
RAW DRINKING MILK (RDM) CONTROLS

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SUMMARY

1. This decision paper presents conclusions and recommendations from the review of official controls for RDM.
2. The Board is asked to:
 - **discuss and agree** with the principle of addressing RDM sales within the context of Regulating our Future (ROF) principles and the Risky Foods Framework (RFF);
 - **consider and agree** the proposal to adopt a proportionate escalation approach to introducing measures and controls on RDM; and
 - **consider and agree** the recommendations to improve the existing controls for RDM.

INTRODUCTION

3. In March 2018, the Board was presented with an interim paper¹ that gave an overview of planned improvements in the delivery of official controls for RDM, updates on progress in implementation of recommendations from the 2015 policy review and the initial findings from the evidence review including the initial risk assessment, economic analysis and consumer insight work. A summary of key findings from the policy review can be found at **Annex A**.
4. After discussing the interim paper's findings, the Board highlighted the following specific areas for inclusion/consideration in this decision paper:
 - presentation of the recommendations in the context of the FSA Risky Foods Framework;
 - review evidence on the perceived health benefits of RDM;
 - consider adoption of the NI approach to registration of RDM businesses;
 - establish a mechanism for triggers for future reviews; and
 - consideration of a range of control options.

BACKGROUND AND CONTEXT

5. This paper outlines the RDM programme of activity and identifies recommendations for the Board's consideration and agreement.
6. The programme of work is aligned to the Regulating our Future (ROF) principles that ensure business operators take primary responsibility for the safety of food they

¹ <https://www.food.gov.uk/sites/default/files/media/document/fsa180307.pdf>

produce, that information is provided to consumers enabling them to make informed choices and that regulatory activity is risk-based, targeted and proportionate.

7. Recommendations follow the direction of the FSA Strategic Plan. As set out in our strategy to 2020, we will put the consumer first in everything we do, acknowledging that consumer interests are multi-dimensional: “food is safe and what it says it is, and we have access to an affordable healthy diet, and can make informed choices about what we eat, now and in the future”.
8. The RFF, agreed by the Board in 2016², sets out a framework to ensure controls on risky foods strike the right balance between protection from risk, support for consumer choice, support for business growth and innovation, while delivering our ambition for future regulation that is effective, proportionate, robust, and sustainable. The 2015 RDM Board paper followed the emerging principles in the RFF. This review follows the principles in the framework for a review of controls of risky foods. This review of controls on RDM considers whether the evidence suggests that there is, or may be a material change in:
 - the nature of the hazard;
 - the potential exposure;
 - the effectiveness of controls in practice; and or
 - the acceptability of controls
9. If there is a material change, this may suggest a change in the preferred options for controlling the risks. The table at **Annex B** indicates where these different areas have been assessed in this paper.
10. In Wales, policy development is subject to the Well-being of Future Generations (Wales) Act 2015³ aimed at improving the social, economic, environmental and cultural well-being of Wales. The Act requires public bodies to act in a sustainable way and to ensure that the decisions that they take are preventative and take account for the impact they could have on people living their lives in Wales now and in the future. While appreciating that the FSA is not a named body in the Act, the FSA has previously agreed to align with the aims of the legislation.
11. The Public Health (Wales) Act 2017⁴ sets out a requirement for mandatory health impact assessments in specific circumstances. Where the FSA is carrying out the functions of Welsh Ministers (such as making legislation), it will be subject to the requirements of the Act.

EVIDENCE BASE

Risk Assessment (RA)

² <https://www.food.gov.uk/sites/default/files/media/document/fsa161107%20%283%29.pdf>

³ <http://www.legislation.gov.uk/anaw/2015/2/contents/enacted>

⁴ <http://www.legislation.gov.uk/anaw/2017/2/contents/enacted>

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12. The key purpose of the RA was to assess whether the microbiological risk associated with consumption of RDM (and certain raw milk products) made in the UK has changed since this issue was considered in 2015.
13. The final draft [risk assessment \(ACM/1269\)](#) was discussed by the Advisory Committee on the Microbiological Safety of Food (ACMSF) on 10 May 2018. The Committee recognised that the microbiological risk associated with consumption of RDM in the UK has increased since this issue was last considered by the Board in July 2015. 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. The following risk and uncertainty classifications were agreed:
- the risk for RDM consumers is currently considered to be **medium** (occurs regularly) **with medium uncertainty**.
 - in terms of milkshakes, smoothies and ice-cream made using RDM, the current risk for the RDM consumers that consume these products is considered **medium** (occurs regularly) with a **high level of uncertainty**.
 - the risk is considered to be **negligible** (i.e. so rare that it does not merit to be considered) with **low uncertainty** for the remainder of the population who do not consume RDM or milkshakes, smoothies and ice-cream made using RDM. This last group is considered so as to provide a baseline against which to benchmark the above groups. **Annex C** includes a risk classification table.
14. The Committee was largely supportive of the risk assessment and suggested some amendments to strengthen and clarify the text. The final RA has now been published⁵. A detailed summary of the findings can be found at **Annex C**.

Economic Analysis and Consumer Research⁶

15. The March Board paper highlighted that there could be a number of reasons why there has been an increase in RDM production, including possible access to Department of Environment Food and Rural Affairs (DEFRA) government grants that encourage diversification of dairy farms into added value products. Further investigation confirms that no DEFRA grants have been awarded for RDM production.
16. Drivers for buying and consuming RDM have altered since 2012 which demonstrates a changing attitude towards its consumption. From our sample survey in 2018, the main driver is its perceived health benefits (59%), with perceptions on digestibility (40%) and protection against allergic disease (28%) being the other main factors. The shift away from a belief in higher animal welfare (reduced from 46% to just 2% between 2012 and 2018) shows that consumers are purchasing RDM mainly for perceived health reasons. Sales routes are altering too: whilst the majority of sales are still through farms, vending machines on the farm/farmers market now account for 17% compared to 4% back in 2012. Internet sales are now at 8%, the third most popular route, making raw milk less geographically limited to the local consumer.

⁵ https://acmsf.food.gov.uk/sites/default/files/acm_1269_revised_final.pdf

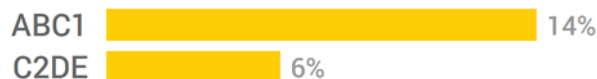
⁶ <https://www.food.gov.uk/sites/default/files/media/document/Raw%20Drinking%20Milk%20Consumer%20Insight%20Report%202018.pdf>

17. Increased availability may mean an overall higher number of consumers compared to 6 years ago, though it is difficult to ascertain this with any degree of accuracy. Consumers are aware of the risks associated with RDM, with a slight increase in knowing that it can be dangerous to vulnerable groups at 80% from 76%.
18. Those from socio-economic groups ABC1 are significantly more likely to consume raw milk than those from C2DE backgrounds (14% compared to 6%), with those aged between 25-44 being the age group most likely to buy it. Fluctuations in price are unlikely to affect the sales of RDM, which might be considered a premium good, with many possibly accepting the higher price due to its perceived health benefits and the values the individual attaches to the purchase. **Annex D - Data Story**

Respondents under 44 years old are much more likely to consume raw milk



Respondents in socio-economic group ABC1 are more likely to consume raw milk



Other Countries

19. Regulation varies internationally for the sale of RDM. In the US, 30 states have varying controls on sales or cow shares (where consumers buy a share in a cow in return for RDM in an effort to circumvent a ban on the sale of RDM) and a ban in the remaining 20 states; outbreaks have been reported in states regardless of legality. New Zealand has recently changed its regulation and consumers must now provide contact details to the farmer when purchasing from them to enable the farmer to contact them if a batch of milk fails safety testing. In Australia, sale is permitted for cosmetic purposes, such as bathing milk, but labelling states that it is not for human consumption. Within the EU, laws differ in Member States (MS) due to the flexibility provided by the legislation with Spain and Poland banning its sale. Some MS allow the use of vending machines on farms and, in some countries such as Germany and Italy, these are coupled with signage recommending boiling the milk before consumption. In the UK, the sale of RDM is banned in Scotland. Further information at **Annex E**.

Perceived Health Benefits

20. Claims have been made that raw milk is nutritionally superior to pasteurised milk. Consumer research suggests this is one of the key drivers for consumption; the

perceived benefits of preventing the development of allergic disease is a significant factor for 28% of consumers (as of 2018).

21. During the last policy review an assessment was conducted of available evidence of any nutritional benefits associated with the consumption of raw milk compared with consumption of pasteurised milk. It concluded that there is little available evidence to indicate that pasteurising milk substantially alters its nutritional composition and that there was insufficient evidence to show the effect of pasteurisation on the functional properties of nutrients in milk.
22. Research on RDM and potential connections with allergic disease are inconclusive, with many confounding factors. Although some studies have shown that children growing up on farms are at a reduced risk of developing allergic diseases such as asthma, hay fever, food allergy and atopic dermatitis, the effects observed were likely to be multifactorial in origin and no single specific factor has been consistently identified in conferring these protections.
23. As no consensus exists regarding any allergenic benefits from the studies conducted to date, we would continue to not recommend the consumption of raw milk to prevent allergic disease. Further, any proven benefits would still have to be considered against possible adverse effects due to potential pathogen consumption.

RISK COMMUNICATION

24. We make it clear in our strategy to 2020 that consumers have responsibilities as well as rights. Those responsibilities extend to the people they care for, and are balanced by a right to be informed and supported in taking on those responsibilities and a right to make informed choices about what they eat.
25. 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. Action may be needed to increase awareness of those risks. The Executive has considered various avenues to communicate the risk to consumers and has developed an action plan which amongst other things includes:
 - Engaging with targeted partner organisations (such as NHS Choices) to ensure that our advice on RDM is included in their advice to the relevant audiences
 - Production of 'FSA Explains' video (short clips which explain key food safety messages to consumers who visit the FSA website).
26. The common understanding of the term 'raw' has changed over time. The Executive will consider what consumers understand by the terminology used, in particular whether consumers know that RDM has not been heat treated and understand the risks involved in its consumption. We are reviewing the language to identify if the terminology is appropriate and will advise once completed.
27. In addition, we are exploring a strategy to meet a variety of user needs in relation to making information about RDM more accessible. A project to provide a live digital service based around RDM data flows is being developed. An approach similar to allergens is being considered; this could include consumer alerts and/or publication of

microbiological sampling results. Early work suggests that an initial prototype of this service could be available for testing in the autumn as a new component of the webservices at data.gov.uk.

CONTROLS AND ENFORCEMENT

28. The evidence base indicates that improved controls are needed to provide better risk management of RDM. An important aspect of the proposed improvements is the need for FBOs to take greater responsibility in ensuring that the RDM they produce is safe when they supply it to the final consumer as well as being aware of the risk the product poses to vulnerable groups. This approach is in line with ROF principles.

Hierarchy of measures

29. The Executive proposes that the Board considers a proportionate escalation approach to introduce further measures and controls on RDM. This approach will comprise measures that we consider will protect public health and appropriately balance consumer choice and business growth. We propose the development of a set of values, contravention of which would trigger consideration of further measures by the FSA, including as appropriate at Board level, should that be necessary, with the options of further action, including legislation if necessary, to protect public health.
30. We consider there are a number of improvements that could be made to controls and enforcement in areas such as the registration process for new entrants, on-farm controls and verification sampling. A brief description of possible measures is below. The Board is not asked to comment on the specific measures but indicate whether it agrees with the objective of improving controls along the lines proposed. Subject to the Board's approval these would be refined and then consulted on.

Legal Requirements and Enforcement Powers

31. RDM producers must comply with the requirements of EU General Food Law (in particular Article 14 of Regulation 178/2002); the EU Food Hygiene package (Regulations 852/2004 and 853/2004) and schedule 6 of the domestic Food Hygiene Regulations which places specific restrictions on the sale of RDM. Under Article 14 of Regulation 178/2002, producers have the responsibility to remove unsafe food from the market and failure to do so is an offence. In England, the legal mechanism that the FSA has to prevent sales of RDM is to apply for a Hygiene Emergency Prohibition Order (HEPO) from the Courts. This requires enforcement officers to prove there is a health risk in order to satisfy the "health risk condition" of the HEPO. The current programme of verification sampling for hygiene indicator organisms does not, on its own, provide sufficient evidence of a health risk to satisfy the Courts which can limit the FSA's scope for taking legal action if an FBO does not voluntarily cease production. In Wales RANs can be served to achieve a similar result.
32. However, these controls can be enhanced to provide additional public health protection for this risky food and there are a number of non-legislative improvements (listed below) that we might seek of RDM producers to provide additional reassurances on the safety of their product.

Registration Process

33. The requirements for new entrants to the market has been reviewed and this suggests that changes to the process are necessary for FBOs to provide greater assurance that the product they intend to produce for sale is safe. The Northern Ireland (NI) process for registration has been considered as a possible model that has several elements that could be adopted in England and Wales. A summary of the NI process is at **Annex F**.
34. FBOs are not permitted to place unsafe food on the market⁷. In meeting this requirement, they should ensure that they have the necessary measures in place that will control hazards and prevent this from happening. There are a number of measures that FBOs could take, but in the context of the risky foods framework we would expect RDM producers and suppliers to have a validated and verified food safety management plan based on HACCP principles that is applied and that combines:
- Appropriate hygiene and temperature controls;
 - Appropriate maintenance controls; and
 - Identification of potential hazards, physical, chemical and microbiological along with steps to control these.
35. In addition, existing and new FBOs should be able to validate and verify their controls by having appropriate pathogen sampling and water testing programmes in place. These proposed changes would require a stakeholder consultation to agree the details that ought to be provided that would furnish the FSA and Local Authorities with such assurances and consider the cost.

Verification Sampling

36. At present, FSA Dairy Hygiene Inspectors (DHIs) are required to sample quarterly for hygiene indicator organisms only. The ACMSF concludes that testing for indicator organisms alone is not a good measure of RDM safety because the prevalence and levels of hygiene indicator organisms is generally not regarded to correlate well with the likelihood of pathogens being present in RDM. We are aware that a limited number of producers already sample for pathogens. We consider that it might be prudent that such sampling is instigated by RDM producers. Whilst, due to the inherent delays in results, it might not be preventative of harm, such an expectation could raise awareness of the producers' milk bacterial counts and should be considered within a suite of measures, mentioned above, as an additional assurance to regulators in determining a well-run business with a culture of care. The introduction of routine pathogen sampling to complement hygiene assessments, coupled with the current sampling for indicator organisms, will provide a more holistic picture of food safety and equip officers with the necessary evidence to take appropriate action when required.

Industry Guidance

⁷ EU Reg 178/2002, Article 14
<http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:en:PDF>

37. The findings from the March Board paper and recent RDM internal audit identified a lack of producer guidance on implementation of hygiene requirements on farm, particularly for new entrants to the market. It is recognised that good animal health and husbandry, good agriculture practices (GAPs) and good hygiene practices (GHPs) are essential to minimise opportunities for contamination of RDM throughout the production to consumption chain and this is reflected in the conclusions of the 2015 EFSA opinion. The EFSA Opinion noted that improvements in on-farm hygiene led to a decrease in the number of predicted cases for some of the main hazards associated with RDM. The Opinion also concluded that no single control could be identified which would provide a significant reduction in risk relative to the baseline provided by GAP and GHP. It is therefore considered that any suite of improvements would need to include appropriate guidance to help producers implement on-farm controls and food safety management practices to minimise risks associated with RDM.
38. A producer workshop, attended by over 70 producers, was held on 3rd May 2018, jointly hosted by FSA, National Farmers Union (NFU) and other industry representatives. The FSA has secured agreement with NFU and other industry representatives for them to produce a “best practice” guidance document and set up a ‘producers group’ with facilitation from the FSA. This will assist producers with best practice guidance and all necessary training to achieve best practice within the industry. We will strongly encourage this action by industry to bring a greater level of intervention and awareness by FBOs themselves.

Routes of sale

39. The FSA has considered whether the current restrictions on the routes of sale for RDM are appropriate, given the outcome of the RA. Currently we consider that the controls around routes do not need to be adjusted, however we will continue to monitor these closely and will propose changes if the risk from specific routes of sale demonstrably increases.

Other Species

40. The RA illustrates that all of the RDM associated outbreaks since 2015 were caused by raw milk from cows rather than other species (sheep, goats, and buffalo). It is possible that this is due to the relatively small number of producers’ and lower volumes of consumption of other species’ milk in the UK. Although there is more evidence that raw milk produced by cows can present a microbiological risk, it is possible that raw milk produced by other species could do so as well. The stakeholder event (para 38) highlighted the need for milk from other species to be considered in its own right. Further consideration needs to be given on what controls are appropriate for this sector in the light of what the triggers for review could be.

CONCLUSIONS AND RECOMMENDATIONS

41. An approach proposing a range of additional control options graduating from the current situation which includes further restrictions on sales is possible. The review of evidence has concluded that the risk from RDM is not so unacceptable as to justify removing the right of adult consumers to choose to drink it, provided certain controls

are met (that right also carries with it a responsibility for vulnerable groups in their care). However, improvements are required in terms of ensuring better controls, accountability and the need for FBOs to provide assurance to their customers and the regulator, coupled with better explaining the risk to consumers.

42. It is proposed that the FSA should adopt a staged approach whereby we introduce better control measures and then review the effectiveness of those proposed measures (summarised below) after an appropriate period. If the measures introduced are not deemed to be effective, then additional, more stringent, controls should be considered and these would be brought back to the Board. Monitoring and evaluating industry's approach could include the extent of implementation of any suite of measures that demonstrates their commitment to providing assurances on their product.
43. As discussed above, the emphasis should be on controls established within food safety management plans rather than just pathogen testing. Pathogen testing has a role in validation and verification of controls, however, it is good hygiene practices that minimise opportunities for contamination of RDM throughout the production process.
44. Work currently in progress includes, the development of an industry guidance document (para 37 and 38), a risk communication strategy (24-26) and a new RDM digital service (para 27).
45. Proposed recommendations:
 - Changes to the registration process for new entrants to the market;
 - Requirement for existing and new FBOs to have a validated and verified food safety management plan based on HACCP principles;
 - Requirement for existing and new FBOs to validate and verify their controls by having a pathogen sampling and water testing programme (or demonstrably equivalent) in place.

Triggers for review of controls

46. The Board has previously recommended that we establish a mechanism for data-enabled "triggers" that would prompt the Board to review the control strategy. This is also in line with requirements in the RFF. The Executive is exploring possible trigger mechanisms, which could include changes to the number of dairy producers who sell RDM, the estimated annual volume that is sold, the number and seriousness of outbreaks, the effectiveness of enforcement controls, as well as any credible new science and evidence which may emerge.
47. The Board is asked to:
 - **discuss and agree** with the principle of addressing RDM sales within the context of ROF principles and the RFF;
 - **consider and agree** the proposal to adopt a proportionate escalation approach to introducing measures and controls on RDM; and
 - **consider and agree** the recommendations to improve the existing controls for RDM.

Annex A

RDM Board Paper – March 2018

Summary of Key Findings

An increased focus on RDM is needed due to the change in the RDM environment:

- **Volume of sales:** 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
- **Registered producers:** The number of registered RDM producers in the UK has increased significantly. In April 2014 (in the UK) there were 108 RDM producers and in January 2018 there were 168 RDM producers.

Figure 1

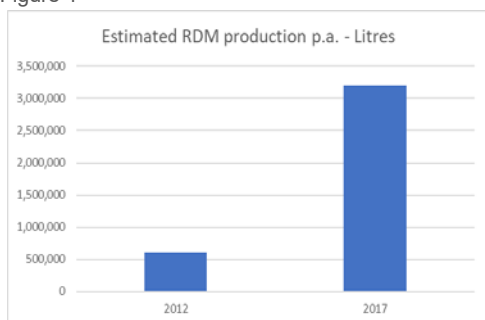


Figure 2

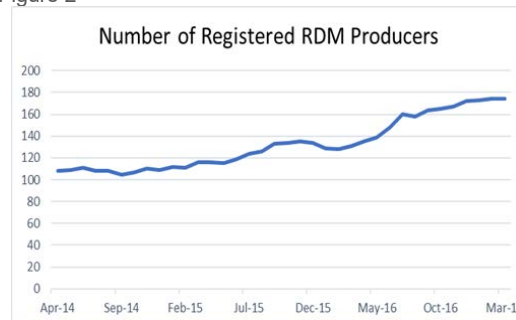


Figure 1: Estimated RDM production in the UK per year during 2012 and 2017 (in litres).
Figure 2: Number of registered RDM producers 2014 - 2017

- **Producer Guidance:** The policy review findings and the more recent internal audit also identified a lack of producer guidance, particularly for new RDM producers. There was limited guidance issued in England and Wales as part of the registration process
- **Outbreaks:** There has been an increase in outbreaks of human illness associated with RDM in the UK since the beginning of 2015 until the end of 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.

Annex B

Risky Foods Matrix

Element of evidence	Factor in Risky Foods Framework			
	Hazard	Exposure	Effectiveness of controls	Acceptability of controls
Risk Assessment	x	x		
Economic analysis		x		x
Consumer research		x		x
Controls in other countries			x	x
Evidence on perceived health benefits	x			x
Risk communication			x	
Controls and their enforcement			x	

Annex C

ACM/1269

**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 2015⁸**

SELECTIVE EXTRACTS TAKEN FROM THE RISK ASSESSMENT, STARTING ON PAGE 28:

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

Key findings in relation to raw drinking milk and certain raw milk products (i.e. milkshakes, smoothies and ice cream) are:

Raw drinking milk

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. Based on the qualitative microbiological risk assessment classification scheme described in the tables at the end of this Annex, the risk for the subpopulation that consume RDM is currently considered to be medium (occurs regularly) with medium uncertainty.

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:

Number of registered producers

- 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).

Volume of production

- 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.

Survey data

- Analysis of RDM samples collected for routine purposes in England and Wales between 2014 and 2015 by PHE showed that 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.
- 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

⁸ https://acmsf.food.gov.uk/sites/default/files/acm_1269_revised_final.pdf

2015 and 1.6% in 2016. This suggests that there may have been a small increase in the proportion of RDM samples that are potentially hazardous since this issue was considered by the Board in July 2015, although this is not statistically significant.

Outbreaks

- 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.
- 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 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.

1) Certain unpasteurised products made using RDM (i.e. milkshakes, smoothies and ice cream)

Other than a single outbreak involving both RDM and milkshakes made using RDM, 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 them (although comparable data from an earlier time point is not available to be able to assess whether this has changed). It is 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 the microbiological risk will be significantly affected. However, 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** (i.e. occurs regularly) with a **high level of uncertainty**.

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

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. 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?

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).

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.

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?

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 2015, 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

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%.

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 classification

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 assessments

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)

Annex D Data Story

Who consumes raw milk?

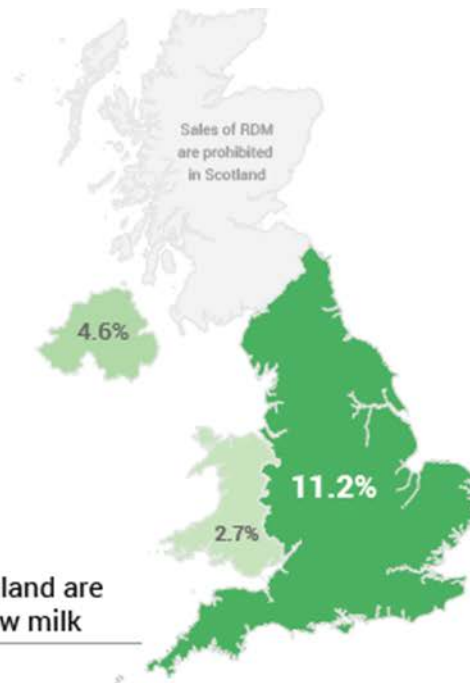
Respondents in socio-economic group ABC1 are more likely to consume raw milk



Respondents under 44 years old are much more likely to consume raw milk

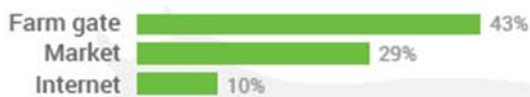


Respondents living in England are more likely to consume raw milk



Patterns of raw milk consumer behaviour

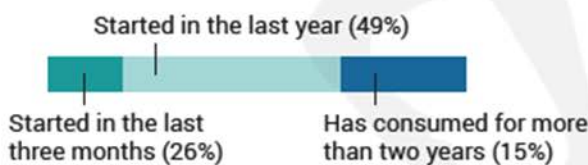
The majority of current RDM consumers buy the raw milk directly from farm gates



The majority of current RDM consumers buy or drink raw milk on a regular basis

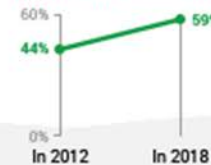


Those who consume RDM are likely to have started consuming it recently (less than a year)

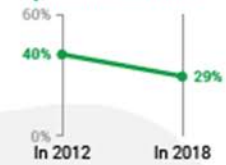


Main drivers for raw milk consumption

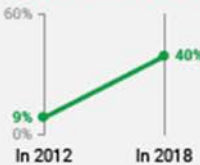
"Believe higher in nutritional content"



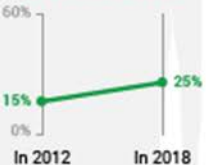
"Tastes better than pasturised milk"



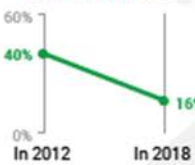
"It is easier to digest than PM"



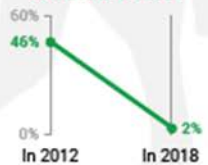
"Environmental impact is less"



"It supports local farmers"



"The animals are treated better"



This data story was created by the data science team (data.science@food.gov.uk)

Annex E International Controls and Outbreak Data

Europe

1. Between 2007 and 2012, there were 27 reported outbreaks linked to RDM in EU Member States (MS), 21 of these were linked to campylobacter.
2. Vending machines are a popular source of mainly raw cows' milk across MS with Italy having 1066 registered as of 2013 but most MS have fewer than 100. They are not permitted in some MS such as Denmark, Ireland and the Netherlands. Amongst MS that allow vending machines, some include signage which recommend boiling before usage however a report in Italy found that 57% of consumers ignore this advice.⁹

International

3. In the USA, between 2007 through to 2012, 26 states reported 81 outbreaks linked to raw milk as detailed in Figure 1. The outbreaks caused 979 illnesses and 73 hospitalisations. The number of outbreaks is four times higher during this period than from 1993 to 2006¹⁰



4. New Zealand has recently changed its regulations in November 2016 after a public consultation in 2013. Farmers are required to collect contact details of those purchasing their milk so that they can recall their products if necessary. Labelling contains warnings for high risk groups as well as information on refrigeration and contact details for the producing farmer. There were 22 outbreaks associated with raw milk between January 2006 and February 2013. Official advice from the Ministry of Primary Industries (MPI) recommends milk to be heated to 70 degrees for one minute, or scalded, before consumption.¹¹

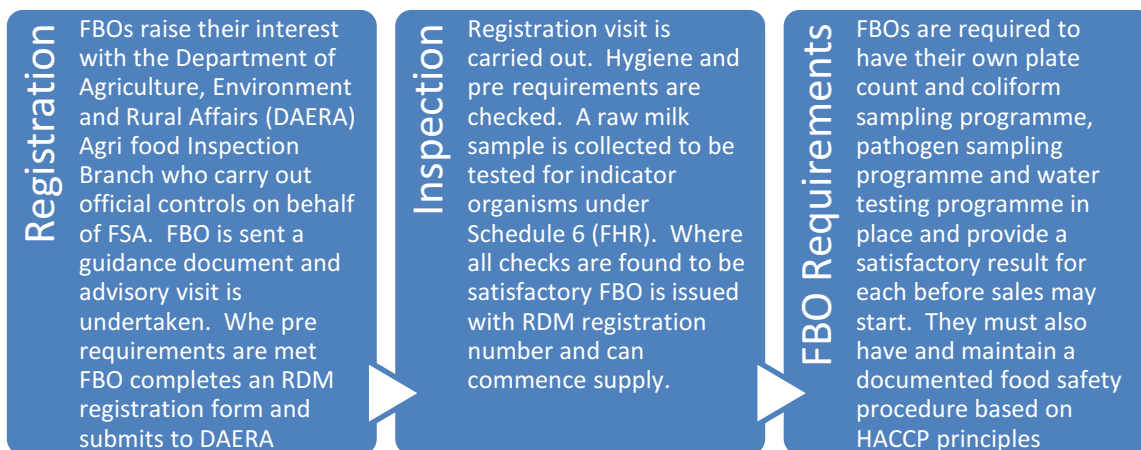
⁹ <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2015.3940>

¹⁰ <https://www.cdc.gov/foodsafety/rawmilk/rawmilk-outbreaks.html>

¹¹ <https://www.mpi.govt.nz/food-safety/food-safety-for-consumers/is-it-safe-to-eat/raw-milk/raw-milk-regulations/>

Annex F

NORTHERN IRELAND PROCESS FOR REGISTRATION



FBOs shall also maintain the following sampling frequencies:

Raw milk: Plate Count and Coliform: weekly for one month. If weekly testing demonstrates compliance with the legislation testing can be reduced to monthly.

Raw milk: Pathogens (*Salmonella* spp, *Listeria* spp, *Campylobacter* spp, *E. coli* O157): monthly for 6 months. If monthly testing demonstrates compliance with the legislation testing can be reduced to six monthly.

Water: Mains direct supply - all tests annually

Other water supplies- all tests monthly for 3 months. If monthly testing demonstrates compliance with the legislation testing can be reduced to a six-monthly frequency