
UPDATE ON FSA REVIEW OF CONTROLS FOR RAW DRINKING MILK

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1 SUMMARY

1.1 In 2012, the FSA Board agreed to review current controls and possible approaches to managing the risks associated with consumption of raw milk and cream from all species in England, Wales and Northern Ireland. Options for controls have been considered in consultation with stakeholders. Initial recommendations were presented to the FSA Board in July 2014 where Board members asked for additional data and for an upcoming EFSA opinion on this issue to be considered before a decision on raw drinking milk (RDM) controls could be made. The Executive has considered all the available evidence including the European Food Safety Authority (EFSA) opinion and considers the review of RDM controls complete. Recommendations are presented to the Board for decision.

1.2 The Board is asked to:

- **Agree:** that the FSA review of RDM controls should conclude, with a significant degree of certainty, that the hazards associated with RDM are well characterized and the level of risk associated with RDM consumption by consumers except those who are vulnerable by virtue of age or underlying health conditions, is acceptable when appropriate hygiene controls are applied throughout the chain;
- To **agree:** that the risk to those who are vulnerable by virtue of age or underlying health conditions is heightened and action is needed to increase awareness of those risks;
- **Agree:** that current restrictions on sale should remain in place as, in the absence of a quantitative risk assessment and limitations in the evidence base, there is uncertainty that the same level of consumer protection could be maintained if the current restrictions were relaxed to allow wider access to RDM;
- **Agree:** that, in the absence of a quantitative risk assessment, any future consideration of extending sales should (i) use principles that already exist in EU legislation (ii) balance any extension to new routes of supply with tighter regulatory controls that would manage the risk to an acceptable level;
- **Agree:** that given the current evidence on compliance, focus should be to ensure RDM producers are implementing current controls and meeting required standards. Any relaxation of current sales restrictions could only be considered when there is evidence to indicate a high level of compliance across the sector; and

- **Agree:** that communication of the risks associated with RDM at the point of sale or equivalent should be improved and, as a first step, labelling requirements in England and Northern Ireland should be extended to include a specific warning for vulnerable groups, as currently exists in Wales.

2 STRATEGIC AIMS

- 2.1 As set out in our strategy to 2020, we will put the consumer first in everything we do, acknowledging that consumer interests are multi-dimensional: “food is safe and what it says it is, and we have access to an affordable healthy diet, and can make informed choices about what we eat, now and in the future”. As we say in the strategic plan, we need to look at an issue through each of these lenses.
- 2.2 We state in our strategy that consumers have a right “to be protected from unacceptable risk”. The previous Board discussions of raw drinking milk predated the development of the framework for the control of “risky” foods, agreed by the Board in November 2014. This framework suggests two questions should be addressed in sequence:
- What is the level of risk, and is it acceptable?
 - If the risk is acceptable, what controls are needed to maintain consumer protection?
- 2.3 The FSA has a statutory duty to consider costs and benefits as well as risks when deciding whether and how to act¹. The explanatory notes to the Food Standards Act says that “This would mean that the Agency must balance obvious compliance costs, as well as matters such as restriction of consumer choice, against the benefits of reduced risk to health etc. arising from any action”. So, although protecting public health remains at the core of the FSA’s mission, it is not the only consideration – where public health impacts are relatively small and incremental, other considerations (such as choice) become highly material.
- 2.4 These duties on the FSA are consistent with the approach to risk proposed by Sir Mark Walport, the Government’s Chief Scientific Adviser² in his first report. He states, “The assessment of public risk alone is insufficient as a basis for managing it. Public risks must be assessed, managed, communicated and

¹ “The Agency, in considering whether or not to exercise any power, or the manner in which to exercise any power, shall take into account (among other things) – (a) the nature and magnitude of any risks to public health, or other risks which are relevant to the decision (including any uncertainty as to the adequacy or reliability of the available information); (b) the likely costs and benefits of the exercise or non-exercise of the power or its exercise in any manner which the Agency is considering...” (Section 23(2), Food Standards Act 1999)

² Annual Report of the Government Chief Scientific Adviser 2014. Innovation: Managing Risk, Not Avoiding It. Evidence and Case Studies.

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/381906/14-1190b-innovation-managing-risk-evidence.pdf

governed: the political, social and organizational aspects of sound risk management are as critical as the technocratic analysis of risk.”

3 BACKGROUND

- 3.1 In March 2012, the FSA Board agreed to review current controls in England, Wales and Northern Ireland³ and possible approaches to managing the risks associated with RDM and cream from all species. Options ranging from a requirement to pasteurise all milk prior to sale through to removal of all sales restrictions were evaluated in a draft impact assessment issued for consultation on 30 January 2014⁴. Those options were reviewed in light of consultation responses and evidence obtained from wider engagement activity and initial proposals for the development of RDM controls were presented to the Board for consideration in July 2014⁵.
- 3.2 The FSA Board was asked to consider whether certain controls (full liberalisation of sales of RDM and introduction of a requirement to pasteurise all drinking milk prior to sale) could be excluded as valid options for control. It was also asked whether mechanisms should be explored for allowing increased consumer access, in particular via vending machines, alongside further controls that might be required to support wider access to RDM.
- 3.3 Board Members recognised this was a difficult issue which needed to balance public health protection with wider consumer interests, in particular consumer choice. They noted concerns about potential wider access to a higher risk product and considered further data on the presence of pathogens in RDM was needed before a decision on controls for RDM could be made. Board members also requested that recommendations be informed by the EFSA opinion on this issue which was subsequently published on 13 January 2015⁶.
- 3.4 The Executive has considered Board member comments, reviewed the EFSA opinion and other new data/evidence (outbreak investigations and surveillance data) emerging since the July 2014 discussions. It has also considered the RDM review in the context of the new strategic plan and the framework for discussions for appropriate controls for risky foods. This paper presents recommendations for future controls for RDM.

4 EVIDENCE

- 4.1 The main evidence underpinning the review is presented in the 2013 previous board papers,^{3, 5} the impact assessment⁴ and responses to the consultation.⁷ The EFSA opinion on the risks associated with RDM, information from outbreak investigations and recent limited surveillance data have added to the evidence base.

³ <http://www.food.gov.uk/sites/default/files/multimedia/pdfs/board/fsa120305.pdf>

⁴ <http://www.food.gov.uk/news-updates/consultations/2014/rawmilk-consult>

⁵ <http://www.food.gov.uk/sites/default/files/multimedia/pdfs/board/board-papers2014/fsa-140704.pdf>

⁶ <http://www.efsa.europa.eu/en/efsajournal/pub/3940.htm>

⁷ <http://www.food.gov.uk/sites/default/files/multimedia/pdfs/consultationresponse/raw-milk-consultation-summary-responses.pdf>

- 4.2 We have reviewed our assessment of the evidence informing our consideration of the options, in light of the new evidence that has become available since the last discussion (outbreak investigation and the data collected as part of the response to them, the EFSA opinion, and data from recent surveillance of RDM). Overall this new evidence is consistent with previous evidence and its assessment. Using the Advisory Committee on the Microbiological Safety of Food (ACMSF) scales, the evidence is of moderate quality and medium uncertainty.
- 4.3 We have also assessed the evidence base using a scale for quality of risk analysis proposed by Professor David Spiegelhalter (Annex 1).⁸ This is derived from similar work as the ACMSF scale, but may be more easily applied to considering confidence in an overall assessment of options for a decision, and how likely it is that changes in evidence would affect this overall conclusion. This is useful in comparing consistency of evidence and of approach across similar types of risk.
- 4.4 Our assessment using this scale is that the evidence underpinning the review corresponds to a '3 star' rating i.e. **we are reasonably confident in our analysis: we can expect numbers to change as we learn more, but not sufficiently to justify major policy shifts.**

Risk assessment

- 4.5 As concluded by the July 2014 discussions, the microbiological hazards associated with RDM and cream are well characterised and this is reflected in the EFSA opinion. The main microbiological hazards associated with RDM are considered to be *Campylobacter* spp, *Salmonella* spp., Shiga toxin-producing *Escherichia coli* (STEC), and *Listeria monocytogenes*. The EFSA opinion identifies further hazards but these are not considered to be a significant risk in the UK.
- 4.6 The EFSA panel concluded it was not possible to carry out a Quantitative Microbiological Risk Assessment (QMRA) due to gaps in the current evidence base. Published QMRA models from US, Australia, New Zealand and Italy were reviewed but uncertainties meant risk estimates could not be extrapolated to the EU as a whole. The approaches taken by EFSA and its main findings are summarised in Annex 2. They recognised the limitations in the evidence base and recommended studies to systematically collect data to provide a better evidence base on hazards that may be present in RDM and collect data to identify and rank emerging milk-borne hazards.
- 4.7 The recommendation for further data gathering is consistent with Board comments made in July 2014 and the FSA has considered the data that might be required to allow us to quantify the risks associated with RDM. Recent sampling activities triggered by an outbreak of STEC illness associated with

⁸ Annual Report of the Government Chief Scientific Adviser 2014. Innovation: Managing Risk, Not Avoiding It. Evidence and Case Studies. Chapter 6 The need for a common language. David Spiegelhalter.

RDM and surveillance carried out by Public Health England⁹ (unpublished data) show similarities to previous studies carried out between 1995 and 2000. Pathogens (*Campylobacter*, *Listeria monocytogenes* and STEC) were present in a small number of samples. Faecal indicators were also present at varying levels, in some cases above levels provided in the legislation. Further sampling over an extended period e.g. 2 years would provide more extensive data on the current prevalence of pathogens in RDM but it is reasonable to expect a similar pattern of contamination. This is consistent with our assessment of the strength of the currently available evidence (para 4.4). We do not therefore believe such further sampling would be a proportionate use of our finite resources for science and evidence.

- 4.8 There were no reported cases of illness associated with RDM in the UK between 2003 and August 2014. Data from investigations associated with enhanced surveillance for STEC illness shows 1-3% (51/2384 in England; 9/1151 in Wales; 18/583 in NI and 14/2313 in Scotland) of cases report RDM consumption. However cases often report exposure to multiple risk factors including contact with farm animals, handling raw meat and/or water from private water supplies. The EFSA opinion reports 27 outbreaks across the whole of the EU between 2007 and 2012 and this includes MS where RDM consumption may be more widespread than in England, Wales and Northern Ireland.
- 4.9 The first UK reported outbreak of STEC associated with RDM in 12 years occurred in autumn 2014 and involved 9 cases (7 primary and 2 secondary cases). This provides direct evidence of the risks associated with RDM and severity of the disease that can occur. It also indicates that foodborne disease surveillance systems are capable of identifying small numbers of cases of illness associated with a particular product, particularly if symptoms are severe.
- 4.10 Prior to the outbreak of STEC O157 in 2014, the last outbreaks of illness directly linked to RDM in England occurred during 2002. In the most recent outbreak, 7 out of 9 cases were children and two cases developed Haemolytic Uraemic Syndrome (HUS), a severe complication that includes kidney failure. This supports the established view that there is a heightened risk for vulnerable consumers which is also noted in the EFSA opinion.

Conclusion

- 4.11 There is sufficient evidence to allow us to conclude with a significant degree of certainty that the level of risk associated with RDM is acceptable for most consumers but this needs to be managed to ensure it remains at the current level. There is direct evidence to support the longstanding view that risks to vulnerable consumers are heightened and action may be needed to increase awareness of those risks.

⁹ Survey of RDM in England and Wales from all species taken at point of sale by Public Health England in 2015. Includes farm gate, farm shop, farmers markets, vending machines, milk rounds, mobile deliveries, internet sales and any other sources of product in finished containers.

Risk management

- 4.12 Where RDM is offered for sale, risk management requirements are observation of good animal health and husbandry, good agriculture practices (GAPs) and good hygiene practices (GHPs). These are essential to minimise opportunities for contamination of RDM throughout the production to consumption chain and this is reflected in the conclusions of the EFSA opinion. The EFSA opinion noted that the Australian QMRA indicated improvements in on-farm hygiene leads to a decrease in the number of predicted cases for some of the main hazards associated with RDM. The opinion also concluded no single control could be identified which would provide a significant reduction in risk relative to the baseline provided by GAP and GHP.

Conclusion

- 4.13 The FSA considers current controls for RDM in England, Wales and Northern Ireland are consistent with the principles of the EFSA opinion and agrees that effective on-farm controls and food safety management practices are essential to minimise the risks associated with RDM.

Enforcement and compliance

- 4.14 All RDM producers are subject to 6 monthly inspection visits and quarterly sampling and testing (cows) or local authority sampling checks (other species) against criteria in the domestic legislation. In practice, this means enforcement officials visit production holdings quarterly. If the milk fails to comply with the microbiological criteria, this prompts an inspection visit and follow-up testing.
- 4.15 Frequency of hygiene inspections for establishments in other sectors are determined by the competent authority based on risk using a scoring system. This considers the potential hazard, history of compliance and confidence in management/control procedures. Under this rating scheme, establishments handling and processing high risk products, those with an unsatisfactory history of compliance and those where there is low confidence in management require inspections at least every 6 months. Similar operations but with a satisfactory level of compliance and confidence in management are to be inspected at least every 12 months. Official controls for RDM premises are therefore comparable or more stringent than the general approach.
- 4.16 Inspections triggered by the outbreak of STEC associated with RDM in autumn 2014 found non-compliances with structural and hygiene standards on 17 out of 68 (25%) farms inspected. There were 15 farms with minor hygiene and/or structure issues, such as removing cobwebs and cleaning walls or ceilings of the milking parlour and verbal advice was provided to ensure these were addressed. More formal enforcement action (warning letters) was initiated in 2 cases. Follow up inspection visits have confirmed these non-compliances have been addressed, except those in relation to

three farms who have voluntarily ceased RDM production and de-registered from RDM sales.

- 4.17 Interim data from PHE surveillance of RDM (unpublished data¹⁰) has indicated 15 out of 62 (24 %) samples contained levels of aerobic colony and/or coliform counts above statutory limits¹¹. In addition pathogens were detected in 4 samples (STEC in 1 sample and *Listeria monocytogenes* in 3 samples, one of which also contained *Staphylococcus aureus*). Data from testing of quarterly official control samples in England and Wales taken during 2014-15 shows non-compliance with unsatisfactory levels of aerobic colony and/or coliform counts in 44 out of 234 (19%) of samples. Official control samples are not tested routinely for pathogens.
- 4.18 Practical experience in applying the current enforcement regime since this became an FSA responsibility in 2012, particularly follow up investigations initiated by the autumn 2014 outbreak and unsatisfactory testing results, has highlighted that some clarification and improvements are required. To support this we have developed advice for Dairy Hygiene Inspectors to clarify expected Food Business Operator (FBO) responses and appropriate enforcement action in response to non-compliances with the legislation to support consistent approaches and future compliance. In general, unsatisfactory results will trigger an inspection visit and follow up sampling.
- 4.19 Experience has also indicated the legal basis for action could be strengthened. The current requirements indicate it is an offence for RDM that does not comply with the microbiological criteria to be sold but there is no specific provision to prevent future production and/or sales. Prosecutions can, and have been taken but this requires evidence to be gathered over a period of time and intervention often relies on voluntary suspension of sales by the producer. It would be helpful if the current controls were amended to provide specific powers for formal action to be taken to prevent further sales when necessary standards are not being met.

Conclusion

- 4.20 The principles underpinning enforcement of controls for RDM are consistent with establishments in other sectors producing high risk foods. Recent evidence indicates a significant level of non-compliance with statutory microbiological criteria and hygiene standards. Action is therefore required to ensure RDM producers are implementing current requirements and complying with the necessary hygiene standards. Clearer legal provisions to prevent sale of RDM that does not meet statutory criteria should be introduced to protect public health and encourage implementation of appropriate hygiene controls.

¹⁰ To be made publically available following completion of the survey and analysis of the sampling and testing data

¹¹ Plate Count at 30°C ≤ 20,000; Coliforms (cfu/ml) <100

Risk communication

- 4.21 We make it clear in our strategy to 2020 that consumers have responsibilities as well as rights. Those responsibilities extend to the people they care for, and are balanced by a right to be informed and supported in taking on those responsibilities and a right to make informed choices about what they eat. Also, the EFSA opinion recommends improved risk communication to consumers, particularly those in vulnerable groups, on the hazards and controls that should be applied to RDM.
- 4.22 The FSA advice on consumption of raw milk is clear and indicates that RDM should not be consumed by vulnerable groups as it may contain harmful microorganisms as it has not been heat treated. This is reflected in labelling requirements for RDM sold in Wales and Board members have previously supported the FSA's proposal to extend this requirement to RDM sold in England and Northern Ireland.
- 4.23 It is difficult to demonstrate quantifiable public health benefits associated with enhanced labelling and consumer research carried out as part of the review provided variable views. Feedback from consumer focus groups and consultation indicated RDM consumers are well informed and they consider additional labelling would not add to current awareness of the risks. Also an online survey of all consumers indicated that the majority in England (66%), NI (56%) and Wales (75%) feel the current labelling provides enough information. The main criticism was that the labelling does not give enough specifics on potential health risks. Concerns have been raised about whether new consumers have the information available to allow them to make informed decisions.

Conclusion

- 4.24 There is sufficient evidence to justify measures to ensure labelling requirements on RDM sold in England and Northern Ireland highlights the specific risks to vulnerable groups.

Changes in the RDM market

- 4.25 Current controls restrict sales of cows' RDM to direct sales to the consumer from the farm premises (including farmer's markets), milk rounds and in farmhouse catering operations. Internet sales are allowed as long as these are direct from the farmer to the consumer. There are no restrictions on sales from other species. These controls limit consumer exposure and, expert opinion suggests this is a key factor in controlling the risks associated with RDM. It is possible however that a number of controlling factors may have contributed to the reduction in cases of illness associated with RDM. It is also widely suggested improvements in on-farm hygiene may be a key factor and conclusions in the EFSA opinion would seem to add further weight to that argument.

- 4.26 The FSA has explored wider access to RDM following feedback from the consultation with consumers and producers and recommended to the FSA Board in July 2014 that mechanisms for allowing wider consumer access to RDM from cows, in particular via vending machines and further controls that might be required to support this wider access should be explored.
- 4.27 Board members requested econometric modelling to predict the potential impact of changes including wider access on the RDM market and consumer exposure. Data requirements for such modelling are very extensive and specific and, even if the data is available, there would be significant uncertainty associated with the outputs. Application of economic theory (supply and demand analysis) suggests that high prices are likely to be a result of higher costs and lower economies of scale associated with the production and sale of RDM rather than an indication that RDM has high enough profit levels to encourage new suppliers to enter the market. There is evidence of new producers moving into the market but this is balanced by producers ceasing production and the number of registered RDM producers has remained relatively stable over recent years.
- 4.28 Recent surveillance data and incident investigations suggest that occasional presence of pathogens in RDM is likely. There is therefore no certainty that public health protection could be maintained even if consumers are allowed wider access to RDM on a restricted basis when produced under the current control regime.

Conclusion

- 4.29 Evidence is required to assess public health risks associated with increased access to RDM and understand whether the potential for changes in the market are substantial and, as noted earlier, we do not believe such further evidence gathering would represent a value for money application of FSA finite resources. Given the current level of uncertainty in the evidence, even limited wider access to RDM would need to be supported by the introduction of more stringent controls to maintain current level of public health protection.

5 DISCUSSION

Public health impact

- 5.1 The FSA strategic plan to 2020 makes it clear that FSA science should focus on the biggest risks and challenges to consumers' current and future interests and be focused on areas where it can make the biggest impacts. The potential hazards associated with RDM are well categorised and, while it is acknowledged that there is a potential for severe illness and illness may be under-reported, the very small number of cases of reported illness (9 cases; autumn 2014) in the last 12 years indicates the likelihood of illness occurring is relatively low. Also RDM is a niche product consumed by a small group of

consumers.¹² The potential public health impact associated with RDM consumption must be considered alongside other strategic priorities such as Campylobacter where there are an estimated 280,000 cases of illness each year.

- 5.2 As noted (para 4.4) we have assessed the available evidence and we are reasonably confident in our analysis: we can expect numbers to change as we learn more, but not sufficiently to justify major policy shifts. Additional evidence is likely to reduce uncertainty in assessment of public health risks but is highly unlikely to change the outcome. It is therefore reasonable to consider there is sufficient evidence to conclude the FSA review of RDM controls and provide final recommendations.

Provisions for new routes of sale

- 5.3 The FSA has been exploring the possibility of introducing provisions to allow restricted wider sales as outlined in the July 2014 Board paper. Feedback from RDM producers suggests some have well developed food safety management procedures which are supported by a regular sampling and testing programme. FSA 2015-20 strategy includes an obligation for the FSA to provide cost effective ways of supporting businesses who want to do the right thing. Provisions to support those producers who have taken full responsibility for safety of the RDM they produce and allowing them opportunities for wider sales would be consistent with that theme. This would also be consistent with the wider government growth agenda and the FSA's commitment to supporting consumer choice.
- 5.4 Initial discussions with stakeholders indicate support for controlled wider access to be linked to tighter controls. Further work would be required to consider such a proposal in light of uncertainty in the risk assessment and explore the practical details of such a provision but this could reflect the following principles:
- Producer responsibility is maintained throughout;
 - There is a history of compliance with current controls and evidence of effective and established on farm and food safety management controls;
 - An established and regular sampling and testing regime is applied by producers to verify controls are effective and results are regularly shared with the regulator;
 - Competent Authority must verify appropriate controls are in place, perhaps through approval of businesses seeking to offer wider sales and collation of producer testing data.

¹² This research indicates that 2% of the population have consumed RDM in the past six months, with 1% of the population reporting consumption on a daily basis. Questions on purchase and consumption of raw drinking milk and cream (RDM) were included in random probability omnibus surveys in England, Wales, and Northern Ireland to provide robust estimates of the proportion of the population who purchase and consume RDM (based on reported only).

http://tna.europarchive.org/20141103165934/http://www.foodbase.org.uk//admintools/reportdocuments/867-1-1611_RDM_Omnibus_Report_FINAL.pdf

5.5 The FSA considers the principles underpinning a provision for restricted wider sales are sound but it is not appropriate to pursue such a provision at this time. The recent evidence indicates levels of non-compliance with statutory microbiological criteria and hygiene standards are relatively high. It would not be appropriate to introduce flexibilities to allow wider sales until there is evidence showing that current controls are being applied consistently and effectively across the sector, for example, only occasional unsatisfactory sampling and testing results or non-compliances with hygiene standards are reported.

6 CONSULTATION

6.1 There has been extensive formal consultation and informal engagement with stakeholders since the review was initiated and we would expect to build on this as the review recommendations are implemented (subject to Board agreement).

7 DEVOLUTION IMPLICATIONS

7.1 The review of RDM controls covers England, Wales and Northern Ireland and there are no specific implications for individual administrations at this stage. Sales of RDM in Scotland are banned and controls in Scotland are, of course, outside of this review.

8 CONSUMER ENGAGEMENT

8.1 There has been extensive consumer engagement over the course of the review including specific focus groups, wider consumer research and a face to face consumer engagement event. We would expect further consumer engagement through wider research on improved risk communication.

9 CONCLUSION AND RECOMMENDATIONS

9.1 The FSA Board is asked to:

- **Agree:** that the FSA review of raw drinking milk controls should conclude, with a significant degree of certainty, that the hazards associated with RDM are well characterized and the level of risk associated with RDM consumption by consumers except those who are vulnerable by virtue of age or underlying health conditions, is acceptable when appropriate hygiene controls are applied throughout the chain;
- To **agree:** that the risk to those who are vulnerable by virtue of age or underlying health conditions is heightened and action is needed to increase awareness of those risks;
- **Agree:** that current restrictions on sale should remain in place as, in the absence of a quantitative risk assessment and limitations in the evidence base, there is uncertainty that the same level of consumer protection could be maintained if the current restrictions were relaxed to allow wider access to RDM;

- **Agree:** that, in the absence of a quantitative risk assessment, any future consideration of extending sales should (i) use principles that already exist in EU legislation (ii) balance any extension to new routes of supply with tighter regulatory controls that would manage the risk to an acceptable level;
- **Agree:** that given the current evidence on compliance, focus should be to ensure RDM producers are implementing current controls and meeting required standards. Any relaxation of current sales restrictions could only be considered when there is evidence to indicate a high level of compliance across the sector; and
- **Agree:** that communication of the risks associated with RDM at the point of sale or equivalent should be improved and, as a first step, labelling requirements in England and Northern Ireland should be extended to include a specific warning for vulnerable groups, as currently exists in Wales.

Annex 1 – EVIDENCE WEIGHTING

ADVISORY COMMITTEE ON THE MICROBIOLOGICAL SAFETY OF FOOD¹³

Qualitative categories for expressing uncertainty in relation to qualitative risk estimates

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

GRADE scale for quality of evidence

High quality	Further research is very unlikely to change our confidence in the assessed risk
Moderate quality	Further research is likely to have an important impact on our confidence in the assessed risk and may change the estimate
Low quality	Further research is very likely to have an important impact on our confidence in the assessed risk and is likely to change the estimate
Very low quality	Assessed risk is very uncertain

¹³

http://acmsf.food.gov.uk/sites/default/files/mnt/drupal_data/sources/files/multimedia/pdfs/committee/acm_1065.pdf

POSSIBLE SCALE OF THE JUDGED QUALITY OF A RISK ANALYSIS¹⁴

Star rating	Meaning
★★★★ 4 star	We are fully confident of our understanding of the underlying process, so although we cannot predict what is going to happen, we can provide good numerical assessments.
★★★ 3 star	We are reasonably confident in our analysis: we can expect numbers to change as we learn more, but not sufficient to justify major policy shifts.
★★ 2 star	New evidence could have a substantial impact on our assessment, although no major new surprises are expected: we encourage a robust decision-making approach with some precaution and adaptivity.
★ 1 star	We have very limited understanding of the process or possibilities, and so resilience to unexpected occurrences is called for.

¹⁴ Annual Report of the Government Chief Scientific Adviser 2014. Innovation: Managing Risk, Not Avoiding It. Evidence and Case Studies. Chapter 6 The need for a common language. David Spiegelhalter.

Annex 2

SUMMARY OF CONCLUSIONS AND RECOMMENDATIONS FROM EFSA OPINION ON RDM

In January 2015, the European Food Safety Authority (EFSA) published a scientific opinion from its scientific panel on Biological hazards on the public health risks related to the consumption of raw drinking milk (RDM) in the EU.

EFSA mandate

In December 2013, EFSA's Biological Hazards Panel began a self-tasking mandate to issue a scientific opinion on the public health risks related to the consumption of RDM, in particular to:

1. identify the main microbiological hazards of public health significance that may occur in RDM from different animal species;
2. assess the public health risk arising from the consumption of RDM;
3. assess the likelihood of RDM being a significant source of antimicrobial resistant bacteria/resistance genes;
4. assess the additional risks associated with the sale of RDM through vending machines and via the internet;
5. Identify and rank potential control options to reduce public health risks arising from consumption of RDM.

Approach

The panel considered the microbiological hazards that may be associated with milk-producing animal species in the EU (cows, sheep and goats, horses and donkeys, and camels) and used a decision tree approach to identify the main hazards. This considered evidence of milk-borne infection and the hazard being present in the EU, the impact on human health and whether there was evidence for RDM as an important risk factor in the EU.

Conclusions

The main hazards were considered to be *Campylobacter* spp., *Salmonella* spp., shigatoxin-producing *Escherichia coli* (STEC), *Brucella melitensis*, *Mycobacterium bovis* and tick-borne encephalitis virus (TBEV) as the main hazards that may be present in raw milk in the EU.

Listeria monocytogenes was not identified as a main hazard due to the lack of robust epidemiological data (including outbreaks) linking listeriosis to consumption of raw milk in Europe, but several risk assessment models outside Europe have been developed for this pathogen. Further study in relation to RDM is recommended.

There is a clear link between drinking RDM and human illness with *Campylobacter* spp., *S. Typhimurium*, STEC, TBEV, *B. melitensis* and *M. bovis*, with the potential for severe health consequences in some individual patients. However, a quantitative

microbiological risk assessment could not be undertaken because country and EU-wide data is limited.

Antimicrobial resistance has been reported in several EU countries in isolates of *Campylobacter* spp., *Salmonella* spp., STEC and *S. aureus* from raw milk or associated equipment such as milk filters, and may be significant for public health. Such isolates have been primarily associated with raw milk from bovine animals, which may reflect the more limited screening of milk from other species.

Sale of RDM through vending machines is permitted in some EU member states, with considerable variation in the number of machines in different countries. Consumers are usually instructed to boil the milk prior to consumption which eliminates the microbiological risks associated with raw milk. The temperature of RDM in vending machines is generally kept below 4 °C and therefore variability in milk temperature is more likely to arise between the farm and vending machine and between the vending machine and point of consumption by the consumer.

Fresh and frozen RDM of different species (cows, goats, sheep and camels) is available via internet sales although there are no data on the microbiological or temperature controls for these milks from the bulk milk tank through to the point of consumption.

The steps in the production to consumption chain for RDM present many opportunities for contamination by microorganisms, some of which may be transmissible to humans. Observance of good animal health and husbandry, together with the application of good agricultural practices (GAPs) and good hygienic practices (GHPs), are essential to minimise opportunities for contamination of RDM with pathogens in the production to consumption chain for RDM.

Recommendations

There is a need for a better evidence base to inform future prioritisation and ranking approaches. Studies should be undertaken to systematically collect data for the hazards identified as associated with RDM. Hazard identification should be revisited regularly because of the diverse range of potential microbiological hazards.

There is a need for validated growth and survival models for pathogens in RDM, particularly in relation to the temperature and storage time of RDM from the producer up to the point of consumption.

There should be improved risk communication to consumers, particularly susceptible/high risk populations, regarding the hazards and control methods associated with consumption of RDM.