

**2019 Eastern Milk Seminar**  
**Madison, Wisconsin**

**Label Review**  
**And**  
**Grade “A” Product Determination**  
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# QUESTIONS AND ANSWERS OF INTEREST

# Questions and Answers of Interest

Fluid milk is being labeled as A2 milk. Is there any guidance on the labeling of A2 milk? Can the labels on A2 milk claim that it is “easier on digestion,” “easier to digest,” and aids in treating autism and diabetes?

*The following answers were provided by FDA’s Center for Food Safety and Applied Nutrition (CFSAN), Office Nutrition and Food Labeling (ONFL):*

a) Identification as “A2 milk” means that there is A2 beta-casein, but no A1 beta-casein present in the milk. Genetic testing of the individual cows in the herd would predict which cows are A2/A2 cows and would produce only “A2 milk” with no A1 beta-casein. The claim must be able to be substantiated. The label must be truthful and not misleading.

b) Generally, we have not taken issue with “easier to digest” claims. Most of the other types of claims could be considered “disease claims” which would NOT be viewed as acceptable. Currently there are no approved or qualified health claims that would associate A1 or A2 beta-casein with diabetes, heart disease, autism or other diseases.



## Questions and Answers of Interest



Can Kefir be infused with Cannabidiol (CBD) and be sold intrastate and interstate?

*No. The dairy food known as “Kefir” is a Grade “A” milk product under the PMO. “Kefir” is a cultured milk and must comply with the Standard of Identity for Cultured Milk, 21 CFR 131.112. The name specified in the Standard of Identity is “kefir cultured milk” (21 CFR 131.112 (f)).*

*According to the Food, Drug, and Cosmetic Act (FD&C Act), CBD is not permitted in any food or dietary supplement involved in interstate commerce. In addition, CBD cannot be added to any food product that has a federal standard of identity, even if it is sold in intrastate commerce. There are no federal standards of identity which permit CBD, and all state standards of identity are preempted by the federal standards of identity if they are not identical.*



Cannabidiol (CBD) (con't)

*• Under section 301(ll) of the FD&C Act, it is prohibited to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which has been added a substance which is an active ingredient in a drug product that has been approved under 21 U.S.C. § 355 (section 505 of the Act) or a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public.*

*• FDA has concluded that it is a prohibited act to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which THC or CBD has been added, regardless of whether these substances are derived from marijuana or hemp.*



## Questions and Answers of Interest



Are milk and cream in glass bottles required to have allergen labeling or is it exempt under the small label exemption due to space issue?

- *The following answer was provided by CFSAN's ONFL:*
- *None of the labeling exemptions, including the small label exemption, apply for allergen labeling required by the Food Allergen Labeling and Consumer Protection Act (FALCPA). Therefore, the glass bottled cream would have to have "milk" either in the list of ingredients or in a "Contains" statement.*



## PMO- Section 4 and Appendix T

As a milk specialist reviewing a plant's food safety plan, would you expect to see soy lecithin in the food allergen control section? I read that the soy protein levels are so low that it only causes a reaction in extreme cases, so is it typically considered an allergen?

## Questions and Answers of Interest

*The following answer was provided by FDA's CFSAN, Office Nutrition and Food Labeling (ONFL):*

- *Yes. Soy lecithin in general is NOT exempt from allergen labeling. Therefore, soy lecithin must be included in the hazard analysis and food allergen preventive controls section within their Food Safety Plan.*
- *A company could request an exemption from allergen labeling for their soy lecithin by filing for a food allergen labeling exemption with FDA.*



## Soy Lecithin (con't)

- *As of November 2019, three (3) companies have filed petitions for use of Soy lecithin as a processing aid or release agent.*
- *Two have been granted and one withdrawn. One other petition regarding a cheese starter culture containing hydrolyzed soy proteins (not specified) was denied because the science was not adequate to show that the hydrolyzing process would cause the soy protein to degrade to the point that it could not cause an allergic reaction.*
- *If an exemption is granted, soy lecithin would still need to be included in the hazard analysis and food allergen preventive controls section of the Food Safety Plan.*

## Questions and Answers of Interest





# Questions and Answers of Interest

## PMO-Sections 1 and 4

May the terms “Vat Pasteurized”, “Low Temp Pasteurization”, and “Gently Pasteurized Milk” be used in the labeling on containers of milk and/or milk products?

*The following answer was provided by CFSAN’s, Office of Nutrition and Food Labeling:*

- *The term “Vat Pasteurized” may be used as it is a defined term.*
- *ONFL would not take issue with either “Low Temp Pasteurized” or “Gently Pasteurized Milk” on containers of milk and/or milk products as long as the label or a web-site link on the label explains what is meant by “Low Temp Pasteurized” or “Gently Pasteurized Milk”, meaning the milk is heated to 145°F for 30 minutes. “Low Temp Pasteurized” and “Gently Pasteurized Milk” are not defined, and consumers may be confused regarding what this actually means.*



Can a manufacturer of a non-standardized Grade “A” product include “probiotic” in the name of the product? For example, Probiotic Sour Cream Dip.

The following answer was provided by CFSAN’s Office of Nutrition and Food Labeling (ONFL):

- Yes. We would not object to the inclusion of “probiotic” in the name of a non-standardized dairy product if the rest of the name adequately describes the product (in accordance with 21 CFR 101.3).
- In the past ONFL has raised objections when probiotics have been added to standardized dairy products because the standard did not allow for the addition of probiotics. This is not an issue for a non-standardized product because there would be no SOI.

## Questions and Answers of Interest



## Probiotic (con't)

- *On the ingredient list, the probiotic ingredient cannot be declared as “probiotic” because that is not a specific common or usual name in accordance with 21 CFR 101.4. The probiotic ingredient can be declared on the ingredient list either by listing the specific ingredient contained in the probiotic or stating the word “cultured” followed by the name of the substrate, e.g., “made from cultured skim milk” (in accordance with 21 CFR 101.4(b)(5)).*

## Questions and Answers of Interest



# ☞☞☞ Labeling Resources

- FDA webpage on Labeling & Nutrition Guidance Documents and Regulatory Information

<https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/labeling-nutrition-guidance-documents-regulatory-information>

- Code of Federal Regulations Title 21 part 100-169

- National Organic Program

<https://www.ams.usda.gov/about-ams/programs-offices/national-organic-program>



## Grade "A" Milk and Milk Products include:

1. All milk and milk products with a standard of identity provided for in 21 CFR Part 131, excluding 21 CFR Part 131.120 Sweetened Condensed Milk.
2. Cottage cheese (21 CFR Part 133.128) and Dry curd cottage cheese (21 CFR Part 131.129)
3. Whey and Whey products as defined in 21 CFR 184.1979, 184.1979a, 184.1979b, 184.1979c, (and Section 1, Definition QQ of this *Ordinance*.)
4. Modified versions of these foods listed above in Items 1 and 2, pursuant to 21 CFR Part 130.10 - requirements for foods named by use of a nutrient content claim and a standardized term e.g. low fat cottage cheese



## Cont'd

5. Milk and milk products as defined in Items 1, 2, 3 and 4 above, packaged in combination with food(s) not included in this definition that are appropriately labeled with a statement of identity to describe the food(s) in final packaged form (e.g., "cottage cheese with blueberries", "fat free milk with plant sterols."



6. Products not included in Items 1-5 are Grade "A" milk products which have a minimum of 2.0% milk protein (Total Kjeldahl Nitrogen (TKN) X6.38) AND a minimum of sixty-five percent (65%) by weight milk, milk product or a combination of milk products.

## Grade “A” Milk and Milk Products

### 2017 PMO, Definition GG

Safe and suitable non-grade “A” dairy ingredients may be used to achieve a functional or technical effect (purpose) in the finished milk or milk product(s).

- Must be reviewed by Regulatory Agency, in consultation with FDA and need supporting documentation from the manufacturer (see p.8 2017 PMO).
- If the product has a SOI, only ingredients permitted can be used.
- Non-grade “A” dairy ingredients can NOT be used to increase weight or volume of the milk and/or milk products, or displace Grade “A” dairy ingredients. Not a suitable functional or technical effect.

# Not Included in Grade "A" Milk and Milk Products 2017 PMO, Definition GG

- 1. A milk or milk product in which the milkfat of the milk or milk product has been substituted in part or in whole by any other animal or vegetable fat; provided that other fat sources may be included when they are used for purposes currently accepted in any other Grade "A" milk or milk product, such as carriers for vitamins and as an ingredient in emulsifiers and stabilizers;**





# Grade “A” Milk and Milk Products

## 2017 PMO, Definition GG

### **Milkfat substituted in part or whole by other animal or vegetable fat:**

- This does NOT automatically make the product a non-Grade “A” product.
- Need to ask the function of the other animal or vegetable fat.
- Adding vegetable oil simply to exempt the product from the PMO is unacceptable.
- The vegetable oil must have a functional or technical purpose and cannot be used to displace or substitute other Grade “A” dairy ingredients, i.e. milkfat.

## **Not Included in Grade “A” Milk and Milk Products 2017 PMO, Definition GG**

- 2. Coffee based products where coffee or water is the primary ingredient as indicated in the ingredient statement;**
- 3. Tea based products where tea or water is the primary ingredient as indicated in the ingredient statement;**
- 4. Dietary products (except as defined herein);**
- 5. Infant formula;**
- 6. Ice cream or other frozen desserts;**
- 7. Butter;**
- 8. Cheese (standardized or non-standardized); or**
- 9. Puddings.**

# Milk or Milk Products that could be

## Grade “A” or Non-Grade “A”

Milk or milk products which have been:

- Retort processed after packaging
- Concentrated
- Condensed, or
- Dried

Are only Grade “A” if they are used as an ingredient to produce a Grade “A” milk or milk product; OR

Labeled as Grade “A” per Section 4. of the PMO

Need to meet PMO requirements

- This includes evaporated milk (M-I-12-9 Q&A#3) and powdered dairy blends



## Grade “A” Milk and Milk Products Determination 2017 PMO, Definition GG

**M-I-12-15: Guidance for Regulatory Agencies to Use when Making Determinations of Whether Milk and/or Milk Products Meet Definition Z (GG, 2017 PMO) Milk Products, Item 6. of Section 1. Definitions of the Grade “A” PMO**

### **4 Primary Criteria to use to make Grade “A” determinations:**

- 1.** Evaluate the product in its final consumable form.
- 2.** Review the information provided on the PDP or the IP to determine if the product and/or the ingredients are those shown in Definition GG – do they meet or not meet the Grade “A” definition. For example: if coffee primary ingredient probably not Grade “A” or if milk ingredient is a predominate ingredient then the majority of protein is probably from milk component(s) but not always.



## Grade “A” Milk and Milk Products Determination 2017 PMO, Definition GG

3. The final product must meet **BOTH** the minimum 2.0% milk protein and the minimum 65% by weight milk. Need the following:

- product batching/formulation/process
- specific ingredient composition with respective percentages
- label example showing Principle Display Panel (PDP) and Information Panel (IP) for ingredients and nutrition facts

### % Protein Determination:

- Final consumable form
- Formula in M-I-12-15
- Specific ingredient composition with respective %

## Grade “A” Milk and Milk Products Determination 2017 PMO, Definition GG

### % Milk Weight Determination in final consumable form:

- Review the Ingredient Statement  
(Ex. milk, cream, sugar, vanilla flavor, stabilizer, vitamins, color)
- Review product batching/formulation/process
- Review specific ingredient composition with respective %  
(Ex. States liquid milk ingredients = 62% milk weight.)

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Water was used to reconstitute whole milk powder to **single strength composition**. It is not required to list water as an ingredient if all is used to reconstitute. Excess water is required to be listed.

## Grade “A” Milk and Milk Products Determination 2017 PMO, Definition GG

4. The weight of water to reconstitute a dairy ingredient to single strength – Need to determine if product meets or not meets the min. 65% by weight milk. Only excess water needs to be included in the ingredient list; not the water used to reconstitute back to single strength. (21 CFR 101.4(c).
- Manufacturer could list the dairy ingredient in the dry milk form or the dairy ingredient after it has been reconstituted.

# Regulations for Milk and Milk Products

- **Federal Food, Drug, and Cosmetic Act**
- **Federal Import Milk Act, and 21 CFR 1210**
- **Title 21 Code of Regulations (CFR):**
  - **Part 131 – Milk and Cream (Standards)**
  - **Part 117 – Current Good Manufacture Practice, Hazard Analysis, and Risk-Based Preventative Controls for Human Food**
  - **Part 133 – Cheese and Related Cheese Products (Standards)**
  - **Part 135 – Frozen Dessert Standards**
  - **Part 1240.61 – Requirement for Pasteurization for milk and milk products in final package, in interstate commerce**



# Questions???



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