NEW EXEMPTIONS—Continued

Application number	Applicant	Regulation(s) affected	Nature of Exemption Thereof
10346-N	Weyerhaeuser Company, Tacoma, WA.	49 CFR 174.67(i), 174.67(j)	To authorize pre-hookup of liquid chlorine filled tank cars to unloading station in advance of unloading or to remain connected if unloading is discontinued. (mode 2).
10347-N	PPG Industries, Inc., Pittsburgh, PA.....	49 CFR 173.247	To authorize shipment of trimethylacetal chloride in DOT Specification 34 containers of 55 gallons capacity. (modes 1, 2, 3).

This notice of receipt of applications for new exemptions is published in accordance with part 107 of the Hazardous Materials Transportation Act (49 U.S.C. 1806; 49 CFR 1.53(e)).

Issued in Washington, DC, on March 8, 1990.

J. Suzanne Hedgepeth,

Chief, Exemptions Branch Office of Hazardous Materials Transportation.

[FR Doc. 90-5887 Filed 3-14-90; 8:45 am]

BILLING CODE 4910-60-M

DEPARTMENT OF THE TREASURY

Customs Service

[T.D. 90-19]

Revocation of Individual Customs Broker's License No. 5987 Issued to Albert Kazangian

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: General notice.

SUMMARY: Notice is hereby given that the Secretary of the Treasury on January 4, 1990, pursuant to section 641, Tariff Act of 1930, as amended (19 U.S.C. 1641), and (111.74 of the Customs Regulations, as amended (19 CFR 111.74)), revoked the individual Customs broker's license no. 5987 issued to Albert Kazangian. This action having received no appeal under 19 U.S.C. 1641(e), is effective as of March 5, 1990

Dated: March 8, 1990.

Victor G. Weeren,

Director, Office of Trade Operations.

[FR Doc. 90-5871 Filed 3-14-90; 8:45 am]

BILLING CODE 4820-02-M

Sunshine Act Meetings

Federal Register
Vol. 55, No. 51
Thursday, March 15, 1990

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

NATIONAL CREDIT UNION ADMINISTRATION

Meeting

TIME AND DATE: 9:30 a.m., Tuesday, March 20, 1990.

PLACE: San Antonio Marriott Rivercenter, 101 Bowie Street, San Antonio, Texas 78205, (512) 223–1000.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Approval of Minutes of Previous Opening Meeting.
2. Economic Commentary.
3. Central Liquidity Facility Report and Review of CLF Lending Rate.
4. Insurance Fund Report.
5. Proposed Rule: §§ 701.14, 741.7, and part 747, subpart L, Reporting Requirements for Newly Chartered and Troubled Credit Unions, NCUA's Rules and Regulations.
6. Proposed Amendment: Part 704 and § 741.6, Fixed Assets for Corporate Credit Unions, NCUA's Rules and Regulations.
7. Legislative Updates.

FOR MORE INFORMATION CONTACT: Becky Baker, Secretary of the Board, Telephone (202) 682–9600.

Becky Baker,

Secretary of the Board.

[FR Doc. 90–6102 Filed 3–13–90; 12:42 pm]

BILLING CODE 7535–01–M

NATIONAL CREDIT UNION ADMINISTRATION

Meeting

TIME AND DATE: 9:30 a.m., Tuesday, March 27, 1990.

PLACE: Filene Board Room, 7th Floor, 1776 G Street, NW., Washington, DC 20456.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Approval of Minutes of Previous Closed Meeting.
2. Application for CLF Agent Membership. Closed pursuant to exemptions (8) and (9)(A)(ii).
3. Delegation of Authority. Closed pursuant to exemptions (2) and (9)(B).
4. Administrative Actions under section 206 of the Federal Credit Union Act. Closed pursuant to exemptions (8), (9)(A)(ii), and (9)(B).
5. Requests for Special Assistance under Section 208 of the Federal Credit Union Act. Closed pursuant to exemptions (8), (9)(A)(ii), and (9)(B).
6. Apportionment of Regional Staff. Closed pursuant to exemptions (2) and (6).

FOR MORE INFORMATION CONTACT: Becky Baker, Secretary of the Board, Telephone (202) 682–9600.

Becky Baker,

Secretary of the Board.

[FR Doc. 90–6103 Filed 3–13–90; 12:42 pm]

BILLING CODE 7535–01–M

SECURITIES AND EXCHANGE COMMISSION

Agency Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission will hold the following meeting during the week of March 19, 1990.

A closed meeting will be held on Tuesday, March 20, 1990, at 2:30 p.m.

The Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c) (4), (8), (9)(A) and (10) and 17 CFR 200.402(a) (4), (8), (9)(i) and (10), permit consideration of the scheduled matters at a closed meeting.

Commissioner Schapiro, duty officer, voted to consider the items listed for the closed meeting in a closed session.

The subject matter of the closed meeting scheduled for Tuesday, March 20, 1990, at 2:30 p.m., will be:

Institution of injunctive actions.
Institution of administrative proceedings of an enforcement nature.
Settlement of administrative proceedings of an enforcement nature.
Settlement of injunctive actions.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: Holly Smith at (202) 272–2100.

Dated: March 12, 1990.

Jonathan G. Katz,

Secretary.

[FR Doc. 90–6141 Filed 3–13–90; 3:58 pm]

BILLING CODE 8010–01–M

Corrections

Federal Register
Vol. 55, No. 51
Thursday, March 15, 1990

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

15 CFR Part 400

[Docket No. 21222-9299]

RIN 0625-AA04

Foreign-Trade Zones in the United States

Correction

In proposed rule document 90-1688 beginning on page 2760 in the issue of Friday, January 26, 1990, make the following correction:

§ 400.31 [Corrected]

On page 2766, in the first column, under § 400.31(c)(2), in the seventh line, "casual" should read "causal".

BILLING CODE 1505-01-D

DEPARTMENT OF COMMERCE

International Trade Administration

Correction

National Institutes of Health; Decision on Application for Duty-Free Entry of Scientific Instrument

In notice document 90-4679 beginning on page 7359 in the issue of Thursday, March 1, 1990, make the following correction:

In the third column, in the first paragraph, in the second line, "Education," should read "Educational,".

BILLING CODE 1505-01-D

DEPARTMENT OF COMMERCE

Minority Business Development Agency

Business Development Center Applications; Charleston, SC

Correction

In notice document 90-3081 beginning on page 4650 in the issue of Friday, February 9, 1990, make the following correction:

On page 4650, in the second column, the heading should read as set forth above

BILLING CODE 1505-01-D

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

[Docket No. 900104-0004]

RIN 0693-AA81

Proposed Revision of Federal Information Processing Standard (FIPS) 54, Computer Output Microform (COM) Formats and Reduction Ratios, 16mm and 105mm

Correction

In notice document 90-4825 beginning on page 7516 in the issue of Friday, March 2, 1990, make the following correction:

1. On page 7516, the heading should read as set forth above.

2. On page 7517, in the second column, in the second paragraph from the bottom of the page, the first sentence should read "This revised standard is effective _____ (6 months after date of publication of final document in the **FEDERAL REGISTER**).

BILLING CODE 1505-01-D

ENVIRONMENTAL PROTECTION AGENCY

[PP 9G3765/T590; FRL 3685-5]

Myclobutanil; Establishment of Temporary Tolerance

Correction

In notice document 90-4687 beginning on page 7465 in the issue of Thursday, March 1, 1990, the cover page of Part VII is corrected to read, "Myclobutanil; Establishment of Temporary Tolerance; Notice".

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Social Security Administration

20 CFR Part 416

[Reg. No. 16]

RIN 0960-AC51

Supplemental Security Income for the Aged, Blind, and Disabled; Interim Assistace Provisions

Correction

In proposed rule document 90-2853 beginning on page 4438 in the issue of Thursday, February 8, 1990, make the following correction:

§ 416.1901 [Corrected]

On page 4439, in the second column, under § 416.1901,"(1) *General.*" should read "(a) *General.*".

BILLING CODE 1505-01-D

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 121

[Docket No. 24792; Amdt. 121-212]

Protective Breathing Equipment

Correction

In rule document 90-3520 beginning on page 5548 in the issue of Thursday, February 15, 1990, make the following corrections:

1. On page 5549, in the second column, in the fourth paragraph, in the seventh line, "certified" should read "certificated".

2. On the same page, in the same column, in the same paragraph, in the 15th line, "FAR" should read "FAA".

3. On page 5550, in the first column, in the 13th line, "closed" should read "located".

BILLING CODE 1505-01-D

federal register

Thursday
March 15, 1990

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 182

Sulfiting Agents; Revocation of GRAS Status for Use on Fresh Potatoes Served or Sold Unpackaged and Unlabeled to Consumers and Request for Data on Use of Sulfites on Frozen Potatoes; Rule and Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 182

[Docket No. 81N-0314]

RIN 0905-AB52

Sulfiting Agents; Revocation of GRAS Status for Use on "Fresh" Potatoes Served or Sold Unpackaged and Unlabeled to Consumers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations on sulfur dioxide, sodium sulfite, sodium and potassium bisulfite, and sodium and potassium metabisulfite (collectively known as "sulfiting agents" or "sulfites") to exclude their use on "fresh" potatoes that are intended to be served or sold unpackaged and unlabeled to the consumer from the uses of these substances that are generally recognized as safe (GRAS). This action is based on FDA's conclusion, following its review of the comments and information that it has received, that a consensus no longer exists among qualified experts that this use of sulfiting agents is safe. This action follows previous actions by the agency requiring that the labels of foods that contain a detectable level of sulfites declare their presence and revoking the GRAS status of the use of sulfites on fresh fruits and vegetables intended to be served or sold to the consumer raw.

EFFECTIVE DATE: April 16, 1990.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-426-9463.

SUPPLEMENTARY INFORMATION:

I. Background

In 1982, FDA proposed to affirm that all known uses of sulfiting agents in food are generally recognized as safe (GRAS). The agency received numerous comments in response to that proposal including information about many new uses of sulfites and reports of adverse reactions that were attributed to consuming foods containing sulfites.

Continuing reports of adverse reactions, including several deaths, together with the new information received in response to the 1982 proposal, prompted the agency in July 1984 to ask the Federation of American Societies for Experimental Biology (FASEB) to reexamine the GRAS status of the use of sulfiting agents. FASEB issued its final report on the health aspects of the use of sulfiting agents on January 31, 1985.

FASEB found that, in some cases, sulfite-sensitive individuals have had life-threatening reactions following exposure to sulfite-treated foods. FASEB specifically noted that the use of sulfites on fresh fruits, fresh vegetables, and potato products had been shown to elicit adverse reactions. FASEB recommended that FDA use the regulatory process to encourage the food industry to discontinue the use of sulfites on precut potato products and on raw fruits and vegetables.

The agency also established an ad hoc Advisory Committee on Hypersensitivity to Food Constituents (the Advisory Committee) to examine the phenomenon of allergic-type adverse responses to food constituents, including sulfiting agents. The Advisory Committee issued its conclusions and recommendations regarding sulfiting agents on December 13, 1985.

The Advisory Committee found that sulfite-sensitive individuals are at moderate to high risk that they will suffer a severe reaction upon exposure to sulfites. The Advisory Committee specifically recommended that the GRAS status of the use of sulfites on "fresh" potatoes and on raw fruits and vegetables, with the exception of mushrooms, be revoked. The Advisory Committee noted that its recommendation would apply to "fresh" potatoes even though they are ultimately cooked. The Advisory Committee's reasoning for including "fresh" potatoes in its recommendation was the evidence of abusive uses of sulfites in this portion of the potato processing industry. The Advisory Committee also stated that the use of sulfites on frozen potatoes was unnecessary.

Based on the reviews by FASEB and the Advisory Committee, and on the agency's own review of the available evidence, the agency initiated several actions to minimize the risk to health from the use of sulfiting agents. First, the agency acted to provide individuals who are sulfite-sensitive with the information that they need to avoid certain processed foods that contain sulfiting agents. In the **Federal Register** of July 9, 1986 (51 FR 25012), FDA published a final rule requiring the listing on the label of nonstandardized food products of any sulfiting agent that is present in the finished food at levels of 10 parts per million (ppm) or more (21 CFR 101.100(a)(4)). (On December 19, 1988 (53 FR 51062), FDA proposed to require that the same information be included on the label of standardized foods.) Also, on July 9, 1986 (51 FR 25021), FDA revoked the GRAS status of the use of sulfiting agents on fruits and vegetables that are intended to be served or sold raw to consumers. (In the **Federal Register** of December 19, 1988 (53 FR 51065), FDA published a proposed rule that would affirm, with specific limitations, that certain uses of sulfiting agents are GRAS.)

Finally, in the **Federal Register** of December 10, 1987 (52 FR 46968), FDA announced its tentative conclusion that there is no longer a basis to find that the use of sulfites on "fresh" potatoes served or sold unpackaged and unlabeled to consumers is GRAS. The agency proposed to amend 21 CFR part 182 to exclude this use of sulfites from those that are listed as GRAS under part 182. FDA defined the term " 'fresh' potatoes" in the proposal as including all sulfite-treated potato products that are not canned, frozen, or dehydrated.

FDA published its tentative conclusion concerning the use of sulfites on "fresh" potato products after reviewing information on sulfiting agents from a variety of sources, including: (1) Comments on the proposal to affirm the GRAS status of sulfiting agents published in the **Federal Register** of July 9, 1982 (47 FR 29956); (2) the January 31, 1985, final report of FASEB on the Reexamination of the GRAS Status of Sulfiting Agents; (3) the hearing conducted by the Advisory Committee; (4) published reports in the medical literature; and (5) consumer complaints received by the agency.

Based on this review, the agency proposed to revoke the GRAS status of the use of sulfiting agents on "fresh" potatoes for the following reasons: (1) The agency's concern about continued adverse reactions to these potato products by sensitive individuals; (2) the trend that Americans are eating a greater portion of their meals in food service establishments; (3) the significant potential for misuse in the application of sulfiting agents to these potato products in retail food establishments; (4) the difficulty in informing consumers of the use/presence of sulfiting agents on "fresh" potatoes in food service establishments; and (5) the apparent lack of a consensus in the scientific community that the use of sulfites on "fresh" potatoes that are unpackaged and unlabeled is safe.

As noted in the proposal, the agency recognizes the difficulty and complexity in assessing the safe use of food and food ingredients, like nuts and shellfish, that are safe for the majority of the

public but that pose acute hazards for small subpopulations. As a general rule, FDA's policy is to address such problems by requiring package labeling that will disclose the presence of the potentially harmful ingredient to purchasers. This general principle is reflected in the previously issued regulations governing sulfites in packaged foods. Sulfite-sensitive individuals can, by reading the label of packaged foods, avoid products that contain sulfites.

The agency also stated in the proposal, however, its belief that labeling may not be an effective means of protecting sulfite-sensitive individuals from such sulfited foods as fruits and vegetables that are served or sold raw to consumers and "fresh" unpackaged potatoes that are served or sold by retail food service establishments. These types of foods are traditionally unlabeled when presented to consumers. They also are presented to consumers as "fresh," thereby suggesting that preservatives have not been used in their preparation. Ingestion of these types of foods has been reported to be associated with life-threatening responses in sulfite-sensitive individuals and, in some cases, with death. Therefore, FDA found that the use of sulfites on fruits and vegetables served or sold raw to consumers is not GRAS and proposed to make a similar finding for "fresh" potatoes.

FDA initially allowed a period of 60 days, to February 8, 1988, during which interested persons could review the proposal and other relevant information on "fresh" potatoes. The agency subsequently extended the comment period to March 9, 1988, at the request of some interested parties (53 FR 4184; February 12, 1988). The agency requested that comments be submitted during this time by all interested persons on all relevant issues relating to the published proposal. The agency specifically sought comments relating to the following issues:

1. Whether FDA should extend the scope of the proposed action to include the use of sulfites in or on canned, dehydrated, or frozen potatoes that are intended to be sold or served unpackaged and unlabeled to consumers;

2. Whether there is an association between exposure to sulfite-treated potatoes and allergic-type responses in sulfite-sensitive individuals;

3. Whether there is scientific evidence that establishes safe conditions of use for sulfiting agents on potatoes; and

4. Whether there are practical alternatives to the use of sulfiting agents on potatoes.

Additionally, the agency invited comments on the practicality and desirability of alternative labeling approaches. The agency also requested substantive data concerning the economic impact of this proposed action.

II. Comments

A. Introduction

FDA received 193 comments in response to the proposal concerning "fresh" potatoes. Individual consumers submitted 128 of these comments. The remaining comments were submitted by health professionals and health organizations (6); State and local government officials (2); Congress (26); a foreign government (1); trade associations (10); the affected industry (16); a consultant (1); a food scientist (1); and consumer groups (2). For the purposes of this discussion, the term "affected industry" refers to both processors and users of sulfited potato products.

Almost all of the comments agreed with FDA's preliminary conclusions that the use of sulfites on "fresh" potatoes served or sold unpackaged and unlabeled to consumers is not GRAS. Of the 16 comments received from the affected industry, 7 were in favor of the proposal, and all but one of the 128 comments received from consumers supported FDA's proposed actions.

The majority of the comments from consumers were from individuals who had experienced adverse reactions themselves from ingesting sulfited foods. The one comment from a consumer that did not support the proposed ban recommended labeling.

All of the comments received from health professionals and health organizations agreed that the use of sulfites on "fresh" potatoes that are served or sold unpackaged and unlabeled to consumers is not safe.

Most of the comments from consumers, consumer groups, health professionals, and State and local government officials went beyond the proposal and requested that FDA revoke the GRAS status of the use of sulfites on all types of potatoes or in all foods.

On the other hand, some comments from industry, trade associations, and members of Congress suggested that the establishment of levels for the use of sulfites or labeling would provide sufficient protection of the sulfite-sensitive individual.

Most of the comments to the proposal were not accompanied by supporting data or information but merely expressed the opinion of the individual. This failure to provide supporting data has prevented the agency from verifying through calculations or other means the allegations made in the comments. Despite the agency's efforts to obtain additional data, these data have not been forthcoming.

The issues raised in the comments and the agency's responses are given below.

B. Adverse Reactions to Sulfites

The agency continues to receive and to monitor reports of adverse reactions to sulfiting agents from consumers. The number of reports received by the agency has decreased in recent years following the regulatory actions that have been undertaken by the agency. Over this period, there has been an increasing awareness of this problem among sensitive individuals.

Some consumers submitted anecdotal information in their comments to the proposal about adverse reactions that they or someone they knew suffered from ingesting sulfited foods. The reactions to sulfites described by consumers included headaches, disorientation, blurry vision, drowsiness, aching body muscles, swelling of the face, anaphylactic shock, wheezing, throat closing up, gastrointestinal problems, diarrhea, coughs, sniffles, and difficulty breathing. For many of these individuals, the symptoms described lingered for several days. Nine of the consumers who reported experiencing adverse reactions to sulfites also stated that they are not asthmatic.

Only one comment contained data on allergic reactions to sulfites in potatoes that had not previously been considered by the agency. These data were derived from a study of asthmatic individuals who had been diagnosed as sulfite sensitive. In a double-blind challenge with sulfited dehydrated potatoes, one patient reacted adversely. However, this response could not be duplicated on a second occasion. Thus, because of the lack of duplication, the agency considers the observed reaction to be an inadequate basis on which to draw conclusions about the effects of ingesting sulfites in dehydrated potatoes.

Other comments asserted that the adverse reactions that were reported in the proposal occurred in California. These comments suggested that these reactions may represent an abusive use of sulfites on "fresh" potatoes unique to that State. The comments argued that the use of sulfites on "fresh" potatoes should not be prohibited on a national basis because of findings from only California.

In the Adverse Reaction Monitoring System maintained by the agency, 12 percent of all adverse reactions attributable to sulfiting agents were caused by potato products (Ref. 1). "Fresh" potato products accounted for 50 percent of these adverse reactions. Considering that only 2 percent of the total U.S. potato production (Ref. 2) goes into "fresh" potato products, and that "fresh" potato products constitute only about 5 percent of processed potatoes (excluding chips), the incidence of adverse reactions associated with "fresh" potatoes is disproportionately large. Additionally, of the 17 deaths that have been associated with the use of sulfites in foods, four were attributed to the consumption of "fresh" potato products.

The agency acknowledges that four of the five serious adverse reactions that were cited in the proposal occurred in California, and that the proposal referenced data generated in California. However, the agency has also received data that establish that there have been adverse reactions involving the use of sulfites in "fresh" potatoes in several other areas of the country. Therefore, the agency concludes that the data demonstrate that the problems associated with the ingestion of "fresh" potato products are not uniquely associated with California, and that the use of sulfites on "fresh" potatoes may render the food injurious to health.

C. Labeling and Education as Alternatives

A number of comments stated the belief that informing the consumer through labeling and education could mitigate or obviate the need to ban the use of sulfites on "fresh" potatoes. One comment, from a trade association, objected to the use of labeling as an alternative.

The agency has traditionally relied on ingredient labeling of food as the best means to inform a subpopulation of sensitive individuals that a food contains an ingredient that the individuals may want to avoid. However, the use of food additives and GRAS substances in a restaurant presents a very different situation for the sensitive individual because in this setting, foods are typically unlabeled. In such a case, the sensitive individual must rely on knowledge gained by reading food labels for products in the retail market to identify those foods that should be avoided.

There is no counterpart product for "fresh" potatoes in the retail market and thus no opportunity for the sulfite-sensitive individual to learn of the types of "fresh" potato products that might contain sulfites. Thus, in a restaurant, if a consumer inquires about the source of potato products, the consumer is likely to be told that the potatoes are frozen, canned, dehydrated, or "fresh." Based on experience with labeled products, the consumer is likely to know that canned and dehydrated potato products contain sulfites, and a sensitive individual can avoid them. However, the term " 'fresh' potatoes" is ambiguous as to the source of potatoes because it describes potato products that are prepared on site or purchased by the restaurant and that either contain or do not contain sulfites. Thus, when presented with a choice in a restaurant concerning "fresh" potatoes, the sulfite-sensitive individual would have no basis upon which to make a selection and might unwittingly make a choice that would expose him/her to sulfites. With the effective date of this final rule, the consumer will know that "fresh" potatoes will not contain sulfites.[1]

The agency has encountered strong resistance to any labeling in restaurants and other food service establishments. Specific labeling by means of menus or signs in food service establishments is not customary. Consequently, labeling requirements would be extremely difficult to enforce by any level of government, be it Federal, State, or local. At one time, FDA encouraged the States to require retail food establishments to place signs at their salad bars advising consumers of their use of sulfites. This effort proved to be unsatisfactory in that compliance was poor, and adverse reactions continued. Also, comments received from the National Restaurant Association state that its members are opposed to a labeling requirement for food service establishments on the grounds that such a requirement would not be effective.

During its deliberations on the proposed rule, the agency did consider the possibility that "fresh" potatoes would continue to be GRAS if processors who supply them to food service establishments clearly labeled the potatoes as containing sulfites, so that restaurant employees would be able to provide information to consumers who inquire as to whether sulfites are used. Although the agency specifically requested comments on this alternative, it has not received any comments from food service institutions that support this approach. To the contrary, the information on this alternative available to the agency demonstrates that this approach is not practical because consumers have reported that food service employees may be unknowledgeable or indifferent. One comment reported witnessing "allergic individuals having a sulfite asthmatic attack after eating potatoes in a facility that stated in writing that they did not use sulfites."

The agency agrees that an educational program could be useful. However, for the reasons noted in this section, the agency believes that education alone is not sufficient to eliminate the potential for adverse reactions that could be caused when sulfite-sensitive individuals ingest sulfited "fresh" potato products.

D. Establishment of Current Good Manufacturing Practice (CGMP) Levels

Comments from some trade associations, potato processors, members of Congress, and a food scientist stated that the establishment of controls on the use of sulfites on "fresh" potatoes would be sufficient to protect the public health. Some of these comments noted that the agency should recognize that potato processors are currently using less sulfites than they were in 1985. The specific approaches that were suggested to address the use of sulfites on "fresh" potatoes were: (1) Adoption of limits on the levels of sulfites that may be added to potatoes; (2) restricting the use of sulfites to certified processors who could demonstrate the ability to control residual sulfite levels; and (3) delaying action while research is conducted to determine safe levels of sulfite use. The only comment that included data not before the agency at the time the proposal was issued was from the food scientist. These data were related to residual levels of sulfites in dehydrated potatoes and non-potato products. The food scientist argued that the relevant consideration in establishing safe conditions of use for sulfites is the residual level of sulfite in the food as served to the consumer.

As noted above, the agency's determination that the use of sulfites on "fresh" potato products is not GRAS is based on a number of factors including: (1) The reports of severe life-threatening responses in asthmatic individuals who consumed sulfited "fresh" potato products in food service establishments; (2) the potential for abuse in the use of sulfites on "fresh" potatoes; (3) the lack of any effective means by which sulfite-sensitive individuals can be informed of the presence of sulfites on unpackaged

[1] For frozen potatoes, the issues are more problematic. Because sulfites are often not used on these products, there is a significant question as to whether consumers would be aware that sulfites may be found on these products. The agency's concerns about this use of sulfites are discussed in section II E of this document.

and unlabeled "fresh" potatoes served or sold in retail food establishments and thus of any means by which they can avoid unwitting exposure to sulfite-treated "fresh" potato products; and (4) the lack of consensus among qualified experts, as evidenced by the FASEB and the Advisory Committee recommendations, that the use of sulfites on "fresh" potatoes is safe.

Even if (1) the potential for abuse is eliminated as a factor, and (2) the relevant consideration in establishing safe conditions of use for sulfites is the residual level of sulfite in the food as served, the fact is that science has yet to establish a residual level of sulfites in "fresh" potatoes that will not cause a reaction in sensitive individuals. This fact, plus the fact that the potential for unwitting exposure to sulfites from "fresh" potatoes is particularly high because of the lack of any corresponding labeled consumer products, has led the agency to conclude that establishment of controls on the level of sulfites in "fresh" potato products would not be adequate to protect the public health. Furthermore, research of the type suggested by the comments could take years to complete. The agency believes that it would be inappropriate to delay regulatory action on "fresh" potatoes pending the completion of research that may provide a basis on which to establish safe levels of use.

Moreover, no information has been submitted that demonstrates to the agency that the problem with sulfites on "fresh" potatoes could be alleviated if controls to limit use to current good manufacturing practice (CGMP) levels were to be established. In determining, tentatively, those uses of sulfites that it could propose to affirm as GRAS in the document that published on December 19, 1988 (53 FR 51065), the agency used the following considerations: (1) The existence of labeling to ensure safety for sulfite-sensitive individuals, and (2) the existence of a chronic acceptable daily intake to ensure safety for long-term exposure to uses of sulfites governed by CGMP levels. Both of these conditions exist for the uses identified in that proposal. However, the condition listed at least in item 1 does not exist for the use of sulfites on "fresh" potatoes.

The agency has tried both formally (in the proposal) and informally to get all interested parties to come forward and present information that would permit the agency to reevaluate its tentative judgment on CGMP levels for sulfites in "fresh" potatoes. Despite these attempts, information has not been forthcoming. Therefore, a convincing basis for concluding that the establishment of CGMP limitations would provide safe conditions for the use of sulfites on "fresh" potatoes does not exist.

E. Issues Related to Canned, Dehydrated, and Frozen Potatoes

Several comments urged FDA not to include canned, dehydrated, or frozen potatoes in the proposed ban. Two comments from trade associations, however, urged FDA to extend the ban to cover these types of potatoes. Another comment recommended that frozen potatoes be included in the proposed ban, but that dehydrated potatoes should not be included. As noted earlier, a number of comments were received that stated that these uses (or all uses of sulfites) should be banned.

One comment from a food service establishment questioned the exclusion of canned, dehydrated, and frozen potato products from the proposed action. Another comment from the food service industry supported the proposal but argued that the proposal should not extend to dehydrated potatoes for food service use.

One comment, from a consumer group, stated that the use of sulfites on unlabeled frozen, canned, and dehydrated potatoes poses as great a risk as the use of sulfites in unlabeled "fresh" potatoes. In support of this contention the comment presented a synopsis of publicly available agency documents and of the comments the agency received in response to the proposal. The thrust of this comment's argument was that FDA's own epidemiological surveillance data show more serious sulfite reactions to non-"fresh" potatoes than to "fresh" potatoes.

The agency has considered these comments and concludes that no evidence has been submitted that would lead the agency to believe that the use of sulfites in or on dehydrated or canned potatoes will render those potatoes injurious to health. This position is consistent with several factors.

First, it is consistent with the recommendations of the Advisory Committee. The Advisory Committee noted that it was concerned about canned or dehydrated potatoes only "* * * to the extent that they would have to be labeled if they contain sulfite and that the sulfites are necessary, and that the minimum amounts of sulfites necessary to achieve the desired effects are being used * * *."

Second, sensitive individuals will know from reading labels that canned and dehydrated potatoes contain sulfites. The agency believes that sulfite-sensitive individuals, by paying attention to the labeling of these products, will be aware when they are in settings in which foods are not ordinarily labeled, such as in restaurants, that certain types of dishes are likely to have been prepared from dehydrated or canned potatoes and thus may contain sulfites. Consequently, they will know to avoid such dishes.

Finally, it is much easier for food service personnel to determine whether potatoes are canned or dehydrated than whether they are sulfited or nonsulfited "fresh" potatoes. Thus, with canned and dehydrated potatoes, it is more likely than with "fresh" potatoes that the sulfite-sensitive individual will receive the information he/she needs to know to avoid the product.

The situation is not as clear with frozen potato products. One comment, from a trade association of frozen food producers, stated that its members do not use sulfites to any significant extent in frozen potato products, and that many of its members do not employ sulfites in frozen potato products at all. This trade association stated that it represents, among others, frozen potato processors who produce 80 percent of the frozen potato products produced in this country. Moreover, the Advisory Committee stated that sulfites are not necessary in frozen potato products.

In view of these comments, the agency believes that the possibility exists that sulfite-sensitive consumers may not encounter frozen potato products that are sulfited and labeled to that effect in the retail marketplace. Thus, when presented with dishes prepared from sulfited frozen potatoes in the restaurant setting, the sulfite-sensitive consumer may not know that it is necessary to avoid such dishes to avoid exposure to sulfites.

In an attempt to clarify the issue of the use of sulfites on frozen potato products, the agency is publishing elsewhere in this issue of the **Federal Register,** a notice requesting data on the extent of the use of sulfiting agents on frozen potato products. The agency is requesting data on the levels of use of sulfiting agents on frozen potato products, methods of treatment, purpose for treatment, and the safety of this use. The agency is also requesting data on the economic impact of a finding that this use is not GRAS. Upon receipt of these data, the agency will review them and decide what action is appropriate with respect to the GRAS status of the use of sulfites on frozen potato products as part of the rulemaking initiated with its proposal of December 19, 1988 (53 FR

51065), to affirm that certain uses of sulfites are GRAS.

F. Other Issues

1. One comment urged the agency to exempt "fresh" potatoes from the sulfite ban where the ultimate use of the potatoes is at a health-care facility with in-house professional dietary controls. The main points presented in this argument were that these places have professional dietary staffs responsible for preparing the menus, and that they also have a record of the patients' allergies. These facilities can protect individuals because these patients would not be served the offending food or chemical that may cause the adverse reaction.

The agency recognizes that health-care facilities control some diets. However, the agency is of the opinion that to say that sulfite-treated "fresh" potatoes are GRAS where the ultimate use of these products is at a health-care facility or othe institution with in-house professional dietary controls is not acceptable. This use of sulfites is too narrow in scope for what the agency has traditionally considered for GRAS affirmation. Moreover, even if the in-house dietary controls worked properly all of the time, one would have to consider the likelihood that visitors may eat at some of these institutions without the visitors' medical history being known to the institutional staffers. Sulfite-sensitive individuals who visit these institutions and consume "fresh" potatoes would most likely be exposed unwittingly. Therefore, the agency is not exempting "fresh" potatoes served in institutional or health-care facilities from this action.

The agency believes that such a specific use application could be entertained only under the provisions of the food additive regulations. Parties interested in pursuing specific use applications for sulfites in "fresh" potatoes should submit a petition to FDA in accordance with 21 CFR 171.1 for the agency's evaluation.

2. One comment from a processor of potato products sought clarification as to whether there cooked potato products that use sulfite treatment in conjunction with other processing techniques are exempted from the proposed rule. In subsequent meetings with this firm, it was established that their products are sold as ready-to-use in the restaurant and food service market.

The agency notes that all of the adverse reactions to "fresh" potatoes occurred even though the potatoes had been cooked. The agency believes that potato products that are offered to the consumer as "fresh" will continue to expose the consumer unwittingly to sulfites.

In the preamble to the proposal, the agency defined "fresh" potatoes as those potatoes that are not canned, frozen, or dehydrated. This definition enables the sulfite-sensitive individual, by reading labels, to learn to identify those types of products that are likely to contain sulfites. There is no counterpart on the retail market for "fresh" potatoes, including the cooked potato products described above, that would permit consumers to learn to recognize that these products may contain sulfites, and that sulfite-sensitive individuals should avoid them.

Because these cooked potato products could lead to unwitting exposure to sulfites by sulfite-sensitve individuals, the agency does not believe that the use of sulfites in these kinds of potato products is GRAS. Therefore, the agency concludes that potatoes processed as described in the comment are included among those uses that are no longer GRAS.

3. One comment claimed that the proposal creates a major inequity between "fresh" potatoes and other vegetables. This comment maintains that the use of sulfites on vegetables is permitted if they are cooked before reaching the consumer, whereas FDA is proposing to ban sulfites on "fresh" potatoes even though they are also cooked before reaching the consumer.

The agency does not agree that this proposal creates a major inequity between "fresh" potatoes and other vegetables concerning sulfites. In the Federal Register of December 19, 1988 (53 FR 51065), the agency considered the uses of sulfites that are GRAS. The agency proposed to affirm as GRAS the use of sulfites in canned vegetables, including canned potatoes, at a maximum level of 30 parts per million (ppm) and in dehydrated vegetables at 200 ppm (500 ppm for dehydrated potatoes). It did not propose to affirm as GRAS the use of sulfites on fresh vegetables that are subsequently cooked and served or sold unlabeled to the consumer. Thus, FDA's treatment of the use of sulfites on "fresh" potatoes and on other vegetables is consistent.

III. Conclusions on Safety

After evaluating the issues and information presented in the comments on the proposal and all other evidence, the agency has determined that a consensus does not exist that the use of sulfiting agents on "fresh" potatoes that are served or sold unpackaged and unlabeled to consumers is safe. Despite the actions described (research, education, selective certification, institutional use) to control consumer exposure to sulfites in "fresh" potatoes, the agency finds that the potential remains for unwitting consumer exposure to these chemicals. When a sulfite-sensitive individual experiences such exposure, he/she is very likely to suffer an allergic-type reaction. Therefore, FDA concludes that this use of sulfites can no longer be considered to be GRAS.

Consequently, the agency is amending part 182 to exclude the use of sulfiting agents on "fresh" potatoes that are served or sold unpackaged and unlabeled to consumers from the uses of sulfiting agents that are GRAS. The use of sulfiting agents on "fresh" potatoes intended to be served or sold unpackaged and unlabeled to consumers would constitute the use of unapproved food additives and would, therefore, cause any "fresh" potatoes to which they have been added to be adulterated and in violation of section 402(a)(2)(C) of the act (21 U.S.C. 342(a)(2)(C)).

No comments that asserted a prior sanction were submitted in response to the proposal. As noted in the proposal, the agency recognizes that the use of sulfites on potatoes predates 1958, and that the use of sulfites on one or more specific potato products may be the subject of a prior sanction. However, reliance on that sanction would not be sufficient justification to continue this use of sulfiting agents. While a prior sanction may exempt a substance from being a food additive under section 201(s) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(s)), use of that substance would still be unlawful because it would render the food adulterated under section 402(a)(1) of the act (21 U.S.C. 342(a)(1)).

IV. Issues Related to Economic Impact

In the December 10, 1987, proposal (52 FR 46968 at 46976), FDA noted that it had examined the economic impact of deciding that the use of sulfites on "fresh" potatoes is not GRAS. The agency discussed the health concerns that prompted the action, certain possible responses to this action by restaurants and the food service industry, and the resultant cost impacts of the proposed action. In recognition of the uncertainty in its estimate of the cost impacts, the agency requested "substantive data concerning the proposed action or other regulatory options to be used in a regulatory impact analysis or a regulatory flexibility analysis." No new data were submitted in response to the proposal that could be used as a basis for a reassessment of the economic impacts

of declaring that the use of sulfites on "fresh" potatoes that are served or sold unlabeled and unpackaged to consumers is not GRAS. The agency discusses below the specific comments that it received that related to the economic impact of the proposal.

A. Direct Economic Effects

Comments from a trade association and a processor claimed that the proposal on the use of sulfites on "fresh" potatoes should be classified as a major rule because the proposal as written grossly underestimates its financial impact. According to these comments, there are no practical alternatives to sulfites. Therefore, because the ban would virtually eliminate the market for "fresh" potatoes, its economic impact would make it a "major rule." According to these comments, the alternative products are more expensive, some potato growers would be left without a market, and some employees would lose their jobs. Specifically, the comments claimed that 2,500 or more jobs would be lost, 50 to 100 potato processors/potato growers would be forced out of business, and $115 to $153 million in sales would be displaced or lost.

The processor of sulfited potato products claimed that a ban on sulfites at the processor level would force it to cease its "fresh" potato operations. This firm stated that it supplies "fresh" potato products to all State-operated health care institutions in eastern and metropolitan New York, all municipal New York City hospitals, and all Marine Corps bases in North Carolina and South Carolina. This firm stated that its "fresh" potato processing business accounts for over $2 million in gross revenues. Its "fresh" potato processing business employs 40 individuals full time, including 25 handicapped persons.

The threshold assessment evaluated all the information available to the agency at the time of publication of the proposal. The threshold assessment discussed the expected economic impacts on users of "fresh" potato products and on processors and suppliers of "fresh" potato products (Ref. 2).

With regard to potato growers, the agency does not have any data to support the view that they will go out of business as a result of this final rule. FDA has received information from potato growers that indicated that "fresh" potato processors usually purchase the lower grades of potatoes for their operation (Ref. 3). According to the United States Department of Agriculture (USDA), however, "fresh" processed potatoes are of the same grade as fresh unprocessed potatoes sold in supermarkets, so that any potatoes not sold to processors will be sold in supermarkets (Ref. 4). In the latter case, the price differential is small enough so that growers should not suffer a large loss. Either way, FDA believes that most growers will continue to sell to the "fresh" potato processors as most "fresh" potato processors will continue to produce their product with sulfite substitutes. The agency has received comments that indicated that alternative methods would increase costs of the products by less than 2 cents per pound. Moreover, because "fresh" potato processors use only 2 percent of the potatoes produced in this country, it is unlikely that any potato growers will go out of business because of this action.

With respect to the comment concerning the direct economic impact on "fresh" potato processors, FDA acknowledges that most of the impact of this regulation will be borne by this segment of the industry. However, the agency believes that the survey upon which the figures contained in the comment were based was flawed. Estimates of sales and numbers of employees were based on all products that these firms produce, not just "fresh" potatoes. Many of the firms that produce "fresh" potatoes also produce other potato products and other prepared vegetables (Ref. 5). Thus, the numbers of total employees and sales were overestimated. Moreover, at the time this survey was conducted (March 1986), much of the recent innovation in sulfite substitutes had not yet been completed. As a consequence, most producers believed that they would no longer be able to produce "fresh" potato products without sulfites because there were no viable substitutes at the time, and they responded to the questions accordingly. There are now a number of viable, albeit more expensive, substitutes on the market.

Thus, the agency finds that the data available to the agency do not provide any basis to conclude that there will be substantial lost or displaced sales or unemployment as a result of this action. Furthermore, FDA does not believe that any firms will go out of business as a result of this final rule. What is more likely is that processors will use one of the chemical sulfite alternatives currently available which are discussed in the next section of this document, possibly accompanied by a modified production procedure and delivery schedule. Furthermore, FDA considers it likely that adoption of this final rule will spur development of more and better chemical and processing alternatives to sulfites. Because of adverse publicity surrounding sulfites, some "fresh" potato processors already have changed to sulfite-free "fresh" potato processing (Refs. 6 and 7).

Based on the above considerations, the agency concludes that the use of sulfiting agents by "fresh" potato processors is not universal, and that current users have not demonstrated that they are economically dependent on sulfiting agents. Therefore, the agency concludes that, given the available information, this regulation will not produce a major economic impact on "fresh" potato processors or a significant economic impact on a substantial number of small entities.

B. Possible Substitutes for Sulfites

Several comments addressed the use of substitutes for sulfites. Members of Congress reported on a survey conducted by the "fresh" potato processing industry. The study found that 94 percent of the 33 respondents stated that they had tried substitutes for sulfites, but that the results were unsatisfactory. The comments did not state why the substitutes were considered unsatisfactory.

On the other hand, one comment from a processor of "fresh" potato products stated that it had not used sulfites since June 1986, and that it had produced products that are adequate to serve a market area with an approximately 400-mile radius. Another comment, from a processor of "fresh" potato products, stated that it has two client companies using its nonsulfite process on "fresh" potatoes, and that these companies have been using its process for over 2 years. A comment from a chemical supplier contended that numerous alternatives to sulfites are available for potatoes and specifically recommended its brand of sodium polyphosphate. Another comment, from a research company, indicated that it has an alternative product available that adds approximately 1 cent per pound to the price of processed potatoes while giving a shelf life of 7 to 10 days. According to this comment, if special packaging is used, the shelf life can be extended beyond 10 days. These comments have generally lacked specifics that would enable the agency to weigh them against the comments that alternatives do not work satisfactorily.

A blanket statement that none of the sulfite-free processes work is belied by the evidence that there are companies marketing "fresh" potato products that do not use sulfites. This evidence supports the conclusion that there are alternatives to sulfites. FDA has had informal discussions with some of these processors. Although they refused to

provide details on proprietary information to the agency, these processors have indicated that they are willing to make their processes available to the "fresh" potato industry.

A comment from a trade association stated that one potential alternative, EDTA (ethylenediaminetetraacetic acid), is not approved by FDA for use on "fresh" potatoes. This comment asked whether the agency would be inclined to put a food additive petition for a substitute for sulfites, such as EDTA, on a fast track.

The agency notes that the length of time necessary to amend food additive regulations is dependent on several variables. Foremost among these variables is the thoroughness and adequacy of the submitted petition in terms of the data required (e.g., chemistry and toxicological data) to demonstrate that the requested use of the substance is safe, and that the substance will have its intended technical effect. Therefore, most of the variables that control the length of time required for the agency to act on a petition are under the control of the petitioner. Nevertheless, consistent with its other priorities, the agency would agree to give prompt attention to petitions for substitutes.

The agency notes that existing safety data for EDTA support only the listed food additive uses of the ingredient. Expanded uses would likely require additional toxicity studies.

In accordance with the Regulatory Flexibility Act, the agency previously considered the potential effects that this rule would have on small entities, including small businesses. The agency determined that no significant impact on a substantial number of small entities would derive from this action. FDA has not received any new information or comments that would cause it to alter that determination.

In accordance with Executive Order 12291, FDA has previously analyzed the potential economic effects of this final rule. As announced in the proposal, the agency determined that the rule is not a major rule as determined by the Order. The agency has not received any new information or comments that would cause it to alter that determination.

The agency's findings of no major economic impact and of no significant impact on a substantial number of small entities, and the evidence supporting these findings, are contained in a threshold assessment which may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm 4–62, 5600 Fishers Lane, Rockville, MD 20857.

V. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposal (December 10, 1987; 52 FR 46968). No new information or comments have been received in response to the proposal that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

VI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum dated January 3, 1989, from Chief, Clinical Nutrition Section to Health Hazards Evaluation Board, "Quarterly Report on Adverse Reactions Associated with Sulfiting Agents".

2. "Threshold Assessment of the Proposed Rule to Revoke the GRAS Status of Sulfiting Agents on 'Fresh' Potatoes", prepared by the Office of Planning and Evaluation, FDA.

3. Memorandum of Conference, held February 21, 1989, between FDA and the National Potato Council.

4. Memorandum of Telephone Conversation between Richard A. Williams, Jr., FDA, and Shannon Hamm, USDA, May 16, 1989.

5. "An Economic Impact Study of a Food and Drug Administration Potential Ban on the Use of Sulfites for Fresh Processed Potatoes—Prepared for the National Coalition of Fresh Potato Processors," by Agri-Commodities, Inc., March 1986.

6. Letter dated February 4, 1988, from John W. Hodder, Double D Foods, Inc., P.O. Box 988, Pleasanton, CA 94566, to Dockets Management Branch, FDA.

7. Letter dated February 5, 1988, from Dennis Hawley, President, Beacon Street Kitchen, P.O. Box 2464, South San Francisco, CA 94083, to Dockets Management Branch, FDA.

List of Subjects in 21 CFR Part 182

Food ingredients, Food packaging, Spices and flavorings.

Therefore, under the Federal Food, Drug, and Cosmetic Act, 21 CFR part 182 is amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR part 182 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

2. Section 182.3616 is amended by revising paragraph (c) to read as follows:

§ 182.3616 Potassium bisulfite.

* * * * *

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with current good manufacturing practice, except that it is not used in meats; in food recognized as a source of vitamin B_1; on fruits or vegetables intended to be served raw to consumers or sold raw to consumers, or to be presented to the consumer as fresh; and on "fresh" potatoes that are intended to be served or sold unpackaged and unlabeled to the consumers. For purposes of this paragraph the term " 'fresh' potatoes" applies to any form of potato other than frozen, canned, or dehydrated potatoes.

3. Section 182.3637 is amended by revising paragraph (c) to read as follows:

§ 182.3637 Potassium metabisulfite.

* * * * *

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with current good manufacturing practice, except that it is not used in meats; in food recognized as a source of vitamin B_1; on fruits or vegetables intended to be served raw to consumers or sold raw to consumers, or to be presented to the consumers as fresh; and on "fresh" potatoes that are intended to be served or sold unpackaged and unlabeled to the consumer. For purposes of this paragraph the term " 'fresh' potatoes" applies to any form of potato other than frozen, canned, or dehydrated potatoes.

4. Section 182.3739 is amended by revising paragraph (c) to read as follows:

§ 182.3739 Sodium bisulfite.

* * * * *

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with current good manufacturing practice, except that it is not used in meats; in food recognized as a source of vitamin B_1; on fruits or vegetables intended to be served raw to consumers or sold raw to consumers, or to be presented to the consumer as fresh; and on "fresh" potatoes that are intended to be served or sold unpackaged and unlabeled to the consumer. For purposes of this paragraph the term " 'fresh' potatoes" applies to any form of potato other than frozen, canned, or dehydrated potatoes.

5. Section 182.3766 is amended by revising paragraph (c) to read as follows:

§ 182.3766 Sodium metabisulfite.

* * * * *

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with current good manufacturing practice, except that it is not used in meats; in food recognized as a source of vitamin B_1; on fruits or vegetables intended to be served raw to consumers or sold raw to consumers, or to be presented to the consumer as fresh; and on "fresh" potatoes that are intended to be served or sold unpackaged and unlabeled to the consumer. For purposes of this paragraph the term " 'fresh' potatoes" applies to any form of potato other than frozen, canned, or dehydrated potatoes.

6. Section 182.3798 is amended by revising paragraph (c) to read as follows:

§ 182.3798 Sodium sulfite.

* * * * *

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with current good manufacturing practice, except that it is not used in meats; in food recognized as a source of vitamin B_1; on fruits or vegetables intended to be served raw to consumers or sold raw to consumers, or to be presented to the consumer as fresh; and on "fresh" potatoes that are intended to be served or sold unpackaged and unlabeled to the consumer. For purposes of this paragraph the term " 'fresh' potatoes" applies to any form of potato other than frozen, canned, or dehydrated.

7. Section 182.3862 is amended by revising paragraph (c) to read as follows:

§ 182.3862 Sulfur dioxide.

* * * * *

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with current good manufacturing practice, except that it is not used in meats; in food recognized as a source of vitamin B_1; on fruits or vegetables intended to be served raw to consumers or sold raw to consumers, or to be presented to the consumer as fresh; and on "fresh" potatoes that are intended to be served or sold unpackaged and unlabeled to the consumer. For purposes of this paragraph the term " 'fresh' potatoes" applies to any form of potato other than frozen, canned, or dehydrated.

Dated: March 8, 1990.

James S. Benson,

Acting Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services

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