RAW DRINKING MILK (RDM) TRIGGERS FOR REVIEW

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SUMMARY

1. At its meeting in June, the Board agreed with the recommendations proposed in the RDM paper to improve the existing controls and to adopt a proportionate escalation approach to introducing measures and controls. It was also agreed that a mechanism for data-enabled "triggers" that would prompt the Executive to review the control strategy should be established.

2. This paper presents recommendations on triggers for review of RDM controls and provides an update on progress on the actions arising from the last Board discussion on RDM in June 2018.

3. The Board is asked to:

   Consider and agree the recommendations on the triggers for review of RDM controls.

INTRODUCTION

4. In June 2018, the Board was presented with a decision paper on the RDM work programme[1]. The paper provided recommendations of planned improvements in the delivery of official controls as well as the findings from the evidence review, including the final risk assessment, economic analysis and consumer insight work.

5. 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 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.

6. The Board also agreed that the FSA should adopt a staged approach, whereby better control measures are introduced, and their effectiveness reviewed after an appropriate period. If the measures introduced are not deemed to be effective, then additional, more stringent, controls would be considered and these would be brought back to the Board.

[1] https://www.food.gov.uk/sites/default/files/media/document/Raw%20Drinking%20Milk%20-%20FSA%2018-06-07.pdf

7. Finally, the Board reiterated the need to establish a mechanism for data enabled "triggers" that would prompt the Board to review the control strategy which would be in line with requirements in the Risky Food Framework (RFF)[2].

8. This paper presents recommendations on the triggers for review of RDM controls. Progress on the other actions from the June Board meeting can be found at **Annex A.**

BACKGROUND AND CONTEXT

9. This programme of work is aligned to Regulating Our Future (ROF) principles that ensure business operators take primary responsibility for the safety of food they produce, that information is provided to consumers enabling them to make informed choices and that regulatory activity is risk-based, targeted and proportionate.

10. The proposal is presented in the context of the FSA Strategic Plan to 2020 and the FSA framework for consideration of "risky" foods. These balance public health protection with wider consumer interests, particularly choice.

TRIGGERS FOR REVIEW

Enhanced Controls

11. Following the June Board discussion, significant progress has been made in reviewing additional controls, incorporating all those the Board agreed to in June. These are that the registration of RDM producers be strengthened; the introduction of routine pathogen sampling and water testing by producers; and a requirement for a verified food safety management plan on HACCP principles.

12. The NI model has been reviewed and work was undertaken to implement this model with minor adaptations for England and Wales. The draft of the guidance document outlining the requirements of this new process has been completed and been shared with Dairy Hygiene Inspectors for feedback. A public consultation introducing the proposed changes will be issued in January 2019. Following consultation, the target implementation date for the enhanced controls will be May 2019.

13. It is envisaged that producers of raw milk from other species (sheep, buffalo and goats) will be subject to similar enhanced controls.

14. The Raw Milk Producers Association (RMPA) is now established and close to 50% of RDM producers have become members. The RMPA has formed a team of committee members and has completed the design and launch of their website[3]. Their industry Code of Best Practice guidance document will be in

[2] https://www.food.gov.uk/sites/default/files/media/document/fsa161107%20%283%29.pdf
[3] https://www.rawmilkproducers.co.uk/about

line with the FSA's proposed enhanced controls and will be published alongside the implementation of the controls next year. A meeting was held on 10 October in which the RMPA provided the FSA with a progress update on the production of their document. Guidance around the implementation of food safety management systems and producer testing programmes is being prioritised and they provided some examples of the proposed content for this.

Escalation Procedure

15. The escalation procedure will encompass: a) the data that will be monitored, b) defined thresholds (as 'triggers'), and c) the action 'triggered' (e.g. investigation, wider review, targeted or increased enforcement activity, Board update, recommendations to the Board for further enhancing controls etc.). Legislative change remains, however, an option should the Board decide that controls are not working and that public health is compromised by lack of legislation.

Monitoring Data

16. The Executive has explored possible mechanisms for review of the controls and instigation of the escalation approach. Analysis of the currently available datasets indicates that there is a lack of robust data to establish evidence-based triggers and thresholds. However, the available data can be used to monitor changes, and intuitive thresholds can be set relative to established baselines (in relation to historical data sets held by FSA).

17. To date, four areas have been identified for monitoring changes, with thresholds defined. To this has been added indicative actions that might be taken. These are set out in Table 1.

18. Changes below trigger levels within each dataset may not require a response, but if there are changes in more than one of the criteria, even below the individual trigger levels, then this may prompt an investigation.

19. Changes within each dataset above the proposed trigger will elicit a response however the nature of the response may vary depending on the combination of triggers. For example, a significant increase in the number of producers will trigger an action/response such as an internal investigation, however if it accompanies an increase in outbreaks the actions could involve both a wider investigation as well as updating the Board on the outcome. *Example* scenarios are given in **Annex B**.

20. The datasets we propose to monitor initially on a more constant basis are:

    1. number and seriousness of outbreaks associated with RDM
    2. proportion of failed hygiene indicator samples
    3. estimated annual volume of RDM sold
    4. the number of registered RDM producers

21. Data on raw milk from other species (sheep, buffalo and goats) will also be monitored for changes in the same way. However, at present data on other species is limited to the number and seriousness of outbreaks and the number of registered producers (more detail in Annex A, *Other Species*). As with raw cows' milk, additional datasets will be added for monitoring in the future as these are developed.

22. A project led by a team of independent expert data scientists, was commissioned to assess the data requirements and how well the existing data support the development of triggers or thresholds. This included user research with producers, consumers and those involved in regulation and enforcement of RDM. It is likely that this work will identify improvements to the data that is currently gathered.

23. The intention is that additional datasets will be added to the current lists for cows and other species when further data are gathered and when the enhanced registration procedure is introduced by May 2019. The Executive is also exploring other potential sources of data, such as PHE's enhanced surveillance for sporadic cases of STEC infection, to see if this can provide useful data in terms of additional indicators.

24. Subject to Board agreement, it is envisaged that the initial datasets (Para 19) will be monitored from January 2019. A system for gathering and monitoring the datasets has been developed. The responsibility for this on-going function will be primarily for FSA Operations with oversight from FSA Policy. A regular monthly dashboard will be produced to enable the Executive to keep track of developments and obtain appropriate assurance that the monitoring 'system' is working as it should.

25. **Table 1** indicates the datasets, the thresholds for action and the triggered action proposed.

Table 1 – RDM Triggers

	Dataset	Threshold	Trigger / Action
OUTBREAKS ASSOCIATED WITH RDM	Outbreaks	3 or more outbreaks from different locations	Investigation and update to Board
	Hospitalisations	3	Investigation and update to Board
	Deaths	1	Investigation and update to Board
FAILED HYGIENE INDICATOR SAMPLE	Non-compliant indicator levels	Reaching 30%	Investigation and update to Board
VOLUME OF RDM SOLD	Volume of sales increasing	reaches 4 million litres (currently 3.2 million)	Investigation and update to Board
REGISTERED RDM PRODUCERS	Number of producers increasing	An increase of 15% or more	Investigation and update to Board

Note – all these figures relate to a rolling 12-month period

Investigation: An internal investigation by Operations and Policy Teams. Outcome of the investigation could lead to actions being taken such as a wider review, targeted or increased enforcement activity. Board updates will be considered at any of the aforementioned actions.

Update to Board: Following the outcome of an investigation and, depending on the severity, we will update the Board via one of the following methods: CE update, weekly Board mailout, or a Board Paper.

ANNEX A - PROGRESS ON ACTIONS

Labelling SI

1. The FSA has been informed by the Parliamentary Business and Legislation Committee (PBLC) that Ministers are concerned about the volume of EU Exit SIs and a decision has been made that only essential non-EU Exit SIs are laid in Parliament before March 2019.

2. The Board has been informed of delays that had affected a number of FSA SIs (including the RDM labelling SI) due to central government guidance on reducing reliance on criminal sanctions in legislation.

3. The FSA has worked closely with Cabinet Office to resolve this issue and was able to reach an agreement in July on the FSA approach, sufficient to enable Ministerial agreement on the FSA measures submitted for collective agreement. However, we have been informed by DHSC officials that the Secretary of State for Health and Social Care has remaining concerns on this issue and we are working with DHSC officials to address these.

Risk Communication

4. As agreed at the June Board meeting, work has been carried out to better communicate the risk to vulnerable consumers. Additional information for consumers has been uploaded onto a dedicated RDM page on the FSA's website[4].

5. As discussed in the June paper, the common understanding of the term 'raw' has changed over time. 'Raw', 'unprocessed' and 'untreated' are increasingly perceived as being healthier. This is the case with RDM despite a lack of robust scientific evidence in support of health benefits (paragraph 14 below refers) and the higher inherent food safety risks. The Executive has reviewed the terminology used to describe RDM and has concluded that despite these perceptions, there is limited scope to change as the term RDM is fixed in legislation. However where ever possible the FSA will ensure the risks associated with RDM are communicated clearly to consumers.

6. An FSA Explains video has been produced. This will be shared across social media platforms and will give consumers information about RDM and the particular risks to vulnerable groups. It also addresses the perceived health claims and, in particular, highlights the risk to children. The video was published on 5 November 2018[5]. The Executive will work with partners, such

[4] https://www.food.gov.uk/safety-hygiene/raw-drinking-milk
[5] https://youtu.be/mmLr9D16d5M

as NHS Choices, to share this message with our target audience (vulnerable consumers).

Consumption by children

7. The FSA holds one set of data on consumption by children from our most recent survey which informed the March and June 2018 Board Papers. The data show that in households consuming RDM, children generally appear to also be consuming the product[6].

8. The FSA will continue to monitor consumption of RDM, particularly by children, via the Public Attitudes Tracker[7], a biannual survey conducted with consumers in England, Wales and Northern Ireland in order to monitor changes in consumer attitudes towards the Agency and food-related issues. This survey has been running in its current form since 2010 and is recognised as an Official Statistic. By including a question on this topic, a clearer picture can be developed over time to support the evidence we currently hold. The question will be included in fieldwork taking place in November 2018.

Other Species

9. Raw milk from other species such as sheep, goats and buffalo is not subject to the same legislative controls/sales restrictions as raw cows' drinking milk. Local Authorities are responsible for the sampling of milk from other species, while FSA Dairy Hygiene Inspectors are responsible for inspections and registration. This sector makes up 16% of RDM producers in the UK; as of October 2018, 27 producers are in operation with one also producing raw cows' milk; this number is down from 31 in January 2018 due to businesses ceasing to trade in the product. Historical data on other species are not available as they have not been specifically identified in previous datasets[8].

10. Whilst there are outbreaks reported in Europe with raw milk from goats (4 out of 27 outbreaks between 2007 and 2012), there have been no reported outbreaks within the UK associated with raw drinking milk from other species since 2003[9]. The data regarding the risks from other species' RDM carry a greater degree of uncertainty due to much smaller sample sizes than that for cows' RDM.

11. There is a low percentage of producers and no outbreaks notified for at least 15 years. With its market limited and even reducing in 2018 alongside a lack of outbreaks associated with the product, the current controls (on sales routes) appear to be adequate until a sufficient change in product or outbreak data triggers a review of these. However, it is envisaged that the enhanced controls that will be introduced for raw cows' drinking milk production (the introduction of

[6] https://www.food.gov.uk/sites/default/files/media/document/Raw%20Drinking%20Milk%20Consumer%20Insight%20Report%202018.pdf
[7] https://www.food.gov.uk/about-us/biannual-public-attitudes-tracker
[8] https://data.food.gov.uk/catalog/datasets/9f6a9a91-4e78-47f8-a5c9-02da83ed07bc
[9] https://acmsf.food.gov.uk/sites/default/files/acm_1269_raw_drinking_milk.pdf

routine pathogen sampling and water testing by producers; and a requirement for a verified food safety management plan based on HACCP principles) are relevant for the production of RDM from other species.

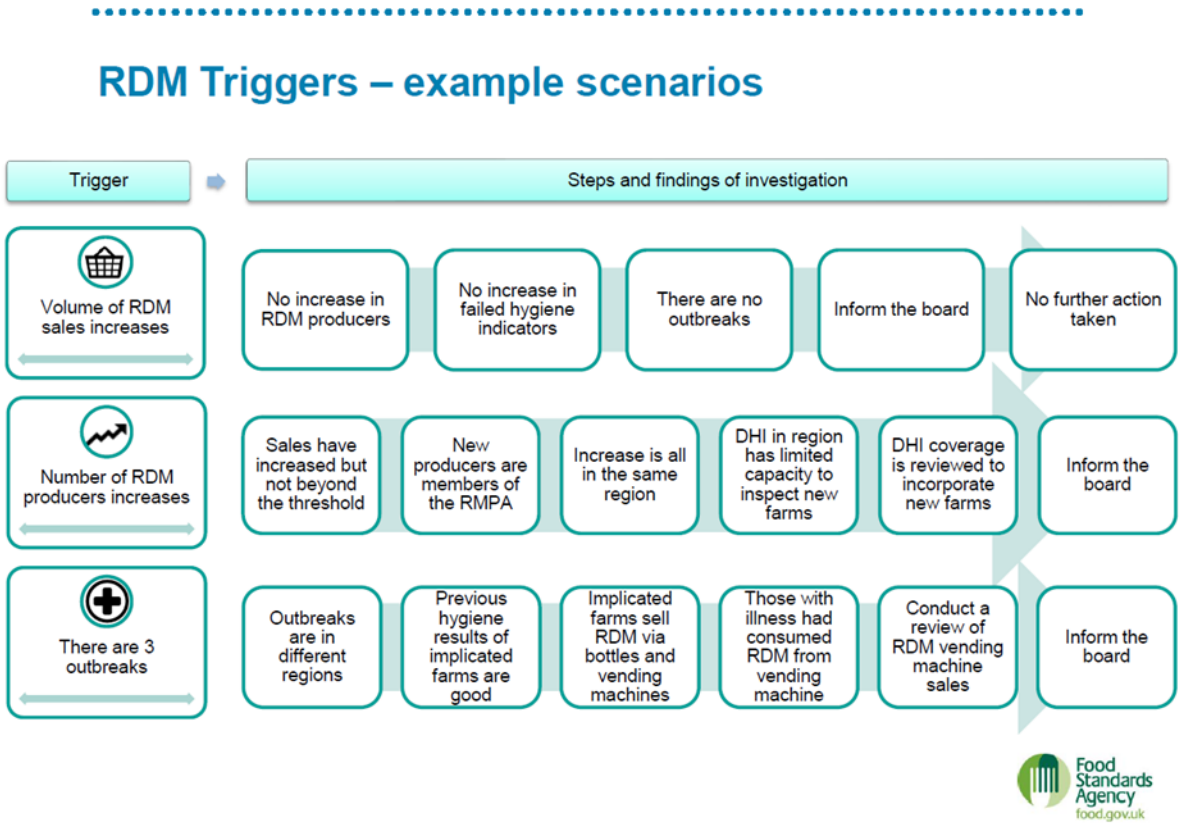
Health Claims

12. Nutrition and health claims on labelling, commercial communications or generic advertising are dealt with by the Department of Health and Social Care (DHSC) and covered by Regulation (EC) 1924/2006. Any health claim made must be approved through validation of scientific research and placed on a central European register. Unverified claims are enforced by Trading Standards (TS).

13. There are currently no authorised health claims for RDM and so any included on current packaging, leaflets or websites are not permitted. If misleading advertising is found during dairy inspections, dairy inspectors will ensure corrective action is taken, reporting to Trading Standards if necessary.

14. Following the June Board meeting, the Executive has reviewed evidence of health benefits from information submitted to the FSA. At present, the evidence that has been submitted still does not provide robust evidence of health benefits to humans. Where benefits are claimed to be found, there are many other confounding factors to the studies quoted that mean that RDM might not be the sole contributor to the claims being made. FSA advice on RDM therefore remains that pregnant women, children and infants should not consume. The FSA remains open to reassessing the situation if new research emerges.

Annex B


RDM Triggers – example scenarios
Trigger
Steps and findings of investigation
Volume of RDM sales increases
No increase in RDM producers
No increase in failed hygiene indicators
There are no outbreaks
Inform the board
No further action taken
Number of RDM producers increases
Sales have increased but not beyond the threshold
New producers are members of the RMPA
Increase is all in the same region
DHI in region has limited capacity to inspect new farms
DHI coverage is reviewed to incorporate new farms
Inform the board
There are 3 outbreaks
Outbreaks are in different regions
Previous hygiene results of implicated farms are good
Implicated farms sell RDM via bottles and vending machines
Those with illness had consumed RDM from vending machine
Conduct a review of RDM vending machine sales
Inform the board
Food Standards Agency
food.gov.uk