

Colostrum

An Overview and Discussion

National Association of Dairy Regulatory Officials 2025 Annual Conference

Burlington, VT

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July 15, 2025

Colostrum

- Colostrum is the lacteal secretion after calving.
- Colostrum does not have a standard of identity.
- Colostrum and milk differ significantly in composition.

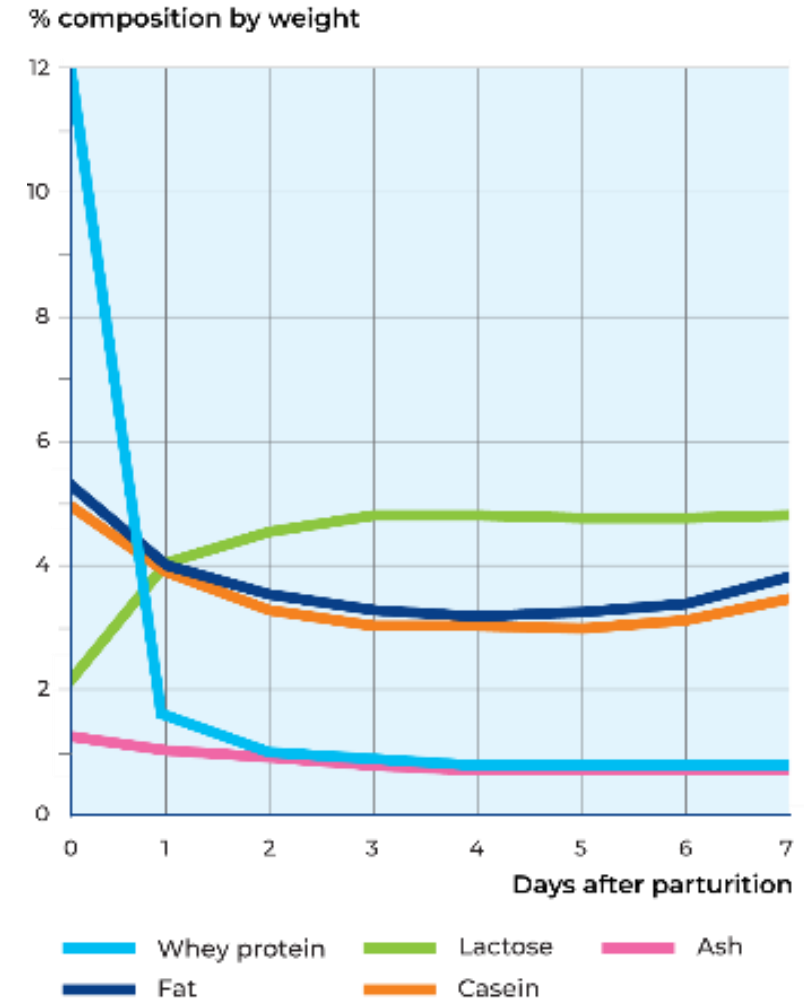


Figure Credit: Dairy Processing Handbook, Tetra Pak,
<https://dairyprocessinghandbook.tetrapak.com/>

Consumer Interest in Colostrum

- Colostrum is being sold in sports nutrition and infant formula products.
- Consumers seek colostrum for purported health benefits (immune system support, gut health, muscle repair and growth).
- Colostrum may be used as an ingredient in human supplements, cosmetics, or functional foods.

Is Colostrum a Grade “A” Milk Product?

- Colostrum is a “milk product” (21 CFR 1240.3(j))
 - Milk products. **Food products made exclusively or principally from the lacteal secretion obtained from one or more healthy milk-producing animals**, e.g., cows, goats, sheep, and water buffalo, including, but not limited to, the following: lowfat milk, skim milk, cream, half and half, dry milk, nonfat dry milk, dry cream, condensed or concentrated milk products, cultured or acidified milk or milk products, kefir, eggnog, yogurt, butter, cheese (where not specifically exempted by regulation), whey, condensed or dry whey or whey products, ice cream, ice milk, other frozen dairy desserts and products obtained by modifying the chemical or physical characteristics of milk, cream, or whey by using enzymes, solvents, heat, pressure, cooling, vacuum, genetic engineering, fractionation, or other similar processes, and any such product made by the addition or subtraction of milkfat or the addition of safe and suitable optional ingredients for the protein, vitamin, or mineral fortification of the product.

Is Colostrum a Grade “A” Milk Product?

- Colostrum is a “milk product” (21 CFR 1240.3(j))
- Colostrum must be pasteurized in interstate commerce (21 CFR 1240.61)
 - **No person shall cause to be delivered into interstate commerce or shall sell, otherwise distribute, or hold for sale or other distribution after shipment in interstate commerce any milk or milk product in final package form for direct human consumption unless the product has been pasteurized** or is made from dairy ingredients (milk or milk products) that have all been pasteurized, except where alternative procedures to pasteurization are provided for by regulation, such as in part 133 of this chapter for curing of certain cheese varieties.

Is Colostrum a Grade “A” Milk Product?

- Colostrum is a “milk product” (21 CFR 1240.3(j))
- Colostrum must be pasteurized in interstate commerce (21 CFR 1240.61)
- Colostrum is not a Grade “A” milk product and cannot be used as an ingredient in a Grade “A” milk product (2023 PMO, Section 1 Definitions p 1, 8).
 - Milk containing colostrum is “undesirable milk” and is “not suitable for sale for Grade “A” purposes”.

Colostrum and Farm Requirements

- Farms may be producing colostrum to feed their calves, or may be sold as animal feed or as an ingredient in human foods or supplements.
- Farms exempt from preventive control requirements.
- PMO requirements do not apply to the production of colostrum on Grade “A” dairy farms.

Colostrum for Supplements

- Manufacturers involved in the manufacturing, packaging, labeling, and holding operations of dietary supplements (both containing colostrum or not) are subject to 21 CFR 111 (*Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements*).

Colostrum for Human Food

- When colostrum is used as an ingredient in foods, those who manufacture, process, pack or hold colostrum for human food are required to comply with 21 CFR 117 *Current Good Manufacturing Practice, Hazard Analysis, And Risk-Based Preventive Controls For Human Food*.
- A domestic or foreign food facility manufacturing colostrum for human food must (1) have and implement a written food safety plan that identifies food safety hazards that require a preventive control and (2) implement preventive controls to significantly minimize or prevent the hazard. This includes:
 - Hazard analysis
 - Preventive controls
 - Supply chain program

