Report to the Technical Consultative Committee (TCC) – Recommended Product Safety Limits for the NZ Dairy Industry

TCC Sub-Group 1 Microbial Product Safety Limits (PSLs)

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1. Introduction:

Safe food is that which does not contain pathogens, toxins or other injurious substance above a level that is likely to endanger consumer health.

Confidence in food safety may exist when a manufacturing process is operating under a product safety or risk management programme (PSP/RMP) and the following have been achieved:

- hazards have been identified by HACCP
- in-process monitoring shows that CCPs are controlled
- pathogens are not recovered during environmental monitoring
- end-product testing verifies compliance with the *product safety limits* (PSLs) (as set out in NZFSA Dairy Standard D107).

Key to this confidence in food safety is that these mandatory *product safety limits* (PSLs) *correctly differentiate between foods that have a low or a high risk of causing illness.*

Objective: Sub-group 1 was set the task of recommending, to the TCC, appropriate PSLs for the main pathogens of concern to the dairy industry and for the wide range of products manufactured by the New Zealand industry.

2. How to Set PSLs?

Before launching in to the PSL-setting process, the sub-group tried to define the methodology it would use for developing the PSLs recommended in this document.

However, as the efforts of previous working groups in developing the old New Zealand Industry Code of Practice NZCP5 & MAF Std D107) have shown, finding a sound, logical basis for the PSLs is not straightforward. For example, should PSLs:

- be based on risk assessment?
- be synchronised with relevant standards of other national and international organisations?
- be generic or product-specific?
- take in to account the risk to different consumer groups?

The sub-group opted for:

- **a two-class PSL approach:**
  - **(1) General PSLs - for the less susceptible / general population.**
  - **(2) Specific PSLs - for products that are specifically designated for / and are likely to form a substantial part of the dietary intake of more susceptible members of the population (ie the young, old, pregnant and immuno-compromised).**

- **generic rather than product-specific PSLs (except when necessitated by certain product / process combinations).**

The approach is summarised in Figure 1. Simplistically, for each pathogen:

The PSL = The UNSAFE LEVEL – a SAFETY MARGIN

A. **Unsafe Level:** For each pathogen, an *'unsafe level'* was derived from various publications etc). For any food, this is the level at or above which there is a *very high risk of illness* if that food is consumed.

B. **Safety Margin:** In each case, a *'safety margin'* was set below the 'unsafe level'. This was to give increased confidence that a food would not contain pathogens at a level that would be likely to cause illness. When setting the 'safety margin' the intention was to take in to account: characteristics of the organism, disease mechanism, illness severity, food matrix, how food is used, amount of food consumed etc.

C. **Product Safety Limit:** The PSL is the figure below which there is an *extremely low risk* that illness will occur when a food is consumed.

When setting each PSL the sub-group took in to account the 'unsafe level', the 'safety margin' as well as the standards and guidelines of other organisations both local and international (Appendix 1).

It should be noted that a food product is not necessarily unsafe when a PSL is exceeded. However the 'safety margin' will have been compromised – thereby reducing the margin between 'high risk' and 'low risk' food – leading to reduced confidence in the safety of the food.

It should also be noted that PSLs do not cover the situation where a product is subjected to significant abuse *after* it has been tested (ie during storage, transport, further processing or use by the consumer).

When a PSL is exceeded, certain mandatory actions are required of the manufacturer, by NZFSA (as detailed in Dairy Standard D108). These requirements include actions such as:

- notifying NZFSA,
- putting product on hold and
- instigating disposal procedures.

'**Product safety limits' must not be confused with customer specifications, importing country requirements or the product quality that can be achieved when GMP is maintained:**

D. **GMP Target:** A GMP target is the upper level of a particular organism (pathogen) that a manufacturing process should never exceed when 'good manufacturing practice' is being applied.

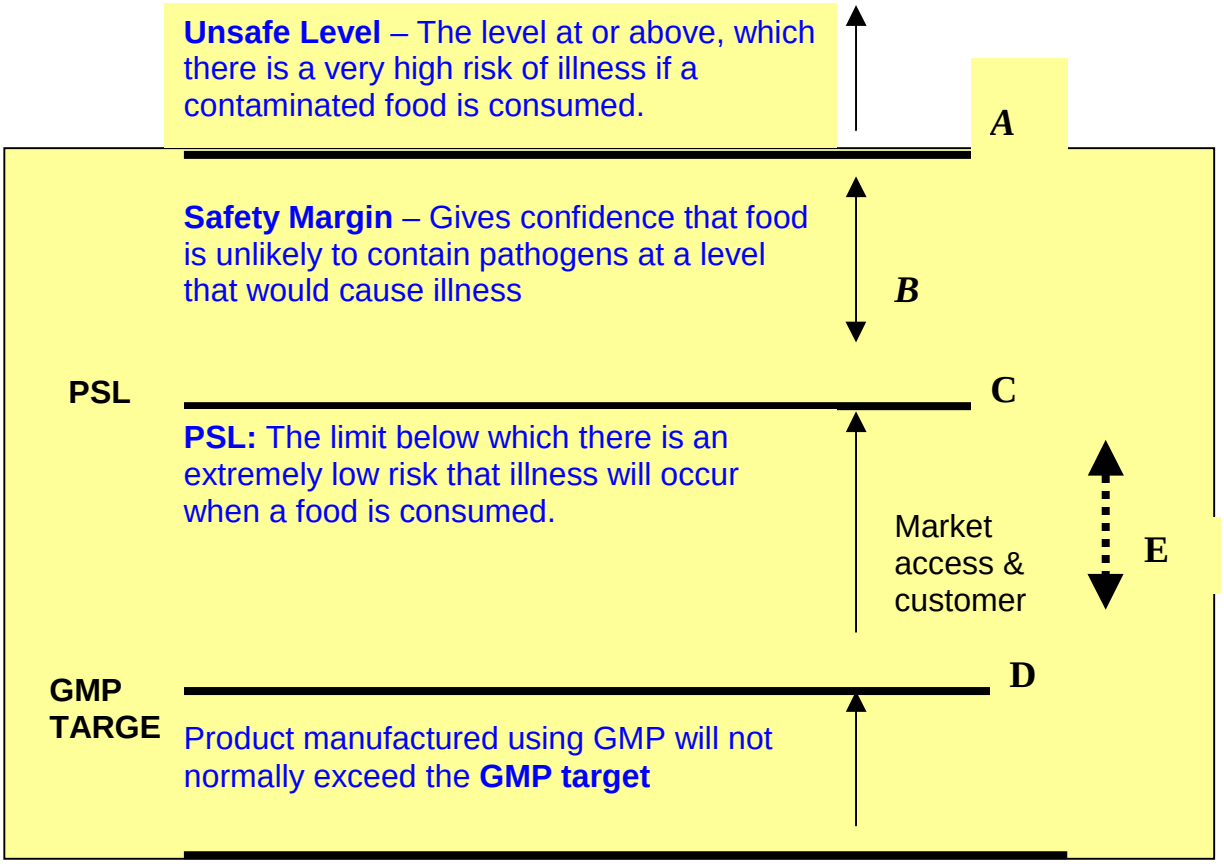
Note that GMP targets are:

- not mandatory.
- set by the manufacturer
- based on various factors (both generic factors and unique characteristics of a particular plant and process).

E. **Market Access & Customer Requirements:** The requirements of the governments of importing countries and the quality specifications of customers will usually fall in the range between the PSL and GMP targets. They are quite independent of PSLs and *should play no part in establishing the PSL for each type of pathogen.*

Even so, it is important to understand that compliance with the PSLs will not guarantee compliance with customer specifications and market access requirements. Manufacturers are responsible for ensuring that their products meet *all* the safety and quality requirements demanded of them.

Figure 1 Methodology for Setting PSLs



3.When Do PSLs Apply? (Figure 2)

A. HACCP-MOTIVATED PATHOGEN TESTING

Hazard Analysis Critical Control Point (HACCP) assessments, which are applied to each manufacturing process (refer to NZFSA Dairy Standard D110), are a central requirement of each manufacturer's PSP/RMP (Step 1 in Figure2).

The HACCP shall identify whether or under what circumstances routine analysis for a particular pathogen is necessary. *When routine pathogen testing is performed, it is the test results that are judged against the PSLs* (Step 2 in Fig 2).

B. OTHER TRIGGERS FOR PATHOGEN TESTING

Even when routine analysis for a particular pathogen is *not required as part of a* PSP/RMP, other situations may *trigger* the need for pathogen testing (Step 3 in Fig 2) eg when

- process-monitoring indicates that *process control at a CCP has been lost* eg pasteurisation failure, loss of pH control
- product testing is triggered when pathogens are recovered during *environmental monitoring.*
- pathogen testing is *required by a customer* ie specifications
- there is a *market access requirement* eg importing country standard

The results of *all* pathogen tests must be judged against the PSLs no matter what triggers the testing.

C. ACTIONS WHEN PSLS ARE EXCEEDED

The presence, in a food, of a potential pathogen, at greater than the relevant PSL, does not necessarily mean that the food is unsafe. In some circumstances, the particular organism may not pose a significant risk to the consumer because *the strain does not possess pathogenic characteristics* eg:

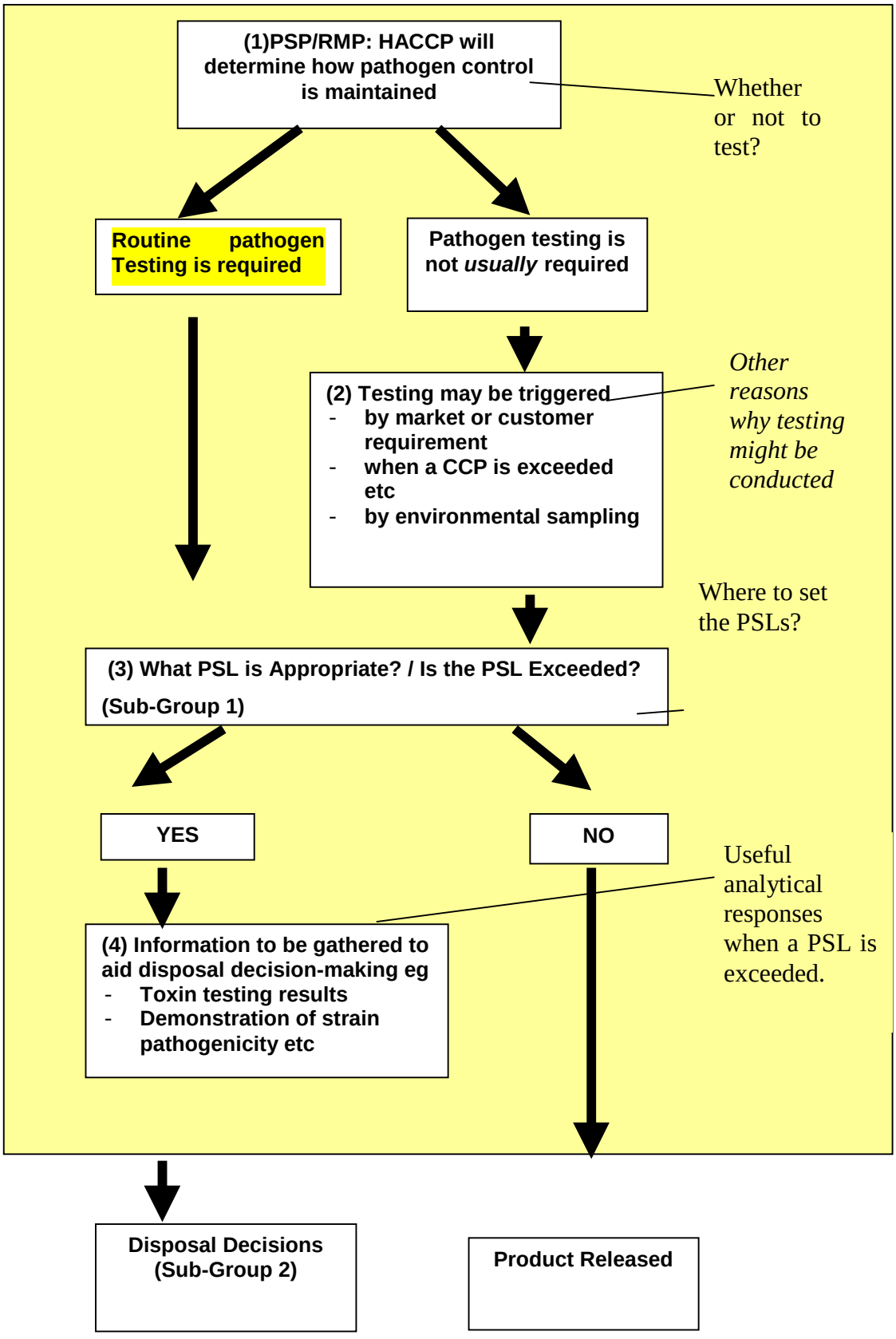
- **Coagulase positive staphylococci**: Many of the coagulase positive staphylococcus strains isolated from dairy products are non-toxigenic ie they are not pathogenic.
- ***E. coli**:* Most strains of *E. coli,* recovered from dairy products, are (like the coliforms) no more than hygiene indicators. And almost invariably, when isolated from pasteurised products, they do not indicate that faecal contamination has occurred. When pathogenic strains are recovered, millions are required to cause illness in most cases (eg EPEC, ETEC, EIEC). It is only the STEC/VTEC/EHECs that endanger consumer health when low levels (1 to 10^3CFU) are present.

This being the case, when a PSL is exceeded, a manufacturer may have the option to obtain important and relevant information that will influence the disposal decisions that are made about a product (Step 4 in Fig 2) eg

- Toxin test results in the case of coagulase positive staphylococci
- Strain identification (to demonstrate whether pathogen characteristics are present) in the case of *E. coli .*

Sub-group 1 has taken responsibility for identifying some of these situations and making recommendations on how to handle them (Section 5).

Figure 2 Decision-Making Flow chart for Establishing PSLs



4.Recommended PSLs

Table 1 presents a summary of the PSLs that sub-group 1 recommends to the TCC for inclusion in D107.

Table 1 The PSLs recommended by sub-group1 for six potential pathogens

Potential Pathogen	**General PSL (Less Susceptible Consumers)+**	**Specific PSL (More Susceptible Consumers)#**	Explanatory Notes / Comments
Salmonella	ND/25g	ND/250g	▪ ND = Not Detected in the volume tested ▪ Composites collected throughout the production run
L. monocytogenes	ND/25g (100/g)(1)	ND/25g	▪ ND = Not Detected in the volume tested ▪ Composites collected throughout the production run
*Coagulase Positive Staphylococci (*S. aureus*)*	1000/g	100/g	• It is critical that sampling & testing are performed in a way that correctly estimates the maximum number of *S. aureus* reached in a product at the peak of growth eg. This could be before pasteurisation or during cheese making with abnormal starter performance. This is important because the risk posed by released enterotoxin is 'estimated' by the bacterial load
B. cereus	1000/g	100/g	• 100/g: Products designated specifically for infants
E. coli	100/g	10/g	
C. perfringens(3)	1000/g	100/g	

Footnotes:

These PSLs apply to all dairy products other than those that are manufactured from raw milk

+ **General PSLs** - for the less susceptible consumers / general population)

Specific PSLs - for products that are specifically designated for / and are likely to form a substantial part of the dietary intake of more susceptible members of the population (ie the young, old, pregnant and immuno-compromised).

(1)***Listeria monocytogenes*:** The 100/g figure is proposed in "the Draft Guidelines for the Control of *Listeria monocytogenes* in Foods" Joint FAO/WHO Food Standards Programme; Codex Committee on Food Hygiene and is obtaining increasingly wide acceptance. A PSL of 100/g may be adopted, in some circumstances. However, before the 100/g PSL can be adopted, a manufacturer must be able to demonstrate to NZFSA that growth is extremely unlikely to occur during the life of the product and that the level is acceptable to customers, importing countries etc.

(3)***C. perfringens****:* Sub-group 1 is not convinced that general or specific PSLs are required for *C. perfringens.* There is no epidemiological link between *C. perfringens* and illness arising from the consumption of dairy products. In addition, it is extremely rare for large numbers of *C. perfringens* to be recovered. However, the PSLs in Table 1 would be appropriate to apply to any food, including dairy products, as a trigger for a traceback, disposal decisions etc in the unlikely event that heavy contamination was discovered.

5. Disposal Options when a PSL is Exceeded

It is important to recognise that exceeding a PSL does not mean that a food must be destroyed. In many cases there are alternative disposal strategies that will protect the health of the consumer eg:

- heat treatment to destroy heat-sensitive pathogens (in the case of organisms that do not release heat stable toxins),
- sub-lotting etc.

These alternatives have been addressed, in detail, by sub-group 2. However, sub-group 1 recommends that sub-lotting (governed by the rules being developed by sub-group 2) be considered in the following situations:

- ***Coagulase Positive Staphylococci:*** When the General PSL is exceeded and the number of coagulase positive staphylococci falls in the range between 1000 & 10 000/g, but enterotoxin is not detected (using MAF-approved test methods). Note: The product will not be considered suitable for human consumption when the number of cells exceeds 10 000/g.
- ***E. coli:*** When the General PSL is exceeded and the number of *E. coli* falls in the range between 100 & 1000/g, but STEC/VTEC/EHEC are not detected (using MAF-approved test methods).
- ***Bacillus cereus:***
  - **Products for Less Susceptible Consumers:** When the General PSL is exceeded and number of *B. cereus* falls between 1000 & 10 000/g, NZSFA may allow the product to be released for its original purpose providing the manufacturer can show that there will be no opportunity for further growth of *B. cereus* during the life, or the later use, of a product,
  - **Products for Susceptible Consumers:** When the specific PSL for *B. cereus* is exceeded but the number of *B. cereus* falls between 100 and 1000/g.
- ***Clostridium perfringens:***
  - **Products for Less Susceptible Consumers:** When the General PSL is exceeded and number of *C. perfringens* falls between 1000 & 10 000/g, NZSFA may allow the product to be released for its original purpose providing the manufacturer can show that there will be no opportunity for further growth of *C. perfringens* during the life, or the later use, of a product,
  - **Products for Susceptible Consumers:** When the specific PSL for *C. perfringens* is exceeded but the number falls between 100 and 1000/g.

Appendix 1: Standards & Guidelines

This section summarises the key standards and guidelines referred to by the sub-group during the development of PSLs for each pathogen.

Table 1: FSANZ Ready-to-Eat Guidelines (Summarised)

Pathogen	Satisfactory	Marginal	Unsatisfactory	Potentially Hazardous	Explanatory Notes
Salmonella	**ND/25g**	**-**	**-**	**Detected**	
L. monocytogenes	**ND/25g**	**Detected but $<10^{2+}$**	**-**	**$\geq 10^2$** for YOPIs Detected	**+ ND/25g for refrigerated products with long shelf-life**
S. aureus	**$<10^2$**	**10^2-10^3**	**10^3-10^4**	**$\geq 10^4$** (Toxin Test +ve)	
E. coli	**<3**	**3 -10^2**	**$\geq 10^2$**	******	****Pathogenic strains should be absent**
B. cereus	**$<10^2$**	**10^2-10^3**	**10^3-10^4**	**$\geq 10^4$**	
C. perfringens	**$<10^2$**	**10^2-10^3**	**10^3-10^4**	**$\geq 10^4$**	

Table 3: FSANZ Microbiological Limits in Food (Summarised)

Food	Pathogen	n	c	m	M
Butter made from Unpasteurised Milk Unpasteurised milk products	***Campylobacter*/25g** *S. aureus*/g Coliforms/g *E.coli*/g *L.monocytogenes*/25g *Salmonella*/25g SPC/g	**5** 5 5 5 5 5 5	**0** 1 1 1 0 0 0	**0** 10 10 3 0 0 $5x10^5$	**-** 100 100 9 - - -
All cheese	***E.coli*/g**	**5**	**1**	**10**	**100**
Soft/Semi-Soft Cheese (>39% moisture, pH.5)	***L.monocytognes*/25g**	**5**	**0**	**0**	
Dried Milk	***Salmonella*/25g**	**5**	**0**	**0**	
Powdered Infant Formula	***B.cereus*/g** *S. aureus*/g Coliforms/g *Salmonella*/25g SPC/g	**5** 5 5 10 5	**2** 1 2 0 2	**10** 0 <3 0 10^3	**100** 10 10 - 10^4

These are all in Standard 1.6.1of the *ANZJFSC.*

Table 3: FDA – Federal Register: Proposed Rules -Infant Foods (1996) (Summarised)

Micro-organism	M Value
Coliforms	3.05 MPN/g
Faecal Coliforms	3.05MPN/g
Salmonella	0
L. monocytogenes	0
S. aureus	3.05/g
B. cereus	100/g

Table 4: Ministry Of Health (1995) – Microbiological Criteria for Foods (Summarised) – *These are now redundant*

Product	Pathogen	m	M
Cheese (Food Regs)	*E. coli* *S. aureus*	- -	100 100
Yoghurt	-	-	-
Cream	*L. moncytogenes* *Salmonella*(/25)	0 0	- -
Soured Cream	Faecal coliforms *Salmonella*	10 0	100 -
Foods Misc Dried	*B. cereus* *S. aureus* Faecal Coliforms *Salmonella* (/25g)	1000 100 10 0	10 000 1000 100 -
Foods Cooked Ready to Eat	*B. cereus* *C. perfringens* *S. aureus* Faecal coliforms *L. monocytogenes* (/25g) *Salmonella* (/25g)	100 100 100 10 0 0	1000 1000 1000 100 - -
Infant Foods (not requiring further cooking)	*B. cereus* *C. perfringens* *S. aureus* Faecal Coliforms *L. monocytogenes*(/25g) *Salmonella*(/25g)	100 10 10 <1.8 0 0	1000 100 10 10 - -
Salted Butter	*S. aureus* Faecal Coliforms *L. monocytogenes*(/25g) *Salmonella*(/25g)	0 50 0 0	- 500 - -
Powder for Infants	*B. cereus* *C. perfringens* *S. aureus* Faecal Coliforms *L. monocytogenes*(/25g) *Salmonella* (/25g)	10 <1 <1 0 0 0	100 10 10 - - -
Powders for General Use	Faecal Coliforms *L. monocytogenes* *Salmonella*	10 0 0	100 - -
Pasteurised Milk	*L. monocytogenes* *Salmonella*	0 0	- -

Table 5: ICMSF (1986) –Microbiological Criteria for Foods (Summarised)

Product	Pathogen	m	M
Dried Milk	Coliforms *Salmonella (Normal/Routine)* *Salmonella (High Risk)*	10 0 0	100 - -
Cheese	*S. aureus*	10 000	-
Foods for Infants & Children	Coliforms *Salmonella* *S. aureus*	10 0 10	100 - 100

Table 6: EU – Compliance Standards (Summarised)

Product	Micro-organism	m	M
AMF	*L. monocytogenes* *Salmonella*	0 0	
Butter	Coliforms *L. monocytogenes* *Salmonella*	0 0 0	10
Hard Cheese	*L. monocytogenes* *Salmonella*	0 0	
Soft Cheese	Coliforms *E. coli* *S. aureus* *L. monocytogenes* *Salmonella*	10 000 100 100 0 0	100 000 1000 1000 - -
Frozen Milk Based	Coliforms *S. aureus* *L. monocytogenes* *Salmonella*	10 10 0 0	100 100 - -
Liquid Milk Based	Coliforms *L. monocytogenes* *Salmonella*	0 0 0	5 - -
All Powders	Coliforms *S. aureus* *L. monocytogenes* *Salmonella*	0 10 0 0	10 100 - -

Table 7 Institute of Food Science & Technology (UK) 1999 -Microbiological Criteria for Foods

	PATHOGEN			***INDICATOR***		
Food Type	**Pathogen**	**GMP**	**Max**	**Organism**	**GMP**	**Max**
Liquid Milk, Cream, Cheese, Ice Cream, Butter, Dairy Desserts, Yoghurts, Fermented Products	*Salmonella* *L. monocytog* *S. aureus* *E. coli* (O157)*	ND/25g ND/25g <20 ND/25g	ND/25g 1000 1000 ND/25g	*E. coli:* ▪ Raw milk soft Cheese ▪ Other cheeses ▪ Other Past Milk Products	 <100 <10 <10	 10 000 1000 1000
Milk Powder	*Salmonella* *S. aureus* *B. cereus* *C. perfringens*	ND/25g <20 <100 <100	ND/25g 1000 10 000 1000	*E. coli*	<10	1000
Infant Foods	*Salmonella* *E. coli* O157+ *C. perfringens* *B. cereus* *S. aureus*	ND/250g ND/250g <10 <10 ND/g	ND/250g ND/250g 100 100 100	*E. coli*	ND/g	10

* Raw milk products only

\+ Products containing beef only

GMP *Values expected immediately after manufacture*

Max Maximum level expected at any time during the shelf life of a product