

ADVISORY COMMITTEE ON THE MICROBIOLOGICAL SAFETY OF FOOD

ASSESSMENT OF WHETHER THE MICROBIOLOGICAL RISK ASSOCIATED WITH CONSUMPTION OF RAW DRINKING MILK (AND CERTAIN RAW MILK PRODUCTS) MADE IN THE UK HAS CHANGED SINCE 2015

Introduction

1. In July 2015, following a policy review, the FSA Board agreed with recommendations to continue with existing controls governing the sale and marketing of raw drinking milk (RDM). The Board generally agreed that the level of risk associated with the product was acceptable when appropriate hygiene controls were applied, this was against a back-drop of a small and stable RDM market and minimal outbreaks associated with the product.

2. Since July 2015, there has been a noticeable increase in the number of RDM producers and RDM-related outbreaks. The FSA is currently looking at different strands of information (microbiological, economic and social science aspects) to inform a wider work programme including a Board discussion scheduled for June 2018. The microbiological risk assessment branch has been asked to assess whether the risk associated with consumption of raw drinking milk (and certain unpasteurised products made using raw milk) made in the UK has changed since July 2015.

3. The approach has been to assess:

- whether newly registered RDM producers in the UK present a greater likelihood of producing unsafe product than more established producers and;
- whether there has been a change in the profile of vulnerable groups becoming ill and;
- the aetiological agents involved.

4. The purpose of this paper is therefore to:

- outline currently available information relating to the microbiological risks associated with consumption of RDM (and certain raw milk products), and;
- seek the Committee's views on the information and conclusions presented in this paper.

¹ The original version of ACM/1269 has been amended to reflect comments made by the Committee on 10 May 2018 (see Annex 8 for list of amendments).

Scope

5. The assessment focusses on raw cows' drinking milk (RCDM), although milk from other species (e.g. sheep and goats) has also been taken into account.

6. The emphasis is on RDM and certain unpasteurised products made using raw milk. Cream, smoothies, milkshakes and ice-cream made using raw milk have been included following a request by risk managers, in particular as the latter three product types could potentially increase raw milk consumption among children. Other products made using raw milk such as butter and cheese are outside the scope of this assessment.

7. The data represent England, Wales and Northern Ireland as the sale of raw drinking milk in Scotland is not permitted. The assessment does not consider the risk associated with consumption in the UK of raw drinking milk produced outside the UK. Bovine tuberculosis (caused by *Mycobacterium bovis*) has not been taken into account because specific risk management controls are in place for this pathogen.

Human illness linked to raw drinking milk and certain raw milk products

8. From the beginning of 2015 to the end of December 2017, there were 5 reported outbreaks in the UK (4 in England and 1 in Wales) involving human illness linked to consumption of RDM (Table 1). There was a total of 103 affected cases, of which 40 were laboratory confirmed through the testing of clinical samples (e.g. stool samples). There were 4 reported hospitalisations and no deaths. One of the outbreaks occurred in 2016 and 4 occurred in 2017.

9. In 2017, a case of illness was linked to consumption of RDM from a farm in England through descriptive epidemiological and microbiological evidence. As only a single case of illness was reported, this is not regarded as an outbreak according to usual definitions but is included in Table 1 as further evidence of RDM-associated illness.

10. In terms of outbreaks before July 2015, in 2014 there was a single outbreak. Prior to that, the last UK outbreaks associated with RDM occurred in England & Wales in 2002 (see Table 2). The most recent outbreak associated with raw milk in Scotland was in 1999. In Northern Ireland only 2 outbreaks linked to raw milk have been reported, both in 1991. There has therefore been a notable increase in outbreaks associated with RDM in the UK since this issue was considered by the Board in 2015.

11. All outbreaks in Table 1 were associated with RDM from cows. No outbreaks associated with RDM from other species (e.g. sheep or goats) were reported.

12. Data was sought on outbreaks associated with specific unpasteurised products made with raw drinking milk (i.e. cream, smoothies, milkshakes and ice-cream) for inclusion in Table 1. In the *Campylobacter* outbreak in Wales in 2017, 8 cases reported consuming milkshake made with raw milk (6 of these cases reported consuming only the milkshake) and 3 of the cases were children. No outbreaks associated with cream, smoothies or ice-cream were reported during the relevant timeframe.

Table 1. Outbreaks involving human illness associated with RDM (and certain raw milk products) in the UK (01/01/2014 to 20/12/2017)^{a, b} Data in columns 2-12 was provided by Public Health England (PHE). Data in the final column was provided by FSA Field Operations.

Farm	Year of outbreak	Region	Agent	Vehicle description	Total cases affected	Laboratory confirmed cases	Hospitalised	Number of deaths	Age and gender ^c	Evidence ^d	Comment (data source)	1) Registration date 2) Start date 3) Trading time ^e
A	2014	South West England	STEC O157 PT21/28	Raw cows' drinking milk	9	9	2	0	7 cases children, 2 cases adult. Age range of cases 1-49 years	Microbiological and descriptive epidemiological	7 primary and 2 secondary cases linked microbiologically and epidemiologically to consumption of raw cows' drinking milk from a single farm. One case was also infected with an identical strain of <i>Salmonella</i> Mbandaka isolated from a sample taken from the bulk tank at the farm. An identical strain of <i>E. coli</i> O157 (PT21/28) was identified from the pooled animal faeces collected on the farm premises. All isolates from humans, food and animals fell into a 5-SNP cluster; SNP address 4.4.4.590.3318.3473.% (eFOSS, outbreak report and GDW)	Pre 2012 September 2014
B	2016	North West England	<i>Campylobacter jejuni</i>	Raw cows' drinking milk	69	16	0	0	Mean age of cases was 44 years (range 1-74); 61.9% male. 2 cases children with WGS results.	Microbiological and analytical epidemiological	Microbiological: WGS identified nine <i>Campylobacter jejuni</i> isolates, seven from human faeces and two from raw milk samples. SNP address 1.2.2.2.2.7 Epidemiological: A case-control study linked the consumption of RDM to illness in cases (outbreak report and GDW).	15/08/13 12/12/16 > 3 years trading (i.e. 40 months)

C	2017	South East England	STEC O157 PT21/28 stx2	Raw cows' drinking milk	7	7	3	0	5 cases were children. Age range of children 1-11 years.	Microbiological and descriptive epidemiological	Microbiological evidence: Case, food and animal isolates all fell within a 5 SNP cluster. SNP address 4.4.4.590.3896.4108.% Descriptive epidemiological: All cases either had some link with the farm or consumed raw milk from the farm. (HPZone/Vessy/GDW)	15/05/12 26/09/17 > 5 years trading (i.e. 64 months)
D	2017	South West England	<i>Campylobacter</i> spp	Raw cows' drinking milk	5	5	0	0	Male x 4, female x 1, age between 41-69 years	Descriptive epidemiological	5 confirmed cases linked epidemiologically to the consumption of raw cows' drinking milk at a farm. Contamination of the milk with <i>Campylobacter</i> was suspected based on the epidemiological evidence but was not confirmed microbiologically. (eFOSS and outbreak report)	21/10/16 27/06/17 <12 months trading (i.e. 8 months)
E	2017	North West England	<i>Campylobacter</i> spp	Raw cows' drinking milk	4	4	0	0	Male x 2, female x 2, ages between 2-69 years.	Microbiological and descriptive epidemiological	Microbiological evidence: Case and milk isolates all fell within a 0-SNP cluster. SNP address 2.2.2.2.3.3.3 (eFOSS and GDW)	29/06/16 26/06/17 Only just 12 months trading (i.e. 12 months)
F	2017	Wales	<i>Campylobacter</i> spp	Raw cows' drinking milk and milkshake made with the RCDM	18	8	1	0	7 cases were aged under 16 (aged 5-13 years)	Microbiological and descriptive epidemiological	(Personal communication Public Health Wales/ Ceredigion County Council)	27/6/16 08/08/17 < 24 months trading (i.e. 13 months)

G	2017	North West England	<i>Salmonella</i> Dublin	Raw cows' drinking milk	1	1	U	0	1 child.	Microbiological and descriptive epidemiological	This incident was not reported as an outbreak due to only one individual being affected. An indistinguishable strain of <i>S. Dublin</i> was detected in bulk milk and farm environmental samples. SNP address. 1.1.1.2.2.2.2 (Personal communication – Health Protection Team and GDW)	29/06/16 05/07/17 Only just 12 months trading (i.e. 12 months)
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^A A food-borne outbreak is defined as 'an incidence, observed under given circumstances, of two or more human cases of the same disease and/or infection, or a situation in which the observed number of human cases exceeds the expected number and where the cases are linked, or are probably linked, to the same food source' (Directive 2003/99/EC¹).

^B Data for 2017 are provisional. Data on foodborne disease outbreaks were extracted from the Electronic Food and Non-Foodborne Gastrointestinal Outbreak Surveillance System (eFOSS). eFOSS is a dynamic database and, as such, data are subject to change. Five of the outbreaks/incidents reported in Table 1 had not yet been formally reported into eFOSS so the information provided was obtained from the outbreak reports and/or direct communication with the outbreak/incident investigators. There may be additional outbreaks or further information on the outbreaks reported in Table 1 added to eFOSS before the annual data is finalised in May 2018. Data presented for RDM and unpasteurised products made with raw milk associated products. Where not specified that the vehicle was RDM or an RDM product, these outbreaks have not been included in the table.

^C Where additional information is available on the specific age of children identified as cases in the reported outbreaks in table 1, the details on case numbers/ages have been extracted from the Gastro Data Warehouse (GDW) based on whole genome sequencing data which may differ from total numbers affected in outbreaks as sequencing results may not be available for all cases.

^D Categories of evidence are defined in the EFSA Manual² on reporting of foodborne outbreaks as follows:

- o Descriptive epidemiological evidence: suspicion of a food vehicle in an outbreak based on the identification of common food exposures, from the systematic evaluation of cases and their characteristics and food histories over the likely incubation period by standardised means (such as standard questionnaires) from all, or an appropriate subset of, cases
- o Analytical epidemiological evidence: a statistically significant association between consumption of a foodstuff and being a case in an analytical epidemiological study (e.g. cohort or case-control study)
- o Microbiological evidence: detection of a causative agent in a food vehicle or its component or in the food chain or its environment combined with detection in human cases, or clinical symptoms and an onset of illness in outbreak cases strongly indicative/pathognomonic to the causative agent identified in the food vehicle or its component or in the food chain or its environment.

^E Registration date = date on which FBO was registered to sell RDM.

^E Start date = date on which issue was reported to FSA Field Operations.

^E Trading time = time period between registration to sell RDM and date on which the issue described in the table was reported to FSA Field Operations. Figure are rounded to the nearest whole month.

U = Unknown

WGS = Whole Genome Sequencing

SNP = Single Nucleotide Polymorphism

All reported foodborne IID outbreaks and IID outbreaks associated with RDM or raw cream in England and Wales (1992-2017)

13. Table 2 contains information on all reported foodborne Infectious Intestinal Disease (IID) outbreaks, and those specifically associated with RDM or raw cream, in England and Wales from 1992-2017 to add some historical context.

14. The number of outbreaks differs from those described in Table 1, which also includes an incident not designated as an outbreak under the official definition (Directive 2003/99/EC). In addition, the data for outbreaks associated with RDM and cream for 2016 and 2017 is not directly comparable with that from previous years as outbreaks not reported in PHE's Electronic Food and Non-Foodborne Gastrointestinal Outbreak Surveillance System (eFOSS) are included following enhanced follow-up with local Health Protection Teams and Health Protection Wales.

15. The number of reported outbreaks of foodborne Infectious Intestinal Disease (IID) in England and Wales associated with food (of any type) has gradually decreased from 1992 to 2017 (from 238 outbreaks in 1992 to 44 in 2016 - although noting that the 2016 and 2017 data are not directly comparable to previous years and the 2017 data is provisional). The decrease in the number of outbreaks was due primarily to the reduction in the number of *Salmonella* Enteritidis outbreaks linked to eggs.

16. The number of IID outbreaks associated specifically with RDM and raw cream in England and Wales has been intermittent from 1992-2017, with none reported during 2003-2013, and outbreaks appearing to have re-emerged from 2014 onwards.

17. In particular, when the number of reported outbreaks specifically associated with RDM and raw cream in England and Wales is considered as a percentage of the total number of outbreaks associated with food (of any type), there appears to have been a significant shift in recent years. Provisional data indicate that up to 14.8% of all foodborne IID outbreaks in England and Wales were associated with RDM (although the dataset is currently being finalised and additional foodborne IID outbreaks are expected to be reported into the system. It is likely that the actual number of foodborne IID outbreaks in 2017 will be greater than 27 and the proportion of outbreaks associated with RDM will be less than 14.8%). In 2016, 2.3% of foodborne IID outbreaks reported in England and Wales were associated with RDM. In previous years 0.0 - 2.4% of all reported foodborne IID outbreaks in England and Wales from 1992 to 2015 were associated with RDM and cream (i.e. an average of 0.51% of the outbreaks during this period - although again noting that the 2016 and 2017 data are not directly comparable to previous years and the 2017 data is provisional). Of note is that the proportion of those affected who were hospitalised was higher for IID outbreaks involving RDM (11.9%) than for all foodborne IID outbreaks (3.7%).

PHE's view on the extent to which the routine use of whole genome sequencing may have contributed to the increase in outbreaks associated with RDM

18. The routine use of Whole Genome Sequencing (WGS) since 2015 now provides unprecedented sensitivity and accuracy in identifying microbiologically linked cases of infection. Confirmation of the association with a suspected/implicated food vehicle is

facilitated by this enhanced sensitivity/accuracy providing increased confidence in source attribution compared to previous less discriminatory phenotypic testing methods for *Salmonella* and *Campylobacter*. However, when specifically considering RDM associated outbreaks, the available evidence for 2015 – 2017 indicates that the implementation of routine WGS has not contributed to increased outbreak detection, although it may have contributed to increased case ascertainment.

Table 2. Reported foodborne Infectious Intestinal Disease (IID) outbreaks and IID outbreaks associated with RDM or cream in England and Wales, 1992-2017^{a,c}
(Data provided by Public Health England)

Year	Total number of foodborne IID outbreaks	Number affected (number hospitalised)	Number of deaths ^b	Total number of IID outbreaks linked to RDM or cream	RDM outbreaks as a % of total number of foodborne outbreaks	Number affected (number hospitalised) ^b
1992	238	6663 (237)	8	1	0.4%	72 (0)
1993	249	6032 (181)	8	3	1.2%	41 (9)
1994	245	5666 (186)	5	3	1.2%	38 (1)
1995	236	6321 (198)	11	1	0.4%	26 (7)
1996	209	4673 (210)	22	3	1.4%	16 (4)
1997	254	5208 (204)	15	1	0.4%	8 (2)
1998	151	3564 (94)	6	2	1.3%	10 (4)
1999	123	2920 (136)	2	0	0.0%	0
2000	125	3261 (101)	2	3	2.4%	9 (3)
2001	105	1806 (94)	4	0	0.0%	0
2002	89	2364 (78)	20	2	2.2%	9 (6)
2003	83	2430 (114)	2	0	0.0%	0
2004	70	1798 (71)	6	0	0.0%	0
2005	87	1957 (85)	4	0	0.0%	0
2006	73	1933 (76)	7	0	0.0%	0
2007	52	1102 (84)	11	0	0.0%	0
2008	41	919 (46)	8	0	0.0%	0
2009	91	3408 (108)	8	0	0.0%	0
2010	63	1418 (83)	5	0	0.0%	0
2011	83	2133 (83)	3	0	0.0%	0
2012	55	1324 (74)	8	0	0.0%	0
2013	77	2552 (62)	13	0	0.0%	0
2014	70	2055 (78)	4	1	1.4%	9 (2)
2015	48	1098 (34)	1	0	0.0%	0
2016	44	2629 (93)	2	1 ^c	2.3%	69 (0)
2017 ^d	27 ^d	667 (24) ^d	0 ^d	4 ^{c,d}	14.8% ^d	34 (4) ^d
Total	2988	75901 (2834)	185	25	0.8%	353 (42)

^aThis table contains only outbreaks that were reported to eFOSS for the years 1992 - 2015.

^bNo deaths have been reported from IID outbreaks associated with RDM or cream.

^cData for 2016 and 2017 has been derived from an enhanced interrogation of other data sources in addition to extraction of data from eFOSS and therefore includes outbreaks not reported to eFOSS, making this data not directly comparable with data from previous years.

^dData for 2017 is provisional. It is anticipated that further reported IID foodborne outbreaks will be added when the data set is finalised. It is therefore likely that the actual figure will be greater than 27 and the proportion of outbreaks associated with RDM will be less than 14.8%.

19. The RDM-associated STEC outbreaks reported between 2015 and 2017 were detected through epidemiological links established by local health protection teams prior to the availability of the WGS results. PHE was not using routine sequencing at the time of the detection of the STEC O157 outbreak in 2014 and this outbreak was detected by local health protection teams evaluating the enhanced surveillance questionnaires to establish the epidemiological links with RDM and the implicated farm. WGS was used retrospectively to definitively link cases to the outbreak strain, however isolates were linked through Multiple Locus Variable Number Tandem Repeat Analysis (MLVA) typing which was in use at the time. WGS did not directly result in detection of the 2016 or 2017 outbreaks, but contributed to case ascertainment with additional cases captured through WGS prior to epidemiologically linking these cases to the outbreaks.

20. From the information available, PHE were not able to establish whether there was additional case ascertainment through use of WGS.

21. It should also be noted that the number of RDM associated outbreaks reported annually and number of cases linked to and investigated during outbreak investigations do not accurately portray the true burden of disease because this data only represents a very small proportion of overall gastrointestinal illness burden.

Human illness linked to raw drinking milk (and certain raw milk products) compared with trading time

22. To assess how the number of outbreaks associated with newly registered RDM producers compares with those associated with more established producers, data on trading time (including for the FBO associated with the single case of salmonellosis, although noting that this is not technically regarded as an outbreak) was extracted from Table 1 and presented in Table 3.

Trading time	Number of outbreaks
12 months or less	3
More than 12 months but less than 24 months	1
24 months or more	2

Table 3. Number of outbreaks in relation to trading time

23. There does not appear to be a correlation between the amount of trading time (i.e. the period between the FBO being registered to sell RDM and the date on which the outbreak was reported to FSA Field Operations) and involvement in outbreaks. However, it is recognised that the number of outbreaks considered here is small and it is therefore difficult to draw firm conclusions.

24. Of the outbreaks included in Table 1, the farms associated with the greatest number of confirmed cases (i.e. farm B), and with the greatest number of reported hospitalisations (i.e. farm C) had been trading for more than 24 months before the outbreaks occurred (i.e. for more than 3 years and more than 5 years respectively).

Vulnerable groups

25. Children, the elderly, pregnant women and those who have a weakened immune system due to illness with underlying conditions are generally regarded as more susceptible to foodborne illness and may develop more serious symptoms.

26. Table 1 includes information on the cases' ages. Most of the outbreaks in 2016 and 2017 (i.e. 4/5), and the single reported salmonellosis case in 2017, involved children. The outbreaks associated with farms C and E, and the single salmonellosis case involved cases aged under 5 years. The outbreaks associated with farms B, C and F involved cases who were children aged 5 years and over. Out of the 103 total cases reported to have been involved in outbreaks associated with consumption of RDM since July 2015, and the single salmonellosis case, 16 were children (of which at least 3 were less than 5 years old).

27. The data available on the number of children involved in outbreaks associated with RDM before July 2015 is more limited. However, the outbreak in 2014 involved a total of 9 cases, of which 7 were children. Of the outbreaks/incidents associated with RDM in England and Wales prior to 2014, limited information on the number and ages of children is available for five outbreaks of STEC O157. One outbreak in 1993 affected four children (age range of cases 3-61 years); one outbreak in 1996 affected six children; one outbreak in 1998 affected three children (aged 1-7 years) and; one outbreak in 2000 affected a child under the age of 5 years. It therefore appears that children were involved in outbreaks associated with consumption of RDM both before and after this issue was considered by the Board in July 2015.

28. Data on other vulnerable groups associated with outbreaks is not routinely collected and so it is not possible to assess the extent to which they are involved in RDM-associated outbreaks and whether this has changed.

Pathogens involved in outbreaks associated with raw drinking milk

29. The pathogens associated with human illness shown in Table 1 were *Campylobacter* spp., STEC O157 and non-typhoidal *Salmonella*. This is in line with a Scientific Opinion published by EFSA in 2015³, which identified these as among the main pathogens for which there is a clear link between drinking raw milk and human illness in the EU. It is also consistent with what has been seen in the UK historically.

30. The strains of STEC O157 associated with the three RDM outbreaks reported since 2014 were fully sensitive to all ten classes of antimicrobial agents tested. A recent publication suggested that over 80% of STEC O157 are fully sensitive to all antimicrobials tested⁴. Antimicrobial resistance information is not available for the other reported outbreaks.

Causes of outbreaks associated with raw drinking milk

31. According to the Scientific Opinion published by EFSA in 2015³, contamination of RDM with microbiological hazards can arise from a number of different sources

involving intrinsic contamination from infection in the animal prior to milking or extrinsic contamination arising from environmental contamination of the milk with faecal material either directly from the animal at the time of milking, or indirectly from the milking equipment, farm environment or at the point of use.

32. The root causes of the outbreaks described in Table 1 are not known. Poor hygiene practices are likely to have been involved although the exact nature of the breakdowns that led to contamination of the milk was not confirmed. It is worth noting that apart for collection of data mostly on sales routes and volumes nothing appears to have changed regarding actual hygiene inspections since July 2015. Information on factors such as herd size and volume of production have not been recorded in real-time historically and so it is not possible to assess whether these factors or changes relating to them may have contributed to the outbreaks described in Table 1.

Enhanced surveillance

33. National enhanced surveillance systems for STEC and *Listeria monocytogenes* collect standardised information which can be used to observe risk factors over time. Data provided by PHE relating to RDM from enhanced surveillance systems are presented in Table 4. Enhanced surveillance provides information on exposure to potential sources of illness and can identify several risk factors for infection. Therefore, it is not possible to use such information to provide a measure of risk associated with the consumption of RDM for ‘sporadic’ cases (i.e. cases that have not been investigated as part of an outbreak) because it is not possible to confirm whether the exposure to RDM caused the case’s illness.

34. For other pathogens such as *Campylobacter* or non-typhoidal *Salmonella*, the collection of this information is subject to local variation and, where information is collected, it is not gathered into a central enhanced surveillance database from which data can be collated.

35. While it would be possible to include enhanced surveillance data broken down by year, to compare data from before and after 2015, this approach has not been taken as this would be less robust than the aggregated data due to small numbers.

Table 4. RDM consumption reported to enhanced surveillance systems, (01/01/2015-20/12/2017).^a

Pathogen enhanced surveillance system	Cases reporting RDM exposure	% cases reporting RDM exposure	Country
STEC	19 ^b	1.48%	England
<i>Listeria monocytogenes</i>	13	2.43%	England

^aData provided by PHE, extracted from the National Enhanced Surveillance System for STEC (NESSS) and the *Listeria monocytogenes* enhanced surveillance system. Data captured systematically for RDM only and NOT products made from RDM.

^bExcludes STEC cases linked to outbreaks

Microbiological status of raw drinking milk and certain raw milk products: surveillance

36. Several surveys^{5,6,7,8,9,10,11,12} have been undertaken between 1995 and 2016 to investigate the microbiological status of RDM and raw cream, providing data on the presence and levels of pathogens and hygiene indicators in milk from cows and other species. These surveys are summarised in Table 5.

37. In the most recent survey Willis *et al.* reviewed the microbiological results for RDM samples collected in England and submitted to PHE laboratories between 2014 and 2016¹². The study focused mainly on cows' RDM (613 samples). Goats' RDM samples were also of relatively well represented (260 samples), but RDM from other species was underrepresented with very few samples (between 3 and 9 samples from ewes, buffaloes and camels). Most samples (n=770) were collected for the purposes of routine monitoring of microbiological quality. The remaining samples were taken to follow up previous poor results (n=114) or in response to a public health incident associated with consumption of RDM (n=18). The interpretation of results was done in accordance with EC Regulation 2073/2005¹³, Health Protection Agency's Guidelines for Assessing the Microbiological Safety of Ready-to-Eat Foods (2009)¹⁴ and the Food Safety and Hygiene Regulations, 2013¹⁵. Overall, 454/770 samples (59.0%) taken for routine monitoring were of a satisfactory quality, whilst eight (1.0%) were 'unsatisfactory and potentially injurious to health' due to the presence of shiga-toxin producing *E. coli* (STEC), *Campylobacter* spp. or elevated levels of *L. monocytogenes* or Coagulase-Positive Staphylococci (CPS). In contrast, 16/114 (14.0%) of samples taken in follow-up to a previous unsatisfactory result and 5/18 (27.8%) of samples related to illness were potentially injurious. A total of 229/902 samples (25.4%) gave unsatisfactory results due to elevated Aerobic Colony Counts and/or coliforms. *L. monocytogenes* was detected at levels of <100 cfu/ml in 66/902 samples (7.3%). Table 6 summarises the results by reason for sampling.

38. The findings are not necessarily directly comparable between the surveys and studies listed above, as in some cases the methods and sampling approach used varied. For example, the recent study by Willis *et al.*¹², included analysis for non-O157 STEC, whereas the surveys conducted before 2000 limited analysis for pathogenic *E. coli* to the serogroup of O157. Also, direct comparisons between the most recent data¹² and previous surveys^{5,6,7,8} are difficult without the full set of data, e.g. to discriminate by animal species.

39. To inform this risk assessment, PHE re-analysed the information used in Willis *et al.*¹² to draw out the data specifically relating to samples of RDM collected for the purposes of routine monitoring, and broke down the data by year and species (i.e. cows and goats). The outputs of this *ad hoc* reanalysis are presented in Table 7. Overall the percentage of cows' and goats' RDM samples taken for routine monitoring that were potentially hazardous was 0.9% in 2014, 0.7% in 2015 and 1.6% in 2016. This suggests that there may have been a small increase in the proportion of RDM samples with potentially hazardous results since this issue was considered by the Board in July 2015, although this is not statistically significant.

40. The re-analysed information showed that of the 8 potentially hazardous results described in Willis *et al.*¹², 7 were from cows' RDM and 1 from goats' RDM. Most of

the potentially hazardous results therefore related to RCDM, although it should be noted that the number of goats' RDM samples that were tested was much smaller and that surveillance data for other species is even more limited.

41. In total, 25.8% of the survey samples described in Willis *et al.*¹² that were taken for routine purposes were unsatisfactory (due to the levels of aerobic colony counts or coliforms). This high figure has remained relatively similar in the last few years (i.e. 28.8% in 2014, 24.7% in 2015 and 24.9% in 2016).

42. 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. Most of the surveys also determined levels of indicator *E. coli* and other indicator organisms in samples. These were present at varying levels in most samples, in some cases exceeding the limits set in legislation.

43. Work previously presented to the Advisory Committee on the Microbiological Safety of Food (ACMSF) on health risks to consumers associated with unpasteurised milk and unpasteurised cream for direct human consumption (ACM/1008)¹⁶ reviewed most of the surveys listed in Table 4^{5,6,7,8,9,11} and concluded that 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. However, according to Willis *et al.*¹², only 6.9% of the samples categorised as potentially injurious to health due to the presence of pathogens had unsatisfactory results for the Aerobic Colony Count and coliform tests. Moreover, for 75.9% of the samples contaminated with pathogens, the corresponding hygiene indicator tests gave satisfactory results. Thus, the review of recent RDM samples collected in England between 2014 and 2016 strongly suggests that microbiological parameters such as Aerobic Colony Counts and coliforms have poor predictive value for identifying food safety concerns in RDM¹². For this reason, the microbiological parameters of direct public health significance in the surveys/studies discussed in this paper should be a prominent consideration in assessing any changes in risk to consumer health from RDM and raw cream over time.

44. In terms of raw cream, data provided by PHE from an unpublished study is presented in Annex 1. A total of 86 samples of cream made from unpasteurised milk were collected from farms, farm shops and a farmers' market between April 2013 and January 2017 and tested by PHE. None of the samples had potentially hazardous results. However, 10% of the samples tested for indicator *E. coli* had unsatisfactory results, suggesting that hygiene issues had occurred. The samples which had unsatisfactory indicator *E. coli* results were taken in 2013-2015, whereas none of the samples taken from 2016 to 2018 were unsatisfactory (PHE, personal communication).

Table 5. Summary of microbiological results from surveys of raw drinking milk and raw cream between 1995 and 2016

Survey	Survey of raw cows' milk, 1995-96 n = 1591	Survey of raw cows' milk, 1996-97 n = 1097	Survey of raw cream, 1997 n = 30	Survey of raw goats' & sheep's milk, 1997-98 n = 111	Survey of raw goats' & sheep's milk, 1998 n = 126	Survey of raw goats', sheep's & buffaloes' milk, 1997-99 n = 384	Survey of raw cows' milk intended for heat treatment, 1999-2000 n = 610	Survey of raw cows', goats', sheep's, buffaloes' & camels' milk, 2014-16 n = 902
Reference	5	6	7	8	9	10	11	12
<i>Campylobacter</i> spp.	0	2 (19)	-	0	0	0.5 (2)	0.8 (5)	0.3 (3)
<i>E. coli</i> O157	0	0.3 (3)	0	0	0	0.5 (2)	0.2 (1)	1.4 (13) incl. non-O157 STEC
<i>Salmonella</i> spp.	0.06 (1)	0.5 (5)	-	0	0	0	0.3 (2)	0.9 (8)
<i>Listeria monocytogenes</i>	2 (32)	-	-	-	0	3 (11)	17 (101)	7.5 (68) Detection by enrichment 0.2 (2) >100 cfu/ml
<i>Listeria</i> spp.	6 (91) Detection by enrichment	-	-	-	0	-	37 (223)	4.9 (44) Detection by enrichment, <100 cfu/ml
<i>S. aureus</i> >10cfu/ml	6 (89)	1 (12) >500 cfu/ml	-	8 (9)	19 (24) >20 cfu/ml 1.6 (2) >10,000 cfu/ml	8 (29)	19 (113) CPS	22.7 (205) CPS >20 cfu/ml 0.3 (3) CPS >10,000 cfu/ml

Survey	Survey of raw cows' milk, 1995-96 n = 1591	Survey of raw cows' milk, 1996-97 n = 1097	Survey of raw cream, 1997 n = 30	Survey of raw goats' & sheep's milk, 1997-98 n = 111	Survey of raw goats' & sheep's milk, 1998 n = 126	Survey of raw goats', sheep's & buffaloes' milk, 1997-99 n = 384	Survey of raw cows' milk intended for heat treatment, 1999-2000 n = 610	Survey of raw cows', goats', sheep's, buffaloes' & camels' milk, 2014-16 n = 902
Reference	5	6	7	8	9	10	11	12
<i>E. coli</i> >10cfu/ml	24 (386)	3 (27) >100 cfu/ml	23 (7)	6 (7)	25 (31) >3 cfu/ml, <100 cfu/ml	17 (65)	52 (316)	-
Coliforms ≥ 100 cfu/ml	25 (390)	-	-	32 (36)	12 (15)	25 (95)	56 (343)	18.2 (164)
Total Viable Counts > 20,000 cfu/ml	16 (255)	4 (39) >50,000 cfu/ml	-	37(41) >10,000 cfu/ml	44 (56) >10,000 cfu/ml	23 (89) >10,000 cfu/ml	56 (344) >10,000 cfu/ml	19.3 (174)
<i>Mycobacterium avium</i> subspecies <i>paratuberculosis</i>	-	-	-	-	-	0	1.6 (4/243)	-

Table adapted from ACM/1008¹⁶. CPS; coagulase positive staphylococci, STEC; shiga-toxin producing *E. coli*.

Table 6. Overall microbiological quality of raw drinking milk samples taken in England between January 2014 and December 2016 (Willis *et al.*, 2017) compared to the reason for sampling.

Reason for sampling	Number of samples	No. (%) satisfactory (including <i>Listeria monocytogenes</i> <100 cfu/g)	No. (%) borderline	No. (%) unsatisfactory (relates to ACCs & coliforms)	No. (%) unacceptable/potentially injurious (relates to <i>Listeria monocytogenes</i> > 100 cfu/g, CPS > 10,000 cfu/g or detection of <i>Salmonella</i> , STEC or <i>Campylobacter</i>)
Routine	770	454 (59.0)	109 (14.2)	199 (25.8)	8 (1.0)
Follow-up of recent failure	114	40 (35.1)	29 (25.4)	29 (25.4)	16 (14.0)
Investigation of illness	18	11 (61.1)	1 (5.6)	1 (5.6)	5 (27.8)
Total	902	505 (56.0)	139 (15.4)	229 (25.4)	29 (3.2)

Table adopted from Willis *et al.*, 2017¹². CPS; coagulase positive staphylococci, STEC; shiga-toxin producing *E. coli*. The interpretation of results was done in accordance with EC Regulation 2073/2005¹³, Health Protection Agency's Guidelines for Assessing the Microbiological Safety of Ready-to-Eat Foods (2009)¹⁴ and the Food Safety and Hygiene Regulations (2013)¹⁵.

Table 7: Results of Microbiological Examination of Raw Drinking Milk Collected for Routine Monitoring Purposes Between 2014 and 2016 (data provided by PHE)

To inform this risk assessment, PHE re-analysed the information used in Willis *et al.*¹² to draw out data specifically relating to samples of RDM collected for the purposes of routine monitoring, and broke down the data by year and species (i.e. cows and goats).

Year	Species	Satisfactory	Borderline	Unsatisfactory	Potentially hazardous	<i>Listeria monocytogenes</i> detected in 25g	<i>Listeria</i> spp. detected in 25g
2014	Cow (n=144)	58 (40.3)	23 (16.0)	51 (35.4)	2 (1.4) Both <i>Campylobacter</i>	5 (3.5)	5 (3.5)
	Goat (n=72)	50 (69.4)	8 (11.1)	13 (18.1)	0	0	1 (1.4)
	Other (n=6)	4 (66.7)	2 (33.3)	0	0	0	0
	Total (n=222)	112 (50.4)	33 (14.9)	64 (28.8)	2 (0.9)	5 (2.3)	6 (2.7)
2015	Cow (n=184)	80 (43.5)	38 (20.7)	48 (26.1)	2 (1.1) Both STEC	12 (6.5)	7 (5.2)
	Goat (n=93)	63 (67.7)	9 (6.1)	20 (21.5)	0	1 (1.1)	0
	Other (n=5)	3 (60.0)	0	1 (20.0)	0	1 (20.0)	0
	Not known (n=13)	9 (69.2)	0	4 (30.8)	0	0	0
	Total (n=295)	155 (52.5)	47 (15.9)	73 (24.7)	2 (0.7)	14 (4.7)	7 (2.4)
2016	Cow (n=176)	97 (55.1)	19 (10.8)	40 (22.7)	3 (1.7) 1: >10 ⁴ CPS 2: >10 ² Lm	14 (8.0)	3 (1.7)
	Goat (n=77)	44 (57.1)	10 (13.0)	22 (28.6)	1 (1.3) >10 ⁴ CPS	0	0
	Other (n=0)	0	0	0	0	0	0
	Total (n=253)	141 (55.7)	29 (11.5)	63 (24.9)	4 (1.6)	14 (5.5)	3 (1.2)

STEC = Shiga toxin producing *E. coli*

Lm = *Listeria monocytogenes*

CPS = Coagulase-positive staphylococci

45. Several surveys have been undertaken between 1995 and 2017 to investigate the microbiological profile (including pathogens and hygiene indicators) of RDM and raw cream. However, their findings are not necessarily directly comparable due to differences in methodology, animal species covered and sampling approach (e.g. routine surveillance vs investigation of potentially associated cases of illness). Overall, these surveys have not identified any correlations between pathogens and hygiene indicators, while the recent surveys strongly suggest that microbiological parameters, such as ACCs and coliforms, have poor predictive value in identifying food safety concerns in RDM.

46. In addition, several microbiological surveys undertaken between 1995 and 2017 on RDM and cream did not find any correlations between hygiene indicator results for RDM and the likelihood of pathogens being present. The recent surveys strongly suggest that hygiene indicators such as aerobic colony counts have poor predictive value in identifying food safety concerns in RDM.

Statutory monitoring of raw cows' drinking milk

47. In England and Wales, RCDM for direct human consumption is sampled and tested quarterly by the Agency to monitor compliance with microbiological criteria set out in the Food Safety and Hygiene (England) Regulations 2013 (as amended) and the equivalent regulations in Wales and Northern Ireland. Schedule 6 of the Food Safety and Hygiene (England) Regulations 2013 (as amended) requires the Agency to test RCDM but does not specify the frequency. Local authorities are required to test non-cows' milk against Schedule 6, although it is for each Local Authority to decide how frequently this occurs.

48. Raw drinking milk must meet the following criteria:

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

49. Enforcement action is taken if a sample fails the criteria. Further details on the sampling programme are given in Annexes 2 and 3.

50. The monitoring data provides an indication of the quality of RCDM. The results of the statutory monitoring programme from 2012 to 2017 for England and Wales are summarised in Table 8. Reported failures are samples that exceeded either the plate count or coliform criteria or both.

Table 8. Results of the raw cows' drinking milk sampling programme in England and Wales from 2012 to 2017

Year	Total number of samples ^a	Number of passes ^b	Pass rate (%)	Number of failures ^c	Failure rate (%)	Number of farms with repeat failures ^d	% farms with repeat failures
2012	189	154	81.5	35	18.5	8	10.5
2013	302	257	85.1	45	14.9	6	7.0
2014	331	262	79.2	69	20.9	17	20.0
2015	365	275	75.3	90	24.7	18	17.8
2016	522	396	75.9	126	24.1	31	21.1
2017	597	491	82.2	106	17.8	26	14.5

^aOne sample was taken per farm on a quarterly basis and tested for both plate counts and coliforms (i.e. 4 samples per farm per year).

^bIf both the plate count and coliform results for a sample were within acceptable limits, the sample was recorded as a pass.

^cIf either the plate count or coliforms exceeded acceptable limits, the sample was recorded as a failed sample.

^dThe number of farms with repeat failures is the number of RCDM producers who had more than one failed sample within that calendar year. As such there may be repeat failures which cross between two calendar years and these will not be counted. It is therefore possible that the approach taken here may underestimate repeat failures, although this approach has been taken to provide a comparison between calendar years.

51. The sample failure rate from 2012 to 2017 varied from 14.9 – 24.7%. The highest failure rates were in 2015 and 2016, during which almost a quarter of samples failed. There was a slight improvement in 2017, when the failure rate reduced to 17.8%. The average failure rate during this period was 20.15%.

52. In Table 8, 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 2017 72% of the failures were caused by one fifth of the Food Business Operators (FBOs).

53. In general, since 2012 there has been a general trend for the percentage of farms with repeat failures to have increased. The highest percentage of farms with repeat failures was in 2016 (i.e. 21.1%) although this decreased in 2017 (i.e. to 14.5%).

54. It is important to note that the results of tests for hygiene indicators are not considered to correlate with the likelihood of pathogens being present and cannot therefore be used as a direct measure of risk. However, the data presented in this paper suggest that there has been an increase in hygiene issues associated with raw cows' drinking milk in England and Wales over time since 2012, although there was a slight improvement in 2017.

Schedule 6 test results and DHI compliance ratings prior to outbreaks

55. Table 9 shows the findings of Schedule 6 test results and Dairy Hygiene Inspection compliance ratings in the period leading up to the outbreaks described in Table 1.

Table 9. Schedule 6 test results and Dairy Hygiene Inspection compliance ratings prior to outbreaks associated with RDM in England, Wales and Northern Ireland (01/01/2014 to 20/12/2017).

Farm	Start date ⁺	Issues identified by Schedule 6 testing identify in the 6 months before the outbreak	Dairy hygiene inspection compliance ratings [*] before the outbreak
A	September 2014	None	Compliance ratings were not used at this time (i.e. introduced after September 2014) and so a rating is not available. However, hygiene issues in and around the dairy/milk storage room were identified and reflected in enforcement. Inspections on 15/07/14 and 15/09/14 both had verbal enforcement entries.
B	12/12/16	Failed for both total viable counts at 30°C and coliforms on 27/6/16, 3/8/16, 9/8/16, 17/8/16, 24/8/16 and 21/9/16.	Rating on 3/8/16 = generally satisfactory Rating on 28/9/16 = good
C	26/09/17	None	All ratings from 23/05/13 to 06/06/17 = good
D	27/06/17	1 failure (10/03/17). Follow up sample on 31/03/17 passed.	All ratings from October 2016 to time of outbreak (including visit on 21/3/17) = good
E	26/06/17	None	10/05/16. Improvement necessary 15/06/16. Good 29/06/17. Good
F	08/08/17	None	All visits before outbreak = good 08/06/17. Good 02/08/17. Good
G	05/07/17	None	All visits before outbreak = good

The farms and outbreaks referred to in this table are those described in Table 1. Please note the single reported case of illness associated with Farm G is not regarded as an outbreak but is included in Table 9 as further evidence of RDM-associated illness in relation to Schedule 6 test results and DHI compliance ratings.

⁺Start date = date on which outbreak/incident reported to FSA Field Operations team

^{*}Descriptions of the other ratings are available at:

<https://www.food.gov.uk/science/raw-drinking-milk-and-cream>

56. For most of these outbreaks (i.e. 5/7), the results of Schedule 6 testing did not identify any issues in the 6-month period before the outbreak was reported to the FSA Field Operations team. One outbreak (involving farm B) involved repeated failures for both total viable counts at 30°C and coliforms prior to the outbreak. For the outbreak involving farm D, a schedule 6 failure occurred 3 months before the outbreak start date, although subsequent results were satisfactory. This suggests that the results of Schedule 6 testing are not a good measure of the safety of RDM, and is understandable because the prevalence and levels of hygiene indicator organisms is generally not regarded to correlate well with the likelihood of pathogens being present. This is supported by the findings from the surveys of RDM (see paragraphs 45 and 46).

57. At the conclusion of an inspection, the Dairy Hygiene Inspector will apply one of four compliance ratings to the farm (good, generally satisfactory, improvement necessary, urgent improvement necessary). The DHI will utilize information from previous inspections and their professional judgement of: 1) hygiene conditions on farm, 2) public health risk from any non-compliance identified, 3) history of compliance, and 4) confidence in management controls.

58. All of the farms involved in the outbreaks after the DHI compliance rating scheme was introduced had good hygiene ratings, including in the 6-month period before the outbreaks were reported to FSA Field Operations team. This suggests that the compliance ratings are also not a good indicator of the safety of RDM.

Microbiological testing by RCDM producers

59. To determine the number of RCDM producers that arrange for samples of their milk to be tested on their behalf, a Dairy Hygiene Inspector contacted registered producers in England and Wales in January 2018. Information was obtained on whether testing is carried out and which microbiological parameters it covers.

60. Out of 92 producers selling RCDM at the time who responded, 32 indicated that they arranged for samples of their milk to be tested whereas 60 indicated that they did not. Of the 32 positive respondents, 4 producers only tested for indicator organisms (i.e. total viable counts and coliforms) whereas 28 tested for pathogens (these included 26 testing for *Listeria*, 28 for *E. coli*, 27 for *Salmonella*, 3 for Staphylococci and 3 for *Campylobacter*). The frequency of sampling ranged from weekly to once every 16 weeks. The majority of producers indicated that if results failed they would stop production. Only one said they would not stop, although their testing related to indicator organisms and not pathogens. Further details are presented in Annex 4. It is noted that the results of RCDM producer's own testing was not gathered as part of this exercise and it is not possible to assess whether the amount or type of testing or the results have changed since July 2015.

Number of registered producers

61. The number of registered RDM producers (all species) in the UK increased between April 2014 and January 2018. In April 2014 there were 108 RDM producers

(i.e. 107 in England/Wales and 1 in Northern Ireland). In January 2018 there were 168 RDM producers (i.e. 151 in England, 11 in Wales and 6 in Northern Ireland).

62. In January 2018, the majority (i.e. 90%) of RDM producers in the UK were in England with much smaller proportions in in Wales (i.e. 6.5%) and in Northern Ireland (i.e. 3.5%).

63. In the UK, RDM is mainly produced by cows. In January 2018, 139 establishments were registered to produce raw drinking milk from cows, 27 from goats, 3 from sheep and 2 from buffalo.

64. Table 10 shows the number of producers registered to produce RDM from different species in the UK, in April 2014 compared with January 2018. Please note that three of these producers had 2 species on their premises, hence the total figure relating to species (i.e. 171) is greater than the number of producers (i.e. 168).

Table 10. Number of producers registered to produce raw drinking milk from different species in the UK (in April 2014 compared with January 2018^{*B})

Species	England and Wales (April 2014)	Northern Ireland (April 2014)	England (January 2018) ^{*B}	Wales (January 2018) ^{*B}	Northern Ireland (January 2018) ^{*B}	UK total (April 2014)	UK total (January 2018) ^{*B}
Cows	^{*A}	1	126	8	5	^{*A}	139
Goats	^{*A}	0	22	4	1	^{*A}	27
Sheep	^{*A}	0	3	0	0	^{*A}	3
Buffalo	^{*A}	0	2	0	0	^{*A}	2
All species	107	1	153	12	6	108	171

^{*A} It is not possible to break down April 2014 data separately for England and Wales or by species.

^{*B} Data from the end of January 2018 listed a total of 168 registered RDM producers in the UK (i.e. 151 in England, 11 in Wales and 6 in Northern Ireland). Three of these producers had 2 species on their premises, hence the total figure relating to species (i.e. 171) is greater than the number of producers (i.e. 168).

65. Figure 1 shows the number of registered RDM producers (all species) in England and Wales (April 2014 to March 2017).

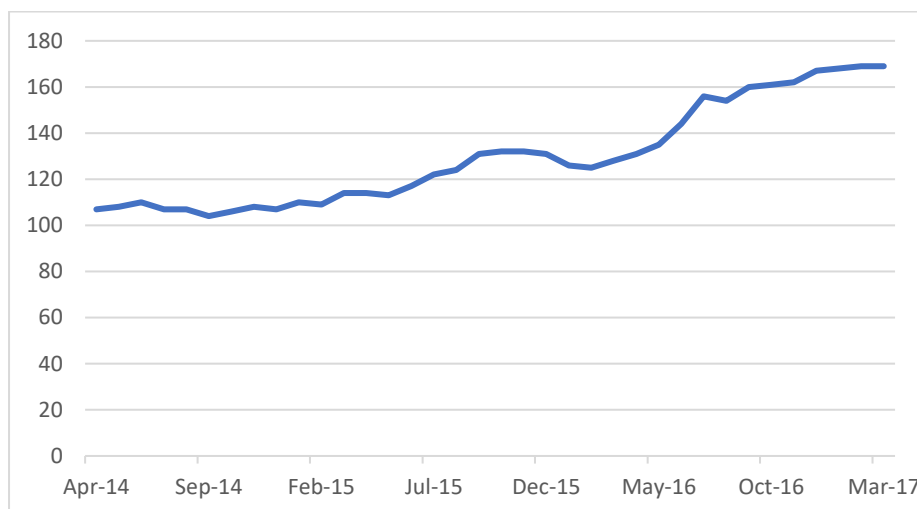


Figure 1. Number of registered raw drinking milk producers (all species) in England and Wales (April 2014 to March 2017).

66. Data on the number of registered producers has only been collected by the FSA Field Operations team from April 2014 onwards and a data gap exists from April to November 2017, making it difficult to assess trends over time and how this correlates with other factors such as the number of outbreaks in more detail.

67. However, historically the number of registered raw cows' drinking milk producers in England and Wales fell from around 570 in 1997 to around 100 in 2010¹⁶ and by 2018 had increase to 134.

68. In any given year, some businesses register while others cease production. The number of new RDM registrations in England and Wales per year from 2013 to 2017 is shown in Table 11. The majority (80 - 90%) of the registrations for RDM relates to cows' milk. 'Current producers' refers to FBOs who were already selling pasteurised milk. The increased number of registrations from 2015 is mainly due to current producers adding RDM to their activities (i.e. rather than request by new producers). In particular, there was increasing awareness of RDM, including a number of features on national television in 2015 and 2016. The number of applications subsequently decreased in 2017.

Table 11: Number of new RDM registrations in England and Wales (current and new producers)

	2013	2014	2015	2016	2017
Total for all species	16	16	32	60	38

69. There is little evidence that milkshakes, smoothies and ice-cream made using raw milk have been on sale in the UK, other than the milkshakes sold by the food business operator involved in the *Campylobacter* outbreak in Wales in 2017 and another

company based in Wales. However, data is not collected on the number of farmers registered to make these products in the UK. A general search on the internet and of the Mintel database for these products in the UK did not yield useful results.

Volume of production

70. According to economic analysis conducted by FSA, the total volume of production of raw drinking milk in the UK increased by 5-fold from an estimated 610,000 litres in 2012 to around 3.2 million litres in 2017 (Figure 2). A small proportion of this relates to Northern Ireland, where average production is currently 1,200 litres per week.

71. The economic analysis also indicated that:

- Around 9% of RDM-producing dairies only produce RDM
- The current inspection estimates of 3.2m litres of RDM in 2017 representing around 0.05% of the 6,811m litres/year total milk utilisation in 2016
- The average volume of RDM produced per dairy is 23,150 litres per year

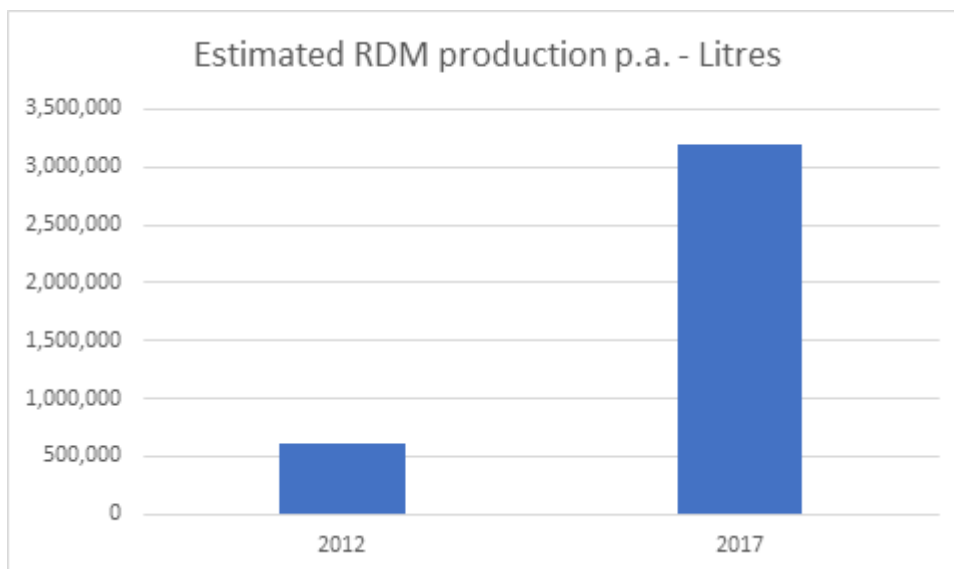


Figure 2. Estimated RDM production in the UK per year during 2012 and 2017 (in litres). Reproduced from economic analysis conducted by FSA.

72. Information on volume of production has only been gathered by FSA Field Operations routinely since mid-2017. It is therefore not possible to analyse trends over time or how this correlates with other factors such as the number of outbreaks in more detail.

73. There is little robust information on the nature and volume of unpasteurised milkshakes, smoothies and ice-cream made using raw milk available on the UK market, or how this may have changed over time. There is currently no system in place

to collate this information in a comprehensive and consistent manner. Instead, the available information is mainly based on anecdotal evidence of such products being seen at producers' premises and described on their social media sites.

Sales routes

74. The proportion of sales completed through different sales routes was assessed in economic analysis conducted by FSA as part of the current work on RDM. The findings are reproduced in Figure 3. These charts provide an illustrative comparison; however, the 2012 data comes from a producer survey questionnaire as part of a consultation document¹⁷ and the 2017 data was taken from producer inspection responses.

75. According to the economic analysis, vending machines serving RDM on farm sites have given producers a new route to access their consumer base. Initial suggestions are that there are 18 vending machines currently in operation in the UK. These vending machines produce sales representing around 17% of total RDM sales, showing that it has become a significant avenue for distribution. In 2012 an estimated 4% of sales of RDM were done through vending machines, evidencing the expansion of this sector of the market¹⁷.

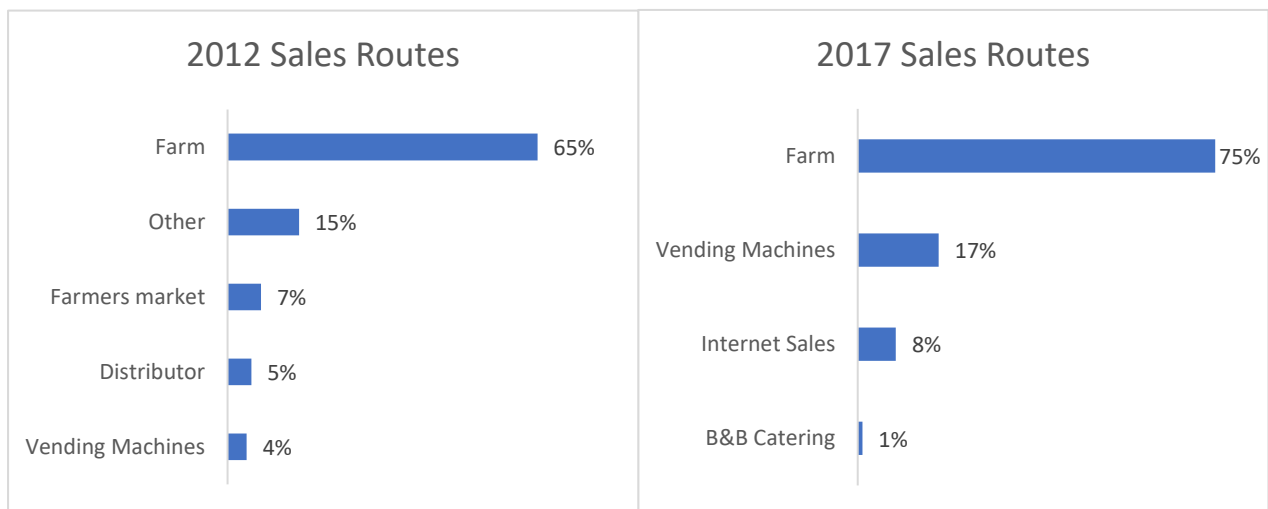


Figure 3. RDM sales routes in the UK in 2012 and 2017. Reproduced from economic analysis conducted by FSA.

76. In two of the outbreaks described in Table 1 (i.e. those associated with farms B and D) the RDM was known to have been sold using vending machines as well as through farm gate sales. It was established that a vending machine used to dispense RDM at farm D was unsuitable for this purpose.

Consumption of raw drinking milk and certain raw milk products

NDNS consumption data

77. The National Diet and Nutrition Survey (NDNS)¹⁸ does not include data on consumption of raw milk or raw milk products. However, consumption data from this dataset for milkshakes, ice cream and smoothies (pasteurisation status unknown but most/all assumed to be pasteurised) may provide a proxy indication of whether a higher proportion of children than adults would consume the raw milk version of these products (see Annex 5). Age stratification was used because consumption by vulnerable groups such as children under five is an area of concern. The data were collected over a six-year period between 2008 and 2014.

78. For ice-cream and milkshakes, a higher proportion of children compared to adults (aged 19 years and over) consumed these products. This was seen for both age groups of children; those under five years old, and those aged five to eighteen, though consumption was higher in the latter group.

79. There were no data for 'smoothies containing milk', only for 'smoothies containing dairy products' (dairy products in this category are presumed to be yoghurt). Children aged 5-8 years consumed the greatest proportion (0.2%) of 'smoothies containing dairy products' compared with adults aged 19+ (0.17 %) and children < 5 years (0.04%). However, the numbers of consumers who reported consuming smoothies made with dairy products is small (n= 6, n=4 and n= 1 respectively) and so the extent to which meaningful conclusions can be drawn is limited.

80. Overall, it may be possible to extrapolate this data to suggest that children may be more likely than adults to consume raw milk ice-cream, milkshakes and smoothies than adults, if these products are placed on the market. However, other factors may also be important such as whether the products are packaged and marketed in a way that is attractive to children.

Consumer Research

81. Following the extensive consumer work carried out as part of the 2012-2015 review, in 2018 the FSA repeated an online consumer survey¹⁹ to determine whether there have been changes to consumer perception of RDM since the last review. The survey was conducted with a nationally representative sample of adults across England, Northern Ireland and Wales to see how and if attitudes and behaviour have changed since 2012. In order to match the 2012 research design, only consumers who regularly bought milk or cream were included in the survey. The 2012 research indicated that this represented 94% of the population.

82. Key finding from the survey of relevance to this assessment are:

- The proportion of the population currently consuming RDM has increased from 3% of the population in 2012, to 10% of the population in 2018.

- The proportion of consumers who have ever tasted or bought RDM has remained similar to 2012 with almost a third (32%) of all consumers ever having done so.
- In total, 11% of the sample reported that a child or children under 18 consumes RDM products. This comprised 8% who reported a child in their own household does so and 3% who reported that a child not in their household is a consumer of RDM products (i.e. if their children do not live with them).
- For 'other raw milk products' (e.g. milkshakes, smoothies or ice cream) in 2018, 14% of the sample reported having tasted them and 12% reported having bought them. Data for 2012 are not available to be able to assess whether this has changed.
- Current consumers are likely to have started consuming quite recently - almost three quarters (72%) of current consumers of RDM only started consuming in the last year, with a quarter (26%) drinking or buying it for less than three months. A smaller proportion (15%), are longer term consumers who have been doing so for over two years.
- The majority of current RDM consumers buy or drink it on a regular basis – almost one third (32%) do so daily, and a similar proportion (37%) do so weekly. Comparing these findings to those from 2012 shows a shift to more frequent consumption amongst consumers of RDM. In 2012 a higher proportion of current consumers of RDM were consuming monthly or less (42%) compared to in 2018 (30%).
- Current consumers also report that they are consuming more RDM than they did 12 months ago (however, information on the actual amounts consumed was not captured in the survey).
- Levels of interest in future consumption of raw milk or cream are broadly consistent with the findings from 2012 with a small upward shift in the per cent of those interested or very interested from 19% in 2012, to 24% in 2018.
- Levels of interest in future consumption of other raw milk products were recorded, with 28% of the 2018 respondents saying they would be interested in raw milk ice-creams, 23% in raw milk milkshakes and 20% in raw milk smoothies. Data from 2012 are not available.
- Those aged 25-44 years are the most likely age group to have bought RDM.
- Men are more likely than women to have tried or bought RDM.
- The main reason for consumption is the belief that RDM has a higher nutritional content than conventional milk.
- Health concerns around the safety of consuming RDM is the main reason for choosing not to consume it.

The impact of the addition of sugar to RDM used as an ingredient in unpasteurised products such as milkshakes, smoothies and ice-cream

82. This part of the assessment considers whether the addition of sugar to unpasteurised products made using RDM (e.g. ice-cream, milkshakes and smoothies) could affect the microbiological risk (in particular by enabling growth to occur to higher levels).

84. *Campylobacter* was involved in a high proportion of the recent outbreaks associated with RDM, including the outbreak in Wales in which RDM was used as an ingredient in milkshakes (see Table 1). The minimum temperature at which this pathogen can grow is 30°C and so it is unlikely that any growth would occur in RDM regardless of the addition of sugar.

85. In theory, the addition of sugar to RDM could potentially allow other pathogens (e.g. STEC and *Salmonella*) to grow to higher levels in chilled products such as milkshakes and smoothies by providing an energy source to support metabolism. However, the minimum temperature at which STEC and *Salmonella* are reported to grow is 7°C²⁰. In England, Wales and Northern Ireland, food that is likely to support the growth of pathogenic micro-organisms or the formation of toxins must be kept by food business operators at a temperature of 8°C or below²¹. Growth of these pathogens could therefore only occur if the product is stored at the upper limit of this temperature range or if the product is temperature abused.

86. The extent to which the effect of adding sugar could affect growth would also depend on the amount of sugar added, although there is likely to be more than sufficient lactose in RDM to support growth. Conversely, very high sugar levels could reduce the potential for growth by reducing the water activity. The extent to which these pathogens could grow will also depend on temperature and time, and so the potential for growth would be limited if products such as milkshakes are chilled and sold for immediate consumption.

87. If pathogens grow to higher levels there would be greater exposure associated with a particular serving. However, the presence of pathogens such as *Salmonella*, *Campylobacter* and STEC at any level in a ready-to-eat food could potentially cause illness, especially in a high-fat product such as RDM as fat can protect bacteria as they pass through the gastric acid and potentially result in a lower infectious dose. It is therefore important to note that the presence of these pathogens at any level in RDM, or products such as milkshakes and ice cream made using it, would present a potential risk to health.

88. Pathogens are unable to grow at the low temperatures found in ice-cream during frozen storage. Although the temperature of ice-cream will increase after removal from the freezer for serving, the limited time until consumption is unlikely to allow pathogens to grow significantly.

89. It is therefore unlikely that the addition of sugar to unpasteurised products made using RDM will have a significant effect on the growth of pathogens and also unlikely that microbiological risk will be significantly affected.

90. This paper has drawn together a substantial amount of information to inform an assessment of the risk associated with raw drinking milk particularly since 2015. It has considered outbreaks of illness involving raw drinking milk, the pathogens involved and consumers affected and examined data on the microbiological status from surveys and routine testing of raw drinking milk. It has also looked at certain raw milk products (cream, ice-cream, smoothies and milk shakes), the changes in raw drinking milk production and sales routes and how consumer attitudes and behaviours have changed since 2012.

Conclusions

91. For the key questions covered by this risk assessment, the following conclusions can be made:

1) Has the risk associated with consumption of RDM (and certain unpasteurised products made using raw milk) made in the UK changed since 2015?

92. Based on the qualitative microbiological risk assessment classification scheme described in Annex 6, the risk for the subpopulation that consume RDM is currently considered to be **medium** (occurs regularly) **with medium uncertainty**. In terms of severity of illness, the outbreaks described in Table 1 that occurred since July 2015 involved 4 reported hospitalisations. In IID outbreaks involving RDM from 1992-2017, the proportion of those affected who were hospitalised (11.9%) was higher than for those in all foodborne IID outbreaks (3.7%). No deaths were reported from outbreaks in England and Wales associated with RDM or cream from 1992-2017.

93. The microbiological risk associated with consumption of raw drinking milk in the UK has increased since this issue was last considered by the Board in July 2015.

94. The increased risk reflects greater levels of exposure due to increases in the number of registered producers and volume of production and consumption, alongside an increase in the number of outbreaks of human illness associated with RDM, as follows:

- The number of registered RDM producers (all species) in the UK increased between April 2014 and January 2018. In April 2014 there were 108 RDM producers (i.e. 107 in England/Wales and 1 in Northern Ireland). In January 2018 there were 168 RDM producers (i.e. 151 in England, 11 in Wales and 6 in Northern Ireland).
- There has been a 5-fold increase in the volume of RDM production in the UK from around 610,000 litres in 2012 to 3.2 million litres in 2017.
- The recent consumer research¹⁹ indicates that the proportion of the population currently consuming RDM has increased (from 3% of the population in 2012 to 10% of the population in 2018), with current RDM consumers reporting that they consume RDM more frequently and in greater amounts in 2018 than in 2012.

- The survey Willis *et al.*¹² assessed microbiological results for RDM samples that were collected in England and submitted to PHE laboratories between 2014 and 2016. The study focused mainly on cows' RDM. Goats' RDM samples were also relatively well represented. PHE carried out an *ad hoc* analysis of results of the routine monitoring data from this survey specifically to inform this risk assessment. The percentage of raw cows' and goats' drinking milk samples taken for routine monitoring purposes that were potentially hazardous was 0.9% in 2014, 0.7% in 2015 and 1.6% in 2016. This suggests that there may have been a small increase in the proportion of RDM samples with potentially hazardous results since this issue was considered by the Board in July 2015, although this is not statistically significant.
- Overall, approximately 1% of RDM samples had potentially hazardous results due to the presence of STEC, *Campylobacter* spp. or due to elevated levels of *L. monocytogenes* or coagulase-positive Staphylococci. Most of the potentially hazardous results related to RDM produced by cows, although surveillance data for other species is more limited.
- In total, 25.8% of the survey samples described in Willis *et al.*¹² that were taken for routine purposes had unsatisfactory levels of hygiene indicator organisms (i.e. aerobic colony counts or coliforms). This high figure has remained broadly similar in the last few years (i.e. 28.8% in 2014, 24.7% in 2015 and 24.9% in 2016).
- In terms of raw cream, a total of 86 samples of cream made from unpasteurised milk were collected from farms, farm shops and a farmers' market between April 2013 and January 2017 and tested by PHE. None of the samples had potentially hazardous results. However, 10% of the samples tested for indicator *E. coli* had unsatisfactory results, suggesting that hygiene issues had occurred.
- Since this issue was last considered by the Board in July 2015 (and until the end of December 2017), 5 outbreaks involving human illness linked to consumption of RCDM were reported in the UK. In these outbreaks there were a total of 103 reported cases, of which 40 were laboratory confirmed. In addition, in 2017 a case of salmonellosis was linked to consumption of RCDM from a farm in England through descriptive epidemiological and microbiological evidence.
- In 2014, there was a single outbreak. Prior to that, the last UK outbreaks associated with RDM occurred in England & Wales in 2002. The most recent outbreak associated with raw milk in Scotland was in 1999. In Northern Ireland only 2 outbreaks linked to raw milk have been reported, both in 1991.
- Whereas the number of reported IID outbreaks in England and Wales associated with food (of any type) has gradually decreased since 1992, the proportion associated with RDM has increased in recent years. Provisional data indicate that in 2017 up to 14.8% of all foodborne IID outbreaks in England and Wales were associated with RDM (although when the data set has been finalised this percentage is likely to be lower). In 2016, this figure was 2.3%. Overall, 0.0-2.4% of reported foodborne IID outbreaks in England and Wales

from 1992 to 2015 were associated with RDM and raw cream (i.e. an average of 0.51% of the outbreaks during this period - although noting that the 2016 and 2017 data are not directly comparable to previous years and the 2017 data is provisional).

- When specifically considering RDM associated outbreaks, the available evidence for 2015 – 2017 indicates that the implementation of routine WGS has not contributed to increased outbreak detection, although it may have contributed to increased case ascertainment. It should also be noted that the number of RDM associated outbreaks reported annually and number of cases linked to and investigated during outbreak investigations do not accurately portray the true burden of disease because this data only represents a very small proportion of overall gastrointestinal illness burden.
- There is therefore increasing evidence of human outbreaks associated with consumption of RDM since this issue was considered by the Board in July 2015.
- It should also be noted that the number of RDM associated outbreaks reported annually and number of cases linked to and investigated during outbreak investigations do not accurately portray the true burden of disease because this data only represents a very small proportion of overall gastrointestinal illness burden.
- In terms of severity of illness, there were 4 reported hospitalisations associated with the outbreaks described in Table 1 that occurred since July 2015. In IID outbreaks involving RDM from 1992-2017 the proportion of those affected who were hospitalised (11.9%) was higher than for those in all foodborne IID outbreaks (3.7%). Data from England and Wales show that no deaths have been reported from IID outbreaks associated with RDM or cream from 1992-2017.

95. A quantitative assessment to measure the risk associated with consumption of RDM and the extent to which this has changed could not be undertaken due limited data and time.

96. Other than a single outbreak involving both RDM and milkshakes made using RDM (associated with farm F in Table 1), there is little direct evidence that unpasteurised products made using RDM (i.e. milkshakes, smoothies and ice cream) have caused illness in the UK. There is high uncertainty about the nature and amount of these products on the UK market, and how this may have changed over time, as the available information is limited. There is currently no system in place to gather this information in a comprehensive and consistent manner. Instead, the available information is mainly based on anecdotal evidence of such products being seen at producers' premises and described on their social media sites. However, the consumer research data gathered in 2018 suggests that around 12% of the population have bought them¹⁹ (although comparable data from an earlier time point is not available to be able to assess whether this has changed). These products are unlikely to receive a processing step that would reduce the risk associated with consumption of the RDM ingredient. Therefore, the current risk for the subpopulation that consume

these products is considered **medium** (occurs regularly) with a **high level of uncertainty**.

97. In terms of the population which does not consume RDM or unpasteurised milkshakes, smoothies and ice-cream made with RDM the risk is considered to be negligible (i.e. so rare that it does not merit to be considered) with low uncertainty.

2) Do newly registered RDM producers in the UK present a greater likelihood of producing unsafe product than more established producers?

98. There does not appear to be a correlation between the amount of trading time (i.e. the period between the FBO being registered to sell RDM and the date on which the outbreak was reported to FSA Field Operations) and involvement in outbreaks.

99. Since 2015, the farms associated with the greatest number of confirmed cases, and with the greatest number of reported hospitalisations, had been trading for more than 24 months before the outbreaks occurred.

3) Has there been a change in the profile of vulnerable groups becoming ill?

100. Most of the outbreaks in 2016 and 2017 (i.e. 4/5), and the single reported salmonellosis case in 2017, involved children. The outbreaks associated with farms C and E, and the single salmonellosis case involved cases aged under 5 years. The outbreaks associated with farms B, C and F involved children aged 5 years and over. Out of the 103 total cases reported to have been involved in outbreaks associated with consumption of RDM since July 2015, and the single salmonellosis case, 16 were children (of which at least 3 were less than 5 years old).

101. Data on the number of children involved in outbreaks associated with RDM before this issue was considered by the Board in July 2015 is more limited. However, the outbreak in 2014 involved a total of 9 cases, of which 7 were children. Of the outbreaks/incidents associated with RDM in England and Wales prior to 2014, limited information on the number and ages of children is available for five outbreaks of STEC O157. One outbreak in 1993 affected four children; one outbreak in 1996 affected six children; one outbreak in 1998 affected three children (aged 1-7 years) and; one outbreak in 2000 affected a child aged less than 5 years. It therefore appears that children were involved in outbreaks associated with consumption of RDM both before and after this issue was considered by the Board in July 2015.

102. Data on other vulnerable groups associated with outbreaks is not routinely collected. Conclusions cannot therefore be drawn on whether the involvement of these groups in outbreaks associated with RDM has changed.

4) Has there been a change in the aetiological agents involved?

103. The aetiological agents involved have not changed since RDM was considered by the Board in July 2015. The main hazards involved in outbreaks since 2015 were

Campylobacter, STEC O157 and non-typhoidal *Salmonella*. This is in line with a Scientific Opinion published by EFSA in 2015³, which identified these as among the main pathogens for which there is a clear link between drinking raw milk and human illness in the EU. It is also consistent with what has been seen in the UK historically.

Additional conclusions arising from this risk assessment

104. Additional conclusions which can be drawn using the information above, which risk managers will wish to be aware of, are as follows:

- Survey results have shown that microbiological parameters such as Aerobic Colony Counts and coliforms have poor predictive value for identifying food safety concerns in RDM.
- Analysis of information relating to outbreaks indicates that the results of Schedule 6 testing and Dairy Hygiene compliance ratings are not a good measure of the safety of RDM.
- When a Dairy Hygiene Inspector contacted registered producers in England and Wales in January 2018 to ask about testing, only a third of the producers selling RCDM who responded indicated that they arranged for samples of their milk to be tested.
- Statutory monitoring results for RCDM in England and Wales, suggest that there has been an increase in hygiene issues associated with RCDM in England and Wales over time since 2012, although there was a slight improvement in 2017. The sample failure rate from 2012 to 2017 varied from 14.9 – 24.7%. The highest failure rates were in 2015 and 2016, during which almost a quarter of samples failed although in 2017 the failure rate reduced to 17.8%. The average failure rate during this period was 20.15%.

Key uncertainties

105. This assessment includes a number of key uncertainties, in particular:

- 1) The number of registered RCDM producers and volume of production over time between when the last outbreaks occurred in 2002 and the current time.
- 2) The volume of unpasteurised smoothies, milkshakes and ice-cream made using RDM on the market in the UK, the number of producers making them, and how this has changed over time.

106. To address these types of uncertainties, and other data gaps if a similar risk assessment needs to be carried out in the future, consideration could be given to routinely gathering the information outlined in annex 7.

Action

107. Members are invited to:

- comment on the data and conclusions presented in this paper;
- comment on the proposed risk and uncertainty classifications in the conclusions section;
- suggest additional types of information to that in Annex 7 that would be useful to gather routinely for future risk assessments on raw drinking milk if needed

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Microbiological quality of cream made from raw (unpasteurised) milk

Public Health England (unpublished data)

25th January 2018

A total of 86 samples of cream made from raw (unpasteurised) milk were located within the laboratory information management system of Public Health England's Food, Water and Environmental Microbiology Laboratories: the search criteria used were dairy product, cream, raw and unpasteurized. All samples were collected from sites within England: 68 were from 15 different farms (1 to 15 samples per farm), 17 were from 4 different farm shops (1 to 14 samples per shop) and 1 was from a farmer's market. All samples were from separate batches of product except 3 batches (13 samples) where 5 or 3 replicates were tested. No samples known to be associated with public health incidents involving cases of human illness were included except for one sample from a farm which had been associated with a Shiga-Toxin-producing *E. coli* (STEC) O157 and Salmonella outbreak in 2015 (Butcher et al., 2016).

Samples were collected between April 2013 and January 2017 and tested in a PHE Food Water and Environmental Microbiology Laboratories located at either Birmingham, London, Porton or York Laboratories using standard methods. These methods comprised: detection of *Salmonella* spp. (BS EN ISO 6579:2002); detection of *Campylobacter* spp. (ISO 10272-1:2006); detection and enumeration of *L. monocytogenes* (BS EN ISO 11290-1:1996 and 11290-2:1998); enumeration of coagulase positive staphylococci, including *Staphylococcus aureus* (BS EN ISO 6888-1:1999 +A1:2003); enumeration of *Escherichia coli* (based on BS ISO 16649-2:2001 but using a surface spread rather than pour plate technique). Detection of *E. coli* O157 was performed using BS EN ISO 16654: 2001, and STEC using CEN ISO TS 13136. All presence/absence tests were performed on 25 g samples. Test results were interpreted using the criteria outlined in Table 1 using the HPA Guidelines (Health Protection Agency, 2009).

Butcher H, Elson R, Chattaway MA, Featherstone C, Willis C, Jorgensen F, Dallman TJ, Jenkins C, McLauchlin J, Beck C, Harrison S. Public health investigation of an outbreak of shiga toxin-producing *Escherichia coli* O157 associated with raw milk using whole genome sequencing. *Epidemiol Infect.* 2016;144:2812-23.

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Table A: Criteria for the interpretation of microbiology results (Health Protection Agency, 2009).

	Satisfactory	Borderline	Unsatisfactory	Unsatisfactory: potentially injurious to health
	cfu/g			
<i>Campylobacter</i> spp.	Absent	NA	NA	Detected
<i>L. monocytogenes</i>	<20	≥20 - <100	N/A	≥10 ²
<i>Salmonella</i> spp.	Absent	NA	NA	Detected
<i>S. aureus</i> and other coagulase-positive staphylococci	<20	≥20 - <10 ⁴	N/A	≥10 ⁴
<i>E. coli</i>	<20	≥20 - <10 ²	≥10 ²	N/A
<i>E. coli</i> O157	Absent	NA	NA	Detected
STEC	Absent	NA	NA	Detected

N/A, Not applicable; cfu = colony forming units.-

¹As defined in Health Protection Agency Guidelines, 2009.

Table B. Microbiological quality of cream made from unpasteurised milk

	Number of samples (%)			
	Total tested	Satisfactory	Borderline	Unsatisfactory
<i>Campylobacter</i> spp.	33	33	NA	0
<i>L. monocytogenes</i>	83	81 ¹	2 (1%) ²	0
<i>Salmonella</i> spp.	85	85	NA	0
<i>S.aureus</i>	11	11	0	0
<i>E. coli</i>	83	64 (77%)	11 (13%)	8 (10%)
<i>E. coli</i> O157	3	3	NA	0
STEC	1	1	NA	0

¹15 samples *L. monocytogenes* detected at <20cfu/g; ²1 sample

L. monocytogenes detected at 20 cfu/g and 1 sample detected at 40 cfu/g

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 Schedule 6 of the Food Safety and Hygiene (England) Regulations 2013 and its devolved equivalents in Wales and N. Ireland.

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 at registered milk production holdings (at the farm gate, from a farmhouse catering operation (Bed & Breakfast) or farm shop on the same site) or through a 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 EU and domestic safety and hygiene legislation;
- 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 Agency inspections twice a year;
- f) The milk is sampled and tested quarterly under the control of the Agency's Dairy Hygiene Inspectors to monitor compliance with standards for total bacterial count and coliforms.

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

Microbiological criteria

Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs, includes a food safety criterion for ready to eat foods that are able to support the growth of *Listeria monocytogenes*. Food safety criteria define the acceptability of products placed on the market. When Food Business Operators fail to comply with this criterion, i.e. if *L. monocytogenes* levels exceed 100cfu/g in any one of 5 samples during its shelf life or is present in any one of 5 samples in 25g of the food prior to it leaving the control

of the producing FBO. Action must be taken under Article 7, the product or batch must be recalled or withdrawn in accordance with Article 19 of Regulation (EC) 178/2002 and take action to find the cause of the unsatisfactory result and make modifications to their HACCP based procedures. The regulation is directly applicable in all Member States.

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

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

b) Raw drinking milk from buffaloes (but not bison) 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 all non-cow's 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 all species, except buffaloes, has to carry the health warning. In Wales, raw milk from all species has to carry the health warning;

f) Compliance with the hygiene requirements are monitored by the Agency at inspections programmed on a risk basis. Compliance with the microbiological parameters are monitored by LA's at varying frequencies.

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.

Northern Ireland

Northern Ireland has controls similar to those in England and Wales, although differences are described in a paper discussed by the FSA Board on 14 March 2018.

<https://www.food.gov.uk/sites/default/files/fsa180307.pdf>

Scotland

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

Microbiological criteria

Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs includes a process hygiene criterion 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 100 cfu/g in any one of 5 samples or exceed 10 cfu/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.

Official controls

1. The Agency's Dairy Hygiene Inspectors are responsible for enforcement on milk production holdings of the Regulations (EC) No's 852/2004, 853/2004 & 854/2004, 2073/2005, 78/2002 and the Food Safety & Hygiene (England) Regulations 2013 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 for sale at the farm gate are taken from the bulk tank or from packaged product for examination 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 enforcement procedures followed. Follow-up sampling and enforcement continue until two consecutive raw milk samples have met the criteria and inspectors are confident the FBO has made appropriate improvements to the hygiene conditions on the farm and that milk being placed on the market complies with the Regulations.

Annex 4

Microbiological testing carried out by RCDM producers in England and Wales (January 2018). Responses were received from 92 producers selling RCDM at the time. Of these, 32 arranged for testing to be carried out on their behalf and 60 did not.

Farm	Sample frequency	Sample for*	Action for failure Stop Yes/No
1	16 weekly	L,E,S	Stop
2	Weekly	TVC, Coliforms	Not stop
3	1 per month	L,E,S	Stop
4	1 per month	TVC Coliforms	Stop
5	3 weeks	L,E,S	Stop
6	Weekly	L,E,S	Stop
7	1 per month	TVC, Coliforms	Stop and investigate
8	Every 2 month	E	Stop
9	1 per month	TVC, Coliforms	Stop
10	3 monthly	L,E,S	Stop
11	2 monthly	L,E,S	Stop
12	1 per month	L,E,S	Stop
13	1 per 2 months	L,E,S	Stop and retest
14	1 per month	L,E,S	Stop and fix problem inform FSA
15	1 per month	C,L,E,S	Stop and fix problem inform FSA
16	Every 6 weeks	L,E,S	Stop and fix problem inform FSA
17	Quarterly	L,E,S	Stop selling until problem fixed
18	Monthly	L,E,S	Stop selling until problem fixed
19	1 per month	L,E,S	Stop selling until problem fixed
20	1 per month	L,E,S,C	Investigate and fix problem
21	Quarterly	L,E,S	Liase with EHO
22	Monthly	L,E,S	Stop selling until problem fixed
23	2 per month	L,E,S,Staph	Fix problem.
24	1 per month	L,E,S Staph	Stop and fix problem inform FSA
25	1 per month	L,E,S, Staph	Stop and fix problem inform FSA
26	1 per month	L,E,S	Stop and fix problem
27	1 per month	L,E,S	Stop and fix problem inform FSA
28	Weekly	L,E,C,S	Stop and fix problem inform FSA
29	1 per month	E,S	Stop and fix problem inform FSA
30	1 per month	L,E,S	Inform FSA and fix problem
31	1 per month	L,E,S	Recall milk Inform FSA
32	6 weekly	L,E,S	Seek advice and stop selling

*L = *Listeria*, E = *E. coli*, S = *Salmonella*, C = *Campylobacter*, Staph = Staphylococci

Annex 5

National Diet and Nutrition Survey consumption data by age group for milkshakes, ice cream and smoothies made with dairy products (pasteurisation status unknown but most/all assumed to be pasteurised). The information relates to combined data from 2008/2009 to 2013/2014 (there are no data after 2014). Individuals were asked to complete a diary of food and drink consumption over four consecutive days (with the start date randomly allocated). The totals will not always add together numerically due to weighting.

Table 1: Chronic consumption estimates for Milkshakes from NDNS years 1 to 6

UK Population age group	Number of consumers	Percent consumers	Mean consumption rate (g/kg bw/day)	Mean consumption rate (g/person/day)
Adults (aged 19+ yrs)	77	2.5	1.39	108.66
Children (aged less than 5 yrs)	62	7.1	3.78	63.05
Children (aged 5 to 18 yrs)	287	11.2	2.27	94.62

Table 2: Chronic consumption estimates for Ice cream from NDNS years 1 to 6

Survey Population	Number of consumers	Percent consumers	Mean consumption rate (g/kg bw/day)	Mean consumption rate (g/person/day)
Adults (aged 19+ yrs)	540	17.2	0.17	13.01
Children (aged less than 5 yrs)	275	33.9	0.61	9.61
Children (aged 5 to 18 yrs)	773	31.0	0.36	12.35

Table 3: Chronic consumption estimates for Smoothies made with dairy products* from NDNS years 1 to 6

Survey Population	Number of consumers	Percent consumers	Mean consumption rate (g/kg bw/day)	Mean consumption rate (g/person/day)
Adults (aged 19+ yrs)	4	0.17	0.99	90.78
Children (aged less than 5 yrs)	1	0.04	4.56	75.88
Children (aged 5 to 18 yrs)	6	0.2	1.80	67.01

* From the NDNS categorisation reported, it is assumed that the dairy products contained in these smoothies would be yogurt

Qualitative microbiological risk assessment classification

The following classification has been used in this risk assessment to express the level of risk, and the following qualitative categories for expressing uncertainty.

Risk level classificationⁱ

Probability category	Interpretation
Negligible	So rare that it does not merit to be considered
Very low	Very rare but cannot be excluded
Low	Rare, but does occur
Medium	Occurs regularly
High	Occurs very often
Very high	Events occur almost certainly

Table from EFSA (2006) modified from OIE (2004)

Qualitative categories for expressing uncertainty in relation to qualitative risk estimatesⁱⁱ

Uncertainty category	Interpretation
Low	There are solid and complete data available; strong evidence is provided in multiple references; authors report similar conclusions
Medium	There are some but no complete data available; evidence is provided in small number of references; authors report conclusions that vary from one another
High	There are scarce or no data available; evidence is not provided in references but rather in unpublished reports or based on observations, or personal communication; authors report conclusions that vary considerably between them

Table from EFSA (2006)

i) http://acmsf.food.gov.uk/sites/default/files/mnt/drupal_data/sources/files/multimedia/pdfs/committee/acmsf/acmsfrltreport.pdf

ii) http://acmsf.food.gov.uk/sites/default/files/mnt/drupal_data/sources/files/multimedia/pdfs/committee/acmsf/acmsfrltreport.pdf

Recommended information to gather routinely to aid future risk assessments

- Bulk tank size
- Number of bulk tanks
- When samples are taken: the volume of the sample, the volume of the bulk tank that the sample came from and the number of animals that contributed RDM to the bulk tank.
- Volume of RDM placed on the market (e.g. litres per week)
- What percentage of milk produced by the FBO is sold as raw drinking milk (as opposed to pasteurised milk or milk used to make other pasteurised products)?
- The nature and volume (e.g. litres per week) of smoothies, milkshakes and ice cream made using unpasteurised milk sold on the UK market
- If the FBO produced unpasteurised smoothies, milkshakes or ice cream using RDM, are they labelled with health warnings?
- If they also produce pasteurised milk, are the same high levels of hygienic standards achieved for both?
- Number of animals in the herd (and if the premises produces both raw and pasteurised milk, the number of animals used for each. Are the same animals used for both)?
- If the FBO makes both raw and pasteurised drinking milk, is the same equipment (such as milking equipment, bulk tank and bottling equipment) used for both?
- Completeness of chill chain (e.g. chill chain from animal to bulk tank, time to cool to 5°C, bulk tanks temperature, chill chain after bulk tank, vending machine temperature, temperature during delivery for RDM ordered via the internet).
- Microbiological analysis carried out on behalf of the FBO (e.g. which microbiological parameters are tested for, frequency of sampling, sample types, results, whether adverse results are reported to DHI, action taken when unsatisfactory results are obtained)
- Product shelf life and how this is determined.
- Have there been any changes in practices, hygiene standards, staff, cleaning practices / disinfectants, equipment, change in personal circumstances recently?
- Routes through which the product is sold (e.g. farm shop, milk round, farmers market, vending machine, internet sales - and the proportion of RDM sold through each route).

Amendments made to ACM/1269 following ACMSF discussions on 10 May 2018

This version of ACM/1269 incorporates changes made to the original version to reflect comments made by the Committee on 10 May 2018, as follows:

1) In Table 2 and the associated text the following amendments were made:

- for 2016: the number of outbreaks associated with RDM was amended from 2 to 1;
- for 2016: RDM outbreaks as a percentage of the total number of foodborne outbreaks was revised from 4.5 to 2.3%;
- for 2016: the number affected (number hospitalised) were amended from 0 (0) to 69 (0);
- for 2017: the number hospitalised was amended from 3 to 4;
- the total number of deaths was amended from 26 to 25;
- the total number of RDM outbreaks as a percentage of the total number of foodborne outbreaks was revised from 0.9 to 0.8%;
- the total number affected (number hospitalised) was amended from 357 (41) to 353 (42).

2) In paragraphs 17, 92 and 94, the proportion of those affected who were hospitalised for IID outbreaks involving RDM was amended from 11.5% to 11.9%.

3) On pages 11 and 29, the term ‘servings’ has been replaced with ‘samples’ in the following text and the following associated changes were made:

- This suggests that there may have been a small increase in the proportion of RDM **servings samples** with potentially hazardous results since this issue was considered by the Board in July 2015, although this is not statistically significant.
- Overall, ~~the results indicate that~~ approximately 1% of RDM **servings samples** had potentially hazardous results ~~are potentially harmful~~ due to the presence of STEC, *Campylobacter* spp. or due to elevated levels of *L. monocytogenes* or coagulase-positive Staphylococci.

4) In the conclusions section, the risk classifications have been amended as follows:

- The statement on page 28 that “*the risk associated with consumption of RDM on a population basis is considered to be low (i.e. rare, but does occur) with medium uncertainty” has been amended to “the risk for the subpopulation that consume RDM is currently considered to be medium (occurs regularly) with medium uncertainty”.*
- In terms of unpasteurised milkshakes, smoothies and ice-cream made using RDM, the statement on page 30 that “*the current risk associated with*

*consumption of these products on a population basis is considered to be **very low with a high level of uncertainty***” has been amended to “the current risk for the subpopulation that consume these products is considered **medium** (occurs regularly) with a **high level of uncertainty**”. In addition, a line has been added indicating that *“these products are unlikely to receive a processing step that would reduce the risk associated with consumption of the RDM ingredient”*.

- The following statement has been added to page 31: *“In terms of the population which does not consume RDM or unpasteurised milkshakes, smoothies and ice-cream made with RDM the risk is considered to be negligible (i.e. so rare that it does not merit to be considered).”*.

5) On page 30, the following paragraph has been added: *“It should also be noted that the number of RDM associated outbreaks reported annually and number of cases linked to and investigated during outbreak investigations do not accurately portray the true burden of disease because this data only represents a very small proportion of overall gastrointestinal illness burden”*.

6) On page 30, the text indicating that *“data from England and Wales show that no deaths have been reported from IID outbreaks associated with RDM or cream from 1992-2017”* has been grouped with the other information relating to severity of illness.

7) In annex 7, the following information to gather routinely to aid future risk assessments has been included:

- When samples are taken: the volume of the sample, the volume of the bulk tank that the sample came from and the number of animals that contributed RDM to the bulk tank.

Additional amendments

8) In light of updated information received from Public Health Wales, the following figures relating to the outbreak associated with Farm F in Table 1 (and in the corresponding text) have been amended:

- the number of confirmed cases has been revised from 9 to 8 and;
- the number of hospitalised cases has been revised from ‘unknown’ to 1.

9) In light of updated information received from Public Health England, the following figure relating to the outbreak associated with Farm C in Table 1 (and in the corresponding text) has been amended: the number of hospitalised cases has been revised from 5 to 3.