RAW DRINKING MILK PROGRAMME (RDM)

Contact: SRO - Simon Dawson

SUMMARY

1. In July 2015, following a policy review, the FSA Board agreed to continue existing official controls and restrictions governing the sale of raw drinking milk. The Board requested some additional changes to improve transparency, provide clearer consumer information and improve information available to producers.

2. Over the last 18 months, there has been a noticeable increase in the number of producers who sell Raw Drinking Milk (RDM) and a rise in the number of outbreaks of human illness attributable to the consumption of the product.

3. An internal audit of official controls in RDM, in summer 2017, also identified areas for improvement in governance, risk management and control.

4. In September 2017, the Board, concerned with this potential changing landscape, asked the FSA to increase its focus on the issues and controls surrounding RDM. This interim paper provides an overview of and an update on improvements in the delivery of official controls for RDM. The paper also includes progress following the 2015 policy review, initial findings from latest economic/customer research and an update on the RDM risk assessment.

5. The paper primarily focusses on raw cows drinking milk, although milk from other species (e.g. sheep and goats) has been considered as part of the risk assessment and customer insight work.

6. In June 2018, a further paper will be submitted to the Board with proposed changes to improve the assurance of RDM Milk production. The paper will present the latest findings and conclusions on RDM and will seek approval on recommendations to improve the existing controls for raw milk.

7. The Board is asked to:

    - **Note progress** at the interim stage
    - **Discuss** any specific areas of interest that need to be drawn out in greater detail in the June paper

RDM CONTROLS IN ENGLAND/WALES AND NORTHERN IRELAND

8. In 2012, the responsibility for the delivery of Official Controls for RDM (for England and Wales) transferred from Animal and Plant Health Agency to the FSA. At that time Northern Ireland (NI) had no registered RDM suppliers. FSA adopted the existing controls in place, including the restriction of sales of the product.

9. During 2014-15 a small number of RDM producers were set-up in NI and FSA NI devised its own approach for the delivery of official controls including registration and sampling requirements. The table at Figure 1. shows the high-level England & Wales and the NI registration control processes.

Figure 1. RCDM registration requirements in England & Wales compared to NI

ENGLAND & WALES	NORTHERN IRELAND
FBOs complete application to register and send to FSA approvals team. Approvals team confirm their TB free status with APHA.	FBOs raise their interest with the Department of Agriculture, Environmental and Rural Affairs (DAERA) Agri-food Inspection Branch (carry out official controls on behalf of FSA). FBOs sent Guidance Document and advisory visit carried out. When pre-requirements met, FBO completes RDM registration form and submits to DAERA.
A visit by a Dairy Hygiene Inspector is arranged within 7 days and a hygiene inspection is undertaken and a raw milk sample collected to be tested for indicator organisms (under Schedule 6)	Registration visit carried out – hygiene & pre-requirements checked. Raw milk sample collected to be tested for indicator organisms (under Schedule 6).
If the hygiene inspection and raw milk sample is found to be satisfactory a confirmation letter is sent to the FBO by the approvals team. Once the letter is received sales may start.	Where all checks satisfactory, FBO issued with RDM Registration Number and can commence supply. FBO's are required to have their own plate count and coliform sampling programme, pathogen sampling programme and water testing programme in place and provide a satisfactory result for each before sales may start. They must also have and maintain a documented procedure based on HACCP principals.
No FBO sampling programme is required in England & Wales.	FBO sampling frequencies (generally: **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

10. The current process in England & Wales differs from the NI approach, areas of interest include:

- There is no requirement for the producer to have a HACCP-based safety management plan (as RDM is "primary production") and the balance of safety monitoring and controls are less focused on the FBO's own responsibilities

- The requirement for the NI FBO to have their own pathogen sampling process in place and demonstrate a level of compliance before sales can start. *In England &*

Wales the FSA require the FBO to have a satisfactory hygiene inspection and have 1 compliant Schedule 6 sample result (taken by the DHI)

- The requirement for the NI FBO to have a water sampling programme in place. In England & Wales, FSA do not stipulate this as a requirement

11. Building on this initial analysis a comprehensive lessons-learned comparison will be conducted on the NI model to reflect these in any recommendations for change to the approach in England and Wales to be presented to the Board in June 2018.

12. Based on the current level of RDM interventions and incidents the estimated cost of delivering Official Controls, in England and Wales is estimated to be over £200,000 per annum, with around 90% of these costs attributable to England (10% to Wales) although around £50,000 of sampling costs are recovered. This compares to overall value of Raw Drinking Milk sales which is currently estimated at £3m.

13. These costs will be validated and analysed in more detail before the submission to the Board in June, which include the cost of any proposed changes and will also consider if there are options for alternate sustainable funding approaches in line with the *Regulating Our Future* principles.

POLICY REVIEW (2015) UPDATE

14. In July 2015, the FSA Board agreed that the risk of RDM was generally acceptable with a request to to improve transparency and provide clearer consumer and producer information. FSA continues to implement changes to address the Board steers including:

- Launched RDM webpage and published a list of all RDM producers on its website (https://www.food.gov.uk/science/raw-drinking-milk-and-cream)

- Published farm inspection ratings for each producer

- Progressing the introduction of additional safety labelling for vulnerable groups (see below for further detail on labelling).

15. Compliance ratings for each raw milk producer are published on the FSA website and updated monthly. FSA are considering further improvements - including publishing trend and compliance data to allow consumers to make informed choices on RDM purchases.

16. The FSA is improving risk communication in England and NI, particularly for vulnerable groups. The FSA website has been updated stating the health risks associated with raw drinking milk and recommending that those with a weakened immune system and vulnerable groups should not consume unpasteurised milk.

17. FSA are finalising legislation that brings in new compulsory labelling that mirrors the labelling requirements already in place in Wales. The legislation is expected to be in place in both countries in March 2018. Currently (in England and NI) RDM is required to include the following health warning:

> This milk has not been heat-treated and may therefore contain organisms harmful to health

18. The proposed amendment will introduce a requirement to add the following advice to the warning:

> The FSA strongly advises that it should not be consumed by children, pregnant women, older people and those who are unwell or have chronic illness

Operational Delivery of Raw Drinking Milk Official Controls

19. An internal audit of Official Controls in Raw Drinking Milk undertaken in summer 2017 identified significant weaknesses in the framework of governance, risk management and control, with the most notable being:

- Confusing split of enforcement responsibilities between Local Authorities and the FSA Dairy Hygiene inspectors in England & Wales
- The need to improve action planning, progress monitoring and escalation processes and develop comprehensive producer performance and quality measures
- A need for improved controls to provide assurance that RDM samples taken by both officials and FBOs are tested at laboratories operated, assessed and accredited in accordance with required standards
- Take the opportunity to learn from the NI approach to RDM Official Controls which appeared to differ in key respects

20. FSA Operations have made some immediate improvements to the delivery in response to the audit findings, these include:

- Updated enforcement training delivered to all 39 Dairy Hygiene Inspectors
- All Dairy Hygiene Inspector equipment has been reviewed to ensure business needs are met
- Agreed and published a raw milk incident protocol
- Implemented an operational incident management structure

21. To clarify the split of responsibilities between FSA and Local Authorities (see Figure 2 for overview) the FSA has consulted all LAs in England and Wales on the potential transfer of responsibility for Official Controls from LAs to FSA (on-farm filling and bottling operations for all raw milk species alongside the verification sampling for all raw milk species.) The consultation closed on 15th February, the outcomes and any resultant recommendations will be included in the June paper.

Figure 2. Current FSA/LA Roles (England & Wales)

Area of control	***FSA***	***LA***
Hygiene inspections (all species).	**X**	
Quarterly verification sampling (cows)	**X**	
Quarterly verification sampling (other species)		**X**
Warning label	**X**	
Filling and bottling (all species)		**X**
Retail outlets including distributors (farm shops etc)		**X**

22. 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. The FSA has supplemented this with a frequently asked questions (FAQ) document which is planned for publication in March 2018. The guidance will provide more detailed information for FBO's on the requirements and expectations when producing raw milk.

23. In January 2018, the FSA secured agreement in principle from NFU to co-sponsor producer guidance with an assurance scheme provider. This proposal has also met with a positive response from RDM producers. The FSA are currently working on a proposed timetable and the approach required to produce this industry guidance to maximise the buy-in from all parts of the sector and devolved administrations.

Policy Evidence Review

24. The FSA has been reviewing the policy evidence base for RDM, including a risk assessment, economic analysis and consumer insight.

Risk Assessment

25. The purpose of the risk assessment is to assess whether the microbiological risk associated with consumption of raw drinking milk produced in England, Wales and NI has changed since this issue was considered in 2015. The assessment considers:

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

26. The emphasis is on raw milk for drinking. Cream, smoothies, milkshakes and ice-cream made using raw milk have been included, in particular, as the latter three product types

could potentially increase raw milk consumption among children, although it is noted that children themselves would not be making the purchasing decision.

27. The first interim version of the risk assessment was presented to ACMSF on 25 January 2018 (see link to interim paper, which includes historic data). Although it was emphasised that the work is still interim there were positive comments from ACMSF members about the information provided and that the committee was being consulted. The assessment will be developed further before it goes back to the main committee in May and the final review and findings will be presented in the Board paper in June. https://acmsf.food.gov.uk/sites/default/files/acm_1256_raw_drinking_milk.pdf

Economic Analysis

28. In 2015, the economic analysis of the RDM sector concluded that the market was likely to be self-limiting and consumption/production levels were likely to remain stable. However, the increase in producers indicates a definite expansion in the RDM market over the last 5 years, and, although there is a difference in the retail price of RDM to pasteurised milk, consumer insight would suggest that demand is relatively price insensitive.

29. Further expansion of the market is possible, but there may likely be an upper limit due to the current controls in place which restrict access for many consumers; the safety concerns; geographical availability and the price which is likely to be too high to the average milk consumer.

30. Defra is currently consulting on proposals to transfer the cost of increased Bovine TB testing to farms producing RDM in the Low-Risk Area (North and East Coast of England) which may reduce incentives for farms in those areas to produce RDM. Defra estimates that around 65 RDM producers would be affected by these changes. FSA economists are checking on the position for NI and Wales and will update accordingly.

31. There are, however, a limited number of matched funding grants that may be available under the Rural Development Programme (there are separate programmes operated in England, Wales and Northern Ireland, based upon the same EU regulations) that farms may be able to access by diversifying into RDM production, if they are able to incorporate a new product or process into their business. As the grant process is competitive however, funding is not guaranteed, but if farms are successful this may represent a potential driver of supply.

Consumer Research

32. Following on from the extensive consumer work carried out as part of the 2012-2015 Review, the FSA has, in 2018, repeated an online consumer survey to research if there are changes to consumer perception of RDM since the last Review. The findings from the consumer research will feed into the recommendations for discussion in June. The published paper can be found at: https://www.food.gov.uk/sites/default/files/rawdrinkingmilkconsumerinsightreport2018.pdf

33. The survey was conducted with a nationally representative sample of adults across England, Northern Ireland and Wales to see how and if attitudes and behaviour have changed since 2012.

34. The panel were asked about the relative importance to them or their families of different benefits or drawbacks associated with RDM when considering whether to purchase it. The potential health risks were considered the most important. Consumers considered the fact that it may contain harmful bacteria such as Salmonella (deemed important by 82% in 2018 and 77% in 2012) and that it can be dangerous to vulnerable groups with weakened immune systems (80% in 2018 vs. 76% in 2012) as most important. Figure 3 shows headline results.

Figure 3. Key headlines 2012 vs. 2018

	2012	2018
% know what raw milk is (prompted)	81%	81%
% aware that some people choose to consume RDM	55%	64%
% currently consume / buy RDM	3%	10%
% tasted raw milk (not including cream)	33%	32%
% interested in trying RDM in the future	19% (inc. 3% very interested)	24% (inc. 6% very interested)
% heard something about raw milk (e.g. in media)	3%	12%
% think raw milk should be banned	23%	23%
% consider risk of RDM containing harmful bacteria such as Salmonella important	77%	82%
% consider danger of RDM to vulnerable groups important	76%	80%

Changes in the RDM landscape

35. As outlined in the summary, an increased focus on RDM is needed due to the change in the RDM environment, including increased volumes and illness. The following paragraphs provide the board with additional context.

Production and supply

36. 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.

37. The number of registered raw drinking milk producers in the UK has also increased significantly. In April 2014 (in the UK) there were 108 RDM producers (ie 107 in England/Wales and 6 in Northern Ireland.

38. Data from January 2018 indentified 168 RDM producers, the majority of which are in England (ie 151 in England, 11 in Wales and 6 in Northern Ireland).

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

Outbreaks

40. There has been an increase in outbreaks of human illness associated with RDM in the UK since the beginning of 2015. In 2014, there was a single outbreak and, prior to that, the last outbreaks associated with RDM UK occurred in 2002.

41. However, from 2015 to December 2017, there have been 5 reported outbreaks linked to RDM. In one of these outbreaks, RCDM was supplied in milkshakes, in addition to raw milk form. There were over 100 potential illnesses, with 41 laboratory confirmed cases, 5 reported hospitalisations and no deaths. Most of these outbreaks involved children. The table at **Annex 1** gives a detailed breakdown of the outbreaks, including their nature and location.

42. Further work is being undertaken to assess whether the increase in outbreaks is a real effect or whether it is due to, for example, the increased ability to detect outbreaks using whole genome sequencing.

NEXT STEPS

43. This interim paper provides an overview of and an update on improvements in the delivery of official controls for RDM, updates on progress to implement recommendations from the 2015 policy review, and shares the initial findings the policy evidence review including the risk assessment.

44. In June 2018, a further paper will be submitted to the Board with proposed changes to improve the assurance of RDM Milk production, reflecting on the outcomes from the policy evidence review and any further operational improvements. The paper will present the latest findings and conclusions on RDM and will seek approval on recommendations to improve the existing controls for raw milk.

45. The Board is asked to:

- **Note progress** at the interim stage
- **Discuss** any specific areas of interest that need to be drawn out in greater detail in the June paper.

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

Farm	Year of outbreak	Region	Agent	Vehicle description	Total cases affected	Laboratory confirmed cases	Hospitalised	Number of deaths	Age and gender[C]	Evidence[D]	Comment (data source)	1) Registration date 2) Start date 3) Trading time[E]
A	2014	South West England	STEC O157 PT21/28	Raw cows' drinking milk	9	9	2	0	7 cases children, 2 cases adult	Descriptive epidemiological	(eFOSS)	Pre 2012 September 2014
B	2016	North West England	*Campylobacter jejuni*	Raw cows' drinking milk	69	16	0	0	Mean age of cases was 44 years (range 1-74); 61.9% male	Microbiological and analytical epidemiological	Microbiological: WGS identified nine *Campylobacter jejuni* isolates, seven from human faeces and two from raw milk samples. SNP address 1.2.2.2.2.2.7 (outbreak report)	15/08/13 12/12/16 > 3 years trading (i.e. 40 months)
C	2017	South East England	STEC O157 PT21/28 stx2	Raw cows' drinking milk	7	7	5	0	5 cases children	Microbiological and descriptive epidemiological	Microbiological evidence: Case, food and animal isolates all fell within a 5 SNP cluster. SNP address 4.4.4.590.3896.4108.% Descriptive epidemiological: All cases either has some link with the farm or consumed raw milk from the farm. (HPZone/Vessy/GDW)	15/05/12 26/09/17 > 5 years trading (i.e. 64 months)
D	2017	South West England	*Campylobacter* spp	Raw cows' drinking milk	5	5	0	0	Male x 4, female x 1, age between 41-69 years	Descriptive epidemiological	(eFOSS)	21/10/16 27/06/17 <12 months trading (i.e. 8 months)

E	2017	North West England	*Campylobacter* spp	Raw cows' drinking milk	4	4	0	0	Male x 2, female x 2, ages between 2-69 years	Microbiological and descriptive epidemiological	Microbiological evidence: Case and milk isolates all fell within a 0-SNP cluster. SNP address 2.2.2.2.3.3.3 (eFOSS)	29/06/16 26/06/17 Only just 12 months trading (i.e. 12 months)
F	2017	Wales	*Campylobacter* spp	Raw cows' drinking milk and milkshake made with the RCDM	18	9	U	0	7 cases were aged under 16 (aged 5-13)	Microbiological and descriptive epidemiological	(Personal communication Public Health Wales/ Ceredigion County Council)	27/6/16 08/08/17 < 24 months trading (i.e. 13 months)
G	2017	North West England	*Salmonella* Dublin	Raw cows' drinking milk	1	1	U	0	1 child	Microbiological and descriptive epidemiological	This incident was not reported as an outbreak due to only one individual being affected. An indistinguishable strain of *S.* Dublin was detected in bulk milk and farm environmental samples. SNP address. 1.1.1.2.2.2.2 (Personal communication – Health Protection Team)	29/06/16 05/07/17 Only just 12 months trading (i.e. 12 months)

[A] A food-borne outbreak is defined 'an incidence, observed under given circumstances, of two or more human cases of the same disease and/or infection, or a situation in which the observed number of human cases exceeds the expected number and where the cases are linked, or are probably linked, to the same food source' (Directive 2003/99/EC[1]).

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

[C] The age cut-off for children is not defined in eFOSS therefore it is not possible to provide number/proportion of children under 5 years of age.

[D] Categories of evidence are defined in the EFSA Manual[2] on reporting of foodborne outbreaks as follows:

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

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

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

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

U - Unknown