FOOD ADDITIVES—EXTENSION OF TRANSITIONAL PROVISIONS

HEARINGS

BEFORE THE

COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE HOUSE OF REPRESENTATIVES

EIGHTY-SEVENTH CONGRESS

FIRST SESSION

ON

H.R. 3980

A BILL TO AMEND THE TRANSITIONAL PROVISIONS OF THE ACT APPROVED SEPTEMBER 6, 1958, ENTITLED "AN ACT TO PROTECT THE PUBLIC HEALTH BY AMENDING THE FEDERAL FOOD, DRUG, AND COSMETIC ACT TO PROHIBIT THE USE IN FOOD OF ADDITIVES WHICH HAVE NOT BEEN ADEQUATELY TESTED TO ESTABLISH THEIR SAFETY," AND FOR OTHER PURPOSES

FEBRUARY 28 AND MARCH 1, 1961

Printed for the use of the Committee on Interstate and Foreign Commerce

U.S. GOVERNMENT PRINTING OFFICE
66738 WASHINGTON : 1961

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FOOD ADDITIVES—EXTENSION OF TRANSITIONAL PROVISIONS

TUESDAY, FEBRUARY 28, 1961

HOUSE OF REPRESENTATIVES,
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The committee met at 10:30 a.m., pursuant to notice, in room 1334, New House Office Building, Hon. Oren Harris (chairman of the committee) presiding.

The CHAIRMAN. The committee will come to order.

Today the committee is meeting to conduct hearings on H.R. 3980, a bill to provide for the continuation of the authority of the Secretary of Health, Education, and Welfare to permit the commercial use of certain food additives and pesticide chemicals pending the outcome of investigations and scientific studies now in progress by both the industries concerned and the Food and Drug Administration to determine, what, if any, tolerance limitations or other conditions should be imposed on their use in order to protect the public health.

The Secretary's authority to permit the continued use of these food additives expires March 4, 1961, and with respect to the pesticide chemicals the expiration date is March 5, 1961.

I have introduced the bill at the request of the Secretary of Health, Education, and Welfare and in view of the urgency which has been expressed as to the need for its prompt enactment, I have scheduled hearings on this bill as the first order of business of the committee during this session.

A copy of H.R. 3980, together with the departmental and agency reports thereon, will be made a part of the record at this point.

(Documents referred to follow:)

[H.R. 3980, 87th Cong., 1st sess.]

A BILL To amend the transitional provisions of the Act approved September 6, 1958, entitled "An Act to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety", and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Food Additives Transitional Provisions Amendment of 1961".

SEC. 2. Subsection (c) of section 6 of the Food Additives Amendment of 1958 (Public Law 85-929, 72 Stat. 1784, 1788) is amended by inserting in such subsection, at the end thereof the following: "Whenever the Secretary has, pursuant to clause (1)(B) of this subsection, extended the effective date of section 3 of this Act to March 6, 1961, with respect to any such particular use of a food additive, he may, notwithstanding the parenthetical time limitation in that clause, further extend such effective date under the authority of that clause (but subject to clause (2)) with respect to such use of the additive (or a more limited specified use or uses thereof) if, in additon to making the findings required by clause (1)(B), he finds (i) that bona fide action to determine the ap-

plicability of such section 409 to such use or uses, or to develop the scientific data necessary for action under such section, was commenced by an interested person before March 6, 1960, and was thereafter pursued with reasonable diligence, and (ii) that in the Secretary's judgment such extension is consistent with the objective of carrying to completion in good faith, as soon as reasonably practicable, the scientific investigations necessary as a basis for action under such section 409. The Secretary may at any time terminate an extension so granted if he finds that it should not have been granted, or that by reason of a change in circumstances the basis for such extension no longer exists, or that there has been a failure to comply with a requirement for submission of progress reports or with other conditions attached to such extension."

SEC. 3. Paragraph (b) of section 3 of the Nematocide, Plant Regulator, Defoliant, and Desiccant Amendment of 1959 (Public Law 86-139, 73 Stat. 286, 288) is amended by inserting in such paragraph, at the end thereof, the following: "Whenever the Secretary of Health, Education, and Welfare has pursuant to clause (1) of this paragraph (b), prescribed an additional period expiring on March 5, 1961, with respect to any such particular use of a nematocide, plant regulator, defoliant, or desiccant, he may, notwithstanding the provision to the contrary in such clause (1), further extend the expiration date applicable under such clause (1) (but subject to clause (2)) with respect to such use of such substance (or a more limited specified use or uses thereof), if, in addition to making the findings required by clause (1), he finds (A) that bona fide action to determine the applicability of such section 408 to such use or uses, or to develop the scientific data necessary for action under such section, was commenced by an interested person before March 6, 1960, and was thereafter pursued with reasonable diligence, and (B) that in the Secretary's judgment such extension is consistent with the objective of carrying to completion in good faith, as soon as reasonably practicable, the scientific investigations necessary as a basis for action under such section 408. The Secretary may at any time terminate an extension so granted if he finds that it should not have been granted, or that by reason of a change in circumstances the basis for such extension no longer exists, or that there has been a failure to comply with a requirement for submission of progress reports or with other conditions attached to such extension."

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
February 24, 1961.

HON. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your request for a report on H.R. 3980, a bill to amend the transitional provisions of the act approved September 6, 1958, entitled "an act to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety," and for other purposes.

This measure, to be known as the Food Additives Transitional Provisions Amendment of 1961, would amend existing law in two respects.

1. The principal purpose of this bill, which would be carried out by section 2 of the bill, is to remove—subject to appropriate safeguards and limitations—the time limit (March 6, 1961) which now exists on the authority of this Department to postpone, when necessary and consistent with public health protection, the effective date of the key operative provisions (sec. 3) of the Food Additives Amendment of 1958 (Public Law 85-929) to the Federal Food, Drug, and Cosmetic Act, as applied to established food additives (i.e., those in commercial use before January 1, 1958). The additional authority conferred by the bill would apply only where such further postponement beyond March 6, 1961, is necessary in order to permit the completion of necessary inquiries or studies started before March 6, 1960, and needed as a basis for determining whether, and if so under what tolerance limitations or other conditions, continued use of the additive should be permitted under the permanent provisions of Public Law 85-929, or whether that law applies to the substance involved at all.

This legislation is needed, both by us, and by industry, because we shall not be able to process all food additive petitions under the Food Additives Amendment of 1958—where extensions have heretofore been granted—before March 6, 1961 (the limit of our present authority to grant extension of the transitional provisions), and because the affected industries will not be able to develop all

necessary scientific data and petitions before that date, even where appropriate action leading to such petitions was started in a timely manner.

2. In order to mesh with the above-mentioned amendment, the bill (sec. 3) would similarly modify the relevant transitional provision of the Nematocide, Plant Regulator, Defoliant, and Desiccant Amendment of 1959 (Public Law 86-139, sec. 3(b)), which, as the indirect result of bringing certain agricultural chemicals—i.e., nematocides, plant regulators, defoliants, and desiccants—under the Federal Insecticide, Fungicide, and Rodenticide Act, had the effect of classifying such chemicals, about 30 in number, as "pesticide chemicals" under the Food, Drug, and Cosmetic Act, rather than as "food additives." (Pesticide chemical residues in or on raw agricultural commodities are not within the purview of the Food Additives Amendment, but rather within the purview of the earlier Pesticide Chemicals Amendment (Public Law 83-518) to the Food, Drug, and Cosmetic Act.) At present, this transitional provision of Public Law 86-139 is in consonance with the transitional provisions of the Food Additives Amendment of 1958 (Public Law 85-929); this would remain true under the present bill.

A detailed explanation of the need for enactment of this bill is enclosed herewith.

We therefore, in view of the need for and urgency of these amendments, recommend prompt enactment of the bill.

We are advised by the Bureau of the Budget that there is no objection to the presentation of this report from the standpoint of the administration's program.

Sincerely yours,

ABRAHAM RIBICOFF, *Secretary.*

ADDITIONAL EXPLANATION OF PROPOSED FOOD ADDITIVES TRANSITIONAL PROVISIONS AMENDMENT OF 1961

1. Section 2 of bill

The Food Additives Amendment of 1958 (Public Law 85-929) amended the Federal, Food, Drug, and Cosmetic Act so as to deem adulterated—and thus bar from interstate commerce—any so-called "food additive," and food bearing or containing such an additive, unless the safety of the particular additive for its intended use had first been established to the satisfaction of the Department of Health, Education, and Welfare and the use of the additive complied with tolerance limitations or other conditions of safe use set forth in a safety-clearance regulation issued with respect to the additive by this Department.

Basically, Public Law 85-929 became effective on March 6, 1959 (180 days after the date of enactment). However, with "respect to any particular commercial use of a food additive, if such use was made of such additive before January 1, 1958," the prohibitory provisions (sec. 3) of Public Law 85-929—i.e., those which had the effect of barring such food additives from the interstate market unless previously "cleared" by this Department—were to take effect only after a variable additional grace period or, if earlier, on the date of the establishment of an order passing upon the safety of such particular use of the additive. This grace period for such commercially established uses of food additives was, in general, 1 year beyond the basic effective date (i.e., March 6, 1960); however, the Secretary was empowered to extend it for as much as another year (i.e., to March 6, 1961) "on the basis of a finding that such extension involves no undue risk to the public health and that conditions exist which necessitate the prescribing of such additional period" (sec. 6(c) of Public Law 85-929).

The purpose of these grace-period provisions was to permit an orderly adjustment, on the part of interested industries, as well as ourselves, to the new requirements imposed by Public Law 85-929 insofar as food additives established in commercial use before January 1, 1958, were concerned, and to permit the affected industries to develop the information and scientific data needed with respect to such additives without meanwhile discontinuing the manufacture, marketing, and use of such additives not prohibited under prior law. It was felt at the time that, in general, a deferred effective date of 18 months from the date of enactment (i.e., March 6, 1960) would suffice for this purpose but it was foreseen that in a number of cases the need for further time, particularly where additional scientific work was required, would arise; hence the Secretary was given the above-quoted flexible authority to allow further time in such cases on an ad hoc basis, provided that no undue risk to the public health was involved in such postponement. However, following the precedent of the Pesticide Chem-

icals Amendment (Public Law 83–518), Public Law 85–929 set an outer limit (i.e., March 6, 1961) to such ad hoc postponements.

Under this authority, we have so far granted over 3,000 ad hoc postponements of the effective date of section 3 of the Food Additives Amendment with respect to commercially established uses of food additives. The question whether Public Law 85–929 should be amended to enable us to grant further postponements beyond March 6, 1961, was raised in January 1960 in the course of our testimony before the House Committee on Interstate and Foreign Commerce on the Color Additive Amendments of 1960 (which became Public Law 86–618). We then expressed the view that consideration of this question was premature but that, if further experience should indicate that the existing authority was inadequate, we would submit an appropriate legislative proposal to Congress (p. 81, report of hearings on H.R. 7624).

Our experience since then indicates that the present cutoff date of March 6, 1961, will in fact operate unfairly in a number of situations in which available evidence indicates that continued use of an additive for limited time will be consistent with the protection of the public health, and the interested persons in industry have exercised due diligence in starting and pursuing the necessary scientific work, but that work cannot possibly be completed, let alone acted upon by us, before arrival of this cutoff date. The scientific problem is accentuated by the fact that the Food Additives Amendment of 1958 applies not only to substances directly and purposefully added to food but also to so-called incidental additives, that is, substances the intended use of which may reasonably be expected to result indirectly in their becoming a component or otherwise affecting the characteristics of food, though this is not the purpose for which they are employed.

For example, if a food wrapping material contains a chemical that "migrates" from the wrapper into the wrapped food the chemical is by definition a "food additive" unless generally recognized by experts as safe. In many cases, it was not known whether certain chemicals long used in food packaging materials were in fact "migratory" and thus "food additives" or, if so, how much of such chemicals migrated to and remained in or on the food. In such cases, therefore, scientific work was required to determine these facts. If the chemical was determined to be a "food additive" in this defined sense, full pharmacological studies on laboratory animals were then required to furnish the necessary scientific basis on which we would have to rest a determination of the long-term safety of the chemical for its use and of the precise conditions under which such use should be permitted.

Where the necessary scientific work in process involves long-term pharmacological studies, there is no way in which it can be expedited. For example, we know of a pharmacological study now underway by a responsible pharmacologist on a series of paper sizings, which will not be finished until about April 1962. Again, ongoing pharmacological industry studies on commercially established waxes for use on fruits, vegetables, and food containers are not expected to be completed by March 6, 1961.

Section 2 of the bill—which is the principal part of the bill—would therefore authorize us, in cases of this kind, to postpone the effective date of section 3 of the Food Additives Amendment of 1960 beyond March 6, 1961, to the extent that this is consistent with public health protection and is, in our judgment, necessary to complete such scientific work in good faith. (This approach is similar in concept to that recently adopted by Congress in the Color Additive Amendments of 1960 (Public Law 86–618)). Moreover, the bill would enable us to invoke this authority only where we have previously granted an extension to March 6, 1961 (the limit of our present authority), and necessary inquiries or studies were started before March 6, 1960, and since then pursued with reasonable diligence. (We do not believe that those who have food additive problems but have done little or nothing to solve them should receive special consideration.) Finally, as in the case of the Color Additive Amendments of 1960, the bill would authorize us to terminate a postponement at any time when we find that it should not have been granted in the first place, or that by reason of a change in circumstances the basis for the postponement no longer exists, or that there has been a failure to comply with a requirement for submission of progress reports or with other conditions attached to the postponement.

2. *Section 3 of bill (re nematocides, plant regulators, defoliants, and desiccants)*

Under the Food Additives Amendment of 1958, the definition of the term "food additive" expressly excludes "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." The reason for this exclusion is that the regulation of residues of "pesticide chemicals" in or on raw agricultural commodities was already adequately provided for from the public-health standpoint by the Pesticide Chemicals Amendment (Public Law 518, 83d Cong.) to the Federal Food, Drug, and Cosmetic Act. The term "pesticide chemical" is defined by that amendment as "any substance which * * * is an 'economic poison' within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C., 135–135(k)) as now in force or as hereafter amended, and which is used in the production, storage, or transportation of raw agricultural commodities."

Originally, the Federal Insecticide, Fungicide, and Rodenticide Act, which established a registration system (administered by the Department of Agriculture) for "economic poisons," confined that term, basically, to insecticides, fungicides, rodenticides, and weedkillers. The Nematocide, Plant Regulator, Defoliant, and Desiccant Amendment of 1959 (Public Law 86–139) expanded the definition of "economic poison" in the Insecticide, Fungicide, and Rodenticide Act to include nematocides, and, also, any substance intended for use as a "plant regulator," defoliant, or desiccant. As a result, chemicals in these four categories, used in the production of agricultural crops, were no longer classified as "food additives" under the Federal Food, Drug, and Cosmetic Act but were automatically classified as "pesticide chemicals."

However, in order to permit an orderly transition for both the Government and industry, section 3 of Public Law 86–139 provided for transitional time periods, eyed to those specified in the Food Additives Amendment of 1958, during which (1) certain civil and criminal sanctions, etc., of the Insecticide, Fungicide, and Rodenticide Act would not apply, and (2) the adulteration provisions of the Food and Drug Act antedating the Pesticide Chemicals Amendment would continue to apply to certain of these products.

Thus, section 3(b) of Public Law 86–139 provides that, with respect to any particular commercial use of a nematocide, plant regulator, defoliant or desiccant in or on a raw agricultural commodity, "if such use was made of such substance before January 1, 1958," the old adulteration provisions of the Food and Drug Act shall continue to apply until March 5, 1960, or until the end of such additional period, not beyond March 5, 1961, as the Secretary of Health, Education, and Welfare may prescribe "on the basis of a finding that conditions exist which necessitate the prescribing of such additional period." (If, however, a tolerance or exemption therefrom under the Pesticide Chemicals Amendment, i.e., section 408 of the Food and Drug Act, were sooner established for such use of the substance, this traditional period would end at that time with respect to such use). The present bill would amend section 3(b) of Public Law 86–139 so to enable the Secretary of Health, Education, and Welfare to postpone the cutoff date of March 5, 1961, on an ad hoc basis where necessary for completion of scientific work, subject to safeguards and limitations exactly parallel to those contained in section 2 of this bill which amend the transitional provisions of the Food Additives Amendment of 1958. This authority is needed in order to make possible the bona fide completion of needed scientific studies that cannot be completed by March 5, 1961.

Changes in existing law made by bill to amend the transitional provisions of the act approved September 6, 1958, entitled "An act to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety," and for other purposes, are shown as follows (existing law in which no changes are proposed are shown in roman; new matter is printed in italic):

1. FOOD ADDITIVES AMENDMENT OF 1958

(Public Law 85–929)

"SEC. 6. (a) Except as provided in subsections (b) and (c) of this section, this Act shall take effect on the date of its enactment.

"(b) Except as provided in subsection (c) of this section, section 3 of this Act shall take effect on the one hundred and eightieth day after the date of enactment of this Act.

"(c) With respect to any particular commercial use of a food additive, if such use was made of such additive before January 1, 1958, section 3 of this Act shall take effect—

"(1) either (A) one year after the effective date established in subsection (b) of this section, or (B) at the end of such additional period (but not later than two years from such effective date established in subsection (b)) as the Secretary of Health, Education, and Welfare may prescribe on the basis of a finding that such extension involves no undue risk to the public health and that conditions exist which necessitate the prescribing of such an additional period, or

"(2) on the date on which an order with respect to such use under section 409 of the Federal Food, Drug, and Cosmetic Act becomes effective,

whichever date first occurs. *Whenever the Secretary has, pursuant to clause (1)(B) of this subsection, extended the effective date of section 3 of this Act to March 6, 1961, with respect to any such particular use of a food additive, he may, notwithstanding the parenthetical time limitation in that clause, further extend such effective date under the authority of that clause (but subject to clause (2) with respect to such use of the additive (or a more limited specified use or uses thereof), if, in addition to making the findings required by clause (1)(B), he finds (i) that bona fide action to determine the applicability of such section 409 to such use or uses, or to develop the scientific data necessary for action under such section, was commenced by an interested person before March 6, 1960, and was thereafter pursued with reasonable diligence, and (ii) that in the Secretary's judgment such extension is consistent with the objective of carrying to completion in good faith, as soon as reasonably practicable, the scientific investigations necessary as a basis for action under such section 409. The Secretary may at any time terminate an extension so granted if he finds that it should not have been granted, or that by reason of a change in circumstances the basis for such extension no longer exists, or that there has been a failure to comply with a requirement for submission of progress reports or with other conditions attached to such extension.*"

2. NEMATOCIDE, PLANT REGULATOR, DEFOILANT, AND DESICCANT AMENDMENT OF 1959

(Public Law 86-139)

"SEC. 3. This Act shall take effect on the date of its enactment, except that—

"(a) with respect to any nematocide, plant regulator, defoilant, or desiccant which was marketed commercially prior to the date of enactment and whose use does not result in residues of same remaining in or on a food, and with respect to any nematocide, plant regulator, defoilant, or desiccant whose use does result in residue remaining in or on a food at the time of introduction into interstate commerce and which use had commercial application prior to January 1, 1958, section 3, "Prohibited Acts"; section 8, "Penalties"; section 9, "Seizures"; and section 10, "Imports", of the Federal Insecticide, Fungicide, and Rodenticide Act, which this Act amends, shall not be applicable until—

"(1) March 5, 1960, or such later date, not beyond March 5, 1961, as the Secretary of Agriculture may prescribe on the basis of a determination that such action will not be unduly detrimental to the public interest and is necessary to avoid hardships, or

"(2) the date on which a registration for such use is issued under the Federal Insecticide, Fungicide, and Rodenticide Act,

whichever date first occurs; and

"(b) with respect to any particular commercial use of a nematocide, plant regulator, defoliant, or desiccant in or on a raw agricultural commodity, if such use was made of such substance before January 1, 1958, section 406(a) and clause (2) of section 402(a) of the Federal Food, Drug, and Cosmetic Act as in force prior to the date of the enactment of the Act of July 22, 1954 (68 Stat. 511) (relating to pesticide chemicals on raw agricultural commodities) shall apply until—

"(1) March 5, 1960, or the end of such additional period, not beyond March 5, 1961, as the Secretary of Health, Education, and Welfare may prescribe on the basis of a finding that such extension involves no undue risk to the public health and that conditions exist which necessitate the prescribing of such an additional period, or

"(2) the date on which an order with respect to such use under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a) becomes effective,

whichever date first occurs. *Whenever the Secretary of Health, Education, and Welfare has, pursuant to clause (1) of this paragraph (b), prescribed an additional period expiring on March 5, 1961, with respect to any such particular use of a nematocide, plant regulator, defoliant, or dessicant, he may, notwithstanding the provision to the contrary in such clause (1), further extend the expiration date applicable under such clause (1) (but subject to clause (2)) with respect to such use of such substance (or a more limited specified use or uses thereof), if, in addition to making the findings required by clause (1), he finds (A) that bona fide action to determine the applicability of such section 408 to such use or uses, or to develop the scientific data necessary for action under such section, was commenced by an interested person before March 6, 1960, and was thereafter pursued with reasonable diligence, and (B) that in the Secretary's judgment such extension is consistent with the objective of carrying to completion in good faith, as soon as reasonably practicable, the scientific investigations necessary as a basis for action under such section 408. The Secretary may at any time terminate an extension so granted if he finds that it should not have been granted, or that by reason of a change in circumstances the basis for such extension no longer exists, or that there has been a failure to comply with a requirement for submission of progress reports or with other conditions attached to such extension."*

The CHAIRMAN. I observe, first, that we have a couple of our colleagues here who are tremendously interested in this problem. My attention has been called to the fact that they have urgent business before their own committees, so, Mr. Secretary, if you will permit, I shall recognize first one of our colleagues who has been interested in this problem over a number of years, and to whom we are indebted for the contribution he has made to the problem, the Honorable James J. Delaney of New York.

Mr. Delaney, we are very glad to have you with us again, and we appreciate your concern and interest in this problem.

STATEMENT OF HON. JAMES J. DELANEY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Mr. DELANEY. Thank you, Mr. Chairman.

Mr. Chairman, I appreciate the opportunity to give my views on H.R. 3980, and I shall be very brief.

The Food Additives Amendment of 1958 was a significant step forward in the protection of the safety of our food supply. As you know, it was the end result of an intensive investigation of the use of chemicals in foods by a select committee of the House, of years of effort by dedicated scientists and representatives of the consuming public and of extensive hearings conducted by this committee.

Efforts will be made to weaken this law and to make its enforcement difficult. This must not be allowed to happen. The public interest demands that the law and its enforcement be strengthened rather than relaxed. All of us have a serious responsibility in this field.

Nevertheless, I realize that a law as far reaching as the Food Additives Amendment of 1958 presents problems to many of the industries affected by it. While I deeply regret that it has apparently been impossible by this date to complete the required testing of all the food additives now in use, we can hardly afford to throw our food supply into chaos by an abrupt and arbitrary withdrawal of them.

I have no quarrel with the principal purposes of H.R. 3980. According to its terms, a company that can show that it has seriously and diligently attempted to comply with the provisions of the law, but was unable to complete its efforts by March 6, 1961, may be granted an extension of time by the Secretary of Health, Education, and Welfare, if he finds that there is no undue risk to the public health. The Food and Drug Administration assures me that no extension will be granted in any case where undue risk is involved.

I understand that some industries object to this requirement, and Franklin M. Depew, president of the Food Law Institute, has been reported as saying that chemicals should not be barred just because of lack of diligence on the part of the supplier.

It is against attitudes like these that we must be on the alert. Certainly, I would vigorously oppose any legislation that did not provide at least these minimum safeguards.

My main objection to H.R. 3980 is that it permits "open end" time extensions. I strongly believe that at the most a 2-year time extension should be granted, and that the new cutoff date for those cases that come within the purview of this bill should be no later than March 5, 1963.

Judging by past attitudes, unless this is spelled out in the legislation, many companies will start dragging their feet, and the result will be that the 1958 enactment will fall far short of its objectives.

If it is argued that a 2-year extension is not enough, then I say, "Let's look at the situation again in 2 years." If, at the end of that time, it can be proven that a further extension is needed in some cases, we can then decide what action to take.

Mr. Chairman, having won ground in our fight to protect the consumer, we can afford no retreat. An open end bill would be a retreat.

H.R. 3980, with the inclusion of a cutoff date of March 5, 1963, would be entirely fair to industry, and, together with other safeguards already in it, would offer the public some assurance that its proper interests are of continuing concern to us.

I urge that the bill be amended to that effect.

The CHAIRMAN. Thank you very much, Mr. Delaney, for your statement.

Mr. Williams, do you have any questions?

Mr. WILLIAMS. I have no questions.

The CHAIRMAN. Mr. Schenck?

Mr. SCHENCK. No questions.

The CHAIRMAN. Mr. Roberts?

Mr. ROBERTS. No questions.

The CHAIRMAN. Mr. Younger?

Mr. YOUNGER. No questions.

The CHAIRMAN. Mr. Friedel?

Mr. FRIEDEL. No questions.

The CHAIRMAN. Mr. Avery?

Mr. AVERY. No questions, but I would like to thank our colleague for giving us the benefit of his judgment on this matter, because we look to him for advice in this whole area.

The CHAIRMAN. Do any of our colleagues have any questions?

Mr. Delaney, you seem to have made yourself very clear to the members of this committee in view of the fact there are no questions about a technical problem like this.

I would like to ask one question. Suppose you had a substance that has not yet been declared to be a food additive, but at some later date is declared to be a food additive. Should the affected industry be given time for investigation to determine the safety of this substance?

Mr. DELANEY. This deals only with the 3,000 petitions that the Food and Drug Administration has before it. Any new additive must meet the requirements of the law, or anything not included up to this date. This deals with only those that are known and on the books where there has been insufficient time to test.

The CHAIRMAN. I realize that. Sometimes it disturbs me a little bit, though, to say that a substance after a great effort has gone into it, is being produced and has not been determined to be a food additive, and then later up comes the decision that this is a food additive. What happens then?

Mr. DELANEY. I think in those cases that we could take another look at it 2 years from now, and if an extension is needed, I feel that it should be granted. We have 3,000. Suppose at the end of the 2-year testing period there were 2,500 that had been acted upon one way or the other, and there were 400 or 500 that needed additional time.

If the petitioners could show to the satisfaction of the Food and Drug Administration that they need more time, we could come in here and I do not know that there would be any objection on my part at that particular time.

The CHAIRMAN. Thank you very much. We appreciate your testimony.

Mr. DELANEY. Thank you, sir.

The CHAIRMAN. We are also glad to have with us this morning our colleague, the Honorable David S. King.

Mr. King, we appreciate your interest in this problem and we are very glad to have your testimony.

STATEMENT OF HON. DAVID S. KING, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF UTAH

Mr. KING. Thank you, Mr. Chairman and members of the committee, I have a short statement which is being distributed consisting of only three paragraphs. Mr. Delaney has covered practically all of the material contained in my statement, and in order to conserve time, therefore, I should like to read just the concluding paragraph of my statement, asking that the entire statement be included in the record.

The CHAIRMAN. Without objection, the entire statement will be included in the record.

Mr. KING. I appreciate the opportunity of appearing before this distinguished committee to give brief testimony on the matter of further extending the effective date beyond March 6, 1961, for the scientific investigations necessary under section 409 of Public Law 85–929, which investigations are designed to safeguard the health of the American public by requiring that food additives be adequately tested by the manufacturers before being authorized for human consumption.

In view of the fact that many additives had been in common use before the enactment of Public Law 85–929 by the 85th Congress, the manufacturers of such additives were granted what was considered

to be a reasonable time in which to complete the scientific testing required by the law. Experience has now proven that the time allowed was not sufficient, in many cases, to complete the required tests, and H.R. 3980 proposes that the Secretary be authorized to grant extensions as necessary for the completion of tests which have been undertaken and carried out with reasonable diligence on the part of manufacturers.

We consider it reasonable that necessary extensions be granted, but we would object strongly to any action which might weaken the enforcement of this highly important act. In order that the Congress might review the progress made by the Secretary in the enforcement of the provisions of Public Law 85–929 and continue its interest in the protection of the health of the American people, we strongly urge that the time extension granted to manufacturers for testing be fixed at March 6, 1953, rather than grant the Secretary open-ended authority for the granting of extensions to manufacturers.

Just in concluding, Mr. Chairman, my feeling is that the public law which we are considering, 85–929, constituted a high watermark, a historical landmark, in the course of legislation dealing with pure foods. We feel that it would be extremely hazardous at this time to do anything which might weaken the enforcement of this act. We realize that a certain amount of elasticity is necessary. We do not object to that.

However, granting an open-end extension, we feel would be going beyond reasonable elasticity and that it would result in weakening the basic law itself. May I say, also, that I should like to associate myself completely with the remarks of the distinguished gentleman from New York, Mr. Delaney, whom I consider to be one of the great heroes in this fight to maintain and preserve pure food for the American public.

Thank you.

The CHAIRMAN. Thank you very much, Mr. King, for your statement. We appreciate having your expression of interest in this legislation.

Are there any questions?

Mr. AVERY. I have just one.

The CHAIRMAN. Mr. Avery.

Mr. AVERY. Mr. King, you made a reference as to "weakening of this bill." Do you consider a simple extension of time as materially or substantially weakening the bill or the statute in any way?

Mr. KING. As I attempted to point out, I think that injecting a little elasticity into the bill would not weaken it. I think the weakening comes when the elasticity is stretched beyond reasonable limits. I feel that granting an open-end extension here would be carrying it too far. That, I think, would be weakening it. I would not object to placing a 2-year limitation, and as Mr. Delaney pointed out. If at the end of that 2 years, we still have a problem, we can reexamine it and perhaps have a further extension at that time.

Mr. AVERY. Thank you.

Mr. KING. Thank you.

The CHAIRMAN. Any further questions?

Thank you very much, Mr. King.

Mr. KING. Thank you.

The CHAIRMAN. We are now gratified to have with us this morning for the first time a former colleague of ours, who has now the distinction, and privilege, and high honor of serving in the position of Secretary of Health, Education, and Welfare.

In view of the fact that we have many problems being administered by your Department, Mr. Secretary, we are exceedingly glad to have you with us this morning for the first time. I am sure that we shall be looking forward to more meetings with you in connection with legislation which your Department will be involved in. I am particularly glad that you were able to meet with us today in view of the fact that this is the first hearing that the committee has scheduled and conducted in this session of Congress. Furthermore, we appreciate you being here in order to renew your acquaintance with some of us who served with you in the Congress when you were here and to meet those who did not have that privilege.

I realize full well that this is a highly technical problem we have before us today and that you may very well call on some of your associates in connection with some of the testimony here this morning. At the outset, I think, it would be helpful if you would identify the associates with you here this morning in order that the committee may know them and they, of course, may know the committee better.

STATEMENT OF HON. ABRAHAM RIBICOFF, SECRETARY, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; ACCOMPANIED BY GEORGE P. LARRICK, COMMISSIONER, FOOD AND DRUG ADMINISTRATION; AND JOHN L. HARVEY, DEPUTY COMMISSIONER, FOOD AND DRUG ADMINISTRATION

Mr. RIBICOFF. Thank you very much, Mr. Chairman, for your gracious remarks.

It is really a pleasure to come here and renew my acquaintanceship with you, Mr. Chairman and many of the members of the committee whom I have known for so many years. I am pleased to see two close friends on the Republican side who are new members. Congressman Sibal of Connecticut was Republican leader in the Connecticut General Assembly during my term of governorship and Congressman Thomson was a fellow Governor from Wisconsin, who I respected so much in our working together in various Governors' conferences.

I am very interested to find that some of the most important work of health, education, and welfare comes within the jurisdiction of this most important committee. Some of these programs are of great importance for the future of our Nation and I look forward to being here many, many times to testify before this committee. I would hope that at any time any member of this committee personally might have a problem, or a question, or an inquiry concerning any parts of my Department, you would not hesitate to pick up the telephone and call me and we will try to get the replies to you as fast as possible.

I did think that since this is a new administration, I would like to introduce to you the top people in this Department who will be here in addition to myself and who will be working with this committee: Mr. Ivan A. Nestigen, Under Secretary, Mr. Wilbur Cohen, Assistant Secretary, Mr. James Quigley—a former colleague of yours—

Assistant Secretary, Mr. Boisfeuillet Jones, Assistant for Medical Affairs, and Mr. Alanson Willcox, General Counsel. I believe you all know Mr. Larrick and Mr. Harvey, who are career men in this particular field.

Mr. Chairman and members of the committee, I appreciate the opportunity to discuss with you the proposal for legislation to authorize further extensions of the date on which the food additives and pesticide chemical amendments of the Federal Food, Drug, and Cosmetic Act will become effective. The two pertinent statutes were to have become effective on March 5, 1960, but in each case there was a provision for administrative action to extend the effective date to March 5, 1961, on a showing that the extension was necessary and that the particular use involved would present no undue hazard to the public during that period.

You will recall that early last year, representations were made to this committee that the 1 additional year provided in the statute would not be sufficient. At that time, my predecessor, Secretary Flemming, urged that the food additives amendment be permitted to stand with a clear understanding that if experience demonstrated the need for further extension beyond March 5, 1961, the Department would so advise this committee.

In the field of food additives real progress has been made during these past 12 months. Industries involved have worked intensively in endeavoring to solve their problems and obtain the necessary data on which suitable regulations can be based to permit the continued use of substances which can be shown to be safe for the public at large.

The Food and Drug Administration advises me that despite the diligent work of the industries and this Department, there is a real need for the authority for further extensions as outlined in H.R. 3980. The bill includes safeguards to prevent dilatory tactics, but the keystone of any extension which could be granted under the authority of this bill is in the requirement for a showing that the extension will not present any undue hazard to the public health.

It is not planned that blanket extensions will be granted for a single period. Instead, the fact in each case must be taken into consideration. No more time should be authorized than is necessary to obtain the required data on this matter of safety for permanent usage of the particular item involved, whether it be a direct additive or one which becomes a part of the food through migration of packaging or plant equipment components.

If at any time a question of safety arises while an extension is effective, the bill authorizes immediate termination of that extension where the facts warrant such action.

The situation with respect to the pesticide portion is a comparable one applying only to nematocides, plant regulators, defoliants, and desiccants. A limited number of substances are involved here, but there has been shown to be need for further time to enable industry and agriculture to acquire the data the scientists of the Food and Drug Administration feel is necessary before formal regulations can be granted.

Mr. Larrick is prepared at any time to provide specific information on developments under this food additives amendment. I do believe that this bill is in the interest of the Government, consumers,

and the affected industries and respectfully request a favorable report.

Mr. Larrick, who is the Commissioner of Food and Drug, is here, gentlemen, to supply any detailed information. He has been working in this field during these years, and is certainly better acquainted at this time with the details than I am, and if there are any questions, Mr. Chairman, I do believe that Mr. Larrick could supply the details to you, Mr. Chairman, and the members of the committee.

The CHAIRMAN. Mr. Secretary, thank you very much for your statement.

Mr. Larrick, do you have any further comments to make?

Mr. LARRICK. Mr. Harris, I would like to tell the committee which passed this food additives legislation, to acquaint my friends on this committee with some of the things that have happened as a result of your handling of this legislation 2 years ago, if you care to hear it. I would like to tell you what has developed under the legislation and then where we stand today.

The CHAIRMAN. Very well. We would be glad to have your comments.

Mr. LARRICK. The food additives amendment of the Federal Food, Drug, and Cosmetic Act is unquestionably a most important addition to the laws designed to safeguard the food supply of this country. Though not yet fully in effect, it has already brought about great improvements in the production and handling of food; because of the amendment the American consumer is receiving greater protection than was possible before. As you know, the amendment requires the person who wishes to introduce an additive into the food supply to establish the safety of the proposed use of the chemical before it is employed commercially in food.

This new look at the ingredients of food has covered not only substances added directly to food, but also substances which get into food in other ways, as from food handling equipment and food wraps.

Since September 1958, the Food and Drug Administration has done much to implement this consumer protection. We have handled over 4,200 formal requests for information or review of data on food additive problems. We have engaged in hundreds of informal discussions with industry to explain and explore the administrative and technical requirements of this law. We have published lists of 718 chemicals used with foods which are generally recognized as safe by appropriately qualified scientists, and thus are exempt from the application of the food additives amendment.

We have published lists of 112 substances that have prior sanction and thus are exempt from the food additives amendment.

We have received 391 petitions for food additive regulations. Of these: 100 were not complete enough to be filed; 42 did not relate to food additives; 178 are being actively evaluated; 59 led to the issuance of regulations stating safe conditions for using and additives involved; and a few petitions were withdrawn after filing.

The 391 petitions received thus far have involved over 1,900 uses of chemicals in food production, processing, or handling.

To permit an orderly transition, the food additives amendment gave us authority to extend the date upon which the law would become fully effective with respect to an additive for a maximum of 30 months

from the date of enactment, that is, to March 5, 1961, provided the extension is necessary and "involves no undue risk to the public health."

In accordance with this authority, we have extended the effective date of the law to March 5, 1961, for over 3,000 uses of chemicals that may be subject to the amendment, and we have about 50 requests for additional extensions whose processing awaits the submission of more data.

In 1958, when the food additives bill was before this committee, we believed that a 30-month transition period would be long enough to permit resolution of the principal problems that would arise. It is now evident that this was not enough time. In large measure this is due to the fact that the problem is much larger than anyone realized in 1958. An occasional expert may have had a good idea of the number of chemicals being used in his particular industry, but no one person was in a position to know of the vast number of uses of food additives in the entire food field that would need to be cleared under the new law.

So there are numerous food additives being employed today to the benefit of consumers and industry which still require clearance. And we have no authority under the law to grant time beyond March 5 of this year.

We believe that it would be in the public interest to amend the food additives law to permit further extensions of its effective date under circumstances that will safeguard the public health. Our Department drafted the bill which is before you as H.R. 3980 to accomplish this.

The safeguards in H.R. 3980 are important. The principal ones are:

1. We could grant further extensions only for products and uses that were being commercially employed before January 1, 1958. This provides a background of experience that lends support to the decisions of our scientists that continued use for a limited time will not jeopardize the public health.

2. We could grant further extensions only where conditions exist which necessitate the prescribing of an additional period.

3. We could grant further extensions only for additive uses that already have been granted extensions to March 5, 1961, or under an amendment which I will discuss in a moment, for uses for which requests for extension are pending on that day. This precaution is desirable to guarantee that the authority for further extensions does not serve as an excuse for inertia and inactivity by the affected industries.

Some could interpret the absence of such a safeguard as an invitation to wait for the Government to determine that their use of a chemical employed before 1958 is in fact subject to clearance under the food additives amendment, at which time they could come in and forestall appropriate legal action by pressing for an extension of the effective date of the amendment, de novo. This clearly would defeat the purpose of the law.

There is clarifying language that would improve the bill as originally drafted and submitted to the Congress: there are a few instances in which firms took timely action to determine the status of their products under the food additives amendment, but final action on their requests for extension has not yet been taken. To take care of such a situation, we recommend that H.R. 3980 be amended by adding on

page 2, immediately after line 3, and on page 3, line 8, immediately after "1961," the following, "or has on that date a request for such extension pending before him."

4. Another safeguard is the proposed requirement that before granting further extensions we must find that bona fide action was taken to determine the applicability of the food additives amendment to the use for which extension is requested or to develop the scientific data necessary for action under the amendment. In the absence of such a provision, a firm that had taken no steps to determine that its products were in compliance with the food additives amendment could argue, when it learned that the Government was investigating its products, that it should be granted a period of time in which to conduct studies of its own.

5. The bill would allow only those extensions that in our judgment are consistent with the objective of carrying to completion in good faith, as soon as reasonably practicable, the scientific investigations necessary as a basis for action under the food additives amendment.

6. The bill would allow us to terminate an extension that we find should not have been granted, one which was proper when granted but is no longer justified by changed circumstances, or one where there is failure of the person who secured the extension to meet conditions attached to it.

H.R. 3980 would apply equally to a small group of agricultural chemicals (nematocides, plant regulators, defoliants, and desiccants) that were food additives until Public Law 86–139 resulted in their being classed as pesticide chemicals in 1959. Until such time as their status can be definitely determined, they should receive the same consideration as though they had not been shifted from the food additive classification.

The bill follows the pattern of the color additive amendments of 1960 (Public Law 86–618) in that it leaves to us the decision as to how much time is needed to complete the testing of an additive. The time will vary for different products. Some items can be handled within a few additional weeks or months, while some may require considerably more time.

The planning and execution of the various tests contemplated by the food additives amendment is a time-consuming operation. In our own laboratories, for example, it takes approximately 3 years from the time we first decide to subject a chemical to chronic toxicity testing until the results of the tests are summarized and available for adminisrative review. And this assumes that nothing unusual develops to require a report test or a more extensive investigation.

To summarize, we now know that if the food additives amendment becomes fully effective on March 5, 1961, it will seriously disrupt established practices in the food industry that are of benefit to the consumer. There is no indication that such disruption is required to protect the public health. H.R. 3980 would permit a more orderly transition to the time when the food additives amendment is fully in effect, and, meanwhile, would protect the public health by sound safeguards.

The CHAIRMAN. Commissioner, thank you very much for your statement on the progress and status of this important matter before your Department. We appreciate having the testimony of you, Mr. Secretary, along with Commissioner Larrick. I think under the cir-

cumstances, it would be appropriate, in view of your statement, Mr. Secretary, to first recognize Mr. Thomson for any comment or questions he may have of either the Secretary or the Commissioner.

Mr. THOMSON. No; I have none.

The CHAIRMAN. Mr. Sibal?

Mr. SIBAL. No, Mr. Chairman.

The CHAIRMAN. I would say that obviously you were convincing. Mr. Williams?

Mr. WILLIAMS. Mr. Chairman, first, I would like to join the chairman and other members of the committee in welcoming our old friend Secretary Ribicoff back to Washington. We look forward to working with you, Mr. Secretary, during your term of office. I do not believe, Mr. Commissioner, that you covered the suggestion made by Mr. Delaney regarding the possible amending of this bill to do away with the so-called open-end approach. Would you like to discuss that?

Mr. LARRICK. Mr. Williams, if you and your committee are willing to take this up again in 2 years, if it is necessary, on the same rush basis that you have this year, I would have no objection whatsoever to Mr. Delaney's suggestion, and I have cleared that with my boss.

Mr. WILLIAMS. Do you feel that it is necessary in order to protect the public interest?

Mr. LARRICK. I feel if we were given the authority to decide it, we would decide it right, but I am not going to argue against Mr. Delaney and Mr. King.

Secretary RIBICOFF. I think, Mr. Williams, in talking with Mr. Larrick—and you appreciate I would have to rely at this stage on his judgment and experience—it is Mr. Larrick's feeling that a more realistic approach would be 3 years.

However, I do appreciate the fact of Congressman Delaney's efforts, because I do recall it was some 10 years ago when I was in Congress that Mr. Delaney was fighting this battle, and it was a lone fight by Mr. Delaney in those days.

We certainly have no objection to coming back here 2 years from now, and we would certainly defer to the judgment of this committee, but the Food and Drug Commissioner and his Department feel that 3 years would be more realistic. However, if there would be an inclination to write 2 years into the limitation, that would certainly be all right with the Department.

Mr. WILLIAMS. I believe that is all, Mr. Chairman.

The CHAIRMAN. Mr. Springer?

Mr. SPRINGER. I do want to welcome my old friend and next-door neighbor when he was in the House to another job in Washington.

Mr. Commissioner, last year when we had this matter up, and I do not know that it was anybody's fault—it may have been lack of personnel or it may have been many other factors beyond our control—but the real concern in many of these instances was how long it was going to take in your Department to get adjudication once a petition had been filed. If you would turn to page 2 of your statement, you will notice the words: "We have received 319 petitions for food additive regulations."

No, turn to the fourth item: "59 led to the issuance of regulations stating safe conditions for using the additives involved."

Would you please tell the committee approximately how many weeks or months or days there were from the time a petition was filed until there was an adjudication? What was the average length?

Mr. LARRICK. Mr. Springer, that varies tremendously. Bear in mind that these petitions ordinarily are concerned with chemistry, they are concerned with pharmacology, and they are concerned with medicine; and routinely, if it truly is a new chemical, it has to go through all of our different divisions and they all have to give it very careful study, and sometimes these petitions will be 6 inches thick.

I would say that at the beginning it took us about 3 months to handle each petition.

Mr. SPRINGER. In other words, this is an average of about 90 days; is that correct?

Mr. LARRICK. That is an approximation, but as we gain experience and as industry gains experience in knowing what our scientists want in the petition, the timelag is getting progressively less.

In other words, we are learning and industry is learning.

Mr. SPRINGER. Do you ultimately hope you can decide these in half that time?

Mr. LARRICK. Some of them. Very often, we have to send them back and say, "You do not have enough animal testing."

Mr. SPRINGER. Are you finding any broad objection in the industry as to the length of time involved in getting adjudication?

Mr. LARRICK. I would say that any Government agency always finds objections of people who want to get their problem solved immediately; but, no, I would say in general we are getting along very nicely with industry.

Mr. SPRINGER. That is all, Mr. Chairman.

The CHAIRMAN. Mr. Mack?

Mr. MACK. Thank you, Mr. Chairman. I have no questions.

The CHAIRMAN. Mr. Schenck?

Mr. SCHENCK. No questions.

The CHAIRMAN. Mr. Roberts?

Mr. ROBERTS. Mr. Chairman, I would like to join one of our colleagues, Mr. Williams, in welcoming our former colleague, Mr. Secretary, to our committee. I am sure there will be many other appearances by the Secretary and he can always find a warm welcome here in this committee.

Just one or two questions, Mr. Larrick. In your statement, at page 2, I notice that you have 178 petitions now being actively evaluated.

Mr. LARRICK. Yes, sir.

Mr. ROBERTS. Could you give us any estimate of how much more time you think might be required to finish those 178 cases?

Mr. LARRICK. To finish all of them, Mr. Roberts, will unquestionably take 3 to 4 months, but some of them we hope to turn loose each day. On some of them, the scientists will say they have not done enough work on the liver of the rat or they will say they are incomplete because of the chemistry, but the great bulk of them we hope to get processed within 3 months. I should add that once a man has filed a petition, even though you did not extend the March 5 deadline, we would not take any action on that article in a legal way until after we had given the man our appraisal of the safety of his product. Once

he has filed his petition and put it in, we do not take any action until we have handled that matter and decided it one way or the other.

Mr. ROBERTS. However, it is your view that the 3-year extension would suit your purposes better than the 2 years?

Mr. LARRICK. Yes, sir.

Mr. ROBERTS. That is all I have, Mr. Chairman.

The CHAIRMAN. Mr. Younger?

Mr. YOUNGER. Mr. Larrick, it would seem to me if we are going to make an extension it would be wise to make an extension other than to March 1963. Here we come up to a situation with a new Congress, and we are meeting on February 28, to consider an extension on March 6. That to me, seems very unwise.

Mr. LARRICK. Mr. Younger, I could not agree with you more.

Mr. YOUNGER. It seems to me that the new Congress in 1963 may be up against the same kind of an operation that we have this year.

Mr. LARRICK. I think you have a very fine point.

Mr. YOUNGER. So, if we are going to extend the time it ought to be extended into May or June so as to give the committee adequate time to make a study before expiration. I certainly would recommend that the extension be made, rather than March, up until May or June. Do you agree with that?

Mr. LARRICK. Yes, I do, Mr. Younger.

Mr. YOUNGER. Thank you. That is all, Mr. Chairman.

The CHAIRMAN. Mr. Moulder?

Mr. MOULDER. No questions.

The CHAIRMAN. Mr. Avery?

Mr. AVERY. Thank you, Mr. Chairman.

Mr. Secretary, I would like to associate myself with my colleagues in welcoming you to the committee. I did not have the pleasure of serving with you as a member of this body, but I look forward to serving with you in the legislative and administrative relationship.

Mr. Larrick, of course, we consider a standing consultant of this committee.

Mr. LARRICK. Thank you, Mr. Avery, I always have a good time up here.

Mr. AVERY. I just have one question and this should be directed to you, Mr. Larrick. I think it is pretty clear about the status of the 3,000 chemicals that are presently listed as food additives. I am not so clear about the chemicals that might presently be used and are not considered suspect at the moment as food additives, but might be so construed at a subsequent date.

Our chairman touched on this just a little in his opening remarks. As I understand the bill, there is no provision for an extension of time in regard to those possible suspect chemicals at all. If they subsequently should be listed as food additives immediately they would either have to suspend their use or have it terminate to the satisfaction of yourself, that there were no cancer-producing elements in them.

Mr. LARRICK. You are quite right, Mr. Avery.

Mr. AVERY. As I read the bill, there is no provision in there. You suggested one amendment that you were going to offer and as I heard you that would only apply to a chemical that is presently pending on the date of the expiration of the time limit in the present statutes.

Mr. LARRICK. You are quite right.

Mr. AVERY. However, you are not suggesting any language that would give any consideration to those chemicals that might so be designated as suspect additives subsequently?

Mr. LARRICK. I think that whole problem is too speculative to deal with. I do not anticipate that sort of situation arising, certainly not very often in the future, and I would hate to see the bill completely open-ended forever. It is conceivable that with respect to some can lining or some packaging material which we now do not think gets into the food, it might be possible that 10 years from now, we would find that the food does absorb it, but then I think we would have to deal with that as it comes up.

I really do not think, Mr. Avery, that there is enough probability of that problem arising.

Mr. AVERY. Then you would oppose language that would give consideration to such chemicals?

Mr. LARRICK. No, I would not say I would oppose it. I would have to see it. I think it is imperative that we get this bill through, because if we do not get it through by March 6, there is going to be chaos in the food industry and then, Mr. Avery, if we do find that there are some bugs in it, we will be the first ones to come up here and try to recommend what is the fair thing to do.

Mr. AVERY. I do not want to belabor this point, but if the committee, in its judgment, would elect to include such language your department, if the language was in good stead, would not oppose it?

Mr. LARRICK. No.

Mr. AVERY. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Friedel?

Mr. FRIEDEL. I have no questions, but I want to say that I am glad to have you, Mr. Ribicoff, as Secretary of Health, Education, and Welfare. I did not have the pleasure of serving with you. I came in just after you left, but I intend to keep in close touch with you. That is all, Mr. Chairman.

The CHAIRMAN. Mr. Collier?

Mr. COLLIER. Mr. Larrick, just to pursue very briefly the line of questioning of Mr. Springer and Mr. Roberts, did I understand you to say that within 3 to 4 months, you anticipated clearing the 178 that appear on the list of those petitions that are actively being evaluated?

Mr. LARRICK. I would say that for the most part, we would be able to dispose of them one way or another within about 3 months. I do not want to be held to that to the dot because I have not looked at the details of all of them.

Mr. COLLIER. I understand that. This, however, would exclude any of those then that are being tested for chronic toxicity inasmuch as your statement says it would take up to 3 years?

Mr. LARRICK. All of these, sir, have had that work done. We do not do the work. The law required that the manufacturer submit to us a complete protocol which will include the chemistry, the pharmacology, the medicine, and everything else involved, and presumably these 178 have all had that work done, so they have already used their 2½ to 3 years.

Mr. COLLIER. Is it not true, however, that there have been instances where the manufacturer has made his submission of this information and there has been a further delay in the department in clearance?

Mr. LARRICK. You have to review this material with great care and there are a great many of them to be considered.

As we say, there are some thousands that we have given extensions to and we have had to determine that there was no undue hazard to the public health, so very obviously, during this transition period, there have been delays.

Mr. COLLIER. I point that out only to establish from my own reasoning the need for more than 2 years then in this extension.

Mr. LARRICK. I will be content to abide by the judgment of this comimttee about the length of time, but I am very certain that if we just get 2 years, we will be back asking for more time.

Mr. COLLIER. That is all, Mr. Chairman.

The CHAIRMAN. Mr. Macdonald?

Mr. MACDONALD. Thank you, Mr. Chairman.

I do not have any questions. I would like to join with my colleagues in welcoming Governor Ribicoff as our new Secretary of Health, Education, and Welfare. I am sure this is just the beginning of a very harmonious period of time for both of us.

Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Devine?

Mr. DEVINE. No questions, Mr. Chairman.

The CHAIRMAN. Mr. Jarman?

Mr. JARMAN. No questions.

The CHAIRMAN. Mr. O'Brien?

Mr. O'BRIEN. No questions, Mr. Chairman.

The CHAIRMAN. Mr. Keith?

Mr. KEITH. I would like to join with my colleagues in welcoming this new Secretary. I am very pleased that he has had experience in the Congress and is therefore, close to our problems with our constituents, the consumers, and the producers. I would like, just for the record, to remind him of the very serious problems that affect an industry in the process of determining what is a carcinogen. This gets to the root of this whole question.

In the case of the cranberry incident of a year ago, when we had that before the Congress, the problem was caused, not by the administration of the law by your office, but by the definition of what was a carcinogen, and what could cause cancer in a human being. The fundamental question really is, What is a carcinogen and what constitutes a significant amount of a carcinogen? And I think there should be an effort to bring into the legislation the opportunity for the Secretary of HEW to use reason and judgment. It does not now exist in the present law.

Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Moss?

Mr. Moss. I have one question, Mr. Chairman.

Mr. Larrick, you indicated that the 2-year suggestion by Mr. Delaney would be inadequate and stated a preference for a 3-year period. What is your best judgment as to a realistic period for extending this in order to permit you to accomplish all of the necessary testing now foreseeable?

Mr. LARRICK. We are going through a period of major readjustment in our food supply and I do not think anyone can honestly tell you with certainty how long it is going to take to get over this hump,

but I am quite content to have 3 years if we could have it, or 2 years, if we could have it, assuming that this committee will continue to show the active interest in this whole subject that they have always displayed in the past.

Mr. Moss. However, you have no best judgment now as to the appropriate extension?

Mr. LARRICK. I think we will have problems at least for 3 years.

Mr. Moss. At least for 3 years?

Mr. LARRICK. At least for 3 years.

Mr. Moss. Those are all the questions I have.

The CHAIRMAN. Mr. Thomson, do you have any questions now?

Mr. THOMSON. No.

The CHAIRMAN. Mr. Dingell?

Mr. DINGELL. Thank you, Mr. Chairman. I would like to commend and to compliment the distinguished Secretary for coming up here. I had an opportunity to meet with him earlier and I had an opportunity to learn how busy his schedule is, and I would like to express my personal thanks to him for making available this time in what I know to be an almost desperately busy schedule.

With the permission of the Chair, I would like to treat two things with Mr. Larrick. The first, Mr. Larrick, has to do with a question asked by Mr. Avery. I refer specifically to the discovery of something which may not previously have been regarded as an additive, on evidences found by the Food and Drug, or by independent researchers to show that this happens to be in effect an additive, or a previously harmless substance now shows that it might perhaps be harmful.

Is it not a fact that there is, without this particular legislation, adequate authority for the Food and Drug Administration to require analysis, examination, and studies to be made which would be appropriate to protect the public interest in those instances?

Mr. LARRICK. Quite right, sir.

Mr. DINGELL. And this bill does not treat with that at all?

Mr. LARRICK. No.

Mr. DINGELL. And there is no reason why it should?

Mr. LARRICK. I do not think it needs to be treated.

Mr. DINGELL. We have been talking about time limits on this. As you perhaps gathered, a number of us in the Congress are very much concerned about the possibility of a blank check extension, even though we regard your efforts and the efforts of your agency very highly. If you were to get 3 years, is there any reason present today to infer that you would not be able to accomplish the great bulk of the work that is imposed upon you by the law right now?

Mr. LARRICK. No. Three years would take care of the great bulk of it, Mr. Dingell.

Mr. DINGELL. Say we were to go to as far as 4 years. Would we be reasonably sure that that would be adequate to accomplish the whole thing?

Mr. LARRICK. For all practical purposes, yes.

There may be a few left over that we would not have the answer to in 4 years, but certainly the great bulk of them ought to be disposed of.

Mr. DINGELL. The reason I talk about 4 years is that 3 years is enough for a good dog test, is that not right?

Mr. LARRICK. Yes. I think Mr. Younger has a very good point when he says that it ought not to expire right at the beginning of a new Congress, and make an emergency if we do have to come back up.

Mr. DINGELL. For this reason, you would suggest 3 instead of 4, so we could look at it more carefully?

Mr. LARRICK. And make it expire later in the year instead of in March.

Mr. DINGELL. Assuming you were then to say fix it at some time other than March, put it back, say to June, would this be better still?

Mr. LARRICK. Yes, much.

Mr. DINGELL. Thank you, sir.

Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Sibal?

Mr. SIBAL. Mr. Chairman, I have no questions, but I would like to take this opportunity to state how happy I am that circumstance has permitted my path to cross with Secretary Ribicoff again. I am afraid it will take me a while to learn to call him Secretary and not Governor.

The CHAIRMAN. Mr. Rogers?

Mr. ROGERS of Florida. Mr. Chairman, just a question or two.

Of course, I want to join in greeting the Secretary and his distinguished staff here, and we are particularly pleased to see Mr. Larrick here and also Jim Quigly. We are all delighted to see he is now in your Department.

Concerning some of the questions, Mr. Larrick, that Congressman Dingell mentioned about the necessary authority for you to inquire into products, I happen to have a matter that I took up with the Department in January concerning, and I will not identify it, a cosmetic application. The people who had bought the product were concerned because it had no clearance on its labeling from Food and Drug, and so forth, and so they wrote to see if there were some way they could find whether this application would be safe to use before they actually used it.

The reply I received back from the Department of Health, Education, and Welfare was that, first of all—

> The Federal Food, Drug and Cosmetic Act applies to the safety of the product and its labeling. No prior clearance is required by law. We have received no complaints of adverse reactions from its use.

And you had none and they gave no adverse reaction because they had not yet used it. This next sentence is what concerns me:

> Information as to composition has been refused by the manufacturer and since we have not found significant claims in the labeling we have not had occasion to analyze the product.

What I want to know is, Do you have necessary authority when a request is made like this to determine whether the products in a cosmetic application are safe enough? Do you have authority to ask the manufacturer to at least let you know what is in that product, or not?

Mr. LARRICK. We have authority in the case of cosmetics to ask him, but we have no power to require him to supply the information, and we are planning with the consent of the Secretary, to send up to this committee during this Congress, broad authority to do factory inspection and to get just that information.

Mr. ROGERS of Florida. Is this a normal practice for manufacturers to refuse to give you such information?

Mr. LARRICK. No. I would say that the great bulk of the manufacturers, in spite of the fact that there is no compulsion to give it to us, except in certain instances, do give it to us voluntarily, but I think that the Government should have the power to require that sort of information in protecting the public health.

Mr. ROGERS of Florida. My present feeling is that I certainly agree with you and I would be interested to follow this up.

Secretary RIBICOFF. I am in favor of that type of legislation. I usually find that legitimate manufacturers who are reputable never object to cooperating and those that are questionable usually do, and the questionable ones are those that raise the problems for the consumer and for the constituents who want to make sure they are doing the right thing.

We are going to send up legislation and we would hope that this committee would give it their most favorable consideration. It is something that the Department has taken up with me.

Mr. ROGERS of Florida. That is fine. Thank you.

The CHAIRMAN. Mr. Hemphill?

Mr. HEMPHILL. I have one question of Mr. Larrick.

If this committee saw fit to put a time limitation of 3 years, would the mechanics be accomplished by adding to the bill on page 2, line 6, after the words, "effective date," the words "not later than May 6, 1964"? Would that accomplish it?

Mr. LARRICK. I believe it would, sir.

Mr. HEMPHILL. Thank you very much.

The CHAIRMAN. Mr. Rostenkowski?

Mr. ROSTENKOWSKI. I have no questions, Mr. Chairman.

The CHAIRMAN. Mr. Roberts?

Mr. ROBERTS. With reference to the suggestion you made, Mr. Larrick, for adding additional language after line 3, page 2, and page 3, line 8, I would like you to elaborate on what you consider meets the test of bona fides on the part of the industry?

Mr. LARRICK. If the industry person or firm has diligently sought to complete this complicated testing that is required but the time was not sufficient to let him complete it—something went wrong with the test, or it took more time than they thought was required—I would think that that would pass the test.

Also, in the case of some additives a literature search is a tremendously involved and time-consuming matter, and if they could show that they diligently tried to search the literature of the world, to see whether or not this chemical is either safe, or generally recognized as safe, or proven safe by previous tests, I would be inclined to let them have the advantage of the extension.

Mr. ROBERTS. Suppose you have an additive that has generally been considered to be safe. Then in the light of new scientific knowledge, it moves into the suspect area. What kind of a test would you apply to that particular industry?

Mr. LARRICK. If it moved into the serious suspect area, Mr. Roberts, my disposition would be to stop its use. If you have a real problem of public health, a real, serious question of injury to the public health, I would stop its use until they had done whatever amount of testing is necessary to clear it.

I would resolve the question in favor of the public health. I do not think that will happen very often.

The CHAIRMAN. Mr. Keith?

Mr. KEITH. Mr. Larrick, you mentioned that if a particular chemical became suspect, you would recognize that factor in your administrative course of action. What about the chemical which by use gradually is found to not be a carcinogen? What action do you take to look out for the consumer and industry protection there?

Mr. LARRICK. Mr. Keith, I would say that in all the administration of this act, and all other acts perhaps, we should employ the rule of reason and resolve the question in favor of the public health, but not conjure up artificial suspicions to do harm to the industry.

Mr. KEITH. To the best of your knowledge, has there been any reason to believe or suspect that any cancer has been induced by the consumption of cranberries at any time?

Mr. LARRICK. We produced a cancer of the thyroid in animals, but I do not have any evidence that it produces cancer in man. I want to forget about the cranberries now.

Mr. KEITH. I would like to correct your testimony. It was not cranberries that caused the cancer.

Mr. LARRICK. That is right. You are right.

Mr. KEITH. I do not believe that your research will ever reveal that cranberries were a vehicle for amino to the extent that any cancer resulted, anyway.

Mr. LARRICK. Mr. Keith, we gave cranberries a clean bill of health.

Mr. KEITH. Costing nevertheless, the industry a tremendous amount of money.

Thank you, Mr. Chairman.

The CHAIRMAN. While you are on that subject, I am constrained to inquire if you gave chickens a clean bill of health.

Mr. LARRICK. We sure did.

The CHAIRMAN. Mr. Secretary, you mentioned it in your statement, but I think it would be appropriate to emphasize the fact that this bill extends your authority to certain food additives and certain pesticide chemicals. I am somewhat of the opinion that most people feel that this bill relates only to food additives. I wanted to emphasize just what it does.

Section 2 of this bill, H.R. 3980, has to do with the extension of this authority as far as it is applicable to food additives, is that not true?

Mr. LARRICK. That is correct, sir.

The CHAIRMAN. And section 3 so far as its application is concerned, would be to pesticide chemicals?

Mr. LARRICK. Let me explain that if I may.

The CHAIRMAN. All right.

Mr. LARRICK. When you handled the pesticide chemical bill, in 1954, I believe it was, it just covered certain types of pesticides. It did not cover the articles mentioned at the top of page 3, which are not things that kill bugs.

The agricultural chemical people preferred to have all of the articles of this type that are used in agriculture handled under the pesticide bill, rather than having part of them under pesticides and part of them under food additives, so they went to the Agriculture Committee

with whom they normally do business, and they got these substances that are listed there at the top of page 3 declared to be pesticide chemicals.

There is no longer authority for deferments under the pesticide bill. We thought it only fair to give them the same opportunities for deferment they would have received if they had remained food additives.

The CHAIRMAN. I though that that should be cleared up or understood.

Under the provisions of the bill, the Secretary could grant an extension of time if he finds that (1) there is a bona fide action to determine the applicability of the food additive law to a particular substance that was commenced before March 6, 1960, and was thereafter pursued with reasonable diligence; (2) and he had additionally granted an extension to March 5, 1961; and (3) a further extension of time is necessary to complete scientific investigations. Those are the limitations on your Department with reference to this proposal?

Mr. LARRICK. Exactly.

The CHAIRMAN. What would happen, as Mr. Roberts mentioned a moment ago, if there was a substance that had not been considered to be a food additive and yet, by some development or because of something that might happen, it was suddenly determined that this was a food additive? What would happen to that substance?

Mr. LARRICK. At that stage, Mr. Chairman, it would become the responsibility of both the manufacturer and the Government to take a look at the question of whether or not in the amount that this product appears in the food it is safe or harmful.

If a conclusion could be reached that it is safe, then nothing would happen. If a conclusion was reached that it was harmful, it would have to get out of the food supply.

The CHAIRMAN. Would there be any time to determine whether or not it was safe or harmful?

Mr. LARRICK. There would be no time if it was definitely shown to be harmful.

The CHAIRMAN. Of course, if it was definitely shown to be harmful you would not need any time.

Mr. LARRICK. That is right.

If it was unknown, then we would have to give time to find out which is right.

The CHAIRMAN. Could you give time under this provision?

Mr. LARRICK. I think that we would have the administrative authority to be reasonable in the matter.

The CHAIRMAN. Mr. Secretary, may I thank you and Mr. Larrick for your appearing here this morning and your testimony. We appreciate your bringing with you your staff and presenting each of them to the members of this committee.

Secretary RIBICOFF. Thank you very much for the courtesy of yourself and the committee, and we will look forward to being here frequently in the many months ahead.

The CHAIRMAN. Thank you.

Mr. LARRICK. And I enjoyed myself.

The CHAIRMAN. Thank you. We are glad to have you back, Mr. Commissioner. We look forward to seeing you here again, too.

We have two witnesses from out of town. Mr. Boyd, I observe that you are from New York. We are going to hear you right now.

STATEMENT OF GEORGE BOYD, JR., COUNSEL, AMERICAN PAPER & PULP ASSOCIATION, NEW YORK, N.Y.

Mr. BOYD. Mr. Chairman and members of the committee, my name is George Boyd, Jr. I am a member of the law firm of Dunnington, Bartholow & Miller, in New York City. We are counsel for the American Paper & Pulp Association, the overall national association for the paper and pulp industry, with which I believe all of you gentlemen are thoroughly familiar. I think you have before you the statement which we have prepared on behalf of the American Paper & Pulp Association, the first page of which sets forth briefly the thoughts of the pulp and paper industry concerning H.R. 3980.

Appended to this is a more detailed explanation of our proposed amendment to the bill. Gentlemen, may I make it perfectly clear that the pulp and paper industry supports H.R. 3980. The one point that I would respectfully make to the Committee on Interstate and Foreign Commerce is that in the letter transmitting the proposed bill to the committee, and to the Speaker of the House, and the President of the Senate, it was suggested that legislation is desirable to ascertain whether the food additives amendment applies to the substances involved at all, and it is my understanding that Secretary Ribicoff, the able Secretary of Health, Education, and Welfare, has endorsed the request by the former Secretary.

The question has been raised before the committee this morning as to what would happen in the case of substances which presently are generally recognized as safe or substances which the Food and Drug Administration has prior sanctioned, both of which categories under the food additives amendment are exempt. The fact of the matter is, gentlemen, under H.R. 3980, as it is presently drafted, after March 6, 1961, if a substance would be determined to be other than generally recognized as safe or if the prior sanction were taken away, but it would be considered by Food and Drug to be safe, the Secretary and the Commissioner of Food and Drug would not legally have any authority to grant an extension of time during which the Food and Drug Administration and the affected industry or companies could ascertain what tolerances might be required, if any at all.

In other words, absent the provision that we have recommended in the attached bill to our statement people would be put in the position of requesting the Food and Drug Administration to perform an act unauthorized by law, and we certainly have had the most friendly and cordial, and helpful relationship with the able Food and Drug Administration both on the administrative and technical side, and I think it undesirable to put any Government agency in a position where they may not exercise authority by benefit of law.

I think this pretty much covers, Mr. Chairman and gentlemen, the views which I have to express on behalf of the industry, except that I would like to state that as far as paper and paperboard for food packaging purposes are concerned, they have been used for 60 years

and there is no case of record where there has ever been any illness caused by any migration or transfer, and in the opinion of competent scientists, paper and board for food packaging purposes are not food additives as defined in the law.

If Mr. Muldoon could have his 25 seconds, Mr. Harris, I would be most grateful, sir.

(Mr. Boyd's statement follows:)

STATEMENT OF AMERICAN PAPER & PULP ASSOCIATION

The former Secretary of HEW, in a letter to Speaker Rayburn, urgently requested the enactment of a bill to remove the time limitations for discretionary extensions under the food additives law, so that FDA and affected industries will have more time to determine, among other things, "whether that law applies to the substances involved at all." Secretary Ribicoff has fully endorsed this request.

Affected industries agree with the Secretary that it is essential to provide additional time to determine the applicability of the law to a particular substance.

The bill submitted, now H.R. 3980, does not accomplish this. H.R. 3980 unnecessarily limits the Secretary's authority to grant extensions to situations where prior extensions have been given.

There are a great many substances now "generally recognized as safe" or that have received prior sanctions for use. If in the future the status of these substances should change for any reason (and this has occurred in the past), additional time would be required by FDA and affected industries to develop scientific data for a required regulation. Under H.R. 3980 the Secretary would be powerless to grant such additional time after March 6, 1961. It is extremely important that this deficiency be corrected. A bill to accomplish this, together with a more detailed explanation, is attached.

A SUBSTITUTE BILL FOR H.R. 3980, THE PROPOSED FOOD ADDITIVES TRANSITIONAL PROVISIONS AMENDMENT OF 1961

A draft bill entitled "Food Additives Transitional Provisions Amendment of 1961," together with accompanying letter and explanatory material, was transmitted to the Speaker of the House of Representatives on January 13, 1961, by the former Secretary of Health, Education, and Welfare. The draft bill was introduced as requested, and is now before the Committee on Interstate and Foreign Commerce as H.R. 3980. The basic concept of this proposed legislation is the removal of the time limit of March 6, 1961, which now exists with respect to a food additive in commercial use before January 1, 1958. The authority of the Secretary of Health, Education, and Welfare to postpone the effective date of the Food Additives Amendment of 1958 for such food additives under the proposed legislation, and under the present law, can only be exercised when there is no undue risk to the public health and conditions exist necessitating the prescribing of an additional period.

As indicated in the letter of transmittal to Speaker Rayburn, legislation to extend the discretionary period for the Secretary to grant extensions is required both by the Food and Drug Administration and by affected industries because the Food and Drug Administration cannot physically process petitions under the food additives amendment before March 6, 1961—the present cutoff date on the authority of the Secretary to grant extensions—and because affected industries cannot possibly develop all necessary scientific data, information and petitions before that date.

H.R. 3980 does not fully meet the needs of the present situation. As pointed out in the former Secretary's letter, the additional authority conferred by the bill is not only necessary in order to permit the completion of inquiries or studies to determine the safe use of an additive under the food additives amendment, but also to permit necessary time in which an interested party might determine "whether that law applies to the substance involved at all."

The language in section 2 of H.R. 3980 is unnecessarily restrictive on the discretion of the Secretary. It is inconsistent with one of the stated purposes of the bill in that it would restrict his authority to grant necessary and desirable extensions only to those substances which were food additives in commercial use

before January 1, 1958, and then only if an extension had been granted prior to March 6, 1961.

It is a known fact that there are many substances which are now generally recognized as safe by qualified scientific experts and which are consequently not food additives within the meaning of the Food Additives Amendment of 1958. It is entirely possible that some of these at some future time will no longer be so recognized. In such event, time will be required for the promulgation of an appropriate regulation governing the conditions under which the food additives may be used. It seems only fair that so long as the Secretary finds there is no undue risk to the public health he should be permitted to grant such time. The Secretary under the present language of H.R. 3980 would be powerless to grant such additional time.

This is just one area in which problems would be created by the present section 2 of the bill. The same argument would apply equally to substances which were sanctioned by the Food and Drug Administration prior to enactment of the food additives amendment on September 6, 1958. Such sanctioned items are presently exempt under the law. However, if any of such sanctions were to be withdrawn, the user would be in the position of having a food additive in violation of law, without recourse to the extension procedure.

Therefore, section 2 of H.R. 3980 should be amended to enlarge the discretion of the Secretary to grant extensions not only with respect to food additives commercially used before January 1, 1958, but also with respect to substances now considered exempt under the law, but which at some future date may be considered a food additive requiring appropriate regulations prescribing conditions under which they may be safely used.

In summary, the Secretary's authority to grant extensions should encompass not only substances now known to be food additives but also those substances for which additional time may be required to determine the applicability of the law. A bill to accomplish this is submitted herewith.

A BILL To amend the transitional provisions of the Act approved September 6, 1958, entitled "An Act to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety," and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Food Additives Transitional Provisions Amendment of 1961."

SEC. 2. Subsection (c) of section 6 of the Food Additives Amendment of 1958 (Public Law 85-929, 72 Stat. 1784, 1788) is amended (i) by deleting the words "if such use was made of such additive before January 1, 1958" and substituting therefor the words "if the substances making up such additive were similarly used before January 1, 1958," and (ii) by inserting in such subsection, at the end thereof, the following: "Notwithstanding the parenthetical time limitation in clause (1)(B) of this subsection, the Secretary may extend such effective date under the authority of that clause (but subject to clause (2)) with respect to such use (or a more limited specified use or uses thereof) if, in addition to making the findings required by clause (1)(B) he finds that bona fide action to determine the applicability or inapplicability of such section 409 to such use or uses, or to develop the scientific data necessary for action under such section, was commenced by an interested person and is being pursued with reasonable diligence. The Secretary may at any time terminate an extension so granted if he finds that it should not have been granted or that by reason of a change in circumstances the basis for such extension no longer exists, or that there has been a failure to comply with a requirement for submission of progress reports or with other conditions attached to such extension."

SEC. 3. Paragraph (b) of section 3 of the Nematocide, Plant Regulator, Defoliant, and Desiccant Amendment of 1959 (Public Law 86-139, 73 Stat. 286, 288) is amended by inserting in such paragraph, at the end thereof, the following: "Whenever the Secretary of Health, Education, and Welfare has, pursuant to clause (1) of this paragraph (b), prescribed an additional period expiring on March 5, 1961, with respect to any such particular use of a nematocide, plant regulator, defoliant, or desiccant, he may, notwithstanding the provision to the contrary in such clause (1), further extend the expiration date applicable under such clause (1), (but subject to clause (2)) with respect to such use of such substance (or a more limited specified use or uses thereof), if, in addition to making the findings required by clause (1), he finds (A) that bona fide action to determine the applicability of such section 408 to such use or uses, or to

develop the scientific data necessary for action under such section, was commenced by an interested person before March 6, 1960, and was thereafter pursued with reasonable diligence, and (B) that in the Secretary's judgment such extension is consistent with the objective of carrying to completion in good faith, as soon as reasonably practicable, the scientific investigations necessary as a basis for action under such section 408. The Secretary may at any time terminate an extension so granted if he finds that it should not have been granted, or that by reason of a change in circumstances the basis for such extension no longer exists, or that there has been a failure to comply with a requirement for submission of progress reports or with other conditions attached to such extension."

The CHAIRMAN. You may identify yourself.

STATEMENT OF THOMAS J. MULDOON, TECHNICAL DIRECTOR, NATIONAL PAPERBOARD ASSOCIATION

Mr. MULDOON. Yes, sir. My name is Thomas J. Muldoon and I am the technical director of the National Paperboard Association. The National Paperboard Association concurs with the American Paper & Pulp Association in its feeling that the Food and Drug Administration should have the necessary power to grant extensions, especially in situations where a material which is now not, that is, before next week's extension, considered to be a food additive or subsequently held to be one. This material, as well as the materials now on extension, would need a time extension in which to prove its safety.

I understand there are presently 700 materials which are generally recognized as safe and also a very large number of materials being used under prior sanctions, and we feel that provision should be made to cover the contingency that one of these materials is removed from its current status.

Thank you.

The CHAIRMAN. Mr. Boyd, when I asked Commissioner Larrick the question as to what would happen, I understood his response to be that if such a condition were to arise, he thought under this bill, or under the existing law, the Food and Drug Administration would have regulatory authority to deal with the subject. You say that they would not under this bill.

Mr. BOYD. Mr. Chairman, I would say under this bill, much as I respect the able Commissioner, that it would be an extralegal act by the Food and Drug Administration to grant an extension after March 6, 1961, to a substance which had not previously been considered to be a food additive by reason of being generally recognized as safe or enjoying a prior sanction status.

Mr. AVERY. Mr. Chairman, I have a question there.

I thought I asked Mr. Larrick essentially the same question as you did and got a different answer. I understood Mr. Larrick in response to my question to say he had no authority to grant an extension of time for testing, if it became suspect and then in response to you, he said that he would have sufficient discretion in that matter. Could we have Mr. Larrick clarify that response for us?

The CHAIRMAN. I would like to get it cleared up, Commissioner.

Mr. LARRICK. I did not think I was doing any doubletalk.

The CHAIRMAN. I am sure it was not intended, if you did.

Mr. AVERY. I did not mean to so infer, but I was confused.

Mr. LARRICK. No. If an article were found to contaminate food and it were shown that the article is harmful to human beings, or is highly suspect—I mean highly suspect so that you can't determine whether it is going to do harm—I think then it would be our obligation to take it out of the food.

On the other hand, under the circumstances that Chairman Harris referred to, where you suddenly discover that an article that you thought did not migrate into a food and you had no facts other than the fact that a small amount of it migrated into the food, and you did not have any reason to be highly suspicious of it, I think that, as Commissioner of Food and Drug, I have the administrative right to do the fair thing and permit time to elapse to test it.

Have I cleared up my answer?

The CHAIRMAN. You have in my mind, so far as your own position is concerned, but let me ask it this way for the record, and I think this is important. It is true that there are many substances now generally recognized to be safe.

Mr. LARRICK. A great many.

The CHAIRMAN. There are many substances that have received prior sanctions for use.

Mr. LARRICK. That is right.

The CHAIRMAN. Now, suppose that a substance that has generally been recognized as safe, or that has received prior sanctions from you, at some future date becomes suspect. Would you then have authority, in your opinion, under the law and the extension under this bill, to give time for that suspicion to be resolved?

Mr. LARRICK. Mr. Harris, I think that would depend on the degree of suspicion of the article. If it were a grave suspicion, I do not think the American public should be subjected to that.

The CHAIRMAN. The point is if you already determined it was unsafe, then its use must be discontinued.

Mr. LARRICK. That is right, and if we do not know, I think we have the authority to let them test it.

The CHAIRMAN. If it becomes suspect and a final determination has not been made you would have authority then to have them test it?

Mr. LARRICK. I think so.

Mr. YOUNGER. Mr. Chairman, may I ask a question?

The CHAIRMAN. Yes.

Mr. YOUNGER. Mr. Larrick, as long as there is some doubt as to whether you have the authority or do not have the authority, do you have any objection to clearing this up and making sure that you do have the authority?

Mr. LARRICK. I never object to anything that this committee does.

The CHAIRMAN. That is a very broad statement.

Mr. LARRICK. When this committee speaks, we follow. I do not think it is necessary, Mr. Younger.

Mr. MOULDER. You say you have the authority, but under what provision of the law do you base your authority?

Mr. LARRICK. I think I have administrative discretion to apply the rule of reason to everything that we do in Food and Drug, and I do not think that we should lower the boom on a mere suspicion. I think we ought to have more than a suspicion.

Mr. MOULDER. Can you point out the specific provision of the law which gives you the authority?

Mr. LARRICK. No.

The CHAIRMAN. Could you supply that?

Mr. LARRICK. We could supply you some Supreme Court decisions that say that an administrator of a Federal law is supposed to use commonsense and apply the rule of reason. That is about as far as we could go.

The CHAIRMAN. Mr. Boyd, does that satisfy you?

Mr. Moss. Would you yield at that point, Mr. Younger?

Mr. YOUNGER. I do not have the floor.

Mr. Moss. Mr. Chairman?

The CHAIRMAN. Mr. Moss.

Mr. Moss. I have been trying to figure out just what we would be discussing by inference here if it is not now regarded as an additive or as an addition of any type potentially dangerous, and at some subsequent date it would become so regarded. There would have to be something occur upon which you would base the conclusion that it would even require examination, and I assume that you would have to have other than just a suspicion. You would have to have some medical evidence before you?

Mr. LARRICK. That is right.

Mr. Moss. Before you would feel that it should be included at all?

Mr. LARRICK. That is right.

Mr. Moss. And so we are in a very highly speculative field and to cover that it would be difficult to draft language, would it not, unless we gave you blanket authority in perpetuity to grant extensions for any reason?

Mr. LARRICK. I have great respect for this great industry that is represented here today, but they have not had experience with the administration of the pure food and drug law. It is new to them.

Mr. Moss. It seems to me that is as far as we can go on at this point.

Mr. LARRICK. I think they are worried about something that is not likely to happen.

Mr. Moss. In reading the language here which was proposed by the witness who just left the stand, I am intrigued with the change in verbiage in section 2 proposing that we delete the words "if such use was made of such additive before January 1, 1958," and substituting "if the substances making up such additive were similarly used."

They could be similarly used, but in an entirely different combination, could they not?

Mr. LARRICK. That is right.

Mr. Moss. In this day and age where we do some very interesting things in remaking from the same substances different products, the rearrangement of the substances might produce an entirely different type and potentially very lethal product; yet we would be going into an indefinite period of extension.

Mr. LARRICK. That is right.

Mr. Moss. It is rather interesting language in that it opens a very broad door here.

Mr. LARRICK. Yes, I think you are quite right.

Mr. Moss. That is all I have.

Mr. COLLIER. Mr. Chairman.

The CHAIRMAN. Mr. Collier.

Mr. COLLIER. To pursue that a little further, let us take a hypothetical case of a product now being wrapped in, say, a chemically coated paper. Let us say right now, there is no problem. Let us say that a year from now, however, the product fell under suspicion, because of something in the coating of the paper.

Under that law, if I interpret it correctly, the department would have no authority or jurisdiction at that point.

Mr. LARRICK. Not unless we have had some real, substantial evidence to show that it is not recognized by appropriately qualified experts as safe.

Mr. COLLIER. But such authority is not provided in this legislation?

Mr. LARRICK. Last year, one of the biggest food companies in this country came to us and said that they were planning to make a dry product that would make a root beer. It would be a dry powder and you would put it in a glass of water and you would have root beer. This firm is a prudent firm. I am not going to identify it.

They took this material to their laboratories and they ran tests on it and they produced tumors, they thought, in some of the laboratory analyses. They brought this evidence to us. We were not content to act on that because the tests had not been made in our laboratories and they were not long enough to convince us, and we wanted two tests, anyway.

We started out with a 2½-year study of the principal ingredient of root beer and when we got about halfway through this test our scientists saw that on further testing this material might be shown to cause cancer, so I called in the principal representatives of the bottling industry of this country and we laid before them all of the facts. It was not a final judgment that this material was poisonous, but it was so highly suspicious that we thought we should share that with the industry.

This industry decided that they would not use safrole any more, safrole being the constituent of root beer in question, and it has been used from time immemorial. They prudently found substitutes for it and took it out of the root beer and today there is none of it in root beer. We have made a survey all over this country and it is out. We were able to do this without any public clamor and they got it out before we concluded our test and we accomplished our objective without any legal actions.

When we can do that, we prefer to handle it that way. That is the way I would handle these very speculative things that are involved in this matter that we are discussing.

Mr. DINGELL. Mr. Chairman, I would like to be recognized for a few questions.

The CHAIRMAN. Mr. Dingell.

Mr. DINGELL. Mr. Larrick, I am going to ask the clerk to hand you a copy of the testimony of the previous witness, and I would like you to—in fact, I will hand you my copy of this—look at the specific language that I outlined and I will read it here for the record. It is about the fourth line down. It says:

If the substances making up such additive were similarly used before January 1, 1958.

That is a substitute as I read the bill for the words which appear just above,

If such use was made of such additive before January 1, 1958.

What is the difference between those two readings and what is sought to be done?

Mr. LARRICK. I have not seen this language before, Mr. Dingell. I am going to ask Mr. Harvey to answer that.

Mr. HARVEY. I would think, Mr. Dingell, that the substances that make up such additive may have been used before, but the additive itself, the substance you are talking about that would go into the food, may not have been used prior to that time.

In other words, a food additive may be made up of a number of different substances. It may have had wide usage, but not in that combination and not in that arrangement.

Mr. LARRICK. We want to deal with the article as it was used in the food, not some different usage.

Mr. DINGELL. Now we are getting down to the real purpose of this suggested amendment. What they seek, then, is a combination exemption for combination additives as opposed to single constituents elements or single additives?

Mr. LARRICK. I would think that is right.

Mr. DINGELL. In other words, under this bill as I read it, they would get a blanket exemption. If one substance was just a part of a whole complex additive, they would get a blanket exemption to cover the whole spectrum that might be involved in that one particular additive.

Mr. LARRICK. Yes, I think this would permit the use of different combinations of additives that had been previously used.

Mr. DINGELL. Do you read any other differences in this particular draft that is submitted to us this morning on this point from the bill that we are considering?

Mr. LARRICK. I think we would have to study this to answer that question.

Mr. DINGELL. Would you like to have time to submit for the record of the committee, your views on this particular piece of legislation?

Mr. LARRICK. I hope there will be no controversy about this bill, because it is tremendously important to get it through by March 6 and if there is something wrong with it and it goes through, it will give relief to the great bulk of the industry and protect the public, and if there is something that we find is wrong with it, we will come back up here.

Mr. DINGELL. Let me go back a little bit. It is my understanding of the law that the duty that the law imposes upon an agency like yours, particularly under the food additives law, is to act only on sound and competent evidence in cases of these sorts, particularly dealing with the situations where a substance might be regarded as being slightly suspicious.

The point I am leading to is just this. As a matter of law, you could not knock out a substance as an additive, either a color additive or a food additive, if you have a mere suspicion. Is that not right?

Mr. LARRICK. No. Everything we do is reviewable in the courts

and we have to have substantial evidence before we act or the courts will knock us down.

Mr. DINGELL. And if you fail to have that substantial evidence the courts will overrule your action; is that not correct?

Mr. LARRICK. As you know very well, that is true.

Mr. DINGELL. Thank you very much.

The CHAIRMAN. There is just one further question I wanted to ask you, Mr. Larrick.

You mentioned your authority. Would you submit for the record at this point two or three citations of the Supreme Court, because I do not want to be in the position of dealing with what appears to be an unknown quantity here, affected by an unknown authority.

Mr. LARRICK. I am going to ask Mr. Goodrich to help me on that one.

The CHAIRMAN. Mr. Goodrich, I am sure, will be glad to assist in doing just that for you.

As I understand, there is no difference between you and what Mr. Boyd has presented for his industry, except Mr. Boyd and his industry are concerned about what would happen to something that has been sanctioned all these years, and suddenly it comes up and some additive authority knocks it out the window all at one time.

Mr. LARRICK. That is right.

The CHAIRMAN. I think that is a proper question to raise. You think you have authority to deal with that.

Now if we do not get this bill through by March 5, which obviously we will not be able to do because it takes a little while for these things to make their way through the Congress, the fact that there will be a few days delay in enactment of this bill would not in any way cause your department to move on any of these pending matters, would it?

Mr. LARRICK. I will have to enforce the law as it is written, but if the legislation is moving forward in due course, I would not be disposed to speed up the action too fast.

The CHAIRMAN. And as you mentioned awhile ago, and as is your duty, you would feel that you should be reasonable about it?

Mr. LARRICK. That is right, but if it did not pass at all, I would have to move.

The CHAIRMAN. Yes, I know that, but if it is moving it is a different proposition.

Mr. Boyd, did you have any further comment, or Mr. Muldoon?

Mr. BOYD. May I just respectfully say to the committee and to its capable chairman, many thanks for the opportunity to appear before you all, and if I just might mention to Mr. Dingell, as far as seeking any exemptions, sir, I do want to disabuse him that we are requesting an exemption. All we want to do, as Mr. Larrick has always made perfectly clear, is to confer upon the Secretary and upon Commissioner Larrick the authority when they have made certain requisite findings under the law, sir, that extensions might be granted.

In other words, we are not suggesting that the law be open-ended and exemptions be conferred. There would be no change as far as exemption status under our proposed amendment to H.R. 3980.

Thank you, sir.

The CHAIRMAN. Thank you very much, Mr. Boyd.

Mr. DINGELL. Mr. Chairman, I would just like to make one remark here for the benefit of Mr. Boyd.

I have the distinct impression, Mr. Boyd, that in view of the comments that you have heard from the experts on this subject, that if you are not starting at shadows, you are seeking to shoot a very large hole or a series of very large holes into the law as it deals now with food additives.

Mr. BOYD. May I say to the able Representatives, that on January 31 in the Federal Register there was published a generally recognized as safe list and there was a specific substance which happens to be a byproduct in the industry which was removed from the generally recognized as safe list. It happens that this particular substance is safe and it is my understanding that an extension is being granted, but that, of course, is prior to March 6, 1961, so my concern, sir, was suppose this very same thing should happen after March 6, 1961 in the light of the language of H.R. 3908, without the amendment, and all we were hoping to do for the benefit of the people and the Department of Health, Education, and Welfare, was to carry out that second part of the statement referred to in the letter of transmittal, sir. It has happened once, sir, it could happen again.

Mr. DINGELL. You heard the comment of Commissioner Larrick on this point. Does that not appear to satisfy any objection you might have to the bill as drafted?

Mr. BOYD. If I could be assured Commissioner Larrick would be here at all times, I would not have any worry.

Mr. LARRICK. I hope I will be.

Mr. BOYD. Thank you, sir.

Mr. DINGELL. I think you have established a very clear legislative history this morning that it would be more inadequate protection.

The CHAIRMAN. Thank you very much.

Mr. BOYD. Thank you, sir.

The CHAIRMAN. I am going to have you gentlemen back in the morning at 10 o'clock, and we are going to hear you, but at 10:30 we are going to conclude the hearing on this subject because we have other legislation that has been scheduled for tomorrow and we will take that up beginning at 10:30.

The committee is adjourned until 10 o'clock tomorrow.

(Whereupon, at 12:30 p.m., the hearing was adjourned, to reconvene at 10 a.m., Wednesday, March 1, 1961.)

FOOD ADDITIVES—EXTENSION OF TRANSITIONAL PROVISIONS

WEDNESDAY, MARCH 1, 1961

HOUSE OF REPRESENTATIVES,
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The committee met at 10 a.m., pursuant to recess, in room 1334, New House Office Building, Hon. Oren Harris (chairman of the committee) presiding.

The CHAIRMAN. The committee will come to order.

At the outset I would like to state that I am in receipt of a letter from Mr. George P. Larrick, Commissioner of Food and Drugs, responding to a request of yesterday with respect to his authority in dealing with a substance which heretofore was considered to be safe, or which is not now a food additive. In view of the questions and discussion we had yesterday, I feel that it would be advisable to read this letter in order that everyone may have the benefit of it.

Since Commissioner Larrick is present, it might be well to ask him to present this letter.

Mr. LARRICK. I would be delighted, sir.

STATEMENT OF GEORGE P. LARRICK, COMMISSIONER, FOOD AND DRUG ADMINISTRATION

Mr. LARRICK. May I say, sir, I have delivered 50 copies to the clerk of the committee so that he can distribute them to the people who are interested.

Should I proceed?

The CHAIRMAN. Yes; you may.

Mr. LARRICK. This letter is dated February 28, 1961, addressed to the Honorable Oren Harris, chairman of the Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your request, at the hearing on H.R. 3980, a bill to amend the transitional provisions of the Food Additives Amendment of 1958, that we supply the committee a statement as to the department's discretion in dealing with a substance which is not now a food additive, under that amendment, but which may sometime in the future meet the statutory definition.

First, it should be made plain that the status of a substance generally recognized as safe by qualified scientists, or of a substance for which there is a prior sanction, cannot change without some new scientific evidence. A prior sanction cannot be withdrawn unless there is a factual basis for withdrawal. We have committed ourselves in our regulations, except in cases of imminent hazard to health, not to withdraw such a sanction without first providing a statement of the reasons for our action. Where the withdrawal of the sanction involves a single party or a limited number of parties, we give our reasons for withdrawal

directly to those interested in it. Where this cannot be done, the notice is published in the Federal Register explaining why withdrawal is necessary.

A substance generally recognized as safe by qualified experts is not subject to the food additives amendment so long as this general recognition of safety exists. Before the status of any such substance can be changed, there must be new scientific data which destroys this universally held belief as to its safety. Normally, this would require the completion of scientific studies and the publication of the results to demonstrate to the scientific community that its long-held beliefs are no longer warranted.

Second, even after a prior sanction has been withdrawn, or the status of a substance generally recognized as safe has been adequately drawn into question, the Department still has the burden of proceeding with enforcement action, if it wishes to require the removal of the substance from the interstate market. This means we must be prepared to prove by a preponderance of the evidence in a civil case, or beyond a reasonable doubt in a criminal case, that the substance meets the definition of a food additive, as it appears in section 201(s) of the Federal Food, Drug, and Cosmetic Act, and that the substance is not within the grandfather-clause exemptions in that definition.

These features of the law, as a practical matter, make it extremely unlikely that the status of an exempt substance might be changed overnight. We consider it our responsibility to communicate any new facts about an exempt substance to the scientific community and to persons known to be directly interested in it. This would give advance notice of the pending change and an opportunity either to start the preparation of a food additive petition to establish safety or to supply controverting evidence with respect to the new scientific developments. When the new science finally reaches the point that the substance can no longer be generaly recognized as safe, or establishes that the prior sanction was granted under a mistake as to the supposed safety of the article, the Department would have to classify it as a food additive. It would then be subject to seizure under the food additives amendment, until a regulation was promulgated permitting its safe use.

It is here that the discretion mentioned [in my testimony yesterday comes] into play. The Department is not bound to proceed immediately against every adulterated article. The Supreme Court, in *United States* v. *Sullivan* (332 U.S. 689), has made it clear that the department has been given broad discretion, "broad enough undoubtedly to enable (the Commissioner) to perform his duties fairly without wasting his efforts on what may be no more than technical infractions of the law." And the Court said that the scope of the law should not be narrowed by "envisioning extreme possible applications of its provisions."

More recently the Court, is an opimon by Chief Justice Warren in *Rathburn* v. *United States* (355 U.S. 107, 109), has said: "Every statute must be interpreted in the light of reason and common understanding to reach the results intended by the legislature."

Applying this rule of reason, and exercising the discretion referred to by the Supreme Court, the Department would be able to cope with the situation in which a long-used substance, either on the generally recognized as safe list or the subject of a prior sanction, is thrown into question under the food additives amendment. If the question arose simply because it was learned that some substance of unknown identity migrated from paperboard, the department would not be compelled to immediately initiate a seizure campaign against all paperboard packaged food. But if it was learned that the migrant was one about which there was a serious question of safety, or one of unknown toxicity, the Department should have the authority to proceed in the public interest. This kind of action is permitted by the permanent provisions of the act.

Thus adequate flexibility in administration already exists. We do not believe that the law should provide for extensions for all substances that may at any time hereafter be found to be food additives. The purpose of the food additives amendment is to provide, after a reasonable transition period, that additives shall meet all requirements without exceptions. Moreover, the possibility that a substance thought not to be within the scope of the food additives amendment might at some future time turn out to be within its scope, is inherent in every provision of regulatory law, including other provisions of the Food, Drug, and Cosmetic Act, and it would manifestly be unsound to create possible loopholes relating to all these situations.

We recently reviewed this whole matter with representatives of the chemical industry and asked for any concrete examples that might justify a permanent provision in the law authorizing the Department to extend its effectiveness for

2 years, or any other period, while new scientific problems arising with respect to an old additive were explored. No such examples could be given to us, and absent such an example we cannot recommend modification of the bill to authorize such an extension.

It may be that some substances which we have listed as generally recognized as safe, and some for which we have granted prior sanctions, will change in status with the emergence of new scientific knowledge. If they do, the new knowledge would have to establish a serious question of doubt of safety. In any such case, we believe the best course would be to remove the substance from the food supply while the issue of doubt was being removed rather than to approve a blanket extension. If the doubt were not a serious one, there would be no need for immediate action.

Additionally, as developed by some of the members of the committee during the hearings, the proposed deletion from subsection (c) of section 6 of the food additives amendment of the words "if such use was made of such additive before January 1, 1958" and substitution therefor of the words "if the substances making up such additive were similarly used before January 1, 1958" would weaken the present concept of the food additives amendment and of the additional extension authority contemplated in H.R. 3980. H.R. 3980 is intended to allow us to grant further extensions only for the exact uses that were made of a food additive before January 1, 1958. The amendment proposed by the American Paper & Pulp Association would greatly expand this authority and would authorize our department to grant extensions for various uses of a given chemical so long as it had been used in a somewhat related manner before January 1, 1958. As I mentioned in my testimony, this requirement that a substance to be granted further extension must have been used prior to January 1, 1958, gives added support to the decisions of our scientists that further limited extension will be without undue risk to the public health; this added support would not exist for new uses of the same chemicals which had not been subjected to the test of time.

Sincerely yours,

GEORGE P. LARRICK,
Commissioner of Food and Drugs.

The CHAIRMAN. Thank you very much, Mr. Larrick.

We will now hear from Mr. Kenneth Mulford, chairman, Food Additives Committee, Manufacturing Chemists' Association.

STATEMENT OF KENNETH E. MULFORD, CHAIRMAN, FOOD ADDITIVES COMMITTEE, MANUFACTURING CHEMISTS' ASSOCIATION, INC.

Mr. MULFORD. Mr. Chairman and members of the committee, with your permission I suggest, in order to conserve time, that, as I did yesterday, the prepared statement which has been submitted to you be incorporated into the record, together with the accompanying letter dated February 21, 1961, from General Hull, president of the association to the chairman of this committee.

The CHAIRMAN. Let it be inserted in the record.

(The document referred to is as follows:)

STATEMENT OF KENNETH E. MULFORD ON BEHALF OF THE MANUFACTURING CHEMISTS' ASSOCIATION, INC.

Mr. Chairman and members of the committee, my name is Kenneth E. Mulford. I am chairman of the Food Additive Committee of the Manufacturing Chemists' Association. The Manufacturing Chemists' Association is a trade association composed of 190 corporate members which are engaged in the manufacture of chemicals.

Among the products sold by chemical producers are products which become food components either intentionally to perform some function in the food, or unintentionally, as, for example, migrants from food wrappers. Both the intentional and unintentional food components are subject to the controls of the Food Additives Amendment of 1958 unless they are used for coloring food,

in which case they are subject to the Color Additive Amendments of 1960.

Under date of February 21, 1961, Gen. John E. Hull, president of the Manufacturing Chemists' Association, wrote a letter to the honorable chairman of your committee endorsing H.R. 3980 with one small amendment. For the benefit of those committee members who may not have had an opportunity to read this letter, I should like to read it into the record. (See letter below.)

As I believe the letter to be self-explanatory as to the position of the Manufacturing Chemists' Association with respect to the need for early passage of this legislation, this will conclude my statement, except that, of course, I shall be glad to answer any questions which you gentlemen of the committee may have.

Thank you very much, Mr. Chairman, for the opportunity to present these views on behalf of the Manufacturing Chemists' Association.

MANUFACTURING CHEMISTS' ASSOCIATION, INC.,
Washington, D.C., February 21, 1961.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives,
Washington, D.C.

DEAR MR. HARRIS: Our association has carefully studied H.R. 3980, a bill introduced by you to amend the transitional provisions of the Food Additives Amendment of 1958 and the Nematocide, Plant Regulator, Defoliant, and Desiccant Amendment of 1959. Your bill appears to be the same as that suggested originally by former Secretary Flemming in a communication dated January 13, 1961. On Thursday, February 16, 1961, Secretary Ribicoff by letter to you, endorsed Secretary Flemming's action and stated that he was in full accord with this legislative proposal and that he hoped your committee would take favorable action on the proposal as soon as possible.

Our association believes that it would be better to have legislation giving the Secretary of Health, Education, and Welfare broad administrative discretion to grant extensions under the two amendments mentioned above after March 6, 1961, if he found that there were reasonable grounds for not having complied with the prerequisites of the amendments.

However, due to the very short period of time before the March 6 deadline, we would like to call to your attention only one minor point. Both in section 2 and in section 3, the Secretary of Health, Education, and Welfare may extend the effective dates of the two amendments where he has already extended the effective date to March 6, 1961. This language would mean that in cases where a manufacturer has in good faith filed with FDA a request for an extension and FDA has not been able to act on such a request, then such a manufacturer would be ineligible for an extension after March 6, 1961. We understand that the Food and Drug Administration is aware of this minor defect in the bill and will shortly suggest language to your committee to correct it. We would like to endorse such FDA action in advance so that manufacturers who have filed requests for extensions without FDA having acted on such requests, would be eligible for extension after March 6, 1961.

As you are aware, the food additives amendment has resulted in a number of problems for the Food and Drug Administration and for affected industries. Many manufacturers have diligently sought to learn whether their products were food additives as defined by the act. In many cases, it has only been with further refinement of analytical techniques that manufacturers were able to conclude that they did have food additives subject to the act. Also, it is well to point out that many required animal tests cover a long period of time.

We respectfully urge that your committee as soon as possible report favorably H.R. 3980 with the one amendment referred to above and which we understand will be suggested by the Food and Drug Administration. In the event that you consider it necessary to hold hearings on H.R. 3980, our association would greatly appreciate receiving notice of this so that we may appear and testify in support of the bill.

Sincerely,

J. E. HULL.

Mr. MULFORD. I will then direct a few remarks to the committee.

First, briefly, the position of our association is that while we would prefer to have the Secretary have greater discretionary power in

granting extensions, we feel that March 6 is not only just around the corner, but we are practically stumbling over it, and, therefore, under the circumstances we feel that this bill, H.R. 3980, should be promptly passed, amended as suggested yesterday by Commissoner Larrick in his testimony.

Now I would like to comment as to why we put this prefatory statement in, that we feel that the Secretary should have more discretionary power. I would like to emphasize that we do not feel this is desirable in any case where there is a public health problem involved or any undue risk to public health. We only felt that the Commissioner should have this authority in the event that some technicality comes up under the present law that would appear on its face to prevent him from granting an extension when there had been no question about the safety of the product, but the person or ingredient just happened to be part under some unfortunate circumstances.

In discussing this with representatives of the Food and Drug Administration, the conclusion was reached that perhaps here this is not necessarily something that should be taken up in this extension bill. As Commissioner Larrick has pointed out, it probably is a question with respect to the bill as a whole. In other words, this type of thing might occur in the year 2000. So that we feel that, rather than try and straighten such a matter out at this time, the present bill should be passed with the amendment that Commissioner Larrick has suggested.

The other point I would like to comment on is the suggestion made yesterday that an overall time limit be placed on this bill. Back in 1958, when we had no idea of the terrific magnitude of this problem, the Manufacturing Chemists' Association position at that time, and the testimony, was that it would take at least 5 years to get his matter straightened out. I just won't take the time to go into the tremendous number of problems involved in compliance with this act, and the wonderful job that I think both industry and the Food and Drug Administration has done in the time that we have had so far.

I would like to say, however, that a great deal more time is going to be needed. And, if it is the judgment of your committee that an overall time limit should be placed on this extension bill, then it should be at least 5 years and certainly no less than 3.

I think that concludes my statement, Mr. Chairman.

The CHAIRMAN. Any questions by members of the committee?

(No response.)

The CHAIRMAN. Thank you very much. We are very glad to have your testimony, Mr. Mulford.

Mr. MULFORD. Thank you.

The CHAIRMAN. Mr. H. Edward Dunkelberger, Jr., of the National Canners Association.

STATEMENT OF H. EDWARD DUNKELBERGER, JR., COUNSEL, THE NATIONAL CANNERS ASSOCIATION

Mr. DUNKELBERGER. My name is H. Edward Dunkelberger, Jr., and I am appearing on behalf of the National Canners Association. We would like to express our appreciation to the chairman and the committee for this opportunity to present this statement to the committee.

The National Canners Association, on behalf of its members, urges

that this committee give immediate and favorable consideration to H.R. 3980. Because Secretary Flemming in his letter of transmittal to Speaker Rayburn and Secretary Ribicoff in his statement before this committee fully outlined the need for this legislation, we will confine this statement to noting our agreement with that letter and the accompanying explanation and the Secretary's statement yesterday.

We would like to suggest, however, a minor amendment to the bill that is entirely consistent with the avowed purpose of the bill and which, in our view, is necessary if that purpose is to be satisfactorily carried out.

Under the bill as presently drafted, and even with the amendment that Commissioner Larrick proposed yesterday, the Food and Drug Administration will be obliged to give individual consideration to each of the 3,000 extensions which have already been granted under the present act, for in no other way can it be determined whether further extensions would meet the specific requirements of the bill. Only if these requirements are met would a further extension be authorized.

It seems clear beyond question that there will not be time after the enactment of this bill and before March 6—indeed, if it comes in that order at all—for all interested parties to present information establishing that the additional requirements of the bill have been satisfied with respect to substances covered by outstanding exemptions. Even if such information were in the hands of the Department, it is unrealistic to suppose that Department personnel will have time prior to March 6 to examine and pass upon this information for all 3,000 extensions. In addition to passing upon extensions and sending extensions, the Department staff will, of course, be actively engaged in processing petitions for final regulations listing food additives for use.

If these assumptions are correct, then it follows that on March 6, or upon whatever date even after the act is enacted, the present extensions will expire and thousands of food products will be in technical violation of the act until such time as the Department has acted upon each of the extensions pending or previously granted.

We feel it is necessary, therefore, that H.R. 3980 be amended to provide an additional 6-month period or whatever period the FDA feels is necessary, during which all present extensions to consider and act on further extensions for each of the food additives for which an extension is in effect or is pending, and at the same time to continue to process petitions for regulations.

This 6-month or 7-month blanket extension could be written into the bill by striking out the word "he" in line 5, page 2, and inserting the following language after the words "food additive," in line 4 on page 2:

such effective date shall be further extended with respect to such use of the additive to September 6, 1961, and the Secretary.

And then it would continue on. That September date, of course, could be changed to whatever period is desired to be necessary. The same amendment, if it is thought to be necessary, could be added to section 3 of the bill.

The CHAIRMAN. Mr. Springer.

Mr. SPRINGER. Could I ask Commissioner Larrick a question?

Do you have any objection to the suggested amendment?

Mr. LARRICK. Mr. Springer, I had anticipated that the question would be asked and one of my able assistants has written out the question and answer. And if I may, I would like to read it.

Question. What happens on March 6, 1961, even though H.R. 3980 were enacted? It seems that FDA would have insufficient time to consider the many requests for extensions that will be forthcoming.

Answer. If H.R. 3980 is enacted, we will advise the affected industries that we are ready to consider requests they wish to make for further extensions of the effective date of the law. We will also advise them that for a reasonable period of time to permit evaluation of their requests the existing extensions will not be canceled. It would appear to us that a couple of months would be a reasonable time within which to handle additional requests for extensions.

Now, answering your question specifically, I do not think it is necessary. If the committee wants to write it in the bill, we would not object.

The CHAIRMAN. You would not what?

Mr. LARRICK. We would not object. We are going to do it anyway.

Mr. SPRINGER. That is all.

The CHAIRMAN. Mr. Keith.

Mr. KEITH. I am not an attorney, but it would seem to me that the action he contemplates would be outside the law, and that in order for him to do what he says he would do anyway we would necessarily have to make this amendment.

The CHAIRMAN. I see no particular reason to belabor the point one way or the other because I think definitely they would have the authority if we passed the legislation. And if it is going to be done anyway, it will be done whether this is entered or not. I see no reason to waste a great deal of time on it myself.

Any further questions?

Mr. MOSS. I have one question of Mr. Larrick on this point.

This would have the effect of giving extensions on all matters for 6 months?

Mr. LARRICK. No; it would not have that effect. It would mean that if someone in good faith——

Mr. MOSS. No; I mean the proposed amendment.

Mr. LARRICK. Oh, this proposed amendment? Of course, yes, that would be a blanket extension.

Mr. MOSS. That would be a blanket extension.

Mr. LARRICK. We do not think that is in the public interest.

Mr. MOSS. That is all.

Mr. DINGELL. Mr. Chairman, could I ask the previous witness, not Mr. Larrick, just one brief question?

The CHAIRMAN. Mr. Dingell.

Mr. DINGELL. You said, your suggested amendment is:

such effective date shall be further extended with respect to such use of the additive to September 6, 1961, and the Secretary—

Now, have you had any experiences with the Food and Drug Administration under the existing law which would, in your mind, make necessary that we adopt such an amendment?

Mr. DUNKELBERGER. Well, our only concern, Mr. Dingell, was to see that—as we read the bill, we agreed with Mr. Keith, that technically there was no authority for blanket extensions in the bill. Each

extension has to be considered separately as the bill is now written. And there has been great emphasis made on this point, that each extension would be considered separately. And, therefore, when March 6 came and went there would not be time for all 3,000 to be considered that way. So we thought there should be a brief period authorized in the law authorizing the FDA to grant a brief time during which all of them can be considered, and then everyone would get off to the same start again with no technical violations of the law.

Mr. DINGELL. That is a very good answer, but it does not come right to the point I was exploring, and that is this: Have you had any experiences with the food and drug that would indicate to you that this amendment is necessary, any specific experiences?

Mr. DUNKELBERGER. No; we have had no experience that the FDA would take advantage—as a matter of fact, the Commission has already indicated they would not, and we have no experience they would take advantage—or what we would say is a technical defect in the bill, to take unfair advantage of industry. We have no experience whatsoever that they would do that.

Mr. DINGELL. I am not a believer in enacting unnecessary legislation if we can avoid it. We have enough to do without passing a lot of unnecessary law. And in view of your statement that you see no reason from your own experience why this is necessary, I wonder why we should bother even considering it?

Mr. DUNKELBERGER. Well, as the Commissioner has assured us, he will grant this anyway whether it is enacted into the bill or not. It would seem that the need for the amendment, therefore, is somewhat diminished, but it is required technically within the wording of the bill that is now written.

Mr. DINGELL. Thank you very much.

The CHAIRMAN. In other words, if it is going to be done, you do not care whether it is in there or not?

Mr. DUNKELBERGER. That is right, sir.

The CHAIRMAN. Thank you, very much.

Mr. Michael F. Markel.

STATEMENT OF MICHAEL F. MARKEL, FOOD, DRUG, AND COSMETICS SECTION, NEW YORK BAR ASSOCIATION

Mr. MARKEL. Mr. Chairman, I do not have a prepared statement. I do appear here in behalf of what I recognize as an organized group of lawyers who are very much interested in this whole problem. And in demonstrating my authorization to speak, and giving my qualifications, I would like to say that the lawyers in the food, drug and cosmetics field are organized formally. We are a division in the corporation, banking, and business law section in the American Bar Association. I am a chairman of that division, and I am a member of the council of that section. However, as the lawyers among you no doubt know, we cannot speak for the American Bar Association without having resolutions approved by the board of governors, so I cannot come in and say I am speaking for the American Bar Association. But the same group of lawyers is also organized as a section in the New York State Bar Association, and we are authorized to act as a group and as a division. And I am past vice chairman of that

division. I am a member of a number of their committees, and last January at their annual meeting I was appointed chairman of the resolution committee, and we adopted a resolution, as the lawyers, and not as a bar group, supporting this bill.

Upon adoption of the resolution a committee was appointed to follow through on this with the Food and Drug Administration and to assist this committee, and I was appointed chairman of that committee. So I am here speaking in that capacity.

As far as my personal interests and experience in this area are concerned, I am a member of Markel & Hill, a law firm here in Washington, and we have a great deal of work in this area. I have been concerned with this problem ever since before there was a food additive amendment. And at the risk of appearing immodest, I want to say that in 1948 I wrote a paper, which was published, where I suggested that it was time to consider legislation such as the food additive amendment, and advised the food industry that they ought to give serious heed to this. At that time I was a lone voice in the wilderness. I am merely mentioning that to show that I have been much concerned.

Now then, to come down to this specific bill, our committee did meet with the Food and Drug Administration, and we did discuss this bill. And Commissioner Larrick yesterday did suggest revision of language which will take care of what our committee wanted to take care of; namely, that the language should be extended so as to include all matters now before the Food and Drug Administration. That is, extensions, pending petitions, and pending requests for a ruling. And that is the revision that Mr. Larrick has suggested, and it is our considered opinion, and I have discussed this with my committee, that a bill along that line should be promptly passed.

During that discussion there also came up the problem that has been discussed at some length here. It was readily apparent to us, and to me, that that has no place in this bill. We are mixing apples and pears here. This matter was something that may come under the other side, something that would require a fundamental amendment of the act. There will be cases such as that for this reason: The single judicial question remaining in this whole area is the question which will arise if some manufacturer of a substance chooses to disagree with the Food and Drug Administration as to whether it is or is not generally recognized as safe. In the event of such a disagreement, the courts would have to decide. Now there may well be possibilities along that line, and that is what the bar group and some of the food groups are concerned about.

For example, last week one industry group filed a list of, I guess, over 100-some substances where they did not ask for a ruling. They said, "We and the board that we have appointed say we have concluded this is generally recognized as safe." Now supposing that the Food and Drug Administration does not agree with them with respect to each item. I happen to know at least two people who do not want to go to court. They want to say, "All right, let's file a petition." So there is this possibility. But there is no present problem, and that should be separated and should be the subject of consideration when you have more time under a separate bill, because that requires a basic amendment to the present law and is not an ex-

tension in any sense of the world; it is a broadening of administrative power.

And I have discussed this now since yesterday with some of my committee members and I am sure—confident—that I speak for the majority of the food and drug lawyers in this instance who understand it, and I would say I could convince the majority of those who disagree if I had a half hour with them to explain it to them, that that question should be eliminated completely from consideration of this bill and this bill should be passed as recommended by the Commissioner yesterday and should be done so promptly.

Now, as to the time element, we have thought that perhaps 5 years would be a more realistic time, but in view of what Congressman Delaney said yesterday, if the time came and there were still demonstrable problems, and in view of what the Commissioner said yesterday, we have concluded, and our committee has concluded, 3 years will do. And we are perfectly happy to accept that.

Now there is only one other point I wanted to make, and that is I want to address myself to the comment that Mr. Delaney made yesterday in quoting Mr. Depew, Franklin M. Depew, president of the Food Law Institute. I want to assure Mr. Delaney through this committee—and I spoke to Mr. Delaney yesterday afternoon about this—that Mr. Depew was fully in accord with what I have said. I know him; I am a member of the advisory legal board of the Food Law Institute. It is a most highly responsible organization, and I want to just make this clear. I do not know what Mr. Depew said; it came from a paper which he gave before our bar association, and the statement that Mr. Delaney read came from that paper evidently. But I want to assure this committee that the organized industry, regulated industry, has no intention of diluting anything here, and particularly not the Food Law Institute. And Mr. Depew, I want to say, is in accord with everything that I have said. So we recommend very strongly that we promptly pass this bill with the amendments that Commissioner Larrick has suggested, and that when and if the need arises, and they are prepared to demonstrate the need for amending the basic act so as to take care of the other problem, there will be time enough to take that up when we have more time to discuss it.

Thank you very much, Mr. Chairman.

The CHAIRMAN. Thank you very much, Mr. Markel.

Any questions by members of the committee?

Thank you, we appreciate having your statement.

This will conclude the hearing on H.R. 3980.

(The following material was submitted for the record:)

THE FOOD LAW INSTITUTE, INC.,
New York, N.Y., March 3, 1961.

Re H.R. 3980, Food Additives Transitional Provisions Amendment of 1961.

Hon. OREN HARRIS,
Chairman, House Committee on Interstate and Foreign Commerce, House Office Building, Washington, D.C.

DEAR MR. HARRIS: The Food Law Institute was and remains a stanch supporter of the Food Additives Amendment of the Federal Food, Drug, and Cosmetic Act, whose House report and passage you successfully directed as chairman of the House Interstate and Foreign Commerce Committee in 1958. My predecessor, Mr. Charles Wesley Dunn, as long as 10 years ago urged that this type of legislation was needed for the protection of the public health.

We now urge your committee's approval of the bill H.R. 3980, the Food Additives Transitional Amendment of 1961. This amendment affords the necessary additional time to complete investigations of various old substances to determine their safety for food use under approved conditions, and subject to strict assurances of consumer protection.

We also urge your approval and recommendation of two possible revisions of the bill: first, to enlarge its application so that requests for rulings and petitions for regulations now pending before the Secretary may qualify, as well as matters already subject to an extension; and, second, to have any time limitation (if one is inserted in the bill) carry the Secretary's discretion for granting extensions, at least into the middle of 1964.

Please accept this letter for the record in lieu of my personal appearance at the recent hearings on this bill held by your committee.

I am, with cordial regards,

Respectfully yours,

FRANKLIN M. DEPEW, *President.*

FEBRUARY 25, 1961.

COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
House Office Building,
Washington, D.C.

DEAR SIRS: The members of the Bridgewater Homemakers Club respectfully protest draft bill H.R. 3980, referred to by title "Food Additives Transitional Provisions Amendment of 1961", to amend the transitional provisions of the act approved September 6, 1958.

This law, we are certain, is not in the public interest and should be defeated, because it defeats the purposes of the act approved September 6, 1958, by circumventing its two safety clauses: (1) "to prohibit the use in the food of additives which have not been adequately tested to establish safety." (2) The Delaney cancer clause which "rules out a substance if it is found to induce cancer in man or animal, after tests which are appropriate for the evaluation of the safety of food additives."

It also gives the Food and Drug Administration unlimited authority to extend the use of these toxic chemicals, at their pleasure. Our study of the actions of the Food and Drug Administration in the past, give us little confidence that this authority will be used in the public interest rather than in the interest of the food processors and manufacturers.

We hope you will be interested in the following selected bibliography which we present as the basis for our statements.

1. Agriculture Department's warning on the subject, in a confidential report prepared by Ralph Trigg of the Production and Marketing Division for Secretary Charles Brannan. This appeared in the Washington Post May 3, 1949.
2. A letter from Dr. William E. Smith to Congressman James J. Delaney of New York—Congressional Record of the 85th Congress, 1st session.
3. "The Poisons in Our Food"—by William Longgood.
4. Food and Drug Administration Reports.
5. The New York Times.

Sincerely,

BRIDGEWATER HOMEMAKERS CLUB,
JOSEPHINE P. SHIVELY,
Editor, Woman's Health News, Route 2, Quaker City, Ohio.

NOPCO CHEMICAL CO.,
Newark, N.J., February 24, 1961.

Subject: H.R. 3980, Food Additives Transitional Provisions Amendment of 1961.

Hon. OREN HARRIS,
Chairman, House Interstate and Foreign Commerce Committee,
House of Representatives,
Washington, D.C.

SIR: As a chemical manufacturer, our company is vitally interested in any action Congress may take in connection with the above-identified bill. As you are well aware, this bill, among other things, will empower the Secretary of the Department of Health, Education, and Welfare to grant, under appropriate

circumstances, further time extensions with respect to food additives which are now being marketed under time extensions. We are, of course, in complete accord with the purpose of this bill and respectfully urge its passage. The chemical industry, as a whole, is in need of additional time to fully comply with the requirements of the Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act.

The foregoing notwithstanding, however, we wish to state that, in our view, the proposed bill, as drafted, is, in one respect at least, far too restrictive. H.R. 3980 reads, in part as follows:

"Whenever the Secretary has * * * extended the effective date * * * to March 6, 1961, with respect to any such particular use of a food additive, he may * * * further extend such effective date * * * with respect to such use of the additive (or a more limited specified use or uses thereof) if * * * he finds (i) that bona fide action to determine the applicability of such section 409 to such use or uses, or to develop the scientific data necessary for action under such section, was commenced by an interested person before March 6, 1960, and was thereafter pursued with reasonable diligence. * * *"

The proposed bill makes no allowance for the grant of further time extensions in the case of food additives, now sold under time extensions, where no steps leading to compliance with the food additives amendment had been initiated in connection therewith on or before March 6, 1960. The primary purpose of this restriction is self-evident. H.R. 3980, in effect, rewards diligence. However, the language of the bill is such that it will have the effect also of penalizing companies who failed to act prior to March 1, 1960, in connection with an additive, not because of lack of diligence, but because no action was deemed necessary. For example, certain products of our manufacture are, and for many years have been, sold for use in the processing of textiles. We were not, on March 6, 1960, aware of the fact that particular products in our line of textile chemicals were used for purposes which would, or could, bring them within the scope of the Federal act. It was not until impurities were received, subsequent to March 6, 1960, from customers for these products, that we became cognizant that they were, or could be considered as "food additives." Upon receipt of such inquiries, we filed with due diligence, requests for time extensions with the Food and Drug Administration in connection with these products.

It is respectfully submitted that the proposed legislation, the purpose of which is to empower the Secretary of the Department of Health, Education, and Welfare to grant further time extensions, should permit the Secretary the use of discretion in any case having unusual circumstances. H.R. 3980, as now written, does not grant the Secretary such discretionary power. Rather, H.R. 3980 will preclude the Secretary from granting relief under circumstances such as are heretofore described, to the detriment both of the industry and the consumer.

Your consideration of this matter will be appreciated greatly.

Respectfully,

JOHN N. GAMMON, *Vice President.*

EASTMAN CHEMICAL PRODUCTS, INC.,
Kingsport, Tenn., February 24, 1961.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House Office Building, Washington, D.C.

DEAR MR. HARRIS: As marketer of a number of products which are covered by the food additives amendment to the Food, Drug, and Cosmetic Act, we wish to urge enactment before March 6, 1961, of legislation enabling the Secretary of Health, Education, and Welfare to grant extensions of the effective date of said amendment after said date. To this end, H.R. 3980 was introduced on February 7, 1961, and referred to your committee. This is a bill sponsored by the Secretary. We wish to urge its immedate enactment, with one change which we understand is agreeable to the Food and Drug Administration.

This is, that instead of the requirement that to qualify for an extension of effective date after March 6, 1961, a food additive must have previously been accorded such an extension to March 6, 1961, the statute permit a further extension to March 6, 1961, has been granted or has been requested and not denied.

The reason for immediate enactment of this legislation is stated as follows in letter from Secretary Flemming to the Speaker of the House dated January 13, 1961:

"This legislation is needed, both by us and by industry, because we shall not be able to process all food additive petitions under the Food Additives Amendment of 1958—where extensions have heretofore been granted—before March 6, 1961 (the limit of our present authority to grant extension of the transitional provisions) and because the affected industries will not be able to develop all necessary scientific data and petitions before that date even where appropriate action leading to such petitions was started in a timely manner.

Yours very truly,

M. C. STONE, *Assistant Secretary.*

THE DOW CHEMICAL CO.,
Washington, D.C., February 24, 1961.

Reference H.R. 3980.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
U.S. House of Representatives,
Washington, D.C.

DEAR CONGRESSMAN HARRIS: We hereby record our support of H.R. 3980 to amend the Food, Drug, and Cosmetic Act to extend the transition period for food additives. We likewise support the proposed change in the wording of the bill to include within its coverage all those food additives for which petitions may be pending action by the Food and Drug Administration on the present deadline date of March 6, 1961.

We firmly believe that conditions dictate the granting of the relief offered by this proposed legislation to manufacturers of food additives who have acted in good faith in attempting to comply with the provisions of the 1958 food additive amendment, and urge prompt affirmative action by your committee and the Congress in clearing and enacting this vitally necessary measure.

Sincerely yours,

RUSSELL A. WHITESELL,
Special Assistant to the President.

NATIONAL COTTON COUNCIL OF AMERICA,
Washington, D.C. February 28, 1961.

Hon. OREN HARRIS,
Chairman, House Committee on Interstate and Foreign Commerce,
New House Office Building,
Washington, D.C.

MY DEAR MR. HARRIS: The National Cotton Council, which is the overall organization of the raw cotton industry, representing cotton farmers, cotton ginners, cotton warehousemen, cotton merchants, cotton spinners, and cottonseed crushers, favors the enactment of H.R. 3980.

As a result of the food additives amendment to the Federal Food, Drug, and Cosmetic Act, rather extensive tests were required of some chemicals used in cotton production. It was not possible to complete these tests within the time originally specified and extensions of 1 year were granted under authority contained in the amendment. These extensions expire next month. There are several chemicals which have not yet been approved for cotton production. These are principally defoliants which facilitate harvest and result in higher grades of cotton. As we understand the situation, it is just not possible for the Food and Drug Administration and the manufacturers of some agricultural chemicals to complete the necessary tests required under the food additives amendment within the time limit allowed.

Accordingly, the time extension provided for in H.R. 3980, which you introduced, seems both reasonable and necessary. The National Cotton Council urges that your committee take favorable action on H.R. 3980 promptly.

Respectfully submitted.

J. BANKS YOUNG.

DIXIE CUP DIVISION OF AMERICAN CAN CO.,
Easton, Pa., February 13, 1961.

Hon. JAMES B. UTT,
House Office Building,
Washington, D.C.

DEAR CONGRESSMAN UTT: As you are no doubt aware, we have a factory in your district in Anaheim and are therefore taking the liberty of writing you with reference to a matter which is of considerable importance to us.

This letter concerns the 1958 food additives amendment to the Federal Food, Drug, and Cosmetic Act. You will recall that the gist of this amendment is that no substance may be added to a food unless it is generally recognized by scientists as harmless or has been specifically approved by the Federal Food and Drug people after the submission of the results of exhaustive scientific tests.

Prior to the passage of this act, as we understand the law, a food manufacturer might use any additive and the burden was on the Food and Drug people to prove that the additive was harmful.

It is generally conceded that the additive amendment is a good piece of legislation and was probably overdue. However, it has posed many difficult problems for the packaging industry due to the position of the Food and Drug people that if the most minute trace of anything from a food package gets into the food, it is up to the seller of the food thus packaged to demonstrate to the Food and Drug people the exact chemical nature of the substance concerned and submit exhaustive tests to the effect that such substance is harmless.

The packaging industry in general had been attempting to apply a commonsense approach to the subject and perhaps had not been too greatly concerned when industry chemists and consultants advised that there was nothing in the packaging which could dissolve into the food in a sufficient amount to be harmful. On the other hand, there are many companies which produce food packaging, each of which in the past was left to measure the public welfare in the light of its own ethics. Therefore we again must generally agree that the additive amendment as applied to food packaging is probably a good thing.

The testing program required by the Federal Food and Drug people for the clearance of a particular "additive" is most exhaustive and the procedures required for the clearance of a single chemical or compound may cost over $100,000. The only practical approach for a company such as ours, which purchases its materials from many different sources, has been to insist that the vendors of the materials in question sell us only materials which have been appropriately cleared by the Federal Food and Drug people. In turn, because of the large expense involved, many suppliers of our raw materials such as paper, plastics, waxes, and adhesives, have undertaken joint industry programs for the testing and clearance of their materials. The FDA understands this and is in agreement with such a procedure, since it also reduces FDA manpower requirements if materials are cleared in an orderly way by groups which represent most of the producers in a particular line.

The additives amendment gives the Food and Drug Administration power to grant certain extensions of time during which "uncleared" items may continue to be used if FDA is convinced that the public will not be harmed. A great many, if not most, components are presently being used in food packaging pursuant to such extensions. One such example is a petroleum wax which is presently undergoing exhaustive tests under the auspices of the American Petroleum Institute.

The authority of the Food and Drug Administration to grant such extensions and the extensions heretofore granted expire by the terms of the additive amendment on March 6, 1961. A great many industry programs which are being conducted in general harmony with the objectives of the Food and Drug Administration cannot possibly be completed by March 6, which is almost upon us. The industry, therefore, may be faced with a completely chaotic situation unless the power of the Food and Drug Administration to grant such extensions is extended prior to March 6 of this year. We understand that the Food and Drug Administration is requesting that this power be granted to it at least for cases in which bona fide testing programs are underway and in which it feels that the industry concerned is cooperating.

The purpose of this letter is to acquaint you with the situation and to strongly urge you to support an immediate extension of the authority of the Food and Drug Administration to grant extensions as heretofore outlined. There has been a great deal of concern that because of the confusion attendant upon the change

in administration, this matter would be overlooked. However, we believe that it is completely nonpartisan and we strongly urge that you assist in any way you can.

Sincerely yours,

R. D. PINE, Jr.,
Resident Counsel.

P.S.—Since dictating the foregoing letter it has come to our attention that some people in our industry feel that the power of FDA to grant extensions should not be restricted to situations in which particular testing programs are presently underway. (1) We think that this industry position is sound. Whether FDA would grant an extension in a particular case would still be discretionary and FDA need not grant it. However, it does not seem wise to so restrict the power of FDA that it cannot under any circumstances grant an extension in some meritorious or unusual case in which no testing program is presently underway. However, a dispute over the extent of authority of FDA should not be permitted to bog down the situation to such an extent that no legislation is forthcoming before March 6. The dispute is minor; some legislation is indispensable.

(1) The FDA proposed bill limits the right of the Secretary to grant extensions to cases in which "he finds (i) that bona fide action to determine the applicability of such section 409 to such use or uses, or to develop the scientific data necessary for action under such section, was commenced by an interested person before March 6, 1960, and was thereafter pursued with reasonable diligence."

(Whereupon, at 10:50 o'clock, the hearing was adjourned.)

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