
MICROBIOLOGICAL SAFETY OF RAW DRINKING MILK

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1 SUMMARY

- 1.1 Following previous FSA Board and Advisory Committee of the Microbiological Safety of Food (ACMSF) discussions on raw drinking milk, the Executive is reviewing the controls in place to manage the public health risks associated with raw drinking milk and cream. This paper provides an opportunity for the FSA Board to comment on potential options for managing the public health risks to inform the policy review process. When the policy review is complete, including any necessary consultations, the FSA Board will be asked to consider their final advice to Ministers on future controls for raw drinking milk and cream.
- 1.2 The Board is asked to:
 - **agree** that, due to the inherent food safety risks associated with raw drinking milk and cream, pasteurisation of all milk prior to direct human consumption is a critical control measure and is the most effective means of protecting public health;
 - **acknowledge** that some consumers prefer to exercise choice in continuing to have access to raw drinking milk and cream;
 - **agree** that, in consultation with stakeholders and consumers, the FSA should fully assess the possible options for managing the food safety risks associated with consumption of raw drinking milk and cream and formulate advice that could be provided to Ministers for discussion by the FSA Board;
 - **agree** that, given the possibility that restricted sales of raw drinking milk and cream may continue following the policy review and decisions by Ministers, the policy review should include consideration of the current statutory controls to ensure they provide a clear, consistent and appropriate regulatory framework to control the public health risk, particularly in the light of developments in the marketing of these products;
 - **agree** that, FSA advice to consumers should continue to emphasise the food safety risks associated with raw drinking milk and raw cream and that, in particular, vulnerable groups should not consume these products.

2 INTRODUCTION

- 2.1 At its meeting of 16 November 2011, the Board was informed that the ACMSF had completed its review of the risks from *Mycobacterium bovis* in

milk and milk products and considered the more general question of the safety of raw drinking milk. The Board was informed that a paper presenting the current policy on unpasteurised (raw) milk and milk products for direct human consumption would be prepared, to seek views from the Board on further work that the FSA could do or ask others to do.

- 2.2 This paper focuses on raw drinking milk and raw cream. Products made from raw drinking milk, such as raw milk cheeses, yoghurt and butter are not considered as the production processes such as heating, acidification and maturation reduce the bacterial load or control bacterial growth and therefore reduce the risk associated with the product. Also, specific controls for raw milk products are provided by the EU hygiene legislation and these require that the potential risks are controlled by food businesses.

3 STRATEGIC AIMS

- 3.1 This work contributes to: Strategic Outcome 1 (food produced or sold in the UK is safe to eat); Strategic Outcome 4 (consumers have the information and understanding they need to make an informed choice); and Strategic Outcome 5 (regulation is effective, risk based and proportionate).

4 BACKGROUND

Science/Risk assessment

- 4.1 The potential risks associated with the consumption of raw drinking milk have long been recognised. Between 1912 and 1937, about 65,000 deaths from bovine tuberculosis were reported in England and Wales. In addition, raw milk was associated with many cases of brucellosis, food poisoning and other diseases. The introduction of bovine tuberculosis eradication programmes between the 1950s and 1980s and the widespread adoption of pasteurisation has meant that milkborne disease is now relatively rare.¹
- 4.2 Annexe 1 provides an overview of the available data on human illness associated with raw drinking milk and raw cream in each country of the UK, and surveillance data on the microbiological status of raw drinking milk and cream in England and Wales.

Human illness

- 4.3 With the caveat that there is always the possibility of under reporting of foodborne illness, the available data indicates that there have been no reported outbreaks of illness associated with raw drinking milk or cream in England and Wales since 2002. There were two reported outbreaks in Northern Ireland in 1991 with no reported outbreaks either before or after that time. Milk related illness in Scotland declined markedly from 1983 when sales of raw cows' drinking milk and cream were prohibited there, although outbreaks associated with raw milk still occurred throughout the 1990s.

¹ I. A. GILLESPIE, G.K. ADAK, S.J. O'BRIEN and F.J. BOLTON (2003) Milkborne general outbreaks of infectious intestinal disease, England and Wales 1992-2000 *Epidemiol. Infect.*(2003). **130**, 461-468

Enhanced surveillance for *E. coli* O157 in Scotland identified raw milk consumption as one of a number of potential risk factors in 11 sporadic (unlinked) cases of *E.coli* O157 occurring between 1999 and 2010. Ten of those 11 cases were residents of private farms.

Surveillance data

- 4.4 Surveillance data (summarised in Annexe 1) on raw drinking milk and cream (the most recent of which was taken from a survey in 2000 of raw milk destined for pasteurisation) shows the presence of pathogens in a small number of samples of raw milk from cows, sheep and goats e.g. *Salmonella* spp in 0.5% and *E.coli* O157 in 0.3% of samples. The surveillance also shows the presence of faecal indicator organisms at varying levels in the majority of samples. It was not possible to establish a direct relationship between the presence of indicator organisms and pathogens.

ACMSF Opinion

- 4.5 Reviews by the ACMSF² and others¹ highlight the role of unpasteurised milk in foodborne disease. ACMSF consideration of the available surveillance and monitoring data, most recently in 2011, highlights the potential for pathogens such as *Salmonella* species, *Campylobacter* and *E.coli* O157 and faecal contamination to be present in raw drinking milk and the importance of pasteurisation as a critical control point in the prevention of milk borne disease. ACMSF risk assessments of the specific risks from milk and milk products associated with the rise in bovine TB in cattle concluded that the risk of *M. bovis* in humans following the consumption of unpasteurised cows' milk and milk products is very low. The ACMSF advised that the risk from unpasteurised sheep, goat and buffalo milk and milk products is also likely to be very low but there are more uncertainties associated with this assessment due to a lack of data on these species.

Current controls

- 4.6 EU food hygiene rules that came into force on 1 January 2006 do not provide specific controls on raw drinking milk or cream but allow Member States to prohibit or restrict the sale of these commodities in domestic markets. If Member States do not establish national measures for these commodities, risk mitigation would rest solely on the general provisions of the European food hygiene legislation and general food law which require producers to control the risks through their own food safety management plans and demonstrate they are complying with the obligation to provide safe food. Domestic legislation in England, Wales and Northern Ireland permits the restricted sale of raw cows' drinking milk and cream and raw milk from other farmed species (i.e. goats, sheep and buffalo). Legislation prohibits the

² ACMSF Report on VTEC <http://www.food.gov.uk/multimedia/pdfs/acmsfvtecreport.pdf>
ACMSF Annual Report 1995 <http://acmsf.food.gov.uk/acmsfrep/acmsfannualreports>
ACMSF Annual Report 1997 <http://acmsf.food.gov.uk/acmsfrep/acmsfannualreports>
ACMSF Annual Report 1998 <http://acmsf.food.gov.uk/acmsfrep/acmsfannualreports>
Minutes of the 39th ACMSF meeting December 2000 <http://acmsf.food.gov.uk/acmsfmeets/>
Minutes of the 74th ACMSF meeting January 2011 <http://acmsf.food.gov.uk/acmsfmeets/>

sale of raw drinking milk and cream in Scotland. Details of the current controls on raw drinking milk and cream from all species are at Annexe 2.

- 4.7 The current controls in England, Wales and Northern Ireland allow raw cows' drinking milk and cream to be sold direct from the farm premises (including at a farmer's market), in a farmhouse catering operation (e.g. bed and breakfast) or by a distributor from a vehicle (e.g. a lorry or milk float) used as a shop premises. Sales through other outlets have been prohibited since 1985. Milk from species other than cows is not subject to these restrictions.
- 4.8 In addition, labelling rules in England and Northern Ireland require that all raw drinking milk must carry a health warning (or such warning to be displayed nearby in the case of catering sales) stating that the milk 'has not been heat-treated and may therefore contain organisms harmful to health'. In Wales, the warning on raw drinking milk and catering sales also adds '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'.
- 4.9 Raw drinking milk producers are subject to twice yearly inspections which primarily verify they are complying with the requirements of the hygiene legislation for the production and handling of the milk. Inspectors normally check the outlets for the milk and would follow up any causes of concern for the raw drinking milk. Official samples of cows' milk are also taken and tested quarterly to verify compliance with microbiological standards which are indicators of the quality of the milk. Analysis of the monitoring data shows that around 12-18% of samples fail to meet the microbiological standards, although this includes repeat samples on farms that have previously failed to meet the criteria. While failure to meet the current microbiological standards does not directly correspond to the presence of pathogens, this does indicate presence of faecal contamination and pathogens are more likely to be present as the levels of faecal contamination increase. There are no specific standards for pathogens in raw drinking milk, although to meet the general obligation for supply of safe food producers need to ensure pathogens are not present at levels that could cause illness.

Market

Scotland

- 4.10 Sales of raw cows' drinking milk and cream have been prohibited in Scotland since 1983 and from other species since 2005.

Northern Ireland

- 4.11 There are no known sales of raw cows' drinking milk or cream in Northern Ireland. There are two low output producers of raw goats milk (18 and 24 goats) selling from the farm.

England and Wales

- 4.12 The number of registered producers who provide raw cows' milk for direct human consumption in England and Wales has fallen from around 570 in 1997 to around 100 in 2010. There are also 27 producers of raw goats' milk and three of raw sheeps' milk which is sold for direct consumption or processing. There are no separate data on raw cream producers but surveillance in 1997 identified 11 producers in England and Wales. Data on production or sales volumes for raw drinking milk/cream is not collected.

Developments the market for raw drinking milk

- 4.13 Raw milk producers are using new routes of sale for raw drinking milk with at least two producers in England offering internet sales. This is permitted under current domestic controls but is not within the spirit of the legislation as these controls were developed to only allow restricted sales and only to a local market. Other producers are exploring sale through vending machines which, based on discussions in European Commission Working Groups, is following practices in some other EU countries such as Italy. Sales from vending machines on farm premises or at a farmers market would be permitted under current domestic controls in England, Wales and Northern Ireland but vending machines cannot be placed in retail outlets.

Stakeholder/Consumer views

- 4.14 There have been several formal consultations on controls for raw drinking milk over the years. Each consultation has produced similar results and consultation responses have been a significant factor in determining the current risk management approaches adopted by Ministers in the different UK countries.
- 4.15 Stakeholders and consumers in Scotland supported the prohibition of sales of raw cows' drinking milk and cream and its extension to other species. The most recent formal consultation in Scotland was in September 2005 prior to the introduction of the 2006 Food Hygiene Regulations.
- 4.16 In England, Wales and Northern Ireland, the most recent public consultation specifically considering controls for raw drinking milk was in 1997. The overwhelming response to this consultation was that sales should continue to allow consumers to make their own choices on whether or not to consume raw drinking milk. This view was expressed in 5,500 of the 5,572 responses received. Some sectors of the industry, enforcement authorities and health care professionals felt equally strongly that drinking milk should be pasteurised before consumption to address the inherent public health risk, although this view was expressed in a much smaller number of responses (22). A formal consultation in Wales in 2002 generated fewer responses but these reflected previous opinion and the majority of respondents (51 out of 63) supported continued sales of raw drinking milk.

5 DISCUSSION

- 5.1 Following previous FSA Board and ACMSF discussions on raw drinking milk, the FSA Executive is reviewing the controls in place to manage the public

health risks associated with raw drinking milk and cream. This paper provides an opportunity for the FSA Board to comment on potential options for managing the public health risks to inform the policy review process.

- 5.2 Responsibility for the production of safe food rests with the food business operator. There is no requirement for Member States to introduce national controls for raw drinking milk and cream, so a possible approach within EU law would be to allow sales with no specific restrictions. Whilst this might be considered to be consistent with the principles of the hygiene legislation and the current deregulatory environment, it would not be consistent with FSA obligations to protect public health and to ensure consumers have sufficient information to make informed choices. As such, this is not considered an appropriate approach for the FSA to recommend.
- 5.3 EU hygiene legislation allows, but does not require Member States to establish national controls for raw drinking milk and cream. As explained at paragraphs 4.6 to 4.9 this flexibility in the legislation has been used to maintain varying controls on raw milk and cream in each country of the UK that reflect differences in each country, e.g. reported outbreaks and stakeholder opinion. It is proposed that the policy review should build on this baseline position by considering the following two risk management options:
- to prohibit sales of raw drinking milk and cream in England, Wales and Northern Ireland i.e. require all milk and cream to be pasteurised prior to sale for direct human consumption, as is the case in Scotland; or
 - to continue to allow sales in England, Wales and Northern Ireland with appropriate consumer information, controls and enforcement action that together provide a clear, consistent and appropriate approach to controlling the public health risk.

Prohibiting sales

- 5.4 An internet search indicates that some countries (e.g. Canada, parts of the US, parts of Australia, some EU Member States) prohibit all sales of raw drinking milk and cream, and the question of introducing a ban is under active consideration in others, e.g. in the Republic of Ireland. Prohibiting sales has been shown to lead to a marked decline in milk related illness, e.g. as in Scotland. However, prohibiting sales does not prohibit consumption and this is likely to continue, especially within the farming community through private on farm consumption.

Allowing sales with controls to manage the risk

- 5.5 Internet sources indicate that many countries (e.g. New Zealand, 28 US States and some Member States including Germany, France, Holland, Belgium, Denmark and Italy in addition to England, Wales and Northern Ireland) allow restricted sales of raw drinking milk and cream direct to the consumer. Permitting restricted sales allows those who wish to consume raw milk and cream to be supplied legitimately. Consumer information and

specific controls aimed at reducing the risk associated with the product, and enforcement of those controls, provides some protection for these consumers

- 5.6 If sales of raw drinking milk and cream are to be allowed to continue, appropriate controls must be in place to reduce the risks associated with consumption. New routes through which raw drinking milk is offered for sale are being established, for example vending machines and internet sales, and it will be necessary to consider the public health risks associated with these developments to ensure the legal provisions provide appropriate public health protection.
- 5.7 There are also differences in the controls applied to the different species supplying raw drinking milk and cream in England, Wales and Northern Ireland. Sales of raw cows' drinking milk are only allowed directly from the farm premises in each of these countries, but there are no such restrictions on the sales of raw drinking milk from other species. The ACMSF indicated that, while there was limited surveillance and monitoring data on raw milk from species other than cows, there was the potential that pathogens could be present. Given the risk assessment indicates potential risks with raw milk and cream from these species, consideration should be given to applying the same risk mitigation measures to all species.

Consumer information

- 5.8 As explained at paragraph 4.8, information available to consumers on raw milk and cream labelling and on display at farmhouse catering operations is not consistent throughout England, Wales and Northern Ireland. The policy review will consider the reasons for this with a view to achieving consistency in this area.

Enforcement

- 5.9 Effective enforcement of the controls for raw drinking milk and cream provides a level of public health protection, but cannot remove the inherent risk associated with the unpasteurised commodity. In practice, it is often difficult to take enforcement action to require immediate corrective action by the Food Business Operator (FBO) based on non-compliance with the current microbiological standards. This is because these standards relate to indicator organisms and there is no direct relationship between these and the presence of pathogens. It is therefore difficult to demonstrate an imminent risk to public health and, as a result of this, authorities often need to rely on voluntary suspensions of sales by producers. The planned introduction of Remedial Action Notices to this and other food sectors would provide an alternative enforcement tool that would be useful in some circumstances where the FBO will not take corrective action voluntarily. Any amendment which would clarify the current legislation relating to raw drinking milk would also support more effective enforcement.

- 5.10 The recent decision to bring dairy hygiene enforcement in-house in England and Wales will also allow the FSA to gain greater knowledge of this sector and the opportunity to introduce greater control over the enforcement action taken. It may also be possible to strengthen the current enforcement regime, for example, to ensure action is taken more quickly when samples fail to meet the current microbiological quality standards. Consideration of enforcement issues will form part of the policy review.

6 IMPACT

- 6.1 The impact of any proposed changes to controls on raw drinking milk and cream will be fully assessed through the development of an Impact Assessment for each UK country. A recommendation to prohibit sales or introduce additional controls would have most impact in England and Wales where there is a continued demand for raw drinking milk and cream. This would have limited or no impact in Scotland where sales are prohibited and in Northern Ireland where there is little commercial activity in this sector.
- 6.2 Farmers and farming communities are likely to be most affected as this is where the supply and demand for raw drinking milk and cream is focussed. There is also the potential that there will be a disproportionate impact on small producers.

7 CONSULTATION

- 7.1 There has been no specific consultation on recommendations in this paper but recent correspondence and comment in response to media articles on the sale of raw drinking milk indicate opinion continues to reflect responses to previous consultations with very strong and polarised arguments on either side of the debate. Further consultation will be required to allow full assessment of the options proposed as a result of the Board discussion.

8 LEGAL IMPLICATIONS

- 8.1 Any changes to the controls on raw drinking milk and cream in any UK country are likely to require an amendment to the Food Hygiene Regulations.

9 RESOURCE IMPLICATIONS

- 9.1 Previous experience shows that this issue is very sensitive and will generate significant interest, requiring staff resource to deal with correspondence, in addition to the normal policy making and consultation process.

10 RISK IMPLICATIONS

- 10.1 Given the sensitivity of this issue, with strong and very polarised arguments on each side of the debate, there could be reputational risks to the FSA from any proposals on future risk management options. Any proposals will be subject to an impact assessment which will consider the risks, benefits and

burdens associated with each option. This process will help mitigate the reputational risks.

- 10.2 The reducing regulation agenda in England places greater onus on Regulators to provide strong evidence to support proposals which may introduce a burden on business, particularly small businesses. This could present a significant hurdle to the introduction of further controls on raw drinking milk in England, particularly as there is an absence of evidence to demonstrate outbreaks of illness associated with consumption of raw milk or cream in England. Any new domestic legislation that introduces restriction on trade or costs to business may be looked at critically by Ministers and the relevant regulatory committees. It should be noted that the Government favours alternatives to regulation over regulation itself where at all possible.

11 DEVOLUTION IMPLICATIONS

- 11.1 As explained earlier in the paper, there are different risk management strategies applied for raw drinking milk in the different countries of the UK. The policy review will develop a clear FSA position on risk management whilst recognising that different approaches may continue to be adopted in each country to reflect local differences. The policy review will also be consistent with the principles outlined in the FSA Board Paper (FSA12/01/07) on The Food Standards Agency as a UK Department Working in an Area of Devolved Competence.

12 CONSUMER ENGAGEMENT

- 12.1 The FSA will seek consumer views during the public consultation on any proposals for managing the food safety risks associated with raw drinking milk. We will also consider holding a series of consumer focus groups to discuss the possible options.

13 CONCLUSION AND RECOMMENDATIONS

- 13.1 There are inherent risks associated with raw drinking milk and cream and those risks can be effectively controlled through pasteurisation. This view is shared by the ACMSF, some sectors of the dairy industry, enforcement authorities and health care professionals who would support a prohibition of raw drinking milk sales across the UK. However, there is a small continuing consumer demand for raw drinking milk and cream and strong opinion in England and Wales that sales should continue to provide consumer choice.
- 13.2 There have been no reported outbreaks of illness associated with raw drinking milk or cream in the UK for over 10 years. Even with the caveats on under reporting of foodborne disease and the potential for undetected sporadic cases, the absence of reported outbreaks gives some assurance that the current controls are mitigating the risks associated with consumption of raw drinking milk. However, if sales are to continue, the statutory requirements must be clear and consistent and control the public health risk,

particularly in the light of developments in the marketing of these products, controls for each species and the information provided to consumers.

13.3 The Board is asked to:

- **agree** that, due to the inherent food safety risks associated with raw drinking milk and cream, pasteurisation of all milk prior to direct human consumption is a critical control measure and is the most effective means of protecting public health;
- **acknowledge** that some consumers prefer to exercise choice in continuing to have access to raw drinking milk and cream;
- **agree** that, in consultation with stakeholders and consumers, the FSA should fully assess the possible options for managing the food safety risks associated with consumption of raw drinking milk and cream and formulate advice that could be provided to Ministers for discussion by the FSA Board;
- **agree** that, given the possibility that restricted sales of raw drinking milk and cream may continue following the policy review and decisions by Ministers, the policy review should include consideration of the current statutory controls to ensure they provide a clear, consistent and appropriate regulatory framework to control the public health risk, particularly in the light of developments in the marketing of these products;
- **agree** that, FSA advice to consumers should continue to emphasise the food safety risks associated with raw drinking milk and raw cream and that, in particular, vulnerable groups should not consume these products.

Annexe 1

SUMMARY OF HUMAN ILLNESS, MICROBIOLOGICAL SURVEILLANCE AND MONITORING DATA FOR RAW DRINKING MILK AND CREAM IN ENGLAND, WALES, NORTHERN IRELAND AND SCOTLAND

The Advisory Committee on the Microbiological Safety of Food (ACMSF) reviewed evidence on the safety of raw drinking milk from all species in January 2011. They considered information on human illness in England and Wales linked to raw drinking milk and cream and data on the microbiological status of raw milk and cream. The Committee concluded they did not feel a need to change their previous view that pasteurisation is an important control measure in reducing the risks from consumption of raw milk.

Human illness linked to raw drinking milk and raw cream

England and Wales

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.

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 (less than 1%). In the last 9 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. Table 1 provides details of the outbreaks of IID linked to raw drinking milk/cream and the organism associated with these outbreaks.

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. 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.

Table 1: Outbreaks of infectious intestinal disease linked to raw drinking milk and raw cream in England and Wales: 1992-2011*.

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

*Data provided by HPA. The evidence linking milk to the reported outbreaks included microbiological evidence, evidence from cohort studies and from case-control studies.

Northern Ireland

Two outbreaks of IID linked to unpasteurised milk were reported in Northern Ireland in 1991, one of which occurred on a farm. Details are provided in table 2. There were no reported outbreaks linked to raw milk between 1984 and 1990 and there have been none since 1992.

Table 2: Outbreaks of infectious intestinal disease linked to raw drinking milk and raw cream in Northern Ireland: 1984-2011*.

<i>Year of outbreak</i>	<i>Organism</i>	<i>No. of people affected</i>	<i>No. of hospitalisations</i>	<i>No. of deaths</i>	<i>Outbreak contributory factor</i>
1991	<i>Campylobacter</i>	3	0	0	Unpasteurised milk
1991	<i>S. Typhimurium</i> DT204a	4	0	0	Unpasteurised milk

*Data provided by Health & Social Care in Northern Ireland

Scotland

The data which is available to the FSA suggests that the numbers of cases of foodborne disease associated with the consumption of milk and cream have decreased significantly since the ban was introduced in 1983. Table 3 provides details of cases and outbreaks associated with raw milk and cream in Scotland.

Surveillance data from Health Protection Scotland (HPS) ObSurv surveillance system³ reported two outbreaks between 1996 and 2011 where raw milk was the suspected vehicle. These involved illness in four people in 1998 attributed to *Salmonella Typhimurium* and illness in three people in 1999 due to *E.coli* O157. No deaths were recorded.

HPS's enhanced surveillance of Verotoxigenic *E.coli* (VTEC), which was established in 1999, collects information on sporadic cases of VTEC infection (i.e. cases in single households who were not linked to general outbreaks) and on exposures to biologically plausible risk factors. Data between 1999-2011 (including provisional figures for 2011), indicated 11 cases of VTEC O157 (all of whom had contact with farms) which were reported to have consumed raw milk, although it should be noted that raw milk was only one of the potential risk factors for these cases and therefore cannot be confirmed as the direct cause of illness. Ten of these 11 cases were residents of private farms. HPS is not aware that any of these cases died as a result of their infections. None of these cases were part of the general outbreaks referred to in the previous paragraph.

³ ObSurv surveillance system is a voluntary system recording general outbreaks of infectious intestinal disease (i.e. two or more linked cases including members of more than one household, or residents of an institution).

Table 3: Outbreaks of infectious intestinal disease in Scotland associated with raw drinking milk 1980 – 1999*

Year	Numbers of Outbreaks	Numbers Affected By Illness (Deaths)
1980	3	98 (4)
1981	8	782 (3)
1982	14	539 (1)
1983	7	29
1984	5	27
1985	8	74
1986	2	10
1987	5	30
1988	1	4
1989	0	0
1990	2	6
1991	4	17
1992	2	6
1993	0	0
1994	0	0
1995	No data	No data
1998	1	4
1999	1	3

* Data provided by Scottish Centre for Infection and Environmental Health, (now HPS).

Microbiological status of raw drinking milk and cream in England and Wales

Surveillance

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.

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.

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

- Not tested for

* Coagulase positive staphylococci

* Detected by enrichment

Statutory monitoring of raw cows' drinking milk

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. This monitoring data provides a useful indication of the quality of raw cows' drinking milk on sale in England and Wales.

Raw drinking milk must meet the following criteria:

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

Reported failures are samples that exceed either the plate count or coliform criteria or both. The sample failure rate from January 2004 to March 2011 has stayed fairly consistent around 12-18%. There was a slight improvement in 2006 and 2007 where the failure rates dropped to 9% and 7% respectively.

The failure rate includes re-samples from farms that have failed the criteria previously. 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.

Table 5 provides an overview of monitoring data and the percentage of samples exceeding the statutory limits for either coliforms or TVCs with results from repeated samples removed. This shows the failure rate of initial samples is lower when retests are excluded and has reduced since 1995-96 and stayed at a fairly constant lower level since 2006.

Table 5: Comparison of failure rates for samples taken in the 1995-96 survey of Raw Cows' Drinking Milk (RCDM) and in the statutory monitoring of RCDM from 2006-2010 with failures due to follow up samples removed.

	1995-96 Survey of RCDM 1591 samples	2005 295 samples	2006 396 samples	2007 454 samples	2008 351 samples	2009 318 samples	2010 217 samples	2011 163 samples
	% of samples exceeding limit (total number of samples exceeding limit)							
Coliforms $\geq 1 \times 10^2$ cfu/ml	25% (390)	10% (30)	6% (25)	5% (21)	4% (14)	4% (14)	6% (14)	8% (13)
Total Viable Counts $> 2 \times 10^4$ cfu/ml	16% (255)	8% (23)	6% (23)	4% (20)	6% (21)	7% (22)	6% (13)	6% (9)

CONTROLS ON RAW DRINKING MILK AND CREAM IN ENGLAND, WALES, NORTHERN IRELAND AND SCOTLAND

	<u>England</u>	<u>Wales</u>	<u>Northern Ireland</u>	<u>Scotland</u>
Raw Cows Drinking Milk				
Sales	<p>Sales allowed direct to consumers at the farm gate, in a farmhouse catering operation or through milk roundsmen.</p> <p>Sales by farmers at farmers market and internet sales allowed.</p> <p>All other sales including vending machines in retail establishments prohibited.</p>			Sales prohibited since 1983
Specific controls	<p>Herd must be officially tuberculosis free, and brucellosis free and comply with EU hygiene rules⁴ and with microbiological standards in domestic Food Hygiene Regulations⁵.</p>			
Labelling requirements	<p>Must comply with requirements in domestic Food Labelling Regulations⁶ and state that: “This milk has not been heat-treated and may therefore contain organisms harmful to health”.</p>	<p>Must comply with requirements in domestic Food Labelling Regulations and state that: “This milk has not been heat-treated and may therefore contain organisms harmful to health. The Food Standards Agency strongly advises that it should not be consumed by</p>	<p>Must comply with requirements in domestic Food Labelling Regulations and state that: “This milk has not been heat-treated and may therefore contain organisms harmful to health”.</p>	N/A

⁴ Regulation EC No. 853/2004, Annexe III, Section IX, Chapter 1, 2

⁵ The Food Hygiene Regulations 2006, Schedule 6, 5 (similar requirements apply in England, Wales and Northern Ireland)

⁶ The Food Labelling Regulations 1996 (equivalent legislation applies in Northern Ireland).

	<u>England</u>	<u>Wales</u>	<u>Northern Ireland</u>	<u>Scotland</u>
		children, pregnant women, older people or those who are unwell or have chronic illness".		
Official controls	Twice yearly inspections. Quarterly sampling and testing.			
Raw milk from other species				
Sales	No restrictions on sales			Sales prohibited since 2005
Specific controls	Buffaloes milk must come from a tuberculosis and brucellosis free herd. Sheep and Goats milk must come from a brucellosis free herd. RDM from buffaloes, sheep and goats must comply with EU hygiene rules and microbiological standards in domestic Food Hygiene Regulations.			N/A
Labelling requirements	<p>Sheep and goats RDM must be labelled to state that: "This milk has not been heat-treated and may therefore contain organisms harmful to health".</p> <p>No requirements in Food Labelling Regulations 1996 for buffaloes RDM, but EU food hygiene rules on labelling for raw milk apply.</p>	<p>Sheep, goats and buffalo RDM must be labelled to state that: This milk has not been heat-treated and may therefore contain organisms harmful to health. 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".</p>	<p>Sheep and goats RDM must be labelled to state that: "This milk has not been heat-treated and may therefore contain organisms harmful to health".</p> <p>No requirements in Food Labelling Regulations 1996 for buffaloes RDM, but EU food hygiene rules on labelling for raw milk apply.</p>	
Official controls	Twice yearly inspections. Sampling subject to Food Authority checks.			

	<u>England</u>	<u>Wales</u>	<u>Northern Ireland</u>	<u>Scotland</u>
Raw Cream				
Sales	No restrictions on sales.			Sales of raw cows cream prohibited since 1983 Sales of raw cream from other species prohibited since 2005.
Specific requirements	Must comply with requirements for milk products in EU hygiene rules. Must meet herd status requirements for milk from same species.			N/A
Labelling requirements	No requirements in Food Labelling Regulations 1996, but EU hygiene rules on labelling for products made with raw milk apply.			
Official controls	Risk based programme of inspections.			