January 2020

Enhanced controls for raw milk production (England & Wales)
Summary report of stakeholders responses

The Enhanced controls for raw milk production (England & Wales) consultation was issued on 7 February 2019 and closed on 30 April 2019. The consultation, developed using a multi-stakeholder working group approach, aimed to provide interested parties with the opportunity to comment and feedback on the proposed changes to Raw Drinking Milk (RDM) control delivery and the associated impact of the changes.

1 The Food Standards Agency (FSA) is grateful to those stakeholders who responded and sets out in the table below responses grouped by respondent type or organisation.

2 The key proposals on which the consultation sought views were:
- The need for producers of RDM to have an effective and verified Food Safety Management System (FSMS) in place
- Effective verification of this system to include testing for pathogens that can be found in RDM

3 The Food Standards Agency's considered responses to stakeholders' comments are given in the last column of the table. A summary of changes to the original proposal(s) resulting from stakeholder comments is set out in the final table.

4 Responses were received from a number of stakeholders which included individuals/consumers, RDM producers, industry/trade organisations and Local Authority groups.

Responses from Consumers/Individuals

Respondent	Comment	Response
Individual	There are both taste and health benefits to consuming RDM, with little risk. Clear labelling should allow consumers to continue to make informed choices.	The FSA recognises there are a number of reasons why consumers choose to drink RDM. Proposed controls seek to provide a balance between protecting public health whilst also allowing consumers to make informed choices. Effective controls are important in protecting public health. RDM can contain pathogens harmful to health and an effective system to reduce the risks of this happening is needed. The FSA is committed to ensuring clear food safety labelling. Labelling is regulated to protect consumers and ensure they have the correct information to make confident and informed food choices based on diet, allergies, personal taste and cost.
Individual	Consider the proposed controls are unenforceable under current legislation as EU Regulations specifically exclude RDM as it is sold to the final consumer and national laws should apply. The new controls will not improve the overall safety of RDM, but make it more difficult for producers, especially new producers i.e. testing a mains water supply.	The EU legislation provides the controls needed for all raw milk regardless of whether it will be supplied direct for consumption or go on for further processing. It allows for national rules to be developed. The UK has established national controls which are specific to Raw Drinking Milk for direct human consumption and these are enforced by our Dairy Hygiene team. The new controls are evidence based and intended to improve food safety. Producers must ensure appropriate steps are included in their FSMS to ensure water is safe at the point of use (e.g.

Summary of substantive comments to the FSA consultation – Enhanced controls for raw milk production (England & Wales)

Respondent	Comment	Response
		taking account of source and methods or systems for delivering water on-farm) and should determine the appropriate testing frequency as part of their FSMS. The guidance document will be amended to clarify advice in relation to water sampling.
Individual	Welcome the proposed enhanced production controls but believe that more health guidance information needs to be clearly signposted at point of sale and in online materials i.e. websites or social media. There should be a regulation to stop the promotion of RDM to parents of young children.	There is a legal requirement for the Food Business Operator (FBO) to have health warnings at the point of sale of RDM. Following its review of controls for RDM, the FSA added information concerning the risks associated with RDM on its website. We are also working with partners, such as NHS Choices, to share this message with our target audiences including vulnerable consumers. Wherever possible the FSA will ensure the risks associated with RDM are communicated clearly to consumers in a manner that compliments mandatory labelling and allows consumers to make informed choices.

Summary of substantive comments to the FSA consultation – Enhanced controls for raw milk production (England & Wales)

Respondent	Comment	Response
Individual	There are health benefits with RDM in comparison to extensively processed milk. Allowing purchasers to use their own bottles is a weakness in the system. Are you able to look at adapting the 'Scores on the Doors' system for these producers/sellers?	The issue of potential health benefits associated with RDM was addressed in the December FSA Board paper which concluded that at present, the evidence that has been submitted does not provide robust evidence of health benefits to humans. The FSA recognises there are a number of reasons why consumers choose to drink RDM. Proposed controls seek to provide a balance between protecting public health whilst also allowing consumers to make informed choices. The FBOs are responsible for ensuring the food they place on the market is safe under Regulation (EC) 178/2002 - Article 14, and thus the duty and onus is on the FBO to ensure that the food they place on the market is fit for human consumption. Decisions on whether to allow customers to fill their own containers and how potential risks should be managed is a decision of the business owner. More information on containers for raw cows' drinking milk can be found on our website. The Food Hygiene Rating Scheme (FHRS) provides a snapshot of hygiene standards found at the time of inspections carried out by local authorities' to check compliance with food hygiene law. The scope of FHRS includes all food businesses that supply food direct to consumers. Therefore, producers of raw drinking milk fall within the scope of the scheme. Following inspections, food businesses covered by the scheme are provided with stickers showing their rating. In Wales, food businesses are required by law to display their food hygiene ratings at their premises,

Respondent	Comment	Response
		whereas in England food businesses are encouraged to do so. A food hygiene rating takes account of how risks are managed by the business and the controls that are in place to manage those risks. It is not an indication that any risks have been entirely eliminated, but is a measure of how a food business complies with food hygiene legislation requirements. Businesses are responsible for complying with food safety legislation at all times. There are increased risks with consuming certain foods such as RDM. The FSA has given advice to consumers on consuming RDM, particularly to vulnerable groups such as pregnant women, the young and elderly and those severely immunocompromised. This advice should be considered even when a business has a top FHRS rating.
Individual	This doesn't cover whether the introduction of an FSMS would be mandatory or not, and what happens on failure to meet the standards. The Sampling Costs section of the document deliberately fails to take into account the water sampling costs, with no guidance in the consultation for what the risk is based on or required frequency of water sampling based on the risk factors involved. Milk samples, as couriered to a lab, have spent time sitting outside of a controlled environment and may arrive significantly bacteriologically different from the state in which they left the farm - do the preservatives used in sample bottles allow for accurate bacteriological counts as they would have been at time of sample collection?	Comment noted. The legal basis for FSMS's will be clear in the guidance document. Regulation (EC) No. 178/2002 General Food Law places the responsibility for the production and supply of safe food, such as raw drinking milk, solely with the FBO. As the supplier of raw drinking milk direct for human consumption, the FBO has responsibility for ensuring that the milk does not present a health risk to consumers. Having a documented FSMS will help FBO's demonstrate how they comply with food safety and hygiene legislation and control food safety hazards. Producers must ensure appropriate steps are included in their FSMS to ensure water is safe at the point of use (e.g. taking account of source and methods or systems for

Respondent	Comment	Response
	Section 13. This states that the levels of consumer risk over time remain constant. However, it's not clear how measurement on the stated "over time" basis averages out. Is the "constant level of risk" based on six outbreaks in fourtheen years (2003 to 2017), or four outbreaks in 2017? Section 21. No livestock gets milked five days a week. Milking is at least once, and most likely twice per day, every day that the animal is producing. Section 23. The "net zero" difference to FBOs under the suggested FSMS appears to be based on four official visits per year at one hour each vs longer but less frequent inspections. However, this takes no account of the additional burden of the required records keeping and sampling. Just the thirty minutes quoted to extract, package and dispatch the samples monthly adds six hours, and this appears to be based on an immediate and convenient dispatch rather than the standard "hang around and hope that the courier arrives in a one-hour timeslot".	delivering water on-farm) and should determine the appropriate testing frequency as part of their FSMS. The guidance document will be amended to clarify advice in relation to water sampling. Sampling frequency should be risk based and established by individual businesses within FSMS. Different tests require different sample bottles, and while some may use preservative, most common bacterial tests require live bacteria to grow in the lab therefore we would not use a preservative in the sample bottle. Sterile empty sample bottles or filled containers as offered for sale are used to ensure that samples are not contaminated during collection. All samples collected by FSA officers are sent to the labs under strict temperature controls to protect and preserve the samples. Equipment is used to monitor and record these temperatures during transit and on arrival at the lab. This ensures the milk samples at point of testing are representative of the milk supplied to the consumer. Due to the rising trend in RDM incidents experienced between 2014 and 2017, it was considered reasonable to assume that the number of cases would stay at 2017 levels or even increase in a worst-case scenario. As the assessment of public health benefits associated with the proposed change in the Impact Assessment has been undertaken qualitatively only, the difference between these assumptions does not alter the assessment nor the rationale for intervention. Further information on the number of outbreaks associated with RDM can be found in the June 2018 FSA board paper.

Respondent	Comment	Response
		The FSA acknowledges that milking takes place seven days per week and that the assumption in the IA is incorrect. If we assume that milking takes place between once and twice a day, the overall annual costs to the industry for record keeping would, on average, increase from £41,000 annually to £71,000 annually. The net zero cost references in paragraph 23 only refers to the additional burden of complying with official controls (i.e. visits by DHIs) in productive time lost to RDM producers. We have taken into account the "additional burden" of sampling and record keeping, based on an assumption of 6 additional hours per week, in paragraph 21 and 22. We appreciate that the assumption might underestimate the costs of individual producers and that these times can vary from case-to-case. However, the assumption was considered a reasonable average and we have not received evidence which would enable us to improve this assumption.
	The second Section 21 (Competition Assessment). The sales channels legally permissable for RDM force producers to limit themselves to a local market. The loss of an RDM producer is likely to simply eliminate the availability of the product in that location. There is significant evidence from animal testing that shows the health protective benefits of raw milk.	This comment is noted. There are no planned changes to the current restrictions on routes of sales. The issue of potential health benefits associated with RDM was addressed in the December 2018 FSA Board paper which concluded that at present, the evidence that has been submitted does not provide robust evidence of health benefits to humans. The FSA recognises there are a number of reasons why consumers choose to drink RDM. Proposed controls seek to provide a balance between protecting public health whilst also allowing consumers to make informed choices.

Respondent	Comment	Response
Individual	In Annex **B** Impact Assessment Section 5 of the consultation documents, the text states that there has been an increase in the number of outbreaks of illness associated with the consumption of RDM, especially over the period 2016/2017. What is the source(s) of this data? Can you provide the references please. Another "risk food" that the FSA has fairly recently issued guidelines/ regulations concerns the preparation and sale of pink burgers. Has the drafting of Annex **D** guidance for RDM producers in England & Wales been influenced in any way by the FSA's experience with pink burgers? Does the FSA think that there is a level playing field regarding what is being demanded of the pink burger FBOs and what is proposed for the RDM producers, including micro-biological data?	Please refer to the risk assessment carried out by the ACMSF on whether the microbiological risk associated with consumption of raw drinking milk (and certain raw milk products) made in the UK has changed since 2015. The FSA has a framework for risky foods and that was used in the development on proposed controls for RDM proposals and less than thoroughly cooked burgers - please refer to the June 2018 FSA Board Paper. The framework for risky food ensures controls 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.

Responses from Food Business Operators (FBOs)

Respondent	Comment	Response
FBO	Paragraph 28. According to the guidance on the FSA website, a raw milk producer, once clear of TB, has to go through the whole registration process again, even if there has been no pause in their FSMS and verification testing. Even for an unconfirmed TB breakdown (e.g 2xIR, no VL at PM and culture -ve), this means being closed for a minimum of 120 days and then having to go through re-registration before being able to sell again. The breakdown may not even have been in the milking herd. We feel the FSA's approach to TB breakdowns need to be rethought and at the very least given more space in the guidance document than it has been.	We note your comments and recognise the issues concerning TB breakdowns and Officially Tuberculosis Free (OTBF) status. We have reviewed our processes for this in relation to RDM production and the guidance document will be amended to provide clarity. Producers must ensure appropriate steps are included in their FSMS to ensure water is safe at the point of use (e.g. taking account of source and methods or systems for delivering water on-farm) and should determine the

	Paragraph 29. It would be usual to make a distinction between a mains water supply and a private one. We question the validity of testing a mains water supply except perhaps once on registration, if no changes are made to the way the water is transported from the point of supply to the property to point of use.	appropriate testing frequency as part of their FSMS. The guidance document will be amended to clarify advice in relation to water sampling.
	Paragraph 54. We would like more clarity on where the FSA remit ends and the EHO remit starts. We were surprised to see that paragraph 21 of the impact assessment assumes that we only milk the cows five days a week, showing a concerning lack of understanding of this part of the process. Generally however, we are supportive of the proposed approach and welcome the provision of the sort of guidance which is already available in other parts of the industry e.g. cheese making.	The split of responsibilities between EHOs and DHIs will be made clear in the guidance document. The FSA acknowledges that milking takes place seven days per week and that the assumption in the IA is incorrect. If we assume that milking takes place between once and twice a day, the overall annual costs to the industry for record keeping would, on average, increase from £41,000 annually to £71,000 annually.
FBO	Are paragraphs 32 and 34 related to mains water too? Also I find paragraphs 16 and 26 confusing and inconsistent.	Producers must ensure appropriate steps are included in their FSMS to ensure water is safe at the point of use (e.g. taking account of source and methods or systems for delivering water on-farm) and should determine the appropriate testing frequency as part of their FSMS. The guidance document will be amended to clarify advice in relation to water sampling. Point 16 is a legal requirement specific to RDM. Point 26 b is a legal requirement for all raw milk Anyone producing RDM must meet both standards.
FBO	One very grey area is the farmers markets from my experience. Not all are registered as such and when you contact the local authority to get some clarification on the process of how they can register, it's very confusing. Opening up our markets needs to be more defined.	Producers of RDM may sell raw cows' drinking milk at a farmers' market, under the following conditions : • the intended market is registered with the local authority as a farmer's market as this can be seen as an extension of the farm gate

		• the producer notifies the local authority or makes their intentions known of the proposed sales prior to market dates • the producer is present during the sale The principal producer, representative involved in the production process or member of the family must attend the stall. Information about selling RDM at farmers markets can be accessed via the FSA website. There is currently no intention to relax restrictions on sales routes for RDM.
FBO	We just wish raw milk was not regarded by the establishment as a risk and more of an answer to a some of the health issues that are now prevailing in our country. We would love to see properly funded independent studies into the health benefits of raw milk, as opposed to the over processed 'fresh' milk that is available for the majority of the population to buy in supermarkets. We do believe raw milk could help in so many ways but, it appears, it's all about the risks for governments agencies, it's a shame they seem blind to the benefits. We have people buying our milk, for example, who are lactose intolerant, have eczema, we have doctors coming who are happy to give it to their children or because they see it as the superfood it is! The new testing will impose extra costs on producers. We assume that these detailed tests already apply to perceived risk foods such as some soft cheeses and washed salads etc, otherwise it would appear that raw milk is potentially being singled out unfairly. We would like clarification on that, based on evidence.	The issue of potential health benefits associated with RDM was addressed in the December 2018 FSA Board paper. which concluded that at present, the evidence that has been submitted does not provide robust evidence of health benefits to humans. The FSA recognises there are a number of reasons why consumers choose to drink RDM. The proposed controls seek to provide a balance between protecting public health whilst also allowing consumers to make informed choices. The legislation assigns the responsibility on the FBO for ensuring food placed on the market is safe. Food businesses including those producing raw milk cheeses and washed salads are required to have effective food safety management systems based on HACCP to identify and address potential hazards. Microbiological testing programmes are one of the mechanisms many businesses

	Also, have there been any further ' health outbreaks' since the consultation was proposed in June 2018, to justify the FSA's views, given the higher number of RDM producers? Perhaps the FSA should consider more stringent requirements for people starting selling raw milk, for example a local authority Food Hygiene course, so the few don't spoil it for the many? Further details are needed as to exactly what tests are required and what are optional, it is not completely clear in the document. With regard to the proposed testing and the consultation document, we understand from a FSA employee that the new testing regime is going ahead, so where is the consultation process in this? With regard to water testing, we assume our water is completely healthy as it is purchased from South Staffs Water. It is confusing as to what circumstances the water would need testing, obviously if a farm had its own supply, eg a bore hole, then that would be applicable.	use to demonstrate their food safety controls are effective and being applied properly. By the end of October 2019 there have been two further outbreaks of illness linked to consumption of RDM. Analysis of the available data has shown that there is no correlation between the occurrence of outbreaks and length of time a producer of RDM has operated. Further details are available in the June 2018 FSA board paper. The new enhanced controls are intended to apply to all producers as they meet their responsibilities for placing a safe product on the market. The FBO is responsible for ensuring the food they place on the market is safe under Regulation (EC) 178/2002 - Article 14, and thus the FBO is responsible for establishing appropriate risk based sampling regimes tailored to the business activities to help demonstrate the controls that they are applying are effective and being applied properly. This will be made clear in the guidance document. Responses to this public consultation have been acknowledged and are being fully considered as final decisions on implementation are made. Producers must ensure appropriate steps are included in their FSMS to ensure water is safe at the point of use (e.g. taking account of source and methods or systems for delivering water on-farm) and should determine the appropriate testing frequency as part of their FSMS. The guidance document will be amended to clarify advice in relation to water sampling.

FBO	We welcome an approach that uses a food safety management system (FSMS) as its basis for assessing, managing and monitoring risks. Reduced DHI sampling in favour of giving greater weight to FBO test results is more cost effective and encourages self-regulation, which we hope will both improve the quality of raw milk and the confidence of regulators, whilst offering producers autonomy in managing risks specifically and proportionately. It is important that following this review both existing and new controls are clearly outlined and implemented with transparency. Having all requirements and procedures clearly outlined in writing will benefit both FSA and FBOs. The roles of DHIs and EHOs could also be more clearly defined so we know who to keep informed/ask questions about what, and so the work of one is not replicated by another. We support the testing requirements detailed in the enhanced controls, provided frequency is set by the FBO as required to verify the FSMS specific to the farm. All of the tests detailed in the guidance document are already part of our farm's testing schedule except for STEC. I understand PHE will be testing for STEC, however, we urge the removal of any requirement for FBO STEC testing. The test for STEC is too expensive to be practical for FBOs and very few laboratories can perform it. Instead we test for *E. coli* O157, which we believe should be sufficient. We propose that temperature of the sample itself on arrival at the lab is recorded, as this may help identify the source of any discrepancies between FBO and DHI results. In recognition that plate count and coliform tests are indicators of hygiene and process control and can not be considered to indicate food safety, we propose that results of these indicators should be interpreted as a rolling geometric average, as is the basis of the plate count requirements in Regulation (EC) No 853/2004. A single sample result is subject to factors such as	Comment noted. Roles and responsibilities of FSA and Local Authorities will be made clear in the guidance document. Testing for *E. coli* O157 rather than all STEC provides reduced protection for public health. We acknowledge the burden on businesses and are working with industry and laboratories to establish a pragmatic approach that balances the need to protect public health and the sampling and testing burden. All samples collected by FSA officers are sent to the labs under strict temperature controls to protect/preserve the samples and equipment is used to monitor and record these temperatures during transit and on arrival at the lab. Hygiene indicators are used to monitor effective application of food safety controls and as such, it is important that if high levels are detected they are acted upon. The use of a rolling average may mask any high results or trends in the data, and could therefore offer reduced public health protection. Testing for plate count and coliforms are not be required at the end of shelf life testing and this will be made clear in the guidance document. We note your comments and recognise the issues concerning TB breakdowns and Officially Tuberculosis Free (OTBF) status. We have reviewed our processes for this in relation to RDM production and this will be clarified in the revised guidance document.

	problems with aseptic sampling, laboratory errors, uneven distribution of bacteria within the milk, issues with maintaining temperature control in transport and time in transportation, and many other factors that can greatly affect hygiene indicator results. FBOs are strongly advised to cease sales after a single result that exceeds indicator criteria, which may be an anomaly. Assessing results based on a rolling average gives a more accurate picture of the cleanliness of the milk and encourages constant monitoring for trends and continuous work to improve test results rather than being satisfied providing the most recent test has passed. Therefore, this measure would be likely to improve the quality and safety of the milk whilst avoiding loss of sales and reputation in the event of an anomalous result. The guidance document raises a new requirement for testing for plate count and coliforms at end of shelf-life. I have seen no historical evidence for this, but it may reasonably be assumed that plate count and coliforms will increase over the life of raw milk, as both of these tests include detection of psychrotrophic organisms that will naturally grow in refrigeration. The only psychrotrophic pathogen of concern is *Listeria monocytogenes*, which is a separate test required at end of shelf-life. *Salmonella spp.,* STEC, *Camplobacter spp.* and Coagulase Positive Staphylococci are unable to grow during refrigeration, and therefore are effectively covered by pathogen testing at end of production. This, combined with the fact that, as mentioned above, plate count and coliforms are not indicators of food safety, suggests that testing for these at end of shelf-life offers no value for food safety. Losing OTBF status represents a great deal of stress and loss of income for a raw milk producer for an absolute minimum of 4 months. Currently, when OTBF status is regained the FBO must re-register to sell raw milk, which in some cases can take 6 weeks. With the enhanced controls registration will take significantly longer. We	The FSA has no current plan to further review sales restriction on RDM.

	suggest that provided the FBO has continued with their FSMS and testing, sales should be allowed as soon as OTBF status is regained. I understand this is outside the scope of this consultation but I hope there is the possibility of reviewing the sale restrictions on raw cows drinking milk in the future.	
FBO	As an RDM FBO, these are my comments on the options. The current controls are not sufficiently adequate to protect the consumer from an FBO that does not understand the pathogen risk in raw milk. With increasing numbers of raw milk producers selling raw milk, there is an increasing risk of food poisoning illness from raw milk with the current controls whereby minimum testing is FSA quarterly testing of coliform and TVC. There currently is no requirement for the FBO to do any testing. Most FBOs would receive Bactoscan testing results provided by their wholesale milk buyer. However, not all RDM producers supply milk to a wholesale supplier. Between quarterly testing by the FSA, a serious pathogen problem has time to develop. Without pathogen testing, this will first manifest itself with food poisoning illness which is too late. Current FSA quarterly testing and no obligation for the FBO to pathogen test will not protect the consumer from pathogen food poisoning from raw milk. It is absolutely essential that FBOS understand the pathogen risks in raw milk production, how to mitigate those risks, and how to validate the production of pathogen free RDCM with testing. No reference is made to the possible health benefits in consuming raw milk, such as alleged improvement in micro biome, allergies, eczema, cholesterol etc. Given that there are possible significant savings on the public purse and cost of health care, should the FSA or Public Health England be conducting research in these areas? Why is this not happening, when it seems there are increasing strains	Comment noted. Effective controls are important in protecting public health. RDM can contain pathogens harmful to health and an effective system to reduce the risks of this happening is needed. The new controls which were agreed by the FSA Board are evidence based and intended to improve food safety. The issue of potential health benefits associated with RDM was addressed in the December 2018 FSA Board paper which concluded that at present, the evidence that has been submitted does not provide robust evidence of health benefits to humans. The FSA recognises there are a number of reasons why consumers choose to drink RDM. Proposed controls seek to provide a balance between protecting public health whilst also allowing consumers to make informed choices. The primary objective of the FSA is to ensure food is safe and what is says it is and our current work on RDM is focused on this objective. We acknowledge this additional information on the expected impacts and have revised the assumptions underpinning the cost estimates for implementing a FSMS accordingly. We assume that it will take each RDM producer at least 8 hours

	put upon the health service by the consumption of increasingly processed foods? The estimate given for four hours to draw up the equivalent of a HACCP for a dairy farm producing raw milk is not realistic. Our own experience involved a great deal of process assessment, in order to pinpoint areas of risk, critical control points, risk mitigation, and validation. This certainly is not a four-hour process. If done properly, expert advice must be employed in producing a HACCP, as this is not an area a dairy farmer knows, and raw milk production is a specialist area of food production within the food industry itself. This will cost at least £1500, depending upon how much the dairy farmer can do. I note it will cost £30,000 to train 41 DH Inspectors, whereas the FSA estimate a raw milk industry cost of £10,055 for 161 producers to get up to speed and who really need to have at least the same level of knowledge being the producer of RDM! I agree that a herd should be TB free. However, the current skin test upon which a herd's TB free status is determined, is simply not fit for purpose, for the farmer, or for the consumer, and does not protect public health. • The skin test only finds 80% of TB animals, 20% of TB infected animals can go undetected • It is a test for immune response to TB, it does not detect the presence of TB itself. Why are animals being culled when they have an immune response to TB? Shouldn't we be blood testing these animals for TB to see if they actually have TB? Otherwise we are continually culling out the TB resistant animals in the national herd! • Currently there is no requirement to test for the actual presence of TB in raw milk, though such testing is available • If for example *E. coli* is found in raw milk, sales are ceased until it is shown there is no *E .coli* in the milk and sales can	to set up an FSMS if they arrange it internally. As a lower bound, we assume that all producers would be able to deliver this internally. As an upper bound estimate, we take into account that up to 50% of RDM producers would require advice from an external party with an estimated cost of between £1500 and £3000. Given these assumptions, the total estimated one-off cost to industry for implementing a FSMS would, on average, increase from £10,000 to £72,000 (or £445 per producer). It should also be noted that costs for individual producers might differ from these estimates due to each producer's own particular set of risks. Moreover, the impact assessment assumes that no RDM producer already has a bespoke FSMS in place. However, based on your response and other information gathered since publication we have been made aware that many RDM producers have a bespoke FSMS already in place which would reduce the associated costs. Responsibility for TB detection and disease control is the responsibility of Defra/Animal and Plant Health Agency and the testing of raw milk for TB is outside the scope of this consultation. The overall TB risk for human consumption of pasteurised milk is "negligible" due to the current control measures such as milk pasteurisation. The FSA has already considered TB risks associated with meat and milk. The ACMSF considered the potential health risks associated with *Mycobacterium bovis* and milk (ACM/1047a, ACM/995). This risk assessment was taken into account as we developed recommendations for RDM controls.

	resume. However, if an animal in the herd is a positive reactor, even though it can be evidenced whether or not there is TB in her milk, sales of raw milk stop until two clear whole herd skin tests are achieved, irrespective of whether TB is actually present. It is incredulous that quite rightly there are proposed improvements to the controls in pathogen risk in raw milk, yet this TB issue is not being addressed, just merely swept under the carpet with only one sentence given to the risk from TB at point 28. Should the FSA or Public Health England look at what the real risk is from TB in meat and milk? Either there is or isn't a public health risk from TB! With the decision to lower the public health risk with increasing raw milk sales have the FSA and Public Health England not also got a duty of care to the British public to use more modern science to now understand better this food TB risk in raw milk and rare cooked beef?	
FBO	We have a large following of customers who rely on our milk for their health and pleasure and would be devastated if we were forced to stop supplying them. The foremost point in your latest Consultation Summary is that of new producers who, of no fault of their own, may never be able to produce sufficiently clean milk consistently with the new methods available. Robotic milking units, with the best will in the World, will never be able to replace the eyes of a herdsman. We all know how long it takes to clean an udder which has been inadvertently placed on a "spring" cowpat and I feel that it is unfair to let a potential producer believe it will be easy. This could also give a bad name to raw milk. It is also becoming popular for people to bring their own bottles which may help the environment but, in our experience these are often extremely smelly and would tum milk in a very short time - with the producer being blamed. I believe all plastic milk bottles are now recyclable so maybe this practice should be discouraged.	The FSA recognises there are a number of reasons why consumers choose to drink RDM. Proposed controls seek to provide a balance between protecting public health whilst also allowing consumers to make informed choices. Analysis of the available data has shown that there is no correlation between the occurrence of outbreaks and length of time a producer of RDM has operated. Further details are available in the June 2018 FSA board paper. The new enhanced controls are intended to help all producers meet their responsibilities for placing a safe product on the market. The FBOs are responsible for ensuring the food they place on the market is safe under Regulation (EC) 178/2002 - Article 14, and thus the duty and onus is on the FBO to ensure that the food they place on the market is fit for human consumption. Decisions on whether to allow customers to fill their own containers and how potential risks should be

	A big danger if the sale of raw milk is banned is that those who now drink it will start pressing unregistered producers to supply them as raw milk is used for the control of many complaints such as Asthma and Eczema with doctors now recognising the fact and sending their patients to us.	managed is a decision of the business owner. More information on containers for RCDM can be found via the FSA website. The issue of potential health benefits associated with RDM was addressed in the December 2018 FSA Board paper which concluded that at present, the evidence that has been submitted does not provide robust evidence of health benefits to humans.

Responses from Trade Associations

Respondent	Comment	Response
Food Solutions	Welcome FSA proposal to enhance labelling rather than to ban the sale of raw milk. A ban would clearly be in breach of the final report of the High Level Forum for a Better Functioning of the Food Supply Chain published by the Commission in February 2019 which makes clear that national rules in excess of EC Regulations should not be a barrier to trade especially to SMEs. Welcome proposal that RDM producers should have in place an effective and verified Food Safety Management System. This we believe is demanded anyway in Article 5 of EC 852/2004 which specifies the HACCP procedure. Urge the FSA to take steps to ensure that there are adequate testing facilities available. Surprised that your report to the FSA Board claimed that there was no scientific evidence that RDM could have any beneficial effects. Comments from consumers quoted in our report following the survey that many well qualified persons claim benefits.	Comment noted. The availability of testing facilities has been discussed in a recent industry stakeholder meeting and we are working with the industry to explore pragmatic sampling and testing regimes for producers. We are aware of some consumers reporting potential health benefits associated with RDM. This was addressed in the December 2018 FSA Board paper which concluded that at present, the evidence that has been submitted does not provide robust evidence of health benefits to humans. The FSA recognises there are a number of reasons why consumers choose to drink RDM. Proposed controls seek to provide a balance between protecting public health whilst also allowing consumers to make informed choices. FSA acknowledges that milking takes place seven days per week and the assumption in the IA is incorrect. If we assume

	Unrealistic assumption where it is claimed that dairy farmers only work a five-day week. If that were the case, then it should be a subject for the animal welfare authorities to take appropriate action. FSA survey only took comments from producers, officials and learned bodies. Need comments from real people who actually use RDM. Therefore to ensure democracy these people's views must be taken into account.	that milking takes place between once and twice a day, the overall annual costs to the industry for record keeping would, on average, increase from £41,000 annually to £71,000 annually. The FSA conducted extensive consumer research to understand more about consumption and attitudes to raw milk to inform its review of RDM controls. This included innovative consumers events, focus groups and consumer surveys. The most recent research, 'Raw Drinking Milk Consumer Research' was published in May 2018.

RMPA	(3). The **health warning** "*This milk has not been heat-treated and may therefore contain organisms harmful to health"* currently applies in England & NI. Does the FSA have a timing for when the additional health warning wording, relating to the recommendation that raw milk should not be consumed by the young, elderly or immuno-compromised, will come into effect in England & NI? And what will the lead-time for label changes / bottle re-prints be? In Annex B of the consultation it states that we should not sell to vulnerable people, but as an FBO this is impossible for us to monitor or control. Can you give more guidance on how we are expected to control this? (8). Can you explain what this statement means "The guidance should not be taken as an authoritative statement of interpretation of the law, as only the courts have this power." (16 & 26. (b)) "**Plate Count**" is used twice with two different reference standards: 16.Schedule 6 of The Food Safety and Hygiene Regulations (England) 2013 and The Food Hygiene (Wales) Regulations 2006, which specify that raw milk must meet the following standards a. Plate count at 30°C(cfu per ml) ≤20,000 and 26.b: Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I, Part III, point 3 which requires Plate Count rolling geometric average must be equal or below 100,000 per ml (over a two-month period, with at least 2 samples per month). Please can you clarify what these two different standards refer to. (16) We understand there is a fairly good conversion of **Bactoscan** to TVC and many producers will be having regular bactoscan done by their first purchaser. Will your DHIs accept bactoscan in place of TVC, if so, what is the equivalent threshold?	A date is not yet known for a label change in England, but any changes to the labelling requirements will provide a 3-year transitional period. In Northern Ireland the additional health warning came into operation in June 2019. FBOs should provide appropriate information to consumers, including vulnerable groups of the risk associated with consumption. The FSA provides recommendation to consumers and highlights the risk to vulnerable groups so they can make informed choices. Comment noted. This statement will not be included in the final guidance document. Point 16 is a legal hygiene requirement specific to RDM. Point 26 b is a legal requirement for all raw milk and an indicator of hygiene and herd health. Anyone producing RDM must meet both standards. Dairy Hygiene Inspector's (DHI) accept TVC values obtained from the conversion of Bactoscan values so they will need to be provided with Total Viable Count (TVC) following conversion. Please see the conversion factor on the FSA website. Yes, for *Listeria monocytogenes* testing for RDM with a shelf-life of 5 days or more there are two options: either absence at bottling (in 25g), or max 100cfu/g at end of shelf life - but not both. There is a legal requirement under Regulation (EC) 853/2004. Food business operators must initiate procedures to ensure that raw milk meets the following criterion. For raw cows milk, plate count at 30ºC (per ml) ≤ 100 000. This must

	(20 & 21) ***Listeria*** *monocytogenes* testing: please would you confirm that for RDM with a shelf-life of **5 days or over** there are two options: *either* absence at bottling, *or* max 100cfu/g at end of shelf life - but *not both?* (32) The **number of tests** required to start selling raw milk are specified in the consultation as a compliant full set of test results (plate count, coliforms and pathogens) for the milk and the water supply for each month during 2 consecutive months. In effect, n=2. Or do producers still have to have TVC done every two weeks regardless? This may be answered under point 37 of the consultation but no equivalent threshold for bactoscan is given. Understood that best practice would be both, but we would like to be clear about what the legal requirement is. The FSMS, that the DHIs will be inspecting, will include measure at the bottling stage, cleaning records, temperature checks, personal training pre-requisites, etc. A visit from an EHO will also include inspecting this same FSMS. Can we get more clear guidance for our producers, that they can show their EHO, which clearly delineates where one functions starts and another stops? Ideally on the FSA website so that we can send a link to our EHO. Please would you confirm if this also applies to shelf-life testing, e.g. producers must have two consecutive set of compliant durability tests? We feel the **TVC and coliform** requirement should be based on rolling geometric average as the EU legislation requires for plate count. Microbiologists agree that a single hygiene indicator result is meaningless viewed in isolation, but highly valuable in viewing trends. FSA data team found that 21% of DHI samples failed on one of the hygiene indicators, whilst hygiene indicator failures has not	be carried out using a rolling geometric average over a two-month period, with at least two samples per month, independently of whether the raw milk is intended for further processing or not. The Regulation establishes the sampling frequency as 2 samples per month. In addition, the Food Safety and Hygiene Regulations (England) 2013 and The Food Hygiene (Wales) Regulations 2006, Schedule 6, criteria applicable to raw drinking milk are plate count at 30°C (cfu per ml) ≤ 20,000 and coliforms (cfu per ml) < 100. There is no testing frequency of plate count, coliforms or pathogens. Producers should establish appropriate sampling and testing regimes based on the risks associated with their business and production and to provide assurances that their FSMS is effective. Dairy Hygiene Inspector's (DHI) accept TVC values obtained from the conversion of Bactoscan values so they will need to be provided with Total Viable Count (TVC) following conversion. Please see the conversion factor on the FSA website. The split of responsibilities between EHOs and DHIs will be made clear in the guidance document. FBOs should determine the appropriate testing frequency as part of their FSMS.This section of the guidance document will be made clear. The use of a rolling average may mask any high results or trends in the data and could therefore result in reduced public health protection. It is correct that *Listeria monocytogenes* can grow at refrigeration temperatures which is why Regulation (EC) 2073/2005 lays down limits and requires shelf life testing in

	been correlated with presence of pathogens or outbreaks. A single result may be caused by a sampling, transport or laboratory error, but a rolling average removes anomalies and provides a real picture of changes in the cleanliness of the milk. If only *Listeria* can grow at fridge temps, why do we need to test for all pathogens at end of shelf-life and not just listeria?	certain circumstances to show levels do not exceed 100 cfu/g. For other pathogens testing can generally be carried out at any point in the shelf life, as determined by the food business operator. We will clarify our advice on shelf life testing in the guidance.

DAIRY UK	Dairy UK supports the need to tighten controls in this area, especially with new developments on the market which have increased and will continue to increase the risk that RDM poses to human health in the UK (e.g. the rise of vending-type machines on farm). However, we do have a number a concerns which we would appreciate clarification on: How often will the FSA monitor these controls and how often will the final product be tested for contaminants (chemical and microbiological) by national authorities? Will RDM producers be required to share relevant results with the FSA on a regular basis, in a similar way as milk processors currently do? What will be the protocols in place for dealing with a potential food incident (e.g. product recall, etc.)? Should these controls not provide the desired effect, what other requirements will be put in place to manage the risk? We do not have comments on the six month transition period. Dairy UK remains of the view that all milk in the UK should be pasteurised before consumption.	Comment noted. The FSA intends to monitor twice yearly for plate count, coliforms, *Salmonella* spp., *Campylobacter* spp., STEC *Escherichia coli*, coagulase positive staphylococci and *Listeria monocytogenes.* This is in addition to the other official controls that take place including inspection visits. More information can be found here. There is a legal requirement for an FBO to notify the competent authority of any indication that their product is unsafe to consume. DHIs will review testing results as part of the audit of the FSMS during their 6 monthly visits. The FSA has an internal incident protocol which would be instigated. Please see our 'Guidance on Food Traceability, Withdrawals and Recalls within the UK Food Industry' to fully understand the responsibilities of the FBO and the coordination role of the FSA, and how to decide, plan and manage a withdrawal or a recall. In the Board meeting of December 2018, the FSA Board agreed the criteria that would prompt the need for a review and reconsideration by the Board. We have noted your comments.
E.Coli UK (Consumer Advisor on E.coli O157)	Increasing hygiene controls by the introduction of a Food Safety Management System (FSMS) may be helpful, but on its own it is not going to solve the problems of increased illness caused by the increased sales of raw milk. This could only become a possibility if all batches of raw milk, including those used for cheeses in England	The FSA Board meeting in December 2018 reported that 'The Board agreed with the conclusion that the risk from RDM is not so unacceptable as to justify removing the right of adult consumers to choose to drink it, provided that certain controls are met (that right also carries with it a

	and Wales and those from elsewhere such as Europe etc., were microbiogically tested and discarded unless they were clear of all bacterium. Your own statistics and other Government Department reports show that as sales of Raw Milk increase, so have the number of outbreaks and cases of illness from bacterium such as *E. coli* O157, *Campylobacter* & *Salmonella.* Reports such as: The Zoonoses Report UK 2017 stated on page 18 under *"Feature article 3: Shiga-toxin producing Escherichia coli O157 outbreak associated with consumption of raw dairy milk. Authors: Lisa Byrne, Gastrointestinal Infections, National Infections Service, Public Health England* The ACMSF said in their report of 07/03/2018 into Campylobacter "7.2.4 The principle cause of contamination in milk is the faeces, on the external surfaces of the udder and teat. Hence reducing faecal contamination of the udder before milking is a key step, as is good animal husbandry through avoiding mastitis. EU Regulation 853/2004 requires that milking is carried out hygienically by ensuring that the teats, udder, and adjacent parts are clean. Despite best efforts, it is inevitable that some contamination with faecal material will occur, and equipment used for milking, such as suction cups, pipes, buffers and holding tanks may allow contamination to spread more widely." This is clearly saying that contamination is inevitable, that is why some experts refer to raw milk as 'liquid manure'. Whilst individual FBO's have a legal responsibility to ensure their food is safe, there is also a morale collective responsibility by Government Departments to ensure the safety of the consumer and citizen in their decision making processes. Given that the FSA was set up in 2000 to protect the public's food after BSE, it seems	responsibility for vulnerable groups in their care). However, the Board recognised that 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. The proposed controls seek to provide this balance between protecting public health whilst also allowing consumers to make informed choices. Outbreak data will be monitored, and this includes the vehicle for the outbreak, for example whether the RDM was sold via a vending machine or not, to see if there are any patterns where action may be necessary. There is a legal requirement for the FBO to have health warnings at the point of sale of RDM.

	strange that they should allow an increase in sales of raw milk knowing scientifically of its dangers to public health. Whilst you appear to be happy to inform consumers on your website, you do not appear to do so at the point of sale via labelling or otherwise such as "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"	

Responses from Local Authorities

Respondent	Comment	Response
South Lakeland District Council Food and Safety Team	We welcome the clarification of the role of the Dairy Operations Unit in paragraph 1 of the Assessment of Impact document. We are concerned that some confusion of enforcement roles remains in that Environmental Health Officers remain responsible for bottling/filling operations of RDM. This situation creates extra burdens on the FBO who having set up a documented management with the DHI must then repeat the process with EHO staff for bottling processes. If this final step is to remain the responsibility of a secondary authority (EHOs) communication links will need to be rigorous between officers/visits. Some of our officers believe the bottling /filling should be enforced more effectively by the DHI as the final step of the FSMS, particularly in view of the warning label requirements. Paragraphs 10 and 11 of the Assessment of Impact document would appear to contradict the dual enforcement roles and does not identify the EHO role. We welcome the additional resource of 9 full time DHIs to examine the FSMS and sample records as well as the structures of the dairy. We suggest however	Comment noted. The split of responsibilities between EHOs and and DHIs will be made clear in the guidance document. Responsibility for controls applicable to vending machines currently sits with LA's. We note the points that you have made around changes to responsibilities but these are outside the scope of this consultation. The FBO is responsible for ensuring the food they place on the market is safe under Regulation (EC) 178/2002 - Article 14, and thus the FBO should establish appropriate sampling regimes to help demonstrate the controls that they are applying are effective and being applied properly. This will be made clear in the guidance document. Yes - the last sentence of paragraph 38 of the guidance refers to DHI carrying out the testing once per year.

	that 4 hours per annum (para 23) would not be sufficient time to examine all aspects of the process. Welcome revised arrangements for microbiological examination parameters to include pathogen testing and Regulation (EC) No 2073/2005 standards and the strengthening of follow up action detailed in the guidance. More clarity on frequency of sampling to provide sound evidence would be useful. (Regulation 2073 should be referenced at paragraph 21 of the guidance). Para. 38 of the guidance concerning compiling evidence from samples seems to be a little limited. Have the microbiologists contributed to what number of samples can be regarded as evidence? Should the last sentence of paragraph 38 of the guidance refer to DHI carrying out the testing once per year.	
East Suffolk Council	When it comes to raw cows drinking milk the big challenge for local authority food hygiene inspectors is the specialist nature of the subject matter. I am of the opinion that all aspects of enforcement should be undertaken by Food Standards Agency dairy inspectors. Having one enforcement body should ensure that a consistent approach is applied to both enforcement and the advice given to the food business operators. In addition to the above comments the confusion over the application of a use by date on bottled raw cows drinking milk desperately needs to be addressed. As it stands at the moment trading Standards are advising raw cows milk providers that there is no requirement to apply a use by date on bottled milk. Food Standards Agency officers however are advising a use by date does need to be applied as per the information on the Food Standards	Comment noted, but outside the scope of this consultation. We acknowledge the need for consistent advice on use by dates and will work with relevant parties to ensure this is provided.

	Agency website. This inconsistent advice put Local authority inspectors in a difficult position and undermines their authority.	
Caerphilly County Borough Council	The FSMS controls should already be in place as they are specified in legislation so a lead in period should not be necessary. Paragraph 10 "For queries on approval and the further processing of dairy products, businesses should contact the environmental health/trading standards department". Environmental health deal with approvals, so it would be more pertinent to put this department as first contact. Paragraph 12 "All farms producing raw cow's drinking milk must notify and register with the FSA's Registrations and Approvals team". Other species of RDM would be LA responsibility so this needs to be specific. The guidance should state:- 'For other species of RDM you should contact your LA for registration'. It would be useful to include a pictogram of DHIs/LAs in relation to responsibilities, activities and species. Paragraph 21-23 This is confusing and open to misinterpretation. There is a risk that FBOs would believe that the product is safe for up to 4 days and that *Listeria monocytogenes* would not grow within this product. It would be more appropriate to say:- "Producers need to demonstrate that *Listeria moncytogenes* will not exceed 100 cfu per ml throughout the shelf life of the product". All pathogens should be considered for shelf life not just *Listeria monocytogenes*.	The recent review of RDM controls highlighted the need to make the requirement of a FSMS more explicit. Not all existing producers will have this in place, therefore a six month transitional period would be proportionate to allow them to meet the requirements. Comments noted and will be taken into account in the guidance document, to make clear the points that have been highlighted as confusing or unclear. The guidance reflects the requirement of regulation (EC) 2073/2005 which states that food with a shelf life of less than 5 days should be considered as a food that will not support the growth of *Listeria monocytogenes*. We will clarify the guidance on the requirements for *Listeria monocytogenes* and on shelf life testing demonstrated. For more information please see FSA guidance on Regulation (EC) 2073/2005. *L. monocytogenes* can grow at refrigeration temperatures which is why Regulation (EC) 2073/2005 lays down limits and requires shelf life testing in certain circumstances to show levels do not exceed 100 cfu/g. For other pathogens, testing can generally be carried out at any point in the shelf life, as determined by the food business operator. We will clarify our advice on shelf life testing provided in the guidance.

	Paragraph 25 Microbiological safety It would be clearer if all the pathogens (including *Listeria moncytogenes*) were listed in one table together with their acceptable limits. **Annex A** Temperature Check Records would benefit from including critical limits to guide the FBO. **Annex B Permitted marketing routes for RCM** This pictogram is very helpful.	We have addressed *L. monocytogenes* separately due to the specific reference to it and its requirements in Regulation (EC) No 2073/2005. The legal temperature requirements are defined in Regulation (EC) 853/2004. Comment noted.
	FSMS It would be very useful if a template FSMS along with the record sheets could be provided to assist FBO's in this process. If the DHI is responsible for deeming the FSMS as satisfactory the document needs to be consulted on with the LA for the bottling aspect and private water supplies prior to the registration visit. **Food Hygiene Rating Scheme** As this product could be sold through farmers markets and vending machines a FHR will be required to be issued and displayed particularly in Wales. Would the DHI/FBO inform the LA of any failures in the FSMS such as unsatisfactory sample results to inform this rating? **General** It would be useful to include this link to the FSAs website in the guidance document:- https://www.food.gov.uk/business-guidance/raw-cows-drinking-milk	FSA considers it is more appropriate for industry to develop its own detailed guidance on implementation of FSMS. The DHI will seek to work collaboratively with the LA to ensure all elements of the FSMS and RDM operation are assessed properly. There is a legal requirement for an FBO to notify the competent authority of any indication that their product is unsafe to consume, if unsatisfactory results are reported then the LA officer responsible will be notified in case of any impact that this may have on any FHRS score. Comments noted. Work is currently underway to review the content on our website, this should be updated soon.

	Is it necessary to have two different pages for RDM? This could be confusing. Should they be merged? https://www.food.gov.uk/business-industry/farmimgfood/dairy-guidance/rawmilkcream	

Actions to be implemented

- Review of guidance document to include changes agreed as part of this consultation, namely once the FSA have received notification of the TB free status from APHA, the DHI will visit the FBO premises. In order to meet their legal obligations, the FBO will need to demonstrate that their FSMS remains effective and provide test results to demonstrate verification of this.
- Taking into account comments raised as part of this consultation that name parts of the guidance document as unclear or confusing and making these elements clearer and more defined
- Making the section on water testing within the guidance document clearer to include that sampling of private water supply will be needed but that for mains water it will be up to the producer and the steps included in their FSMS to meet their legal obligation of proving that the water is safe.