SPRING SHEEP
— MILK CO. —
New Zealand

Spring Sheep Milk Co (SSMC) submission to FSANZ regarding the proposed P1028 changes. 17 June 2022

Protein Source

1. FSANZ's preferred approach is that the protein sources in infant formula be specified to be cow's milk protein, goat's milk protein, protein hydrolysates of one or more proteins normally used in infant formula and soy protein isolate. Any protein sources outside of those specified will need to undergo a premarket assessment through FSANZ.

    1.1 SSMC agrees that protein is essential for life and an important component of the infant diet (including infant formula). Protein supplies the body with essential amino acids, the building blocks for growth and maintenance of our cells and tissues. Protein occurs in all living cells and has both functional and structural properties (NHMRC, 2006). Proteins play a particularly important function in infancy when growth and development are at their peak.

    1.2 The Food Standards Code already controls the amount of protein and protein quality through establishment of essential amino acid minimums. SSMC agrees with INC.

    1.3 The amino acid profile of SSMC infant formulas mimics the profile in human milk, in addition the ratio of whey to casein proteins being adjusted to comparable levels of whey to casein observed in human milk. (Nagasawa et al., 1972; Nagra, 1989; Kunz and Lönnerdal, 1992; Montagne et al., 2000; Lönnerdal and Kelleher, 2009).

    1.4 SSMC however disagrees that sheep milk is a novel protein source. Sheep have been milked for thousands of years and were milked before cows. The world's commercial dairy sheep industry is concentrated in Europe and the countries on or near the Mediterranean Sea. New Zealand, USA and China have emerging commercial sheep dairy industries. The dairy sheep industry is growing in the United States. There are about 200 dairy sheep farms in the U.S. There are several large commercial sheep dairies in New York and California.

2. SSMC believes a novel protein source for use in infant formula is one that has been concentrated, refined or synthesised to achieve a nutritional purpose, and this would require premarket approval (as per Standard 1.1.2—12). Also, that an enzyme used in the preparation of protein hydrolysates for infant formula needs to be approved within the Food Standards Code, in alignment with INC.

3. INC and SSMC strongly opposes a positive list of permitted proteins from animal sources. FSANZ does not appear to provide any scientific justification to vary from Codex internationally. Codex STAN 72-1981 and Codex draft FUFOI clearly allow milk of other animals as the following attests:

    Codex draft FUFOI

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*3.1.1. Follow-up formula for older infants is a product based on **milk of cows or other animals or a mixture thereof** and/or other ingredients which have been proven to be safe and suitable for the feeding of older infants. The nutritional safety and adequacy of follow-up formula for older infants shall be scientifically demonstrated to support growth and development of older infants.*

Codex STAN 72-1981
3.1.1 *Infant formula is a product based on **milk of cows or other animals or a mixture thereof** and/or other ingredients which have been proven to be suitable for infant feeding. The nutritional safety and adequacy of infant formula shall be scientifically demonstrated to support growth and development of infants. All ingredients and food additives shall be gluten-free.*

4. Currently, sheep milk-based infant formulas are made in New Zealand exported to Australia and other international markets including China, Malaysia and Hong Kong. Sheep milk formula has been available for years on the market without any issues raised by Authorities in New Zealand or Australia. Notably, the FSANZ proposal and submitters for CP2 did not raise any issues specifically with sheep milk or other mammalian milk. In fact, the New Zealand Food Authority submission did not support the restriction for mammalian milks. The main concerns for protein source raised under the proposal and by submitters were in relation to plant-based proteins and the presence of anti-nutritive factors. Therefore, if FSANZ are going to implement a positive list then this should be limited to plant-based proteins only.

5. Although most products (including infant formulas) are based on cow's milk which accounts for 82% of global milk production, the use of other mammalian milks has increased in recent years. The contributions of buffalo (14%), goat's (2.3%), sheep's (1.4%) and camel's (0.3%) milk are ever-increasing, and these milk alternatives have the potential to contribute to food security, nutrition and health (Verduci et al. 2019). Milk from Ovis aries (sheep), is currently available in New Zealand, China, Turkey, Greece. Syria and Romania, amongst others (Maryniak et al. 2022). Sheep milk, like all mammalian milks, has a high nutritional content and quality protein even before modification in accordance with infant formula standards.

   World Milk Production (FAO of United Nations, 2017)

Species	Tonnes	Percent of total
Cow	675,621,019	82
Buffalo	120,353,705	14
Goat	18,656,727	2
Sheep	10,400,639	1
Camel	2,852,213	0.3
Total	**827,884,30**	**100**

6. Although SSMC are opposed to a positive list for animal sources, on the advice of FSANZ, have included data that would support the inclusion of sheep milk–formula–in this submission.

7. Sheep's milk is similar to goats' milk and it contains high amino acid sequence identities with cows' milk protein ranging between 85 and 95% (Maryniak et al. 2022). This is not surprising given the relationship between species. The *Ovis aries* (sheep) species belongs to the same suborder (Ruminantia) and family (Bovidae) as *Bos Domesticus* (cow) and *Capra hircus* (goat). This similarity also unfortunately means that sheep's milk cannot be used as an alternative protein source for infants diagnosed with cows' milk protein allergy. Similar to cows' milk, sheep's milk also contains a ratio of caseins to whey proteins at 80:20 and contains all necessary amino acids for infant formula as set out in the table below.

8. Sheep milk compositional data (SSMC can provide seasonal milk composition data if requested). Data has been included to highlight the similarities in mammalian milk composition with emphasis on the amino acids required to meet the infant formula standard.

Protein and Amino Acid Content of Different Species of milk (adapted from Claeys, 2014) including confidential SSMC data

Nutrient	**Sheep**	**SSMC 2021/22 Seasonal data (n=6)**	**SSMC 2020/21 Seasonal data (n=21)**	**Goat**	**Cow**
Total Protein Content	5.75	5.63	5.59	4.1	3.45
Amino Acid	**(mg/g protein)**	**(mg/g protein)**	**(mg/g protein)**	**(mg/g protein)**	**(mg/g protein)**
Histidine	29	26	27	24	29
Isoleucine	59	50	51	50	41
Leucine	102	92	96	77	84
Lysine	89	79	81	71	78
Threonine	47	43	44	59	43
Tryptophan	15	14	13	11	14
Valine	78	62	64	59	46
Methionine	27	25	26	20	17

n = composite weekly whole milk powder analysis

Protein Profile (g/L) of milk from different mammalian species (adapted from Roy D)

Protein Fractions	**Sheep**	**Goat**	**Cow**
Total casein	41.8-52.6ꝏ	23.3-46.3	24.6 – 28
Total whey proteins	10.2-16.1ꝏ	3.7-7.0	5.5 - 7.0
Casein-to-whey protein ratio	76 : 24	78 : 22	82 : 18
Major caseins			
αs1-Casein	2.4ꝏ-22.1	0 -13.0	8 - 10.7

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αs2-Casein	6	2.3 -11.6	2.8 - 3.4
β-Casein	15.6-39.6ꝏ	0 - 29.6	8.6 - 9.3
κ-Casein	3.2-12.23ꝏ	2.8 - 13.4	2.3 - 3.3
Major whey proteins			
β-Lactoglobulin	6.5-13.5ꝏ	1.5 - 5.0	3.2 - 3.3
α-Lactalbumin	1-1.9	0.7 - 2.3	1.2 - 1.3

Nutrient Content of Different Species (adapted from Park 2006, 2007)

Constituents (100g milk)	**Sheep**	**Goat**	**Cow**
Calcium (mg)	193	134	122
Phosphorus (mg)	158	121	119
Magnesium (mg)	18	16	12
Potassium (mg)	136	181	152
Sodium (mg)	44	41	58
Chlorine (mg)	160	150	100
Iron (mg)	0.08	0.07	0.08
Copper (mg)	0.04	0.05	0.06
Manganese (mg)	0.007	0.32	0.02
Zinc (mg)	0.57	0.56	0.53
Iodine (mg	0.02	0.022	0.021
Selenium (µg)	1	1.33	0.96
Vitamin A (IU)	146	185	126
Vitamin D (IU)	7.2	2.3	2
Thiamin (mg)	0.08	0.068	0.045
Riboflavin (mg)	0.376	0.21	0.16
Niacin (mg)	0.416	0.27	0.08
Pantothenic acid (mg)	0.408	0.31	0.32
Vitamin B6 (mg)	0.08	0.046	0.042
Folic acid (µg)	5	1	5
Biotin (µg)	0.93	1.5	2
Vitamin B12 (µg)	0.712	0.065	0.357
Vitamin C (mg)	4.16	1.29	0.94

Milk Composition Comparison (adapted from park 2006, 2007)

	Sheep	**Goat**	**Cow**
Fat (%)	7.9	3.8	3.6
Solids-not-fat (%)	12	8.9	9
Lactose (%)	4.9	4.1	4.7
Protein (%)	6.2	3.4	3.2
Casein (%)	4.2	2.4	2.6
Albumin, globulin (%)	1	0.6	0.6
Non-protein N (%)	0.8	0.4	0.2
Ash (%)	0.9	0.8	0.7
Calories/100 ml	105	70	69

9. The fatty acid profile of sheep's milk is quite similar to that of goats' milk, and the content of saturated fatty acids is comparable to that of cows' and goats' milk (Verduci et al. 2019)

10. A number of New Zealand government authorities already refer to sheep milk formula which demonstrates acceptance that sheep milk formula complies with the current Food Standards Code and is a suitable protein source. This includes:

    10.1 the New Zealand Ministry of Health "…when breast milk is not available, a dairy-based infant formula (made from cows', goats' or sheep milk) is the next best choice for most babies. Research suggests that no particular infant formula offers benefits over any other"

    10.2 MPI in the New Zealand *Labelling Requirements for Exports of Dairy Based Infant Formula Products and Formulated Supplementary Food for Young Children* "dairy based means the formula contains, as its predominant protein constituent, protein derived or processed from milk extracted from a milking animal such as a cow, goat or sheep"

11. Sheep milk is not only a great source of nutrition it is safe to consume. Sheep milk farming in New Zealand is governed in the same way as bovine and caprine milk and all farms operate under strict RMPs. SSMC supplier farms are held to a very high standard of practice. Sheep milk is also included in the NZ Food Safety National Chemical Contaminants Programme. Raw Milk Results Summary (July 2020 to June 2021) (mpi.govt.nz) This gives SSMC confidence in the safety and suitability of the milk produced to be used for sensitive population products including infant formula.

    Results from the NZ Food Safety National Chemical Contaminants Programme (Raw Milk) July 2020-June 2021
    Over the 1 July 2020 to 30 June 2021 dairy season there were **no results exceeding New Zealand maximum residue levels (MRLs) for sheep milk**
    14 samples in total tested for sheep milk (statistically based at farm level) - The NCCP is designed to:

    - confirm the effectiveness of the regulatory controls in place for ensuring residues and
    - contaminants in raw milk and manufactured dairy products do not pose a threat to human health;
    - that Good Agricultural Practice is being followed; and
    - that relevant importing country requirements will be met.

    The randomly allocated sampling of raw milk occurred at the farm bulk milk tank prior to any further consolidation, co-mingling, or dilution with raw milk from other farms.
    More than 500 individual compounds or elements including:

    - veterinary medicines
        1. antibiotics
        2. anthelmintics
        3. NSAIDS
    - contaminants
        1. aflatoxins

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2. chemical elements
3. process contaminants and biocides

- agricultural compounds
  1. insecticides
  2. herbicides
  3. fungicides
- other compounds such as withdrawn compounds or those not permitted for food producing animals

12. Sheep milk proteins are more easily digested than cow's milk proteins. This makes sheep milk infant formula an important offering to those who are looking for an alternative to bovine infant formula. (Sheep milk nutrient bioavailability and digestive comfort: A randomised control trial *see attached document*) Sheep and goat milk have been shown to have softer curds, which is a principal factor to digestibility. However, the mechanisms of digestion between cow, sheep and goat are similar. (Roy et al, 2021) this shows that both goat and seep milk are once again very similar in their composition and digestibility.

Sheep milk infant formula in various markets

13. The use of sheep milk protein as the protein source in Infant formula products is already approved in countries and is currently sold in many countries including Australia, New Zealand, China, Hong Kong and Malaysia.

14. Many other countries, that have adopted the CODEX ALIMENTARIUS International standards, also permit sheep milk protein based infant formula on their markets without pre-market assessment of the protein source.

    14.1 The GCC (United Arab Emirates, Qatar, Saudi Arabia, etc) and Russian food standards do not specify animal sources of milk and does not exclude sheep milk.

    14.2 Taiwan has adopted the Codex definition and defines infant formula as “a product based on the milk of cows and other animals”.

    14.3 The South Korean Ministry of Food and Drug Safety’s Food Code 2021 defines ‘Milk’, in Chapter 3 Section 9, to be from mammals and specifies cow, goat and sheep milk as examples. Chapter 3 Section 15 list the specifications for sheep raw milk. Another definition of ‘milk’ under the ‘Milk products’ section in the Food Code 2021 only requires that it originates from 100% raw milk. The ‘Infant Milk Formula’ definition allows for ‘milk’ as the base and does not further detail the protein source.

15. Since the use of sheep milk protein as the protein source in Infant formula products is already approved in many countries, the ability to include it in Infant formula products for sale in Australia and New Zealand will facilitate trade with countries where it is already permitted due to exemptions for export of Infant formula products with sheep milk protein as the protein source no longer being required. This will help level the playing field for ANZ manufacturers, providing a better competitive position.

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16. There is a history of safe consumption, over a number of years, in the countries where sheep infant formula products are on the market.

Spring Sheep's proven track record of sales & distribution around the world.

17. Spring Sheep has been a high-quality ingredient (mainly whole sheep milk powder) provider to the Infant Formula industry since March 2017.

18. In 2018, Spring Sheep completed a full-scale blending and canning trial and commenced shelf-life testing of its infant formula, follow-on formula and young child formula for the Chinese market.

19. In February 2020, Spring Sheep's Stage 3 Toddler Milk was manufactured for the Hong Kong market and launched later that year. The Stage 2 Follow-on Formula was launched early 2021 in Hong Kong.

20. Spring Sheep launched their Gentle Sheep® Stage 3 Sheep Milk Formulated Milk Powder for Children into the Malaysian market in July 2020. Then in June 2021, after successfully achieving market registration and label vetting with Malaysia's Ministry of Health, they launched their GS-Ovi 1™ Stage 1 Sheep Milk Infant Formula into the Malaysian market.

21. In January 2021, Spring Sheep launched their Gentle Sheep early life range (infant formula, follow-on formula and toddler milk drink) into the New Zealand market for the first time as well as on their flagship store on Tmall Global which is the largest online cross border e-commerce sales platform in China. This range has since launched, been sold online in NZ, in NZ supermarkets and recently have branched out into multiple other Chinese cross border e-commerce platforms.

Protein Range **(~~Cow's and Goat's~~ Milk Proteins)**

22. SSMC agrees with the FSANZ proposal for a protein range of 0.43 – 0.72 g/100kJ (maximum corrected to two significant figures).
    - SSMC recommends that this range is applied to ***milk of cows or other animals*** based infant formula products, which is consistent with international standards (CODEX STAN 72'1981 and EU Regulation 2016/127).

SSMC Submission Proposal Consolidated

- SSMC recommends that protein source is applied to ***milk of cows or other animals*** which is consistent with international standards (CODEX STAN 72'1981 and EU Regulation 2016/127).
- Or we submit that sheep milk is added to the list of positive inclusions. Protein source is from **cow's milk protein, goat's milk protein, sheep's milk protein, protein hydrolysates of one or more proteins normally used in infant formula and soy protein isolate**

[redacted]

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