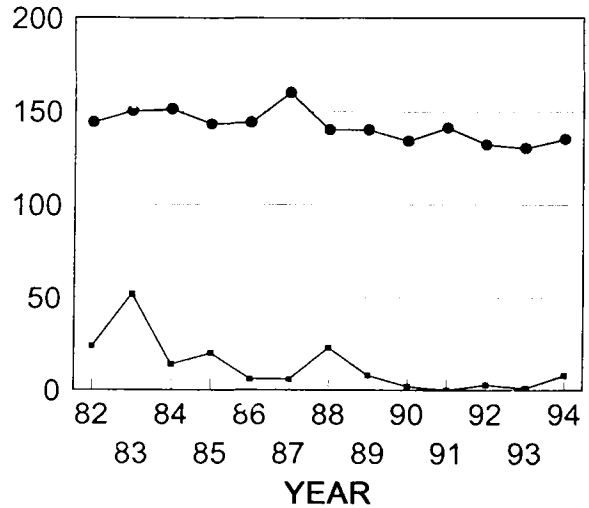
FDA GRAS Affirmation Trends
1982-1994



Industry Petitions Pending

Industry Petitions Approved

- No data for industry petitions approved in 1982



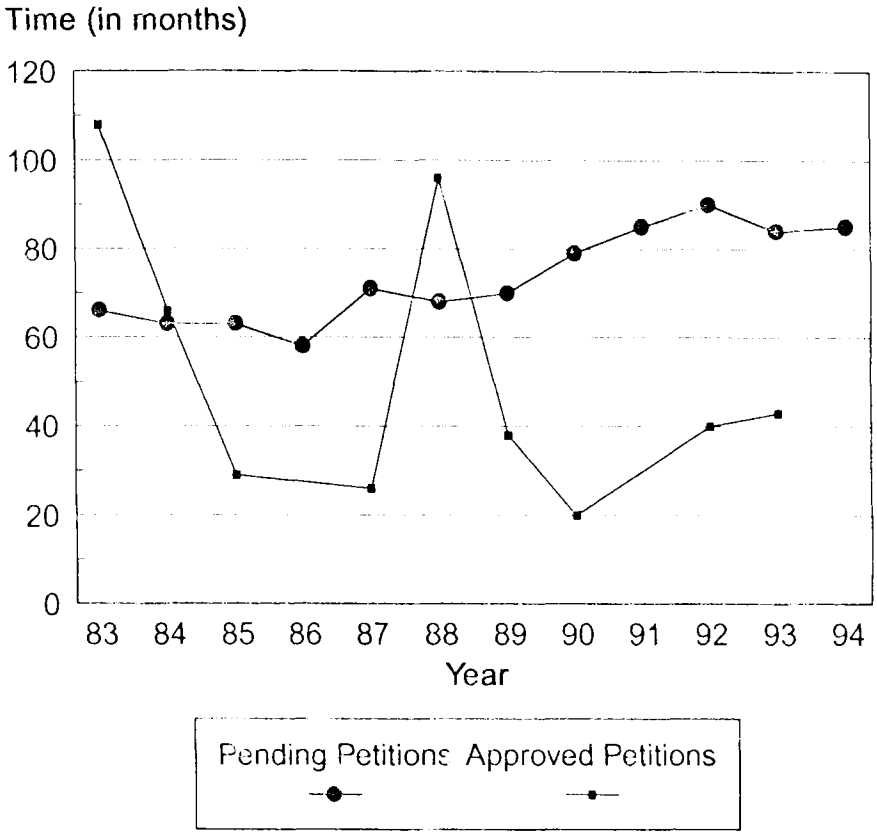
Total Petitions Pending

Total Petitions Approved

- Includes FDA and industry generated proposals

FDA GRAS Affirmation Petitions 1983 - 1994

Average Time Pending
Industry Petitions Only

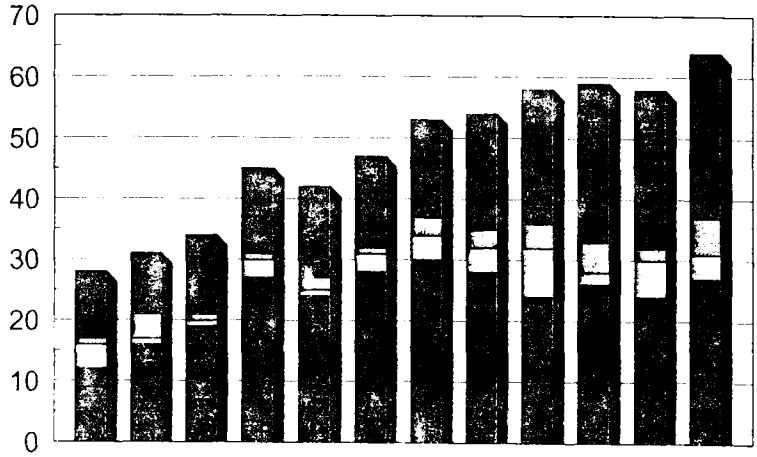


- For Approved Petitions, time from initial filing to approval; there were no affirmations in the years for which no average is given
- For Pending Petitions, time from initial filing to end of year

FDA GRAS Affirmation Petitions Pending 1983 - 1994

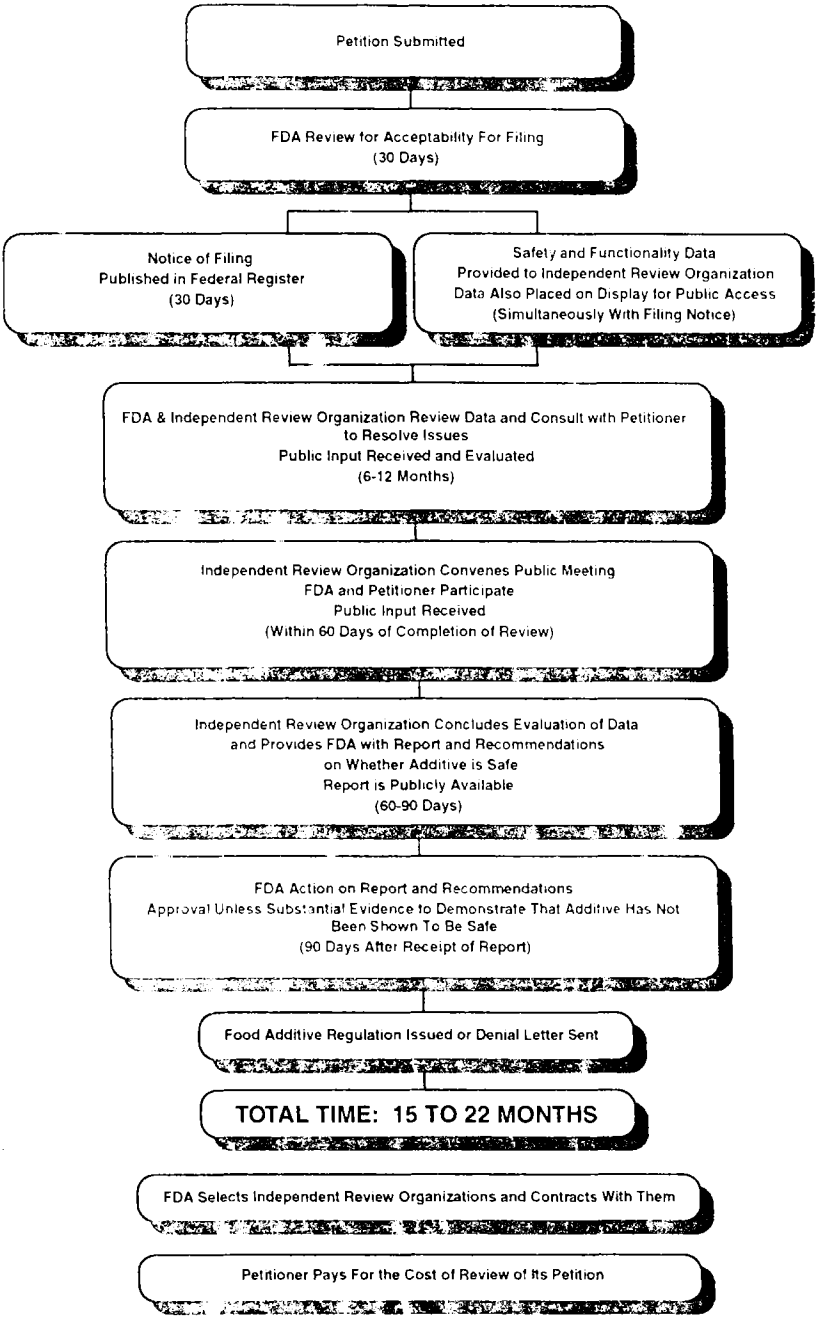
In months - Industry Petitions Only

Petitions Pending (total)



Year	83	84	85	86	87	88	89	90	91	92	93	94
1-12 mos	3	6	6	12	2	8	8	4	4	8	6	8
13-24 mos	2	3	5	6	10	2	8	8	4	3	7	5
25-36 mos	4	2	3	5	4	10	2	6	8	4	3	7
37-48 mos	2	4	1	3	5	4	8	2	6	5	4	3
49-60 mos	1	1	4	1	3	4	4	8	2	6	4	4
61-72 mos	4	1	1	3	1	3	4	4	8	2	6	4
73-84 mos	1	4	1	1	2	1	3	3	4	5	2	6
85+ mos	11	10	13	14	15	15	16	19	22	26	26	27

PROPOSAL TO REFORM FDA FOOD ADDITIVE PROCESS
THIRD PARTY REVIEW



Mr. SOUDER. Thank you very much. Mr. Heckman.

Mr. HECKMAN. My name is Jerome H. Heckman. I am the senior partner of Keller & Heckman and serve as general counsel to the Society of the Plastics Industry, whose members probably file more food additive petitions than any other industry segment. I greatly appreciate this opportunity to appear before this important oversight committee.

I would like to start by noting that I agree entirely with Mr. Pape's statement and with the recommendations that he has made, as well as those relating to indirect additives made last week by the National Food Processors Association and the Grocery Manufacturers of America.

My purpose here is to urge that Congress move to correct a legislative error that I feel occurred 37 years ago. I participated in those 1957 hearings and remain convinced that, at that time, there was an almost complete lack of knowledge about the differences between substances intentionally added to foods and those that are not intended to become food components at all.

Our inability to communicate effectively on this point in 1957 and 1958 because of the clamor at the time that arose as a result of the Delaney hearings. Fears that the public had about additives in general resulted in the inclusion of the language in the current food additives amendment that has led FDA to treat food contact materials as food ingredients when no scientific premise or real life experience existed or exists as a basis for this act. Thereafter, and contrary to what FDA indicated its treatment of such materials would be in the early statutory period from 1958 to 1960, the level of regulation has sort of fed on itself and intensified and become ever more complex for purely bureaucratic reasons totally unrelated to science.

My written testimony contains a lengthy discussion of the history of indirect additive regulation. I believe it is a sorry story, but it accurately reflects how the current overkill approach came to be and was made even more burdensome and necessary by the agency's bizarre actions and interpretations in the 1960's and 1970's.

Our main concern now is that unless this subcommittee moves to deal with this matter, expensive and wasteful overregulation of indirect additives for the past four decades will continue despite agreement by virtually everyone in government and industry that the uses and substances being regulated present no risk worthy of such regulation.

This is evidenced not only by the facts that I will recite, but even by testimony that I believe Mr. Jacobson will give later to the effect that most indirect additives are not likely to cause health problems. That is really the core of this matter.

No cases have ever been brought against a food product because of an uncleared indirect food additive, to the best of my knowledge. There have been no FDA seizures because of packaging and there have been no reported indirect additive-based health problems. Also, there have been no problems with the hundreds of substances cleared by no objection letters before the food additives amendment was adopted and some that were issued later.

Most important, there is basically no chance of a real problem arising in this area because the industry's customers, the food proc-

essors, have and will always insist on assurances of technological suitability and the absence of any significant migration from packaging to the foods they sell, so it is a self-executing system in principal part. My own experience is that the simple and most effective self-executing requirement that a package not cause any off taste or odor in food is, by itself, the strongest protector of the public health where packaging materials are concerned.

With almost 40 years of experience now to support the view that there is essentially no risk as a result of the use of food packaging or other food contact surfaces, what we urge is the replacement of the present arcane petitioning system as it relates to indirect additives with a 90-day pre-marketing notification plan essentially exactly like what FDA proposed last week for GRAS food ingredients.

Since indirect additives obviously present a lesser risk than any direct food additive, even GRAS ones, the only reason I can think of to explain why FDA is not recommending this same treatment itself for indirect additives as it has for GRAS substances is because the agency may have concluded that the statute does not permit this at the present time. And I suspect that, if pressed, I might have to agree with that.

That is why we consider it essential that the statute be amended as representatives of the food industry recommended in their testimony last week and as I have recommended in exactly the same language in my written testimony that I assume will be included in the record.

The virtues of such a pre-manufacture or pre-marketing notification system would be far superior to what we have for these reasons. First, it would be much more consistent with the level of risk presented and would yet let FDA pass on the safety of these ingredients in a more sensible way so that the wild iris that sometime might present a health hazard could be reviewed much more closely and would not be permitted to become effective. The notification would not be permitted to become effective. The way the proposal is written, that would be the course of action that could exist.

No. 2, adopting this system would eliminate more than half of the present pending food additive petition backlog that I believe this committee expressed great concern about last week. That would enable FDA to deal more promptly, hopefully, and in a more effective way in processing direct food additive petitions so that they could get that job done and perhaps reduce that backlog.

In addition, this system could be made self-liquidating from a financial point of view because there could be nominal service charges for the simple notification reviews, if that were desired. That would be feasible under this system and not under the current system because the current system involves petitioning and rulemaking, both of which I think are protected by the first amendment and probably, therefore, could be attacked if fees were assessed. That would no longer be the case under the pre-marketing notification plan.

Two other features that would be useful would be that these notifications, at least to a degree but protecting trade secrets, could be put on computer and on networks if need be so that foreign governments, for example, could know and, we hope, be influenced by what has been cleared in this country.

That is becoming more and more important because processes are underway in Europe which, in a sense at least or in effect at least, model our erroneous system and which, if continued to be followed, will impose substantial trade barriers and hasten difficulties in that area; whereas, if the new plan is adopted, I think it might help us harmonize with the Europeans a lot better.

We had an international conference here last week where a lot of this information was discussed. All of the leading European officials were here. All of them are proceeding down a path that is similar to the path taken with regard to indirect additives in the current food additives amendment. And I, as you will see if you get a chance to look at my full testimony, gave a talk in which I urged that that not be done and was pleased to hear that there was some interest in changing the pattern if we are able to do something about it in this country.

I appreciate this opportunity to present the committee with my views and stand ready to answer any questions I can.

[The prepared statement of Mr. Heckman follows:]

PREPARED STATEMENT OF JEROME H. HECKMAN, ON BEHALF OF THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

I. INTRODUCTION

My name is Jerome H. Heckman. I am the Senior Partner of the Washington, D.C., law firm of Keller and Heckman and also serve as the General Counsel of The Society of the Plastics Industry, Inc. ("SPI" or the "Society"). This statement is presented on behalf of SPI and reflects my 37 years of practicing food and drug law on behalf of the Society and a large number of chemical and plastics manufacturers. Having testified during the hearings that led to the Food Additives Amendment of 1958, I am grateful for this opportunity and consider it a special privilege to appear before this Subcommittee to urge the prompt enactment of some necessary and long overdue changes in the law.

SPI represents some 2,000 member companies and is the major national trade association of the plastics industry. Its membership represents over 90% of the production of plastics packaging materials (such as resins and adjuvants) in the United States. Since it was founded in 1937, SPI has served as the plastics industry's primary spokesman on regulatory and legislative matters of concern and, since 1956—two years before the enactment of the Food Additives Amendment—it has been the spokesman for the industry on food packaging regulation; this has occasioned our consistent and well-recorded protests against the over-regulation that we believe started soon after the Food Additives Amendment was passed. At the same time, we believe the Food and Drug Administration would agree that, since 1958, SPI has done more than any other organization to cooperate with the Agency in solving a variety of technical questions and in educating all industries on food packaging safety issues.

We view these hearings as the first real opportunity to correct a very obvious case of unnecessarily burdensome and expensive regulation. During its 37 years of existence, the Food Additives Amendment of 1958 has intruded into the packaging and equipment areas in such a way as to inhibit innovation and saddle industry with regulatory procedures that are not needed to assure public safety. We are unaware of a single FDA case aimed at condemning or seizing food because the packaging material or processing equipment used to make it presented a health hazard due to the chemistry of the products used. However, indirect food additives are subject to an incredibly complex, time-consuming, and costly regulatory clearance scheme of no real public health value.

II. INTRODUCTION AND STATEMENT OF POSITION

In the remainder of this statement, I will discuss (1) the need for, and history of packaging materials clearance prior to and after passage of the Food Additives Amendment of 1958; (2) the peculiar way in which the Agency embarked on a course that led to the present excesses in expenditures of time and money on this obscure aspect of food regulation; (3) the lack of any real public health problem here;

and (4) the points that militate in favor of a simple statutory change that will bring about a form of regulation that is consistent with the risk. My hope is that this discussion will lead you to conclude that a statutory change is needed and would very much serve the best interests of the public and good government. Change along the lines we suggest would bring about the following salutary revisions which I respectfully submit will be consistent with all of the government reform and reengineering objectives now being advocated so vigorously by legislators on both sides of the aisle:

1. A new procedure, whereby clearances will become automatic in ninety days upon the submission to FDA of all the relevant data now required, will lift the unnecessary burdens occasioned primarily by the inordinate amount of time the Agency takes to complete clearances; moreover, it will do so without any adverse effect on the public health. Such a system would be put in place by enactment of the attached (Appendix A) new "Food Contact Substances" section of Section 409 of the Federal Food, Drug and Cosmetic Act; this is the same change advocated by the National Food Processors Association and the Grocery Manufacturers of America during their testimony last week. This system would assure that FDA is even more fully informed than at present about what is being used and that it will have an adequate opportunity to prevent the sale of any product if one ever appears that presents a possibility of causing harm.

2. It is our belief that this system would result in regulation that is consistent with the limited nature of the risk. It is our further belief that it could be implemented with far fewer personnel than are now required to deal with indirect food additive petitions, that other FDA resources used unnecessarily in the bureaucratic clearance process would be conserved, and that reasonable charges (not in excess of $500 per filing) could be charged that would offset the government's costs for the clearances desired.

3. The enactment of legislation to authorize such a notification system would be entirely consistent with the intent expressed in FDA's testimony before this Subcommittee to the effect that it will be instituting the precise system we are advocating for petitions that seek affirmation of Generally Recognized as Safe (GRAS) status.[1] Since this FDA plan for allowing notification and an automatic 90 day effective time will include many direct additives where food ingredients are involved, it is clear that the Agency considers such a system sensible in a much more sensitive area than indirect additives. Indeed, it appears to us that the only reason FDA is not proposing it for indirect additives is because an indirect additives "notification only" plan will require legislative enabling action whereas the GRAS situation does not. Now that it is clear that the Agency is likely to have to seek legislation to cure its inability to take timely action under the current statutory deadlines, perhaps its position against sensible remedial legislation will become less fixed.

4. The action by Congress we urge will help provide a new model for the legislation now being adopted by the European Union and other countries around the world. The legislation now being considered and enacted overseas may be even more restrictive than the United States system and, therefore, is already presenting some serious non-tariff trade barrier problems. If Congress were to signal a change in approach here, our continuing friendly contact with the European Union and our efforts to bring about mutually desired harmonization could help avoid the creation of further unnecessary restrictions on international trade.[2]

III. STATUTORY AND REGULATORY HISTORY

A. FDA REVIEW OF FOOD CONTACT SUBSTANCES BEFORE 1958

Prior to 1958, to the best of my knowledge, there were no laws designed to govern the use of food packaging materials, per se. Many statutory systems, though, made it a criminal offense to sell adulterated or misbranded food. All of these provisions left little doubt that effective government action could and would be taken if anything, packaging included, adulterated food. Until 1958, the Federal Food, Drug, and Cosmetic Act thus did not require premarketing clearance for any type of packaging material. Nor were there any known problems that indicated a need to clear "indirect additives" in a formal way. Nonetheless, long before consideration of any

[1] See Oversight Hearings on Need for Modifying the Food Additive Regulatory Process Before the Subcomm. on Human Resources and Intergovernmental Relations of the House Comm. on Government Reform and Oversight, 104th Cong., 1st Sess. (June 22, 1995) (statement of Linda A. Suydam, Interim Deputy Commissioner for Operations).

[2] See Jerome H. Heckman, Esq., "Is It Time to Look For a New Approach to Harmonization?" address before the ICI/PIRA International Plastics for Packaging Food Symposium, in Washington, D.C. (June 21, 22, 1995), attached hereto as Appendix C, for a more complete explanation of this strategy.

specific legislation to require FDA review of food packaging materials, food industry purchasers of containers or equipment used in food-contact applications required some reasonable assurance that the products would not present any undue hazard to the public health or create any liability in the ordinary course of business. Food packagers and processors had to be convinced that the package could not reasonably be expected to adulterate the food or otherwise violate the Act.[3] These prospective customers were keenly aware of the necessity for protecting themselves against potential liability resulting from the use of food-contact materials that might in some way contaminate foods.

It was readily apparent to both the packaging materials providers and potential customers that one way of assuring statutory compliance would be to secure a written opinion by the appropriate federal authorities concerning the safety of a material or component for an intended use. Thus, data were submitted voluntarily to federal officials and their reactions were solicited to satisfy customers. The practice of soliciting a response from FDA was exceptionally widespread long before 1958.

Customarily, a company submitted its data, perhaps after conferences with the appropriate FDA officials, and received advice as to whether there was any objection to the proposed use, or whether additional data might be required. If more information was deemed necessary, it was supplied. The amount of data depended on the precise circumstances relevant to the specific packaging material. The important point is that FDA was being asked to examine only a specific product made by a specific manufacturer ready to supply all the information required to assure safety. In contrast to the present system, FDA was not attempting to devise broad regulations concerning the generic use of a packaging substance. Because of the specific nature of the inquiry, obtaining "no objection" letters from FDA was not an inordinately time-consuming or expensive matter. Usually, delays were attributable to a genuine need for additional scientific information.

Once questions bearing on safety were resolved, the manufacturer received one or more letters from FDA or the U.S. Department of Agriculture (USDA).[4] A typical USDA letter advised that a product was "acceptable for use in federally-inspected meat plants." An FDA response indicated that the Agency "would raise no objection" to the use of the product in food-contact applications.[5] The great virtue of these informal proceedings was the prompt establishment of a basis for allaying customer fears about possible government agency enforcement action.

B. FOOD ADDITIVES AMENDMENT OF 1958

1. LEGISLATIVE HISTORY

In large part, the Food Additives Amendment of 1958 resulted from the so-called Delaney Hearings held between 1950 and 1952.[6] To the best of our knowledge, the entire record of the Delaney Hearings and FDA's statements concerning a need for new legislation that would require formal agency clearance prior to marketing dealt only with substances directly and intentionally added to foods. Unfortunately, this avowed necessity for new regulatory authority to control the intentional and direct addition of various substances to food resulted in legislation that regulated packaging and processing materials in precisely the same way as substances deliberately added as food ingredients.

I recall quite vividly an appearance in the 1957 hearings by the Chairman of the SPI Food Packaging Materials Committee urging that the 1958 Amendment not apply the same law to both direct additives and food-packaging components. On behalf of SPI, he recommended the passage of a bill that would make "mandatory the advance submission of pretesting data to the FDA prior to the marketing of new substances . . . " through a system of premarket notification. Laws addressing food and intentional additives to food, he argued, should not be "indelicately applied to

[3] 21 U.S.C. §§301 et seq.

[4] In November, 1982, USDA published a proposed rule to clarify that USDA letters are not a mandatory premarket approval process and that letters from materials' manufacturers assuring compliance with applicable Food Additive Regulations are sufficient. 47 Fed. Reg. 50,914 (Nov. 10, 1982).

[5] This pre-1958 approach is used for essentially all food-contact applications in Canada since Canadian law exempts packaging materials from the type of regulation imposed on direct food additives. See generally, Canadian Food and Drug Regulations, Section "B.01.001(e)". See Michael A. Pelletier, "Food Packaging Regulations in Canada," address before the ICI/PIRA International Plastics for Packaging Food Symposium, Washington, D.C. (June 21, 22, 1995), attached hereto as Appendix D.

[6] Hearings Before the House Select Comm. to Investigate the Use of Chemicals in Foods and Cosmetics, 81st Cong., 2d Sess. and 82d Cong., 1st and 2d Sess. (1950–1952); see H.R. Rep. No. 2356, 82d Cong., 2d Sess. (1952).

packaging components without careful deliberation." The industry feared that a rulemaking system for food additives would prove cumbersome and misguided when applied to packaging materials and that it would undoubtedly stifle innovation, require an immense increase in FDA's budget, create delay in securing regulatory approval, and ultimately limit manufacturer and consumer choices for food packaging.[7]

Unhappily, little discussion took place about the potential impact of the legislation on so-called indirect additives. It is with some personal regret that I confess we were unable to attract Congressional attention to the problems inherent in the approach taken under the 1958 Amendment. The past thirty-seven years have proven that industry fears concerning the effects of a premarketing clearance system were justified. Indeed, experience teaches that the dangers of over-regulation were understated in the 1958 hearings.

2. STATUTORY PLAN

The Food Additives Amendment of 1958 added two significant provisions to the Act concerning FDA regulation of food packaging. First, it added a definition for "food additive." Section 201(s) of the Act defines a food additive as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly in its becoming a component . . . of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food . . .)" except for substances that are generally recognized as safe by qualified experts or are prior-sanctioned.[8]

Secondly, it declared, in Section 409 of the Act, that any food additive shall be deemed unsafe unless it is used in conformity with a regulation issued by FDA or an investigational use exemption. To support promulgation of a regulation, the manufacturer must file a petition with FDA containing the necessary safety information. Based on this submission, the Commissioner makes a determination on the safety of the packaging material under the intended conditions of use. This includes an evaluation under the prohibitions of the Delaney Clause, embodied in Section 409(c)(3) of the Act.[9] In addition, the rulemaking encompasses consideration of the probable consumption of the additive, the cumulative effect of the additive in the diet and other safety factors.[10]

The statute directs FDA to issue a regulation authorizing use or an order denying the petition within 90 days after the petition is filed. FDA may extend the 90-day period an additional 90 days if it deems it necessary to study the petition. The regulation or order must be published, objections may be received and public hearings held. Judicial review may follow.

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[7] Food Additives, Hearings on Bills to Amend the Federal Food, Drug, and Cosmetic Act with Respect to Chemical Additives in Food Before the Subcomm. on Health and Science of the House Comm. on Interstate and Foreign Commerce, 85th Cong., 149–153 (1957–1958). Others expressed similar misgivings. 1958 Food Additives Hearings at 207–208 (National Canners Association), 410 (Waxed Paper Institute), 444 (American Paper and Pulp Association), and 482–488 (Adhesives Manufacturing Association); see also, pp. 494–495 (Supplemental SPI Statement).

[8] 21 U.S.C. § 321(s):

"The term 'food additive' means any substance the intended use of which results or may be reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include——

(1) a pesticide chemical in or on a raw agricultural commodity; or

(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or

(3) a color additive; or

(4) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act, the Poultry Products Inspection Act (21 U.S.C. 451 and the following) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 and the following);

(5) a new animal drug; or

(6) an ingredient described in (ff) in, or intended for use in, a dietary supplement."

[9] 21 U.S.C. § 348(c)(3).

[10] Section 409(c)(5) of the Act, 21 U.S.C. § 348(c)(5).

C. FDA REGULATION OF "INDIRECT ADDITIVES"

FDA's erratic treatment of indirect additives over the course of the last thirty-seven years has been nothing short of a roller coaster ride for industry, all in the face of knowledge that the use of packaging and like materials presents no real public health concern.

1. 1958–1961: AGE OF REASON

After passage of the 1958 Amendment, FDA initially exercised its new regulatory authority over packaging materials in a reasonable manner. Agency spokesmen advised manufacturers that if extraction studies indicated no migration, then the packaging material was not a food additive.[11] Often, packaging manufacturers would submit the results of extraction studies and obtain formal concurrence from FDA that the packaging was not a food additive or presented no food additive problem. Indeed, FDA rejected some food additive petitions for packaging materials on the basis that extraction studies indicated no migration with methods sensitive to 1 ppm. The Agency simply concluded that the packaging was not reasonably expected to become a component of food and was not a food additive.[12]

2. 1960'S: TESTING MEANS THERE IS "MIGRATION"

FDA's reasonable interpretation of the term food additive as applied to packaging substances began to erode within two brief years. In 1960, for reasons unrelated to public health and safety, the Agency abruptly abandoned its formal practice of concurring in non-additive status where extraction studies indicated an absence of migration.

Industry maintained that FDA had an obligation under its procedural regulations to provide clear advice on the status of products under the 1958 Amendment. In response, the Agency's attorneys stated that if a company went to the trouble of conducting extraction studies, the company must have believed that some or all of its product might reasonably be expected to become a component of food, and, therefore, the product or its components are legally food additives even though the extraction studies detect no migrating materials.[13]

Under this theory, there really could be no meaningful exemption for packaging materials that did not migrate to the food. As a practical matter, no responsible manufacturer would conclude that a food-contact substance is not a food additive without performing some type of extraction study.

3. EARLY AND MID-1970S: TEST TO EQUILIBRIUM

In the seventies, FDA scientists again began advising manufacturers in a few cases that a packaging material would not be considered a food additive if no detectable extraction was observed with a validated analytical method when the material was tested "to equilibrium" in accordance with the Agency's guidelines.[14] These official guidelines were intended to provide an estimate of the maximum amount of a packaging substance that might migrate to foods under intended conditions of use.

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[11] "Food Packaging Under the Food Additives Amendment-What Needs to be Done," pp. 2,3. Paper presented by Mr. Arthur Checchi (then Assistant to Deputy Commissioner Harvey) at the 14th Annual Paper and Plastics Conference, Chicago, Illinois (September 22, 1959):

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

[12] Color Additives, Hearings on H.R. 7624 and S. 2197 Before the House Comm. on Interstate and Foreign Commerce, 86th Cong., 2d Sess., 104–5 (1960).

[13] This FDA legal theory was first formally explained in an address given by the then Deputy Commissioner of FDA, John L. Harvey, at Rutgers University on January 18, 1962. In pertinent part, Deputy Commissioner Harvey's explanation was as follows:

"We came to the conclusion that we had opened Pandora's box and had better find a way to close it before the situation got completely out of hand. We therefore reevaluated our position after consultation with our legal counsel and came to the conclusion that basically, if there was enough reason to run extraction studies on packaging or equipment materials, why shouldn't it be concluded that it would be reasonable to expect that the substances involved would, in fact, become a part of the food? Since the law refers to 'reasonably to be expected' we then began to advise those who asked that we were not in a position to give them a letter which would absolve their product from any responsibility under the Food Additives Amendment but instead suggested that they file petitions. That is the present status of this item." Harvey, Food Additives and Regulations, 17 Food Drug Cosm. L.J. 275 (1962).

[14] FDA Guidelines for Chemistry and Technology Requirements for Indirect Additive Petitions (March 1976); these guidelines were updated and re-issued in 1995 as Recommendations for Chemistry Data for Indirect Food Additive Petitions (June, 1995).

Thus, FDA required that the testing exaggerate time, temperature and exposure conditions. On rare occasions, FDA reviewed a manufacturer's data indicating no migration based on extraction studies performed under simulated conditions of use and issued letters stating that "no food additive problem" was presented.

4. FDA'S REGULATION PREDICATED ON THEORETICAL DIFFUSION

In the context of an essentially adjudicatory proceeding in 1977, FDA chose not to rely on measurements or sound projections of migration as a basis for regulating packaging. Rather, it adopted a position that would have based the regulation of packaging components on a principle derived from the second law of thermodynamics. That principle predicts some migration, however minor, when any two substances come into contact. In other words, FDA asserted jurisdiction based on the theoretical diffusion of the packaging components into the food as opposed to regulating packaging components as food additives only when there is significant detectable migration into food under intended conditions of use.

The United States Court of Appeals for the District of Columbia Circuit rejected this position in Monsanto Co. v. Kennedy.[15] There, the court held that FDA must determine with a fair degree of confidence that a substance actually migrates into food in more than insignificant amounts before it becomes a food additive. The Court also ruled that FDA has discretion to decline to regulate when it finds migration to be "insignificant."

5. THRESHOLD OF REGULATION

In 1990, after the appearance of a seminal paper written by Dr. Alan Rulis of FDA,[16] under the sponsorship of SPI, the Canadian Center for Toxicology (CCT) convened a panel of renowned independent experts to study the scientific concepts for evaluation of trivial, or de minimis, carcinogenic and non-carcinogenic risks resulting from low level exposure to food-contact substances. The study was designed to evaluate the scientific basis for the safety of trace levels of food-contact materials that may migrate into food or otherwise become components of food.[17] The panel concluded that substances present in the diet at concentrations below 1.0 part per billion (ppb) can be considered safe even if no toxicity testing has been performed on the specific chemical, if there is no reason to believe that the substance demonstrates unusual toxicological properties. For substances with some toxicology data which indicate a lack of genotoxic potential, a regulatory threshold might be set at a higher level based upon classical toxicological principles.

In keeping with this principle, on October 12, 1993, FDA published a notice of proposed rulemaking for the Agency's threshold of regulation policy, which is currently being applied informally by FDA to the evaluation of food-contact materials.[18] The threshold policy is described as a "process for determining when the likelihood or extent of migration to food of a substance used in a food-contact article is so trivial as not to require regulation of the substance as a food additive."[19] FDA proposes to exempt non-carcinogenic food-contact substances from the need for regulation based either on a showing that the dietary concentration of the substance does not exceed 0.5 ppb or that the substance is regulated as a direct food additive and its use in the proposed food-contact application will not represent a dietary exposure in excess of 1 percent of the acceptable daily intake. The policy will permit exemption of substances that contain carcinogenic constituents or impurities, provided the TD_{50} of the constituents is 6.25 mg/kg body weight per day or greater.[20]

While SPI views the Threshold policy as a significant and welcome step forward, the Threshold of Regulation concept falls short in two respects. First and foremost, in FDA's proposal, rather than concluding that indirect additives that meet the "threshold" can be marketed immediately without any FDA review, FDA proposed that a Threshold of Regulation determination resides solely with the Agency and that FDA's explicit concurrence regarding the applicability of the Threshold policy

[15] 613 F.2d 947 (D.C. Cir. 1979).

[16] Alan M. Rulis, "De Minimis and the Threshold of Regulation," Food Protection Technology 29 (1987).

[17] The full report and all of the individual papers written as part of the study were published in the August, 1990 issue of Regulatory Toxicology and Pharmacology, the Journal of the International Society of the Regulatory Toxicology and Pharmacology (ISRTP). See Munro, "Safety Assessment Procedures for Indirect Food Additives: An Overview," 12 Regulatory Toxicology and Pharmacology 2 (August, 1990).

[18] See 58 Fed. Reg. 52719, et seq. (Oct. 12, 1993).

[19] Id. at 52719.

[20] Id. at 52727. The TD_{50} is the feeding dose that causes cancer in 50 percent of the test animals.

is necessary. Thus, to fall under the Threshold policy, a company is required to submit a written request for FDA's no objection to the use of a material.

The second shortcoming of the Threshold policy stems from the first. FDA readily admits that Threshold requests are backlogged at about six months, about the statutory time frame for the review and action on a full scale food additive petition.

D. TIME REQUIRED FOR FDA CLEARANCE

The current conventional system used by FDA to clear indirect food additives where the concept of threshold of regulation does not apply is archaic, has proven unnecessarily demanding given the safety track record for such substances, and is patently inefficient in the use of manpower and other scarce resources. In the words of a distinguished colleague, these processes are "bankrupt" and constitute a complete failure.[21] The proof of this bankruptcy is immediately visible in the fact that obtaining action on a simple packaging Food Additive Petition requires anywhere from 1 to 5 years or more.[22]

Under existing section 409(c)(2), FDA is required to act on a food additive petition within 90 days, although it may extend this period an additional 90 days, if needed, for a total time of six months. Although the statutory mandate is clear, the time limits are meaningless in practice. By way of illustration, in the period from 1990 through 1994, of those indirect additive petitions on which FDA ruled favorably, 15% of the petitions had been pending for one year or less, while another 30% had been pending for up to two years; almost 30% had been pending for more than three years. This is particularly egregious considering that of the 105 petitions ruled on in this period, only 8 related to major components of food packaging materials. The remainder were for minor constituents (generally present at levels considerably below 1% of the packag( ) and substances with only incidental food contact.

The situation looks even worse when all pending petitions are considered, since a significant number of these remain before the Agency for many years. For the calendar years 1990 to 1994, the number of petitions filed annually ranged from a high of 41 in 1993 to a low of 19 in 1994, with the average being about 32 petitions per year. Yet, at the end of each year, between 94 and 131 petitions were still pending, i.e., 3 to 4 times the average of petitions submitted per year. As of the end of 1994, 90% of the pending petitions had been pending in excess of the six-month statutory time limit.

Based on statistics more fully set forth in Appendix B of this statement, averages over the period 1990–1994 show that about 72% of the petitions are still pending after one year and 47% are pending over two years. Approximately 30% are still pending three years after filing.

These figures clearly represent unacceptable delay but, in fact, they understate the actual amount of time the petitions have been before the Agency. When a manufacturer wishes to obtain FDA clearance for an indirect food additive, it is common practice to correspond and/or meet with Agency personnel prior to filing the petition to discuss data needs and testing approaches. Moreover, because of the difference between the official filing date and the actual submission to FDA, determining the total time a petition has been pending is difficult. Typically, a petition will have been pending for at least several months (and in some cases, a year or longer) before a filing notice is published. Thus, the figures presented here and in Appendix B necessarily understate the length of time from submission of a petition to final FDA approval. Certainly, some delay must be attributable to petitioners who do not respond to FDA requests for clarification or additional information. However, there is

[21] Peter Barton Hutt, Esq., "Approval of Food Additives in the United States: A Bankrupt System," address before the Annual Meeting of the Institute of Food Technologists (June 5, 1995), at a symposium in his honor. Mr. Hutt is a former Chief Counsel of the Food and Drug Administration. The following quotation from pages 20, 21 of this paper is particularly relevant to this presentation. With respect to FDA indirect additive petitions, Mr. Hutt noted:

"Indirect food additives are important, serve a highly useful purpose, and should not be given inadequate attention. At the same time, they do not deserve the same degree of scrutiny and FDA priority as new food additives added in significant amounts directly to the food supply. It is apparent that a completely separate and different process, with far less government involvement, must be identified and put in place for the category of indirect food additives."

[22] Alan M. Rulis, Director of the Division of Food and Color Additives, Food and Drug Administration, "The Food Additive Petition Process: An FDA View," address before the National Meeting of the Calorie Control Council, LaJolla, CA (November 9, 1992) Transparency No. 4 and pages 4–9.

something drastically wrong with a system where the time limits are met only one time in ten.[23]

IV. INDIRECT ADDITIVES DO NOT WARRANT THE CURRENT REGULATORY SCHEME

A. PACKAGING PRESENTS REGULATORY CONCERNS THAT ARE DISTINCT AS REGARDS CONCERNS ABOUT DIRECT ADDITIVES

Separate statutory treatment for packaging and other food-contact substances is merited because the use and potential for ingestion of these substances differ dramatically from substances directly and deliberately added to food. When substances are directly and intentionally added to food, there is little, if any, disagreement concerning their presence or the quantity involved. The only issue to decide is whether the additive is safe. For packaging materials and other food-contact substances, however, the controlling question is often whether any of the material migrates into food and, if so, how much. If no detectable migration is demonstrated with an adequately sensitive test method, toxicological issues are essentially irrelevant.

FDA recognizes these differences. In 1982, the Agency issued a revised handbook for assessing the toxicological properties of direct food and color additives. To explain why the handbook did not apply to indirect additives, which are treated separately, FDA stated:

> The safety review of indirect additives often involves different chemical structure classes, and special problems in estimating consumer exposure, *including the possibility of migration of minuscule amounts of chemical substances to food that make them of extremely low or no toxicological concern in terms of food safety or for the purposes of applying legal standards.* Therefore, FDA intends to publish a separate system of tiered information requirements for indirect additives.[24] (Emphasis supplied.)

B. MARKET FORCES ADEQUATELY REGULATE PACKAGING

The record of the past 40 or 50 years has demonstrated that packaging materials components are subject to sufficient industry imposed strictures and that there is, at best, doubt as to the necessity for any government regulation.

The technological acceptability for use of a packaging material from the viewpoint of the food processor is in and of itself a very substantial limiting force which may well be sufficient to assure suitability and safety of 90% of the packaging components of commercial interest. With rare exceptions perhaps, experience indicates that concern about a packaging material is usually signalled by a food taste or odor problem which, obviously, will restrict the use of the component. No government action is needed to do this restricting. Food processor customers will not use such materials; they do not reach the public at all.

C. INNOVATION IS STIFLED BY FDA'S CURRENT REGULATION OF PACKAGING

Innovation in the packaging world is a fast moving process, one that is incompatible with requirements for government action that can hold up a new use or a new material for anywhere from 6 months to 4 or more years even if the product is one that will clearly qualify for Threshold of Regulation treatment in the United States. In today's fast moving global markets where the emphasis on competition is so intense, it is unacceptable for government command and control processes in the United States to make world-wide marketing a nightmare due to regulatory requirements that are unrealistic and seem to exist more to block new products or uses unnecessarily than to deal with any true public health problem.

Enactment of a premarket notification system for food contact substances will assist the United States in promoting the international harmonization of packaging laws in a sensible, cost-effective, and non-restrictive way.

V. A PREMARKETING NOTIFICATION SYSTEM FOR INDIRECT ADDITIVES IS MERITED OVER THE BURDENSOME CLEARANCE SYSTEM IN PLACE

FDA's current regulation of indirect food additives has become a burden on government and industry and "the flame here is simply not worth the candle." To coin a phrase, "there must be a better way." As far as food contact substances are con-

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[23] In testimony prepared in 1983 for the Senate Committee on Labor and Human Resources on the need for food safety amendments to the Federal Food, Drug, and Cosmetic Act, we noted that during the period of 1977 to 1982, only one petition in four was acted on within the statutory timeframe. The situation has grown even worse in the intervening years.

[24] FDA, Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food, p. 5 (1982) (NTIS No. PB83-170696).

cerned, the "better way" embodies an entirely new approach to regulating what are essentially the very minimal risks presented by components of food contact surfaces. I say the proposal is "new," but this is not entirely true; in principle, it embodies some of the same concepts we attempted to advance (1) in 1957 in HR 8115, a bill introduced by then Congressman Miller of Nebraska as an alternative to the packaging coverage parts of the bill that became the Food Additives Amendment in 1958, and (2) a similar premarketing notification plan introduced into both the House of Representatives of the United States (HR 4014) and the Senate (S 1442) in 1981.

It is our view that a premarketing notification system should be enacted to replace the entire system of Food Additive Petition filing for food contact substances. A premarketing notification system would permit any company to advise FDA in a formal notification about everything it tells the government now in a Petition or a letter requesting a "no-objection" response.

The change in the law we seek would provide that all such premarketing notifications would become effective within 90 days unless FDA concludes that substantial evidence demonstrates that the food contact substance may reasonably be expected to become a component of food and that risks to human health presented by the food contact substance under the intended conditions of use are not negligible or insignificant. If this system is enacted, delays in clearances would be no more than 90 days except in cases where screening of a notification gives rise to a proper government concern, something that experience has taught happens only rarely in the course of FDA regulation of packaging materials.

The essence of this new approach is the fact that it would automatically reorient the use of government skills and time so that they would be spent primarily on areas of real concern and not on having to process and write regulations for a myriad of minor food contact substances. The savings in time that would occur by use of this system would be enormous, commerce would benefit, and FDA would likely be more fully informed than it is now about what is being used. We would be on the road to prioritizing and using resources on the basis of risk instead of being bound to a system that exalts form over substance where insignificant risks are concerned.

Under this approach, modest filing fees could be charged for such food contact materials notifications since they would be basically proprietary. This could relieve FDA of some of their resources shortages occasioned in part by the fact that they must now draft, internally circulate, and negotiate broad regulatory language for every additive, no matter how insignificant, if any sort of food additive petition is filed.

This premarket notification plan accords with the current interests of the Administration and Congress in eliminating excessive regulation in favor of more rational, less costly approaches that, nonetheless, provide the public with the protection to which it is entitled.

I ask you to consider this set of possibilities and the added benefits that a premarketing system with self executing effective dates for registrations could bring in the way of making the marketing of safe, cleared components a timely event, one consistent with the needs of everyone in the chain of commerce, and with the low risk level involved.

VI. CONCLUSION

The experience of the last 37 years teaches that industry significantly underestimated the burdens that would be imposed by the 1958 Food Additives Amendment and that Congress also misjudged the adverse effects that would follow. There is a pressing need for a simplified approval procedure for food-contact substances apart from the existing rulemaking proceeding designed for direct food additives. At the present time, it can take three or more years between the filing of a food additive petition and final approval. Ultimately, FDA has been forced to misallocate or waste its administrative resources in the food area. Moreover, current law can be and is construed to bar substances even when the risk is insignificant.

We urge the Subcommittee to develop legislation as soon as possible that recognizes the need for a premarket notification system for indirect additives as an alternative to the Food Additive Petition rulemaking process. Such a provision is long overdue.

Again, I appreciate this opportunity to present the views of the plastics industry and would be glad to answer any questions the Subcommittee may have on our position.

APPENDIX A

FOOD CONTACT SUBSTANCES

(a) Amend section 409(a) by deleting "or" at the end of paragraph (1) and the period at the end of paragraph (2); insert a semicolon at the end of paragraph (2), followed by "or," and insert the following new paragraph (3):

"(3) in the case of a food contact substance as defined in subsection (p)(4), there is in effect, and it and its use or intended use are in conformity with, a notification submitted under subsection (p) of this section."

(b) Amend the concluding paragraph of section 409(a) to read as follows:

"While such a regulation relating to a food additive, or, in the case of a food contact substance, a notification, is in effect, a food shall not, by reason of bearing or containing such an additive or food contact substance in accordance with the regulation or notification, be considered adulterated within the meaning of clause (1) of section 402(a)."

(c) Amend section 409 by adding at the end thereof the following new subsection (p):

"(p)(1) At least 90 days before being introduced or delivered for introduction into interstate commerce, the manufacturer of a food contact substance shall notify the Secretary of the identity and intended use of the substance and provide the Secretary with information to establish either that the substance is not reasonably expected to become a component of food, if the manufacturer has elected to file a notification in such circumstance, or that the risk of the use of the substance under the intended conditions of use is negligible or insignificant.

"(2) A notification submitted under this paragraph shall become effective after ninety days unless the Secretary concludes that there is substantial evidence to demonstrate either that the food contact substance is reasonably expected to become a component of food, if that was the basis of the notification, or that the risks of the food contact substance under the intended conditions of use are not negligible or insignificant, in which case the Secretary shall promptly notify in writing the person who submitted the notification of such conclusion and the basis for it. The decision of the Secretary to deny effectiveness to a notification shall constitute final agency action subject to judicial review.

"(3) The Secretary shall keep confidential any information provided in a notification under paragraph (1) for 90 days following receipt. After the expiration of 90 days, the Secretary shall place the information on public display, except for matters in the notification which are trade secrets or confidential commercial information.

"(4) For purposes of this section and section 402, the term "food contact substance" means any substance intended for use as a component of materials used in commercially manufacturing, packing, packaging, transporting or holding food or other substances used in commercial food contact surfaces if such substance may reasonably be expected to result, directly or indirectly, in its becoming a component of food, and is not intended to have any physical or other technical effect in such food."

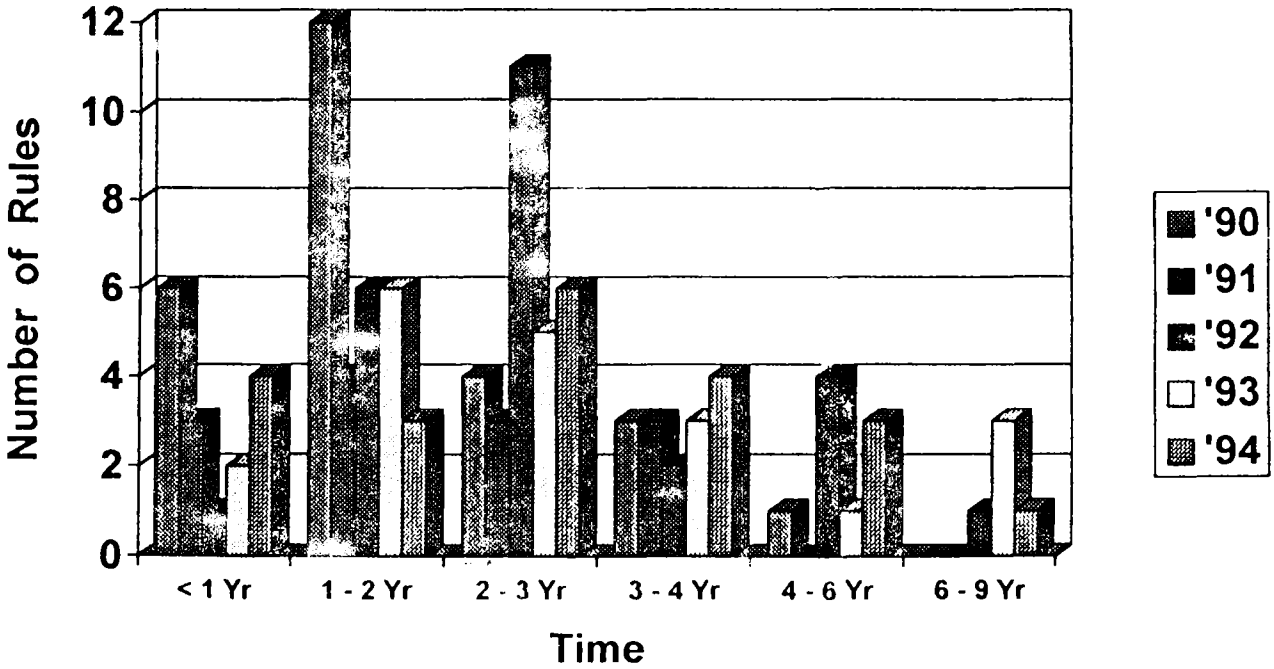
APPENDIX B

PETITION REVIEW TIMES (1990–94)

[Indirect Food Additive Petitions]

	Number of Rules
Petition Filing to Final Rule:	
less than 1 Yr	16
1–2 Yr	31
2–3 Yr	29
3–4 Yr	15
4–6 Yr	9
6–9 Yr	5

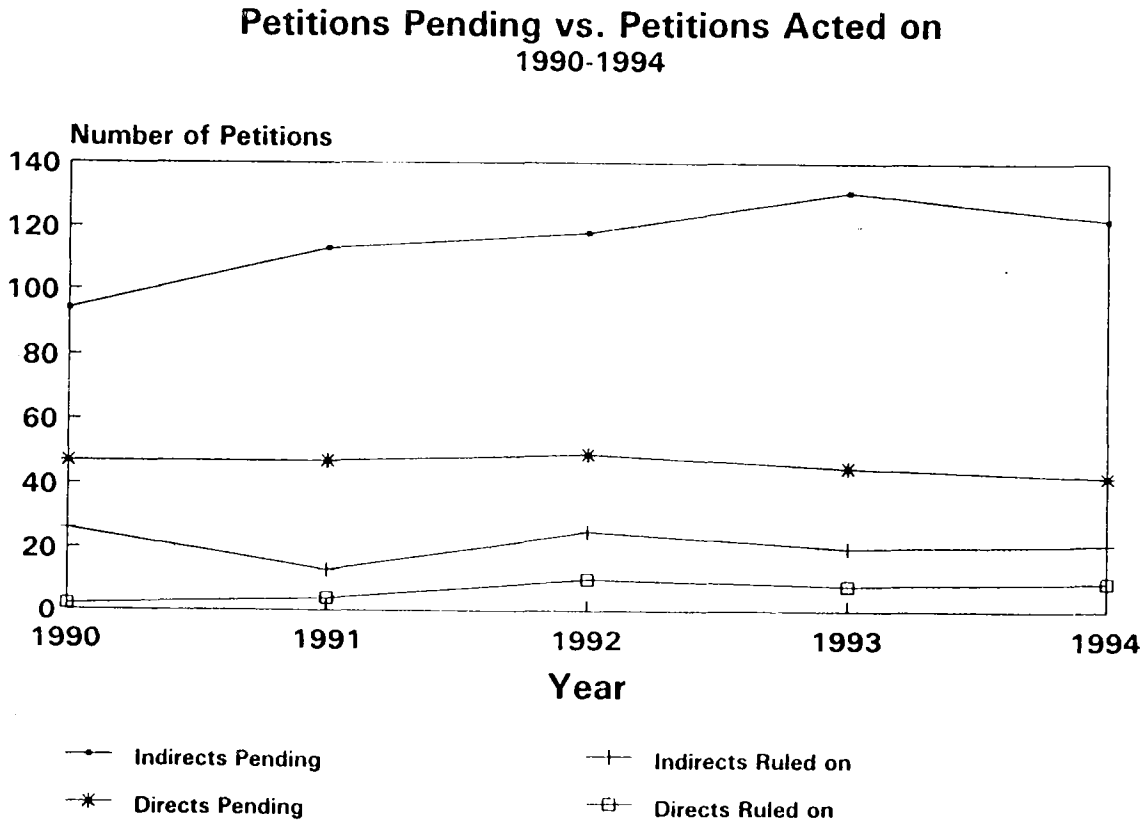
PETITION TO FINAL RULE
(Indirect Food Additive Petitions)



INDIRECT ADDITIVE PETITIONS PENDING AT END OF YEAR—NUMBER OF YEARS UNDER REVIEW

1990–1994

Years Pending	Number of Petitions Pending				
	1990	1991	1992	1993	1994
less than 1	31	36	33	39	18
1–2	27	25	34	27	34
2–3	15	22	17	26	21
3–4	5	10	12	14	18
4–5	6	4	8	8	11
5–6	3	6	2	7	5
6–7	1	3	4	2	6
7–8	3	1	2	2	2
8–9	3	3	1	.....	1
9–10	.....	3	2	1	.....
10–11	.....	.....	3	2	1
11–12	.....	.....	.....	3	2
12–13	.....	.....	.....	.....	3
TOTAL	94	113	118	131	122


Petitions Pending vs. Petitions Acted on
1990-1994
Number of Petitions
140
120
100
80
60
40
20
0
1990
1991
1992
1993
1994
Year
Indirects Pending
Directs Pending
Indirects Ruled on
Directs Ruled on

INDIRECT ADDITIVE CLEARANCES BY INTENDED APPLICATION

[1990–1994]

Year	Major Component of Food Package	Minor Component (usually < 1%) of Food Package	"Incidental" Additives*
1990	1	15	9
1991	0	8	5
1992	2	12	11
1993	2	8	8
1994	3	14	4
Total	8	57	37

* "Incidental additives" includes, e.g., non-food contact components of food packages, components of food processing equipment, and sanitizing solutions and lubricants for treating food processing equipment.

INDIRECT ADDITIVE PETITION TIMING AND COSTS

	Time Required (Months)	Typical Costs
PETITION PREPARATION/SUBMISSION:		
Analytical Studies	2–12	$15,000–100,000
Toxicological Studies*	2–24	5,000–300,000
Administrative**	2–12	20,000–70,000
TOTAL TIME AND COSTS:	6–48	$40,000–470,000

* Cost of toxicity testing does not include cost of chronic (two-year) toxicity and carcinogenicity studies, which almost always are prohibitively expensive for indirect additives.

** This includes, e.g., initial analysis of FDA status, preparation of test protocols, assembly and review of pertinent data, preparation of petition and environmental assessment, post-filing follow-up with FDA.

FDA REVIEW:	
"Simple" Petition	1–2 yrs
"Complex" Petition	3–4 yrs, frequently longer

[FDA estimates 250–500 person hours to review a petition.]

FOOD ADDITIVE PETITIONS RECEIVED BY FDA

1990–1994

Type of Petition	1990	1991	1992	1993	1994	total
Indirect	32	36	33	41	19	161
Direct	12	7	11	9	8	47
Irradiation	1	2	1	2	2	8
Veterinary	3	0	3	0	2	8
Total/yr	48	45	48	52	31	224

PETITIONS ACTED ON (1990–94)

[Indirect (105) vs. Direct (33)]

Year in Final Rule	Number of Rules	
	Indirect	Direct
1990	26	2
1991	13	4
1992	25	10
1993	20	8
1994	21	9

APPENDIX C

IS IT TIME TO LOOK FOR A NEW APPROACH TO HARMONIZATION?[1]

This is the third time you have honored me by giving me a platform before what is becoming the most important plastics food packaging forum in the World. I am particularly pleased that you have chosen my home city for your meeting place, and that so many of the major figures in the packaging regulatory universe are here with us to tell us about their views on regulatory methodology, analytical chemistry systems, and international harmonization. I am sure we are all as anxious as ever to help bring about true harmonization so that regulatory hurdles with no true relationship to public health will not continue to constitute artificial trade barriers and inhibit the exchanges of goods between the nations of the world.

In light of certain recent changes in the regulatory climate in this country, I decided it might not be as futile as I have believed in recent years to go back to some very basic principles and analyze the regulatory systems applicable to packaging materials under the crucible of whether they really make common sense. This seems like an especially good question to ask when one looks at the record and notes that obtaining the sort of clearances that most companies feel they must have, i.e., clearances from the Food and Drug Administration by way of formal regulations and clearances from the European Union by way of listings in the Monomers Directive (90/128/EEC) or the famous Synoptic Document, requires so long that, at best, innovation and trade are discouraged and, worse, clearance delays and confusion are causing a complete loss of respect for all such systems. Thus, it is my thesis here that it is time to consider once again what it is the world community is trying to accomplish in this area. It is just possible that we are all seeking to kill a mouse with a herd of elephants.

Prior to 1958, to the best of my knowledge, there were no laws designed to govern the use of food packaging materials, per se. There were, of course, many systems that made it a criminal offense to sell adulterated or misbranded food. All of these provisions left little doubt but that effective government action could and would be taken if anything, packaging included, adulterated food. This provided an impetus for food processors to demand safety assurances from the suppliers of packaging and packaging materials components. More specifically, at some point prior to 1958, perhaps beginning at the end of World War II, or even earlier, food processors in the United States began to demand that their packaging materials suppliers get what have come to be known as "no objection" letters from the Food and Drug Administration and the United States Department of Agriculture. I suspect that the same was true in some of the European countries since I know, for example, that the Canton scientists in Switzerland and the forerunners of the Health Protection Branch in Canada were issuing such letters before I entered upon the practice of food and drug law almost 40 years ago.

And, again, what was the driving force for obtaining such letters by the presentation of suitable analytical chemistry and related scientific data? Certainly not public outcry or governmental agencies made fearful by some dramatic health threatening incident like Sulfonilamide or Thalidomide—there has never been such an incident relating to packaging materials. Nor has there ever been serious concern about the safety of packaging on the part of government or any responsible authority—they invariably label packaging and similar food contact applications a low priority issue even if it is one that commands a great deal of staff time and attention. The driving force was purely and simply a matter of needing to reassure food processor customers and anyone who sold packaging to them that they need not be worried about their packaging materials contaminating foods.

I suggest to you that this basic drive remains the main reason for the excessive regulatory construct which has risen up to deal with what is essentially a non-problem in the public health world. As I see it, the 37 years of expansive command and control regulation by the Food and Drug Administration, and my exposure to it and to the European move in this same direction in the past twenty years, have in no way changed the following basic perceptions.

It is my belief that almost all of us can agree on these facts:

1. The technological acceptability for use of a packaging material from the viewpoint of the food processor is in and of itself a very substantial limiting force which may well be sufficient to assure suitability and safety of 90% of the packaging components of commercial interest. With rare exceptions perhaps, experience indicates that concern about a packaging material is usually signalled by a food taste or odor

[1] Prepared for presentation at the ICI/PIRA International "Plastics for Packaging Food" Symposium in Washington, D.C., June 21 & 22, 1995.

problem which, obviously, will restrict the use of the component. No government action is needed to do this restricting. Food processor customers will not use such materials so they do not reach the public at all.

2. In the few cases where new toxicological data has given rise to questions about the use of a few monomers or additives in food packaging applications, e.g., vinyl chloride or acrylonitrile, the new safety data came to light as a result of testing done to determine whether such substances presented workplace or similar hazards where the exposures were enormous as compared to anything that might result from a food contact application. In such cases as those of vinyl chloride and acrylonitrile used to make polymers, no government action was required to delimit their use in food packaging. Immediate steps were taken by industry to make certain that any public exposure to the offending chemicals from such uses would be so insignificant that the government agencies found it possible to agree that they could continue to be used. For example, as regards vinyl chloride, in Europe this was done by special EEC directives limiting residual monomer in polyvinyl chloride articles used in packaging. In the United States, the same end was achieved by recognizing that unwanted constituents present at extremely low levels in packaging materials give rise to no Delaney Clause or other safety concerns. Thus, everywhere these materials are still permissible for use, and industry, under pressures imposed by the marketplace, not governments, have made their products in ways that leave no doubt about the safety of their use.

3. The passage of time has shown that scientists like Jack Frawley,[2] a special United States Academy of Science: National Research Council Panel,[3] and FDA's Lessel Ramsey[4] were always correct in advocating a degree of packaging deregulation because of their recognition that the use of the same methods to regulate direct and indirect additives ignored the fact that food contact substances more often than not present no risk worth regulating, much less over-regulating. The new FDA Threshold of Regulation proposal finally demonstrates recognition of the principles espoused in the earlier work. This evolution was hard in the borning but is laudable in all respects; it seems to be failing only in that European scientists are expressing reluctance about accepting it and FDA now has a backlog of 6 to 8 months for acting on threshold inquiries.[5]

In sum, the record of the past 40 or 50 years has demonstrated that packaging materials components are subject to sufficient industry imposed strictures and that there is, at best, doubt as to the necessity for any government regulation. As a minimum, it should be clear as a matter of common sense that the level of regulation imposed should be consistent with the risks presented and should be no more burdensome than is really necessary to protect the public health. Excessive regulation results in the misuse of scarce scientific and administrative talent, and of equally scarce public and private funds. Moreover, it results in unnecessarily complicated procedures, intolerable delays, and policies that frustrate general understanding as well as harmonization, thereby creating serious non-tariff trade barriers without a conscious intent to do so.

There are also some derived truths here that must be stated to make this analysis as complete and cogent as may be done in a relatively short paper.

1. Innovation in the packaging world is a fast moving process, one that is incompatible with requirements for government action that can hold up a new use or a new material for anywhere from 6 months to 4 or more years even if the product is one that will clearly qualify for Threshold of Regulation treatment in the United States, and any similar system Europe embraces in the years to come. In today's fast moving global markets where the emphasis on competition is so intense, it is unacceptable for government command and control processes in one or several coun-

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[2] Dr. Frawley advocated a sort of threshold of regulation that would have resulted in a Food and Drug Administration policy dropping any requirement for Food Additive Petitions for substances used at a level of 0.2% or less. John P. Frawley, "Scientific Evidence and Common Sense as a Basis for Food-Packing Regulations." Food and Cosm. Toxicology 5 (1967):293.

[3] Quantitative Guidelines for Toxicologically Insignificant Levels of Chemical Additives, National Academy of Sciences. This report called for the cessation of regulation of substances that would not be present at levels of more than 1 ppm in the diet.

[4] Ramsey's landmark 1968 proposal to reduce the overregulation of the rank and file of chemicals used in packaging would have brought an end to the promulgation of regulations for substances which do not migrate at levels higher than 50 ppb, provided the chemicals exempted did not present any cause for special toxicological concern as would be the case, for example, with known carcinogens or heavy metals.

[5] Both of these factors are of serious concern since what they portend is that even the Threshold idea, specifically designed to try to bring about more expeditious clearances, is not being administered in a way that indicates the hopes for it will be attained in the United States; the fact that some of Europe's leading experts are so skeptical about it also implies it may not be a useful tool to help bring about prompt harmonization.

tries to make world-wide marketing a nightmare due to regulatory requirements that are unrealistic and seem to exist more to block new products or uses unnecessarily than to deal with any true public health problem.

2. The current systems used by the Food and Drug Administration to clear indirect food additives are archaic, have been proven unnecessarily demanding by the safety track record for such substances, and are patently inefficient in the use of manpower and scarce other resources. In the words of a distinguished colleague, these processes are "bankrupt" and constitute a complete failure.[6] The proof of this bankruptcy is immediately visible in the facts that obtaining action on a simple packaging Food Additive Petition requires anywhere from 1 to 5 years or more,[7] and obtaining a "no objection" letter evidencing a favorable determination under the Threshold of Regulation principle requires anywhere from 4 to 8 months.

3. In Europe, the situation is even more confounding despite the unbelievably heroic, dedicated efforts of the inestimable Dr. Luigi Rossi. The European effort is now about twenty years old and has resulted in one final Monomers Directive (90/128/EEC) and Three Amendments (95/3/EC being the latest). These directives may ultimately result in a true positive list but even Dr. Rossi cannot guess at how long this will take. In the meantime, food processor's demands for reassurance that a packaging material component be acceptable in European applications can only be met by citations to the limited Monomers Directive which covers established monomers reasonably well and also covers a relatively short list of additives, to Dr. Rossi's amazingly comprehensive Synoptic document, and to individual country clearances where they exist. However, to use a new material, no matter how innocuous, and assuming the customer will not accept the fact that no formal clearance is possible in most cases, one must file a dossier equivalent to a United States Food Additive Petition and wait for at least 6 months before this material can be listed in a Synoptic document or otherwise reviewed for the first time by the SCF's Working Group for Packaging. Actual inclusion in the Monomer Directive is likely to take an additional two or three years.

I respectfully submit that these systems have become a burden on government and industry and that "the flame here is simply not worth the candle." To coin a phrase, "there must be a better way," and I believe there is. In the past few weeks, and even as we speak, as part of a more general new look at food safety regulatory reform, discussions are taking place on a proposal we are hoping will advance in the legislative arena. As far as food contact substances are concerned, it embodies an entirely new approach to regulating what are essentially the very minimal risks presented by components of food contact surfaces. I say the proposal is new but some of you will recognize that this is not entirely true because, in principle, it embodies some of the same concepts we attempted to advance (1) in 1957 in HR 8115, a bill introduced by then Congressman Miller of Nebraska as an alternative to the packaging coverage parts of the bill that became the Food Additives Amendment in 1958, and (2) a similar premarketing notification plan introduced into both the House of Representatives of the United States (HR 4014) and the Senate (S 1442) in 1981. These issues are now the subject of new Congressional Hearings—indeed, these are the hearings in which Dr. Alan Rulis is testifying today, and at which I have been invited to testify on June 29. While the House Government Reform and Oversight Committee's Subcommittee on Human Resources and Intergovernmental Relations, which is conducting these sessions, is holding them in the oversight mode at this time, it is widely anticipated that it is doing so with a view towards drafting remedial legislation.

Our hope is that the remedial legislation will look towards taking justifiable steps to completely change the way indirect additives are regulated in the United States.

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[6] Peter Barton Hutt, Esq., "Approval of Food Additives in the United States: A Bankrupt System." address before the Annual Meeting of the Institute of Food Technologists (June 5, 1995), at a symposium in his honor. Mr. Hutt is a former Chief Counsel of the Food and Drug Administration. The following quotation from pages 20, 21 of this paper is particularly relevant to this presentation. With respect to FDA indirect additive petitions, Mr. Hutt noted:

"More than 80 percent of these notices [of Food Additive Petition Acceptances For Filing] relate to obscure indirect food additives that have no possible bearing upon the public health. Indirect food additives are important, serve a highly useful purpose, and should not be given inadequate attention. At the same time, they do not deserve the same degree of scrutiny and FDA priority as new food additives added in significant amounts directly to the food supply. It is apparent that a completely separate and different process, with far less government involvement, must be identified and put in place for the category of indirect food additives."

[7] Alan M. Rulis, Director of the Division of Food and Color Additives, Food and Drug Administration, "The Food Additive Petition Process: An FDA View," address before the National Meeting of the Calorie Control Council, LaJolla, CA (November 9, 1992) Transparency No. 4 and pages 4–9.

If this is the case, we would hope that the legislation will look towards the following major changes and would also hope that if such changes are made, our European colleagues may consider them worthy of consideration for use in the European Community.

1. To replace the entire system of Food Additive Petition filing, it is our view that a premarketing notification system should be enacted that would permit any company to advise the Food and Drug Administration in a formal premarketing notification about everything it tells the government now in a Petition or a letter requesting a "no-objection" response. Thus, the filing of the kind of data that reflects the teaching of the past 37 years under the Food Additives Amendment would continue and remain important. Nor would there be any less need for harmonizing on subjects like analytical data developments toxicological considerations, and other technical information. Even with respect to subjects on which we seem to have major differences of opinion such as the use of consumption factors, functional barriers, and threshold of regulation concepts, data could be supplied in both this country and others asking for the application of these principles in appropriate cases to demonstrate the lack of any need for concern about the safety of a given additive or use.

The big change here would be that the law we envisage would provide that all such premarketing notifications would become effective within 90 days unless the government concludes that there is substantial evidence to demonstrate that the food contact substance may reasonably be expected to become a component of food and that the risks of the food contact substance under the intended conditions of use are not negligible or insignificant. If this system is enacted, delays in clearances would be no more than 90 days except in cases where screening of a notification gives rise to a proper government concern, something that experience has taught happens only rarely in the course of FDA regulation of packaging materials.

Of the essence of this new approach is the fact that it would automatically reorient the use of government skills and time so that they would be spent primarily on areas of real concern and not on having to process and write regulations for a myriad of minor food contact substances. We would be on the road to prioritizing and using resources on the basis of risk instead of being hidebound to a system that exalts form over substance where insignificant risks are concerned.

The savings in time that would occur by use of this system would be enormous, commerce would benefit, and FDA would likely be more fully informed than it is now about what is being used. Moreover, it would seem feasible for short summaries of the filings to be put on computer networks immediately upon their becoming effective so that any interested party in the world, including packaging materials customers, and foreign governments could become aware of when a notification has become effective. Why not use the so-called "Communications Superhighway" for this type of constructive attempt at closer harmonization of world acceptance of materials clearances.

2. Some of the other interesting features of this approach would be the possibility for the charging of modest filing fees for such food contact materials notifications since they would be basically proprietary. This could relieve FDA and other government agencies around the world of some of their resources shortages occasioned in part by the fact that they must now draft, internally circulate, and negotiate broad regulatory language for every additive, no matter how insignificant, if any sort of Food Additive Petition is filed. Europe, too, might find it worth considering whether it might not be better to adopt such a notification system, charge a reasonable fee for filing the notifications, and let our good friend, Dr. Rossi, and the Scientific Committee for Food spend their time on issues that truly affect food safety, whether they be special food contact questions, or questions related to protecting the food supply from microbiological contamination.

3. To Dr. Rossi and our other European visitors, I note especially that it seems to me that the use of such a modified ad hoc approach might go a long way to resolving some of the difficulties you are having with the unexpected need to deal with Specified Migration Limits much more than you had contemplated, and to being subjected to a kind of regulation that is so dependent on abstract toxicological considerations that there is little room for making arguments based on limited exposures, functional barriers, or any of the other concepts used elsewhere to make intended use the truly significant factor it should always be in product clearances or regulation. If your basic system were reoriented to a premarketing notification plan to serve in lieu of the hoped for positive lists, would not your opportunities to use the facts about the use of your products count for more in establishing their satisfactory status for real time applications. Might you be relieved of the burden of providing inordinate amounts of toxicological data for minor uses of innocuous materials?

And so I complete my journey with you by coming full circle. In my first talk to this distinguished audience in 1992, after describing some of the world regulatory systems, I said:

In general, it is my opinion that both the United States and European Community systems are inferior to the ad hoc 'no objection letter' approach in all respects except that they provide written ground rules and lists of cleared materials, not simply the unpublished 'no objection' letters sent to each inquirer. To achieve this apparently laudable end, they are forced to either bring into play all sorts of fictions and legal contortions attendant to day-to-day regulation, or to employ a rigidity that defeats rather than helps accomplish public health and harmonization objectives. One cannot help but wonder wistfully, almost hopelessly, whether it might not be more advisable to use the ad hoc, no objection letter approach and accomplish the public information purpose by reporting the nature of each clearance and its limitations in public journals and computerized information systems to make them immediately available to any interested party.

I close then by asking you to consider this set of possibilities and the added benefits that a premarketing system with self executing effective dates for registrations could bring in the way of making the marketing of safe, cleared components a timely event, one consistent with the needs of everyone in the chain of commerce, and with the low risk level involved. My hope is that you may perhaps join me in approaching this possibility with the attitude of "Why not?" instead of "not now" or "yes, but" and that we can perhaps use this approach as a short cut to immediately meaningful international harmonization.

APPENDIX D

FOOD PACKAGING REGULATIONS IN CANADA

Michel A. Pelletier
Health Protection Branch
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INTRODUCTION

This paper is intended to provide an overview of the regulatory control of food packaging materials in Canada. It will discuss the Canadian legislation that deals with the safety of food packaging materials and how it is administered by the Health Protection Branch (HPB) of Health Canada, particularly as it relates to the submission evaluation process and the issuance of no objection letters for food packaging materials or their components. It will also outline the major differences between the Canadian and U.S. legislation dealing with food packaging materials.

LEGISLATION

1. The Food and Drugs Act and Regulations

The history of Health Protection in Canada began 120 years ago when parliament passed the Inland Revenue Act of 1875, cited as "an act to impose licence duties on compounders of spirits; to amend the act respecting inland revenue; and to prevent the adulteration of food, drink and drugs".

Since then there have been several amendments to that act. In 1920, it's name was changed to the Food and Drugs Act, which was subsequently amended in 1939 to include cosmetics, and again finally in 1954 to include medical devices; and it is that act which is currently in force, accompanied by the many amendments of the regulations to the act that have been promulgated in the interim.

The Food and Drugs Act is intended to protect Canadian consumers from health hazard and fraud in the sale and use of foods, drugs, cosmetics and medical devices. It is considered to be part of criminal law, and as such, falls within the authority of the federal government of Canada.

2. Health Protection Branch

The task of administering the Food and Drugs Act rests with the Health Protection Branch (or HPS) of the federal department of Health Canada. This act is the principal piece of legislation administered by the Health Protection Branch. The Health Protection Branch (Appendix 1) is made up of several directorates, only 1 of which, the Food Directorate, is directly involved in the regulatory control of the sale of foods and hence, of food packaging materials.

The prime responsibility of the Food Directorate under the Food and Drugs Act is to ensure the safety, nutritional quality and wholesomeness of the Canadian food supply.

For this task, the Food Directorate is organized into 3 bureaux, namely Chemical Safety, Nutritional Sciences and Microbial Hazards, however, only the first one, Chemical Safety, is of interest to us in this paper. As can be seen from this organizational chart, we have, within the Bureau of Chemical Safety, 3 activity oriented divisions—Food Research, Toxicology Research and Chemical Health Hazard Assessment—each of which is further broken down into sections. In one of these, the Chemical Health Hazard Assessment Division, is the Food Packaging Materials and Incidental Additives Section (lower right corner of the chart) which is responsible, among other things, for interpreting and developing regulations and for providing advice to industry and other departments on matters pertaining to the safety of food packaging materials.

3. Division 23—Food Packaging Materials

The relevant parts of the Food and Drugs Act relating to food packaging safety are,

Section 4(a), which prohibits the sale of an article of food that has in or upon it any poisonous or harmful substance; and,

Section 30, which gives authority to the governor-in-council to pass into law regulations to carry the purposes and provisions of the act respecting food packaging materials into effect.

It is these sections of the act which provide the basis for Division 23 (Appendix 2) of the Food and Drug Regulations entitled "Food Packaging Materials", which is the only division of the regulations that is specifically concerned with the chemical safety of food packaging materials.

Division 23 comprises only 8 sections, the most important one of which is,

Section B23.001—a general prohibition against the sale of foods in packages that may impart harmful substances to their content.

Other sections in Division 23 include,

Sections B23.002 to B23.006—which permit the use of only specified octyltin stabilizers in rigid pvc compounds and which set a use level limit of 3% by weight and a 1 ppm migration limit to foods for these stabilizers; and,

Sections B23.007 and B23.008—which prohibit the sale of foods in packages that impart detectable amounts of vinyl chloride and acrylonitrile respectively to foods, as determined by official analytical methods.

4. Package Definition

A "package" is defined in the act to include "anything in which any food, cosmetic or device is wholly or partly contained, placed or packed." Therefore, by this definition, a package may be regarded as any article that a food contacts during processing and distribution for sale, and thus would include the various containers used at the food retail level, as well as bulk food handling articles such as food processing equipment, drums, pails, and transportation vehicles like tanker trucks, rolling stock, barges and fishing vessel holds.

Section B23.001 clearly makes the food seller responsible for the safety of any packaging materials which he uses in the sale of his food products. An important point worth noting here is that, consistent with Section 4(a) of the Act, Division 23 is concerned with regulating the safety of only those food packaging materials that are used in the sale of foods. Consumer products such as kitchen utensils, household wrap and microwave cookware therefore fall outside the purview of the Canadian Food and Drug Regulations.

Another very important point to note is the fact that under Section B01.001(e) of the regulations, food packaging materials and their components are not considered to be food additives. They are not therefore subject to the statutory preclearance requirements that food additives must meet under section B16.002 of the regulations. Instead, they are regulated in their own right as food packaging materials under Division 23, which, as indicated previously, does not at present delineate statutory preclearance requirements other than those described earlier.

We can therefore see a major difference already in the regulatory status of food packaging materials under the food laws of Canada and those of the United States.

SUBMISSIONS AND NO OBJECTION LETTERS

Given the legal responsibility placed upon them by regulation B23.001, it is entirely reasonable to expect that food manufacturers will seek assurance from their packaging suppliers regarding the safety of any packaging materials they may be considering purchasing. That is why those who are directly or indirectly involved in supplying packaging products to the Canadian food industry may be faced with the question "do you have an HPB no objection letter for your product?", and why, as a result HPB, and more particularly the Chemical Health Hazard Assessment

Division, receives several hundred submissions annually from food packaging and related suppliers requesting safety evaluations and no objection letters on products they wish to sell to the food industry.

A no objection letter is a mechanism whereby HPB, in the absence of comprehensive positive list regulations, provides a service to packaging suppliers and related companies to assist them in supplying products to the Canadian food industry which are likely to be acceptable under Division 23 of the Food and Drug Regulations.

A typical example of a no objection letter is shown in Appendix 3. These letters are fairly simple and straight forward—they contain, basically, a specific identification of the product and a statement of no objection to specified food contact end uses, based upon supporting data submitted by the petitioner, followed usually by a technical suitability proviso.

Those who are familiar with the way in which the FDA handled food contact articles prior to the 1958 Food Additives Amendment to the Federal Food, Drug and Cosmetic Act, will recognize the close similarity between the no objection letters issued by the FDA some forty years ago and those issued by HPB today. As a matter of interest, HPB (which was then known as FDD—the Food and Drug Directorate) began the practice of issuing no objection letters about the same time that the FDA preclearance regulations began to be promulgated in the 1960s.

Once a no objection letter has been issued by HPB on a particular product, the recipient is free to present it to potential customers. It's important to note however that a no objection letter expresses only an opinion by HPB on the acceptability of a product. It does not constitute an approval of the product in a legal sense, nor does it relieve the food manufacturer from the ultimate responsibility for the product's safety under Division 23. However, the intent of the letter is to make it highly unlikely that the specified use of the product in question would lead to a violation of this regulation.

Because submissions by packaging suppliers are made to HPB on a voluntary basis, at least insofar as the Food and Drugs Act and Regulations are concerned, a letter reflecting an HPB objection rather than a no objection would not necessarily prevent the supplier from selling that product to a food manufacturer who wished to use it. In the final analysis, the decision to use that product rests with the food manufacturer. However, most food manufacturers are fully aware of that statutory responsibility, and would not likely proceed to use a product whose safety was in question.

While many of the submissions received by HPB originate with companies that supply finished packaging materials directly to the food industry, a large proportion are initiated by companies like plastic resin manufacturers, compounders, additive and colour concentrate suppliers. As a consequence, no objection letters run the gamut of all these products, so that in the ideal scheme of things, each company in the supplying chain should be in a position to satisfy its customer's requests for no objection letters.

While we recognize that there are differences in the present regulatory approaches to controlling food packaging materials in Canada and the United States, we believe that the scientific principles and criteria used by HPB and FDA in assessing their safety are closely similar. Consequently, generally speaking, packaging materials permitted for use in the US under FDA regulations would also likely be deemed acceptable, in principle, for use in Canada. There are exceptions of course, and it should be stressed here that any decisions reached by HPB regarding the acceptability of any packaging materials are never based on sanctions made by another agency, but rather on HPB's own evaluation of the supporting data upon which those sanctions were based. It follows that statements made in HPB submissions attesting to the compliance status of a product with FDA regulations, is not considered by HPB to be sufficient evidence of the acceptability of that product for use in Canada—HPB requires the same supporting data to back up these statements.

SUBMISSION REQUIREMENTS

An HPB no objection letter is the end result of a safety evaluation of a particular packaging material in consideration of basically 4 elements of information.

Product identity—to characterize, chemically and otherwise, the material and thus identify chemical constituents that may be potentially extractable by foods coming into contact with the material.

Proposed usage of packaging material—to estimate the dietary intake of the foods involved and also to establish appropriate extraction test protocols.

Food extractability characteristics of packaging material—to identify and quantify those constituents that are likely to be extracted by foods. Evaluation of this infor-

mation in conjunction with usage information permits the estimation of the PDI (Probable Daily Intake) in mg/kg b.w./day of extracted constituents in the average diet of the consumer.

Toxicological data on extractable constituents—to permit the establishment of an ADI (Acceptable Daily Intake) in mg/kg b.w./day for humans for extracted constituents.

From an evaluation viewpoint, submissions to HPB fall into 2 general categories: those concerning individual constituents of packaging materials and those concerning formulated or finished products. While the same principles are used in evaluating both types, generally speaking, the information package requirements and the evaluation process are more demanding for individual constituents. Most submissions, however, fall into the formulated or finished product category.

1. Formulated or Finished Products

The initial submission requirements for a formulated or finished product are listed in Table 1. It is important to note that these are only basic initial requirements because evaluation of this information may reveal data gaps regarding extraction study data or toxicological data on certain constituents, thus requiring follow-up correspondence with either the petitioner or his suppliers to provide the missing information.

It may be worth mentioning also that many companies, notably plastic resin manufacturers, have opted to establish master listings with HPB covering all their resin products destined for food packaging applications in Canada. These master listings, which contain detailed confidential compositional information on each resin along with intended end use information and pertinent documentation in support of their safety, and which can be updated on a regular basis, have proved to be most useful in expediting HPB's evaluation of submissions from customers wishing to use these companies' resins. The marketing advantages to companies who submit master lists are therefore self evident.

TABLE 1

SUBMISSION REQUIREMENTS FOR A FORMULATED PRODUCT OR A FINISHED PACKAGING MATERIAL—INITIAL REQUIREMENTS

Product Identity

—trade name and number
—structure
—composition (quantitative list of components in which each component is identified by chemical name, trade name and manufacturer)
—specifications
—chemical/physical properties relative to proposed use

Proposed Usage

—form of finished package
—dimensions of package (volume, wall thickness)
—ratio weight food: surface area package (g/in^2)
—types of foods involved
—conditions (time, temp.) To which package will be exposed during packaging, distribution and use by consumers
—projected market penetration

2. Specific Constituents

The requirements for a specific packaging constituent such as a base resin or an antioxidant are shown in Table 2. This is much more detailed and is similar to the type of information that is submitted to the U.S. FDA by petitioners seeking to amend the indirect food additive regulations—and indeed, quite often, what HPB receives in submissions to fulfil its requirements, is a duplicate copy of the full FDA petition, which usually, but not always, suffices for our evaluation purposes.

TABLE 2

SUBMISSION REQUIREMENTS FOR A SPECIFIC FOOD PACKAGING MATERIAL CONSTITUENT

1. Component Identity

—chemical name
—empirical/structural formula
—molecular weight
—details of manufacturing process

—composition/impurities present
—specifications
—chemical/physical properties

2. Proposed Usage

—intended technical effect
—efficacy data
—types of packaging materials involved
—maximum level(s) of use of component
—analytical method for determining level of use
—types of foods involved
—single or multiple use of packaging material
—conditions (time, temperature) of exposure of packaging materials involved to foods
—chemical stability in intended end-use.

3. Constituent Extractability Characteristics

—as determined by appropriate extraction study tests using foods or food simulants.

4. Toxicological Profile of Extractable Constituents

—as determined by appropriate animal feeding studies, mutagenicity studies, etc.

3. Extraction studies

As regards extraction studies, HPB recognizes the difficulties inherent in analyzing foods for packaging migrants and accepts the use of food simulants or surrogates for such studies. Those simulants which are considered acceptable are listed in Table 3.

TABLE 3

FOOD SIMULANT EXTRACTION STUDIES

Food Type	Simulant
Aqueous (pH > 5)	Distilled water
Aqueous acidic (pH > 5)	3% Acetic acid
Fatty	Vegetable oil, HB-307 or 95% ethanol
Alcoholic	8% Or 50% Ethanol

However, HPB is reasonably flexible, and depending upon the circumstances, it may accept the use of other simulants such as 86 ethanol for acidic foods and n-heptane or ethanol for fatty foods.

Table 4 lists the recommended extraction test temperatures corresponding to the intended end uses indicated to be observed in conducting the tests. Generally speaking, it is recommended that they be run to equilibrium concentrations of the extracted constituent in each simulant.

TABLE 4

EXTRACTION STUDY TEST CONDITIONS

End Use	Extraction Temp, °F
Frozen, refrigerated	40
Ambient	120
Hot fill	Hot fill temp., then 120
Pre-cook, cook or re-heat in package (<212°F)	212
Retort in package	Retort temp./2 hr.
Special use (eg. microwave or oven cooking)	Max. temp. attained by Packaging material in contact with food

4. Estimation of Probable Daily Intake

The whole purpose of this exercise is to allow HPB to estimate the PDI (Probable Daily Intake) of the migrating food packaging constituent. This estimation is done using the following formula.

$$PDI\ (\mu g/kg\ b.w.) = \frac{D_P P_P}{b.w.} \frac{(C_{aq}XF_{aq}) + (C_{acid}XF_{acid}) +}{(C_{alc}XF_{alc}) + (C_{fat}XF_{fat})} \qquad (1)$$

—While this calculation may appear complex at first glance, it is relatively simple when broken down into its various components. Thus in this equation,

—C is the concentration (µg/kg) of extracted constituent in aqueous, acidic, alcoholic and fatty food simulants, normalized to an exposure ratio of 5g/in^2;

—F is the intake of aqueous, acidic, alcoholic and fatty foods in the daily diet. The food intake figures used here are based on the results of a survey published by Nutrition Canada in 1975 supplemented by more recent data obtained from other government agencies at the provincial level;

—D_p is the fraction of the total diet likely to be packaged in a particular type of material in which the additive may be present;

—M_p is a "market penetration" factor which represents the fraction of p type packaging material which realistically is likely to contain the additive; and,

—b.w. is the average body weight of the age group under consideration. For the average adult, the figure used is 60kg.

Except for the fact that it does not employ a packaging use distribution factor for each food type, this approach is very similar to the one used by FDA (1)—and indeed HPB's experience has shown that, in most cases, the PDI's calculated using this approach are reasonably close to those calculated using the FDA approach.

5. Toxicological Studies

The types of toxicological testing which may be required to assess the safety of a given packaging constituent are shown in Table 5. The word may should be stressed here because the specific testing requirements for a particular constituent will be dependent upon consideration of several factors including level of exposure (PDI), chemical structural similarity between the constituent and those of other chemicals of known toxicological profile and the existing toxicological data base on the constituent itself. Before embarking on any testing, it is recommended that petitioners discuss requirement details with HPB staff toxicologists.

TABLE 5

TOXICOLOGICAL REQUIREMENTS FOR MIGRATING PACKAGING CONSTITUENT

STUDY	SUGGESTED ANIMAL TEST SPECIES
acute toxicity:	
1 day oral	rat, mouse, hamster
repeated intake—short term:	
28-day oral	rat, mouse
90-day oral	rat, mouse, dog
1-year oral	rat, dog
long term:	
chronic oral toxicity/oncogenicity	rat
oral oncogenicity	mouse or hamster
genotoxicity studies:	
gene mutation.	
chromosomal aberrations.	
teratogenicity:	two species (preferably rabbit and rat)
multi-generation reproduction	one species used for teratogenicity study preferably rat.

Submission of the appropriate toxicological data will allow hpb toxicologists to ascertain a NOAEL (No Observable Adverse Effect Level), in mg/kg b.w./day, for the packaging constituent in the test animals which, by the application of established safety factors, will permit them to calculate an Acceptable Daily Intake (ADI) in humans.

It is understandable that companies contacting HPB for the first time may have some concerns about the confidentiality of proprietary information they are sending

to HPB. In that regard, the Branch recognizes the need to guard the confidentiality of information contained in submissions. Petitioners can feel assured therefore that all the information presented in their submissions is used solely for evaluation purposes, and would not be released to a third party without the express written consent of the originator.

Finally, any changes made to the chemical composition of a product will automatically invalidate the no objection letter issued for that product. For the letter to remain in effect, the Branch requires pre-notification of any such changes, so that it can assess their impact on the original evaluation.

HPB AND OTHER ORGANIZATIONS

As part of its responsibilities in administering the Food and Drugs Act and Regulations, HPB has for many years provided advice to several other federal government departments in Canada on matters pertaining to food packaging material safety.

• Science and Technology Services (formerly Agri-Food Safety and Strategies Division)/Food Production and Inspection Branch/Agriculture and Agri-Food Canada—regarding preclearance safety evaluation of products used in food processing establishments registered under the Meat Inspection Act and other acts administered by that Department.

• Product Management Division/Plant Industry Directorate/Agriculture and Agri-Food Canada—regarding the safety evaluation of food packaging constituents such as papers pulp slimicides and paper coating preservatives which are subject to registration under the Pest Control Products Act. This group, however, is now part of the new Pest Management Regulatory Agency which was formed on April 1st, 1995 and which incorporates a number of groups from three different federal departments—Agriculture and Agri-Food, Environment and Health—all involved in the evaluation and regulation of pesticides. This new agency has been placed under the responsibility of the Minister of Health.

• Inspection and Enforcement Directorate/Fisheries and Oceans—on the safety evaluation of materials used on fishing vessels and fish processing plants subject to control under the Fish Inspection Act.

• Supply and Services Canada and the Department of National Defence—regarding specifications for procurement of food packaging materials by these departments.

HPB also interacts with the following organizations and other government agencies on similar matters.

• Codex Committee on Food Additives of FAO/WHO Codex Alimentarius Commission—regarding international guideline standards for food packaging materials.

• Center for Safety and Applied Nutrition/U.S. Food and Drug Administration—regarding the impact of the Canada/US Free Trade Agreement on the regulation of food packaging materials in both countries and,

• Committee for Industrial and Consumer Health/SPI of Canada—with whom SPB officials have been meeting essentially on an annual basis to discuss issues of mutual interest concerning the safety of plastics used in Canada in food packaging applications. In addition to facilitating an informal exchange of information, these meetings give the Canadian plastics industry an opportunity to provide input to assist HPB in its deliberations on both short term regulatory actions and long term regulatory policies.

CURRENT ISSUES

1. Recycled Plastics for Food Packaging Uses.

Over the past several years, there has been a growing interest in Canada, as in many other countries, for the use of recycled materials in food packaging applications. As a result, HPS has been contacted on several occasions by recyclers regarding the regulatory status of recycled materials, including plastics, for use as food packaging materials.

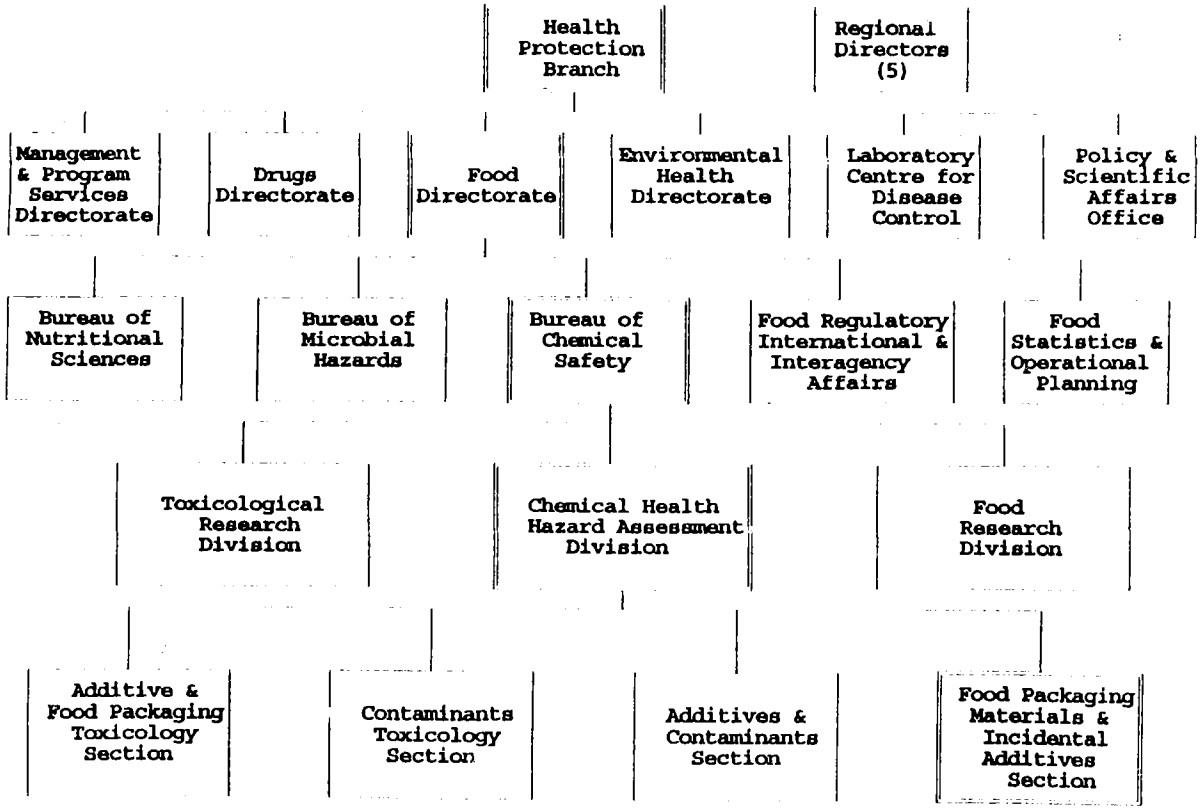
There is no provision at present in the Food and Drug Regulations which specifically prohibits the use of recycled materials in food packaging applications. Therefore, a food manufacturer could quite legally use recycled materials for such use, provided of course that they complied with the requirements of Division 23. However, the task of providing sufficient supporting data that would satisfy HPB's concerns about the safety of contaminants that may be present in a given recycled product, to the point that it would be comfortable in issuing a no objection letter for its use for food packaging, would likely be a costly and time-consuming undertaking.

As a result of the Regulatory Review (2) conducted by Health Canada in 1993, it was recommended that consideration be given to the development of guidelines to control the use of recycled materials intended for food packaging applications in Canada. Such guidelines would assist manufacturers in preparing submissions to the Health Protection Branch on products that contain recycled materials. Guidelines for plastic materials are now being developed by HPB and should be available in June 1996. One of the main considerations in the drafting of these guidelines was to ensure that they were consistent with those published by the US FDA in May 1992.

2. Threshold of Regulations

Another important issue which has drawn considerable attention in the past year is the concept of a "Threshold of Regulation" for substances used in food packaging materials. On October 12, 1993, the FDA proposed to establish a process whereby a substance used in the manufacture of food packaging materials could be exempt from food additive status if it met certain criteria, one of which being that it migrated to foods at negligible levels (3). The dietary concentration proposed by FDA for this threshold was 0.5 ppb which, in a body weight basis, corresponds to 25 ng/kg b.w. for a 60-kg individual. Toxicologists at the Health Protection Branch have studied the FDA proposal and based on the data that they have accumulated during the past 15 years, they have given their support both to the concept as a whole and to the figure of 25 ng/kg b.w. proposed as the probable daily intake (or PDI) threshold level for food packaging materials in Canada. What this means then in terms of the voluntary premarket clearance system employed in Canada is that a manufacturer seeking a no objection letter from HPS would not be required to submit any toxicological data on a food packaging material component if the probable daily intake for that substance has estimated to be less than 25 ng/kg b.w. using the calculations described earlier. Prior to the adoption of this policy, the lowest level of concern (level 1, PDI of 0–100 ng/kg b.w., as defined by HPB's toxicologists) called for at least short term genotoxicity studies to be conducted on any ingredient used in a food contact material before a no objection letter could be issued for that component.

In conclusion, the approach used in Canada for regulating the safety of food packaging materials may be described as a voluntary pre-market clearance system. In our opinion, this approach provides Canadian consumers with a reasonable measure of protection against the use of unsafe food packaging-materials in the marketplace while at the same time allowing considerable flexibility to industry. Because it is more flexible also from an administrative perspective, it lends itself to faster decision-making than would be otherwise possible under a mandatory positive list system.


Health Protection Branch
Regional Directors (5)
Management & Program Services Directorate
Drugs Directorate
Food Directorate
Environmental Health Directorate
Laboratory Centre for Disease Control
Policy & Scientific Affairs Office
Bureau of Nutritional Sciences
Bureau of Microbial Hazards
Bureau of Chemical Safety
Food Regulatory International & Interagency Affairs
Food Statistics & Operational Planning
Toxicological Research Division
Chemical Health Hazard Assessment Division
Food Research Division
Additive & Food Packaging Toxicology Section
Contaminants Toxicology Section
Additives & Contaminants Section
Food Packaging Materials & Incidental Additives Section

APPENDIX 3

BUREAU OF CHEMICAL SAFETY
4TH FLOOR EAST
SIR FREDERICK BANTING BLDG.
TUNNEY'S PASTURE
OTTAWA, ONTARIO
K1A OL2
January 31, 1995

Regulatory Specialist
New Polymers Corp.
Newark, N.J.
U.S.A.

DEAR SIR:

RE: HDPE—UV 23 Resin

This is in reference to your submission of December 12, 1994 regarding the proposed use of the subject high density polyethylene resin for food packaging applications in Canada.

Based on the information that you and your suppliers have submitted, we see no reason to object to the use of the subject UV-stabilized resin to fabricate food containers having a capacity greater than 5 gallons for holding all types foods (except alcoholic foods) at temperatures not exceeding 120°F, provided that it is technically suitable for the intended end uses.

Yours truly,

MICHEL A. PELLETIER,
Head Food Packaging Materials
and Incidental Additives Section,
Chemical Evaluation Division.

Food Packaging Materials

B.23.001. No person shall sell any food in a package that may yield to its contents any substance that may be injurious to the health of a consumer of the food.

B.23.002. Subject to section B.23.003 no person shall sell any food in a package that has been manufactured from a polyvinyl chloride formulation containing an octyltin chemical.

4-12-86

B.23.003. A person may sell food, other than milk, skim milk, partly skimmed milk, sterilized milk, malt beverages and carbonated non-alcoholic beverage products, in a package that has been manufactured from a polyvinyl chloride formulation containing any or all of the octyltin chemicals, namely, di (n-octyl)tin S,S'-bis(isooctylmercaptoacetate), di (n-octyl)tin maleate polymer and (n-octyl)tin S,S',S''-tris (isooctylmercaptoacetate) if the proportion of such chemicals, either singly or in combination, does not exceed a total of 3 per cent of the resin, and the food in contact with the package contains not more than 1 part per million total octyltin.

4-12-86

B.23.004. (1) Di (n-octyl)tin S,S'-bis (isooctylmercaptoacetate) shall be the octyltin chemical made from di (n-octyl)tin dichloride and shall contain 15.1 to 16.4 per cent of tin and 8.1 to 8.9 per cent of mercapto sulfur.

(2) For the purposes of this Division, di (n-octyl)tin dichloride shall be the chemical having an organotin composition of not less than 95 per cent di (n-octyl)tin dichloride and shall contain not more than

(a) 5 per cent total of n-octyltin trichloride or tri (n-octyl)tin chloride or both;
(b) 0.2 per cent total of other eight (8) carbon isomeric alkyltin derivatives; and
(c) 0.1 per cent total of the higher and lower homologous alkyltin derivatives.

B.23.005. Di (n-octyl)tin maleate polymer shall be the octyltin chemical made from di (n-octyl)tin dichloride and shall have the formula $((C_8H_{17})_2SnL_4H_2O_4)n$ (where n is between 2 and 4 inclusive) and a saponification number of 225 and 255, and shall contain 25.2 to 26.6 per cent of tin.

4-12-86

B.23.006. (1) (n-octyl)tin S,S',S''-tris (isooctylmercaptoacetate), being an octyltin chemical having the formula $n\text{-}C_8H_{17}Sn(SCH_2CO_2C_8H_{17})_3$, shall be made from (n-octyl)tin trichloride and shall contain 13.4 to 14.8 per cent of tin and 10.9 to 11.9 per cent of mercapto sulfur.

(2) For the purposes of this Division, (n-octyl)tin trichloride shall be the chemical having an organotin composition of not less than 95 per cent (n-octyl)tin trichloride and shall contain not more than

(a) 5 per cent total of di (n-octyl)tin dichloride, tri (n-octyl)tin chloride or the higher than eight (8) carbons) alkyltin chlorides or any combination of the foregoing;
(b) 0.2 per cent total of alkyl tin derivatives; and
(c) 0.1 per cent of the lower (less than eight carbons) homologous alkyltin derivatives.

5-8-82

B.23.007. No person shall sell a food in a package that may yield to its contents any amount of vinyl chloride, as determined by official method FO-40, Determination of Vinyl Chloride in Food, October 15, 1981, in respect of that food.

27-5-82

B.23.008. No person shall sell a food in a package that may yield to its contents any amount of acrylonitrile as determined by official method, FO-41, Determination of Acrylonitrile in Food, February 16, 1982, in respect of that food.

Mr. SOUDER. Thank you. Mr. Farley.

Mr. FARLEY. Thank you, Mr. Chairman, Mr. Towns. My name is Donald Farley and I serve as president of Pfizer's Food Science Group. We appreciate the opportunity to present our views and our activities related to the food additive petition approval process.

I would like to begin with some background information about Pfizer and Food Science. Pfizer is a diversified health care company with major businesses in pharmaceuticals, animal health products, medical devices and consumer health care products, as well as food ingredients.

We are headquartered in New York and manufacture and sell our products on a worldwide basis. Our principal research headquarters and largest facility is located in Groton, CT, and of the $8.2 billion in sales that Pfizer recorded in 1994, about $1.4 billion is reinvested in advanced R&D.

The Food Science Group discovers, develops, manufactures, and markets ingredients for the food processing industry with a special emphasis on ingredients that enable the formulation of a variety of foods that improve human health and dietary choice. One of the primary current objectives of our research is to discover ingredients for use in foods that provide reduced calories and fat and, thereby, contribute to health and wellness. Pfizer's extensive research over the years has resulted in "lite" ingredients and other innovative healthful products for the food industry, not only here in the United States but globally.

At present, we conduct all of our research and development in the United States and we generally look to gain approval for new ingredients in the United States as a market of first opportunity. Unfortunately, this goal is seldom realized since there is a major impediment to the timely introduction of such new food ingredients. That impediment, as you have heard, is the extensive delay in obtaining regulatory approvals at the FDA. And this delay, in our view, is due in part to inadequate resources and the absence of appropriate internal practices which prevent FDA from expeditiously processing and reviewing food additive petitions, which serve as our primary approval vehicle for new direct food ingredients. It has been repeated throughout the hearing that the FAPs for novel food ingredients are submitted to the FDA, about four or five per year; that there is now a substantial backlog not only of FAPs but FAP addenda and other related petitions for FAP revisions and modifications.

In Pfizer's view, the average approval time that we have come to expect has increased over the past decade to a period that now averages anywhere from 6 to 8 years. Such lengthy approval times are really unacceptable. They deny consumers new and improved products that promote healthy diets and serve as a barrier to research and innovation. Likewise, extensive delays in the review of addenda filings—these are suggestions for adding to already approved food ingredient uses—really serve as a penalty rather than a reward for costly investments in research and development.

Confronted with this situation, about 2 years ago Pfizer Food Science assessed several options. They ranged all the way from initiatives to reduce the time it takes for FAP approvals to, in fact, a consideration of even abandoning our U.S. based research. In the

end, we decided to take a positive approach and to pursue an initiative aimed at reducing by at least 50 percent FAP review times. In effect, developing a proposal to reduce FAP reviews from 6 to 8 years to an average of 3 years, we hope. Pfizer viewed this initiative as a first step aimed at progressively assisting the FDA to come closer to meeting its statutory mandate for reviews.

To achieve this initial objective, Food Science evaluated the FAP review process in detail and we concluded that the FDA review of safety, toxicology, and clinical data represented the most time-consuming effort in the review process. Timing, in turn, appeared to be affected by limited resources and an inability of the FDA to consult with outside experts who might also have access to a common data base; for example, access to the same safety data that FDA was reviewing.

There are other important issues affecting the FAP review process that need to be addressed. You have heard of several today. Many of these were also discussed by Robert Gelardi on behalf of the Calorie Control Council in his testimony before the committee a week ago. However, in Pfizer's view, we felt that enhancing the science based resources to streamline the FAP safety, toxicological, and clinical data was the most important step to improve the timeliness of the review process.

So over the last year, Pfizer, with advice and support from several colleague companies in the U.S. food industry, has been working on a proposal to improve the safety review component of the FAP review process. It is this proposal that I will describe today.

Now, to be clear, Pfizer believes that implementation of this proposal is one critically important step and that there are other fundamental changes in the way food additive petitions are reviewed and approved at the FDA that need to be addressed. You have also heard testimony regarding other needed changes. We believe that this proposal would, in fact, be complementary to other initiatives that the subcommittee has heard about last week and today.

Specifically, our plan calls for use of expert panelists to review the scientific data of FAP petitions that are submitted to the FDA. As such petitions are submitted, the relevant safety sections would be concomitantly submitted to expert panels. The panels would be selected and administered by a third party institution—a university prominent in food science and nutrition, an organization such as the National Center for Food Safety and Applied Nutrition, which is a research consortium in Chicago jointly funded by FDA and industry, or another reasonable alternative.

A permanent secretariat composed of three professionals would administer the effort. It would be financed by annual grants from a group of ingredient suppliers and food companies, and the expert panels would be funded by an assessment fee for each petition.

The panels would be selected by the administering institution on a customized basis for each FAP, and this would allow the proper types of scientists to review the FAPs and they would address the particular needs of each submission. Panel reports and recommendations would be submitted via the petitioner to the FDA, providing expert scientific input and, we believe, substantially shortening the approval process, as I mentioned, by at least 3 years. Of course, this presumes that the FDA also establishes pro-

cedures and systems to review data on a schedule consistent with the expert panels. The FDA would retain the final authority to approve FAPs under this proposal, and, FAP petitioners, whether the funding companies or non-funding companies, would have access to the expert panels and could use them on a for-fee basis.

Now, we see several benefits to this proposal, principally in the following areas. Consumers would benefit because new and improved food ingredients would be available to food processors sooner. Industry would benefit in many ways because of a greater level of confidence and predictability in a professionally organized and appropriately financed review process. Innovation would be enhanced by reducing the significant risks of patent life loss and by enhancing returns on advanced research and development investments.

The FDA would also significantly benefit from the use of outside experts, including specialists who are not on the permanent FDA staff. This should allow the agency to approve products more efficiently without requiring an increase in agency manpower or resources.

As mentioned, the Pfizer initiative has been highly focused and aimed at the most complex and time-consuming part of the FAP process. We also support agency accountability to conduct the other elements of the review process in a more organized and open manner and with appropriate time constraints. Other individuals and association representatives have testified with respect to these issues and are suggesting changes that we believe are consistent with Pfizer's concerns about the extensive delays that are currently encountered.

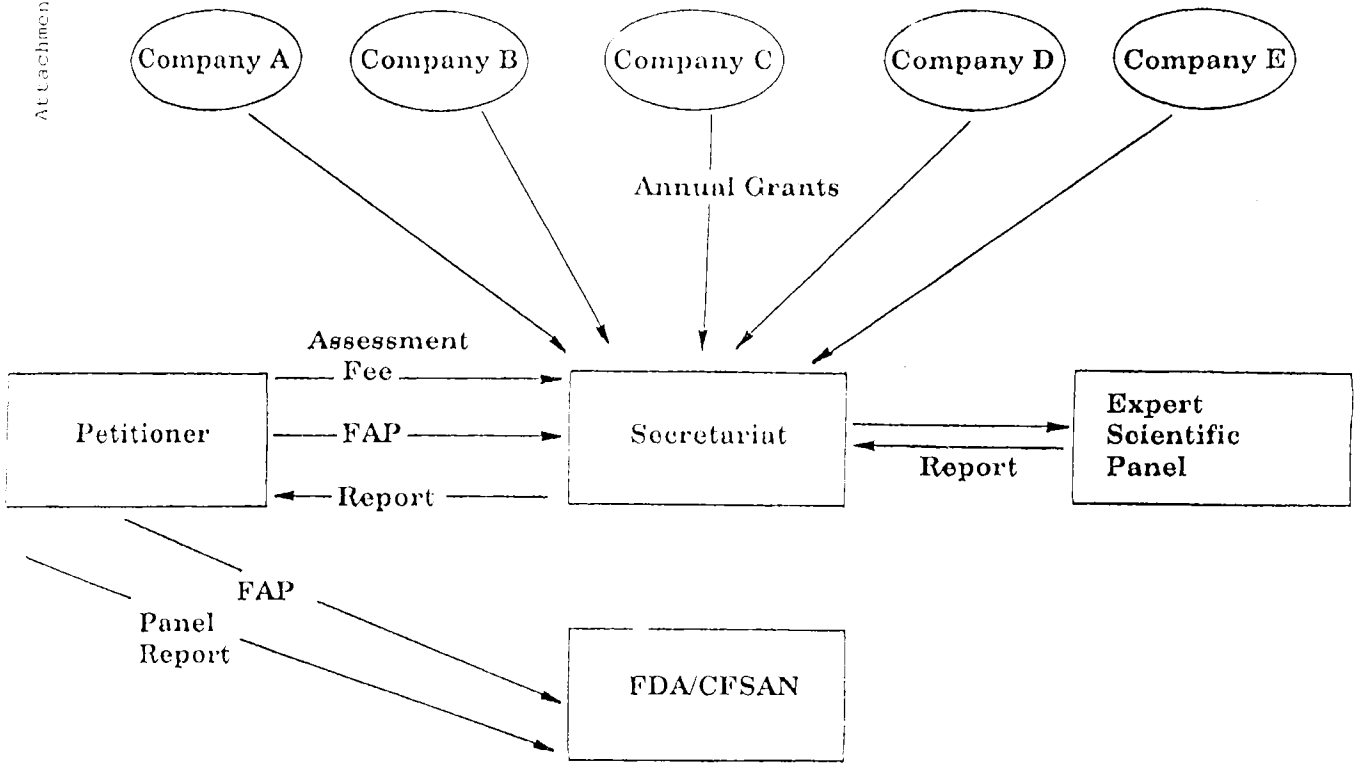
Finally, in relation to our overall commitment to research and innovation, we believe that it is important to patients, consumers, and our industry that the FDA become more efficient in its review and approval of new life-enhancing products that are being developed not only in the area that we serve, healthful food ingredients, but also with regard to human and animal medicines, medical devices, and other regulated products.

Our proposal as described today would be but a first step in addressing one specific aspect of the food additive petition process. Thank you very much, Mr. Chairman, for the opportunity to address the subcommittee, and I would be happy to answer any questions.

[The graph referred to follows:]

Attachment 1

FDA/INDUSTRY INITIATIVE



Mr. SOUDER. Thank you all very much for coming. I yield to Mr. Towns.

Mr. TOWNS. Thank you very much, Mr. Chairman. Let me begin by first saying that I have no intentions of being confrontational in any kind of way; however, I just think that when you see something that has been around for so long and it sort of appears that nobody is doing anything about it, and recognizing that in order to correct it a lot of folks have to cooperate. The industry itself would have to cooperate and, of course, FDA would have to do what it is supposed to do. And then when we look at the fact that since 1957, you know, this has sort of been going on.

And let me just begin, I guess, with you, Mr. Heckman. Being you were around during that time, it would be appropriate to start with you. There are 295 backlog petitions at the FDA. Of that number, 84 are awaiting petitioner action.

How much delay problem is attributed to slow action or inaction by the petitioner? Would you know?

Mr. HECKMAN. I certainly can't say precisely, but I can give you some examples of where some of those petitions have been sitting there for a year between the time a draft regulation is sent to the petitioner to sign off on to say it's acceptable and having not yet been printed in the Federal Register. That is clearly not the fault of the petitioner.

There are certainly other cases in which the petitioners need to come forward with data, I suppose. We file a lot of petitions and, by and large, I think that we get the data in pretty promptly and don't delay the process very much.

I've got some examples here of a petition on a virtually nothing type indirect additive that started off with a request for FDA agreement that it wasn't even a food additive because it wasn't reasonably expected to become a component of food. That occurred in 1990 and they insisted that a petition be filed, and that petition hasn't been granted yet. Now there is a real de minimis case where 5 years have gone by and the company that makes the product is still waiting for that approval and, in this particular case, because of the customer point of view, even though they could legally sell it, the customer won't buy it without an FDA seal of approval.

Mr. TOWNS. Thank you. Let me just say then to you, Mr. Farley, on that note, and let me make certain I understood you clearly toward your testimony. Did you say that due to impediments that new products are sometimes developed in other countries that should be developed in the United States?

Mr. FARLEY. Yes. I think some companies are conducting research offshore simply for that purpose; they obtain faster approvals in foreign countries, who have a professional regulatory authority who review detailed safety petitions.

Mr. TOWNS. And it's just basically because of the fact that just slow in terms of giving information? It's not from the lack of you not doing what you're supposed to do, but it's basically——

Mr. FARLEY. Yes, decisions are based on comparable data which would be submitted to the FDA.

Mr. TOWNS. Mr. Pape, in your reform proposal you suggest that a suitable period of review for direct additives petitions may be 6

to 12 months. Our concern is, however, that some particularly complex petitions could require additional time for review.

Does your proposal have some type of escape mechanism that would grant additional time when a very complex petition is being reviewed?

Mr. PAPE. Yes, it does, Mr. Towns. The proposal would provide that the petitioner can, if you will, suspend the timeframes while the independent organization is reviewing the petition if more time is needed.

And I think certainly there are petitions of the sort you refer—some petitions submitted today are 15,000 pages—that is a complex petition. Any timeframe that we might establish as a norm is probably not going to be relevant to a petition of that magnitude.

I think the proposal which I described today is intended to embrace special timeframes for special cases but to establish some real timeframes for the normative, for most of the petitions that are submitted.

Mr. TOWNS. In your reform proposal—is that light right? Is that accurate time? Anyway, in your reform proposal you suggest that the petitioner should be able to designate which third party review organization should review the petition.

What is the benefit of giving petitioners the flexibility to choose the third party reviewer?

Mr. PAPE. Mr. Towns, that arises out of the process that petitioners properly engage in now. A well-counseled petitioner will consult with FDA along the development process to have the benefit of FDA's views about how to structure a study program, how to develop protocols, and how to approach the development of the data. That occurs years before you ever submit a petition.

If we are to have a system that embraces external third party reviews, then it would be expected that prospective petitioners would want to consult with not only FDA, which would remain, obviously, in an important role in the system, but also with others at the independent review organizations who will also have views about how to design a protocol.

If, for example, FASEB were to be one of the independent review organizations and a petitioner were attempting to determine what kind of study program would properly answer the questions to demonstrate safety, that petitioner might well want to consult with the scientists at FASEB and get the benefit of their advice, as well as FDA's. The thinking is that if that happens, then when the petition is filed there is a learning curve at FASEB, in my example, that could be taken advantage of.

Mr. TOWNS. Mr. Chairman, I yield. I'm hoping to get a second round.

Mr. SOUDER. Under the statute, an ingredient that is generally recognized as safe can be sold without FDA approval. Why do you believe it is necessary to have the FDA affirm that GRAS status?

Mr. FISHER. Who are you asking, sir? Anybody?

Mr. SOUDER. Yes, anybody. But, Mr. Heckman——

Mr. HECKMAN. That is what the customers want and it is, in effect, a customer service activity. It is difficult to get some of the major companies, including some of the major soft drink companies and others who are major customers, to buy unless they feel com-

fortable that there is some sort of an imprimatur on it because FDA does, regardless of what some might think, have a major reputation here and around the world for doing excellent scientific work.

And that is why I don't think any of us want to see anything terrible happen to FDA. We all are major supporters of the agency. We just want to see its processes improved.

If I can ride this question one more second and respond in a way to a question Mr. Towns asked before, they use a system in Canada that is more like pre-market notification, except that it's a letter of no objection system.

In Canada there are three people who work on packaging. They are not considered food additives in Canada. There are three people that work on indirect additive no objection letter requests, and last year they processed 900 of them. They don't have any backlog to speak of.

That tells me that somehow or another when you are dealing with minimal risk there ought to be a way to deal with it, and that is why we have suggested the pre-market notification. In Europe, by the way, there is one person who just got an assistant that does somewhat the same thing.

Mr. TOWNS. Where in Europe?

Mr. HECKMAN. The whole Economic Community.

Mr. TOWNS. Oh, the Economic Community.

Mr. SOUDER. Mr. Pape, what should the FDA burden of proof be to justify reversing the finding of a third party review panel?

Mr. PAPE. The proposal which I described today, Mr. Chairman, would require substantial evidence. A favorable report from the independent review organization would create a presumption of approvability. The proposal we made would require FDA to have substantial evidence, not to demonstrate that the additive is unsafe, but simply substantial evidence to demonstrate that safety hasn't been shown.

Stated differently, a trivial question, a question that while unanswered is not material to the conclusion of safety, ought not to be grounds for rejecting or rebutting the presumption.

If, in the unlikely event—I think it would be quite unlikely—an independent review organization, bearing in mind that these organizations would be chosen by and under contract with FDA. These aren't industry chosen groups. The agency contracts with the independent groups. It decides which ones are qualified to conduct these reviews.

But I think in all fairness it is unlikely that there would be a favorable recommendation, conclusion of safety, by an independent organization and then the agency would have substantial grounds on which to disagree with that conclusion.

I think it entirely appropriate that it be required to have substantial grounds because otherwise, quite frankly, we are not changing the dynamic which exists today, which is where any unanswered question can rise to an impediment to approval without regard to its materiality.

Mr. SOUDER. Let me ask you—this is just a lay person's relatively uninformed question here. In both the last two answers you were talking about relative importance and the consumer value,

and your value as manufacturers of the FDA proof, seal, kind of like a good housekeeping seal. At the same time, part of that may be because it is perceived as completely independent.

If you go to the third party could you, in fact, while you are accelerating the approval process, even though it is still independent, be a step away from what you were seeking?

Mr. PAPE. The chairman's preface to the question was unneeded. It's an entirely appropriate question, Mr. Chairman.

I think that that is a theoretical concern. It is certainly one that when industry representatives were discussing the problems in the system and trying to come up with a solution that we paid a lot of attention to.

As I said in my testimony, we don't want to sacrifice the integrity or credibility of the FDA approval process, and that is why the proposal provides for the FDA to determine which are the qualified independent organizations, to enter into contracts with them, to set forth the ground rules and the like for the conduct of the reviews.

And it's not simply a system in which the petitioner could pick from any, you know, from any of a hundred possible places the one most likely to give a favorable answer that the FDA would then be obligated to abide by. That is not the system we are proposing.

What we are trying to do is leverage the resources, the limited resources, that FDA has in this area with the much more extensive resources that are available at places like FASEB and elsewhere. And if FDA is comfortable that FASEB can conduct competent and conflict-free reviews, then it should be obligated to go along with the results.

Mr. SOUDER. Thank you. I yield to Mr. Towns, if you have questions.

Mr. TOWNS. Thank you very much, Mr. Chairman. Let me begin again with you, Mr. Heckman. Since GRAS affirmation is a commercial service, should industry pay for it through, maybe, user fees?

Mr. HECKMAN. Well, first let me say this: GRAS affirmation or GRAS itself is, in effect, an exemption from the definition of food additive. The reason it is different than some of the other subjects we are talking about is because if you can establish GRAS status you have, in effect, established the fact that you are not dealing with a food additive at all. And that is why when you ask FDA to affirm GRAS status you are asking for a kind of customer service, so to speak.

On the other hand, as long as they do that by regulation that, it seems to me, precludes the charging of user fees because it makes the affirmation applicable to the world at large. So you, in effect, get no proprietary benefit from it, no exclusive rights, no patent rights, nothing of that sort.

On the other hand, what FDA proposed when they were here last week is that they undertake to do that in the future by means of, in effect, a pre-market notification system where you file and, once you file, after 90 days your GRAS affirmation is in effect. It seems to me, although I don't want to necessarily speak for the direct additive folks, that it should be possible to make a reasonable charge, not some outlandish amount but some reasonable charge for that service. I would think that would be reasonable.

Mr. PAPE. Mr. Towns, if I might just briefly comment on that, I think we should not proceed on the assumption that the GRAS affirmation process is of exclusive benefit to the person who submits the affirmation documents to FDA. Indeed, there are very important public benefits that arise by submitting the documentation, the GRAS affirmation petition, to the FDA. That is the mechanism by which FDA becomes aware of a private person's determination that something is generally recognized as safe.

And so I think the notion of payment has to be considered in light of the fact that there are both private and public consequences from the GRAS affirmation process.

Mr. HECKMAN. And I would certainly agree with that, and that makes it a little bit different than the straightforward pre-market notification for an indirect additive.

But, in either case, I suspect that if Congress wanted to impose some sort of reasonable fee consonant with what it would cost to deal with the material, I doubt that that would cause a great furor. I'm not talking about the kind of fees they charge for drug applications. In those cases they are getting major propriety benefits.

Mr. TOWNS. A different situation, yes.

Mr. PAPE. Without signing on specifically to this fee proposal, Mr. Towns, I think it is fair to assume that within reason the food industry is willing to pay for some of the activities here. You will note in the proposal I described the food industry would pay, the petitioner would pay, for the cost of the independent review.

And that is a product of the fact that we think it entirely appropriate to do that. And if we need to bring more resources to bear to bring some efficiency and timeliness to the system, the dollars have got to come from somewhere, and I don't think they are going to come from the taxpayers.

Mr. FISHER. Mr. Towns, let me add just to what Mr. Pape was saying. Since 1989, FASEB has done five or six GRAS affirmation petition reviews for industry and, indeed, what industry was seeking was generally recognized as safe GRAS status. And as was mentioned a little earlier, the impediment came from the person who wished to purchase or utilize those GRAS substances because FDA over the past several decades has made the GRAS affirmation process analogous to the food additive petition process.

Now, it was very enlightening last week to learn that they were going to separate these and make the GRAS affirmation process perhaps what it was originally intended to be: a way to separate food additives and GRAS substances.

Mr. TOWNS. It means that the hearing is doing a little something, at least.

Mr. FISHER. I suspect you will find that the hearing is doing a great deal, a great deal.

Mr. TOWNS [presiding]. Thank you. Let me, I guess, Mr. Pape, since the third party reviewer would assume substantial responsibility for food safety under your proposal, we must take every step to insure their independence and integrity. I mean, that's important.

In the suggested legislative language provided with your testimony, I must admit I like the provision included for maintaining third party independence. Would you also advocate establishing

some degree of legal liability for the third party reviewer to insure accountability and prevent the reviewer from becoming captured by industry's interest? What type of mechanism can we create to insure that the third party has the accountability and the independence?

Mr. PAPE. Well, I think, Mr. Chairman, these are—I guess you are the chairman at this point. You are the only Member up there. I think that those questions are properly addressed through the contracts that FDA enters into.

What we tried to do in the legislative language to which you refer is identify the principal criteria for the selection of independent organizations, and the capability to conduct the reviews and independence and the like were clearly important criteria.

I think such things as conflict of interest and the like are best dealt with in the form of the contracts. As Dr. Fisher suggested, however, I don't think we want a system in which we micro-manage the activities of the independent organizations.

If I understood Ken's testimony correctly, and I think I did, what he said was that the GRAS review between 1972 and 1982 had worked so successfully in part because there was a meeting of the minds between FDA and FASEB at the outset and FDA did not attempt to micro-manage the FASEB process. So that confidence in FASEB's ability to conduct an honest and fair and competent process and it let FASEB select the people. This is all very public. I mean, if any of the problems to which your question alludes manifest themselves, everybody will know about them.

If, by chance, an independent review organization had—oh, to think of a crazy example—a full-time employee of a company that was involved in developing food additives reviewing food additives, that wouldn't be a secret. That would be well-known to everybody and I suggest it would not be a situation that would persist for very long.

Mr. FISHER. Mr. Towns, I might add to that that you have several types of third party organizations. An organization such as the one that I worked for is a 501(c)(3) nonprofit organization. All of its activities are controlled by a board of directors and all of the activities that we were involved in in the GRAS review included a rather stringent conflict of interest and at least three levels of internal review.

I can't speak for other independent third parties, but most of the organizations that I know of, scientific societies and scientific institutes, do have rather stringent requirements on their own employees and consultants. So that might be a problem in the situation that Mr. Pape has indicated, but I don't believe it would be a problem in any organization that jealously guarded its nonprofit tax-exempt status.

Mr. TOWNS. All right, just give me a moment. Let me get a check here. We just have a temporary recess. You know we have to vote around here and one is on, so let me just sort of run to vote and we'll be right back immediately after the vote. So we'll take a 10-minute recess.

[Recess.]

Mr. TOWNS. I guess this would be for you, Mr. Farley. How does Pfizer's proposal provide some reasonable assurance of certainty

with respect to the length of the review times? Under Pfizer's proposal, would the FDA have the authority to request that additional testing be done after referring a petition to the expert panel?

Mr. FARLEY. In answer to the latter point, yes. If there is more testing required, that would have to be recommended and, as usual, the petitioner would discuss that with the FDA. If more testing were merited, it would have to be done.

With respect to the former questions, the independent panel, we believe that it would provide the FDA with access to another—to an objective party other than the petitioner, who FDA might assume not to be necessarily objective, to discuss scientific issues to discuss questions about the data that is submitted by the petitioner. This is often a significant time-consuming portion in the review process, so we believe that that would reduce the amount of time that is currently taken in the review by the FDA.

Mr. TOWNS. Pfizer's reform proposal actively involves the FDA in petition review relative to the proposals advocated by Mr. Pape. Do you have any concerns with Mr. Pape's proposal as it relates to FDA's involvement actually in the review process?

Mr. FARLEY. I think where we differ is Pfizer's proposal suggests that there is an outside independent body who is fulfilling a mission to assemble expert scientists and that petitioners go through that outside body versus going to the FDA, and then letting the FDA contract specifically. That is what the difference is, in our view.

We think the outside body would be set up to react more quickly, have access to a wider variety of scientists to fulfill its mission, and still it would allow independence.

Mr. TOWNS. So I think it's just safe to say that under the present structure that it's just impossible for this to be done. I think all of you are saying that and that, in order for it to make it work, some major changes would have to take place.

Mr. FARLEY. Correct.

Mr. FISHER. I'm not sure I necessarily agree with that, sir.

Mr. TOWNS. You're not?

Mr. FISHER. Major changes in the law, no. Major changes in the regulations, perhaps. Major changes in attitude and administration, yes.

Mr. TOWNS. But you don't think it would require any changes—no legislation would be needed, you are saying?

Mr. FISHER. I'm not sure. I think both the proposals that Mr. Pape and that Pfizer have developed are certainly worthy of further consideration and certainly could work. They have built on what we have done in the past, but I'm not sure that legislation would be needed other than perhaps to look carefully at the timeframes that are in the law and the regulations, provided there was some kind of exemption clause for very complicated cases.

Mr. TOWNS. Do you want to add something, Mr. Heckman?

Mr. HECKMAN. I want to comment on that to the effect that that's clearly not true with regard to the part of the law I'm discussing. We need a statutory change or FDA can't do what I'm saying. They don't have the statutory authority to do it. And I'm not sure I agree that they have the statutory authority to do what Mr. Pape advocates either without some statutory change.

Mr. PAPE. I would agree with that, Mr. Towns. We're not talking about major statutory change here. You made reference earlier to the proposed legislative language. As you can see, all of what both Mr. Heckman and I talked about in terms of a proposal is done in less than eight or nine pages of legislative language. I don't consider that to be a major change.

I think the ideal way to fix these problems is, in fact, through legislation because I think it's only in that way that we can get reasonable timeframes, that we can leverage FDA's resources, and that we can insure that the process will work. I think everything else is likely to be patching a very leaky roof.

Mr. TOWNS. Well, let me thank all of you for your testimony. I think you have been extremely helpful and I think you further pointed out that there is a lot of work that needs to be done. I think we can all agree on that.

And we look forward to probably working and also probably getting additional information as we move forward to try and to bring about some real changes that everybody can sort of be able to live with. So thank you very, very much for your time.

Our next panel, Dr. Michael Jacobson. Will you stand and we can swear you in.

[Witness sworn.]

Mr. TOWNS. Let the record reflect that the witness has answered in the affirmative.

STATEMENT OF MICHAEL JACOBSON, CENTER FOR SCIENCE IN THE PUBLIC INTEREST

Mr. JACOBSON. Good afternoon, Mr. Chairman. It's nice to see you again after having—you may recall we worked together on a hearing on diet and cancer.

Mr. TOWNS. Yes, I was the real chair then. Good to see you again.

Mr. JACOBSON. My name is Michael Jacobson. I am the executive director of the Center for Science in the Public Interest. CSPI is a nonprofit public health group that focuses largely on nutrition and food safety. We endorse I think practically every other witness at this series of hearings in applauding the subcommittee for holding this first ever hearings on the way in which FDA reviews food additives.

CSPI has long been interested in food additives and, in fact, I wrote a book on the subject in 1972. Although most of the additives are safe, some are not and a few have proven to cause illnesses and deaths. In fact, numerous additives that were once thought to be safe turned out to have toxic, carcinogenic, or other effects.

That past history underlines exactly why it is so crucial to the public's health that new additives be very carefully scrutinized before they are allowed into the food supply. However, the FDA could certainly conduct safety reviews much more expeditiously than it is now without sacrificing quality.

Petitions for additives have often languished at FDA for years. Some of that slowness is clearly the agency's fault. Some is Congress' fault for not providing greater resources to the agency. But some delays in the review process are due to the petitioners themselves. For instance, Proctor & Gamble's business decisions and in-

complete testing have added many years to the review process of its artificial fat called olestra. Companies shouldn't complain about the FDA's slowness when they, themselves, are responsible for the delays.

We sympathize with companies' concerns about the long periods of time it takes to clear additives through the review process, partly because the FDA takes just as long to respond to citizens' petitions concerning hazards in our food supply. But the data needed for responsible decisionmaking are voluminous and often difficult to interpret.

Furthermore, to insure safety the FDA might well require additional studies. We caution against the imposition of unrealistic and rigid time limits for the data collection phase of the review process. Review by the FDA would be speeded up if the studies supporting food additive petitions were well-designed, well-executed, and well-reported. A baseline data set and quality assurance guidelines could help in this regard. We recommend that the FDA emphasize its Red Book as the bench mark for developi..g scientific data to support food additive petitions.

A major source of delay in the approval process is the FDA's policy of never rejecting a petition. The review policy for Hoechst-Celanese's artificial sweetener, acesulfame potassium, is a good example of the consequences of FDA's disinclination to disapprove early in the review process petitions with inadequate safety data. The FDA spent several years working with the company to salvage very poor test data, rather than simply requiring new high quality tests.

Congressman, if you are looking in my testimony, my written testimony, for these comments it's kind of scattered around there and it's hopeless, I think.

Mr. TOWNS. Your entire statement will be included in the record.

Mr. JACOBSON. Thank you. The agency could have quickly rejected the petition for acesulfame-K without prejudice and told the company to provide better data if it wanted to seek approval in the future. We recommend that FDA consider changing its interminable "getting-to-yes" approach to a speedy "just-say-no" policy when that's appropriate.

We recommend setting a realistic time limit, say 1 year, for FDA's decision as to whether to approve or deny a petition once the agency has in hand all the data it needs for its decision; however, the FDA must always be permitted to protect the public health by requiring additional studies. Of course, if the statute does not allow for additional time, the FDA could simply deny a petition.

We have heard suggestions for contracting out FDA's food additive petition review and approval process. The National Food Processors Association's proposal for third party review isn't really about third party review. It takes approval authority away from FDA and we strongly object to that approach. NFPA's proposal would jeopardize the public's health. Approval decisions and safety evaluations must be made by FDA officials who are publicly accountable, not by private third-party organizations.

Furthermore, third-party reviewers don't necessarily stick to strict deadlines. For instance, in September 1992, the FDA hired FASEB to review the additive MSG with a deadline of March 1994.

Here it is June 1995, and FASEB still has not given FDA its report.

Nevertheless, there are ways in which third-party organizations could be used to speed up the review process. For instance, consultants could work with companies to make sure their petitions are complete and accurate. Also, the FDA could send newly arrived petitions to toxicology consulting firms for an audit of submitted data to make sure that those piles of data, in many cases, really piles of data, are accurate, that the numbers add up right.

Those firms would not make, should not make, safety evaluations, but that data audit is extraordinarily time-consuming, and it would be very nice to have an outside agency do it instead of FDA.

When the food industry talks about being willing to pay for these third-party reviews, why not have them give the money to FDA and let FDA make those decisions? I think what industry would like is to get those decisions out of the hands of FDA into some obscure third-party, easily lobbied agency.

Finally, FDA, as it promised at your June 22nd hearing, should redeploy staff to expedite review of food additives and Congress should provide the agency with adequate funding to do its job right.

I would be pleased to answer any questions you might have.

[The prepared statement of Mr. Jacobson follows:]

PREPARED STATEMENT OF MICHAEL F. JACOBSON, PH.D., EXECUTIVE DIRECTOR, CENTER FOR SCIENCE IN THE PUBLIC INTEREST

Good afternoon, and thank you for inviting me to testify at these important hearings on the Food and Drug Administration's process for reviewing food-additive petitions.

My name is Michael Jacobson, and I serve as executive director of the Center for Science in the Public Interest (CSPI), located in Washington, D.C. I hold a Ph.D. in microbiology from M.I.T.

CSPI, founded in 1971, is a nonprofit public health group with approximately 750,000 members and subscribers. We focus primarily on nutrition and food-safety issues. CSPI is supported largely by its membership and does not accept funding from industry or government. That has enabled our organization to praise or criticize individual products, companies, or government policies, as appropriate, without questions of conflict of interest.

Food additives have long been of interest to CSPI. In fact, my first task when I came to Washington in 1970 was to write a book on additives, Eater's Digest: The Consumer's Factbook of Food Additives. In that book and in more recent CSPI publications, we assert that most food additives are safe. I have included as part of my written statement a chapter on food additives from a 1991 book, Safe Food, that I co-authored.

Additives make it possible to market an increased range of processed foods, but it's unusual for additives to provide consumers with measurable health benefits. Congress acknowledged this difference from drugs—where there is a measurable health benefit—by requiring that food additives be shown to be safe before they are marketed without consideration of economic benefit to food processors or manufacturers of additives.

Although most food additives are safe, some are not, and some have proven to pose serious risks to health. In fact, numerous additives that were once thought to be safe turned out to cause toxic, carcinogenic, or other effects. For instance,

- In the mid-1960s, cobalt sulfate was permitted as a foam enhancer in beer. Though it was to be used only in beer and thought to be perfectly safe, cobalt sulfate turned out to cause congestive heart failure and killed a number of heavy drinkers.
- In the early 1970s, CSPI urged the FDA to ban Violet 1, the dye that was then used to stamp USDA's safety mark on meat. The dye had not been tested adequately when it was approved. A few years after we filed our petition, Violet 1 was found to cause cancer, and the FDA banned the additive.

• In 1982 the FDA proposed that sulfite preservatives—which were widely used to preserve the appearance of salad-bar vegetables—be declared GRAS. CSPI informed FDA that sulfites caused severe allergic reactions. Several years and several unnecessary deaths later, FDA banned sulfites from most fresh foods and required better labeling on packaged foods so that consumers sensitive to sulfites could avoid the products.

Since some food additives can be hazardous and are consumed by almost the entire population, protection of the public's health is paramount when additives are being reviewed by FDA. However, safety reviews could be done expeditiously by the FDA without sacrificing quality.

We believe that it is in the interests not only of the public, but also of every manufacturer who uses additives in its foods, that our nation's system for approving food additives be of the highest quality and beyond reproach. Information presented to this subcommittee indicates that petitions for direct additives, indirect additives, color additives, and GRAS self-determination affirmations often languish at FDA for years, sometimes decades. There appear to be several reasons for those delays.

DIRECT ADDITIVES

Chairman Shays asked a good question last week: Why would any company put up with a ten-year wait for a decision on a food additive when the statutory limit for a decision is 180 days? Oddly enough, one reason could be the FDA's stated policy of never rejecting a petition. Instead, the agency works endlessly with a petitioner to prepare an "approvable" document. For additives that pose complex or difficult safety questions, or where there is some evidence of risk, it could take years beyond the 180-day time limit to assemble data supporting a decision to approve. For instance, we have criticized FDA's decision to approve acesulfame potassium, an artificial sweetener that may be a carcinogen, but which was, in any case, inadequately tested for carcinogenicity. FDA spent several years working with the company to salvage very poor test data rather than simply requiring new high-quality tests. The company got its initial approval twelve years after first meeting with the agency and six years after submitting its petition to the FDA. The agency could have quickly rejected the petition without prejudice and told the company to provide better data if it wanted to seek approval in the future.

Most additives are consumed in tiny amounts. The likelihood of toxic effects, especially acute toxic effects, is low for most such additives. However, some additives, called macronutrients, are expected to be consumed in large amounts. Fat substitutes are probably the most frequently discussed macronutrient additives. For reasons connected to the way scientific studies are done, it is difficult to do conventional safety evaluations for certain macronutrients. They are chemicals to which humans have never been exposed and which may have unusual chemical and physical properties. Assembling and then assessing the studies to establish safety could well take years. The FDA is working on policies for evaluating macronutrient safety that should, in time, rationalize and speed up such evaluations. For the time being, though, products such as Procter & Gamble's olestra present novel and difficult questions that justifiably take years to resolve.

Incidentally, some macronutrients are easy to deal with. Simplesse is a fat substitute made out of natural protein. It is easy to evaluate and is safe. FDA should develop a macronutrient review policy, or report to Congress on why it is impractical to develop such a policy, necessitating case-by-case review of such additives.

Delays have also occurred because companies submitted petitions filled with poor-quality data. Ironically, some of those same companies have criticized FDA for seemingly endless requests for data and studies. Similarly, if a company has failed to carry out a critical study, such as a carcinogenicity test in animals, years can be added to the time it takes to review a petition.

It is important to emphasize cooperation between FDA and petitioners before petitions are filed to ensure smooth passage through the process. A good example of what happens when a company ignores FDA's pre-filing suggestions is the petition from Hoechst-Celanese for the use of acesulfame potassium as an artificial sweetener. Although the manufacturer did go to FDA to discuss its testing program and test results several years before the 1982 filing of its petition, the company appears to have ignored the FDA's advice on design, execution, and reporting of studies. Years of delay ensued.

Sometimes a company is responsible for delays because of its own business decisions. That appears to be the case with Procter & Gamble's olestra, an additive whose slow movement through the review process was discussed by several of your earlier witnesses.

Olestra was developed by a Procter & Gamble scientist in 1968. In the early 1970s, P&G found that olestra lowered blood cholesterol levels, and, evidently changing its corporate mind about marketing the product as a food additive, initiated the drug approval process at FDA. Pursuit of drug approval for olestra continued until the mid-1980s, when it became apparent that olestra didn't lower blood cholesterol enough to get drug approval. In 1987, P&G filed its food additive petition for olestra. Unfortunately, P&G hadn't conducted certain critical studies, particularly a long-term mouse carcinogenicity study that is normally necessary for consideration of additive petitions. Moreover, the long-term rat study indicated a possibility of liver damage and cancer. CSPI urged FDA to require further long-term tests, which FDA did, adding about four years to the approval process.

In the context of P&G's efforts to win extensions to its patents on olestra, a review of the olestra food additive petition process by the General Accounting Office concluded that FDA did not bear primary responsibility for delays. Although P&G has been doing a lot of complaining about its treatment by FDA, it really shouldn't complain when it itself has been responsible for the delays in the review process.

With that as background, we support measures that would accelerate the review of food additives without jeopardizing the public's health.

First of all, some petitions have been on the books for two decades, with one filed in 1971. Although FDA cannot withdraw petitions on its own, it stands to reason that after years have elapsed without approval, petitioners might well have found other solutions to their needs and might no longer have any interest in their now-ancient petition. FDA does not appear to have a process for checking on whether petitioners want old petitions to be acted upon, but FDA should check, on a regular cyclic basis, to see whether these petitions are still active. Undoubtedly, some of the backlog is simply dead wood.

Improvements in the completeness and quality of data should help speed the review of additive petitions. In order for FDA to conduct its review, studies should be well-designed, well-conducted, and well-reported.

We have seen petitions where those criteria were not met, resulting in lengthy delays. Establishment of a minimum data set would at least start a review off right. The FDA's Red Book includes guidelines for minimum data sets, keyed to the nature of the additive and type and extent of expected exposure. The Red Book also has criteria for quality assurance, which are critical to ensure that data submitted will be good data. Some industry spokespersons have complained about the Red Book being a straitjacket, but its guidelines are actually quite flexible and adaptable to varied circumstances. Since FDA emphasizes working with petitioners to develop their data so that an additive is approvable, combining FDA consultations with information in the Red Book would help accelerate FDA's review process. The importance of the Red Book's guidelines for conducting tests on additives should be emphasized by publishing in the Federal Register a notice to the effect that the Red Book is the benchmark for developing scientific data to support food-additive petitions.

We recommend setting a time limit for an agency decision once the FDA has in hand all the data it needs for its decision. A relatively brief time limit, perhaps one year, could be set if FDA staff were working closely with the company as data were developed or refined. Collecting an adequate data set is especially important if FDA is going to continue its policy of working towards approval of all petitions. If FDA were willing to "just say no" rather than always "getting to yes," it could reject, without prejudice, a petition quickly, perhaps telling a company that an additive appears unacceptably risky or that the data are insufficient to demonstrate safety at that time. A company could then consider whether it wishes to conduct further tests and return later with a new petition.

Alternatively, rather than reject petitions while companies are conducting more tests, FDA could simply put a petition in abeyance, re-starting the decision clock as soon as the data set is complete. In any case, industry should realize that a rigid time limit for the review process could well mean that FDA would simply reject a petition that currently would be put in abeyance pending further research and analysis.

THIRD-PARTY REVIEWS

Suggestions have been made for the use of third-party organizations to review petitions to speed up the process. We hope that this subcommittee will recognize that contracting out analyses would not ensure timeliness. The fact is, food-additive petitions are voluminous and complex, reflecting the need to conduct a wide variety of chemical, metabolic, and toxicological studies to provide a basis for evaluating a chemical's safety. It takes time to analyze all those studies, perhaps having an FDA

pathologist re-read thousands of microscope slides. It could also take time for FDA to assess whether a toxic effect reported in animal studies would be likely to occur in humans.

The Federation of American Societies for Experimental Biology (FASEB) has been mentioned as one organization that could review food additive petitions and prepare evaluations for FDA approval, potentially speeding up the review process. In September 1992, FASEB started work on a review for FDA of the safety of the widely used additive monosodium glutamate (MSG). The review was supposed to be completed in March 1994. It is now June 1995, and FASEB still is not finished. Considering that MSG is an old and relatively well-understood additive, we question how expeditiously FASEB or any other consultant organization would be able to evaluate petitions for new additives that pose complex or novel safety questions.

The National Food Processors Association's (NFPA) proposal for third-party review isn't really about third-party review. It's really about taking approval authority away from FDA. We strongly object to that approach. The NFPA proposal shifts the burden of proof from the company having to demonstrate that its additive is safe to making the FDA prove that an additive is not safe. That would turn the clock back to the pre-1958 safety standard and invert the current statutory approach to pre-clearance. It would apply to products not yet on the market the standard now used to get previously approved products restricted or banned. It would be very difficult for FDA to meet this standard, and shifting the burden of proof as proposed by NFPA would jeopardize the public health.

Safety reviews by one of several outside agencies, as NFPA has proposed, also are rife with opportunities for conflicts of interest among reviewers and forum shopping by additive manufacturers.

However, there are ways in which third-party firms could be used to speed up the review process. For instance, consultant organizations could work with companies to organize their food additive petitions for submission, ensuring that petitions are complete and presented in a fashion so as to make it as easy as possible for FDA staff to review them. FDA need not play any role in such third-party activities.

Furthermore, the FDA could send new petitions to an outside organization, such as one of the large toxicology consulting firms, to make sure the data are clear and accurate. Such an audit of numerous test-tube, animal, and clinical studies is extremely time consuming and would free up FDA's thinly spread staff for the more important job of making safety evaluations. In any case, safety evaluations should be made by FDA officials, who are publicly accountable, not by outsiders.

So far, I have focused my testimony on the delays in reviews of petitions for direct additives. However, there have been major delays in reviews of indirect additives and affirmation letters for self-determined GRAS status as well, and both types of products also deserve speedier resolution of their approval status.

INDIRECT ADDITIVES

As regards improving review of indirect additives, we endorse FDA's proposal for a threshold of regulation (T/R) review process, which would exempt from full petition review indirect additives for which there is minimal concern about toxicity.

Most indirect additives are not likely to cause health problems. Levels of exposure are likely to be low, and many indirect additives are of natural origin and unlikely to be toxic, especially at low doses. However, certain chemicals proposed for use as indirect additives are known toxins and could present problems. This is especially true for indirect additives used in such applications as meat wrap or containers for fatty foods such as cooking oil. In such applications, fats in the foods can extract fat-soluble chemicals from plastic wraps or containers. Thus, FDA has been considering since the 1970s whether polyvinyl chloride (PVC) bottles are safe for use as containers for cooking oil. Tests conducted in the 1970s demonstrated that residues of vinyl chloride, a human carcinogen, appeared in cooking oil stored in PVC containers. It's time FDA completed its work on this and similar outstanding petitions for indirect food additives.

FDA's T/R proposal provides a margin of safety if an additive was found to be carcinogenic after the additive was put on the market. However, a suggestion made by Dr. Saunders, representing Frito-Lay, at your hearing on June 22, that higher concentrations of indirect additives be exempted under T/R would not be acceptable to us, since the one in a million risk factor would be lost. Also, we oppose suggestions by industry representatives that FDA be removed completely from approval of indirect additives and that companies be allowed to self-approve additives without informing FDA. The existence of hazardous indirect additives militates against any process which removes FDA oversight.

GRAS ADDITIVES

Finally, FDA provides a valuable commercial service for manufacturers of food additives and food processing companies by giving letters of affirmation to companies that have made self-determinations of GRAS status. Except for those unusual occasions when a substance determined by a manufacturer to be GRAS is found to be otherwise, the affirmation letters are the FDA's only contact with the GRAS process. Since substances determined to be GRAS are considered of low hazard to the public, it does not make much sense for FDA to assign to GRAS affirmation letters staff who could be working on direct additives and the T/R process for indirects. However, companies seeking GRAS affirmation letters should be able to get expeditious treatment for their requests. In the absence of adequate appropriations, a fee-supported mechanism would ensure that the FDA had staff to provide prompt reviews. In any case, preparation of GRAS affirmation letters should be the lowest priority additive-review function at FDA. The agency should focus its attention on those additives which are most likely to pose health hazards.

ADDITIONAL RECOMMENDATIONS

We also recommend the following measures for improving petition review:

• FDA should, as promised by the agency at the June 22 hearings, redeploy staff to review of direct food additives.

• The Administration should ask Congress for greater funding for FDA's Center for Food Safety and Nutrition, which is called upon to perform ever larger tasks with ever smaller budgets. A complementary measure would be to authorize FDA to collect fees from companies submitting food-additive petitions. The fees would fund external data audits. Currently, the FDA's drug-review process is partially funded by user fees, and the Environmental Protection Agency (EPA) levies fees on companies submitting pesticide registration applications.

To sum up, we congratulate this subcommittee for holding the first hearings ever on FDA's food additive petition review process, and we commend the FDA for its commitment to redeploy staff and improve procedures in order to speed up decision-making on food additives. We urge the subcommittee to continue its efforts to rationalize the food additive petition review process, while maintaining the safety of our food supply. And we urge the subcommittee to extend its hearings by investigating FDA's lengthy delays in responding to health concerns associated with food additives. Thank you.

Mr. TOWNS. Let me begin by saying to you thank you for testifying today, and I also thank you for all the help you have given us in the past.

Does the proposal put forth by the National Food Processors Association have adequate measures to insure the independence of the third-party review body, in your opinion?

Mr. JACOBSON. It doesn't at all. They talk now at this kind of a hearing about independence and objectivity. The moment the law is passed, they are going to be lobbying the Food and Drug Administration regarding which agencies it chooses and then lobbying those organizations regarding the scientists who are on the committees.

Mere disclosure of conflict of interest isn't enough. If there is a conflict those people shouldn't be involved.

And I think there is a lot of duplicity, a lot of pretending, that professors who consult for food corporations are objective. They are not. They are inclined to support the safety of food additives, to not ask the kind of tough questions that FDA staff are trained and expected to ask.

Mr. TOWNS. Let me just say, and I apologize, Dr. Jacobson, but there is this vote on and then immediately behind this there is another vote. And what I would like to do is just get permission to submit a few questions to you in writing and hold the record open and hope that you would respond, rather than to just sort of delay

you and delay you, because I'm not certain as to how long this is going to go on over there.

Mr. JACOBSON. Well, I would be pleased to answer any number of questions. I feel a little—after hearing from 13 industry witnesses and consultants I feel like I'm standing in for consumers here alone.

Mr. TOWNS. Well, no, I would be delighted to, as I indicated, submit questions. What is happening over there, as you know, the Members were up all night last night and some of them are having some difficulty dealing with that and it is beginning to affect their personalities.

So, anyway, but I would appreciate it if you would allow us to do that and you would respond to it within a reasonable period of time, let's say five working days. We would be delighted to hold the record open.

Mr. JACOBSON. I would be pleased to.

[The information referred to follows:]

FROM: THE COMPLETE EATER'S DIGEST AND NUTRITION SCOREBOARD BY MICHAEL F. JACOBSON, NEW YORK: ANCHOR PRESS (DOUBLEDAY), 1985, PP. 361–362.

Table 2.—Additives That Have Been Banned *

Additive	Function	Source	Last used	Reason for ban
agene (Nitrogen trichloride)	flour bleaching and aging agent	synthetic	1949	dogs that ate bread made from treated flour suffered epileptic-like fits; the toxic agent was methionine sulfoxime
dyes:				
butter yellow	artificial coloring	synthetic	1919	toxic, later found to cause liver cancer
FD&C Green 1	artificial coloring	synthetic	1965	liver cancer
FD&C Green 2	artificial coloring	synthetic	1965	insufficient economic importance to be tested
FD&C Orange 1	artificial coloring	synthetic	1956	organ damage
FD&C Orange 2	artificial coloring	synthetic	1960	organ damage
FD&C Orange B	artificial coloring	synthetic	1978**	cancer
FD&C Red 1	artificial coloring	synthetic	1961	liver cancer
FD&C Red 2	artificial coloring	synthetic	1976	possible carcinogen
FD&C Red 4	artificial coloring	synthetic	1976	high levels damaged adrenal cortex of dog; after 1965 used only in maraschino cherries and certain pills; it is still allowed in externally applied drugs and cosmetics
FD&C Red 32	artificial coloring	synthetic	1956	damages internal organs and may be a weak carcinogen; since 1956 used under the name Citrus Red 2, to color oranges (2 ppm)
Sudan 1	artificial coloring	synthetic	1919	toxic, later found to be carcinogenic
FD&C Violet 1	artificial coloring	synthetic	1973	cancer
FD&C Yellow 1 and 2	artificial coloring	synthetic	1959	intestinal lesions at high dosages
FD&C Yellow 3	artificial coloring	synthetic	1959	heart damage at high doses
FD&C Yellow 4	artificial coloring	synthetic	1959	heart damage at high doses

Table 2.—Additives That Have Been Banned*—Continued

Additive	Function	Source	Last used	Reason for ban
cinnamyl anthranilate	artificial flavoring	synthetic	1982**	liver cancer
cobalt salts	stabilize beer foam	synthetic	1966	toxic effects on heart
coumarin	flavoring	tonka bean	1954	liver poison
cyclamate	artificial sweetner	synthetic	1970	bladder cancer
diethyl pyrocarbonate (DEPC)	preservative (beverages)	synthetic	1972	combines with ammonia to form urethan, a carcinogen
dulcin (p-ethoxyphenyl urea)	artificial sweetner	synthetic	1950	liver cancer
ethylene glycol	solvent, humectant	synthetic	.....	kidney damage
monochloroacetic acid	preservative	synthetic	1941	highly toxic
nordihydroguaiaretic acid (NDGA)	antioxidant	desert plant	1971***	kidney damage
oil of calamus	flavoring	root of calamus	1968	intestinal cancer
polyoxyethyl-8-stearate (Myrj 45)	emulsifier (used in baked goods)	synthetic	1952	high levels caused bladder stones and tumors
safrole	flavoring (root beer)	sassafras	1960	liver cancer
thiourea	preservative	synthetic	c. 1950	liver cancer

* Ref.: 21 CFR 189; "Food Colors", Nat. Acad. Sci. Committee on Food Protection (1971); other sources.
** Ban not yet finalized.
*** NDGA was banned by the FDA in 1968, but the Department of Agriculture did not ban it until 1971.

QUESTIONS FROM CONGRESSMAN SHAYS AND ANSWERS FROM DR. JACOBSON

Question 1: Do you feel that your organization has been used by anti-competitive forces to delay decisions on pending petitions?

Answer: The Center for Science in the Public Interest has not been used by anti-competitive forces to delay decisions on pending petitions.

It is in the interest of the public and the public health to have companies that have developed factual information on safety hazards associated with a competitor's product bring that information to the attention of government authorities and the public. In the case of food additives, companies would bring such information to the attention of the Food and Drug Administration (FDA). It is particularly helpful if such information is provided to FDA before the additive is approved for sale, since safety questions should be resolved before a product goes onto the market. Also, it is much more difficult for FDA to remove an unsafe additive from the market than to keep an additive from getting onto the market until safety questions are resolved or the agency has determined the additive is unsafe and cannot be approved.

When companies provide government agencies and the public with information on hazards associated with competitors' products, the companies providing the information are acting in a true pro-competitive and free enterprise fashion. Competition on safety issues is just as valid as competition based on price or other qualities. This sort of competition can ultimately result in products which are both effective for their intended use and safe, and we applaud such efforts.

Question 2: Why in your testimony do you state that "it's unusual for additives to provide consumers with measurable health benefits." Last week one of our other witnesses, Dr. Michael Davidson of Rush-Presbyterian-St. Luke's Medical Center, quoted you in his testimony "reducing saturated fat by eight grams a day will save as much as $24 billion a year in the treatment of chronic diseases and two million fewer Americans would have heart attacks"?

Answer: The vast majority of food additives do not provide any health benefits. Those additives include preservatives, colorings, flavorings, emulsifiers, thickening agents, and indirect additives. In fact, some additives reduce the nutritional quality of foods. For instance, artificial colorings and flavorings replace real fruit in everything from gelatin desserts to beverages; consumers thereby lose out on the vitamins, minerals, and phytochemicals that are present in real fruit or fruit juice. Furthermore, some additives have introduced health risks into food: the preservative sodium nitrite may react with other chemicals in the food or in the consumer's stomach to form cancer-causing nitrosamines; sulfite preservatives can cause life-threatening allergic reactions, especially in a subgroup of asthmatics; caffeine added to soda pop (as well as that which is naturally present in coffee and tea) may interfere with reproduction; artificial colorings have caused hyperactivity in some children; saccharin has been linked to cancer in animals and in one human study; mono-

sodium glutamate can cause headache and other adverse effects in a large number of people.

Occasional additives can be used to improve the nutritional profile of foods. For instance, vitamins and minerals are frequently added to breakfast cereals, fruit drinks, and white flour, thereby increasing their otherwise limited nutritional value. In the past several years, innocuous additives have been used to replace fat in cakes, cookies, frozen desserts, and margarine. The lower fat content can help people reduce their overall fat intake. However, there is limited evidence that consumers actually use those lower-fat foods to improve their overall diets. Similarly, artificial sweeteners can be used to lower the sugar content of diets. However, despite soaring sales of artificially sweetened foods in the past fifteen years, overall sugar consumption (as measured by USDA's disappearance data) has risen by twenty percent. It is possible that the same phenomenon would occur if fat substitutes were more widely used.

CSPI has indeed estimated that reducing saturated fat intake by eight grams a day would save as much as $24 billion a year. We believe that that tremendous possible benefit justifies major health education campaigns sponsored by government and private agencies to encourage Americans to eat less and/or lower-fat meat and dairy products. Fat substitutes could well contribute to such reductions if they are used judiciously. We endorse the use of safe fat substitutes, and some—such as vegetable gums, water, and Simplesse (made of egg or milk protein)—are certainly safe. We have had serious questions about the quality of testing and the safety of olestra, a sucrose polyester fat substitute.

Question 3: On what basis do you state in page 3 of your testimony that Acesulfame Potassium or AcK, an artificial sweetener, "may be a carcinogen, but which was, in any case, inadequately tested for carcinogenicity. FDA spent several years working with the company to salvage very poor test data rather than simply requiring new high-quality tests."

Answer: The basis for this statement is FDA staff memoranda for the period 1980–1986. To sum up the memoranda, even before Hoechst (now Hoechst-Celanese) filed their food additive petition in 1982, FDA staff had told the company that there were problems with their cancer studies (reporting of data). When the initial staff review of safety data was made after the petition was filed, FDA scientists pointed out many flaws in design, execution and reporting of the company's rat and mouse cancer studies. These flaws should have disqualified the results from being used to justify approval of the additive.

The Hoechst tests were carried out in the mid-1970s in a European laboratory using non-standard animals, questionable study design (including inadequate length of time for the mouse study), inadequate and possibly improper procedures for conducting autopsies and selecting/collecting tissues from dead animals and inadequate statistical analysis of results.

When FDA began its review of the cancer data in the early 1980s, test methodologies had moved well beyond those used in the Hoechst tests and, in any case, the flaws identified by FDA staff should have led FDA to require new tests. Instead, FDA permitted the company to have a consultant pathologist in the United Kingdom redo the pathology work done by the Dutch laboratory that carried out the original studies. This effort, which took several years, included searching in pots of tissue for organs from which samples were not taken during the original evaluation of the study data. FDA also allowed Hoechst to abandon their initial rat study, which showed that acesulfame potassium caused cancer, because of the company's unjustified claims that the animal colony had a high incidence of a respiratory disease that was linked to development of the cancers. The rat study run to replace the study in which the rats developed cancer was flawed, and a reconstruction job had to be done on it before FDA could review the results.

FDA's actions in regard to cancer testing of acesulfame potassium would appear to stem from the agency's policy of never rejecting a food additive petition, instead working with the company to develop data which can justify approval. Approving acesulfame potassium despite the flaws in the cancer tests required FDA to go through major contortions in their 1988 Federal Register notice (53 Fed. Reg. 28379–28383 (July 28, 1988), disavowing the guidelines in the agency's Red Book, and generally disregarding basic principles of public health and good science.

CSPI first objected to the acesulfame potassium cancer tests in 1987, and has continued to urge FDA to require good cancer tests. This is especially important now that FDA is considering Hoechst-Celanese's food additive petition for use of acesulfame potassium as an artificial sweetener in soda pop. The prospect of many millions of Americans, especially children, consuming this poorly-tested additive is cause for great concern.

Question 4: What factors did GAO identify as causes of delays in the Olestra petition review?

Answer: The United States General Accounting Office (GAO) identified several causes of what Procter & Gamble has claimed as delay in the Food and Drug Administration (FDA) pre-market review of the food additive petition for olestra. To answer your question, we quote from and refer to GAO's report FDA Premarket Approval: Process of Approving Olestra as a Food Additive (GAO/HRD–92–86; April 1992).

1. Procter & Gamble made a business decision to wet olestra approved as a drug; this decision cost the company approximately ten years.

To quote from the GAO report:

". . . Between 1975 and 1985, P&G spent significant time and resources exploring the product's properties and its potential as a drug.

It was the decision to concentrate company resources on getting Olestra approved as a drug that a P&G competitor alleges cost the company valuable time. P&G officials deny this, stating that they pursued only one regulatory goal with FDA on Olestra: to follow the fastest possible route to approval, supported by appropriate safety data, of Olestra's use in foods. In response to our written questions, however, FDA stated that, had P&G focused on Olestra's use as a food additive in the early 1970s and pursued it vigorously, the company could have had a head start in resolving current safety questions." (pp. 2–3).

Procter & Gamble's decision to attempt to market olestra as a drug, and the lengthy regulatory activities entailed in the company's unsuccessful efforts to obtain drug approval, are described in an article from Advertising Age (Whatever Happened to Olestra?, Advertising Age Extra, Advertising Age, May 2, 1994; pp. 16–18). A copy of the article is attached to be included as part of our reply to this question.

A 1990 article in Adweek's Marketing Week also discusses the delays in the review process caused by Procter & Gamble's decision to stress drug rather than food additive approval during the 1970s. (Has the Window of Opportunity Slammed Shut on P&G?; Adweek's Marketing Week, January 1, 1990, pp. 2–3.) A copy of the article is attached to be included as part of our reply to this question.

[NOTE.—The articles can be found in subcommittee files.]

2. Olestra's unique properties and its status as a macroingredient/ macronutrient required novel and extensive review by FDA; this was not the agency's fault.

According to GAO:

"In 1985, P&G learned that it might be able to make limited health claims about food products. Accordingly, in 1987 P&G submitted a food additive petition (FAP) for Olestra. The FAP raised issues with which FDA had little experience. Because Olestra was a unique substance, the agency's guidance was more tentative than usual . . .

. . . . . .

"Another lengthy process concerned developing testing protocols and conducting tests for Olestra. P&G first needed to develop, in collaboration with FDA, innovative approaches for testing macroingredients. FDA stated that it preferred tests to be sequential rather than concurrent because some were done simply to design more conclusive studies."

3. Procter & Gamble applied for a broad spectrum of uses for Olestra, making safety review difficult. According to GAO:

Also a source of delay was the broad range of Olestra's intended uses, as cited in P&G's 1987 petition, which required the company to respond to reviewers' questions about all intended uses. P&G's strategy until 1990, when it did narrow down its FAP, was to introduce Olestra in a wide variety of products. However, the petition created major challenges for FDA reviewers because P&G's test results and other data applied to various formulations and potentially broad uses of Olestra, such as shortenings, sald oils, cooking oils, and snacks (potato chips, corn chips, and the like).

It is readily apparent from the Principal Findings in the GAO report that delay in review of Olestra was due to business decisions made by Procter & Gamble and to the unique nature of the additive and its planned uses. FDA should not be blamed for these delays.

QUESTIONS FROM CONGRESSMAN TOWNS AND ANSWERS FROM DR. JACOBSON

Quetion 1: Dr. Jacobson, in your testimony you state that it is important to emphasize cooperation between the FDA and petitioners before petitions are filed. To this end, the FDA has pre-filing suggestions for petitioners.

How could these pre-filing suggestions be improved to expedite petition review?

Answer: 1. Cooperation between FDA and companies planning to file food additive petitions could speed up petition review. Steps would have to be taken by both FDA and industry to improve review times.

—FDA should provide a clear definition of the minimum safety testing content and quality needed for agency review of a petition. The Red Book is a good start.

—Cooperation between FDA and company staff to tailor testing to the additive before a food additive petition is filed would certainly improve initial review and speed up decision-making. There is enough flexibility in the guidelines set out in the Red Book to make "custom tailoring" possible.

—Companies have to take seriously and act on FDA's pre-filing suggestions for improving a food additive petition. A notable example of what happens when a company ignores FDA's suggestions can be found in the petition for acesulfame potassium. The company was informed by FDA staff in 1980, two years before the initial food additive petition was filed, that analysis and reporting of test data were inadequate. It appears that the company had not corrected these problems when the petition was filed, and FDA staff had a very difficult time sorting out and assessing data during initial data review and subsequently.

—As regards FDA's proposal to hold workshops for companies wishing to file food additive petitions, we question whether scarce agency resources should be devoted to such an effort. As was noted in testimony by a representative of the National Food Processors Association, manufacturers of food additives tend to be large companies. These companies have on staff or can afford to hire the consultants, lawyers and other technical specialists who are familiar with food additive petitions and can shepherd petitions through the FDA review process. FDA's only role here should be to encourage companies to make contact as early as possible, well before filing a petition, so as to facilitate review.

—Perhaps the best way for FDA to get out its message that cooperation with the agency in the pre-filing stage is imperative would be for FDA to implement a policy of quick rejections, without prejudice, of petitions filed with inadequate safety data.

Question 2: Dr. Jacobson, you recommend setting a time limit for agency decision once the FDA has all the data it needs to make a decision. However, my concern is that uncertainty would remain for the period after submission of the petition, but prior to having all necessary data.

Do you have suggestions for adding greater time certainty to this period?

Would the FDA's proposal for performance standards achieve this end?

Is the FDA's performance standards proposal workable?

Answer: During the period between filing of a food additive petition and the completion of the data set needed for a decision as to whether to approve, FDA staff reviews data submitted by a company, identifies gaps in the data base and inadequate studies, and interacts with the company to resolve safety and other questions. This period of agency-company interaction to foster development of data is critical to the review process and to protection of public health.

Efforts to accelerate the review process must take into account the complexity of this post-filing review, and must acknowledge that clearing up unresolved issues can take years. There are good reasons for what may look from the outside like expensive delay: some tests may take years to carry out and resulting data may take years to analyze, but if the tests are not done right, safety can not be assured. Imposition of stringent time limits on this phase of petition review may not be feasible.

The FDA's proposals for performance standards could improve the efficiency of petition review. We are uncertain as to whether FDA has the resources to carry out the proposed standards. If the agency reprograms staff to food additive petition review and makes use of outside consultants for data audits (not safety determinations, which should be done by FDA staff), improved petition review times should result.

Question 3: Dr. Jacobson, I am truly interested in involving all affected parties in our efforts to reform the petition review process. Given this, I would like to know what proposals or aspects of proposals presented today that you support.

Answer: We support several of the proposals presented by FDA at your hearings:

—The threshold of regulation procedure for indirect additives.

—Redeployment of FDA staff to work on food additive petition review.

—FDA's proposed performance standards. We would encourage FDA to make speedy decisions even if that means disapproving, without prejudice, food additive petitions filed with inadequate safety data.

—Use by FDA of contract reviewers. However, we are not in favor of FDA leaning too heavily on FASEB or other organizations closely associated with the food industry. Other consultant organizations with experience in toxicology questions are available.

We are in favor of FDA using outside scientists to conduct audits of completeness and accuracy of data in food additive petitions, but any safety determinations must be done by FDA staff. We would want more information before endorsing the agency's proposal to use outside contract reviewers for indirect additive reviews, since we do not want FDA to end up, as the National Food Processors Association has proposed, being forced to rubber-stamp a private organization's safety determinations.

Data reviews carried out by consultants to FDA could be supported by charging fees to companies filing food additive petitions.

—We are not sure whether FDA's proposal for simple notification of GRAS status will be adequately protective of public health. Will companies take advantage of the short time frame FDA plans to impose on itself to make GRAS claims which may be both unsupportable and difficult for FDA to deny?

—We support FDA's plans to work with companies to improve food additive petition quality; this could speed up petition review. However, we question whether the big firms that make up most of the additive industry really need "food additive petition workshops". We suspect FDA's scarce resources would be better utilized emphasizing to individual companies who approach the agency before petitions are filed the importance of the Red Book safety testing guidelines, and working with companies before a petition is filed to resolve as many safety questions as possible.

Question 4: Does the notification system for indirect additives that is advocated by Mr. Heckman provide enough time for the FDA to test indirect additives for safety?

Answer: Mr. Heckman's proposal for removing from FDA authority the review of indirect food additives is not acceptable to us, since it is insufficiently protective of public health. We support the FDA's threshold of regulation proposal, which could speed up approval of indirect food additives while leaving control of the process in FDA's hands. The FDA proposal, as opposed to Mr. Heckman's, would give the agency the opportunity to require increased testing or filing of a full-scale food additive petition when an indirect additive's potential toxicity and exposure warrant concern.

Mr. TOWNS. Thank you very much. And at this time this hearing is adjourned.

[Whereupon, at 3:50 p.m., the hearing was adjourned, subject to the call of the Chair.]

[Additional information submitted for the hearing record follows:]

PREPARED STATEMENT OF KEITH C. TRIEBWASSER, PH.D., DIRECTOR, REGULATORY AND CLINICAL DEVELOPMENT

Procter & Gamble is a consumer products company with over 30 billion dollars annual sales. Over 3 billion dollars of this is provided by our foods business. P & G also develops new food ingredients with a special emphasis on products that enable the preparation of foods that promote human health. P & G's current interest is in new ingredients that can provide good tasting foods with reduced fat and calorie content which enable food companies to develop and offer to consumers food choices that have less fat and fewer calories without sacrificing taste and convenience. These products in turn can provide a health benefit to consumers by reducing the fat in their diet.

One of these new ingredients, caprenin, is a partially digested, reduced calorie fat invented in 1989. Caprenin was reviewed by The Federation of American Societies for Experimental Biology (FASEB) in 1991, judged GRAS, and is the subject of a pending GRAS affirmation petition accepted by FDA in 1991. Caprenin is marketed in reduced fat and calorie confectionery products.

The other ingredient is olestra, a non-digestible, non-caloric fat replacer developed in the early 70's Olestra is the subject of a food additive petition filed with FDA in 1987 after 10 or more years of discussion with FDA. Use of olestra to replace fat in snack products awaits FDA approval.

Congress, when it enacted the Nutrition Labeling and Education Act of 1990 recognized that reduction of fat and calories in the diet was a fundamental objective which needed to be met to improve the health of the American diet. FDA recognized this as it developed the regulations which implemented this landmark public health act.

The development of innovative food ingredients to help people better manage their diets has the potential to provide significant health benefits. An analysis of the health care impact of replacing excess fat in the US diet indicates that over 100,000 coronary heart disease and cancer deaths could be saved over the next ten years,

with a savings of over 25 billion dollars in health care costs. Further savings in lives and dollars would accrue from reductions in obesity, a condition which contributes to heart disease, diabetes and hypertension.

Both Procter & Gamble and the FDA agree that the overall review process could be improved, thereby bringing new food ingredient innovations and attendant public health benefits to fruition sooner.

The time consuming process of FDA approval of food ingredients appears to stem from: 1) A statutory situation that provides no incentives for action and, 2) FDA resources that are not commensurate to the task which the agency faces.

There are a number of potential solutions for this situation which the subcommittee may consider. Any solution should not eliminate or lower the standards that provide a safe and wholesome food supply.

The subcommittee should consider the appropriate level of FDA resources which should be applied to the evaluation of new food ingredients. This consideration should examine the distribution of resources within the FDA's centers (historically the resources allocated to CFSAN have remained flat while centers for drugs and biologics have enjoyed significant growth). The subcommittee should also seek to solve the problem of distribution of resources within CFSAN between the regulation of direct and indirect food additives to more adequately reflect the potential risks (and benefits) presented by these materials.

The subcommittee should also seek to provide relief for the resource inadequacies via the use of external scientific reviews of direct food additives by third party groups qualified to carry out such assessments. These reviews should be sanctioned by changes in the food additive portions of the Federal Food, Drug and Cosmetic Act and should be paid for by the petitioner, not the tax payer. These review groups should be verified by FDA as being capable of conducting such reviews. An example of such a review group is an organization like FASEB.

FDA should maintain final authority to approve new ingredients. However, the law should specify that the presumption of approvability arising from a favorable report of an independent review organization would be acted upon by the agency within a specified time frame. If the agency fails to take action within the specified time frame, the decision of the review group should become the agency's decision and marketing proceed.

The subcommittee must also address another aspect of current law which seriously erodes industry incentive to develop new food ingredients. This is the uncertain prospect of market protection. Without a statutory period of market exclusivity, such as that provided to new drug products, American industry cannot be expected to invest in new food ingredients that cannot be patented, even if the regulatory process itself is reformed. This is especially true for novel new macro-ingredient replacers where the time needed to complete the required testing and evaluation significantly erodes the available patent life, similarly to the situation with new drug entities.

In addition, in a situation where a petitioner not only must pay the cost of development and testing, but also pay the cost of an independent science review to obtain clearance, it is only appropriate that they obtain market exclusivity to protect their investments before generic competitors enter the scene. Patents alone do not provide this security, since patents are difficult to obtain in the food industry and difficult to enforce. Margins in the food industry are too low to support protracted patent battles.

Approvals of new drugs are private licenses while approvals of new foods are general rules that any "free rider" can exploit. We know today that nutritional innovation can be just as important to general public health as drug innovations. In 1958, when the food additives laws were passed, this wasn't known.

We look forward to working with FDA and the committee on updating the regulatory process of approving food additives.

DRAFT CONCEPT PAPER TO IMPROVE THE FDA FOOD ADDITIVE PETITION APPROVAL PROCESS

INTRODUCTION AND SUMMARY

A number of major food and food ingredient companies are developing a proposal to help address a major barrier to innovation in the U.S. food industry today—the FDA approval time for new Food Additive Petitions (FAPs) and GRAS ingredients. The 6–8 years now required for FAP approval stifles innovation and hinders introduction of new ingredients, including products which could contribute to healthy diets and improved nutrition.

This proposal could eventually shorten the approval process by addressing delays in reviewing the scientific aspects of FAP's. The delays are due, at least in part, to inadequate resources at the Center for Food Safety and Applied Nutrition (CFSAN).

The proposal would address these resource problems through the use of expert panels to review scientific data in FAP's. The panels would be recruited and administered by the National Center for Food Safety and Technology (NCFST), a research consortium in Chicago, currently funded by FDA and industry. A permanent secretariat at NCFST would be financed by annual grants from a group of ingredient suppliers and food companies, and the expert panels would be funded by separate FAP assessment fees. Panel reports and recommendations would be submitted via the petitioner to the FDAs providing expert scientific input and, we believe, substantially shortening the technical review process.

This idea has been shared with FDA/CFSAN, and NCFST, all of who have expressed interest in exploring this approach further.

BACKGROUND

Regulatory delays constitute the major impediment to the introduction of new food ingredients in the United States. This is due, in large part, to the inability of the FDA to process FAP's quickly, which are the primary approval vehicles for new food ingredients. FAP's for new ingredients are submitted to the FDA at the rate of 4–5 per year; the FDA now has a backlog of more than 50 FAP's.

The average approval time for major FAP's has increased over the past decade and is now 6–8 years. Examples include: aspartame (6 years); acesulfame-K (8 years); olestra (7 years, still unapproved), sucralose (8 years, still unapproved); and alitame (8 years, still unapproved). The FAP for polydextrose was approved in 1981 after a three-year review. An addendum to expand polydextrose uses was submitted to the FDA in 1988 and was approved in 1994.

There are two main reasons for this situation.

(1) CFSAN operates within a rigid framework specified by the FFDCA and the Administrative Procedures Act. Every review requires independent approval from at least 5 different disciplines (chemistry, toxicology, nutrition, environmental science, etc., and specific cases require microbiology, genetics, etc.), any one of which can stop the approval process. This management style prevents the agency from resolving issues and disagreements. The system applies not only to petition review but also to the writing of the regulation, which must be approved on a timely basis (particularly in those cases where the scientists of the same discipline are limited in number), by each review group, by the General Counsel's office, and by the Director. Changes in the draft regulation often require recycled approval from the various disciplines.

(2) The FDA does not have adequate resources. Because of government salary restrictions, CFSAN has been unable to attract and keep top-quality scientists in all disciplines, and because of budgetary constraints, the Agency is grossly understaffed. One manifestation of this is that CFSAN simply does not have enough in-house experts in all relevant areas of food safety. Here, the situation is worsening.

PROPOSAL

This proposal would facilitate the FAP approval process by the use of expert panels. The panels would be funded by FAP assessment fees and administered by the National Center for Food Safety and Technology (NCFST), an existing research institution in Chicago, administered by IIT and funded by the FDA and industry.

The process would work in the following way. A consortium of U.S. ingredient suppliers and food companies would provide annual grants of $25,000–50,000 each to NCFST to establish a permanent secretariat. The secretariat would consist of a scientist, an administrator and secretarial/clerical help—a total of 34 people. FAP's would be submitted to the FDA and to NCFST, accompanied by an "assessment fee" to NCFST. Any party could submit an FAP with an assessment fee, and petition rights would not be limited to those organizations that provide annual grants. The NCFST Secretariat would use the assessment fee to select a panel of experts, largely from academia, to review all scientific aspects of the FAP—chemistry, nutrition, toxicology, environmental science, etc.—the panel to be customized for each petition. The scientist on the NCFST Secretariat would serve on all panels, providing consistency among reports and an institutional memory. Petitions would be reviewed on a first-come, first-served basis. with no priority given to any type of ingredient.

The panel would be chosen from the top echelon in their respective discipline(s). Full disclosure of the panelists' financial and professional interests would be made

before panel review commenced. An administrative record of each panel's work would be maintained by the NCEST Secretariat to allow for an auditable decision.

The panel, individually and later as a group, would review the petition in detail and prepare a comprehensive report with conclusions, findings, and recommendations within six months of receipt of the FAP. The NCFST Secretariat would establish general panel procedures that facilitate the review and lead to a definitive position. The report would be submitted via the NCFST Secretariat and the petitioner to the FDA, thus providing a prompt, independent expert reading of all scientific elements of the petition. Panel membership would remain intact until the FAP was approved or withdrawn, providing the capability to respond to questions raised by the FDA throughout the petition approval process.

It is estimated, based on a study of five previously-approved FAPs, that this procedure could speed petition approval by as much as 3 years. This, of course, presumes expeditious review by the FDA and acceptance of the outside scientific expertise offered by the panels.

The proposal does not intend to limit the scope of the NCFST panels to review direct food additives only. Using the same assessment fee procedure, any party could submit a petition on a GRAS ingredient, a packaging component, or submit a dossier covering a broader safety issue for evaluation that may cover several petitions, or a broad-based issue exclusive of petitions that is of general interest to the food industry or other interested parties.

In addition to the obvious benefits to ingredient suppliers and food processors, more rapid approval of petitions could benefit the public in a number of ways:

(1) Consumer access to healthful reduced-calorie, reduced-fat processed foods would be facilitated.

(2) This, in turn, could contribute to reduction of diseases exacerbated by high-fat, high-calorie foods.

(3) Rapid FAP approvals would contribute to increased employment in the U.S. food processing industry and would improve the U.S. trade balance.

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