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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. 02–068–2]

Change in Disease Status of Poland Because of BSE

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Affirmation of interim rule as final rule.

SUMMARY: We are adopting as a final rule, without change, an interim rule that amended the regulations by adding Poland to the list of regions where bovine spongiform encephalopathy exists because the disease had been detected in a native-born animal in that region. Poland had already been listed among the regions that present an undue risk of introducing bovine spongiform encephalopathy into the United States, so the effect of the interim rule was a continued restriction on the importation of ruminants, meat, meat products, and certain other products of ruminants that have been in Poland. The interim rule was necessary in order to update the disease status of Poland regarding bovine spongiform encephalopathy.

EFFECTIVE DATE: The interim rule became effective on May 5, 2002.

FOR FURTHER INFORMATION CONTACT: Dr. Gary Colgrove, Chief Staff Veterinarian, Sanitary Trade Issues Team, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–4356.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR parts 93, 94, 95, and 96 (referred to below as the regulations) govern the importation of certain animals, birds, poultry, meat, other animal products and byproducts, hay, and straw into the United States in order to prevent the introduction of various animal diseases, including bovine spongiform encephalopathy (BSE).

In an interim rule effective May 5, 2002, and published in the **Federal Register** on July 1, 2002 (67 FR 44016–44018, Docket No. 02–068–1), we amended the regulations in § 94.18(a)(1) by adding Poland to the list of regions where BSE exists. Poland had previously been listed in § 94.18(a)(2) as a region that presents an undue risk of introducing BSE into the United States. However, due to the detection of BSE in a native-born animal in that region, the interim rule was necessary to update the disease status of Poland regarding BSE.

Comments on the interim rule were required to be received on or before August 30, 2002. We received one comment by that date. The commenter fully supported the interim rule.

Therefore, for the reasons given in the interim rule, we are adopting the interim rule as a final rule.

This action also affirms the information contained in the interim rule concerning Executive Order 12866 and the Regulatory Flexibility Act, Executive Order 12988, and the Paperwork Reduction Act.

Further, for this action, the Office of Management and Budget has waived its review under Executive Order 12866.

List of Subjects in 9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, HOG CHOLERA, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

Accordingly, we are adopting as a final rule, without change, the interim rule that amended 9 CFR part 94 and that was published at 67 FR 44016 on July 1, 2002.

Authority: 7 U.S.C. 450, 7711–7714, 7751, 7754, 8303, 8306, 8308, 8310, 8311, and 8315; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 42 U.S.C. 4331 and 4332; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 30th day of September 2002 .

Peter Fernandez,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 02–25247 Filed 10–3–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 163

[Docket Nos. 86P–0297 and 93P–0091]

White Chocolate; Establishment of a Standard of Identity

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is establishing a standard of identity for white chocolate. This standard will provide for the use of the term ''white chocolate'' as the common or usual name of products made from cacao fat (i.e., cocoa butter), milk solids, nutritive carbohydrate sweeteners, and other safe and suitable ingredients, but containing no nonfat cacao solids. The standard for white chocolate will promote honesty and fair dealing in the interest of consumers and, to the extent practicable, will achieve consistency with existing international standards of identity for white chocolate. This standard is established in response to citizen petitions submitted separately by the Hershey Foods Corp. (Hershey) and by the Chocolate Manufacturers Association of the United States of America (CMA).

DATES: This rule is effective January 1, 2004. This rule is applicable to all affected products initially introduced or initially delivered for introduction into interstate commerce on or after January 1, 2004. Voluntary compliance may begin immediately.

FOR FURTHER INFORMATION CONTACT: Geraldine A. June, Center for Food Safety and Applied Nutrition (HFS–822), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 10, 1997 (62 FR 10781), FDA published a proposal to establish a standard of identity for white chocolate. The proposal responded to petitions submitted separately by Hershey and by CMA. The petitions requested that FDA establish a standard of identity for ''white chocolate.'' Both Hershey and CMA described ''white chocolate'' as a food that deviates from the standardized cacao products in part 163 (21 CFR part 163) in that: (1) It is prepared without the nonfat components of the ground cacao nibs but contains the fat (cocoa butter) expressed from the ground cacao nibs; and (2) it may contain safe and suitable antioxidants. The petitioners further described ''white chocolate'' as the solid or semiplastic food prepared by mixing and grinding cocoa butter with one or more nutritive sweeteners and one or more of the optional dairy ingredients provided in part 163. The petitioners stated that ''white chocolate'' contains not less than 20 percent cocoa butter, not less than 14 percent of total milk solids, not less than 3.5 percent milkfat, and not more than 55 percent nutritive carbohydrate sweeteners.

The petitioners maintained that a standard of identity for ''white chocolate'' would provide several benefits: (1) Reducing economic deception and promoting honesty and fair dealing in the interest of consumers, (2) increasing the availability of products containing white chocolate by eliminating the requirement that firms receive temporary marketing permits (TMPs), and (3) enhancing the international marketability of white chocolate by establishing a standard consistent with international standards for white chocolate.

Based on FDA's review of the information provided in the petitions, we (FDA) tentatively concluded that it would be reasonable to establish a standard of identity for ''white chocolate.'' We tentatively concluded that use of the term would aid consumer recognition of the food and would promote honesty and fair dealing in the interest of consumers by eliminating the potential for economic fraud and consumer deception through the substitution of cheaper ingredients for cacao-derived ingredients. Furthermore, the agency tentatively concluded that: (1) Consumer confusion created by the use of alternative names for white chocolate-type confections would also be eliminated and (2) use of the standardized term ''white chocolate'' would enhance the international marketability of such products. Based on these tentative conclusions, FDA published a proposed rule to establish a standard of identity for ''white chocolate,'' consistent with the product described in the petitions (62 FR 10781 at 10786).

FDA received seven responses to the proposal, each containing one or more comments. Six responses were from companies that manufacture or market chocolate products, and the other was from a trade association. Most of the comments supported the establishment of a standard of identity for white chocolate. Other comments either opposed the establishment of a standard of identity for white chocolate or suggested modifications or revisions to various provisions of the proposed standard.

After considering the comments, FDA concludes that issuing a food standard for white chocolate will promote honesty and fair dealing in the interest of consumers. Specifically, a food standard for white chocolate will permit the sale of a product labeled ''white chocolate'' without TMPs and ensure that such products contain cacao-derived ingredients. The standard will distinguish white chocolate from the other standardized chocolate products, which contain chocolate liquor. Also, by eliminating requirements for TMPs, the standard will benefit consumers by allowing manufacturers to introduce white chocolate more quickly. Finally, the white chocolate food standard, which is consistent with the standards of Canada, the European Union (EU), and Codex Alimentarius Commission (Codex), will promote international harmonization.

II. Comments and the Agency's Response

(Comment 1) One comment opposed creating a standard of identity for white chocolate. The comment contended that a TMP is not required to sell white chocolate in the United States because the name ''white chocolate'' is sufficiently different from the names of standardized chocolate products. Thus, the comment contended, elimination of the TMP process is not a valid justification for the establishment of a standard of identity. The comment maintained that FDA is promoting the use of TMPs for all new products that may be perceived as variations of existing standardized products, no matter how easily distinguishable they may be, and even though there is no consumer confusion or deception. The comment further maintained that FDA could conserve agency resources by giving guidance that the TMP process will no longer be required for white chocolate products.

We disagree with the assertion that TMPs are not needed to market white chocolate products in the absence of a standard of identity. A product labeled as ''white chocolate'' contains the term ''chocolate,'' an alternative nomenclature for chocolate liquor that indicates the presence of cacao-derived ingredients. All existing chocolate standards include the cacao-derived ingredient chocolate liquor, which contains both the nonfat and the fat components of the cacao nibs. In contrast, the cacao-derived ingredient contained in products that consumers have come to know as ''white chocolate'' is cacao fat (i.e., cocoa butter), not chocolate liquor. Because the term ''chocolate'' implies that the product contains cacao-derived ingredients similar to those in standardized chocolate products, in the absence of a standard of identity or TMP, the product described in the proposed standard could not use the term ''chocolate'' on its labeling. Specifically, a product labeled ''white chocolate'' would purport to be chocolate, but it would not comply with the current food standards for cacao products in part 163. Therefore, the product would be misbranded under section 403(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343 (g)).

(Comment 2) The one comment that objected to the establishment of a standard of identity for white chocolate suggested that FDA should reconsider the need for a standard of identity and should regulate white chocolate like other nonstandardized products. The comment maintained that: (1) Only a few foods are currently governed by standards of identity; (2) most existing standards were adopted more than 25 years ago; (3) thousands of newly introduced foods have been regulated successfully under common or usual name regulations part 102 (21 CFR part 102) and under general misbranding provisions (section 403 of the act); and (4) standards do not play the same role in the regulatory scheme as they did many years ago when product names were the primary source of product information for consumers. The comment credited the success of using common or usual name regulations and general misbranding provisions to regulate nonstandardized foods to the additional ingredient and nutrition information now required on food labels. The comment pointed out that even though there is a standard for French dressing, there is no standard for ranch dressing. Analogously, the

comment asserted that white chocolate is not inherently different from the thousands of other nonstandardized foods and, therefore, there is no need for a standard of identity for white chocolate.

FDA does not agree that a common or usual name regulation for white chocolate is sufficient to ensure honesty and fair dealing in the interest of consumers. First, FDA disagrees with the assertion that there are only a few standards of identity and that many more foods are regulated under common or usual name regulations. There are over 280 standards of identity, but there are only 16 common or usual name regulations.

When deciding whether it is appropriate to establish a standard of identity or a common or usual name regulation, FDA must consider which is more likely to ensure that consumers are not deceived or misled. Food standards are appropriate and necessary when there is a need to prescribe the entire compositional requirement for a food, in addition to the name of the food. In contrast, common or usual name regulations are appropriate if there is a need simply to establish a uniform and informative name for the food.

Because products bearing the name ''chocolate'' would be expected to contain some cacao-derived ingredients, we believe that it is necessary to ensure that ''white chocolate'' contains cacao-derived ingredients. If FDA establishes a common or usual name regulation for ''white chocolate,'' rather than a standard of identity, it would be necessary to include in the common or usual name a statement of the percentage of the characterizing ingredient, cacao fat, as provided in § 102.5(b). We disagree that establishing a common or usual name in this manner is the appropriate way to protect consumers' interests. The required additional labeling regarding the name and percentage of the characterizing ingredient, cacao fat, in the common or usual name might be confusing to consumers, especially because the amount of cacao fat would be disclosed differently than the amount of total fat in the nutrition label. A food standard eliminates the need for additional labeling. Therefore, FDA concludes that the appropriate way to ensure the composition of ''white chocolate'' and to protect consumers' interests is by establishing a standard of identity and not a common or usual name.

Moreover, at the time that they were established, one of the benefits of common or usual name provisions in part 102 was that names of new products could be established by regulation using ''informal'' notice and comment rulemaking, rather than the lengthy formal rulemaking procedures required for food standards. Since passage of the Nutrition Labeling and Education Act of 1990 (Public Law 101–35), which amended the act, FDA can establish new standards of identity for most foods by ''informal'' notice and comment rulemaking proceedings. In view of this change, FDA does not see any benefit to establishing a common or usual name regulation instead of a food standard to ensure that the product known as ''white chocolate'' contains cacao-derived ingredients.

Finally, FDA agrees that there are many products on the market that are regulated without standards of identity. However, we disagree with the comment's suggestion that requirements imposed after most of the food standards were created have rendered food standards unnecessary. The nutrition information that is required on the labels of standardized and nonstandardized foods gives consumers information on the levels of nutrients in products to assist them in making purchasing choices related to nutrient content. Nutrition information does not inform consumers of a product's formulation. In addition, ingredient labeling alone may be insufficient to differentiate two standardized products. For example, the ingredient lists for both milk chocolate and sweet chocolate may be identical (containing chocolate, nutritive carbohydrate sweeteners, and dairy products).

(Comment 3) The comment that opposed creation of a food standard further stated that, from a legal perspective, a standard of identity is not needed to authorize the sale of white chocolate in this country because: (1) White chocolate is an appropriately descriptive statement of identity, independent of existing standards; (2) the name ''white chocolate'' is sufficiently different from the names of other chocolate products; (3) white chocolate does not purport to be a standardized food; (4) the identity and fundamental positioning of white chocolate are predicated on the difference between white chocolate and chocolate; and (5) the appearance of white chocolate is in such stark contrast to traditional chocolate, which is brown in color, as to guarantee that no ''passing-off'' issue exists. The comment contended that FDA cited no evidence of consumer confusion with white chocolate, no evidence that consumer confusion would exist in the absence of a standard of identity for white chocolate, and no evidence of consumer confusion regarding the thousands of other nonstandardized foods on the market. The comment asserted that, in the absence of such evidence, FDA has no grounds for creating a standard of identity for white chocolate because the statutory threshold for regulation is not satisfied, i.e., that a standard of identity for white chocolate would promote honesty and fair dealing in the interest of consumers. The comment contended that FDA is maintaining and extending food standards without consideration of their actual utility or consumer benefit, and without regard to the labeling requirements now in effect. Therefore, the comment urged FDA to regulate white chocolate as a nonstandardized food and not to establish a standard of identity for white chocolate.

FDA disagrees with the comment's assertion that a standard of identity is not needed to sell a product bearing the name ''white chocolate.'' Our reasoning as to why a food standard or TMP is required to label a product as ''white chocolate'' is set forth in response to comment 1, section II of this document. In short, absent a food standard or TMP, a food labeled ''white chocolate'' purports to be chocolate, which is the subject of a food standard under § 163.111(c) requiring that the product be prepared by finely grinding cacao nibs (contains both the nonfat and fat components). The product is misbranded in violation of section 403(g) of the act because it does not conform to the definition and standard for chocolate in that it does not contain the nonfat portion of the cacao nibs.

Furthermore, we disagree with the comment that there is no legal basis on which to establish a food standard for white chocolate. The term ''chocolate'' has traditionally been used for standardized foods that contain cacao-derived ingredients, specifically chocolate liquor (§ 163.111). These standardized foods include sweet chocolate (§ 163.123), milk chocolate (§ 163.130), buttermilk chocolate (§ 163.135), skim milk chocolate (§ 163.140), mixed dairy product chocolate (§ 163.145), sweet chocolate and vegetable fat coating (§ 163.153), and milk chocolate and vegetable fat coating (§ 163.155). Because of this longstanding practice, consumers expect that products bearing names that include the term ''chocolate'' contain certain cacao-derived ingredients. While the product described in the proposed standard deviates from the other standardized chocolate products in that it contains only the cacao fat (i.e., cocoa butter) component of chocolate liquor, consumers' expectations that the food's basic component is derived from cacao

are met by establishing a standard with that requirement.

Moreover, use of the term ''white chocolate,'' without an accompanying food standard, does not provide consumers with sufficient information as to the ingredients of the product. Historically, FDA has created separate standards of identity for different kinds of chocolate (e.g., milk chocolate, sweet chocolate). These standards ensure that consumers who purchase products labeled as ''chocolate'' receive a familiar product with a certain basic nature and composition. Neither the term ''white'' nor the white appearance of the product itself is sufficient to distinguish a white chocolate-type product that does not contain cacao-derived ingredients from a product that does contain cacao-derived ingredients. Use of the term ''chocolate'' in the name ''white chocolate'' implies that the product is cacao-derived. Thus, without a standard of identity prescribing that white chocolate be made from cocoa butter, manufacturers may produce products not containing cacao-derived ingredients and use the term ''white chocolate'' in a misleading manner.

(Comment 4) The one comment that objected to establishing a standard of identity for white chocolate stated that a standard of identity for white chocolate is not needed because white chocolate-type products made with ingredients not derived from cacao could be identified as ''white chocolate-flavored'' or ''artificially flavored'' to sufficiently distinguish them from white chocolate products derived from cacao. The comment further stated that consumers could look at the ingredient list to discover the substitution of less expensive ingredients not derived from cacao; thus, current regulations are sufficient to prevent economic deception.

FDA does not agree that identifying white chocolate products made from cheaper noncacao ingredients as ''artificially flavored'' or ''white chocolate-flavored'' would be sufficiently descriptive with regard to the composition of white chocolate. These terms refer to the characterizing flavor of a food, not its composition. The terms suggest products that are flavored to taste like white chocolate, but they do not provide guidance as to white chocolate's composition. Thus, use of such terms does not negate the need for a standard of identity, but rather further supports its need because, without a definition and standard for ''white chocolate,'' there is no way to define ''white chocolate-flavored.'' Moreover, FDA regulations governing use of the term ''flavored'' § 101.22(i)(1)(i) (21 CFR 101.22(i)(1)(i)) provide that a product that is expected to contain an ingredient, e.g., ''white chocolate,'' must bear the term ''flavored'' in the name of the food if the food contains natural flavor derived from that ingredient and either an amount of the ingredient insufficient to independently characterize the food or none of the ingredient. Therefore, unless a food contains the flavoring constituents derived from white chocolate, it cannot be named ''white chocolate-flavored.''

Once a standard for white chocolate has been established, the term ''white chocolate-flavored'' could be used to describe a food that is commonly expected to contain the characterizing food ingredient, white chocolate, and which contains natural flavor derived from such an ingredient (i.e., cocoa butter or cacao fat) (§ 101.22(i)(1)(i)). The term ''artificially-flavored white chocolate'' could be used in cases where the food contains an artificial flavor that simulates, resembles, or reinforces the characterizing flavor (§ 101.22(i)(2)).

The only constituent in white chocolate that is derived from the cacao bean is cacao fat (i.e., cocoa butter); therefore, the agency assumes that if a cheaper ingredient that was not derived from cacao were used to replace the cacao-derived ingredient, the substitute ingredient would be some type of fat or oil used to replace the cacao fat. In this case, the agency would treat such products as substitute or imitation white chocolate products (21 CFR 101.3(e)) and would not regulate them by requiring that they be labeled ''white chocolate-flavored.''

(Comment 5) The one comment that opposed issuing a standard of identity for white chocolate argued that food standards should be reformed. The comment stated that, in the advance notice of proposed rulemaking (ANPRM) (60 FR 67492, December 29, 1995) that responded to the Regulatory Reinvention Initiative, FDA acknowledged that existing food standards of identity are the types of regulations that need reform. The comment stated that there is no special circumstance that justifies a reversal of regulatory direction for white chocolate.

A few comments addressed the nature of the proposed standard of identity for white chocolate, objecting to its being prescriptive, recipe-based, and rigid. One of these comments, while supporting establishment of a standard of identity for white chocolate, made broader general statements about reforming food standards. In addition, several comments from manufacturers who support creating a standard for white chocolate supported FDA's intention to address all standards, including any new standard of identity for white chocolate, as a separate subject in accordance with the Regulatory Reinvention Initiative.

FDA stated in the ANPRM that standards of identity may need reform, and we are reviewing existing food standards in response to the Regulatory Reinvention Initiative. After deciding to establish a standard of identity for white chocolate, FDA considered whether to: (1) Continue the TMP process until all standards are reviewed in response to the Regulatory Reinvention Initiative and then establish a standard for white chocolate, (2) use different guiding principles to issue a standard, or (3) issue a standard consistent with the petitioners' requests and with existing standards. We concluded that the third approach was the most reasonable and efficient, considering our limited resources, industry's desire to establish a standard, and recognized consumer demand for the product. This approach avoids the time consuming task of reviewing and revising standards for a group of foods, e.g., chocolate products, in a piecemeal fashion, especially when no guiding principles have been published, and relieves industry and the agency from the burdensome TMP process. Therefore, FDA concludes that a standard for white chocolate should be issued that is generally consistent with current standards for U.S. chocolate products. FDA will address comments concerning the revision of the standard for white chocolate at such time as we consider revision of all chocolate standards.

FDA recognizes that the proposed standard of identity is prescriptive in nature. However, we believe that until all standards of identity are reviewed and decisions are made regarding whether to retain, revoke, or revise them, it is in the interest of consumers to establish a standard of identity for white chocolate that is generally consistent with other chocolate products in part 163. We also note that standards of identity for white chocolate established by Canada, Codex, and the EU are also prescriptive. Therefore, FDA finds that, at this time, it is appropriate to retain the recipe-like nature of the standard for white chocolate because it is consistent with current U.S. standards for other chocolates and with international standards of identity for white chocolate.

(Comment 6) Two comments suggested changes to the proposed standard to make the U.S. standard for white chocolate more consistent with international standards. One comment

noted that the maximum level for emulsifiers in the proposed standard for white chocolate is adequate, but suggested that in the interest of international harmonization, FDA consider raising this level from 1 percent to 1.5 percent. The comment stated that if this were done, the proposed standard would then be consistent with those of Canada and Codex. The comment emphasized that it raised the issue solely in the interest of international harmonization, but did not want the issue to delay a prompt promulgation of the standard.

We agree that international harmonization should be taken into consideration in establishing standards and should be supported when such support promotes honesty and fair dealing in the interest of consumers, does not endanger the public health, and does not reduce the integrity of the standard. FDA believes that raising the level of permitted emulsifiers to 1.5 percent will not result in an inferior product, and the standard for white chocolate will still promote honesty and fair dealing in the interest of consumers. Therefore, the agency agrees that, to reduce barriers to trade, the level of emulsifiers should be changed to 1.5 percent.

The other comment recommended that FDA revise the proposed standard to permit the use of whey as an optional ingredient up to a level of 5 percent. The comment stated that whey should be listed in § 163.124(b)(6) as an optional ingredient so that it would not count toward the minimum milk solids content otherwise specified in the standard (§ 163.124(b)(2)). The comment contended that whey is a safe and suitable ingredient for use in chocolate and confectionery products.

The comment further stated that if the U.S. standard were adopted without permitting whey, it would be the only major white chocolate standard in the world that did not permit its use. According to the comment, Canada plans to issue a standard that expressly permits the addition of whey up to 5 percent. The comment stated that both the Codex and the EU standards permit the addition of whey in chocolate products. The comment asserted that the United States should include whey in its standard for white chocolate in the interest of international harmonization. Finally, the comment noted that delaying consideration of the use of whey until the generalized review of chocolate standards takes place would likely result in a delay of several years.

FDA agrees with the comment that whey should be permitted as an optional ingredient up to a level of 5 percent but should not count toward the minimum milk solids content otherwise specified in the standard. Listing whey as a separate ingredient, as suggested by the comment, permits the inclusion of whey in addition to, not in place of, the total milk solids specified in § 163.124(b)(2). FDA notes that since publication of our proposed rule to establish a standard for white chocolate, Canada has established a standard for white chocolate that permits as an optional ingredient less than 5 percent whey or whey products. Codex permits no more than 5 percent milk solids in its white chocolate standard, whereas the EU permits edible substances that do not exceed 40 percent of the total weight of the finished white chocolate product. Thus, FDA believes that the change to the proposed standard to permit whey as an optional ingredient would maintain the core ingredients required in the U.S. standard while promoting international harmonization and trade. Accordingly, FDA is modifying the proposed standard to include whey up to a level of 5 percent as a separate, optional ingredient in § 163.124(b)(6).

(Comment 7) One comment recommended deleting the requirement that white chocolate contain a minimum of 23.5 percent fat (20 percent cacao fat + 3.5 percent milkfat). The comment asserted that this high level of fat is inconsistent with current dietary guidelines and with FDA's stated goal to encourage the creation of products lower in fat and calories. The comment stated that it recognized that in order for the product to be designated as ''chocolate,'' it should contain some cacao-derived ingredients. However, the comment contended that the requirement to contain some minimum amount of cacao-derived ingredients could be met by having a minimum amount of cocoa solids. The comment argued that since milk chocolate must contain a minimum of 10 percent cocoa solids in the form of chocolate liquor, it would be consistent for white chocolate to contain a minimum of 10 percent cocoa solids, albeit in the form of cocoa butter. The resulting product, according to the comment, would contain a total of 13.5 percent fat (3.5 percent milkfat and 10 percent cacao fat).

FDA disagrees with changing the minimum level of fat required in white chocolate. The purpose of a standard of identity is to promote honesty and fair dealing in the interest of consumers. The product labeled ''white chocolate'' that has been marketed under TMPs for more than 10 years contains a minimum of 23.5 percent fat. We believe that consumers have come to know the product with this composition. This level is the same as that suggested by the petitioners and required by international standards for white chocolate. Accordingly, FDA has not been persuaded to change the minimum level of fat required.

We appreciate the comment's concern regarding dietary guidelines and note that manufacturers who wish to market products that are lower in fat relative to the standard product may develop lower fat white chocolate products in accordance with the provisions in 21 CFR 130.10.

III. Effective Date

In the proposed rule, FDA proposed that the effective date for a final rule for white chocolate be January 1, 1998 (62 FR 10781 and 10784). The only comment that addressed the proposed compliance date of January 1, 1998, stated that if FDA acted quickly in finalizing the proposal, the proposed compliance date would allow sufficient time for manufacturers to make label and formula changes. Further, the comment encouraged the FDA to state that compliance with the regulation could begin immediately after publication of the final rule issuing the standard.

Due to other agency priorities and to limited resources and staff, FDA is publishing this final rule later than it intended and after the proposed effective date. Consequently, we are revising the effective date of this regulation to the next uniform compliance date, i.e., January 1, 2004, to minimize costs associated with any necessary label changes. However, compliance with this final regulation may begin immediately. All affected products initially introduced or initially delivered for introduction into interstate commerce on or after January 1, 2004, shall fully comply.

There are many firms using TMPs to market products in the United States that are labeled ''white chocolate'' and that comply with the proposed standard. These products will not have to be relabeled. Other products that are labeled with descriptive names (e.g., ''white confection'') will have to relabel their products in compliance with the new standard by the effective date of this rule.

IV. Benefit-Cost Analysis

FDA has examined the economic implications of this final rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select

regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive effects; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of $100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation also is considered a significant regulatory action under Executive Order 12866 if it raises novel legal or policy issues. FDA finds that this final rule is neither an economically significant rule nor a significant regulatory action as defined by Executive Order 12866.

The Unfunded Mandates Reform Act of 1995 (Public Law 104–4), requiring cost-benefit and other analyses, in section 1531(a) defines a significant rule as ''a Federal mandate that may result in the expenditure by State, local, and tribal governments in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation) in any one year.'' FDA has determined that this rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

A. Regulatory Options

FDA is establishing a standard of identity for white chocolate. This standard will provide for the use of the term ''white chocolate'' as the common or usual name of products made from cacao fat, milk solids, nutritive carbohydrate sweeteners, and other safe and suitable ingredients, but containing no nonfat cacao solids. In the benefit-cost analysis of the proposed rule, FDA considered three options:

1. Do not establish a standard and allow manufacturers to market products bearing the name ''white chocolate'' only with TMPs.

2. Establish a standard for white chocolate that is consistent with the standard described in the petitions where the levels of the ingredients are prescribed.

3. Establish a standard of identity for white chocolate with different criteria than those proposed in the petitions.

FDA received no comments that directly addressed the economic analysis of the proposed rule. Results of benefit-cost analysis suggest that the best choice for this proposed rule is the second option: Establish a standard for white chocolate consistent with the standard in the petitions where the levels of ingredients are prescribed. This option is the best choice for several reasons.

First, as stated in the comments that we received, the second option eliminates the time-consuming and burdensome task to manufacturers of applying for TMPs. By establishing a standard of identity for white chocolate and eliminating the need for TMPs, the proposed rule furthers a goal of the Paperwork Reduction Act by eliminating paperwork burden.

Second, while the standard of identity of white chocolate in the second option is somewhat prescriptive, the comments indicated that, at this time, the manufacturers favor a minimum of 23.5 percent total fat in white chocolate. This ''prescriptive'' standard of identity for white chocolate is similar to other published standards for chocolate and will prevent fraudulent or deceptive confections from being offered for sale as ''white chocolate.''

Finally, the standard of identity for white chocolate proposed in the second option is in harmony with the white chocolate standards in use by Canada, Codex, and the EU. Comments on this rule supported the globalization of the white chocolate standard as an important market share-increasing tool.

B. Benefits

We do not estimate benefits and costs for option 1, because it is the baseline. Although the benefits of options 2 and 3 are similar, we expect option 2 to generate higher benefits because it will lead to harmonization with international standards. The other benefits associated with option 2 would also be realized with option 3.

Currently, manufacturers must obtain TMPs if they want to use the term ''chocolate'' to market white chocolate products that meet the proposed standard. The TMPs are required because white chocolate products are considered to deviate from the existing standards of identity for chocolate products. In a recent year, FDA received more than one dozen requests for TMPs for white chocolate. Thus, one benefit of issuing a standard of identity for white chocolate is that it will eliminate a manufacturer's need to prepare and submit requests for TMPs in order to market products bearing the name ''white chocolate.'' This will reduce the paperwork burden to white chocolate manufacturers and reduce the burden to FDA of processing the TMPs.

Establishment of standards of identity for a product is thought to reduce consumer confusion and deception. Well-defined standards of identity, which establish consistent product names, can assist consumers in finding and comparing products by the name of the food. The standard of identity for white chocolate will establish a new product name that, according to the petitions, is consistent with the name that a majority of consumers are already using to describe this product. Comments to this rule indicated that the proposed standard of identity is compatible with not only the perception of United States consumers, but also aligns with the standard of identity for white chocolate as set by Canada, Codex, and the EU. This international harmonization of the white chocolate standard should make U.S.-produced white chocolate more competitive with internationally produced white chocolate, both at home and abroad.

C. Costs

Although we cannot estimate the total costs of this final rule, we expect that the costs of options 2 and 3 will be approximately the same.

The establishment of a standard of identity requires that all products that meet the standard bear the standardized name. If there are products that are formulated in accordance with the standard of identity but are not currently labeled as ''white chocolate,'' then those products will have to be relabeled.

Because ''white chocolate'' will need to appear on each product's principal display panel, the cost for label changes will depend on the number of products that must be relabeled and the amount of time manufacturers are given to complete the label changes. Many of the large chocolate manufacturers are already marketing their white chocolate products under TMPs and will not need to relabel their products.

There are approximately 250 firms that produce chocolate products in the United States, but the number of products whose formulation satisfies this new white chocolate standard of identity is unknown. To estimate the labeling change costs to chocolate producers as a result of the new white chocolate standard of identity, the ''FDA Labeling Cost Model'' (Ref. 1) is used. This model replaces the 1990 version of the model used in the white chocolate proposed rule estimates.

There are 9558 stock keeping units (SKUs) for products represented by the North American Industry Classification System (NAICS) code for Chocolate & Confectionery Products made from cacao beans. Using this SKU information, the ''FDA Labeling Cost Model, Final Report'' estimates the costs per product for a chocolate manufacturer to change the standard of

identity on their principal display panel.

The actual cost of relabeling will be determined largely by the length of time between the date that the rule becomes final and date it becomes effective (the compliance period). Given that January 1, 2004, is the uniform compliance date for food labeling regulations that are issued between January 1, 2001, and December 31, 2002, the cost of relabeling per product for firms averages $4,300 for a minimum-allowed 12-month compliance period, $2,000 for a 24-month compliance period, and $120 for the maximum-allowed 36-month compliance period. Relabeling costs are comprised of administrative costs, printing costs, and costs of lost label inventory.

This final rule will not affect products that do not meet the standard, because they may continue to be produced and marketed as they currently are. FDA is not able to estimate the total cost of this final rule because we received no comments that supplied the additional information necessary.

V. Small Entity Analysis

FDA has examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. FDA finds that this final rule will have a significant economic impact on a substantial number of small businesses.

This final rule will establish a standard of identity for white chocolate. Although the amount of the costs depend on the length of the compliance period, this final rule may impose significant compliance costs on industry, and there may be a significant impact of these provisions on a substantial number of small businesses.

FDA believes that the provision of this final rule most likely to have a significant impact on a substantial number of small businesses is the labeling requirement. There are approximately 250 firms that produce chocolate products (NAICS code 311320) in the United States. Almost all of these businesses have fewer than 500 employees, and thus are small businesses, as defined by the Small Business Administration, FDA has no data on the number of products that will meet the proposed standard and that, therefore, may need to be relabeled.

As discussed in section IV.C of this document, FDA has estimated the average relabeling costs per product for firms to be $4,300, $2,000, and $120, for a 12-month, 24-month, and 36-month compliance period, respectively. Using these average relabeling costs and the ''Model for Estimating the Impacts of Regulatory Costs on the Survival of Small Businesses'' (Ref. 2), the possibility of a small firm closing due to this standard of identity regulation can be estimated. If the compliance period is 12 months in length, the model predicts that approximately 6 firms with less than 500 employees are likely to go out of business. For the 24-month compliance period and the 36-month compliance period, it is expected that no firms are likely to go out of business.

FDA received no comments on the effects of the proposed rule on small businesses or on the length of the compliance period. Because so many small entities are in the industry, we believe that the final rule establishing a standard of identity will have a significant economic impact on a substantial number of small businesses.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we have concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism impact statement is not required.

VII. Environmental Impact

FDA has previously considered the environmental effects of this rule, as announced in the proposed rule (62 FR 10781 at 10785, March 10, 1997). No new information or comments have been received that would affect our previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

VIII. The Paperwork Reduction Act of 1995

In the proposal, FDA stated its tentative conclusion that the proposed rule contains no reporting, recordkeeping, labeling, or third party disclosure requirements and asked for comments on whether the proposed rule imposed any paperwork burden. No comments were received addressing the question of paperwork burden. FDA concludes that the labeling requirements in this document are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the labeling statements are a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320(c)(2)).

IX. References

The following references have been placed on display at the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. ''FDA Labeling Cost Model, Final Report;'' M. K. Muth, E. C. Gledhill, and S. A. Karns; RTI, Health, Social, and Economics Research, Research Triangle, NC; April 2002.

2. ''Model for Estimating the Impacts for Regulatory Costs on the Survival of Small Businesses and its Application to Four FDA-Regulated Industries,'' final report, Eastern Research Group, July, 2002.

List of Subjects in 21 CFR Part 163

Cacao products, Food grades and standards.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 163 is amended as follows:

PART 163—CACAO PRODUCTS

1. The authority citation for 21 CFR part 163 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 341, 343, 348, 371, and 379(e).

2. Section 163.124 is added to subpart B to read as follows:

§ 163.124 White chocolate.

(a) *Description.* (1) White chocolate is the solid or semiplastic food prepared by intimately mixing and grinding cacao fat with one or more of the optional dairy ingredients specified in paragraph (b)(2) of this section and one or more optional nutritive carbohydrate sweeteners and may contain one or more of the other optional ingredients specified in paragraph (b) of this section. White chocolate shall be free of coloring material.

(2) White chocolate contains not less than 20 percent by weight of cacao fat as calculated by subtracting from the weight of the total fat the weight of the milkfat, dividing the result by the weight of the finished white chocolate,

and multiplying the quotient by 100. The finished white chocolate contains not less than 3.5 percent by weight of milkfat and not less than 14 percent by weight of total milk solids, calculated by using only those dairy ingredients specified in paragraph (b)(2) of this section, and not more than 55 percent by weight nutritive carbohydrate sweetener.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) Nutritive carbohydrate sweeteners;

(2) Dairy ingredients:

(i) Cream, milkfat, butter;

(ii) Milk, dry whole milk, concentrated milk, evaporated milk, sweetened condensed milk;

(iii) Skim milk, concentrated skim milk, evaporated skim milk, sweetened condensed skim milk, nonfat dry milk;

(iv) Concentrated buttermilk, dried buttermilk; and

(v) Malted milk;

(3) Emulsifying agents, used singly or in combination, the total amount of which does not exceed 1.5 percent by weight;

(4) Spices, natural and artificial flavorings, ground whole nut meats, ground coffee, dried malted cereal extract, salt, and other seasonings that do not either singly or in combination impart a flavor that imitates the flavor of chocolate, milk, or butter;

(5) Antioxidants; and

(6) Whey or whey products, the total amount of which does not exceed 5 percent by weight.

(c) *Nomenclature.* The name of the food is ''white chocolate'' or ''white chocolate coating.'' When one or more of the spices, flavorings, or seasonings specified in paragraph (b)(4) of this section are used, the label shall bear an appropriate statement, e.g., ''Spice added'', ''Flavored with ___ '', or ''With ___ added'', the blank being filled in with the common or usual name of the spice, flavoring, or seasoning used, in accordance with § 101.22 of this chapter.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

Dated: September 27, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–25252 Filed 10–3–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD09–02–521]

Safety Zone; Captain of the Port Milwaukee Zone

AGENCY: Coast Guard, DOT.

ACTION: Notice of implementation of regulation.

SUMMARY: The Coast Guard is implementing a safety zone for annual fireworks displays in the Captain of the Port Milwaukee Zone during October 2002. This action is necessary to provide for the safety of life and property on navigable waters during these events. These zones will restrict vessel traffic from a portion of the Captain of the Port Milwaukee Zone.

DATES: The safety zone for the Sheboygan South High School Fireworks—Sheboygan, WI (165.909(a)(29)) will be enforced on October 3, 2002, from 7:50 p.m. until 8:40 p.m., but in the event of inclement weather the safety zone will be enforced from 7:50 p.m. until 8:40 p.m. on October 4, 2002.

FOR FURTHER INFORMATION CONTACT: Marine Science Technician Chief Dave McClintock, U.S. Coast Guard Marine Safety Office Milwaukee, at (414) 747–7155

SUPPLEMENTARY INFORMATION: The Coast Guard is implementing the permanent safety zone in 33 CFR 165.909 (a)(29) (67 FR 44560, July 3, 2002) for fireworks displays in the Captain of the Port Milwaukee Zone during October 2002. The following safety zone is in effect for fireworks displays occurring in the month of October 2002:

Sheboygan South High School Fireworks—Sheboygan, WI. This safety zone will be enforced on October 3, 2002, from 7:50 p.m. until 8:40 p.m. In the event of inclement weather on October 3, 2002, the safety zone will be enforced from on October 4, 2002 from 7:50 p.m. until 8:40 p.m.

In order to ensure the safety of spectators and transiting vessels, this safety zone will be in effect for the duration of the event. Vessels may not enter the safety zone without permission from Captain of the Port Milwaukee Zone. Requests to transit the safety zone must be made in advance by contacting the person listed in **FOR FURTHER INFORMATION CONTACT** and must be approved by the Captain of the Port Milwaukee before transits will be authorized. Spectator vessels may anchor outside the safety zone but are cautioned not to block a navigable channel.

Dated: September 27, 2002.

M.R. DeVries,

Commander, Coast Guard, Captain of the Port Milwaukee.

[FR Doc. 02–25278 Filed 10–3–02; 8:45 am]

BILLING CODE 4910–15–P

POSTAL SERVICE

39 CFR Parts 952, 957, 958, 960, 962, 964, 965

Rules of Practice Before the Judicial Officer

AGENCY: Postal service.

ACTION: Final rule.

SUMMARY: The Postal Service is amending the Rules of Practice in Proceedings Relative to the Program Fraud Civil Remedies Act to reflect the change in primary responsibility to investigate violations of the Program Fraud Civil Remedies Act from the Postal Inspection Service to the Postal Service Inspector General. In addition, these rules of practice as well as the rules of practice in other proceedings before the Judicial Officer are being amended to correct typographical errors and omissions and make other technical changes.

EFFECTIVE DATE: October 4, 2002.

FOR FURTHER INFORMATION CONTACT: Diane M. Mego, (703) 812–1905.

SUPPLEMENTARY INFORMATION: As part of the creation of the Office of Inspector General in 1996, certain functions were transferred from the Postal Inspection Service to the Postal Service Office of Inspector General. Part 962 is being revised to reflect that investigations under this part are now conducted by the Office of Inspector General. In addition, these rules of practice as well as the rules of practice in other proceedings before the Judicial Officer are being amended to correct typographical errors and omissions and make other technical changes.

These revisions are changes in agency rules of practice before the Judicial Officer and do not substantially affect any rights or obligations of private parties. Therefore, it is appropriate for their adoption by the Postal Service to become effective immediately.

List of Subjects

39 CFR Part 952

Administrative practice and procedure, Fraud, Lotteries, Postal Service.