AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its decision to defer any revision in the regulatory status of salt (sodium chloride). Salt is currently considered to be generally recognized as safe (GRAS) for use as an ingredient in food. There is considerable health concern about the levels of use of salt in the food supply. FDA is not now proposing any change in the regulatory status of salt, however, because the agency believes that the proposed sodium labeling regulations, published elsewhere in this issue of the FEDERAL REGISTER, will respond to those concerns. FDA is also announcing its policy of encouraging food manufacturers to reduce voluntarily the amount of added salt and other sodium-containing substances in processed foods. The agency requests comments on this approach and on the other regulatory options presented in this notice.

DATE: Comments may be submitted until (insert date 60 days after date of publication in the FEDERAL REGISTER).

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

I. INTRODUCTION

Salt occurs abundantly in nature in sea water, salt lakes, mineral springs, and other natural waters, and in the form of large underground deposits in various parts of the world. The mineral form is called halite. Commercially, salt is obtained by direct mining from underground and surface deposits, and by evaporation and crystallization from natural brines and seawater.

Historically, salt has been considered an essential part of the diet and has been used as a preservative and a seasoning agent. The traditional foods of many cultures contain salt. Salt is found in almost every home and restaurant as a condiment. In the food industry, salt is widely employed for a number of different purposes: e.g., as a seasoning agent and flavor enhancer, a preservative and curing agent, a formulating and processing aid, a nutritional supplement, and a dough conditioner.
In this century, excessive sodium consumption has been cited as one of the factors contributing to the development of hypertension. Salt is the principal source of dietary sodium. A number of professional and governmental organizations have expressed the view that salt consumption by Americans far exceeds their nutritional needs, that high salt intake may contribute to hypertension, and that it would be prudent if people reduced their salt intake. Examples of groups supporting this position are the Food and Nutrition Board of the National Academy of Sciences, the Council on Scientific Affairs of the American Medical Association, and the National Heart, Lung, and Blood Institute (NHLBI).

FDA has also been conducting a review of the health implications of salt in the food supply as part of the agency's comprehensive safety review of substances added to food to determine whether they are GRAS for use as food ingredients.

FDA has traditionally regarded salt as GRAS both for direct use in food (21 CFR 182.1) and as a substance that migrates to food from paper and fabric packaging materials (21 CFR 182.70 and 182.90). Salt is an optional or required ingredient in many food standard regulations promulgated by FDA or the U.S. Department of Agriculture (USDA).
As part of the GRAS review, a committee of scientific experts from the Federation of American Societies for Experimental Biology (FASEB) evaluated the safety of salt as a food ingredient, and submitted a tentative report to FDA in 1978. In the FEDERAL REGISTER of June 13, 1978 (43 FR 25487), FDA announced that FASEB would provide an opportunity to present at a hearing scientific data, information, and views on the safety of salt. After holding this public hearing on September 25, 1978, FASEB submitted a final report to the agency in 1979. This notice presents FASEB's findings and conclusions, discusses the regulatory options considered by FDA, and explains other factors that affect FDA's decision on an appropriate approach to take in determining the regulatory status of salt. Finally, this notice announces an agency policy encouraging manufacturers to reduce voluntarily the salt and sodium content of processed foods.

II. SALT USAGE IN FOODS

FDA surveyed a representative cross-section of food manufacturers to determine the specific foods in which salt is used and the levels of use. The agency combined that information with information from surveys of consumer consumption to estimate consumer exposure to salt. The total amount of salt used by the U.S. food industry in 1970 was estimated to be greater than 3 billion pounds. Because
salt is used extensively as a processing aid and in brines that are often discarded, the per capita use of salt for all purposes in the manufacturing of processed foods is greater than the actual per capita intake of salt.

Many attempts have been made to estimate the total dietary intake of sodium. Available estimates are summarized in the table below, which is taken from FASEB’s 1979 final report.

Sources of Dietary Sodium and Estimates of Total Sodium Intake

<table>
<thead>
<tr>
<th>Sodium intake Comment</th>
<th>Sodium intake (expressed as sodium chloride)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>grams per day</strong></td>
<td></td>
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</tbody>
</table>

**A. Nondiscretionary sources of sodium**

1. Naturally occurring sodium in foods  
   - 2.5-4.5 Estimated food composition
   - 3.0 Chemical analysis (institutional diet)

2. Sodium added by industrial processing  
   a. Salt  
      - 7.1 1970 NRC estimate (~3200-kcal diet)
      - 8 1966-70 Bureau of Mines data
      - 8.4 Total 1975 usage by food industry
   b. Other sodium-containing ingredients  
      - 1.0 Calculated from 1970 NRC survey
### 3. Total nondiscretionary sodium

12-12.5 Calculated from 1972-73 and 1976 FDA Selected Minerals in Food Survey (~3900-kcal diet)

### B. Discretionary addition of salt to foods by the consumer

<table>
<thead>
<tr>
<th>Value</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.4</td>
<td>1968 retail sales</td>
</tr>
<tr>
<td>4.4-6</td>
<td>1965 USDA survey</td>
</tr>
<tr>
<td>6.5</td>
<td>1966-70 Bureau of Mines data</td>
</tr>
<tr>
<td>10-11</td>
<td>Urinary excretion</td>
</tr>
<tr>
<td>14.5</td>
<td>1966-70 Bureau of Mines data</td>
</tr>
<tr>
<td>12</td>
<td>Estimated from review of literature in 1976</td>
</tr>
<tr>
<td>17.1</td>
<td>1976 FDA Selected Minerals in Food Survey (~3900-kcal diet)</td>
</tr>
</tbody>
</table>

* These values are not necessarily additive.

Given the diversity of the data and the range of individual intakes, these estimates are rough approximations. Based on these data, the best estimate of sodium intake by adults is an average daily intake, expressed as salt, of about 10 grams (g) to 12 g. Discretionary use by the consumer may account for about one-third of this total; estimates vary from about one-fourth to one-half (3.4 g to 6.5 g). The nondiscretionary intake, expressed
as salt, is about 3 g from sodium occurring naturally in foods and about 4 g to 6 g from salt and other sodium-containing ingredients that are added to foods during commercial processing.

Although the 1970 survey showed that many other sodium-containing ingredients were added to processed foods, salt accounted for about 90 percent of the sodium used by the food industry in 1970. Available data are insufficient to determine the contribution of other sodium-containing ingredients to the sodium content of specific foods. However, on the basis of the total poundage of sodium-containing ingredients used by food processors, FDA estimates that as much as 1 g of sodium might be added daily to the average diet by ingredients other than salt that are used in processed foods.

III. STATUTORY BACKGROUND AND THE GRAS REVIEW

Generally recognized as safe (GRAS) and "prior sanctioned" categories of food substances were established by Congress when it enacted the Food Additives Amendment of 1958 (Pub. L. 85-929, 72 Stat. 1784-1789). In that amendment to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 et seq.), Congress defined the term "food additive" in section 201(s) (21 U.S.C. 321(s)) as follows:
The term 'food additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include--
(4) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act, the Poultry Products Inspection Act (21 U.S.C. 451 and the following) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 and the following); * * *

Under the statute, substances that are GRAS, or that are subject to a prior sanction, are not food additives and, thus, are not subject to the premarketing safety review of food additives established by the 1958 amendment (see section 409 of the act (21 U.S.C. 348)). Prior-sanctioned substances remain subject, however, to the general adulteration provisions in section 402 of the act (21 U.S.C. 342) which prohibit, among other things, the use of added substances that "may render [the food] injurious to health."

In order to clarify the food additive status of many substances that were being used in food at the time the 1958 amendment was enacted, and thus facilitate implementation of the new provision requiring premarket approval of food additives, FDA
established partial lists of substances that the agency considered to be GRAS (21 CFR Part 182) or subject to a prior sanction (21 CFR Part 181). The regulations establishing the original lists of GRAS and prior-sanctioned substances became final in 1959 and 1960 (see 24 FR 9368; November 20, 1959 and 25 FR 866; February 2, 1960). The statute, however, does not preclude manufacturers from making their own decisions concerning the GRAS status of ingredients before marketing them. If FDA disagrees with a manufacturer's determination that a substance is GRAS (and thus eligible for marketing without the FDA safety review and approval required for food additives), it is FDA's burden to take appropriate action.

FDA's decisions to place substances on the original GRAS lists were based on the data available at the time the lists were established and on the then current state of knowledge in the field of toxicology. Likewise, the pre-1958 approvals by FDA and USDA that qualified substances for prior-sanctioned status reflected the best safety judgments that could be made at the time based on existing knowledge. During the ensuing years, however, as more data became available on the properties of particular substances and as the science of toxicology developed, it became apparent that, in order to ensure the safety of the food supply, the agency's earlier safety determinations should be reviewed and modified where appropriate. Thus, FDA initiated the GRAS review program in 1970.
To implement the GRAS review, FDA conducted surveys of food manufacturers and searched the scientific literature to collect current data on the levels of consumption and toxicity of substances that are listed as GRAS or subject to a prior sanction. Under a contract with FDA, FASEB, acting through its Select Committee on GRAS Substances (Select Committee), evaluated the data and made recommendations to the agency concerning the appropriate action to take with respect to each substance under review. In preparing its recommendations on particular substances, FASEB held public hearings to provide an opportunity for interested persons to submit additional information and to express their views about the tentative report. A detailed discussion of the role FASEB plays in the GRAS review is provided in Federation Proceedings, Vol. 36, No. 11 (October 1977) (Ref. 1).

FDA reviews FASEB's evaluation of the data and its recommendation and considers any additional information not available to FASEB. The agency then makes its own determination concerning the GRAS status of the substance. The procedures and the criteria that FDA applies in making this determination are set forth in 21 CFR 170.30, 170.35, 184.1, and Part 186.
If FDA concludes that the substance is GRAS it proposes to remove the substance from the original GRAS list (21 CFR Part 182) and proposes a regulation for inclusion in 21 CFR Part 184 or 186 affirming the substance's GRAS status and specifying the conditions of use for which the substance is considered GRAS. That regulation may also establish or prescribe any specific limitation(s) necessary to the safe use of the substance. If the agency concludes that a substance can no longer be considered GRAS, the usual course of action is to propose to remove the substance from the GRAS list, and to declare that the substance is a food additive that cannot be used in food unless approved under section 409 of the act (21 U.S.C. 348). FDA may also permit the continued use of the substance on an interim basis, notwithstanding the safety questions that preclude affirming GRAS status if the agency finds that "* * * there is a reasonable certainty that the substance is not harmful and that no harm to the public health will result from the continued use of the substance for a limited period of time while the question raised is being resolved by further study." (21 CFR 180.1(a).) Substances approved on this basis are referred to as "interim food additives."

As part of the rulemaking process FDA uses to implement the conclusions reached in the GRAS review process, FDA routinely determines whether any prior sanctions exist for the substance under review. If a prior sanction for a particular use is found to exist, then, of course, the substance is exempt from regulation as a food additive.
IV. SCIENTIFIC EVIDENCE

As part of the GRAS review, FDA searched the scientific literature from 1920 to the present for articles on salt's toxicity and other data. The literature search covered 3,643 abstracts; 181 particularly pertinent reports were summarized in a scientific literature review (Ref. 2).

FASEB considered the scientific literature review and biological studies. In a report entitled "Evaluation of the Health Aspects of Sodium Chloride and Potassium Chloride as Food Ingredients" (Ref. 3), FASEB expressed the following opinion:

Sodium chloride, an essential constituent of the body and present in many foods, exhibits acute and chronic toxic effects when ingested in excessive amounts. Excess sodium chloride may induce hypertension in rats. There is a strong genetic component in the hypertensive response, and by selective breeding, strains of
'spontaneously' hypertensive rats have been developed. Hypertension has been evoked by excess sodium chloride in the food or drinking water of dogs but the effects were reversible and related to osmotic factors.

Salt appetite is an important expression of personal preference in relation to diet, and salt contributes to palatability of foods. For some, salt-containing foods have important cultural values. Foods in which salt is important for preparation or preservation are a prominent component of many diets.

The causes of hypertension in man are related to genetic and environmental factors: race, family history, variations in endocrine and kidney function, degree of obesity, and lifestyle. Although the findings of epidemiological studies suggest a relationship between salt intake and onset of hypertension, the evidence
that salt consumption is a major factor in causing hypertension is not conclusive. However, available data suggest that 10 to 30 percent of the U.S. population is genetically predisposed to hypertension and is exposed to a higher risk by ingestion of sodium chloride at current levels. The Select Committee believes that a reduction of sodium chloride consumption by the population will reduce the frequency of hypertension.

For man, the daily requirement of sodium chloride is less than 1 g (17 mg per kg), an amount exceeded by that present as a naturally-occurring ingredient of most diets. The daily requirement is subject to considerable fluctuation from such conditions as excessive sweating and diarrhea. It is not possible, on the basis of currently available data, to recommend a level of intake of sodium chloride that could be considered optimal for health. Other dietary sources of sodium, the level of potassium, and the sodium to potassium ratio in the diet need to be considered.
Because of increasing use of processed foods in the diet, individuals who prefer to restrict salt intake find it difficult. The amount of sodium chloride consumed as a result of commercial food processing is about 70 to 100 mg per kg per day. The average daily intake of sodium expressed as sodium chloride from all sources is about 180 mg per kg for an adult (10 to 12 g per day). Such an intake exceeds estimates of the amount (range 2 to 10 g per day) that may elicit hypertension in susceptible individuals. A lower daily consumption of sodium chloride promises health benefits for the proportion of the population susceptible to hypertension.

It is the prevalent judgment of the scientific community that the consumption of sodium chloride in the aggregate should be lowered in the United States. The Select Committee agrees and favors development of guidelines for restricting the amount of salt in processed foods, a major contributor of dietary sodium. Adequate labeling of the sodium content of foods would help meet these objectives.
The Select Committee then concluded that:

The evidence on sodium chloride is insufficient to determine that the adverse effects reported are not deleterious to the health of a significant proportion of the public when it is used at levels that are now current and in the manner now practiced.

In a study not reviewed by the Select Committee, salt did not exhibit genetic activity in a series of in vitro microbial assays, either with or without metabolic activation (Ref. 43).

Although scientists disagree about the role of salt intake as a basic causative factor in essential hypertension, there is a broad consensus in the scientific community that salt is one of the factors in the development of hypertension in susceptible individuals, and that excessive sodium consumption aggravates hypertension.
V. REGULATORY OPTIONS

The agency considered five regulatory options in determining a rational response to the current concern about salt intake. These five options are:

1. To propose to revoke the GRAS status of salt, declare it to be a food additive, and propose a food additive regulation that prescribes the permitted uses and use levels of salt in manufactured food.

2. To propose to revoke the GRAS status of salt, declare it to be a food additive, and propose an interim food additive regulation that prescribes the permitted uses and use levels of salt in manufactured foods to current uses and use levels pending the completion of additional safety studies.

3. To defer action on the GRAS status of salt, but to propose a regulation requiring the labels of all manufactured foods containing added salt to declare quantitatively the total sodium content of the food.

4. To propose to affirm salt as GRAS with specific limitations, and to define those limitations as informative labeling that would adequately alert the public to the health risks associated with a high level of sodium intake.

5. To defer any action on the current GRAS status of salt until the agency can assess the impact of the sodium labeling regulations proposed elsewhere in this issue of the FEDERAL REGISTER and the efforts by manufacturers to reduce voluntarily the salt and sodium content of their products.
VI. OPTION TENTATIVELY SELECTED

For the reasons discussed below, FDA has tentatively selected option five. Although the agency is not acting at this time to revise the GRAS status of salt, it has developed and is implementing a program aimed at alerting the public to the health risks associated with excessive salt consumption and encouraging manufacturers to reduce the amount of salt and other sodium-containing substances in processed foods. As noted above, FDA is publishing elsewhere in this issue of the FEDERAL REGISTER proposed changes in the agency's regulations concerning nutrition labeling and definitions for "sodium free," "low sodium," "moderately low sodium," and "reduced sodium" foods. On June 30, 1981, the Secretary of Health and Human Services and the Commissioner of Food and Drugs held a meeting with industry representatives to discuss the agency's pending sodium program and to ask for industry's cooperation. FDA has since begun meeting individually with firms and trade associations to discuss voluntary steps that might lead to a lower sodium content in processed foods. These steps include the use of alternative non-sodium-containing ingredients that perform the same technical effect
as salt, reevaluation of the need for that technical effect, and reevaluation of the amount of salt necessary to accomplish the intended technical effect. The agency will continue to monitor the sodium content of the food supply and the extent to which the proposed labeling, if adopted, is used.

VII. FACTORS AFFECTING FDA'S DECISION

The question of the safety of current levels of salt usage was the impetus for FDA's review of the regulatory status of salt. However, a number of other factors had a bearing on FDA's tentative selection of a regulatory approach.

Salt occupies a special place in our food supply. It is used directly by consumers as well as added by food processors. Salt and other sodium compounds occur naturally in food. Salt added to processed food constitutes about one-third to one-half of the total sodium intake of American consumers. The use of salt as a table condiment adds another dimension to the regulatory issue because the amount used is controlled by the consumer rather than by manufacturers directly subject to FDA's authority. In order to limit the sale of table salt, the agency would have to establish that salt "bears or contains [a] poisonous or deleterious substance" under section 402(a)(1) of the act. These practical considerations further support FDA's decision to seek a reduction of salt intake through voluntary efforts and informative labeling.
As discussed above, scientists do not fully understand the association between sodium and hypertension. Nonetheless, the relationship is sufficiently well established that a significant portion of the medical community believes that current levels of American salt consumption may not be healthful, at least for that part of the population that is predisposed to hypertension.

FDA agrees with FASEB that "a reduction of sodium chloride consumption by the population will reduce the frequency of hypertension" (Ref. 3). The issue before the agency is how to accomplish this goal effectively and expeditiously. As the FASEB report makes clear, salt is harmful to hypertensive patients in varying degrees, depending on each patient's genetic make-up, individual diet, and other variables. Hypertensive patients also may be on widely varying degrees of sodium restriction—from 200 to 300 mg/day for extreme restrictions to 2,000 to 3,000 mg/day for mild restrictions. Thus, setting some upper level on the amount of salt that can safely be used in a particular food is almost impossible. Most hypertensive patients can eat some salt, and almost everyone would prefer to decide how and from which foods to select a daily allotment of sodium. FDA
has decided to address the concerns about sodium consumption and hypertension, announced by FASEB and echoed throughout the scientific literature, by providing the public with information on the sodium content of foods. Thus, consumers can allocate their sodium intake as they choose. The agency believes that the sodium labeling proposals published elsewhere in this issue of the FEDERAL REGISTER and the other measures described above will provide the consumer with information on the sodium content of about half of all processed food.

Because FDA believes that information on sodium content and not restrictions on sodium usage is an appropriate approach at this time, FDA is deferring action on the GRAS status of sodium chloride. After publication of the sodium labeling proposal, FDA will assess the market to determine how many processed foods include sodium labeling and the impact of that labeling.

The agency wishes to emphasize that if there is no substantial reduction in the sodium content of processed foods and if informative sodium labeling is not adopted after a reasonable time period, FDA will consider additional regulatory actions, including proposing a change in salt's GRAS status.

VIII. OPTIONS NOT SELECTED

A. Declaring salt to be a food additive. Based on the FASEB report, FDA considered revoking salt's GRAS status and declaring it to be a food additive. The agency rejected this option for three reasons. First, FDA believes that informative labeling is more responsive to the health concerns about sodium.
Second, it would be extremely difficult to prescribe and enforce fair use limitations for salt that would be safe for all consumers (including those hypertensive patients on severe sodium restrictions). Third, FDA believes that many uses of salt are prior sanctioned. Although the existence of prior-sanctioned uses of salt does not affect FDA's authority to regulate other uses, the practical effect of regulating salt as a food additive might be quite small.

1. **Goal of regulation should be information disclosure.**

FDA recognizes the significance of the health concerns associated with sodium. The agency believes, however, that consumers will ultimately have to limit their sodium intake themselves. The American food supply is too diverse and complex for the Federal government to be able to regulate successfully an individual's sodium consumption. FDA encourages the food industry to reduce the amount of sodium added to processed foods and to market a greater variety of foods that are lower in sodium. The agency believes that this effort, coupled with the sodium labeling proposal published elsewhere in this issue of the FEDERAL REGISTER, will produce a wider selection of foods that contain low or moderately low amounts of sodium and will also increase consumer awareness of the beneficial aspects of a lower sodium intake.
2. Difficulty of setting and enforcing limitations.
Although most consumers think of salt principally as a flavoring agent, it has numerous other uses in a wide variety of processed foods, as noted above. Thus, it would be exceptionally difficult to establish limitations for the addition of salt to processed foods. Substances that are food additives or GRAS food ingredients perform 32 different technical functional effects (21 CFR 170.3(o)) in 43 food categories (21 CFR 170.3(n)). FDA would have to establish a limitation for each technical effect for which salt is used in each food category. That difficulty is compounded by the fact that salt may often be used for several different technical effects in a single food.

The promulgation and enforcement of limitations for salt would constitute an extraordinary regulatory burden. Moreover, the risk of excessive salt consumption is associated with high levels of sodium in the total diet and not the level in a particular food. FDA's decision to seek reduction in salt levels in processed foods avoids the difficulties and regulatory burdens posed by mandatory limitations.
3. **Existence of prior sanctions.** Many uses of salt are prior sanctioned. Some food standards promulgated before September 6, 1958, the effective date of the Food Additives Amendment, list salt as an ingredient. For example, 21 CFR Part 133 (Cheeses) (formerly Part 19) was originally promulgated in 1948, and additional sections were incorporated in 1950. Most of these cheese standards list salt either as an optional ingredient or as a required ingredient. Salt is a required ingredient in certain cereal flours (21 CFR 137.180 and 137.270, published in 1948 in 21 CFR Part 15) and in catsup (21 CFR 155.194, published in 1948 in 21 CFR Part 53). The original regulation (21 CFR Part 17, now Part 136) establishing standards for bakery products, bread, rolls, and buns included salt as a mandatory seasoning ingredient. (Since that time, the standard for bakery products has been modified to include salt as an optional rather than mandatory ingredient.) In the period from 1948 to 1951 FDA promulgated a number of food standards that included salt as an optional ingredient. Those standards cover noodle and macaroni products, jellies and preserves, cacao products, margarine, and food dressings and flavorings (21 CFR Parts 139, 150, 155, 156, 161, 163, 166, and 169).

Evidence of approval for a number of uses is contained in correspondence and press releases. For example, in 1924 USDA's Bureau of Chemistry (FDA's predecessor) issued a press release discussing certain specifications for table salt (Ref. 5). The press release in turn refers to a 1915 ruling.
concerning the quality of salt that may be offered for sale for food purposes. A 1957 letter from FDA to a salt company addresses when iodized salt may be substituted for ordinary salt in food production and the labeling requirements in the event of such substitution (Ref. 6).

FDA's burden in regulating a prior-sanctioned ingredient is considerably greater than in regulating a food additive. Under section 409 of the act, a food additive may be used only in a manner and under conditions in which it has been shown to be safe. By contrast, FDA may take regulatory action against a prior-sanctioned ingredient only under the general adulteration provisions of the act (21 U.S.C. 342(a)(1)). To establish that the use of salt renders a manufactured food adulterated, FDA would have the burden of showing that salt in food is a "poisonous or deleterious substance." The current uncertainty about the precise role of salt as a basic causative factor in essential hypertension, however, leaves unclear whether the use of salt in a particular food would render that food uniformly injurious to health.

In sum, FDA believes that providing information on sodium content will offer the consumer the opportunity to select foods containing appropriate amounts of sodium. Such an approach offers more public health benefit than attempting the cumbersome job of setting tolerances for the safe use of salt in manufactured food and dealing with those uses of salt that are prior sanctioned.
B. Interim food additive regulation. FDA also considered removing salt from GRAS status and permitting its use on an interim basis, under 21 CFR Part 180, while studies are being conducted to resolve the questions about the health concerns associated with sodium chloride. An interim food additive regulation can be issued only for a food additive. As noted above, many uses of salt are prior sanctioned and therefore are not subject to control under an interim food additive regulation. Moreover, if FDA were to regulate salt as an interim food additive when used in processed food, the agency would need to define the nature of the required studies and to monitor their progress. There are already numerous studies planned or in progress to determine the causes of hypertension. It is not clear that any of these studies will resolve the basic questions about whether excess salt consumption causes hypertension, and there is no general agreement that a definitive study could be designed. Instead, additional basic scientific research is required so that eventually the causes of hypertension will become clear. Interim food additive regulations are most appropriately used where specific studies can promptly be undertaken to resolve safety questions, rather than where a general advance in scientific knowledge is necessary. Therefore, FDA has concluded that an interim food additive regulation for sodium chloride is not appropriate.
C. Sodium content labeling. The third option considered and rejected by FDA was to defer action on the GRAS status of salt but to promulgate a regulation that proposed to require that the labeling of manufactured foods containing added salt declare quantitatively the total sodium content of the food. Elsewhere in this issue of the FEDERAL REGISTER, FDA is proposing a revision of the nutrition labeling regulations to require the declaration of sodium content whenever nutrition labeling is required or is provided voluntarily. The proposal also requires quantitative sodium declaration whenever a food is labeled "sodium free," "low sodium," "moderately low sodium," or "reduced sodium," and it provides definitions for those terms.

In deciding to propose the declaration of sodium content as part of nutrition labeling, FDA considered and rejected mandatory sodium content labeling. FDA believes that the regulatory burden that would be imposed by mandatory sodium labeling is not justified at this time for the reasons discussed in the following section.
D. Affirm sodium chloride as GRAS with specific limitations. One of the regulatory options available to FDA is to affirm salt as GRAS with certain specific limitations. Normally, such limitations restrict the amount of a substance that can safely be used in food. Unlike a substance that is generally toxic above a certain known level, the threshold level for chronic toxicity of salt in specific segments of the population has not been determined. Moreover, because of the practical difficulties inherent in regulating salt as a food additive and setting fair use levels, the agency has concluded that labeling requirements would be more informative to the consumer and thus more useful in helping individuals restrict salt intake. Thus, FDA considered proposing a regulation in accordance with § 184.1(b)(2) (21 CFR 184.1(b)(2)) affirming sodium chloride as GRAS subject to certain specific limitations on its use. The specific limitations would have consisted of informative labeling, such as including information on sodium in the nutrition labeling.

Although FDA believes that this option would accomplish the desired goals, the agency rejected it at this time because the Commissioner believes that a voluntary program will produce the desired results with less regulatory burden. Moreover, the food industry is in the best position to reduce sodium levels in processed food and to provide more information to consumers. The Commissioner believes that the industry should be given a chance to do so.
FDA is committed to working with industry to accomplish the goal of reducing the amount of sodium in processed foods and in providing more information on sodium to consumers. If no significant progress occurs toward these goals in a reasonable time, the agency will consider additional regulatory actions, including one or more of the options discussed in this notice.

IX. OTHER ACTIONS

FDA is currently pursuing several other courses of action that may affect the regulatory status of salt.

The agency currently monitors, both qualitatively and quantitatively, the national food supply for certain contaminants, toxins, and nutrients. Sodium is, and will continue to be, one of the elements included in the monitoring, which will be one of the means of monitoring sodium intake that the selected option requires.

The agency intends to continue participating with other public and private groups in education programs that acquaint the public with scientific views about the relationship between sodium usage and hypertension. FDA will also continue to keep the public informed of this topic through its Consumer Affairs Officers in the field and its Public Affairs Office.
X. REQUEST FOR COMMENTS

To provide for public participation in its decisionmaking process, FDA requests the submission of comments on its tentative decision to defer any revision in the GRAS status of salt and to seek a reduction in salt intake through proposed sodium labeling regulations and voluntary reductions in salt usage by food manufacturers. Comments may suggest options in addition to those presented here, including suggestions for implementation.

As discussed above and in the preamble to the notice of availability of information on the status of review of GRAS and prior-sanctioned direct human food ingredients (38 FR 20054; July 26, 1973), many substances currently considered to be GRAS were approved for specific uses by USDA or by FDA before 1958. Thus, many of these ingredients are subject to specific prior sanctions for specific uses in addition to GRAS status. No comprehensive list of such prior sanctions exists.

Persons who believe they hold proof of a prior sanction for the use of salt are requested to submit proof of the existence of the prior sanction. Prior-sanctioned status constitutes an exemption from section 409 of the act (21 U.S.C. 348). The agency has therefore concluded that prior-sanctioned status should be construed narrowly and the burden of coming forward with the evidence of the sanction properly rests upon the person who asserts it.
XI. REFERENCES

The following information has been placed in the Dockets Management Branch (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.


3. FASEB/SCOGS Report (SCOGS-102), "Evaluation of the Health Aspects of Sodium Chloride and Potassium Chloride as Food Ingredients."


5. Press release issued by USDA's Bureau of Chemistry, December 24, 1924.

Copies of the full report of the Select Committee, the scientific literature review, and mutagenic and teratogenic evaluations are also available for review at the Dockets Management Branch, Food and Drug Administration, and may be purchased from the National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22151, as follows:

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<tr>
<th>Title</th>
<th>Order no.</th>
<th>Price code</th>
<th>Price*</th>
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<td>Sodium chloride, potassium chloride (scientific literature review)</td>
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<td>A13</td>
<td>$16.00</td>
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<td>Sodium chloride (mutagenic evaluation)</td>
<td>PB257-870/AS</td>
<td>A04</td>
<td>7.00</td>
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<tr>
<td>Sodium chloride (teratogenic evaluation)</td>
<td>PB234-878/AS</td>
<td>A03</td>
<td>6.00</td>
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<td>Sodium chloride, potassium chloride (Select Committee report)</td>
<td>PB298-139/AS</td>
<td>A04</td>
<td>7.00</td>
</tr>
</tbody>
</table>

*Price subject to change.

Interested persons may, on or before (insert date 60 days after date of publication in the FEDERAL REGISTER), submit to the Dockets Management Branch (address above) written comments regarding this notice. Two copies of all comments shall be submitted,
except that individuals may submit single copies of comments, and shall be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: FEB 8 1982

Arthur Hull Hayes, Jr
Commissioner of Food and Drugs

Dated: APR 28, 1982

Richard S. Schweiker
Secretary of Health and Human Services