

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the FAA proposes to amend 71.181 of Part 71 of the Federal Aviation Regulations (14 CFR Part 71) as follows:

Hampton, AR [New]

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of the Hampton Airport (latitude 33°31'30"N., longitude 92°27'30"W.) and 3 miles each side of a 007° bearing from the airport to 8.5 miles north.

(Sec. 307(a), Federal Aviation Act of 1958 (49 U.S.C. 1348(a)); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)); and 14 CFR 11.61(c))

Note.—The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Issued in Fort Worth, TX, on August 26, 1982.

F. E. Whitfield,

Acting Director, Southwest Region.

[FR Doc. 82-24183 Filed 9-3-82; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 922

National Marine Sanctuary Program Regulations

AGENCY: Office of Coastal Zone Management (OCZM), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule.

SUMMARY: These proposed regulations revise existing procedures for identifying and selecting potential marine sanctuary candidates, as well as for designating these sites as national marine sanctuaries. The regulations reflect a management-oriented approach to protecting special marine areas. They reflect the refinements and programmatic policies outlined in the Program Development Plan (PDP) for the

National Marine Sanctuary Program (January 1982). The rules will amend existing procedures by providing greater selectivity in initially identifying and processing potential national marine sanctuaries. They are intended to reduce delay and uncertainty in the site selection and approval process.

DATES: Comments will be accepted until November 8, 1982. After the close of the comment period and review of comments received, final regulations will be published in the *Federal Register*.

ADDRESS: Send comments to: Dr. Nancy Foster, Deputy Director, Sanctuary Programs Office, Office of Coastal Zone Management, NOAA, 3300 Whitehaven Street, NW., Washington, D.C. 20235.

FOR FURTHER INFORMATION CONTACT: John Epting, (202) 634-4236.

SUPPLEMENTARY INFORMATION: NOAA is publishing revised regulations for implementing the National Marine Sanctuary Program, pursuant to Title III of the Marine Protection, Research and Sanctuaries Act, as amended in 1980, 16 U.S.C. 1431-1434, (the Act). Since its establishment in 1972, the National Marine Sanctuary Program has had a number of years of operating experience. Through this experience and considerable commentary on the Program, a number of refinements in operational policy and procedure have been designed. These refinements are discussed at length in the PDP for the National Marine Sanctuary Program. The PDP describes the Program's mission and goals; changes in the site identification and selection criteria; the nomination and designation process; and the components and purposes of site-specific management plans.

The proposed regulations implement these refinements, which include:

I. Adoption of the Mission and Goals for the Program

The Mission Statement and Goals for the continued implementation of the National Marine Sanctuary Program stress the importance of comprehensive long-term management. Although broad in scope, they establish a framework within which specify program activities are conducted. The Mission Statement and Goals are adopted by the revised regulations (§ 922.1).

II. Revision of the Procedures for Initially Identifying Potential Sanctuary Candidates

(A) Elimination of the List of Recommended Areas.

In regulations published on July 31, 1979 (44 FR 44531), NOAA established the List of Recommended Areas (LRA)

as a means of eliminating clearly inappropriate proposals, advising the public at large of recommended sites, cataloging potentially significant marine sites, and soliciting information on those sites. The LRA, however, did not totally fulfill these purposes. Since the LRA site evaluation criteria were broad and allowed marginally acceptable nominations to qualify for further consideration, the procedure resulted in much unnecessary controversy over the Program as a whole. A great number of nominations were received, many of which were minimally acceptable, in some instances incorporating large areas of Outer Continental Shelf waters and encompassing thousands of square miles. This caused substantial confusion and concern over the status of sites on the LRA and the likelihood of further action. Even though the majority of the listed sites would never become active candidates, the LRA has often been perceived as the blueprint for the sanctuary program. These regulations eliminate the LRA process from the program, and replace it with the procedure set forth below:

(B) Establishment of a Site Evaluation List.

The Site Evaluation List (SEL) process, described in section 922.20(a), is proposed to eliminate the problems created by the LRA. Under this process, NOAA is using regional resource evaluation teams, comprised of knowledgeable scientists, to identify, evaluate, and recommend sites suitable for sanctuary consideration in accordance with redefined site identification and evaluation criteria. The criteria and methodology have been refined to focus more clearly on those sites with special resource and human use values that have a high likelihood of eventual designation. The revised criteria and an explanation of their application are provided in Appendix 1. By actively seeking sites based on sound criteria, resource data and scientific experts; and by assuring early public review at the regional level, highly-qualified marine sites can be identified. The regional resource evaluation teams recommend the final sites to NOAA; final selection for placement on the SEL will be made by NOAA and published in the *Federal Register* by March 1983.

After NOAA adopts the SEL, it will review an additional site only if it is an important new discovery of national significance. NOAA will make this determination in consultation with appropriate scientists and resource manager. If the newly discovered site is determined to be of national significance, the selection criteria

specified in Appendix I will be applied, and qualified sites will be placed on the Site Evaluation List for further evaluation as a national marine sanctuary, consistent with the procedures in § 922.21.

III. Selection of Active Candidates and the Actual Designation of Marine Sanctuaries

Selection of a site from the SEL to be an active candidate is the second step in evaluating a site for potential designation (section 922.21). Only a limited number of sites at a time will be selected as active candidates and evaluated by NOAA for possible sanctuary designation. NOAA's selection and scheduling of sites from the SEL for active candidate evaluation necessarily involves a balancing of ecological factors and relevant policy considerations including: ecological conditions, immediacy of need, timing and practicality, and public comment.

IV. Enforcement Activities

Subpart D has been revised to reflect the 1980 amendments to the Act explicitly authorizing NOAA to utilize the resources of other agencies including State agencies for enforcement purposes (section 922.30).

V. Other Actions Associated With the Notice of Final Rulemaking

(A) Classification Under Executive Order 12291.

NOAA has concluded that these regulations are not major because they will not result in:

- (1) An annual effect on the economy of \$100 million or more;
- (2) A major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; or
- (3) Significant adverse effects on competition, employment investment, productivity, innovation or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The final rules amend existing procedures by providing greater selectivity in initially identifying and processing potential national marine sanctuaries in accordance with the recent Program Development Plan for the National Marine Sanctuary Program. These rules establish a revised process for identifying, designating, and managing national marine sanctuaries. They will not result in any direct economic or environmental effects nor will they lead to any major indirect economic or environmental impacts. They are intended to reduce delay and

uncertainty in the site selection and approval process.

(B) Regular Flexibility Analysis.

A Regulatory Flexibility Analysis is not required for this notice of proposed rulemaking. The regulations set forth procedures for identifying, selecting, and, if designated, managing national marine sanctuaries. These rules do not directly affect "small government jurisdictions" as defined by Pub. L. 96-354, the Regulatory Flexibility Act, and the rules will have no effect on small businesses.

(C) Paper Work Reduction Act of 1980 (Pub. L. 96-511).

These regulations will impose no information collection requirements of the type covered by Pub. L. 96-511.

(D) National Environmental Policy Act.

NOAA has concluded that publication of the proposed rules does not constitute a major Federal action significantly affecting the quality of the human environment. Therefore, an environmental impact statement is not required.

List of Subjects in 15 CFR Part 922

Administrative practice and procedure, Environmental protection, Marine resources, Natural resources.

Dated: July 9, 1982.

William Matuszeski,

Acting Assistant Administrator for Coastal Zone Management.

(Federal Domestic Assistance Catalog Number 11.419 Coastal Zone Management Program Administration)

Accordingly, it is proposed that 15 CFR Part 922 be revised as follows:

PART 922—NATIONAL MARINE SANCTUARY PROGRAM

Subpart A—General

- Sec.
- 922.1 Mission and goals.
- 922.2 Definitions.
- 922.10 Effect of national marine sanctuary designation.

Subpart B—Potential Sanctuary Sites

- 922.20 Site evaluation list.

Subpart C—Selection of Active Candidates and the Designation of National Marine Sanctuaries

- 922.21 Selection of active candidates.
- 922.22 Designation process.
- 922.23 Coordination with States.

Subpart D—Enforcement

- 922.30 Enforcement entities.
- 922.31 Penalties.
- 922.32 Notice of violation.
- 922.33 Enforcement hearings.
- 922.34 Determinations.
- 922.35 Final action.

Appendix 1—Selection Criteria.

Authority: Title III, Public Law 95-532, as amended. (16 U.S.C. 1431-1434).

Subpart A—General

§ 922.1 Mission and goals.

(a) The mission of the National Marine Sanctuary Program is the establishment of a system of national marine sanctuaries based on the identification, designation, and comprehensive management of special marine areas for the long-term benefit and enjoyment of the public. The goals of the Program are to carry out this mission by designating national marine sanctuaries to:

- (1) Enhance resource protection through the implementation of a comprehensive, long-term management plan tailored to the specific resources;
 - (2) Promote and coordinate research to expand scientific knowledge of significant marine resources and improve management decisionmaking;
 - (3) Enhance public awareness, understanding, and wise use of the marine environment through public interpretive and recreational programs; and
 - (4) Provide for optimum compatible public and private use of special marine areas.
- (b) The National Marine Sanctuary Program will seek maximum public participation throughout all the stages that may lead to the designation of a sanctuary.

§ 922.2 Definitions.

- (a) "Act" means Title III of the Marine Protection, Research and Sanctuaries Act of 1972, as amended, 16 U.S.C. 1431-1434.
- (b) "Active Candidate" means a site selected by NOAA from the Site Evaluation List for further consideration leading to possible designation.
- (c) "Affected State" means any State in which a proposed marine sanctuary includes waters lying within the territorial limits of that State or superjacent to the subsoil and seabed within the seaward boundary of that coastal State.
- (d) "Administrator" means the Administrator of the National Oceanic and Atmospheric Administration, United States Department of Commerce.
- (e) "Assistant Administrator" means the Assistant Administrator for Coastal Zone Management, National Oceanic and Atmospheric Administration, United States Department of Commerce, or his successor or designee.
- (f) "Person" means any private individual, partnership, corporation, or other entity; or any officer, employee, agent, department, agency or

instrumentality of the Federal government, or any State, local or regional unit of government.

(g) "Secretary" means the Secretary of the U.S. Department of Commerce.

(h) "Site Evaluation List" means that list of high resource and human use value sites having met program identification criteria and qualifying for further evaluation as a potential national marine sanctuary.

§ 922.10 Effect of national marine sanctuary designation.

The designation of a national marine sanctuary, and the management plan implementing it (including regulations, if applicable), are binding on any person subject to the jurisdiction of the United States. Designation does not constitute any claim to territorial jurisdiction on the part of the United States, and the management plan implementing it applies to foreign citizens only to the extent consistent with recognized principles of international law or otherwise authorized by international agreement.

Subpart B—Potential Sanctuary Sites

§ 922.20 Site evaluation list.

(a) The Assistant Administrator (AA) will establish a Site Evaluation List (SEL) comprising the most highly qualified marine sites identified and recommended by the regional resource evaluation teams in accordance with the Program's mission and goals set forth in section 922.1 and the site identification criteria set forth in Appendix 1. The SEL will be published in the *Federal Register*. NOAA will prepare a written analysis of each site on the SEL describing the relation of the sites to the selection criteria and evaluation matrix described in Appendix 1. Such analysis shall be part of the administrative record for that site. The List of Recommended Areas is abolished.

(b) The AA will consider future recommendations of potential sanctuary sites only if such sites are important new discoveries of national significance. NOAA determines whether the newly discovered site is of national significance in consultation with appropriate scientists and resource managers. If the site is so determined, the selection criteria specified in Appendix 1 will be applied; qualified sites will be placed on the Site Evaluation List for further evaluation as a national marine sanctuary, consistent with the procedures in § 922.21.

Subpart C—Selection of Active Candidates and the Designation of National Marine Sanctuaries

§ 922.21 Selection of active candidates.

(a) Only a limited number of sites at one time will be selected as active candidates and further evaluated for possible sanctuary designation. The AA will select sites from the SEL for active candidate evaluation based both on the value of the site as determined by the written analysis described in § 920.20(a) and on a balancing of relevant considerations including: (1) Ecological conditions; (2) immediacy of need; (3) timing and practicality; and (4) public comment.

(b) Before selecting a site as an active candidate, the AA shall undertake preliminary consultation on the considerations described in subsection (a) with relevant local, State, and national government agencies and appropriate regional fishery management councils. The AA shall request additional comments from the public and any relevant international agencies. NOAA's written analysis described in § 922.20(a) will be provided for review. Notice of such preliminary consultation shall be published in the *Federal Register*.

(c) Within 90 days of initiating preliminary consultation, the AA shall determine whether to select the site as an active candidate and publish a notice of this determination in the *Federal Register*. If the site is not selected, a short statement of the reasons for the determination shall be specified in the notice.

§ 922.22 Designation process.

(a) After selecting a site as an active candidate, the AA shall prepare a draft designation document and draft management plan to implement the designation in consultation with relevant Federal, State, and local agencies, Regional Fishery Management Council members, and other interested persons. Management plans generally shall include sections on: goals and objectives; management responsibilities; resource studies; interpretive and educational programs; and regulations (where applicable). Where a proposal for a sanctuary requires the preparation of a draft environmental impact statement (DEIS) under the National Environmental Policy Act, the designation document and management plan, including regulations if applicable, shall be included in the DEIS.

(b) The terms of designation shall include the geographic area included within the Sanctuary; the characteristics of the area that give it conservation,

recreational, ecological, or esthetic values; and the types of activities that will be subject to regulation in order to protect those characteristics. The terms of the designation may be modified only by the same procedures through which the original designation was made. If regulations are promulgated, they shall be consistent with and implement the terms of the Designation. All amendments to these regulations must remain consistent with the Designation.

(c) Where essential to prevent immediate, serious and irreversible damage to the resources of a sanctuary, activities other than those listed in the Designation may be regulated within the limits of the Act on an emergency basis for an interim period not to exceed 120 days, during which time an appropriate amendment of the Designation will be sought.

(d) Early in the development of the sanctuary documents and the DEIS, if required, meetings shall be held in the area or areas most affected to solicit public and government input on the significant issues related to the proposed action.

(e) The AA will publish the draft designation and a summary of the management plan including the draft regulations, where applicable, in the *Federal Register*. If a DEIS is required, the *Federal Register* notice shall be published concurrently with the Environmental Protection Agency (EPA) Notice of Availability of the DEIS. Not less than 30 days after publication of the applicable documents, the AA shall hold at least one public hearing in the area or areas most affected by the proposed designation in accordance with section 302(e) of the Act.

(f) After final consultation with all appropriate Federal agencies, including the Departments of State, Defense, the Interior, Transportation, Energy, and the Environmental Protection Agency, and publication of a final environmental impact statement where necessary the Secretary shall transmit the proposed Designation to the President for approval. Where sites include state waters, the applicable documents will be sent to the Governor of the State for final consultation, as provided under subsection (h)(1) below.

(g) The AA shall announce the designation of a Sanctuary and publish the designation document and implementing regulations in the *Federal Register*.

(h) A designation shall become effective unless either:

(1) The Governor of any affected State, as defined in § 922.2(c) certifies to the Secretary, before the end of the

sixty-day period beginning on the date of the publication of the designation, that the designation or any of its terms described in subsection (b), are unacceptable to the State, in which case those terms certified as unacceptable will not be effective in the waters described in § 922.2(c) until the Governor withdraws his certification of unacceptability; or

(2) both Houses of Congress adopt a concurrent resolution, consistent with section 302(h) of the Act, within sixty calendar days of continuous session of Congress after the date on which the designation was transmitted, which disapproves the designation or any of its terms described in subsection (b).

§ 922.23 Coordination with States.

(a) The AA shall make every effort to consult and cooperate with affected States throughout the entire national marine sanctuary review and consideration process. In particular the AA shall:

(1) Consult with the relevant state officials prior to selecting any site on the SEL as an Active Candidate, pursuant to § 922.21(b), especially concerning the relationship of any site to state waters and the consistency of the proposed designation with an approved State Coastal Zone Management Program.

(2) Ensure that any relevant state agency is consulted prior to holding any meeting pursuant to § 922.22(d) or public hearing pursuant to § 922.22(e).

(3) Provide the Governor an opportunity to certify the designation as unacceptable as specified in § 922.22(h).

Subpart D—Enforcement

§ 922.30 Enforcement entities.

(a) The AA is responsible for enforcing the provisions of the Act and is authorized to enter into agreements with federal or state agencies as may be necessary to carry out the enforcement responsibilities of the Act.

(b) The U.S. Coast Guard is the primary enforcement agency for the National Marine Sanctuary Program in accordance with section 302(f)(4) of the Act. In high use areas or where the need for additional enforcement arises, State law enforcement entities may be deputized consistent with subsection (c). The Coast Guard retains concurrent enforcement authority whenever a state law enforcement entity is deputized to assist in sanctuary enforcement.

(c) Where the need arises and a state agency possesses appropriate law enforcement capabilities which could assist the AA in carrying out the Act's law enforcement responsibilities, these state law enforcement officers may be

deputized as Federal law enforcement agents and authorized to enforce those provisions of the Act and applicable regulations. State enforcement activities shall be conducted in accordance with any guidelines or limitations which the AA may, from time to time, impose.

(1) State enforcement officials shall prepare such reports as may be required by the AA relating to contact made, documentation or written warnings issued and suspected violations, locations and times of patrols, and other actions taken pursuant to the Act.

(2) The state shall immediately notify the AA of any violation issued pursuant to the Act and shall submit an investigation report within 15 days of issuance.

(3) Any vessel, fish, or cargo seized by a State enforcement officer under the Act may be delivered to a U.S. Government official designated by the AA or other appropriate Federal authority. If such official, however, is unable to properly provide for the care, handling, and preservation as evidence of such seized property, employees of the State will be expected to make reasonable arrangements for such care, handling, and preservation as evidence. Costs to third parties with whom arrangements for the care, handling, and preservation of seized property are made under this paragraph shall be considered as separate items for payment by the AA and will not be the responsibility of the State.

§ 922.31 Penalties.

Any person subject to the jurisdiction of the United States who violates any regulation issued pursuant to the Act shall be liable for a civil penalty of not more than \$50,000 for each such violation. Each day of a continuing violation shall constitute a separate violation. No penalty may be assessed under this section until the person charged has been given notice and an opportunity to be heard. Upon failure of the offending party to pay an assessed penalty, the Attorney General, at the request of the AA, will commence action in the appropriate district court of the United States in order to collect the penalty and to seek such other relief as may be necessary. A vessel used in the violation of a regulation issued pursuant to the Act will be liable in rem for any civil penalty assessed for such violation and may be proceeded against in any District Court of the United States having jurisdiction. Pursuant to section 303(a) of the Act, the District Courts of the United States have jurisdiction to restrain a violation of the regulations issued pursuant to the Act, and to grant such other relief as may be appropriate.

§ 922.32 Notice of violation.

Upon receipt of information that any person has violated any provision of the Act, the AA shall notify such person in writing of the violation with which charged, and of the right to demand a hearing to be held in accordance with § 922.33. The notice of violation shall inform the person of the procedures for requesting a hearing and may provide that, after a period of 30 days from receipt of the notice, any right to a hearing will be deemed to have been waived.

§ 922.33 Enforcement hearings.

Hearings requested under § 922.32 shall be held not less than 60 days after the request is received. Such hearings shall be on the record before a hearing officer. Parties may be represented by counsel, and shall have the right to submit motions, to present evidence in their own behalf, to cross-examine adverse witnesses, to be apprised of all evidence considered by the hearing officer, and, upon payment of appropriate costs, to receive copies of the transcript of the proceedings. The hearing officer shall rule on all evidentiary matters and on all motions, which shall be subject to review pursuant to § 922.34.

§ 922.34 Determinations.

Within 30 days following conclusion of the hearing, the hearing officer shall make findings of facts and recommendations to the AA, unless such time limit is extended by the AA for good cause. When appropriate, the hearing officer may recommend a penalty, after consideration of the gravity of the violation, prior violations by the person charged, and the demonstrated good faith by such person in attempting to achieve compliance with the provisions of the Act and regulations issued pursuant to it. A copy of the findings and any recommendation of the hearing officer shall be provided to the person charged at the same time they are forwarded to the AA. Within 30 days of the date on which the hearing officer's findings and recommendations are forwarded to the AA, any objecting party may file written exceptions with the AA.

§ 922.35 Final action.

A final order on a proceeding under this part shall be issued by the AA no later than 30 days following receipt of the findings and recommendations of the hearing officer. A copy of the final order shall be served by registered mail (return receipt requested) to the person charged or his/her representative.

Appendix 1.—Selection Criteria

A. NATIONAL MARINE SANCTUARY SITE IDENTIFICATION CRITERIA

During summer 1981, the National Marine Sanctuary Program Draft Site Identification Criteria were reviewed and refined by three marine scientists: Drs. Walter H. Adey, Reznat M. Darnell, and G. Carlton Ray. Taking their recommendations into consideration, the criteria presented below and the Site Evaluation Matrix in Appendix 1.B were developed.

The site identification criteria are directly related to the Program's purposes: (1) That the system of sanctuaries established is illustrative of the variety of ecosystems found in the United States; (2) that sanctuaries allow, to the maximum extent feasible, multiple use for public and private interests; (3) that sanctuaries are designated for the purpose of protecting or restoring conservation, recreational, ecological, or esthetic values; and (4) that sanctuaries are established to serve as a conservation component, or a management tool, in a broad national-interest approach to marine resource development, conservation, and utilization. The criteria are grouped accordingly into four categories: (1) Natural resource values; (2) human use values; (3) potential activity impacts; and (4) management concerns. The criteria under each category reflect concerns significant to the Program.

Sites initially identified using the Sanctuary Program Classification System in the PDP are evaluated in terms of these criteria (i.e., to see which criteria are met). Appendix 1.B. describes how sites are further assessed to identify priority sites. The Regional Resource Evaluation Teams utilize these criteria in their site evaluations.

I. Natural Resource Values

A. Subregional Representation. The area under consideration is representative of the biogeographic subregion in which it is located. (Reference: Sanctuary Program Classification System in the PDP).

Examples: This criterion would apply to an area containing species assemblages which are especially characteristic of the Oregonian subregion of the British Columbian region. Another example would be an area containing species assemblages which are especially characteristic of the Floridian or American Atlantic Antillean subregion of the West Indian region.

B. Community Representation. The area under consideration is significant in relation to the ecological communities which are found within the specified habitat type or within the biogeographic region or subregion (i.e., on a macroscale, communities are assemblages of species populations within a prescribed area or habitat).

Examples: (1) The wide spectrum of marine habitats in the Channel Islands National Marine Sanctuary in California created by accentuated bottom relief, varied bottom substrates, and gradation in water depth from island shorelines to deep coastal basins support a variety of ecological communities.

(2) Coral reef, grass bed, soft bottom, and open-bay habitat areas in the Key Largo National Marine Sanctuary support a variety

of ecological communities associated with the east Florida reef tract.

C. Biological Productivity. The area under consideration is significant in relation to its level of primary and/or secondary production.

Examples: (1) East Breaks at the edge of the outer continental shelf off Corpus Christi, Texas is characterized by intense local upwelling, high primary productivity, and exceptional fish production.

(2) In the Gray's Reef National Marine Sanctuary, much production may be imported; outcroppings of limestone rocks may serve to entrap, conserve, and circulate detritus and plankton which provide energy sources for reef invertebrates, which in turn support marine fisheries and sea turtles.

(3) In the Channel Islands National Marine Sanctuary, the cold waters of the California Current flowing north meet the warm waters of the California Counter Current flowing south to create upwellings of cold nutrient-rich waters that enhance the biological productivity of the area. (Note: This example also meets Criterion I.F.)

(4) In many cases, coral reefs are not only energetically self-sustaining (i.e., they produce locally enough food to support the community), but they are also specifically organized to entrap, hoard, and recycle materials received from the surrounding waters (i.e., products that are imported and conserved).

D. Biotic Character/Species Representation. The area under consideration is of special interest because it supports:

- (1) Ecologically limited species;
- (2) Ecologically important species; or
- (3) Unique species associations or biological assemblages.

Examples: (1) This criterion would apply to marine habitat areas upon which ecologically limited species (e.g., threatened, endangered, rare, depleted, endemic, or peripheral species) are dependent during all or part of their lives.

(2) This criterion would apply to marine areas containing species which contribute in a significant way to the maintenance of a specified ecosystem found in the region or subregion, such as the Channel Islands National Marine Sanctuary which supports one of the largest and most varied assemblages of marine mammals and seabirds in the world.

(3) The waters off Point Lobos, California support a unique assemblage of kelp, sea urchin, abalone, and sea otters.

(4) Submarine canyons support unusual biological communities of soft corals, crustaceans, and fish known as "pueblo villages."

(5) This criterion would also apply to wide sandy bottom areas which are characterized by low productivity, but unique species composition, such as certain areas off central Texas.

E. Species maintenance. The area under consideration is important to life history activities, including special feeding, courtship, breeding, birthing/nursery, resting/wintering, and migration areas.

Examples: (1) The waters off the Point Reyes-Farallon Islands provide deep and

shallow water feeding areas for a wide variety of marine organisms, including seabirds, marine mammals, and marine fisheries. The Farallon Islands support the largest seabird rookeries in the contiguous United States and are used, along with the mainland, by California sea lions, harbor seals, and elephant seals for hauling out and pupping purposes. Whales, including several endangered species, and porpoises pass through the sanctuary on annual migrations.

(2) The waters around certain Hawaiian Islands are important wintering, birthing/nursery, and perhaps courtship/breeding areas for endangered humpback whales.

(3) Spiny lobster migration routes off Florida are important for the "off shelf" movement of this species.

(4) The mouth of the Mississippi River is an important brown shrimp overwintering ground.

F. Ecosystem Structure/Habitat Features. The area under consideration is characterized by special chemical, physical, and/or geological habitat features.

Examples: (1) The Florida Middle Grounds on the Gulf of Mexico continental shelf represent an unusual geological formation—a drowned Pleistocene reef—which supports rich and diverse reef communities.

(2) Transition zones occur where two different marine systems converge—such as at coastal/marine system interfaces, shelf/slope interfaces, soft bottom/hard bottom ecotones, or cold water/warm water current convergence zone. These areas of mixing often have unique physical and ecological characteristics, high production, and species diversity/population densities which are often greater than in areas flanking them. For example, a transition zone is formed near Cape Hatteras where cold northern waters of the Labrador Current mix with warm water eddies of Gulf Stream/Florida Current and as a result, northern and southern species mix and co-exist with species endemic to the area. (Note: This example also meets Criterion I.C.)

(3) Easternmost coastal areas of Maine—with unique bay-heads and rocky coasts, varied substrates derived from glacial materials, extensive sub-fjord character, and numerous offshore islands—are matched by few areas in the world in habitat types and species diversity.

II. Human-Use Values

A. Fishery Resources of Recreational Importance. The area under consideration contains fish and shellfish species, species groups (e.g., snapper-grouper complex), or fishery habitats which are important to the recreational fishing industry/community and for which conservation and management are in the public interest.

Example: The Florida Middle Grounds rank high in statistical surveys of demersal and pelagic fish catch and effort, recreational sector participation, and socioeconomic contribution.

B. Fishery Resources of Commercial Importance. The area under consideration contains fish and shellfish species, species groups (e.g., snapper-grouper complex), or fishery habitats which are important to the

commercial fishing industry and for which conservation and management are in the public interest.

Example: The waters of the Point Reyes-Farallon Islands National Marine Sanctuary provide substantial fishing opportunities, including commercial fisheries for bottom fishing, crab, salmon, albacore, and pelagic anchovy, herring, and other species.

C. Ecological/Aesthetic Resources of Importance For Recreational Activities Other Than Fishing. The area under consideration contains exceptional natural resources and features which, because of their importance to nature watching and other nonconsumptive recreational activities, enhance human appreciation, understanding, and enjoyment of nature.

Examples: (1) Rocky shorelines, shallow nearshore waters, and intertidal pools in the Channel Islands and Point Reyes-Farallon Islands National Marine Sanctuaries have rich and varied plant and animal life which attract many persons interested in photography and nature study.

(2) The prominent topography around the Channel Islands and Point Reyes-Farallon Islands National Marine Sanctuaries provides outstanding ocean vistas.

(3) The spectacular spur-and-groove coral reef formation in the Looe Key National Marine Sanctuary attracts SCUBA and snorkeling enthusiasts from all over the world.

(4) The waters off Maui, Hawaii are popular for humpback whale watching.

D. Research Opportunity. The area under consideration provides exceptional opportunities for research in marine science and resource management.

Examples: (1) The Gray's Reef National Marine Sanctuary serves as a natural laboratory or control area for research in live bottom ecology.

(2) The Key Largo National Marine Sanctuary is amenable to onsite research activities for many reasons, including the diversity of resources available, the past history of scientific research and education in the area, the compatibility with similar research efforts in adjacent John Pennekamp State Park and Biscayne National Park, and the proximity of the site to user groups. In addition, the Carysfort Reef Lighthouse provides a unique research base from which to launch studies concerning the sanctuary environment.

(3) The Channel Islands National Marine Sanctuary offers a special opportunity to coordinate research with the Channel Islands National Park. Such coordination will contribute to a better scientific understanding of the marine environment and to more effective management by answering questions such as those related to fisheries, marine mammals, seabirds and those related to development and use of marine resources.

E. Interpretive Opportunity. The area under consideration provides an excellent opportunity to interpret the meanings and relationships of special marine resources in order to enhance general understanding, appreciation, and wise use of the marine environment.

Examples: (1) Through a variety of interpretive media, including aquaria

displays, narrated slide shows and glassbottom boat tours, a visitor to the Key Largo National Marine Sanctuary is exposed to a variety of marine and coastal ecosystems, including open ocean, fringing coral reefs, patch reefs, mangroves, open bay, and barrier islands.

(2) The Channel Islands National Marine Sanctuary provides an exceptional opportunity to interpret marine and insular ecosystem features through the use of various interpretive "hands on" techniques that go beyond traditional educational tools, such as brochures and pamphlets.

F. Historical, Archaeological or Paleontological. The area under consideration contains (or is likely to contain) submerged remnants of past life that are of special historical, cultural or paleontological value.

Examples: (1) This criterion would apply to marine areas where known or possible shipwrecks, armaments, or other maritime relics occur and where protection is desirable to conserve or restore aesthetic values and to advance the goal of the United States antiquities laws to protect historical resources.

(2) This criterion would apply to marine areas containing, or suspected of containing, remnants of historic human occupation by Indians, Eskimos, early Americans, or other peoples.

(3) This criterion would apply to marine areas containing fossils and geological formations whose study would reveal clues to the earth's geologic history, the characteristics of ancient environments and the relationship of ancient plants and animals to the earth's evolutionary history.

Additional Factors in Site Identification

III. Potential Activity Impacts

Many marine areas are subject to human use, some of which bring adverse pressures to bear on the natural resources. The initial identification of potential marine sanctuary areas includes a summary of existing and potential human activities in these areas as well as a preliminary assessment of environmental impacts. Since the pressures may arise from various activities, the present or potential ecological significance of each activity, as well as the cumulative impact of several activities, must be analyzed so that appropriate management action can be designed and implemented. Definitive environmental impact analyses, however, are hampered by the fact that adequate field data on natural or "existing" conditions are often lacking, thus making assessments of "human-induced" versus "natural" conditions difficult. Many judgments are, therefore, based on projections and can be subjective, i.e., the evaluation depends largely upon the experience and special interest of the reviewer.

Regional resource evaluation teams will preliminarily assess activity impacts based on a review of scientific literature (e.g., baseline studies and environmental impact studies) and discussions with persons knowledgeable in the field. The types of activities which might be considered for potential impacts include: (1) vessel traffic; (2) aircraft overflights; (3) commercial and

recreational fishing; (4) other recreational activities such as SCUBA, snorkeling, spearfishing, and specimen collecting; (5) ocean dumping and waste disposal (including litter); (6) scientific research and educational demonstrations; (7) dredging and dredge disposal; (8) disturbing marine mammals and seabirds; (9) anchoring; (10) salvage operations; and (11) oil and gas recovery and associated activities. This is not meant as an exhaustive listing, but rather to illustrate the range and types of activities which may be evaluated for potential impacts on resources within a site identified for future marine sanctuary consideration.

IV. Management Concerns

A. Relationship To Other Programs. While some sanctuaries may be designated to protect resources not currently managed by other existing programs (e.g., the U.S.S. MONITOR on the continental shelf off North Carolina), most recommendations involve cooperation with some other Federal, State, or local agency or organization. The ability of existing regulatory mechanisms to protect the values of the area and the contribution of the Sanctuary Program to that existing management effort may be an important factor in selecting sanctuary candidates. Depending on the location, the resource, and the existing system, the Program could either complement the status quo by filling specific gaps or form a management umbrella over a fragmented system to help coordinate and strengthen diverse, but related efforts. At different sites, NOAA may work to complement other programs efforts such as estuarine sanctuaries, national parks, wildlife refuges, or state preserves, among others. There may be instances where NOAA's primary contribution to protection of special marine areas will be in the form of enhanced public awareness through interpretive and research programs.

B. Management of a Conservation Unit. Optimum size of a marine sanctuary is an issue to be considered in potential sanctuary sites. The size or extent of a marine sanctuary should be a cohesive conservation unit amenable to effective management given fiscal and staff constraints of the managing entities. A discussion of sanctuary size is included in the PDP.

C. Accessibility. Since national marine sanctuaries are to be readily available for public use, when use is compatible with the sanctuary's goals and objectives, consideration should be given to factors which limit or enhance public access to a particular site.

D. Surveillance and Enforcement. Another issue to be considered when evaluating a potential sanctuary site is the degree to which the area lends itself to adequate endorsement and surveillance and the capabilities of responsible agents (e.g., U.S. Coast Guard, state law enforcement divisions, or the like). This depends on the location, its size, and the types of resources involved. Consideration is also given to: (1) degree of surveillance/enforcement presence needed in the area—light, medium, or heavy; (2) schedule—routine, prescribed, or case-by-case basis; and (3) logistics—vessels, aircraft,

manpower, equipment, and budgetary requirements.

E. Economic Considerations. The designation of any national marine sanctuary could have economic effects at both local and national levels. Prior to the development of a management plan for a particular site which describes permitted and restricted activities, it is difficult to calculate the economic impact of sanctuary designation. It is even more difficult to determine the economic value of the sanctuary to society as a whole based on such things as public use, research and interpretive value. Sanctuary designation often enhances economic value by ensuring long-term protection for commercially significant resources, such as commercial or recreational fish stocks, vital habitats, and resources which generate tourism. Conversely, a marine sanctuary may also have negative economic impacts if management regulations restrict activities that generate income. However, in these cases, the economic value is usually not irretrievably lost since the resources remain protected for the long term and could be used if necessary. In cases where certain economic values are reduced or foregone, this impact must be weighed against the long-term benefits to society. Analysis of a potential site for marine sanctuary status will take socioeconomic impacts into consideration.

B. SITE EVALUATION MATRIX

Appendix 1.A. outlines the criteria for identifying potential marine sanctuary sites. Four categories of criteria are presented; namely, natural resource values, human use values, potential activity impacts, and management concerns. The criteria address characteristics which are of particular significance to the national marine sanctuary program.

After a site is examined to determine which criteria are met, the next step involves an evaluation of the relative value of each criterion. This is accomplished using the guidelines provided below. Sites are evaluated in terms of the individual value of each criterion met (e.g., low, moderate, or high value) and in relation to other sites with complimentary characteristics. The following rating system is recommended:

Low Value (L)—Low quality; not significant but still a viable concern; of minor contribution to national system; of minor importance; other equally good representatives are available; or duplicates, in significant measure, another recommended area or designated sanctuary.

Moderate Value (M)—Moderately good quality; significant but not the most important concern; help to support species, but not critical; helps to support the regional ecology, but only in a small measure or in a general way; a few other good representatives are available; or moderate contribution to the national system.

Moderate Value (H)—Very high value; high quality; a major reason for sanctuary consideration; extremely important to regionally significant species; of great importance in terms of ecological features and processes; regional ecology would

likely be significantly altered if the values were not protected; no significant duplication of other recommended areas; absolutely unique; one of a kind; best available regional representative; or excellent contribution to the national system.

Unknown Value (X)—Value or consequences unknown; more study needed to determine value or consequence; factor does not apply; or factor is not an issue, does not need to be considered.

Sites which consistently have relatively low values receive an overall "low priority", assessment and are eliminated. In contrast, sites which consistently have relatively high values receive a "high priority" assessment and are recommended for further consideration.

I. NATURAL RESOURCE VALUES

A. Subregional Representation

L—Other equally good or better sites available; not a good representative of the subregion.

M—Few other sites available; good representative of the subregion.

H—Best available site; only one or two sites in the subregion; best representative of subregional characteristics.

B. Community Representation

L—Poor representation of the community types found within the specified habitat type or within the biogeographic region or subregion; low percentage of communities on site; low percent cover of communities on site.

M—Good representation of the community types found within the specified habitat type or within the biogeographic region or subregion; limited number of communities on site; good range of common communities present; moderate percent cover of communities on site.

H—Excellent representation of the community types found within the specified habitat area or within the biogeographic region or subregion; good or very good range of habitats and communities on site; localized, relict, or special communities present.

C. Biological Productivity

L—Contribution to local production minor; low productivity as defined by the classical definition of productivity.

M—Contribution to local production moderate; trophic relationships are typical or common for the region or subregion.

H—Contribution to local production extremely important; local ecology would likely be significantly altered if natural (normal) production levels change; highly exemplary, special or unusual trophic relationships.

D. Biotic Character/Species Representation

L—Characteristic species are common in the region/subregion; few, if any: (1) ecologically limited species (e.g., threatened, endangered, rare, depleted, endemic or peripheral species); (2) ecologically important species; or (3) special species combinations or biological assemblages; low percentage of regionally

or locally available species; other equally good or better sites available.

M—The area is only of moderate importance to populations of ecologically limited species or ecologically important species; few, if any, special species combinations or assemblages; percentage of regionally or locally available species is moderate; some other similar sites available.

H—Very important to species which are of high ecologic value or ecologically limited in regional, national or international distribution or existence (e.g. endemic, threatened, endangered, rare, depleted); contains special species combinations or biological assemblages; outstanding diversity for a particular habitat or community type; best available site; only one or two sites in the region or subregion.

E. Species Maintenance

L—Of some importance to supporting life history activities of regional/subregional species; no local dependence upon this area; many other equally important sites available.

M—Important to supporting life history activities of regional/subregional species, but not critical; some other equally important sites available.

H—Extremely important to supporting life history activities of regional/subregional species; only one or two other sites available.

F. Ecosystem Structure/Habitat Features

L—Habitat features are common in the region/subregion, but are not outstanding representatives; no significant contribution to regional/subregional ecosystem structure; no special chemical, physical or geological habitat features.

M—Habitat features are common in the region/subregion; some special features are available; few other sites available; moderate contribution to the regional/subregional structure.

H—Unique, different or special habitat features; only one or two other sites available; significant contribution to regional/subregional structure; structural features have strong influence on ecological processes in the area.

II. HUMAN USE VALUES

A. Fishery Resources of Recreational Importance

L—Low recreational importance; many other fishery opportunities available.

M—Moderate recreational importance; some other fishery opportunities available.

H—High recreational importance; only one or two other fishery opportunities available.

B. Fishery Resources of Commercial Importance

L—Low commercial importance; many other fishery opportunities available.

M—Moderate commercial importance; some other fishery opportunities available.

H—High commercial importance; only one or two other fishery opportunities available.

C. Ecological/Aesthetic Resources of Importance for Recreational Activities Other Than Fishing

- L—Low value; minimum opportunity for recreation; many other sites available.
 M—Moderate value; good opportunity for recreation; few other sites available.
 H—High value; excellent opportunity for recreation; rare in the region; only one or two sites available.

D. Research Opportunity

- L—Very limited research opportunities; the site has already received considerable research attention (i.e., "researched to death"); not suitable for study; many other sites available.
 M—Good research opportunities; good for use at most levels of research, formal and informal; few other sites available.
 H—Excellent research opportunities; outstanding for use at all levels of research, formal and informal; can withstand some pressure from these activities; only one or few other sites available.

E. Interpretive Opportunity

- L—Low or minimal interpretive value; opportunities for interpretation are limited; has already received considerable interpretive attention; resource features are common in the region; many other sites available.
 M—Moderate or good interpretive value; opportunities for interpretation fairly good; visually attractive features; resource features are fairly limited in the region; few other sites available.
 H—Excellent interpretive value; opportunities for interpretation excellent or unusual; visually attractive features; resource features are special in the region or subregion; only one or two other sites available; good potential for interpretive center and/or displays; the enhancement of public awareness through this resource is paramount.

F. Historical, Cultural or Paleontological Importance

- L—Little or no historical, cultural or paleontological importance; many other sites available.
 M—Moderate or good historical, cultural or paleontological importance; few other sites available.
 H—Very special historical, cultural or paleontological value; only one or two other sites available.

III. POTENTIAL ACTIVITY IMPACTS

Existing and potential activities within a particular area are listed by Resource Evaluation Teams on the Site Evaluation Matrix. The potential impact of each activity is evaluated using the following recommended scheme:

- L—This activity is not highly significant, but still a viable issue; little or no impact at current activity levels; very little potential for harm by increase of this activity; if the activity is remote, there is an adequate buffer to protect the area; no known or proposed future development which could affect resource or human use value; no current or potential user conflict.

M—This activity is significant, but not the most important issue; some impact on resources of current activity levels, but the system is resilient with little permanent damage or other long-lasting effect; some possible negative impact if activity level increases; if the activity is remote, there is a fairly good buffer zone to protect the area; some possible future development likely which could affect resource or human use values; some current or potential user conflicts which threaten resource or human use value.

H—Potential for impact at current activity levels is high or is already major issue; resources are suspected to be very sensitive to environmental change, not resilient; resource would likely be significantly altered if values are not protected; the area is in immediate need of protection; negative impact likely if activity levels increase or continue at present level; current or potential user conflicts could significantly threaten resource or human use values.

X—Environmental consequences unknown. More study is needed.

IV. MANAGEMENT CONCERNS

A. Relationship to Other Programs

- L—Other equally good or better programs in effect.
 M—Few complementary programs in place, but none that offer the same comprehensive management opportunities or public benefits.
 H—No other programs available or in place; marine sanctuary program is the best available program; offers unique or special management opportunities or public benefits; fills existing regulatory or non-regulatory management gaps; coordinates management, research and education efforts.

B. Management of a Conservation Unit

- L—Does not represent a conservation unit; contains only fragments of the ecosystem of concern; protection of a portion of the system does not help or only minimally helps the overall system; not a manageable unit; excessive size; some boundary problems foreseen.
 M—Represents a good portion of the ecosystem in question; represents fairly good conservation unit; protection of this area would benefit the ecosystem, but only in a small measure or in a general way; fairly manageable unit; moderate size; few, if any, boundary problems.
 H—Represents a complete and ecologically sound conservation unit; protection of this area would benefit the ecosystem in a significant way; manageable unit; not of excessive size; no boundary problems foreseen.

C. Accessibility

- L—Inaccessible or accessible with considerable difficulty; situated in an extremely remote area; no human interest in visiting the site.
 M—Fairly accessible; if remote, access is good, but often with some difficulty (e.g., weather or sea conditions variable); only limited human interest in visiting the site.

H—Easily accessible, with no major difficulty; considerable human interest in visiting the site; not adversely impacted visitation; inaccessibility of the site is desirable because increased visitation is likely and/or could severely threaten resource or human use values without some management structure.

D. Surveillance and Enforcement

- L—Open, long, or insecure boundary; remote, not amenable to surveillance and enforcement efforts; requires considerable commitment of manpower, equipment and budget, no on-going or potential activities that would require an increase in surveillance and enforcement efforts.
 M—Moderate boundary, fairly secure; accessible; requires moderate commitment of manpower, equipment and funds; some on-going or potential activities in the area which would require an increase in current surveillance and enforcement efforts.
 H—Reasonable boundary, secure; accessible; amenable to surveillance and enforcement efforts; minimal commitment of manpower, equipment and funds; major activity(ies) in the area which require an increase in surveillance and enforcement efforts.

E. Economic Considerations

- L—High management costs likely; designation or restriction of certain activities would result in negative economic impact; public benefit does not outweigh economic values which may be reduced or foregone by designation.
 M—Moderate management costs likely; designation or restriction of certain activities would result in some short-term negative economic impact, but public benefit outweighs economic values which may be reduced or foregone; resources are protected for the long term.
 H—Low management costs; designation or restriction of certain activities would result in very minor if any negative economic impact; benefit to society greatly outweighs any reduction of economic value; designation enhances economic value.

Overall Site Evaluation By Resource Evaluation Teams. Even though a value rating scheme is used, the overall assessment of a particular site is based on a subjective evaluation. This is preferred over adding-up a total score for each site—a procedure which tends to mask significant features, gives poor discrimination among sites, and leads to faulty assumptions about the value of a particular site. Instead, evaluation scheme present are meant to be used only as a sorting mechanism; i.e., to compare complementary sites and to eliminate those sites which are inappropriate. As mentioned previously, sites which consistently have relatively low values receive an overall "low priority" assessment and are eliminated. In contrast, sites which consistently have relatively high values receive an overall "high priority" assessment and are recommended for further consideration.

The Regional Resource Evaluation Teams consider each category of criteria separately so that any one category does not override the others and thus affect the overall evaluation. For example, the rationale for low

priority judgment might be based on the following observations: low natural resource values; low human use value; low protection interest; or management problems likely. In contrast, high priority sites might be characterized as having: outstanding natural resource value; high human use value; special features requiring higher level of protection; or no management problems foreseen.

A narrative is written by the Regional Resource Evaluation Teams to support the evaluation. The narrative provides the rationale for the particular priority ranking and identifies sources of information.

At this point, public on priority sites is sought and based on this comment, a list of three to five sites per region along with the written narrative is submitted to NOAA. NOAA makes the final decision as to which sites are to be placed on the SEL.

Later, when NOAA considers a particular site on the SEL for active candidate status, its selection will depend not only on the evaluation performed by the resource evaluation teams, but also upon specific policy considerations and the political climate, as described in the PDP.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 184 and 186

[Docket No. 82N-0120]

Substances Generally Recognized as Safe

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations on substances that the agency has affirmed as generally recognized as safe (GRAS). This proposal was prompted by the agency's experience during its comprehensive safety review of GRAS ingredients. The agency is proposing to amend its regulations to define more clearly the meaning of "current good manufacturing practice" for GRAS ingredients, to eliminate the requirement that a GRAS affirmation regulation contain explicit details of the conditions of use that are affirmed as GRAS, and to make editorial changes.

DATE: Comments by November 3, 1982.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mary C. Custer, Bureau of Foods (HFF-335), Food and Drug Administration, 200

C St. SW., Washington, DC 20204, 202-426-9463.

SUPPLEMENTARY INFORMATION: FDA is conducting a comprehensive safety review of direct and indirect human food ingredients classified as GRAS or subject to a prior sanction. In the Federal Register of September 23, 1974 (39 FR 34194), FDA published proposed regulations that set forth the procedures to be used during this review. The agency issued the final procedural regulations in the Federal Register of December 7, 1976 (41 FR 53600). FDA is proposing to amend § 184.1(b), (b)(1), and (c) and § 186.1(b), (b)(1), (c), and (d) of these procedural regulations.

In § 184.1(b)(1), FDA explains the meaning of regulations that affirm a substance as GRAS with no limitation other than current good manufacturing practice. The regulation states that FDA will report in this type of GRAS affirmation regulation the conditions of use that provided the basis for FDA's decision to affirm the substance as GRAS. It also states that the ingredient shall be regarded as GRAS so long as its conditions of use are not significantly different from those reported in the GRAS affirmation regulation. Section 186.1(b)(1) contains identical provisions for substances in food-contact surfaces that FDA affirms are GRAS.

In implementing §§ 184.1(b)(1) and 186.1(b)(1), FDA has usually set forth in GRAS affirmation regulations the current good manufacturing practice conditions of use that were reported to the agency and evaluated during the safety review of the substance. These conditions of use have generally included the technical effects for which the ingredient is used, the food categories in which the ingredient is used, and, for each food category, the maximum level at which the ingredient is used. FDA decided to report these conditions of use in GRAS affirmation regulations because it was concerned that the proliferation of food uses for GRAS ingredients that had taken place between 1958 and 1972 would continue and would result in new uses for these ingredients that the agency had not considered when it affirmed the ingredients as GRAS. The agency felt that it consequently was important to make prominent in GRAS affirmation regulations the data upon which the affirmation determinations were based.

The agency discussed its intent to incorporate conditions of use in GRAS affirmation regulations, and its reasons for so doing, in the preambles to the Federal Register documents published on July 26, 1973 (38 FR 20044), September 23, 1974 (39 FR 34173 and 34194), and

December 7, 1976 (41 FR 53600). In the preamble to the September 23, 1974 proposal, the agency specifically stated that regulations that affirmed substances as GRAS with no limitations other than current good manufacturing practice would specify the conditions of use that were reported in the 1971 National Academy of Sciences/National Research Council (NAS/NRC) survey of food manufacturers (39 FR 34195). However, after 7 years' experience in the GRAS review program, several factors have convinced the agency to reevaluate this practice.

The agency's determination to incorporate detailed conditions of use in GRAS affirmation regulations has elicited public comment since the early stages of the GRAS review program. In response to the proposed procedural regulations for the GRAS review, FDA received numerous comments expressing concern about the inclusion of conditions of use. The agency addressed these comments in the preamble to the final regulation published in the Federal Register of December 7, 1976 (41 FR 53601). FDA explained that its intent in including conditions of use in GRAS affirmation regulations was not to establish rigid restrictions on the use of GRAS substances but to set forth the conditions of use that the agency had reviewed and was affirming as GRAS. The agency also explained that it would not object to deviations from these conditions, so long as the conditions of use were not significantly different from those reported in the regulation.

Despite the agency's efforts to explain the purpose of the conditions of use, FDA has continued to receive comments about them from industry in response to individual GRAS affirmation proposals. These comments assert that the conditions of use are confusing, and that they are being interpreted by a significant segment of the food industry as specific limitations. These comments claim that as a result, the inclusion of the conditions of use in the regulations inhibits the use of GRAS ingredients in new food products that have been developed since the 1971 NAS/NRC survey.

The agency has continued to give these comments consideration. In addition, FDA has become aware through its experience that listing detailed conditions of use is not always possible or practical. For instance, FDA has published GRAS affirmation regulations for garlic and dill (December 7, 1976; 41 FR 53616 and 53614, respectively) and clove (January 19, 1979; 44 FR 3962) that specify the