

January 17th, 2006

The Division of Dockets Management

(HFA-305)

Food and Drug Administration

5630 Fishers Lane

Room 1061

Rockville, MD 20852

Dear Sir/Madam:

Re: Docket No. 2000P-0586 -- Cheeses and Related Cheese Products; Proposal to Permit the Use of Ultrafiltered Milk

These comments are submitted by Dairy Australia on behalf of the Australian Dairy Industry. Dairy Australia is a private, not-for-profit industry services association. Dairy Australia's activities are funded by a compulsory check-off on all cows milk produced in Australia. The size of the check-off is decided by a weighted vote of all economically active dairy farmers every three years.

Dairy Australia welcomes the opportunity to provide comments on the United States of America (US) Government's Federal Register Docket No. 2000P – 0586, notice on a proposal to amend 21 CFR Part 133 – Cheese and Related Cheese Products; Proposal to Permit the Use of Ultrafiltered Milk.

Australian dairy processors are globally competitive; producing high quality milk protein concentrates (MPC's). Exports of these value added dairy ingredients to the United States and a range of other countries are not subsidized i.e. Australian dairy processors rely solely on the market place for turnover and profitability. Australian origin MPC exports have entered the US market for over 20 years, since 1982.

Introduction:

The comments below outline Dairy Australia's position regarding the proposed amendments to the definitions of "milk" and "nonfat milk" set forth in 21 C.F.R. § 133(a) and (b) respectively, namely revising the current definitions to allow for the use of liquid ultra-filtered (UF) milk and liquid ultra-filtered nonfat (or skim) milk in the manufacture of standard of identity cheeses.

In summary Dairy Australia supports FDA's conclusion that the basic nature and essential characteristics of cheeses are maintained when fluid UF milk is used in the cheese making process. This is also the outcome, however, whether the UF milk used is liquid or dry; the latter embodied in the form of MPC.

Drawing from the 'Summary' of the Federal Register (F.R.) notice the three key response topics are;

- Are the reasons for FDA approved use of fluid ultra-filtered (UF) milk in the manufacturer of standardised cheeses and related cheese products sufficiently sound
- Does the proposed rule promote honesty and fair dealing in the interests of consumers, and
- Will consistency with existing international standards of identity for cheeses and related products with specific reference to Codex decisions be established by the proposed rule-making

1). Are the reasons for FDA approved use of fluid (or wet) ultra-filtered milk in the manufacture of standardised cheeses and related cheese products sufficiently sound?

From the perspective of Dairy Australia there are a number of inter-related factors or reasons, including sound science that should influence the rule making. These factors should not be considered in isolation but form essential components of a balanced opinion and final rule making by FDA.

The benefits of competition:

FDA's cost benefit analysis neglects important upstream and downstream linkages arising from incorporating competitively priced and functionally and nutritionally beneficial inputs into cheese make.

Competition benefits the whole supply chain, from dairy farmers through to the consumer by creating dairy products able to compete successfully with non-dairy alternatives and through transmitting

appropriate commercial signals back to processors and farmers about the value of their products (or ingredients) and raw milk respectively. The lower the cost of manufacturing cheese, through the economic benefits conferred by using either dry or fluid UF milk, creates the opportunity for reducing prices to downstream buyers including food service firms, retailers and consumers. A lower wholesale and retail price in turns grows demand for cheese, thereby benefiting both processors and producers through greater demand for the essential milk solids (fat and protein) used in cheese make. Greater demand has the potential, particularly in the short-term when supply constraints such as cow numbers are difficult to adjust, of raising milk and wholesale cheese prices and in the medium to longer-term of raising cash-flow from respective farm and factory operations.

Impact on smaller business entities:

The Regulatory Flexibility Act ("RFA") requires that the FDA consider the economic impact that a proposed rule will have on small entities. Specifically, the RFA mandates that the Agency conduct an analysis describing "the impact of a proposed rule on small entities" (5 U.S.C. § 603). "The initial regulatory flexibility analysis or a summary shall be published in the Federal Register at the time of the publication of the general notice of proposed rulemaking for the rule." When an agency promulgates a final rule, the required regulatory flexibility analysis must set forth in detail "the steps the agency has taken to minimize the significant economic impact on small entities," including "a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected" [5 U.S.C. § 604(a)(5)].¹

The FDA proposal to allow only fluid UF milk (Option 1) would disadvantage smaller U.S. cheese manufacturers economically (purchased volume too large) and logistically (handling, refrigeration and storage capacity) relative to larger manufacturers (page 60,760). Fluid UF milk is purchased by the truck

¹ The final regulatory flexibility analysis must also contain (1) a succinct statement of the need for, and objectives of, the rule; (2) a summary of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments; (3) a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available; (4) a description of the projected reporting, record-keeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record. See 5 U.S.C. § 604(1)-(4).

load or 50,000 pounds. While the FDA notes that the high cost of implementing dry UF technology may be prohibitive for small dairy processors (page 60,763) this outcome will not arise with dry UF milk protein products, the latter can be purchased in volumes to suit the ingredient requirements of the cheese plant.

Innovation:

Dairy Australia does not believe that governments should stifle innovation by regulating specific manufacturing processes² and therefore it should be up to the manufacturer to devise processes and sequences of process steps that will reflect raw materials that they use; as long as the final product characteristics³ are consistent with the relevant international standard and consumers' expectations. Consequently Dairy Australia does not accept as relevant arguments against the use of microfiltered milk, fluid or dried, and some arguments in relation to dried UF milk.

The technical straight jacket imposed on manufacturers and the dairy industry as a whole by Government attempts to "qualify" R&D developments and applications may place use of milk and dairy products at an economic disadvantage because these procedural restraints may not apply in competitor (non-dairy substitutes) food standards

Technical parameters:

The development of membrane filtration technology has led to the development of a wide range of protein ingredients whose suitability for use in cheese make was highlighted was supported by email advice dated December 14, 2005 from Peter Hobman, General Manager, MG Nutritionals & Corporate R & D to Robert Pettit of Dairy Australia⁴. To quote;

"Further to our recent conversation, I can confirm that our studies indicate that spray dried MPC with suitable functional properties can be successfully used by addition to milk in the manufacture of cheese such as Cheddar and similar varieties. There are no technical reasons that we are aware of that would make use of liquid UF retentate preferred to a high quality spray dried MPC manufactured by ultrafiltration of fresh skim milk using appropriate conditions".

² Other than safety and hygiene systems.

³ Characteristics are embodied in the consistency (texture, colour and flavour) of the cheese.

The high levels of lactose content in nonfat (skim) milk, nonfat dry milk powder (or SMP) or condensed skim makes standardization with MPC an attractive alternative given the latter's relatively high protein and low lactose content. In such a process, MPC's functionality is exactly the same manner as UF nonfat milk.

UF milk sourcing, pricing and demand is influenced by the following inter-related factors;

- Government mandated regulations such as creating a favourable but unjustifiable commercial advantage for fluid UF milk usage as compared to dry UF milk may lead to two unfavourable outcomes encouraging;
 - Movement of cheese make into non-standard identity of cheeses, and
 - Fostering technical developments including replacement of dairy with non-dairy ingredients such as soy
- The adverse competitive position that dairy may find itself in if artificial restrictions are imposed on sourcing of high quality UF milk, for example;
 - Cost pressures as a result of a combination of unfavourable currency movements and changes in the protein (NDM) support price and/or international prices creating an economic incentive to sell proteins in the form of NDM to the CCC rather than commercially; noting the unfeasibility of exporting wet UF milk to the U.S. by sea, or
 - If a shortage of fluid UF milk occurs in the United States as a result of demand/supply imbalance, will drive up the price of the ingredient and the final product for the consumer and thereby reducing total demand with attendant adverse financial impacts on consumers and cheese maker

These factors if either unduly influenced or determined by non-essential (for consumer welfare) and non-commercial factors will ultimately impact upon factory employment and dairy farmer's income through reduced demand for milk.

Import and Export of Milk Proteins:

Australia since 1995 has been the third largest supplier of imports of MPC's to the United States; behind New Zealand and the European Union. Imports of MPC under chapters four and 35 of the Harmonized

⁴ MG Nutritionals, a subsidiary of Murray Goulburn Co-operative Ltd. are Australia's largest manufacturer of MPC.

Tariff Schedule of the United States peaked in 2000 at 64,599 tonnes; see table below. The subsequent decline in imports occurred, however, during a period of growing demand for MPC. The growing price competitiveness of U.S. origin milk proteins, particularly since mid 2003 has resulted in a surge in domestic MPC production in both wet and dry forms i.e. U.S. manufacturers are moving from an uncompetitive position to a competitive position compared to the pricing of imported milk proteins by mid 2003.

US Imports of MPC - Total Volume (Tonnes) by Origin								
Origin	Tariff Id	Descriptio	2000	2001	2002	2003	2004 Jan-Oct 2005	
AUST	0404901000	Milk Proteii	6,936	2,154	2,564	4	76	144
	3501101000	Milk Proteii	20	117	1,453	5,510	5,431	2,478
AUST Total			6,956	2,271	4,017	5,513	5,506	2,622
EU-25	0404901000	Milk Proteii	22,874	4,846	10,018	6,981	4,451	2,183
	3501101000	Milk Proteii	8,425	2,606	3,535	4,120	1,548	4,205
EU-25 Total			31,299	7,452	13,553	11,101	5,999	6,388
NZ	0404901000	Milk Proteii	19,352	21,192	20,610	28,360	31,720	32,111
	3501101000	Milk Proteii	3,263	4,081	2,681	2,908	2,728	2,476
NZ Total			22,614	25,274	23,290	31,268	34,448	34,587
Other	0404901000	Milk Proteii	3,516	276	433	153	793	896
	3501101000	Milk Proteii	214	130	147	211	943	447
Other Total			3,730	406	580	364	1,735	1,343
Grand Total			64,599	35,403	41,441	48,246	47,689	44,940

Source: US Customs

US Exports of SMP & MPC - Total Volume (Tonnes)							
Tariff Id	Description	2000	2001	2002	2003	2004 Jan-Oct 2005	2005
0402100000	Skim milk powde	101,048	96,159	74,063	114,778	230,909	245,205
Total SMP		101,048	96,159	74,063	114,778	230,909	245,205
0404900000	Milk Preparations	4,540	2,843	2,323	1,491	3,581	8,522
3501100000	Casein, lactic	2,121	1,072	448	671	826	770
3501902000	Casein glue	1,403	741	1,266	1,011	1,066	1,045
3501906000	Caseinates, co-p	1,450	1,537	705	1,221	2,100	2,791
Total casein and milk proteins		9,514	6,194	4,742	4,394	7,572	13,128

The changing dynamics of trade reflect favorable international market developments. Consecutive reductions in the NDM support price in May 2001 and November 2002 and a sustained upswing in the international (or traded) price for milk proteins since mid 2003 has resulted in the following favorable impacts for the U.S. dairy industry;

- The United States has emerged in 2004 and 2005 as a major, non subsidized exporter of milk proteins, primarily but not solely in the form of NDM

- The last subsidized sale under the Dairy Export Incentive Scheme or DEIP was awarded in January 2004
- The absence of sales of NDM to the Government (CCC) since November 2004
- The emergence of an unsubsidized, import replacing MPC industry in the United States. Since the second half of 2003 a joint venture between Fonterra and Dairy Farmers of America the U.S.'s largest dairy co-operative has resulted in profitable production, using the filtration method, at Portales, New Mexico. A second MPC plant for operation in 2006 is being developed in Arizona to produce MPC70; a joint venture between the United Dairymen of Arizona and Fonterra. Combined both plants are estimated to meet half of total US demand, a complete turnaround from almost total import dependence in 2000!

2). Does the proposed rule promote honesty and fair dealing in the interests of consumers?

Dairy Australia believes that consumers should make, and are capable of making, an informed decision based on correct and truthful ingredients labelling (and the US legislation already requires that).

The use of MPC benefits both consumers and manufacturers through:

- Ease of use; MPC easily dissolves in milk or can be reconstituted in water before adding to milk.
- Provides economic advantages; MPC can be purchased in specified volumes rather than by 50,000 pound truck loads as necessitated in fluid form. Liquid UF milk has to be kept refrigerated, increasing storage costs and suitability for cheese make is limited to a few days
- Standardization of milk with MPC results in higher cheese yields per unit of milk input into the vat when compared with either traditional cheese making processes or standardization with nonfat UF milk. This improves labor productivity and potentially profitability
- Reduced volume of whey and ensuing disposal costs when MPC is added directly to milk for cheese making compared to using nonfat UF milk or skim milk for standardization. Also, the resultant whey produced has reduced lactose due to the low lactose content of MPC.
- Use of MPC retains the nutritional value of the cheese as compared to the use of liquid UF milk.

3). Will consistency with existing international standards of identity for cheeses and related products with specific reference to Codex decisions be established by the proposed rule-making

The FDA prohibition on the use of UF milk protein in standard of identity cheese puts U.S. cheese plants at a disadvantage in world markets where Codex Alimentarius Commission (Codex) allows European manufacturers to make cheese with UF milk protein.

Dairy Australia also believes that, to reflect the generality and non prescriptiveness of relevant Codex standards (Codex Stan A-6-1978, Rev 1-1999, Amended 2003; Codex General Standard for Cheese; Standards C for various types of cheeses; and also CAC/RCP 57-2004 Code of Hygienic Practice for Milk and Milk Products), both fluid and dried ultrafiltered and microfiltered milk should be allowed in the manufacture of standardised cheeses and related cheese products provided that the final product characteristics (texture, colour, flavour) are consistent with relevant international standards and consumer's expectations.

Such a definition would be consistent with FDA's endorsement of the international harmonization of regulatory requirements. Specifically, in its proposed rule addressing food standards' modernization, the Agency stated that "[w]ith the rising trend in globalization and increased accessibility of U.S. goods to other nations' markets, efforts to harmonize U.S. food standards with international food standards will facilitate international trade and foster competition." (70 Fed. Reg. 29,212, 29,214 and 29,223)⁵.

Additional issues: WTO:

As a result of the realities of trade in milk and milk products, the decision not to allow dried UF and microfiltered products in the manufacture of standardised cheeses and related cheese products would favour domestically produced (fluid) products and hence would be against the spirit of WTO agreements.

Conclusion:

⁵ The Codex standard of identity for cheese not only permits the use of UF technology, but more broadly provides that cheese must contain "milk and/or products obtained from milk," Codex General Standard for Cheese, A-6-1978, amended 2003. Under Codex Standard 206-199, a "milk product" is "a product obtained by any processing of milk".

The use of dry or fluid U/F milk in cheese make does not alter the basic characteristics (essential chemical and physical properties or sensory attributes or the nutritional value and profile) of the finished cheese when compared to traditional cheese making⁶.

The proposed rule also does not go far enough technically and commercially. The rule making should also encompass the utilization of dry UF in standard identity of cheese make. Such an extension would benefit both consumers and processors through providing high quality, competitively priced inputs from a wide range of sources.

Yours sincerely,



Robert Pettit
Manager Americas and Caribbean
Trade and Strategy Group
Email address: rpettit@dairyaustralia.com.au

⁶ In traditional cheese making milk is used as a starting material and the water-soluble constituents of the whey (i.e., water, lactose, whey proteins, and vitamins and minerals) are wholly or partially removed from the cheese curd through a draining procedure known as "whey syneresis." Whether the water-soluble constituents are removed during the draining procedure or during filtration of the milk, the end result is exactly the same; a finished cheese with the same chemical properties, sensory attributes, and nutritional value.