ACM/1008

ADVISORY COMMITTEE ON MICROBIOLOGICAL SAFETY OF FOODS

HEALTH RISKS TO CONSUMERS ASSOCIATED WITH UNPASTEURISED MILK AND UNPASTEURISED CREAM FOR DIRECT HUMAN CONSUMPTION

Introduction

1. In July 2010, the FSA Board requested that the Agency review the evidence on the safety of unpasteurised milk for direct human consumption (also termed 'raw drinking milk').[1] The request arose in response to a concern about the proportion of raw cows' drinking milk samples failing microbiological criteria specified in the Food Hygiene (England) Regulations 2006 and Food Hygiene (Wales) Regulations 2006 (as amended). The results were contained in a quarterly report to the Board (See Annex 1) from the newly formed FSA Operations Group created following the merger of the FSA and the Meat Hygiene Service in April 2010.

2. The purpose of this paper is therefore:

- To bring together the available data on the microbiological quality of raw drinking milk and raw cream and outbreaks of foodborne illness associated with such products.

- To provide information on the current legislation in relation to raw drinking milk and cream, official controls, the number of registered producers and the market for such products.

- To request the Committee consider if the data presented are sufficient to assess the current risks to human health and, if so, to review its previous assessment of the risks to consumers from raw drinking milk and raw cream.

3. In the context of this paper raw drinking milk and raw cream means milk or cream which has not been pasteurised and is sold direct to the consumer. It encompasses raw drinking milk or raw cream from any species farmed for its milk (e.g. cows, sheep, goats, buffaloes).

Background

4. The sale of raw milk and cream intended for direct human consumption is permitted in England, Wales and N. Ireland but is subject to certain restrictions and labelling requirements (see Annex 2). Sales of raw drinking milk and raw cream have been banned in Scotland since 2004 when the existing ban on raw cow's drinking

[1] http://www.food.gov.uk/multimedia/pdfs/board/boardmins072010.pdf

milk and raw cream was extended to all species. There are no known sales in N. Ireland.

5. The ACMSF have considered data on the microbiological status of raw drinking milk (and raw milk for processing) several times over the last 15 years, most recently in 2000, and have regularly stressed the importance of pasteurisation in the protection of human health.

6. The 1995 ACMSF report on Verocytotoxin-producing *E. coli* (VTEC) highlighted that a number of outbreaks of human foodborne infection associated with consumption of raw cows' milk in the UK and North America were due to *E. coli* O157. The report recommended that the Government reconsider its position on a raw milk sales ban in England, Wales and N. Ireland and further recommended that the Chief Medical Officer (CMO) advise vulnerable groups not to consume raw milk and to amend the labelling accordingly [1,2]. The CMO issued this advice to vulnerable groups in 1995 and also committed to reviewing the ban when surveillance data from two surveys on the microbiological quality of raw milk became available[3].

7. In 1997, the results of the surveys undertaken by the Public Health Laboratory Service and ADAS were considered by the ACMSF. The Committee was concerned that surveillance data on the microbiological status of raw drinking milk showed that samples carried substantial amounts of faecal indicator organisms and in some cases pathogens. The Committee concluded that the sale of raw drinking milk should be banned in England, Wales and N. Ireland[4].

8. In 1998, the Committee were presented with data on the microbiological quality of raw drinking milk from sheep and goats gathered during a three month survey of all producers in England and Wales. The data presented showed that such milk can carry faecal indicator organisms. On the basis that animals can shed pathogens intermittently and in view of the evidence of human illness associated with raw milk consumption, the Committee gave the view that all raw milk intended for human consumption should be pasteurised[5].

9. The ACMSF also considered the results of a national survey on the microbiological quality and heat processing of cows' milk in 2000. The samples tested were of raw milk intended for pasteurisation, not raw drinking milk. However, the Committee considered that the survey results served to underline the importance of their previous advice on the dangers inherent in the consumption of raw milk and the contribution made by pasteurisation to the prevention of milk-borne disease[6].

10. In 2010, the ACMSF undertook the first of a two part assessment of the potential for milk and milk products contaminated with *Mycobacterium bovis* to enter the food chain and whether the risk has changed in light of the increase in *M. bovis* infection in cattle in the UK. The Committee concluded that the risk from pasteurised milk and milk products contaminated with *M. bovis* has changed but in milk that is properly pasteurised the risk remains acceptably low. The risks from unpasteurised milk and milk products will be considered by the ACMSF later this year.

Paper outline

11. This paper will provide information on:

- Human illness linked to raw drinking milk and raw cream
- Microbiological status of raw drinking milk and raw cream
    - Surveillance
    - Statutory monitoring

Plus background information on:

- Legislation
- Official controls
- Producer and market information

Human illness linked to raw drinking milk and raw cream

Data

12. The Health Protection Agency has operated a system of surveillance for general outbreaks of infectious intestinal disease (IID) in England and Wales since 1992, which includes foodborne and non-foodborne gastrointestinal outbreaks. Data are collated on outbreak setting, mode of transmission, causative organism, epidemiological and microbiological investigations. To inform the Committee, data on all foodborne outbreaks of IID in England and Wales linked to milk and cream from 1992 to the present has been provided by the HPA. Information on the total number of foodborne outbreaks of IID was also provided for comparison.

13. Between 1 January 1992 and 31 December 2002 there were 2024 outbreaks of IID linked to food. Of these, 31 outbreaks (1.5%) were associated with milk or cream, raw and pasteurised (outbreaks due to Infant formula/follow-on formula and powdered milk/cream have been excluded).

14. From 2003 to 2009 none of the 497 reported outbreaks of foodborne IID have been associated with milk or cream, raw or pasteurised (see Table 1).

15. Of the 31 milk and cream associated outbreaks between 1992 and 2002 nearly two-thirds (20) were linked to raw drinking milk and raw cream (just less than 1% of total foodborne outbreaks during this period). Pasteurised milk and cream was a contributory factor in 11 IID outbreaks over the same period. Pasteurisation failure was identified as the main contributory factor in the majority of these outbreaks.

16. Tables 2 and 3 provide details of the outbreaks linked to raw drinking milk/cream and pasteurised milk/cream and the organism associated with these outbreaks. The evidence supplied to the HPA linking milk to the reported outbreaks included microbiological evidence, evidence from cohort studies and from case-control studies.

17. The pathogens most frequently implicated in milk and cream-associated outbreaks of IID between 1992 and 2002 in England and Wales were *E.coli* O157 (11 outbreaks), *S*. Typhimurium (8 outbreaks), and *Campylobacter* (8 outbreaks). The consumption of raw drinking milk and cream was associated with 8 of the outbreaks of *E. coli* O157, 6 of the outbreaks of salmonellosis and 5 of the outbreaks of campylobacteriosis.

18. Statistical analysis of the outbreak data for 1992 to 2000[7] found that *E.coli* O157, campylobacters and *S.* Typhimurium were more commonly implicated in milkborne outbreaks compared with outbreaks of other foodborne origin. There were also no statistical differences between the distribution of pathogens implicated in outbreaks linked to milk sold as pasteurised or raw.

Table 1: Comparison of IID outbreaks associated with food and with raw drinking milk and raw cream each year from 1992 to 2009.

Year	Total number of foodborne IID outbreaks	Number affected and hospitalised	Number of deaths	Total number of IID outbreaks linked to raw drinking milk and raw cream	Number affected and hospitalised*
1992	238	6663 (237)	8	1	72 (0)
1993	249	6032 (181)	8	3	41(9)
1994	245	5666 (186)	5	3	38 (1)
1995	236	6321 (198)	11	1	26 (7)
1996	209	4673 (210)	22	3	16 (4)
1997	254	5208 (204)	15	1	8 (2)
1998	151	3564 (94)	6	2	10 (4)
1999	123	2920 (136)	2	0	0
2000	125	3261 (101)	2	3	9 (3)
2001	105	1806 (94)	4	0	0
2002	89	2364 (78)	20	3	22 (6)
2003	83	2430 (114)	2	0	0
2004	70	1798 (71)	6	0	0
2005	87	1957 (85)	4	0	0
2006	73	1933 (76)	7	0	0
2007	52	1102 (84)	11	0	0
2008	41	919 (46)	8	0	0
2009	91	3408 (108)	8	0	0
Total	**2521**	**62025 (2303)**	**149**	**20**	**242 (36)**

*No deaths have been reported from IID outbreaks associated with raw drinking milk and raw cream.

Table 2: General outbreaks of infectious intestinal disease linked to raw drinking milk and raw cream in England and Wales: 1992-2009.

Year of outbreak	*Organism*	*No. of people affected*	*No. of hospitalisa-tions*	*No. of deaths*	*Outbreak contributory factor*
1992	*Campylobacter*	72	0	0	Unpasteurised milk
1993	*S*. Typhimurium DT193	13	3	0	Unpasteurised milk
1993	*E. coli* O157	6	4	0	Unpasteurised milk
1993	*Campylobacter*	22	2	0	Unpasteurised milk
1994	*S*. Typhimurium DT12	11	0	0	Unpasteurised milk
1994	*S*. Typhimurium DT104	4	1	0	Unpasteurised milk
1994	*Campylobacter*	23	0	0	Unpasteurised milk
1995	*S*. Typhimurium DT104	26	7	0	Unpasteurised milk
1996	*Campylobacter*	5	0	0	Unpasteurised milk
1996	*S*. Typhimurium DT104	5	0	0	Unpasteurised milk
1996	*E. coli* O157	6	4	0	Unpasteurised milk
1997	*E. coli* O157	8	2	0	Unpasteurised milk
1998	*E. coli* O157	3	0	0	Unpasteurised milk
1998	*E. coli* O157	7	4	0	Cream made from unpasteurised milk
2000	*E. coli* O157	4	1	0	Unpasteurised milk
2000	*E. coli* O157	2	2	0	Unpasteurised milk
2000	Unknown aetiology	3	0	0	Whipping cream – made from unpasteurised milk
2002	*Campylobacter*	3	0	0	Unpasteurised milk
2002	*S*. Typhimurium DT12	13	0	0	Unpasteurised milk
2002	*E. coli* O157	6	6	0	Unpasteurised milk
Total		**242**	**36**	**0**	

Table 3: General outbreaks of infectious intestinal disease linked to pasteurised milk and cream in England and Wales: 1992-2009.

Year of outbreak	*Organism*	*No. of people affected*	*No. of hospitalisa-tions*	*No. of deaths*	*Outbreak contributory factor*
1992	*S*. Enteritidis PT4	44	0	0	Food handler worked while ill
1992	*Campylobacter*	110	0	0	Pasteurisation failure
1993	*S.* Enteritidis PT4	8	0	0	Whipped cream
1994	*S*. Typhimurium DT104	26	2	0	Pasteurisation failure
1995	*Campylobacter*	12	0	0	Bird pecked milk
1995	*Cryptosporidium*	52	2	0	Pasteurisation failure
1995	*Campylobacter*	35	0	0	Bird pecked milk
1996	*E. coli* O157	12	4	0	Pasteurisation failure
1998	*S.* Typhimurium DT104	121	4	0	Pasteurisation failure
1999	*E. coli* O157	114	28	0	Pasteurisation failure
1999	*E. coli* O157	11	3	0	Pasteurisation failure
Total		**545**	**43**	**0**	

Analysis

19. From 1992 to 2002 outbreaks of IID linked to consumption of raw drinking milk and raw cream represented a very small proportion of the total number of reported outbreaks of foodborne IID. In the last 8 years there have been no reported outbreaks of IID associated with consumption of raw drinking milk or raw cream, suggesting that the burden of disease from consumption of these products has declined significantly.

20. As with most IID the size and frequency of outbreaks is likely to be under reported and sporadic cases may also remain undetected. The extent of any under reporting of illness linked to raw drinking milk and raw cream consumption is unknown. The absence of any reported outbreaks associated with these foods since 2002 may in part be due to the decline in the numbers of raw drinking milk and raw cream producers and subsequent lower sales. However, it is also possible that the development in popularity of sales through farmers markets mean the product is now available to more people. Available information on the market for raw drinking milk and raw cream is provided in Annex 3 but the level of human exposure to raw

drinking milk and cream is difficult to determine as sales volumes and the number of consumers purchasing the products are unknown.

Microbiological status of raw drinking milk and cream

Surveillance

21. Several surveys have been undertaken in the last 15 years to investigate the microbiological status of raw drinking milk and raw cream, providing data on the presence and levels of pathogens and hygiene indicators in milk from cows and other species. The results of these surveys are summarised in Table 4 and more details are provided in Annex 5. The findings are not necessarily directly comparable between surveys as in some cases the methods and sampling approach used varied. However, the British Standard method for microbiological examination for dairy purposes was used in the majority of surveys.

22. The surveys carried out between 1995 and 2000 showed that pathogenic micro-organisms were present in low numbers of samples of raw milk from cows, sheep and goats. Pathogens were not consistently detected in all surveys and the frequency of each pathogen detected varied between the different surveys. As these surveys do not represent routine year on year surveillance it is difficult to compare surveys and identify any trends. The majority of the surveys also determined levels of *E.coli* and other indicator organisms in samples. These were present at varying levels in the majority of samples, in some cases exceeding the limits set in legislation. It was not possible to correlate the results for levels of faecal indicators such as *E.coli* and presence of pathogens for individual survey samples as this data was not available.

Table 4: Summary of microbiological results from previous surveys of raw drinking milk and raw cream

	Survey of raw cows' milk, 1995-96, 1591 samples % positive (total numbers)	Survey of raw cows' milk 1996-97, 1097 samples % positive (total numbers)	Survey of raw cream, 1997 30 samples % positive (total numbers)	Survey of raw goats' & sheep milk 1997-98, 111 samples % positive (total numbers)	Survey of raw goats',sheep & buffaloes' milk 1997-99, 384 samples % positive (total numbers)	Survey of raw cows' milk intended for heat treatment, 1999-2000, 610 samples % positive (total numbers)
Campylobacter spp.	**0**	**2** (19)	-	**0**	**0.5** (2)	**0.8** (5)
E.coli O157	**0**	**0.3** (3)	**0**	**0**	**0.5** (2)	**0.2** (1)
Salmonella spp.	**0.06** (1)	**0.5** (5)	-	**0**	**0**	**0.3** (2)
L. monocytogenes	**2** (32)	-	-	-	**3** (11)	**17** (101)
Listeria spp.	**6** (91)*	-	-	-	-	**37** (223)
S. aureus >10cfu/ml	**6** (89)	**1** (12) exceeded 500cfu/ml	-	**8** (9)	**8** (29)	**19** $^{+}$(113)
E.coli >10cfu/ml	**24** (386)	**3** (27) exceeded 100cfu/ml	**23 (7)**	**6** (7)	**17** (65)	**52** (316)
Coliforms ≥1x10^2 cfu/ml	**25** (390)	-	-	**32** (36)	**25** (95)	**56** (343)
Total Viable Counts > 2 x10^4 cfu/ml	**16** (255)	**4** (39) exceeded 5x10^4cfu/ml	-	**37**(41) exceeded 1x10^4cfu/ml	**23** (89) exceeded 1x10^4cfu/ml	**56** (344) exceeded 1x10^4cfu/ml
Mycobacterium avium subspecies *paratuberculosis*	-	-	**-**	-	**0**	**1.6** (4 out of 243)

- Not tested for $^{+}$ Coagulase positive staphylococci * Detected by enrichment

Statutory monitoring of raw cows' drinking milk

23. In England and Wales, raw cows' drinking milk for direct human consumption is sampled and tested quarterly to monitor compliance with microbiological criteria set out in The Food Hygiene (England) Regulations 2006 (as amended) and the equivalent regulation in Wales. There are no known sales of raw cows' drinking milk in N. Ireland therefore there is no monitoring. There is no routine monitoring programme of raw drinking milk from other species.

Raw drinking milk must meet the following criteria:

Plate Count at 30 °C (cfu per ml)	≤ 20,000
Coliforms (cfu per ml)	< 100

24. Enforcement action is taken if a sample fails the criteria and further details on the sampling programme are given in the section on official controls and monitoring and enforcement (Annex 2 and 3).

25. This monitoring data provides a useful indication of the quality of raw cows' drinking milk on sale in England and Wales. The results of the statutory monitoring programme from 2004 to September 2010 are summarised in Tables 5 and 6. Reported failures are samples that exceed either the plate count or coliform criteria or both. Results from 2007 onwards were reported by financial year rather than calendar year and are therefore presented in a separate table.

26. It is notable that the total number of samples collected over the years has declined markedly, from over 1800 in 2004 to just over 400 in 2009/10. Although slight changes in the enforcement policy have affected the number of repeat samples taken, the drop in numbers is most attributable to the steady decline in the number of farmers selling raw drinking milk, from just under 600 in 1997 to around 100 in 2010.

27. The sample failure rate from January 2004 to March 2010 has stayed fairly consistent around 12-16%. There was a slight improvement in 2006 and 2007 where the failure rates dropped to 9% and 7% respectively. The results for financial year 2010/11 represent only the first six months of the year so cannot be compared directly to previous full years but the sample failure rate for April to September 2010 has risen to 22%. This may reduce when the full data for 2010/11 is available, although compared with the same quarters last year the rate is slightly increased. For the April 2007 to March 2010 data failure levels are generally similar for England and Wales.

28. The total number of failures includes re-samples from farms that have failed the criteria. Farms that fail are therefore sampled more frequently than farms that pass and a small number of farms that consistently fail the criteria can skew the failure rate/year. For example in 2009/2010 three producers were responsible for a quarter of all the failures in England. Further more detailed analysis of these results

could be undertaken if the Committee considers it necessary for the risk assessment.

Table 5: Results of the raw cows' drinking milk sampling programme in England and Wales from January 2004 to November 2007

Year	Total number of samples*	Number of passes	Pass rate (%)	Number of failures	Failure rate (%)	Number farms with repeat failures	% Farms with repeat failures
2004	**1817**	**1533**	**84**	**271**	**15**	**49**	**30**
2005	**1428**	**1208**	**85**	**193**	**14**	**41**	**31**
2006	**1184**	**1040**	**88**	**108**	**9**	**21**	**17**
2007**	**972**	**879**	**90**	**68**	**7**	**14**	**13**

* includes samples where no results were attained
** January to November (11 months)

Table 6: Results of the raw cows' drinking milk sampling programme in England and Wales from April 2007 to September 2010

Year	Total number of samples	Number of passes	Pass rate (%)	Number of failures	Failure rate (%)	Number farms with repeat failures	% Farms with repeat failures
April 07 – March 08	**509**	**450**	**88.4**	**59**	**11.6**	**11**	**11**
April 08 – March 09	**476**	**403**	**84.7**	**73**	**15.3**	**13**	**14**
April 09 – March 10	**405**	**341**	**84.2**	**64**	**15.8**	**13**	**16**
April 10 – Sept 10[+]	**204**	**158**	**77.5**	**46**	**22.5**	**10**	**16**

[+] April to September (6 months)

Discussion

29. ACMSF views on the current risk to health associated with consumption of raw drinking milk and raw cream are sought as part of an Agency review of the evidence on the microbiological safety of such products. The ACMSF have considered the risks associated with raw drinking milk on several occasions in the past, most recently in 2000. On previous occasions, the Committee's view has been that there are significant risks to human health from consumption of raw drinking milk and they have stressed the importance of pasteurisation to ensure food safety.

30. The main findings of this review are summarised below, with data limitations highlighted.

Human Illness

31. No outbreaks of human illness associated with raw drinking milk or raw cream have been reported in England and Wales since 2002. Although it is recognised that there is potential under reporting of IID associated with raw drinking milk and raw cream, the lack of reported outbreaks suggests that pathogen levels may have declined and/or there have been changes in the pattern of consumption or supply.

32. Analysis of outbreak data prior to 2000 has shown there were no statistical differences in the distribution of pathogens associated with outbreaks linked to raw milk and those linked to pasteurised milk.

33. The level of human exposure to raw drinking milk is difficult to assess. Raw drinking milk and raw cream represent a very small fraction of the total milk consumption in the UK and the number of producers has declined significantly in the last 10 years. However, there is a lack of data on the actual volume of raw drinking milk that is being sold and through which outlets. New outlets, such as farmers markets and internet sales, mean that a wider range of consumers are likely to be able to purchase these products direct from farmers.

Surveillance of raw drinking milk and cream

34. Data from several surveys carried out between 1995 and 2000 showed low levels of pathogenic microorganisms present in raw milk and cream from cows, goats and sheep. Comparison of the survey results show no discernable trends in the incidence of pathogens over time or associated with raw milk/cream from different species, however differences in survey design make comparisons of limited value. There have been no more recent surveys of pathogen levels in raw milk/cream produced in the UK.

35. Indicators of faecal contamination were present in many of the samples at a range of concentrations in the surveys. However, the most up to date information on the microbiological quality of raw cows' drinking milk is available from the results of monitoring for compliance with the statutory criteria for raw drinking milk. Data available from 2004 shows the percentage of samples failing to meet the criteria for plate count and coliforms to be fairly consistent (between 12% and 16%) apart from

a slight improvement seen in 2006/7. The scientific basis for the plate count and coliform levels in the legislation is unclear but they are significantly lower than the criteria for raw milk for processing (cows' milk plate count < 100,000 cfu/ml).

36. The sample failure rates for monitoring in 2009/10 (15.6% for England and 19% for Wales) were noted by the FSA Board and raised a concern. It should be appreciated that the failure rates include re-samples from farms that failed the criteria previously. Therefore poor performing premises are sampled more frequently and these results will inflate the failure rate reported for each year.

37. Areas where information on which to base a risk assessment are lacking are recent surveillance data on the frequency of pathogen contamination and information on the microbiological quality of raw drinking milk from other species, such as goats, sheep and buffaloes.

38. The ACMSF is requested to consider:

- Are the data presented sufficient for the Committee to assess the current risks?
- If so, what is the Committee's view on the current risk to public health from unpasteurised milk and unpasteurised cream for direct human consumption? Does the Committee consider there is a need for the FSA to review its policy on these foods?
- If the data is not sufficient, what further data would be required for the Committee to fully assess the current risks? For example, more up to date microbiological data on pathogens and indicator microorganisms from a surveillance study, or information on the amount of raw drinking milk consumed in England and Wales.

Secretariat
January 2011

Annex 1

Extract from the July 2010 FSA Board paper: First Quarter Report From the Interim Director of Operations: 1 April to 30 June 2010

Milk Production Hygiene Operational Information

Sampling and Failure Rates

Number of samples of raw cows drinking milk

	2009/10	
	Pass	**Fail**
England	324	60
Wales	17	4

Absolute and percentage failure rate for all tests carried out:

	2009/10		
	Samples	**Fail**	**%**
England	384	60	15.6
Wales	21	4	19

Annex 2

Legislation on raw drinking milk and raw cream

Since 2006, following consolidation of the hygiene legislation, a member state has been able to introduce or maintain national rules prohibiting or restricting the placing on the market, within its territory, of raw milk or raw cream intended for direct human consumption. Such national rules in the UK are contained within the Food Hygiene Regulations[14] for England, Wales, N. Ireland and Scotland respectively.

England and Wales

The current controls on the sale of raw cows' milk for direct human consumption are:

1. a) The milk may only be sold direct to consumers by registered milk production holdings (at the farm gate or in a farmhouse catering operation) or through milk roundsmen. Sales through other outlets have been banned since 1985 (although sales by the farmer at farmers markets are allowed);

b) The supplying animals must be from a herd that is officially tuberculosis free, and either brucellosis free or officially brucellosis free;

c) The production holding, milking premises and dairy, must comply with hygiene rules;

d) The milk must bear the appropriate health warning 'This milk has not been heat treated and may therefore contain organisms harmful to health' in England and additionally in Wales 'The Food Standards Agency strongly advises that it should not be consumed by children, pregnant women, older people or those who are unwell or have chronic illness';

e) Compliance with a) to d) above is monitored by inspections twice a year;

f) The milk is sampled and tested quarterly under the control of Animal Health Dairy Hygiene to monitor compliance with standards for total bacterial count and coliforms.

Plate Counts at 30 °C (cfu per ml)	≤ 20,000
Coliforms (cfu per ml)	< 100

The sale of raw milk for direct human consumption from sheep, goats or buffaloes:

2. a) Is not subject to the restriction at 1a) above;

b) Raw drinking milk from buffaloes has to comply with the herd status requirement at 1b) above;

c) Raw drinking milk from sheep and goats must come from animals belonging to a production holding that is either officially brucellosis free or brucellosis free;

d) Raw drinking milk from these 3 species must comply with dairy hygiene rules and the following microbiological standards;

Plate Counts at 30 °C (cfu per ml) ≤ 20,000
Coliforms (cfu per ml) < 100

e) In England, raw drinking milk from sheep and goats, but not buffaloes, has to carry the health warning. In Wales, raw milk from all three species has to carry the health warning;

f) Compliance with these requirements is monitored at inspections programmed on a risk basis.

The sale of raw cream for direct human consumption:

a) Is not subject to the restrictions at 1a) and d) above;

b) Must comply with all the requirements that apply to milk based products under dairy hygiene rules and microbiological standards;

c) Must be made with milk meeting the herd status criteria described in paragraphs 1b) and 2b) and c) above;

d) Raw cream is not required to carry the health warning;

e) Compliance with these requirements is, again, monitored at inspections programmed on risk.

Scotland

Sales of raw milk and raw cream for direct human consumption from any species farmed for its milk are prohibited Scotland.

Northern Ireland

Northern Ireland has controls similar to those in England and Wales however there are no known sales of raw milk or cream for direct human consumption in Northern Ireland.

Microbiological criteria

Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs includes a process hygiene criteria for cream made from raw milk which applies at the end of the manufacturing process. Process hygiene criteria indicate that processes are functioning correctly and hygiene is acceptable. When Food Business Operators fail to comply with the criterion, i.e. if *E.coli* levels exceed 100cfu/g in any one of 5 samples or exceed 10cfu/g in more than 2 out of 5 samples, action must be taken to improve production hygiene and quality of raw materials. The regulation is directly applicable in all Member States.

Annex 3

Official controls

1. Animal Health Dairy Hygiene is responsible for the enforcement on milk production holdings of the Regulations (EC) Nos 852/2004, 853/2004 & 854/2004 and the Food Hygiene (England) Regulations 2006 and of the Food Hygiene (Wales) Regulations 2006.

2. Dairy hygiene inspectors also supervise the monitoring programme for raw cows' drinking milk in England and Wales. Raw cow's milk samples from retailers and caterers are taken from the bulk tank or packaged product for analysis approximately four times a year. If a sample does not conform with the plate count and coliform criteria in the regulation the producer is advised to cease placing raw milk on the market. If they continue to market raw milk, follow-up samples are taken and specified enforcment procedures followed. Follow-up sampling and enforcement continue until two consecutive raw milk samples have met the criteria and inspectors are confident the milk being placed on the market complies with the Regulations. For more details on the sampling procedures and enforcement policy the Animal Health Dairy Hygiene operating procedures can be accessed via the following link:

   http://www.food.gov.uk/multimedia/pdfs/opsprocedure0709.pdf

Annex 4

Number of producers and the market for raw drinking milk and cream

1. The number of registered raw cows' drinking milk producers in England and Wales has fallen from around 570 in 1997 to around 100 in 2010. There are also currently 27 producers of raw goat's milk and 3 of raw sheep milk which may be sold for direct human consumption or for processing. There are no separate data on the number of producers of raw cream but surveillance in 1997 only identified 11 producers in England and Wales.

2. There are no accurate data on production or sales volumes for raw drinking milk/cream from any species as this data is not collected. The volumes produced annually are likely to be difficult to estimate as they will probably vary for individual producers on a regular basis according to demand. Raw cream production, for example, is believed to be seasonal, mainly in summer and at Christmas.

3. Although the total number of raw drinking milk and cream consumers is unknown relatively few people are thought to buy and drink raw cows' milk in England and Wales, given the small and declining number of producers. There is also thought to be limited consumption of raw drinking milk from other species. In addition to raw drinking milk sales farmers and their families are likely to consume the milk produced on their farms. There are no data available to estimate how frequently this occurs but a study on zoonoses and risk factors in farming families in Preston, Hereford and Norwich published in 1997 found that nearly 100% of dairy farmers reported consumption of raw milk[15].

4. The sale of raw cows' drinking milk is confined to farm gate sales, farm catering, milk rounds and farmers markets (which are considered a legitimate outlet for the sale of raw cows' drinking milk, as an extension of the farm premises providing the sale is direct from the farmer to the final consumer). It is also known that two producers offer internet sales of raw cows' drinking milk. As internet sales would be considered to be sales made at *or* from the farm, orders for milk direct to the final consumer received via e-mail or an e-commerce site are permitted.

5. There is anecdotal evidence that raw milk in other EU countries is being sold through vending machines and there has been interest in the use of these vending machines at a recent UK trade fair. However, the Agency's current advice is that this would not be permitted under the Food Hygiene Regulations unless the vending machine was situated on the farm premises (or at a farmers market).

Annex 5

Surveillance on raw drinking milk, raw cream and raw milk for processing

1. ADAS (formerly the Agricultural Development Advisory Service) carried out a survey of 1591 samples of raw cows' drinking milk between May 1995 and May 1996 for the Department of Health[8]. Samples with undetectable or low levels of phosphatase were excluded as these could not be considered raw milk. The survey found that 32 samples (2%) contained *L. monocytogenes*, and one sample (0.06%) contained *S. typhimurium*. The survey did not detect *E. coli* O157 or *Campylobacter* spp. in any of the samples. In addition, 89 samples (6%) contained *S. aureus* at a level greater than 10cfu/ml and 386 samples (24%) contained *E. coli*, an indicator of faecal contamination, at a level greater than 10cfu/ml. Total viable counts (TVC) and coliform counts exceeded the statutory microbiological criteria (2.0×10^4 cfu/ml TVC and 1×10^2 cfu/ml coliforms) in 255 samples (16%) and 390 samples (24.5 %) respectively.

2. A Public Health Laboratory Service (PHLS) survey of raw cows' drinking milk was carried out from May 1996 to July 1997[9]. *E.coli* O157 was detected in 3 samples (0.3%), *Campylobacter* spp. in 19 samples (2%), and *Salmonella* spp. in 5 samples (0.5%). *S. aureus* was present at levels greater than 500 cfu/ml in 12 samples (1%) and Streptococci at levels greater than 100 cfu/ml were present in 2 samples (0.2%). Samples were also tested to give an indication of the hygienic quality of the milk, *E.coli* was present at levels greater than 100 cfu/ml in 27 samples (3%) and plate counts exceeded 5×10^4 cfu/ml in 39 samples (4%).

3. A microbiological survey of raw cream to investigate the prevalence of *E. coli* O157 was undertaken between in 1997 by the Ministry of Agriculture, Fisheries and Food (MAFF)[10]. Only 11 raw cream producers were identified in England and Wales and all were sampled. None of the 30 samples collected contained *E. coli* O157. *E.coli* was present at levels greater than 10cfu/ml in 7 samples (23%).

4. In order to address the lack of data on the microbiological status of raw goats' and sheep drinking milk MAFF carried out a survey sampling all producers in England and Wales from November 1997 to January 1998[11]. A total of 111 samples were examined, 94 goats' milk and 17 sheep milk. No *Campylobacter* spp., *Salmonella* spp. or *E.coli* O157 were isolated. *S. aureus* was present at levels greater than 10 cfu/ml in 9 samples (8%) and *E. coli* at levels greater than 10 cfu/ml in 7 samples (6%). Coliform levels exceeding 1×10^2 cfu/ml were found in 36 samples (32%) and TVCs exceeded 1×10^4 cfu/ml in 41 samples (37%).

5. A further survey to determine the microbiological quality of unpasteurised goats', sheep and buffaloes' milk was undertaken by MAFF between December 1997 and January 1999[12]. This differed from the above survey in that samples were taken from bulk milk tanks and included milk for drinking

and for making into products, both pasteurised and unpasteurised. A total of 384 samples were taken, 286 goats' milk, 90 sheep milk, and 8 buffaloes' milk. No samples were positive for *Mycobacterium avium* subspecies *paratuberculosis* (MAP) or *Salmonella* spp. *Campylobacter* spp. were detected in 2 sheep milk samples (0.5%), *L. monocytogenes* in 11 goats', sheep and buffaloes' milk samples (3%) and *E. coli* O157 in 2 goats' milk samples (0.5 %). *E. coli* was present at levels greater than 10 cfu/ml in 65 samples (17%) and *S. aureus* at levels greater than 10 cfu/ml in 29 samples (8%). Coliform counts exceeding $1x10^2$ cfu/ml were found in 95 samples (25%), and TVCs exceeded $1x10^4$ cfu/ml in 89 samples (23%). It should be noted the statutory microbiological criteria ($2.0\ x10^4$ cfu/ml TVC and $1x10^2$ cfu/ml coliforms) are not applicable for milk that is intended for pasteurisation.

6. An 18 month national study on the <u>microbiological quality and heat processing of cows' milk</u>, undertaken by the FSA in 1999-2000, surveyed a representative sample of approved dairy establishments in the UK which heat treat milk[13]. The objective was to obtain data on the microbiological quality of cows' milk in the UK before and after heat processing. All the samples of raw cows' milk tested were destined for pasteurisation, so findings cannot necessarily be considered relevant to the microbiological status of raw cows' drinking milk. A total of 610 samples of raw milk were tested. *Campylobacter* spp. were detected in 5 of these samples (0.8%), *Salmonella* spp. in 2 samples (0.3%), *Listeria* spp. in 223 samples (37%), *L. monocytogenes* in 101 samples (17%) and *E. coli* O157 in 1 sample (0.2%). Coagulase positive staphylococci were present at levels greater than 10 cfu/ml in 113 samples (19%). *E.coli* was present at levels greater than 10 cfu/ml in 316 samples (52%). Coliform levels exceeding $1x10^2$ cfu/ml were found in 343 samples (56%) and TVCs exceeded $1x10^4$ cfu/ml in 344 samples (56%). These figures are provided for comparison as the coliform and TVC criteria for raw drinking milk do not apply for milk that is to be heat treated. A subset of samples were tested for MAP which was detected in 4 out of 243 samples (1.6%).

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