bases the decision against retroactivity on equity and policy grounds, which I also support. The *Williams* court expressly acknowledged the possibility that the Commission could conclude that retroactive termination would exceed our statutory authority under both the NGPA and the Administrative Procedures Act. If the Commission did make such a legal conclusion, as urged by the opponents of the Williams Motion, the Commission would dispose of the retroactive termination aspect of this proceeding on strict legal grounds, as supplemented by the supporting equity and policy considerations discussed in the supporting final Rule. Such legal disposition also would preclude any future debate as to the public interest nature of incentive pricing, declared contrary to the public interest in the 1983 NOPR and now again here in the 1990 Final Rule, with regard to the intervening period on a retroactive basis.

Much of the Commission debate about prospective termination of incentive pricing focused on the asserted need to establish a balanced approach reflecting the decision against retroactive termination as a matter of policy. If, however, retroactive termination was disposed of as a matter of law, there would be no apparent need to terminate incentive pricing prospectively in order to achieve a policy balance on remand. On that basis, the Commission could then conclude that the 1989 Decontrol Act largely disposed of the legal and/or policy issues associated with continuation of incentive pricing, taking into account the tax credit and new spudded well concerns. Potentially, the Commission also would be able to modify the Final Rule by deciding to terminate the 1983 rulemaking in an Order on Remand reflecting a 1990 analysis that incorporates all these factors, and by deferring to Congressional decisions in the 1989 Decontrol Act.

Interested parties should provide comments on these alternative approaches to responding to the *Williams remand.*

H. *Order No. 500 and Take-or-Pay Policy.* The Final Rule also is responsive to our commitment in Order No. 500-H to consider further the section 107(c)(5) pricing issue initially raised in the Order No. 500 Interim Rule issued in August, 1987. Here, the Commission does have some extensive data developed during the Order No. 500 proceedings. That data clearly demonstrates that the section 107(c)(5) incentive pricing has had and will have a *de minimis* impact on the multi-billion dollar take-or-pay problem. Consequently, there does not appear to be any take-or-pay policy rationale to support the termination of incentive prices in this Final Rule, apart from any perceived symbolism associated with the mere existence *per se* of Federal incentive pricing under the NGPA in today's natural gas market, or the termination thereof, in the context of the Commission's actions in the Order No. 500 proceedings.

Interested parties may wish to comment on the relative impact of terminating section 107(c)(5) price incentives in order to address the take-or-pay problem and achieve the Commission's policy objectives in Order No. 500.

3. Conclusion

I have concurred in this Final Rule, because it is my judgment that the Commission would benefit from additional data and information addressing section 107(c)(5) incentive pricing, to respond to the remand in the *Williams* case and to consider the take-or-pay impacts in the Order No. 500 proceedings. I also have concluded that the Commission may wish to consider an alternative result as a matter of law and policy on rehearing of this order. Hopefully, the discussion of the procedural and substantive issues in this separate opinion will assist in providing the public comments necessary for that effort.

For these reasons, I concur.

Charles A. Trabandt,

Commissioner.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 184

[Docket No. 88G-0371]

Direct Food Substances Affirmed as Generally Recognized as Safe; Microparticulated Protein Product

AGENCY: Food and Drug Administration

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations for substances that are generally recognized as safe (GRAS) to affirm as GRAS the use of microparticulated protein product in frozen dessert-type products. This action is in response to a petition filed by The NutraSweet Co. requesting that a microparticulated egg white and milk protein product be affirmed as GRAS for use as a direct food ingredient.

EFFECTIVE DATE: February 23, 1990.

FOR FURTHER INFORMATION CONTACT: JoAnn Ziyad, 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

A. Regulatory History

In accordance with the procedures described in § 170.35 (21 CFR 170.35), The NutraSweet Co., Box 1751 Lake Cook Rd., Deerfield, IL 60015, submitted a petition (GRASP 8G0345) proposing that microparticulated egg white and milk protein product be affirmed as GRAS as a direct food ingredient. FDA published a notice of the filing of this petition in the **Federal Register** of November 23, 1988 (53 FR 47580), and gave interested persons an opportunity to submit comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. The five comments received in response to the filing notice are discussed below.

B. Standards for GRAS Affirmation

Pursuant to 21 CFR 170.30, general recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances.

The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, experience based on common use in food. General recognition of safety based upon scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation and ordinarily is to be based upon published studies, which may be corroborated by unpublished studies and other data and information (21 CFR 170.30(b)). General recognition of safety through experience based on common use in food prior to January 1, 1958, may be determined without the quantity or quality of scientific procedures required for approval of a food additive regulation but ordinarily is to be based upon generally available data and information concerning its pre-1958 history of use.

II. Manufacturing Process/Use/Exposure

A. Manufacturing Process

According to the information in the petition, microparticulated protein product is manufactured from egg whites or milk protein or a combination of egg whites and milk protein. The protein-containing mixture is high-shear heat processed to produce particles of protein that are microscopic in size. According to the petition, these microparticles are roughly spheroidal in shape. The particles are basically nonaggregated when formed, although aggregation does occur upon heating. High-shear heat processing is followed by a series of steps that may include ultrafiltration, dry-blending of ingredients, hydration with water, and pH adjustment with food-grade acids, bases, or both. Other steps may include deaeration and heat pasteurization. Safe and suitable ingredients may be added to the egg whites and milk proteins to aid in accomplishing the desired technical effect before or after the high-shear heat processing. The use of these ingredients must be in accordance with the regulations in 21 CFR parts 172, 182, or 184.

B. Uses

The proposed use of the substance is as a thickener or texturizer in frozen dessert-type products at levels not to exceed current good manufacturing practice. The petition states that a typical use level would be 32 percent by weight of product, with a range of 25 to 53 percent. The petition also states that there is no technical limitation on either the minimum or maximum amount of microparticulated protein product that can be added to a frozen dessert-type product. The desired sensory qualities determine the level of use of the substance in the finished product. The petitioner found that the oral sensation produced by the hydrated microparticles of gelled product is one of smoothness and is much the same as that produced by fat.

C. Consumer Exposure

The only proposed use for microparticulated protein product requested in the petition is as a fat replacer to perform the technical effects of fat in frozen dessert-type products.

FDA based its daily intake calculations for the petitioned ingredient on the food intake values for frozen desserts of the Market Research Corp. of America (MRCA) Survey of Frequency of Food Consumption, 1977–1978, using the U.S. Department of Agriculture-National Food Consumption Survey (USDA–NFCS), 1977–1978, for portion size. The frozen dessert intake values (eaters-only) are as follows: 2 to 5 year age group, 29.5 grams per person per day (g/p/d) (mean) and 61.1 g/p/d (90th percentile); for the 2+ years age group, the values are 38.5 g/p/d (mean) and 80 g/p/d (90th percentile). At a use level of 53 percent, and assuming that all frozen desserts consumed contain the petitioned products, the microparticulated protein product daily intake would be 15.6 g/p/d (2 to 5 years, mean), 32.4 g/p/d (2 to 5 years, 90th percentile), 20.4 g/p/d (2+ years, mean), and 42.4 g/p/d (2+ years, 90th percentile). Because no product-specific use levels were available, and because there are no known technologically self-limiting use levels, FDA used the maximal likely use level (53 percent) to calculate a conservative estimated daily intake of microparticulated protein product.

Because microparticulated protein product will replace a portion of fat in the diet of people that consume frozen desserts, the petitioner estimated that the proposed use of the product will increase the protein intake of the consumer by 3.5 g/p/d (90th percentile). Based on the information provided in the petition and the above referenced data bases (MRCA and USDA–NFCS), FDA estimated the mean and the 90th percentile increases in protein intake from the maximal proposed use of microparticulated protein product in frozen dessert-type product to be 2.3 and 4.9 g/p/d for 2- to 5-year-old children and 3.1 and 6.4 g/p/d for the 2+ year-old group, respectively. Assuming that there is no change in the amount of protein contributed by other ingredients, this additional protein intake represents an increase in the average protein intake of the two age groups of 4 percent for average consumers of microparticulated protein-containing products and of about 9 percent for heavy consumers. After adjusting for expected decreases in fat intake, the protein intake estimates represent an increase in dietary energy (calorie) contribution from protein for all age groups and intake categories of about 0.5 to 1.5 percent. Based on calculations derived from the above data, the agency finds that this amount does not represent a significant increase in dietary protein (Ref. 41).

III. Evaluation of the Microparticulation Process

The major constituents of microparticulated protein product, egg whites and milk protein, have been safely consumed by humans as sources of food protein throughout recorded history and, therefore, are GRAS (§ 170.30(d)). In evaluating the petition to determine whether the use of microparticulated protein product as a fat replacer in frozen dessert-type products can be affirmed as GRAS, the agency focused on the steps that make up the microparticulation process. FDA discovered that these steps were nothing more than commonly used food processing steps that have been shown through published studies not to change the nutritional value and, therefore, the safety of food, including egg whites and milk protein. Thus, based on published data, for the reasons discussed below, FDA concludes that egg whites and milk protein treated by microparticulation processing can be affirmed as GRAS.

A. Homogenization/Microparticulation

Published studies show that commonly used food processing techniques that reduce the size of food particles, such as homogenization and high-speed, high-shear mixing, modify the sensory properties (viscosity, texture, mouthfeel) of the food that is processed (Ref. 23). To maintain these modified sensory properties, it is routinely necessary to use gums (such as xanthan gum) to stabilize the particles (Refs. 23 and 24). The reduction in particle size produced by these techniques often increases the digestibility of the food. For example, Renner reports that in rat studies, homogenized milk produced a better utilization of protein compared with whole milk (Ref. 20). Although these processing techniques produce some reduction in vitamin concentration, they generally do not change the nutritional value of the food (Ref. 23).

Based on its evaluation of these published studies, the agency finds that these techniques do not affect the safety of milk and egg protein. In addition, these studies demonstrate that microparticulated egg and milk protein products will act as thickeners and texturizers and therefore can serve to replace the fat ordinarily used for these purposes (Refs. 23 and 24).

B. Heating

Eggs and milk have been heat-processed for probably as long as humans have cooked food. A rather extensive literature exists on heat processing of raw food ingredients. In summarizing much of our knowledge concerning the heating of milk, FDA notes the following facts:

1. Heat-induced denaturation of milk proteins is not detrimental to nutrition (Ref. 20).

2. Heating changes the secondary and tertiary structure[1] of proteins, increasing accessibility to digestive enzymes and thus increasing utilization of the protein (Ref. 20).

3. Milk proteins undergo chemical reactions during the heating of milk. The products of these reactions have been consumed without adverse effects since milk was first cooked in food preparation. Therefore, the normal heating of milk-containing foods is not harmful (Ref. 20).

Other reports show that heat sterilization of milk has little effect on levels of vitamins and virtually no effect on lipids, carbohydrates, and minerals (Ref. 21).

Concerning the effects of cooking on eggs, studies show that some loss of vitamins occurs. The loss is dependent on the method of cooking (Ref. 22). With respect to protein quality, Froning (Ref. 22) reports a study showing a slightly lower protein efficiency ratio (PER) value for hard-boiled eggs than for dried eggs. (Dried eggs have a PER value identical with fresh eggs.) Therefore, the effects of heat on egg protein may differ slightly depending on the extent and method of heating. However, the agency finds based on the foregoing data that within the temperature ranges employed, the level of heat has no adverse effect on the safety of the food.

C. pH Modification

Food-grade acids and bases are commonly used to adjust the pH of foods and food formulations. The available information indicates that pH modification does not adversely affect the quality and utility of food protein. Acidification is extensively used in cooking; for flavor, color, and texture modification; for preservation; and for aiding in the gelling of proteins (especially in baked products) (Ref. 25). Additionally, acidification is used to denature proteins (e.g. curdling milk or making cottage cheese). Ingested foods are subjected to acid conditions in the stomach. Under these physiological conditions proteins are denatured and rendered more accessible to attack by digestive enzymes. Alkali is used to modify proteins, to enhance emulsification properties of proteins, and to increase the solubility, elasticity, and resistance to heat-induced aggregation of proteins (Ref. 26).

[1] The secondary structure of a protein refers to the regular structural arrays found in proteins, principally helices, which are formed by folding a single segment of polypeptide chain, and β structures or pleated sheets, formed by two or more chains. The tertiary structure is the total conformation of the molecule, that is, its disposition in three dimensions (Ref. 43).

D. Ultrafiltration

Ultrafiltration is a process by which water is removed from a solution by passing the solution through a semi-permeable membrane. It is routinely used in food processing because the food being filtered is not heated, resulting in little loss of nutrients or volatile flavor components (Ref. 27). In addition, it is very energy efficient compared with other methods of concentration (Ref. 27). Ultrafiltration is commonly used to concentrate whey proteins from cheese manufacture and to concentrate milk products before the manufacture of dairy products.

As stated above, ultrafiltration has little effect on the nutritional quality of foods (Ref. 27). Some low molecular weight sugars, vitamins, and amino acids may be lost during ultrafiltration, but fats, proteins, and carbohydrates are retained without loss of sensory or nutritional qualities (Ref. 27).

E. Conclusion

Based on the summaries above, it is clear that there is adequate published information for experts to conclude that the processes used in the microparticulation of egg and milk protein are commonly used food processing techniques that do not materially change the quality, utility, functionality, or safety of food products. The use of these techniques is just as common in the home as it is in the food industry, and it is generally known by experts and laypersons alike that these techniques do nothing except make food more palatable or appealing. Therefore, FDA concludes on the basis of the published data discussed above that microparticulated egg and milk protein is safe.

IV. Corroborating Evidence of No Adverse Effect on Protein Quality and of Safety

A. Microparticles in Other Foods

Protein microparticles occur in many foodstuffs, such as in milk from humans, cows, goats, and camels and in the cheeses made from some of these milks (Refs. 1 through 4). The formation of microparticles also occurs during the normal processing of foods, e.g., blending, mixing, pasteurizing, pH-modification, and baking (Ref. 42). As discussed above, the petitioner has incorporated established food processing techniques into a distinct process that consistently yields a product containing protein microparticles that are roughly uniform in size, quality, and distribution (GRASP 8G0345).

B. Structure of Microparticles

The petition contains unpublished studies on the morphology of the microparticles using scanning electron microscopy and transmission electron microscopy to look for changes in the microparticulated protein product before and after freezing (GRASP 8G0345, pp. 559–596). These studies show the product's microparticle stability through several freeze-thaw cycles such as might be encountered by the product in transit through the food-distribution system. The studies found no significant differences in protein structure before and after freezing.

The petition also includes the results of studies using transmission electron microscopy and scanning electron microscopy that investigated the microstructures of the constituent, and of the final, microparticulated protein product. These studies showed that the high-shear heat treatment of the mixture of milk and egg white protein yields casein micelles (predominantly spheroidal in shape) surrounded by flocculated egg white protein.

Further characterization of the proteins by one- and two-dimensional gel electrophoresis showed "marked similarity (to one another) among all gels in which all the protein bands could be identified as either milk or egg white proteins" (Ref. 18). Therefore, these studies demonstrate that the microparticulation process does not change the egg and milk protein into new or novel substances that do not have a history of safe use.

C. Amino Acid Profiles

The amino acid profile can be used to characterize proteins (Ref. 43). Recognizing this, the petitioner submitted data that provide evidence that the amino acid profiles of the egg white and milk proteins used as test materials and those of the processed product are not significantly different. Because there are no significant differences between the amino acid profiles of the source protein and of the processed protein, the agency concludes that the microparticulation process does not cause changes in the amino acid composition of the egg and milk protein product that would affect its safety.

D. Protein Efficiency Radio (PER)

To provide additional evidence of the safety of microparticulated protein products, the petitioner submitted data from unpublished studies that compare the PER's of the source proteins and of the processed product. In these studies, rats were fed either of the following diets: (1) Casein (standard reference

protein for PER bioassay); (2) casein plus 15 percent sucrose; (3) mixture of unprocessed starting ingredients for the product (premix); (4) premix exposed to gentle heat (325 °F for 1 hour); (5) premix exposed to severe heat for 15 minutes; (6) premix processed to contain microparticulated egg white and condensed milk proteins; and (7) processed product with 20 percent sucrose (weight/weight) to potentially enhance the stability of the product during long-term storage at freezer temperatures. The rats were fed the diets for 28 days. There were no statistically significant differences between the PER's of the processed and the unprocessed materials. These studies provide evidence that the microparticulation process does not change the nutritive value of the egg white and milk protein.

E. Allergenicity Studies

Published studies show that both eggs and milk produce allergic reactions in sensitive individuals (Ref. 45). To test what effect the microparticulated protein product would have on such individuals, the petitioner submitted an unpublished in vitro allergenicity/antigenicity study of the product with sera from 13 people with an allergy to either milk or egg proteins or to both. The test employed the sodium dodecyl sulfate-polyacrylamide gel electrophoretic (SDS–PAGE) analysis of the test materials. The test materials included: (1) Premix containing a mixture of unprocessed starting materials; (2) premix gently heated (custard-like); (3) premix severely heated (scrambled egg-like); (4) properly prepared microparticulated protein product; (5) properly prepared product with extra sugar; (6) ultrafiltered egg white and condensed milk; (7) fresh egg whites; and (8) fresh cow's milk.

If antibodies to proteins in the test material are present in human sera, they can react with the SDS-PAGE-separated proteins to form antibody-antigen complexes. Seven patients who were clinically symptomatic (allergic) to both eggs and cow's milk were chosen for the study. The study also included three patients symptomatic to eggs only, three symptomatic to milk only, and two controls. The results of these studies produced no evidence of novel proteins in the test materials and no evidence of increased immunologic activity when the final product was compared with the premix of unprocessed starting materials and discrete ingredients (Ref. 19).

The agency concludes, however, that patients clinically allergic to either eggs or cow's milk, or to both, have antibodies to protein fractions in eggs, cow's milk, and the five test materials at approximately equal levels of binding. If an individual who is allergic to either egg or cow's milk, or both, ingested microparticulated protein product test materials, it is likely that he/she would experience an allergic reaction similar to that produced by egg or cow's milk or both.

Under section 409(c)(1) of the act (21 U.S.C. 348(c)(1)), FDA is authorized, in approving the use of a food additive, to list the conditions under which the additive may be safely used. These conditions may include any labeling requirements that the agency finds necessary to ensure the safe use of the additive.

Similarly, under 21 CFR 184.1(b)(2), in affirming a substance as GRAS, FDA is authorized to set forth, by means of specific limitations, the particular conditions, including labeling, under which there is general recognition among qualified experts that use of a substance is safe. After careful review of the information on the allergenicity of egg and milk protein, given the fact that the microparticulated protein products will continue to produce allergic-type reactions, FDA has concluded that the use of microparticulated egg and milk protein product is GRAS only (except in the restaurant-type setting) when the conditions of its use include a declaration on the label or labeling of the presence of the egg and milk protein in the food. This specific limitation is set forth below in new § 184.1498(b)(3). Persons who know that they are sensitive to the protein used in the product are likely to be selective in the types of foods that they use and, with appropriate label declaration, will be able to avoid the potential hazard from allergic-type reactions to the proteins in the product by reading the label.

F. Biotin/Avidin Binding

The agency has considered the possible effect of increased egg white consumption on biotin deficiencies. Biotin, a water- and alcohol-soluble vitamin essential for the activity of many enzyme systems, may be inactivated by avidin, a glycoprotein found in egg whites. Avidin has a high affinity for biotin, and the prolonged ingestion of very large quantities of raw eggs may result in a biotin deficiency. However, because biotin is widely distributed in the food supply and is formed by the intestinal flora, biotin deficiencies occur very infrequently, only with abnormal diets low in biotin or very high in avidin (200 g of dried egg whites per day (Ref. 5)) or a combination of these conditions (Ref. 6). Heat processing, such as the high-shear heat treatment used in microparticulation, readily denatures avidin and prevents its binding to biotin (Ref. 7). For this reason, the agency finds that there is no basis for concern that a biotin deficiency will develop in people consuming microparticulated protein product.

V. Comments

FDA received five comments in response to the published notice. One comment was from a nutrition consultant, one from a physician, one from a consumer, one from a consumer interest group, and one from a law firm. The specific comments and the agency's responses are discussed below.

1. The comment from the nutrition consultant questioned whether there was breakdown of protein in the microparticulated product into amino acids, particularly glycine, and if so, whether the level is less than the) 0.2 percent limitation specified in the food additive regulation for the use of glycine in § 172.812 (21 CFR 172.812).

The agency finds that there is no basis for the concerns expressed in this comment. Based on published information about the effects of processing techniques on food protein (Refs. 20, 21, 22, and 46), the agency finds that under the conditions used in the processing of the egg whites and milk proteins to form microparticulated egg white and milk protein products, the proteins would not break down into the component amino acids, including glycine, during the processing. Further, § 172.812 (21 CFR 172.812) establishes a 0.2 percent limit for the food additive use of the free amino acid glycine in certain foods to produce limited and specific technical effects. This limit on an added amino acid has no relationship to consumer exposure to the amino acids that are present in intact food proteins such as those found in the egg whites and milk protein in microparticulated protein product at physiologically safe levels. Thus, the comment is irrelevant to the exposure to the amino acids derived from microparticulated protein product.

2. Citing five specific references (Refs. 9, 10, 14, 15, and 16), the comment from the physician identified six issues that he believes should be addressed in the evaluation of the safety of microparticulated protein product. However, the comment did not provide copies of these five references or of others identified in his letter (see GRASP 8G0345—comment 3) (Refs. 8, 11, 12, and 13). The agency has evaluated the available references as

reflected in the responses provided below. The physician did not present any conclusion on whether the use of microparticulated protein product is GRAS.

The first issue identified by the comment is whether particle size and homogenization influence the absorption and metabolism of the component amino acids. The comment stated that "it is known * * * for example, that such alteration of milk or whole eggs increases the absorption of free cholesterol and * * * that particle size significantly alters the physical characteristics of aspartame."

The agency has evaluated the relevant references cited by the comment and finds that the references document a controversy regarding the subject of absorption of cholesterol as a function of homogenization of milk or eggs that contain both protein and fat. The studies referred to in the references submitted in the comment were designed to measure fat absorption, which would include cholesterol absorption, but were not designed to measure amino acid/protein absorption. Amino acids/proteins are absorbed by a different mechanism than cholesterol. Therefore, the comment and references are not relevant to the absorption of the microparticulated protein product, which consists of only the protein from milk and eggs.

Although the references cited in the comment address the absorption of a different macromolecule (cholesterol) that is absorbed by a different mechanism than that by which protein and amino acids are absorbed, it is true that modification of amino acid/protein absorption may be influenced by homogenization (Ref. 20). Studies have shown that homogenization of milk produces a better utilization of the protein in milk (Ref. 20) as compared with nonhomogenized milk.

Also, as discussed in section IV, protein quality (PER) data show that there were no significant differences between the growth responses of rats fed the simple mixtures of egg white and milk proteins and of those fed microparticulated protein product. Based upon its review of all the data, the agency finds that decreased particle size and homogenization may favorably influence the absorption and utilization of the protein in microparticulated protein product and finds no evidence of adverse effects from these factors.

The significance of the comment "that particle size significantly alters the physical characteristics of aspartame" is unclear to the agency. No data were submitted to support this contention or to explain what its implications would be. Therefore, it provides no basis for the agency to alter its evaluation of the petition.

The second issue identified by the comment is whether independent peptide chemists have demonstrated stereochemical changes from heating or prolonged storage of the microparticulated protein product.

The comment appears to question whether conditions of heating or prolonged storage would alter protein conformation (e.g., the folding pattern of the protein), which might affect the availability of the protein for digestion and metabolism. The comment submitted no specific study reports on the stereochemical conformation (spatial arrangement) of protein in the microparticulated protein product after heating or storage or both.

Based on a review of published studies about the effects of processing on food proteins (Refs. 20, 21, and 46), the agency finds no evidence that would lead one to believe that the stereochemical conformational changes in the structure of the product's protein during heating and storage are different from those that occur during heating and storage of other dietary egg and milk protein products. Therefore, this issue does not require further study by independent peptide chemists.

The third issue identified by the comment is, "Can this product induce malabsorption and nutritional deficiencies other than the excessive caloric reduction sought by weight-conscious persons, or undermine an adequate diet in young children through massive promotion?"

Based on a review of the published information on both the steps used in the production of microparticulated egg and milk protein products and on the properties of the constituents of the product (Ref. 46), the agency finds no evidence that would lead one to believe that these products will induce malabsorption or nutritional deficiencies. No such evidence was presented by the comment. Therefore, the agency finds that there is no basis to consider this issue further.

The fourth issue identified by the physician concerns whether the brain "is capable of adapting to the rapid influx of phenylalanine and other amino acids present in 'egg whites' without neurologic, psychiatric or behavioral risk * * * especially in a fetus."

In response to this issue, the agency finds that, as stated above in its response to comment 1, microparticulated protein product contains intact protein and not free amino acids as indicated in the comment. Thus, microparticulated protein product is metabolized in the same manner as egg white and milk protein. The agency concludes, therefore, that there is no basis for the concerns expressed in the comment, and that the use of microparticulated protein product will not present a neurologic, psychiatric, or behavioral risk to the general public or to the fetus.

The fifth issue identified by the comment was whether the risks of neurologic, psychiatric, or behavioral and fetal effects cited in its first question might be compounded by the projected combination of aspartame and microparticulated protein product in certain products.

Based on a review of published information on the constituents of microparticulated protein product (Ref. 46) and because the individual would be consuming intact protein rather than free amino acids, the agency finds no reason to expect any risks of neurological, psychiatric, behavioral, or fetal effects from the consumption of microparticulated protein product if it is combined with aspartame. Persons routinely consume food products containing aspartame and intact egg or milk protein similar to that found in microparticulated protein product, e.g., frozen desserts and flavored milk beverages, with no evidence of adverse effects. The agency also has no evidence to indicate adverse neurological, psychiatric, behavioral, or fetal effects from aspartame when it is consumed at levels that would be expected in frozen dessert-type products (see the **Federal Register** of June 7, 1988 (53 FR 20842)). Therefore, the agency finds no reason to expect that an adverse effect would result from a combination of microparticulated protein product and aspartame. The comment provided no information to indicate or to suggest that these ingredients would cause adverse effects.

The last issue identified by the physician was whether sugar consumption will rise as more fat-substituted frozen dessert-type products include various natural sweeteners, such as cane sugar, in their formulation.

The agency has no evidence, nor did the physician provide any, to suggest that the use of natural sweeteners in frozen dessert-type products will increase, or that the intake of frozen dessert products or substitutes will increase because of the use of microparticulated protein product in these products. Based on proposed formulations in the petition, the same level of sugar will typically be used in the frozen dessert-type products as is

used in ice cream or other frozen desserts.

3. Comment number three was from a consumer who expressed concern that glutamate intake from the use of casein (milk protein) in microparticulated protein product would be increased. The comment provided a reference on the "Brain Damaging Potential of Protein Hydrolysates," and asked about the amount of the product that would be fed to babies.

The reference (Ref. 17) submitted in this comment on potential brain damage from protein hydrolysates reports the results of a study of the effects of total parenteral nutrition using hydrolyzed protein (free amino acids) but does not consider the normal absorption, digestion, and metabolism of intact protein such as that from egg whites and milk, which is the nature of the substance at issue in this proceeding. Therefore, the reference is not relevant to the issue of the consumption of microparticulated protein product. In response to the question on the amount of the product consumed by babies (6 to 23 months), the agency estimates that the intake of microparticulated protein product from its use in frozen dessert-type products will be 9.8 g/p/d (mean) and a 90th percentile) 22 g/p/d for "eaters only" based on the proposed maximum 53 percent use level (Ref. 44).

4. The comment from the consumer interest group stated that there does not appear to be a safety concern with the petitioned product. However, it expressed concern, as did the comment from the consumer, about the undesirable effects on the total dietary pattern of replacing fat. The comment stated that people will consume more "junk foods" containing fat replacers, and that, as a result, there will be less room for the consumption of foods containing whole grains, fruits, and vegetables. The comment noted that there are groups, such as the growing elderly population and obese people on low calorie diets, that particularly need nutrient-dense food. These groups may be particularly vulnerable to the replacement of macro-nutrients in the diet. The comment asked the agency to monitor the nutrient composition of diets of individuals who consume the most fat replacers as a proportion of their diets and to determine whether certain groups may be vulnerable to the effects of fat displacement.

Certain subpopulations do have special dietary needs that require that they control their eating behavior patterns. The U.S. Department of Health and Human Services (DHHS) has a role in educating consumers about diet and has issued dietary recommendations (Dietary Guidelines for Americans, 2d Ed., 1985, USDA and DHHS). However, FDA finds no basis to question whether microparticulated protein product is GRAS simply because certain individuals may not make good judgments about their dietary choices.

The comment does not contain any data or other information to support the necessity of monitoring dietary habits of the consumers expected to be exposed to fat replacers in frozen desserts. The agency does monitor the use of food ingredients by the industry and, as appropriate, may evaluate the consumption of specific ingredients. Without data to suggest that the level of use of microparticulated protein product as a fat replacer is sufficient to adversely affect the health of consumers, the agency does not see a basis for conducting a separate study as suggested in this comment.

5. The comment from the consumer group also requested that the agency require that the labeling of microparticulated protein product ensure the protection of consumers who are allergic to egg white or milk protein or to both. The comment argued that restaurants and other institutions should be required to notify consumers of foods containing these products.

The agency agrees that consumers should be informed of the presence of microparticulated protein product in foods so that they can avoid those foods if they are allergic to egg white and milk protein. As stated above, given the fact that microparticulated protein products will produce allergic-type reactions in sensitive individuals, FDA has concluded that the use of microparticulated egg and milk protein product must be labeled as set forth below in § 184.1498(b)(3). The agency believes that where the identify of the source of the protein in the product is included in the name of the ingredient, no additional label statement is necessary.

Because the source of the protein in the microparticulated protein product will be listed in the ingredient statement on the label of frozen dessert-type products that contain this substance, persons who are allergic to egg white and milk protein, and who purchase frozen dessert-type products at the retail level (for example, at grocery stores), will be able to become familiar with the possible presence of egg and milk proteins in frozen dessert-type products. In a restaurant, allergic individuals will know to seek information from restaurant employees about whether the frozen dessert products contain microparticulated protein.

Because of the requirement that the source of the protein be included on the name of the product, workers in institutions will also be aware of the presence of the constituent ingredients (egg white and milk protein) and can inform inquiring customers who are allergic to egg and milk protein of their presence if or when requested.

6. The last comment, from a law firm, agreed that the petitioner is correct that the ingredients used for making the subject microparticulated protein product are GRAS, and that particle size reduction processes are not new. However, the comment opposed GRAS affirmation of the microparticulated protein product for the "new" use on the grounds that the product is a combination of ingredients already commonly used for the requested function. In support of its position, the comment provided limited data on the particle size of certain components of currently available standardized frozen desserts to demonstrate that they contain microparticles well within the size specifications for the petitioned product.

The comment stated that FDA would not be able to monitor the presence or absence of this "new" ingredient as compared to ingredients that have been subjected to a similar or identical process. The comment further asked FDA to reject the special labeling provisions asked for by the petitioner which would not require the listing of all ingredients in the microparticulated protein product because to permit such labeling would be, in effect, to grant a special license.

The agency agrees that the submitted data show that prepared food products have similar particle size profiles. However, simple particle size is not the only issue involved. The petition for microparticulated protein product claims that this product is a new ingredient. The petition contains information that describes a process whereby the ingredients are processed under high-shear and heat conditions to produce a densely packed mass of particles that resembles an oil in water emulsion. This form is what is to be recognized as the "new" product or ingredient. This new form of product is what is to be accepted as a replacement for fat as a thickener and texturizer in food.

In response to the comment's concern about the special labeling provisions asked for by the petitioner, the agency notes that it is not permitting such labeling. The ingredients of the product must be listed on the label in accordance with 21 CFR 101.4(b)(2).

Moreover, § 184.1498 specifies that the name of the product should contain the source of the microparticulated protein.

VI. Conclusion

Based on its evaluation of the published information on the steps used in the production of microparticulated protein products, FDA concludes that these steps are nothing more than commonly used food processing steps that have been shown through published studies not to change the nutritional value or the safety of food, especially egg and milk protein. These normal and widely used processing techniques, e.g., heating, pH control, homogenization/microparticulation, and ultrafiltration, do not cause the appearance of unknown or unexpected compounds that would adversely affect the safety of routinely processed dairy products. Further, the agency finds the scientific literature confirms the existence of protein microparticles (e.g., micelles and aggregates) in normal and widely consumed dairy products (Refs. 1 through 4). The literature also establishes that microparticulated protein products will have their intended technical effects.

In addition, FDA finds that the likely increase in the intake of dietary protein from the consumption of microparticulated egg and milk protein product is not significant. Based on a review of the published literature, the agency finds no basis for the concerns expressed by the comments on the adverse effects of increased levels of free amino acids, particle size, stereochemical changes, malabsorption, and nutritional deficiencies. The agency concludes that the labeling of the product as required in § 184.1498 will address concerns of persons who may be allergic to egg and milk proteins.

Therefore, based on published data on the steps in the microparticulation process and corroborated by results of animal studies on the similarity of the protein quality (PER and amino acid profiles) of milk and egg protein and the microparticulated protein product, FDA concludes that the use of microparticulated protein products in frozen dessert-type products is GRAS.

VII. Environmental Effects

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch, Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857 between 9 a.m. and 4 p.m., Monday through Friday. This action was considered under FDA's final rule implementing the National Environmental Policy Act (21 CFR part 25).

VIII. Economic Effects

FDA, in accordance with the Regulatory Flexibility Act, has considered the effects that this regulation would have on small entities, including small businesses, and has determined that the effect of this final regulation is to provide for the new use of microparticulated protein product by both large and small businesses. Therefore, FDA certifies in accordance with section 605(b) of the Regulatory Flexibility Act that no significant economic impact on a substantial number of small entities will derive from this action.

In accordance with Executive Order 12291, the agency has analyzed the economic effects of this final rule and has determined that this rule will not be a major rule as defined by that Order.

The agency's finding of no major economic impact and 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 (address above).

IX. 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.

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List of Subjects in 21 CFR Part 184

Food ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 184 is amended as follows:

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR part 184 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. New § 184.1498 is added to subpart B to read as follows:

§ 184.1498 Microparticulated protein product.

(a) Microparticulated protein product is prepared from egg whites or milk protein or a combination of egg whites and milk protein. These protein sources may be used alone or in combination with other safe and suitable ingredients to form the microparticulated product. The mixture of ingredients is high-shear heat processed to achieve a smooth and creamy texture similar to that of fat. Safe and suitable ingredients used in the preparation of the microparticulated protein product must be used in compliance with the limitations of the appropriate regulations in parts 172, 182, and 184 of this chapter.

(b) The ingredient is used in food in accordance with § 184.1(b)(2) at levels not to exceed current good manufacturing practice. The affirmation of the use of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following conditions of use:

(1) The ingredient is used in food as a thickener as defined in § 170.3(o)(28) of this chapter or as a texturizer as defined in § 170.3(o)(32) of this chapter.

(2) The ingredient is used in frozen dessert-type products except that the ingredient may not be used to replace the milk fat required in standardized frozen desserts.

(3) The name of the ingredient used in the ingredient statement on both bulk and packaged food must include the source of the protein (e.g., "microparticulated egg white protein"), followed by a parenthetical listing of each of the ingredients in the microparticulated protein product, in descending order of predominance. Microparticulated protein product must be used in accordance with this requirement or its addition to food will be considered by FDA to constitute the use of an unapproved food additive (see § 184.1(b)(2)).

Dated: February 14, 1990.

Douglas L. Archer,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 90–4199 Filed 2–22–90; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972

AGENCY: Department of the Navy, DOD.

ACTION: Final rule.

SUMMARY: The Department of the Navy is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Judge Advocate General of the Navy has determined that USS *Guardian* (MCM–5) is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with certain provisions of the 72 COLREGS without interfering with its special functions as a mine countermeasures ship. The intended effect of this rule is

to warn mariners in waters where 72 COLREGS apply.

EFFECTIVE DATE: February 14, 1990.

FOR FURTHER INFORMATION CONTACT: Captain P.C. Turner, JAGC, U.S. Navy, Admiralty Counsel, Office of the Judge Advocate General, Navy Department, 200 Stovall Street, Alexandria, VA 22332–2400, telephone number: (202) 325–9744.

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 33 U.S.C. 1605, the Department of the Navy amends 32 CFR part 706. This amendment provides notice that the Judge Advocate General of the Navy, under authority delegated by the Secretary of the Navy, has certified that USS *Guardian* (MCM–5) is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with 72 COLREGS, Annex 1, section 3(a), pertaining to the placement of the after masthead light and the horizontal distance between the forward and after masthead lights, without interfering with its special functions as a Navy ship. The Judge Advocate General of the Navy has also certified that the aforementioned lights are located in closest possible compliance with the applicable 72 COLREGS requirements.

Moreover, it has been determined, in accordance with 32 CFR parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on this ship in a manner differently from that prescribed herein will adversely affect the vessel's ability to perform its military functions.

List of Subjects in 32 CFR Part 706

Marine safety, Navigation (water), Vessels.

Accordingly, 32 CFR part 706 is amended as follows:

PART 706—[AMENDED]

1. The authority citation for 32 CFR part 706 continues to read:

Authority: 33 U.S.C. 1605.

§ 706.2 [Amended]

2. Table Five of § 706.2 is amended by adding the following vessel:

Vessel	Number	Forward masthead light less than the required height above hull. Annex I, sec. 2(a)(i)	Aft masthead light less than 4.5 meters above forward masthead light. Annex I, sec. 2(a)(ii)	Masthead lights not over all other lights and obstructions. Annex I, sec. 2(f)	Vertical separation of masthead lights used when towing less than required by Annex I, sec. 2(a)(i)	Aft masthead lights not visible over forward light 1,000 meters ahead of ship in all normal degrees of trim. Annex I, sec. 2(b)	Forward masthead light not in forward quarter of ship. Annex I, sec. 3(a)	After masthead light less than ½ ship's length aft of forward masthead light. Annex I, sec. (3)(a)	Percentage horizontal separation attained.
USS Guardian.	MCM–5	.....	.....	.....	.....	.....	.....	X	69

Dated: February 14, 1990.

Approved:

E.D. Stumbaugh,

Rear Admiral, JAGC, U.S. Navy, Judge Advocate General.

[FR Doc. 90–4143 Filed 2–22–90; 8:45 am]

BILLING CODE 3810–AE–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Public Land Order 6769

[CO–930–00–4214–10; C–28613]

Partial Revocation of Executive Order Dated August 9, 1916, Powersite Reserve No. 539; Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.

SUMMARY: This order revokes an Executive order insofar as it affects 27.82 acres of public land withdrawn for Powersite Reserve No. 539. This revocation is needed to permit consummation of an exchange. The land is no longer needed for waterpower purposes. This action will open the land to surface entry and disposal. The land has been and remains open to mining and to mineral leasing.

EFFECTIVE DATE: March 26, 1990.

FOR FURTHER INFORMATION CONTACT: Doris E. Chelius, BLM Colorado State Office, 2850 Youngfield Street, Lakewood, Colorado 80215–7076, 303–236–1752.

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 90 Stat. 2751; 43 U.S.C. 1714, it ordered as follows:

1. Executive Order dated August 9, 1916, which withdrew public land for Powersite Reserve No. 539, is hereby revoked insofar as it affects the following described land:

Sixth Principal Meridian

T. 16 S., R. 68 W.,
sec. 6, lot 3.
The area described contains 27.82 acres in Teller County.

2. At 9 a.m. on March 26, 1990, the land described in paragraph 1 will be opened to the operation of the public land laws generally, subject to valid existing rights, the provisions of existing withdrawals, and the requirements of applicable law. All valid applications at or prior to 9 a.m. on March 26, 1990, shall be considered as simultaneously filed at that time. Those received thereafter shall be considered in the order of filing.

Dated: February 14, 1990.

Dave O'Neal,

Assistant Secretary of the Interior.

[FR Doc. 90–4160 Filed 2–22–90; 8:45 am]

BILLING CODE 4310–JB–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 2 and 80

[Gen. Dkt. No. 88–550; FCC 90–39]

Accommodation of the Government Next Generation Weather Radars in the 2900–3000 MHz Band

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: By this action the Commission is amending the Table of Frequency Allocations to permit Government Next Generation Weather Radars (NEXRAD) to operate in the 2900–3000 MHz band on a co-primary basis. The 2900–3000 MHz band is currently allocated to Government and non-Government Maritime Radionavigation on a primary basis and