

## **FINDING OF EMERGENCY**

The California Department of Food and Agriculture (Department) finds that an emergency exists, and that the attached regulation is necessary for the immediate preservation of the public peace, health and safety, or general welfare.

### **Emergency Defined**

“Emergency’ means a situation that calls for immediate action to avoid serious harm to the public peace, health, safety, or general welfare,” Government Code section 11342.545. If a state agency makes a finding that the adoption of a regulation is necessary to address an emergency, the regulation may be adopted as an emergency regulation pursuant to Government Code section 11346.1(b)(1). In this document the Department is providing the necessary specific facts demonstrating the existence of an emergency and the need for immediate action to preserve the public peace, health and safety, or general welfare.

Government Code section 11346.1(a)(2) requires that, at least five working days prior to submission of the proposed emergency action to the Office of Administrative Law, the adopting agency provides a notice of the proposed emergency action to every person who has filed a request for notice of regulatory action with the agency. After submission of the proposed emergency to the Office of Administrative Law, the Office of Administrative Law shall allow interested persons five calendar days to submit comments on the proposed emergency regulations as set forth in Government Code section 11349.6. The Department has complied with the requirements to provide notice of the proposed emergency rulemaking action at least five days prior to submitting the proposed rulemaking action to the Office of Administrative Law, pursuant to Government Code section 11346.1(a)(2).

The information contained within this finding of emergency also meets the requirements of Government Code Sections 11346.1 and 11346.5.

### **Background**

The Department received a petition on April 20, 2015 from Fairlife LLC requesting a temporary standard for a new milk product, ultra-filtered milk. Article 2 of Chapter 1 of Part 3 of Division 15 of the Food and Agricultural Code provides an avenue to allow novel products to be legally produced and sold in California.

### **SPECIFIC FACTS DEMONSTRATING THE NEED FOR IMMEDIATE ACTION**

The Department is seeking to adopt emergency regulations pursuant to the authority in existing law, section 36637 of the Food and Agricultural Code, which states that “Upon granting a petition under this article, the director shall adopt the standard as an emergency regulation pursuant to Chapter 3.5 (commencing with section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. For the purposes of this chapter, any regulations adopted under this article shall be deemed to be necessary for the immediate preservation of the public peace, health and safety, or general welfare.”

The Department received a petition on April 20, 2015 from Fairlife LLC requesting a temporary standard for a new category of milk product, ultra-filtered milk products. Pursuant to Food and Agricultural Code section 36634, the Department was required to notify the petitioner within 15 days of receipt of the petition as to whether a hearing would be granted. The hearing was required

to be held no later than 65 days following receipt of the petition. The hearing was conducted via a written legal brief, which any interested person could submit to the Department from May 5, 2015 through June 19, 2015 to establish if the product proposed for a temporary standard qualified for that standard. Interested parties were given the opportunity to submit testimony via a written legal brief. The submitted comments in the testimony were considered and used to amend the petition. The Department considered whether the proposed temporary standard differed significantly from that of existing definitions and standards. The Department also considered the health and safety conditions under which the proposed product will be processed and distributed. In granting a temporary standard, the Department has established appropriate definitions and nomenclature as well as quality and labeling requirements applicable to the permitted products. The petitioner is required to be notified no later than 30 days following the closing of the written comment period if the temporary standard was approved by the Department.

### **Alternatives Considered Other Than This Proposed Emergency Regulation**

No alternative exists for the Department other than this emergency rulemaking action. The Department is mandated to adopt the standard as an emergency regulation if a petition for a temporary standard is granted. Food and Agricultural Code section 36634 mandates a timeframe, as detailed above, for making a decision on a petition for a temporary standard. Given this mandate, the Department had no option other than an emergency regulation, as the time constraints mandated by Food and Agricultural section 36634 would not be met if the regular rulemaking process was followed.

The only viable option for the Department is to pursue an emergency rulemaking action to implement the temporary standard for Ultra-Filtered Milk Products, in accordance with Food and Agricultural Code sections 36633, 36634 and 36637. Any delay would result in the Department not being able to meet the timeline required for a decision on the petition as mandated in Food and Agricultural Code section 36634.

### **Authority and Reference Citations**

Authority: Sections 407, 36601 and 36637, Food and Agricultural Code.

Reference: Sections 32912, 32912.5, 35784, 36631, 36632, 36633, 38181, 38182, 38183, 38191, 38192, 38211, 38213, 38651, 38652, 38653, 38654, 39701, 39702, 39711, 39712, 39713, 39721, 39722, 39723, 39731, 39732, 39733, 39741, 39742, 39761, 39762, 39841 and 39842, Food and Agricultural Code.

### **INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW**

Existing law, section 407 of the Food and Agricultural Code, provides that the Department may adopt such regulations as are reasonably necessary to carry out the provisions of this code which it is directed or authorized to administer or enforce.

Existing law, section 36631 of the Food and Agricultural Code, provides that the Department administer article 2 of Chapter 1 of Part 3 of Division 15 of the Food and Agricultural Code, to accommodate, in a timely fashion, safe and wholesome milk products.

Existing law, section 36633(c) of the Food and Agricultural Code provides that in granting a temporary standard, the Department shall establish an appropriate definition and nomenclature as well as quality and labeling requirements applicable to the permitted product.

Existing law, section 36637 of the Food and Agricultural Code states that upon granting a petition under article 2 of Chapter 1 of Part 3 of Division 15 of the Food and Agricultural Code, the Department shall adopt the standard as an emergency regulation pursuant to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. For the purposes of Chapter 1 of Part 3 of Division 15 of the Food and Agricultural Code, any regulations adopted under article 2 of Chapter 1 of Part 3 of Division 15 of the Food and Agricultural Code shall be deemed to be necessary for the immediate preservation of the public peace, health and safety, or general welfare.

This proposal will adopt sections 450, 450.1, 450.2, 450.3, 450.4, 451 and 452 of Article 7, Chapter 1, Division 2 of Title 3 of the California Code of Regulations to establish a temporary standard for Ultra-Filtered Milk Products pursuant to Food and Agricultural Code sections 36633 and 36637. This temporary standard will allow for the production and sale of Ultra-Filtered Milk Products in California.

The Department has evaluated this proposal, and believes that it is not duplicative of, inconsistent with or incompatible with existing State regulations, as no regulations exist that define this new milk product. The Department believes the proposal is consistent with its mission statement, particularly encouraging innovation and creating fairness by allowing into the marketplace a new dairy product category, produced by a novel technology.

On May 5, 2015, the Department issued a notice of a public hearing to all interested and affected parties, and posted the notice on its Internet web site. The purpose was to consider the adoption of a temporary standard for ultra-filtered milk products in accordance with Food and Agricultural Code sections 36631 through 36638. The hearing was conducted exclusively by written brief, unless an oral hearing was specifically requested by an interested person. The Department did not receive a request for an oral hearing. After the close of the comment period ending at 5:00 p.m., June 19, 2015 the Department evaluated the public comments, and on July 17, 2015 granted the approval for a temporary standard. By approving the temporary standard, the Department is enhancing openness and transparency in business and government.

### **Description of Emergency Regulatory Text**

#### **Adopt Sections 450, 450.1, 450.2, 450.3, 450.4, 451 and 452 of Article 7, Chapter 1, Division 2 of Title 3 of the California Code of Regulations**

- Section 450 (Ultra-Filtered Milk Products) defines ultra-filtered milk products and states the standards and requirements that are to be met, as well as indicating that products shall be labeled in accordance with Title 21 of the Code of Federal Regulations.
- Section 450.1 (Ultra-filtered milk) specifies the milkfat, milk solids not fat and total milk solids requirements for ultra-filtered milk, and specifies to what degree the milk solids not fat and total milk solids may be reduced if lactose is removed by filtration. It also specifies what the product shall be labeled.
- Section 450.2 (Reduced Fat Ultra-Filtered Milk) specifies the milkfat and milk solids not fat requirements for reduced fat ultra-filtered milk, and specifies to what degree the milk

solids not fat may be reduced if lactose is removed by filtration. It also specifies what the product shall be labeled.

- Section 450.3 (Lowfat Ultra-Filtered Milk) specifies the milkfat and milk solids not fat requirements for lowfat ultra-filtered milk, and specifies to what degree the milk solids not fat may be reduced if lactose is removed by filtration. It also specifies what the product shall be labeled.
- Section 450.4 (Nonfat Ultra-Filtered Milk) specifies the milkfat and milk solids not fat requirements for nonfat ultra-filtered milk, and specifies to what degree the milk solids not fat may be reduced if lactose is removed by filtration. It also specifies what the product shall be labeled.
- Section 451 (Flavored Ultra-Filtered Milk Products) specifies the standards and requirements for flavored ultra-filtered milk, and specifies to what degree the milk solids not fat may be reduced if lactose is removed by filtration. It also specifies what the products shall be labeled.
- Section 452 (UHT Ultra-Filtered Milk Products) specifies the standards and requirements for UHT ultra-filtered milk and UHT flavored ultra-filtered milk, and specifies to what degree the milk solids not fat or total milk solids may be reduced if lactose is removed by filtration. It also specifies what the product shall be labeled.

#### **The Department relied upon the following information in making its determinations:**

The Department evaluated the petitioners request for a temporary standard as stated in their letter to the Department dated April 20, 2015 by comparing it to existing standards of identity, confirming that it did not meet any current standards of identity and then evaluated the proposed product standards and labeling as compared to requirements in the Food and Agricultural Code and Title 21 of the Code of Federal Regulations. The Department took comments received during the written comment period into account and made appropriate changes to the petitioner's original proposed standard. The Department evaluated the proposed product labels to confirm compliance with Title 21 of the Code of Federal Regulations, and also with the Food and Agricultural Code.

#### **Duplication or Conflicts with Federal Regulation**

This proposal does not duplicate or conflict with federal regulations because there are no federal regulations defining ultra-filtered milk products.

#### **Anticipated Benefits from this Regulatory Action**

The California dairy industry generates approximately \$21 billion in direct activity and \$65 billion in dairy related activity to California's economy. This proposal benefits the dairy industry by allowing a new product into the marketplace. There is considerable competition in the beverage industry for "shelf space" at retail. Encouraging innovation by allowing novel dairy products that are safe and wholesome, benefits the dairy industry and consumers as a whole.

## **FISCAL IMPACT ESTIMATES**

Fiscal impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None

Nondiscretionary Costs/Savings to Local Agencies: None  
Local Agency or School District Mandate: None

Cost to Any Local Agency or School District for Which Government Code Sections 14500 et Seq. Require Reimbursement: None

Business Impact: The Department has made an initial determination that the proposed regulatory action will have no significant statewide adverse economic impact directly affecting California businesses, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the fact that the proposed regulation imposes no new fees or costs to the dairy industry. The proposal benefits the industry and the public by allowing a new dairy product category to be manufactured, sold and consumed in California.

Cost Impacts on Representative Private Persons or Businesses: The Department is not aware of any cost impacts that representative private persons or businesses would necessarily incur in reasonable compliance with the proposed action. The proposed regulation does not impose any new fees or costs to persons or businesses. There is not a paperwork requirement as a result of this proposal.

Effect on Housing Costs: None

Effect on Small Business: This regulatory action may affect small businesses.

## REGULATORY TEXT

Department of Food and Agriculture  
Milk & Dairy Food Safety Branch  
Proposed Regulations – Ultra-Filtered Milk Products

Adopt Sections 450, 450.1, 450.2, 450.3, 450.4, 451 and 452 of Article 7, Chapter 1, Division 2 of Title 3 of the California Code of Regulations, to read as follows:

### Section 450. Ultra-Filtered Milk Products.

(a) Ultra-filtered milk products are market milk products resulting from the filtration of milk to alter the relative quantities of milk solids not fat components, including proteins, lactose, and minerals.

(b) Except as otherwise provided in this article, ultra-filtered milk products shall meet all standards and requirements that are specified in Division 15 (commencing with section 32501) of the Food and Agricultural Code for market milk.

(c) Ultra-filtered milk products shall be labeled in accordance with the applicable provisions of Title 21 of the Code of Federal Regulations.

Note: Authority cited: Section 407, 36601 and 36637 Food and Agricultural Code. Reference: Sections 32912, 32912.5, 35784, 36631, 36632, 36633, 38181, 38182, 38183, 38191, 38192, 38211, 38213, 38651, 38652, 38653, 38654, 39701, 39702, 39711, 39712, 39713, 39721, 39722, 39723, 39731, 39732, 39733, 39741, 39742, 39761, 39762, 39841 and 39842, Food and Agricultural Code.

### Section 450.1. Ultra-Filtered Milk.

Ultra-filtered milk shall contain not less than 3.5 percent of milkfat and not less than 8.7 percent milk solids not fat. The minimum percentages of milkfat and milk solids not fat required by this section may vary by an amount no greater than 0.1 of 1 percent, provided that the total combined percentages of milkfat and milk solids not fat, at the time of delivery to the consumer, shall equal or exceed 12.2 percent. However, when lactose has been completely or partially removed by filtration the total milk solids and the milk solids not fat percentages may be reduced by no more than the percentage of lactose removed. It shall be labeled "ultra-filtered milk."

Note: Authority cited: Sections 407, 36601 and 36637, Food and Agricultural Code. Reference: Sections 32912, 35784 and 36633, Food and Agricultural Code.

### Section 450.2. Reduced Fat Ultra-Filtered Milk.

Reduced fat ultra-filtered milk shall contain not less than 1.9 percent milkfat, not more than 2.1 percent milkfat, and not less than 10 percent of milk solids not fat, provided that when

lactose has been completely or partially removed by filtration the milk solids not fat percentage may be reduced by no more than the percentage of lactose removed. It shall be labeled "reduced fat ultra-filtered milk."

Note: Authority cited: Sections 407, 36601 and 36637, Food and Agricultural Code. Reference: Sections 32912, 36633, 38211 and 38213 Food and Agricultural Code.

#### Section 450.3. Lowfat Ultra-Filtered Milk.

Lowfat or light (lite) ultra-filtered milk shall contain not less than 0.9 percent milkfat, not more than 1.1 percent milkfat, and not less than 11 percent of milk solids not fat provided that when lactose has been completely or partially removed by filtration the milk solids not fat percentage may be reduced by no more than the percentage of lactose removed. It shall be labeled "lowfat ultra-filtered milk", "light ultra-filtered milk" or "lite ultra-filtered milk".

Note: Authority cited: Sections 407, 36601 and 36637, Food and Agricultural Code. Reference: Sections 32912, 36633, 38191 and 38192, Food and Agricultural Code.

#### Section 450.4. Nonfat Ultra-Filtered Milk.

Nonfat, skim or fat free ultra-filtered milk shall contain not more than twenty hundredths of 1 percent of milkfat and not less than 9 percent of milk solids not fat, provided that when lactose has been completely or partially removed by filtration the milk solids not fat percentage may be reduced by no more than the percentage of lactose removed. It shall be labeled "nonfat ultra-filtered milk", "skim ultra-filtered milk" or "fat free ultra-filtered milk".

Note: Authority cited: Sections 407, 36601 and 36637, Food and Agricultural Code. Reference: Sections 32912, 36633, 38181 and 38182, Food and Agricultural Code.

#### Section 451. Flavored Ultra-Filtered Milk Products.

(a) Flavored ultra-filtered milk shall contain not less than 3.25 percent milkfat and not less than 8.7 percent milk solids not fat, provided that when lactose has been completely or partially removed by filtration the milk solids not fat percentage may be reduced by no more than the percentage of lactose removed.

(b) Flavored reduced fat ultra-filtered milk shall contain not more than 2.1 percent milkfat and not less than 10 percent milk solids not fat, provided that when lactose has been completely or partially removed by filtration the milk solids not fat percentage may be reduced by no more than the percentage of lactose removed.

(c) Flavored lowfat ultra-filtered milk shall contain not more than 1.2 percent milkfat and not less than 11 percent milk solids not fat, provided that when lactose has been completely or

partially removed by filtration the milk solids not fat percentage may be reduced by no more than the percentage of lactose removed.

(d) Flavored nonfat, skim or fat free ultra-filtered milk shall contain not more than twenty hundredths of 1 percent of milkfat and not less than 9 percent milk solids not fat, provided that when lactose has been completely or partially removed by filtration the milk solids not fat percentage may be reduced by no more than the percentage of lactose removed.

(e) Flavored ultra-filtered milk products shall be labeled with the respective product name described in sections 450.1 through 450.4 of this article preceded by the term "flavored." The principal flavor may be substituted for the word "flavored" in the name of the product as, for example, "chocolate nonfat ultra-filtered milk." Flavored ultra-filtered milk products shall be so colored or contain ingredients that cause it to differ distinctly from milk in appearance and other characteristics.

Note: Authority cited: Sections 407, 36601 and 36637, Food and Agricultural Code. Reference: Sections 32912, 36633, 38651, 38652, 38653 and 38654, Food and Agricultural Code.

#### Section 452. UHT Ultra-Filtered Milk Products.

(a) Ultra-filtered milk products may be aseptically processed and packaged such that they would be UHT milk products.

(b) UHT ultra-filtered milk shall contain not less than 3.25 percent milkfat and not less than 8.25 percent milk solids not fat, provided that when lactose has been completely or partially removed by filtration the milk solids not fat percentage may be reduced by no more than the percentage of lactose removed.

(c) UHT reduced fat ultra-filtered milk shall contain not more than 2.1 percent milkfat and not less than 8.25 percent milk solids not fat, provided that when lactose has been completely or partially removed by filtration the milk solids not fat percentage may be reduced by no more than the percentage of lactose removed.

(d) UHT lowfat or light (lite) ultra-filtered milk shall contain not more than 1.2 percent milkfat and not less than 8.25 percent milk solids not fat, provided that when lactose has been completely or partially removed by filtration the milk solids not fat may be reduced by no more than the percentage of lactose removed.

(e) UHT nonfat, skim or fat free ultra-filtered milk shall contain not more than twenty hundredths of 1 percent of milkfat and not less than 8.25 percent milk solids not fat, provided that when lactose has been completely or partially removed by filtration the milk solids not fat percentage may be reduced by no more than the percentage of lactose removed.

(f) UHT flavored ultra-filtered milk shall contain not less than 3 percent milkfat and not less than 16 1/2 percent total solids, provided that when lactose has been completely or partially



removed by filtration the total solids percentage may be reduced by no more than the percentage of lactose removed.

(g) UHT flavored reduced fat ultra-filtered milk shall contain not more than 2.1 percent milkfat and not less than 8.25 percent milk solids not fat, provided that when lactose has been completely or partially removed by filtration the milk solids not fat percentage may be reduced by no more than the percentage of lactose removed.

(h) UHT flavored lowfat or light (lite) ultra-filtered milk shall contain not more than 1.2 percent milkfat and not less than 8.25 percent solids not fat, provided that when lactose has been completely or partially removed by filtration the milk solids not fat percentage may be reduced by no more than the percentage of lactose removed.

(i) UHT flavored nonfat, skim or fat free ultra-filtered milk shall contain not more than twenty hundredths of 1 percent of milkfat and not less than 8.25 percent of milk solids not fat, provided that when lactose has been completely or partially removed by filtration the milk solids not fat percentage may be reduced by no more than the percentage of lactose removed.

(j) UHT Ultra-filtered milk products shall be labeled with the respective product name described in sections 450.1 through 450.4 of this article, preceded by the term "UHT" and by the term "flavored" as applicable. The principal flavor may be substituted for the word "flavored" in the name of the product as, for example, "UHT chocolate lowfat ultra-filtered milk.".  
Notwithstanding other provisions of Food and Agricultural Code section 39715, the term "ultra-filtered" may be used in lieu of the term "modified" in the product name. UHT flavored ultra-filtered milk products shall be so colored or contain ingredients that cause it to differ distinctly from milk in appearance and other characteristics.

Note: Authority cited: Sections 407, 36601 and 36637, Food and Agricultural Code. Reference: Sections 32912, 36633, 39701, 39702, 39711, 39713, 39721, 39722, 39723, 39731, 39732, 39733, 39741, 39742, 39761, 39762, 39841 and 39842, Food and Agricultural Code.