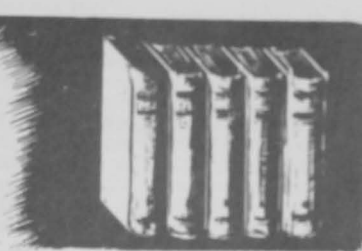




# FEDERAL ACTIONS



## Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

### POLICY ON EFFECTIVE DATE OF FOOD ADDITIVES AMENDMENT:

The food additives amendment to the Federal Food, Drug, and Cosmetic Act (72 Stat. 1785 et seq., U.S.C. 342, 348) is scheduled to become fully effective on March 6, 1960, according to a statement of policy issued by the U. S. Food and Drug Administration and published in the December 31, 1959, Federal Register. Extension of time for compliance by food and chemical manufacturers with the requirements of the Food Additives Amendment are covered.

However, the effective date may be extended on a product-by-product basis for a time not to exceed 12 months "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."

After this amendment becomes fully effective, any food in interstate commerce may contain a food additive as de-

defined in section 201(s) of the act only under certain prescribed conditions.

In order that decisions on requests for extension could be published before March 6, 1960, requests and supporting data were to be submitted by February 1, 1960.

Although there are many chemicals commonly used in foods which are generally recognized as safe, there are numerous others for which safe tolerances must be established by regulation. The Agency said it is not possible at this time to determine whether tolerances will be established for them before the Food Additives Amendment will become fully effective. Manufacturers, distributors, users, and food law enforcement officials needed to know the status of those additives under the amendment prior to March 6, 1960, so that they would know whether they may be employed after that date.

The Agency pointed out that all food additives had to be cleared for use before the March 6 date unless an extension was granted. Use of a food additive without a formal authorizing regulation or an extension of time after March 6, 1960, will cause the food containing it to be adulterated and illegal for shipment, the Agency added.

## Title 21—FOOD AND DRUGS

### Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

#### SUBCHAPTER B—FOOD AND FOOD PRODUCTS

#### PART 121—FOOD ADDITIVES

#### Subpart A—Definitions and Procedural and Interpretative Regulations

#### STATEMENT OF POLICY WITH REFERENCE TO EFFECTIVE DATE OF FOOD ADDITIVES AMENDMENT

Under the authority vested in the Secretary of Health, Education, and Wel-

fare by the Federal Food, Drug, and Cosmetic Act (sec. 6(c), Public Law 85-929; 72 Stat. 1789; 21 U.S.C., note under section 342 (1958 amendment)), the following statement of policy is issued:

§ 121.85 Statement of policy with reference to effective date of food additives amendment.

(a) The food additives amendment to the Federal Food, Drug, and Cosmetic Act (72 Stat. 1785 et seq., 21 U.S.C. 342, 348) is scheduled to become fully effective on March 6, 1960. However, this date may be extended on a product-by-product basis for a time not to exceed 12 months "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."

(b) After this amendment becomes fully effective, any food in interstate commerce may contain a food additive as defined in section 201(a) of the act only if:

- (1) The additive and its use, or intended use, conform to the terms of a regulation that provides for an exemption from the requirements of the food additives amendment for any food additive, and any food bearing or containing such additive because it is intended solely for investigational use by qualified experts; or
- (2) There is in effect, and the additive and its use or intended use are in conformity with a regulation issued under section 409 prescribing the conditions under which such additive may be safely used.

(c) Many chemicals commonly used in foods are generally recognized as safe. A number of them have been listed in regulations in this chapter. However, there are food additives in common use that are not generally recognized as safe and for which tolerances must be established by regulation. It is not possible at this time to determine whether tolerances will be established for them before the food additives amendment will become fully effective. Manufacturers, distributors, users, and food-law enforcement officials need to know the status of these additives under the amendment prior to March 6, 1960, so that they will know whether they may be employed after that date.

(d) The Commissioner of Food and Drugs is prepared to consider requests for an extension of the effective date of the law, for specific additives. The following criteria, among others, will be used in evaluating and acting upon such requests:

(1) The effective date of the amendment can be extended for a specific additive only upon a finding, based on a study of the available facts about the additive and its toxicity, that such extension will involve no undue risks to the public health and that conditions exist that necessitate such extension.

(2) There should be evidence about the amounts of the additive present in the food and about its chronic toxicity before an extension is granted.

(3) Extensions will not be granted for a food additive if appropriate tests show the production of cancer in test animals at any dosage level, nor will they be granted if such tests show alarming symptoms other than cancer in any dosage, unless experimental data show a level of feeding to test animals that is safe to the animal and provide a satisfactory margin of safety for the levels in the human diet.

(4) Where a regulation provides for the presence of an additive in certain foods at a given level, and the other criteria of this statement of policy are met, the effective date may be extended for other similar uses of the additive.

(5) Extension should be granted only for those uses of a food additive which had been employed prior to January 1, 1958.

(6) Notice of the decisions of the Food and Drug Administration on requests for extensions will be published in the FEDERAL REGISTER.

(e) Each request for an extension should be addressed to the Commissioner of Food and Drugs, and should give:

(1) The name and chemical composition of the food additive for which extension is requested.

(2) A statement of the uses of the food additive for which extension is requested and evidence that these uses were recognized prior to January 1, 1958.

(3) Information about the physical or technical effect produced by the additive, and the quantity needed to produce such effect.

(4) Information about the quantity of the additive expected in or to be added to the food.

(5) Available information which indicates that these amounts of the additive in food will not jeopardize the public health.

(6) A statement of the reason(s) why a tolerance has not previously been requested.

(7) In order that decisions on requests for extensions may be published before March 6, 1960, requests and supporting data should be received by February 1, 1960.

(Sec. 701(a), 52 Stat. 1055; 21 U.S.C. 352(a). Interprets or applies secs. 402, 409, 72 Stat. 1785, 1789; note under 21 U.S.C. 342; 21 U.S.C. 348)

Dated: December 23, 1959.

[SEAL] GEO. P. LARRICK,  
Commissioner of Food and Drugs.

\* \* \* \* \*

#### PROPOSED SUPPLEMENTAL LIST OF FOOD ADDITIVES GENERALLY RECOGNIZED AS SAFE:

A list of food additives or substances generally recognized as safe appeared in an order issued by the U. S. Food and Drug Administration and published in the Federal Register of November 20, 1959. The order became effective on December 20, 1959, under the provisions of the Federal Food, Drug, and Cosmetic Act.

In the February 2, 1960, Federal Register the Agency published a supplemental list of food additives which it proposes to include in the regulation and asked for comments prior to inclusion of the supplemental list in the regulation.

Included in the supplemental list are chemical preservatives, buffers and neutralizing agents, nonnutritive sweeteners, nutrients, stabilizers, anticaking agents, and a group of miscellaneous additives. The supplemental list includes about 52 substances, and for some substances limits are designated.

Also in the February 2 Federal Register, the Agency also amended the food ad-

ditives regulations by adding a list of substances employed in the manufacture of food-packaging materials for which prior sanctions have been granted. Included in that list are certain antioxidants, antimycotics, driers, drying oils, plasticizers, release agents, stabilizers, and a few others--about 82 substances.

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#### LIST ISSUED OF SPICES, SEASONINGS, ETC., RECOGNIZED AS SAFE:

A list of spices, seasonings, essential oils, oleoresins, and natural extractives that are generally recognized as safe for intended use, within the meaning of section 409 of the Federal Food, Drug, and Cosmetic Act, was published by the U. S. Food and Drug Administration in the January 19, 1960, Federal Register. The order became effective upon publication.

The common name and the botanical name of plant source is given in the list. Included are about 70 spices and other natural seasonings and flavorings (leaves, roots, barks, berries, etc., including pepper, parsley, paprika, etc.); 128 essential oils, oleoresins, and natural extractives, including distillates; and 3 miscellaneous additives.



## Treasury Department

### COAST GUARD

#### STANDARDS FOR NUMBERING OF UNDOCUMENTED VESSELS ISSUED:

Certain regulations pertaining to the numbering of undocumented vessels have been issued by the U. S. Coast Guard and published in the December 29, 1959, issue of the Federal Register. They became effective on March 15, 1960. The purpose is to publish procedures with respect to numbering of undocumented vessels under the Federal Boat Act of 1958; to provide for temporary exemptions from numbering requirements in order to allow states which have under active consideration or have nearly perfected their numbering systems additional time in which to obtain approval; and to reduce the fee for an original number from \$5.00 to \$3.00, which is based on the cost for administration of the Coast Guard numbering system.

The Federal Boat Act of 1958 included provisions for establishment of a new system of numbering small undocumented vessels propelled by machinery of 10 or more horsepower, using the navigable waters of the United States. The Act permits the several states to have concurrent jurisdiction with the Federal Government over the navigable waters within their respective boundaries and to enforce their respective laws on all the waters within such boundaries whether they be intrastate waters or navigable waters of the United States. The states can assume the responsibility for numbering undocumented vessels and for the passage and enforcement of laws regarding small boats. If a state does not assume responsibility, U. S. Coast Guard regulations will apply in that state.

The new Coast Guard regulation designated 46 CFR 171.01-6 is to provide a temporary exemption until July 1, 1960, for all undocumented vessels principally used within a particular state in which it is found that such state's system for numbering is under active consideration or nearly perfected for approval and may be approved by July 1, 1960. This temporary exemption may be permitted so that the assumption of functions with re-

spect to numbering by a particular state may be accomplished in an equitable manner.

The new regulation (designated 46 CFR 171.10-2) describes the procedures for making application for a Coast Guard number on and after April 1, 1960. Arrangements have been made with the Post Office so that applications (Forms CG-3876 and CG-3876A) will be available at all First Class and Second Class Post Offices throughout the United States and at designated Third and Fourth Class Post Offices in those states in which the undocumented vessels must be numbered by the Coast Guard. No applications will be accepted before April 1, 1960.

The amendment to 46 CFR 171.10-25 revises the procedures for obtaining a duplicate certificate of number in event the original certificate of number is lost or destroyed. Arrangements have been made with the Post Office so that applications for duplicate certificates of number (Form CG-3919) will be available at all First and Second Class Post Offices throughout the United States and at designated Third and Fourth Class Post Offices in those states in which vessels must be numbered by the Coast Guard. No applications will be accepted before April 1, 1960. No application will be processed without a special fee stamp attached thereto and postmarked.

Thirty states have enacted legislation to set up their own registering and numbering systems but all have not yet been formally approved by the Coast Guard. Additional states probably will act but the Coast Guard will take over the responsibility in those which do not conform on April 1, 1960.

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#### COURT OF CUSTOMS AND PATENT APPEALS

#### CONSTITUTIONALITY OF TRADE AGREEMENTS ACT UPHELD:

The U. S. Court of Customs and Patent Appeals on December 16, 1959, issued a ruling upholding dismissal of the suit by a West Coast tuna canning firm, which sought to have the Trade Agreements Act declared unconstitutional.

The five-judge court unanimously upheld the decision of the U. S. Customs Court, which had dismissed the firm's suit.

The tuna canning firm had asked that tariff reductions negotiated with other countries under the Act be declared null and void because the Act amounted to an unconstitutional delegation of legislative powers by the Congress to the President, and because the tariff-cutting agreement actually was a treaty with a foreign nation which should have been ratified by the Senate.

The Court, in an opinion by Judge I. Jack Martin, rejected both arguments. It cited Supreme Court decisions which it said approved Congressional delegation powers which are limited and which indicate the intent of Congress.

The Court held that in the 1934 Act "the Congressional policy is pronounced very clearly. The stated objectives are to expand foreign markets for the products of the United States. . . ."

The Court said: "These objectives are in their nature no different than those" of the Tariff Acts of 1890 and 1922 which the high court has upheld.

Decisions of the Customs and Patent Court can be appealed to the Supreme Court.



## Eighty-Sixth Congress

### (Second Session)

Public bills and resolutions which may directly or indirectly affect the fisheries and allied industries are reported upon. Introduction, referral to committees, pertinent legislative actions, hearings, and other chamber actions by the House and Senate, as well as signature into law or other final disposition are covered.



**AMERICAN SAMOA PROBLEMS:** Senator Bartlett introduced into the Congressional Record of January 13, 1960, an article written by Senator Long of Hawaii on problems in American Samoa. The article mentions that assistance is needed in developing a more adequate economy in American Samoa. Enlargement is needed of the present fish cannery which employs 450 people. One of the greatest needs is for financial assistance in providing fishing vessels capable of competing with vessels used by other fishermen in American Samoa waters. The article further states that the Bureau of Commercial Fisheries should provide assistance in a future aid program to American Samoa.

**COLOR ADDITIVES IN FOODS:** The House Committee on Interstate and Foreign Commerce held hearings February 10 and 11 on H. R. 7624 (Harris) and S. 2197 (Hill & Goldwater), color additive amendments to the Food and Drug Act.

**FISHERIES ASSISTANCE ACT OF 1959:** House disagreed to certain Senate amendments to H. R. 5421 (MacDonald)--passed House August 26, 1959, and passed and amended in Senate September 11, 1959--to provide a program of assistance to correct inequities in the construction of fishing vessels and to enable the fishing industry of the United States to regain a favorable economic status, and for other purposes. Conference on the bill was requested with the Senate and House and Senate conferees were appointed.

**IMPORTED COMMODITY LABELING:** The House on February 2, 1960, passed by a voice vote H. R. 5054 (Herlong), a bill to amend the Tariff Act of 1930 with respect to the marking of imported articles and containers, as amended. Provides that imported articles removed from original container, repacked, and offered for sale in a new package or container, shall be marked to show the country of origin. Bill referred to the Senate, where no companion bill has been introduced to date.

**INCOME TAX LAW REVISION IN FAVOR OF FISHERMEN:** H. R. 10305 (Wilson), a bill to extend to fishermen the same treatment afforded farmers in relation to estimated income tax; to the Committee on Ways and Means; introduced in House February 9, 1960. Similar to H. R. 604 (Pelly), H. R. 1925 (King of Calif.), and S. 774 (Magnuson); all introduced during first session of the 86th Congress.

**INTERIOR APPROPRIATIONS:** H. R. 10401 (Kirwan), a bill making appropriations for the Department of Interior and related agencies for the fiscal year ending June 30, 1961, and for other purposes; filed on February 12, 1960 (H. Rept. 1264). The House passed the bill by a voice vote on February 16, 1960. Included in the bill is an increase of \$4,090,800 for the Fish and Wildlife Service, primarily to replace permanent appropriations from receipts, including duck stamps, which will no longer be available for operations, enforcement, or research.

**Department of the Interior and Related Agencies Appropriations for 1961, Part I (Hearings January 12, 13, 14, 26, 27, and 28, 1960, before a Subcommittee of the Committee on Appropriations, House of Representatives, 86th Congress, 2nd Session, on**

appropriations for the Department of Interior except Bonneville Power Administration, Bureau of Reclamation, Southeastern Power Administration, and Southwestern Power Administration), 1027 pp., printed. Includes hearings on operations of the Fish and Wildlife Service and also specifically the Bureau of Commercial Fisheries.

Department of the Interior and Related Agencies Appropriations for 1961, Part II (Hearings January 21, 22, and 25, 1960, before a Subcommittee of the Committee on Appropriations, House of Representatives, 86th Congress, 2nd Session, on appropriations for several related agencies of the Department of the Interior, including the Outdoor Recreation Resources Review Commission, Smithsonian Institution, and Transitional Grants to Alaska), 517 pp., printed.

LAW OF THE SEA: Public hearings were held by the Senate Committee on Foreign Relations on January 20, 1960, at 10:30 a.m. in the New Senate Office Building, Washington, D. C., on four conventions and an optional protocol on the Law of the Sea: Executive J, "A Convention on the Territorial Sea and Contiguous Zone;" Executive K, "A Convention on the High Seas;" Executive L, "A Convention on Fishing and Conservation of the Living Resources of the High Seas;" Executive M, "A Convention on the Continental Shelf;" Executive N, "An Optional Protocol of Signature Concerning the Compulsory Settlement of Disputes."

FISH AND WILDLIFE: Miscellaneous Fish and Wildlife Legislation (Hearings May 5, June 3, 30, July 1, and August 4, 1959, before the Subcommittee on Fisheries and Wildlife Conservation of the Committee on Merchant Marine and Fisheries, United States House of Representatives, 86th Congress, 1st Session, on H. R. 350, H. R. 1984, H. R. 2398, H. R. 2565, H. R. 3087, H. R. 4019, H. R. 4402, H. R. 5004, H. R. 5119, H. R. 5271, H. R. 5813, H. R. 5814, H. R. 5954, H. R. 7045, and H. R. 7455), 301 pp., printed. Contains purpose and provisions of each bill, and statements, reports, and recommendations of representatives of Government and industry. Also includes individual views and comments on bills, and various statistical tables.

Of special interest to commercial fisheries are the hearings on H. R. 4402, a bill to provide for the construction of a salt-water research laboratory at Seattle, Wash.; H. R. 350, a bill to provide for the construction of a fish and wildlife marine laboratory and experiment station in the central Gulf coast area of Florida; H. R. 5954, a bill to clarify a provision in the Black Bass Act relating to the interstate transportation of fish and for other purposes; and H. R. 1984, H. R. 3087, H. R. 4019, H. R. 5119, and H. R. 5271, all providing for the eradication of starfish in Long Island Sound and adjacent waters.

OCEANOGRAPHIC SURVEYS: H. R. 10412 (G. P. Miller), a bill to establish a public policy with respect to oceanographic surveys, and to provide for coordination of the efforts of Federal agencies with respect to oceanographic surveys; to the Committee on Merchant Marine and Fisheries; introduced in House February 15, 1960.

SHRIMP CONSERVATION CONVENTION WITH CUBA: H. R. 9917 (Bonner), a bill to give effect to the Convention between the United States and Cuba for the conservation of shrimp, signed at Havana, August 15, 1958; to the Committee on Merchant Marine and Fisheries; introduced in House January 26, 1960.

Identical to S. 2867 (Magnuson), referred to the Committee on Interstate and Foreign Commerce; introduced in Senate January 20, 1960.

SHRIMP IMPORTS: H. Res. 442 (Boggs), a resolution directing the Tariff Commission to make an investigation of the effect of the existing customs treatment of shrimp upon the domestic shrimp industry; to the Committee on Ways and Means; introduced in House February 8, 1960.

The House Committee on Ways and Means announced on February 9 its approval of a Committee resolution directing the Tariff Commission to make an investigation of the effect of the existing customs treatment of shrimp upon the domestic shrimp industry. The Committee resolution is identical to H. Res. 442.

TARIFF NEGOTIATIONS: H. Con. Res. 503 (Thomson), concurrent resolution expressing the sense of Congress that the United States should not grant further tariff reductions in the forthcoming tariff negotiations under the provisions of the Trade Agreements Extension Act of 1958, and for other purposes; to the Committee on Ways and Means; introduced in House January 25, 1960. Identical to H. Con. Res. 512 (Bailey), H. Con. Res. 513 (Berry), H. Con. Res. 515 (Dent), H. Con. Res. 516 (Dorn of S. C.), H. Con. Res. 517 (Fisher), H. Con. Res. 518 (Gross), H. Con. Res. 519 (Hemphill), H. Con. Res. 520 (McIntire), H. Con. Res. 521 (Mason), H. Con. Res. 522 (Oliver), H. Con. Res. 523 (Smith of Kan.), H. Con. Res. 524 (Stratton), and H. Con. Res. 525 (Utt); all introduced in House January 26, 1960. Also identical to H. Con. Res. 527 (Mack of Wash.), introduced January 27; H. Con. Res. 554 (Saylor), introduced February 1; H. Con. Res. 560 (Tollefson), introduced February 2; H. Con. Res. 580, introduced February 4; and H. Con. Res. 583 (Hays), introduced in House February 8, 1960.

TRANSPORTATION: S. 3048 (Magnuson), a bill to amend the Interstate Commerce Act with respect to reasonable differentials in favor of joint rates for through transportation by rail and water, and for other purposes; to the Committee on Interstate and Foreign Commerce; introduced in Senate February 16, 1960.

VESSELS ADMEASUREMENT SIMPLIFICATION: S. 2916 (Magnuson), a bill to simplify the admeasurement of small vessels; to the Committee on Interstate and Foreign Commerce; introduced in Senate January 26, 1960.

Also identical bill H. R. 9916 (Bonner); to the Committee on Merchant Marine and Fisheries; introduced in House January 26, 1960.

