

FOOD STANDARDS AGENCY CONSULTATION

Title: Impact Assessment on the review of the controls governing the sale and marketing of unpasteurised, or raw drinking milk and raw cream (RDM) in England, Wales and Northern Ireland.

CONSULTATION SUMMARY PAGE

Date consultation launched:	Closing date for responses:
30 Jan 2014	30 April 2014

Who will this consultation be of most interest to?

Raw Drinking Milk and Cream (RDM) producers, RDM consumers, the dairy industry and enforcement authorities

What is the subject of this consultation?

An Impact Assessment on the options identified following a review of the controls governing the sale and marketing of RDM in England, Wales and N. Ireland.

What is the purpose of this consultation?

To seek stakeholder views on the Agency's preferred option that was identified following a review of the current RDM policy. Also to determine whether the Agency's assumptions are a fair reflection of costs, benefits and wider impacts for stakeholders.

The overall objective of this review is to ensure that the controls in place to manage the food safety risk associated with RDM are proportionate and risk-based, taking into account the latest scientific evidence and information and views from producers, consumers and parties with an interest in this sector.

Responses to this consultation should be sent to:

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Is an Impact Assessment included with this consultation?

Yes ☒

No ☐ See Annex A for reason.



INVESTOR IN PEOPLE

If you would prefer to receive future FSA consultations by e-mail, or if you no longer wish to receive information on this subject please notify the named person in this consultation.



FOOD HYGIENE RATING

Impact Assessment on the review of the controls governing the sale and marketing of unpasteurised, or raw drinking milk and raw cream (RDM) in England, Wales and Northern Ireland.

DETAIL OF CONSULTATION

Introduction

1. It is known that pasteurisation of milk prior to direct human consumption is a critical control measure and is the most effective means of protecting public health from pathogens which may be present in milk. Most milk and cream consumed in the UK is pasteurised, however it has been recognised that some consumers prefer to exercise choice in continuing to have access to raw drinking milk and cream (RDM¹) despite the potential food safety risk associated with such products. Therefore, the current rules in England, Wales and Northern Ireland concerning the sale of RDM for direct consumption make allowances for restricted sales of RDM from cows and put in place labelling requirements for such milk when sold. RDM from other species is not currently subjected to the same restrictions, though some labelling requirements do apply to RDM from other species.

2. The current controls have not been reviewed for a number of years and we are aware that there have been developments in the marketing of RDM and an increase in consumer interest for raw cows' drinking milk and raw milk from other species. For these reasons, along with the current Government focus on rural economies, the FSA Board recommended an evaluation of the current RDM requirements to ensure they are clear and consistent, they provide proportionate and effective consumer protection, and they are applicable to a developing market. In order to review the policy thoroughly it was necessary to assess the latest scientific evidence including outbreak data, the situation in other countries as well as stakeholder and consumer views on raw milk consumption and production practices to ensure controls are proportionate to the risk and reflect the changing market.

3. The sale of RDM in Scotland is banned; the Scottish policy is not under review and is outside the scope of this consultation as are the controls for raw milk products.

Policy Review

4. The first phase of the review consisted of collating evidence to consider the key issues around the available science, consumer and stakeholder views and controls applied internationally. The second phase of the review consisted of analysing the evidence and using this to develop risk-based policy options.

5. The evidence generated from the work streams has allowed us to develop four policy options and identify a preferred option relating to the sale and marketing of RDM. Each option considers four different elements; a) sales of cows' RDM, b) sales of RDM from other species, c) labelling and d) other routes of sale. The options include a range of possibilities from removing restrictions on sales through to maintaining the status quo or introducing a ban on sales.

¹ RDM refers to raw drinking milk and raw cream

Control options

6. Options being considered are:

- Option 1: Do nothing
- Option 2: All milk to be pasteurised prior to sale
- Option 3: Allow sales of raw drinking milk from all outlets
- Option 4: Introduce measures to harmonise and clarify current controls.

Preferred option

7. **Option 4 is preferred.** This option would continue to achieve a balance between informed consumer choice and maintaining a significant level of public health protection. The addition of guidance on the intention of the legislation will help to clarify routes of sale, particularly with regard to the new developments in the market. This should help to make enforcement of the rules clearer. In addition, harmonising the controls so they are consistent across all species either through legislation or non-legislative approaches such as the introduction of a voluntary code of practice for should ensure the same level of public health protection for all RDM. An important factor in consumer choice is ensuring that the information on the label of the product allows the purchaser to make an informed choice. Therefore, amending the labelling requirements to reflect the outcome of the consumer survey and to harmonise the requirements across all countries and all species is an important measure. This will also help to simplify requirements for producers and enforcers.

Key proposals of preferred option:

- **RDM from cows:** No change to current restrictions in national law but FSA to publish guidance on intention of the law
- **RDM other species:** Introduce same sales restrictions as cows' milk through either a legislative change or a voluntary measure, such as an industry Code of Practice;
- **Labelling:** Amend the wording and make the requirements consistent across England, Wales and Northern Ireland and across all species;
- **Other routes of sale:** No change

Consultation Process

8. There has been communication and consultation with stakeholders throughout the review and during the development of the Impact Assessment (IA). The Agency is committed to consumer engagement and has consulted consumers through face to face meetings and an online survey to get consumer views and understanding of RDM. Producers of raw milk were also approached to obtain further information on current production and sales routes of RDM to help us understand the sector better and in turn inform policy options and development of the IA. In addition, a meeting with a wider stakeholder group involving the dairy industry, consumer representatives, public health and enforcement bodies and other Government departments took place at the beginning of the review process to discuss the scope and intention of the review.

9. The FSA has now produced a draft IA to assess the costs and benefits of the four options identified, on which we would welcome comments from all interest parties. Interested parties are particularly invited to respond to the questions around:

Key issues stakeholders are asked to comment and provide evidence-based information on in the consultation are below - please note this is not an exhaustive list of all the questions in the IA, just an indication of the areas we have asked for feedback on.

- Whether you agree with the preferred option identified together with your reasons for this view.
- Whether you prefer an alternative option, again with your views.
- The proposed revised wording for the labels of all RDM and assumptions on the cost of relabelling and proposed transition period for using new labels.
- The risk assessment of RDM from other species and views on whether new legislation or voluntary Code of Practice by the industry should be used to implement consistent controls, including how to develop and implement such a Code of Practice as well as costs to producers
- The accuracy of data on RDM producers in England, Wales and Northern Ireland and the request for information on the size of businesses.
- Assumptions around familiarisation costs for producers and enforcers
- Views on guidance to clarify the current legislation to farmers

10. The preferred option represents a preliminary view, and is without prejudice to the final decision of the FSA Board following consideration of the consultation responses and wider engagement activity.

Responses

11. **Responses are required by close on 30 April 2014.** Please state, in your response, whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents).

Thank you on behalf of the Food Standards Agency for participating in this public consultation.

Yours,

Linden Jack

Branch: Food Hygiene Policy

Division Hygiene and Microbiology Division

Enclosed

Annex A: Standard Consultation Information

Annex B: Draft Impact Assessment

Annex C: List of interested parties

Queries

1. If you have any queries relating to this consultation please contact the person named on page 1, who will be able to respond to your questions.

Publication of personal data and confidentiality of responses

2. In accordance with the FSA principle of openness we shall keep a copy of the completed consultation and responses, to be made available to the public on receipt of a request to the [FSA Consultation Coordinator](#) (020 7276 8140). The FSA will publish a summary of responses, which may include your full name. Disclosure of any other personal data would be made only upon request for the full consultation responses. If you do not want this information to be released, please complete and return the Publication of Personal Data form, which is on the website at <http://www.food.gov.uk/multimedia/worddocs/dataprotection.doc>. Return of this form does not mean that we will treat your response to the consultation as confidential, just your personal data.
3. In accordance with the provisions of Freedom of Information Act 2000/Environmental Information Regulations 2004, all information contained in your response may be subject to publication or disclosure. If you consider that some of the information provided in your response should not be disclosed, you should indicate the information concerned, request that it is not disclosed and explain what harm you consider would result from disclosure. The final decision on whether the information should be withheld rests with the FSA. However, we will take into account your views when making this decision.
4. Any automatic confidentiality disclaimer generated by your IT system will not be considered as such a request unless you specifically include a request, with an explanation, in the main text of your response.

Further information

5. A list of interested parties to whom this letter is being sent appears in Annex C. Please feel free to pass this document to any other interested parties, or send us their full contact details and we will arrange for a copy to be sent to them direct.
6. A Welsh version of the consultation package can be found at www.food.gov.uk
7. Please contact us for alternative versions of the consultation documents in Braille, other languages or audiocassette.
8. This consultation has been prepared in accordance with HM Government consultation principles².
9. An Impact Assessment will normally be published alongside a formal consultation. Please see the Impact Assessment at Annex B.
10. For details about the consultation process (not about the content of this consultation) please contact: [Food Standards Agency Consultation Co-ordinator](#), Room 2B, Aviation House, 125 Kingsway, London, WC2B 6NH. Tel: 020 7276 8140.

² <http://www.bis.gov.uk/policies/bre/consultation-guidance>

Comments on the consultation process itself

11. We are interested in what you thought of this consultation and would therefore welcome your general feedback on both the consultation package and overall consultation process. If you would like to help us improve the quality of future consultations, please feel free to share your thoughts with us by using the Consultation Feedback Questionnaire at <http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc>
12. If you would like to be included on future Food Standards Agency consultations on other topics, please advise us of those subject areas that you might be specifically interested in by using the Consultation Feedback Questionnaire at <http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc> The questionnaire can also be used to update us about your existing contact details.

Title: Review of the controls governing the sale and marketing of unpasteurised, or raw drinking milk and cream (RDM) for direct human consumption in England, Wales and Northern Ireland. IA No: FOODSA00121 Lead department or agency: Food Standards Agency Other departments or agencies: None	Impact Assessment (IA)		
	Date: 17/01/2014		
	Stage: Development/Options		
	Source of intervention: Domestic		
	Type of measure: Secondary legislation		
Contact for enquiries: Food Hygiene Policy team, RDM@foodstandards.gsi.gov.uk			
Summary: Intervention and Options			RPC Opinion: RPC Opinion Status

Cost of Preferred (or more likely) Option				
Total Net Present Value	Business Net Present Value	Net cost to business per year (EANCB on 2009 prices)	In scope of One-In, Two-Out?	Measure qualifies as In/Out/zero net cost
£0.26m	£0.25m	£0.02m	Yes	In/Out/zero net cost

What is the problem under consideration? Why is government intervention necessary?

The current controls in England, Wales and Northern Ireland place restrictions on the sale of cows' raw drinking milk intended for direct human consumption in order to manage the inherent food safety risk associated with raw drinking milk and cream (RDM). There are also labelling requirements associated with the sale of RDM. However, these controls have not been reviewed for a number of years and we are aware that there have been developments in the marketing of RDM and an increase in consumer interest in this product. These issues, along with the current Government focus on rural economies, mean that it is timely to review these controls.

What are the policy objectives and the intended effects?

The objective of this review is to ensure that controls in place to manage the food safety risk associated with RDM are proportionate and risk-based, and takes account of the latest scientific evidence and information and views from producers, consumers and parties with an interest in this sector.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)


Option 1: Do nothing
Option 2: All milk to be pasteurised prior to sale
Option 3: Allow sales of raw drinking milk from all outlets
Option 4: Introduce measures to harmonise and clarify current controls. The preferred option represents a preliminary view, and is without prejudice to the final decision of the FSA Board following consideration of the consultation responses and wider engagement activity.

Will the policy be reviewed? It will/will not be reviewed. If applicable, set review date: 12/2019

Does implementation go beyond minimum EU requirements?			Yes		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	Micro Yes	< 20 Yes	Small Yes	Medium Yes	Large Yes
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)			Traded:		Non-traded:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Chief Executive:


Date: 20/1/14

Summary: Analysis & Evidence

Policy Option 1

Description: Do nothing - leave current RDM requirements unchanged.

FULL ECONOMIC ASSESSMENT

Price Base Year 2013	PV Base Year 2013	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: n/a

COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	Optional
High	Optional		Optional	Optional
Best Estimate	n/a		n/a	n/a

Description and scale of key monetised costs by 'main affected groups'
None. This is the baseline against which all other options are appraised.

Other key non-monetised costs by 'main affected groups'
None. This is the baseline against which all other options are appraised.

BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	Optional
High	Optional		Optional	Optional
Best Estimate	n/a		n/a	n/a

Description and scale of key monetised benefits by 'main affected groups'
None. This is the baseline against which all other options are appraised.

Other key non-monetised benefits by 'main affected groups'
None. This is the baseline against which all other options are appraised.

Key assumptions/sensitivities/risks			Discount rate (%)	3.5
This option assumes that there is no change in policy. It is envisaged that all variables in the baseline will remain constant across the lifespan of the policy, such as consumer awareness of risks, number of outbreaks associated with RDM and the production and sales of RDM.				

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: n/a	Benefits: n/a	Net: n/a	No	IN/OUT/Zero net cost

Summary: Analysis & Evidence

Policy Option 2

Description: Pasteurisation of all milk prior to sales

FULL ECONOMIC ASSESSMENT

Price Base Year 2013	PV Base Year 2013	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: -£21.31

COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	1	Optional	Optional
High	Optional		Optional	Optional
Best Estimate	£0.01		£2.47	£21.31

Description and scale of key monetised costs by 'main affected groups'
Industry: one-off costs: familiarisation costs: £2,683 (PV, ten years); **ongoing:** lost premium/lost sales: £10,241,287 (PV, ten years).
Enforcement: one-off costs: familiarisation costs: £8,503 (PV, ten years).
Consumers: ongoing costs: lost access: £11,058,667 (PV, ten years).

Other key non-monetised costs by 'main affected groups'
Wider impacts: we have been unable to monetise the potential cost of a rise in illegal sales.

BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	Optional
High	Optional		Optional	Optional
Best Estimate	£0		£0	£0

Description and scale of key monetised benefits by 'main affected groups'
None identified.

Other key non-monetised benefits by 'main affected groups'
Consumers: We have been unable to quantify the potential public health impact that would be associated with introducing the requirement to pasteurise all milk. The potential for pathogens to be present in RDM remains and the impact of that illness occurring could be severe which the requirement to pasteurise would reduce. However, given that there have been no reported outbreaks associated with RDM over the past 10 years the increase in quantifiable public health benefits, compared to option 1, seem to be low.

Key assumptions/sensitivities/risks	Discount rate (%)	3.5
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Assumes 1 hour of familiarisation costs to enforcement and businesses.
Assumes that consumers value their access to raw drinking milk at the price at which it is sold (average of £2.30 per litre).
Assumes that half of producers lose all sales of RDM, which is valued at the price at which it is sold (£2.3), and that half of producers move to pasteurisation and therefore lose the premium attached to RDM (£2 per litre, calculated as the price of RDM (£2.3) minus the farm gate price of pasteurised milk (£0.3 per litre)). Production figures are based on responses to the producer questionnaire (63% response rate) and then extrapolated to include all registered producers.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: £0	Benefits: £0	Net: £0	Yes	OUT

Summary: Analysis & Evidence

Policy Option 3

Description: Allow sales of RDM from all outlets

FULL ECONOMIC ASSESSMENT

Price Base Year 2013	PV Base Year 2013	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: -£28.25

COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	1	Optional	Optional
High	Optional		Optional	Optional
Best Estimate	£0.01		£3.28	£28.5

Description and scale of key monetised costs by 'main affected groups'

Industry: one-off costs: familiarisation: £2,683 (PV, ten years);

Enforcement: one-off costs: familiarisation: £8,503;

Consumers: ongoing costs: risk of illness: £28,241,404.

Other key non-monetised costs by 'main affected groups'

Potential decline in consumer trust in food safety regulation, and potential impact on the wider dairy industry producing pasteurised milk and milk products and raw milk products if increased consumer exposure to RDM results in an increase in outbreaks associated with RDM

BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	Optional
High	Optional		Optional	Optional
Best Estimate	£0		£0	£0

Description and scale of key monetised benefits by 'main affected groups'

None identified.

Other key non-monetised benefits by 'main affected groups'

Industry: increased sales of raw drinking milk which would reflect the premium attached to RDM in comparison to pasteurised milk or raw milk sold as an ingredient for raw milk products;

Consumers: increased access to raw drinking milk.

Key assumptions/sensitivities/risks

Discount rate (%)

3.5

Assumption that familiarisation would take 1 hour for industry and enforcement.

Assumption that current sales restrictions have reduced the risk of disease associated with RDM.

BUSINESS ASSESSMENT (Option 3)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: £0	Benefits: £0	Net: £0	Yes	IN

Summary: Analysis & Evidence

Policy Option 4

Description: Introduce measures to harmonise and clarify current controls

FULL ECONOMIC ASSESSMENT

Price Base Year 2013	PV Base Year 2013	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: -£0.26

COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	1	Optional	Optional
High	Optional		Optional	Optional
Best Estimate	£0.20		£0.01	£0.26

Description and scale of key monetised costs by 'main affected groups'

Industry: one-off costs: familiarisation: £2,683 (PV, ten years); relabeling: £187,200 (PV, ten years); sales restrictions: £60,719 (PV, ten years).

Enforcement: one-off costs: familiarisation: £8,503 (PV, ten years)

Other key non-monetised costs by 'main affected groups'

Cost to the FSA from the introduction of guidance.

BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	Optional
High	Optional		Optional	Optional
Best Estimate	£0		£0	£0

Description and scale of key monetised benefits by 'main affected groups'

None identified.

Other key non-monetised benefits by 'main affected groups'

Industry: greater clarity and consistency of rules.

Enforcement: greater clarity and consistency of rules.

Key assumptions/sensitivities/risks

Discount rate (%)

3.5

Assumption that familiarisation requires 1 hour for industry and enforcement.

Production figures are based on responses to the producer questionnaire (63% response rate) and then extrapolated to include all registered producers and are likely to be an overestimate.

BUSINESS ASSESSMENT (Option 4)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: £0.02	Benefits: £0	Net: £0.02	Yes	IN

Evidence Base

Problem under consideration and Rationale for Intervention

1. The majority of milk in the UK is pasteurised before consumption and this destroys any pathogens that might be present. There is also a small market for raw drinking milk (RDM) (milk that is not pasteurised). Advice from the relevant scientific advisory committee is that pasteurisation is an important control measure for reducing the risks associated with raw drinking milk (see paragraphs 13-15). The current controls, including rules concerning the sale and labelling of raw drinking milk, were designed to help manage the well-characterised risks (see paragraph 6) associated with this commodity and allow consumers to make informed choices about the food they eat. The FSA Board requested (<http://food.gov.uk/multimedia/pdfs/board/fsa120305.pdf>) a review of the current RDM requirements to ensure they are clear and consistent and applicable to a developing market.
2. Raw milk products (i.e. raw milk cheese, yoghurt, butter) are outside the scope of the review. Production processes such as heating, acidification and maturation reduce the bacterial load or control bacterial growth and therefore reduce the potential risk associated with these products in comparison to RDM. Also, the EU hygiene legislation provides for specific controls for raw milk products which require that the potential risks are controlled by food businesses.
3. This policy review covers controls in England, Wales and Northern Ireland. Legislation in Scotland prohibits the sale of any RDM and is not being reviewed.

Policy Objective

4. The statutory objective of the FSA is to protect public health in relation to food and consumers' other interests in relation to food. In doing so, we have a statutory duty to have due regard to all relevant risks, costs and benefits. Accordingly, the objective of this review is to ensure that the controls in place (see Annex 1) to manage the food safety risk associated with RDM are proportionate and risk-based, and takes into account the latest scientific evidence and information and views from producers, consumers and parties with an interest in this sector.

Policy Background

5. RDM may contain a number of harmful micro-organisms such as *Salmonella*, *E. coli* 0157, *Listeria monocytogenes* and *Campylobacter* that can cause severe

illness. Vulnerable consumers such as the young, elderly, pregnant or immuno-compromised individuals are at greatest risk from infection. RDM can become contaminated by bacteria from an animal's udder or from animal faeces and other contaminants in the farm environment during milking and storage. The pasteurisation process that applies to other drinking milk is designed to eliminate such pathogens and is therefore a key food safety control.

6. While good animal husbandry and hygiene practices can reduce the risks of and from bacterial contamination of the milk they cannot eliminate them, so there is a potential food safety risk associated with RDM which has long been recognised. However, despite these known risks, some consumers choose to drink RDM and feel strongly that they should continue to have the freedom to do so. Advocates of RDM often report perceived benefits such as nutrition and wider health benefits above those of pasteurised milk. Additionally, feedback from individual producers on volumes sold indicates potential income from RDM sales direct to the consumer will be variable.
7. A summary of the current EU and domestic controls and enforcement regime for RDM is provided at Annex 1. Government in England, Wales and Northern Ireland has publicly assessed the health risk posed by RDM three times since 1984, most recently in 1997. The Government initially introduced measures to restrict the RDM market allowing only sales direct from the farm to the consumer and then added measures such as introducing health warning labelling and increasing the frequency of inspection and microbiological sample testing of RDM, to protect consumers. A review was carried out in Wales in 2000 that resulted in a specific warning to the most vulnerable consumers being added to the labelling for RDM sold in Wales.
8. Legislation prohibits the sale of RDM from all species in Scotland. The Scottish ban on sales was introduced in 1983 following a significant number of large food poisoning outbreaks linked to the consumption of RDM, where nearly 800 people were affected including 8 confirmed deaths. The ban is considered a key public health measure in Scotland and has been maintained given the history of previous deaths. There is also concern around the higher rates of human *E.coli* O157 and *Campylobacter* infection in Scotland compared with the rest of the UK. Management of food safety risks is an area of devolved competence, and Scottish Ministers and stakeholders continue to support mandatory pasteurisation as the most appropriate control measure for Scotland.

The Current Review of Raw Drinking Milk Policy in England, Wales and Northern Ireland

9. The FSA has completed an evidence-gathering and analysis exercise which included an assessment of the available science, current views and information from consumers and stakeholders on consumption of RDM and the RDM sector, a review of current policy and enforcement regime, and data from European and other countries with different control regimes for RDM.
10. The current review of the science considered additional data to that considered by the Advisory Committee on the Microbiological Safety of Foods (ACMSF) when it last considered the issue in 2011, including:
- Wider and more recent data on illness from across the UK including data from enhanced VTEC surveillance.
 - Assessment of the impact of controls introduced in the UK on reported illness associated with RDM.
 - consideration of the potential for nutritional benefits and possible protective effects against development of allergies
11. A summary of the scientific data and other evidence collated to support the review can be seen below.
12. While extensive data has been gathered and analysed, there are still gaps in our knowledge and there is uncertainty associated with the assessment of public health risk from consumption of RDM. The ACMSF has agreed a method of ranking evidence and expressing uncertainty in relation to qualitative risk assessments¹². This system was not in place when they considered raw milk but application of this ranking to the current evidence base would indicate the scientific data is of moderate quality (further research is likely to have an important impact on our confidence in the assessed risk and may change the estimate) and there is medium uncertainty associated with the risk assessment (some, but incomplete data available). More recent data on the prevalence of pathogens in RDM, the volumes of RDM sold and data on species other than cows would strengthen the evidence base and may reduce the uncertainty in the analysis of evidence.

Summary of data and assessments of microbiological safety, development of allergic disease and nutritional qualities

Advisory Committee on the Microbiological Safety of Foods (ACMSF)

13. In January 2011^{3,4}, the FSA consulted the ACMSF on the health risks to consumers associated with unpasteurised milk and cream for human

¹ ACM/1065 : http://www.food.gov.uk/multimedia/pdfs/committee/acm_1065.pdf

² <http://acmsf.food.gov.uk/acmsfmeets/acmsf2012/acmsf290512/acmsfmin290512>

³ <http://www.food.gov.uk/multimedia/pdfs/committee/acm1008rawmilk.pdf>

⁴ <http://acmsf.food.gov.uk/acmsfmeets/acmsf2011/acmsf200111/acmsfmin200111>

consumption. The background was concerns raised about the proportion of raw cows' milk samples failing to meet microbiological criteria requirements in the national legislation. The Committee reviewed microbiological data from UK surveys of raw milk and cream from cows and other species, data on outbreaks linked to raw drinking milk and cream and results of the raw cows' milk sampling programme.

14. The Committee noted that much of the data was old and due to gaps in data in many areas a robust risk assessment was difficult. The risk to human health was considered to be non-negligible, as in previous assessments, but it was difficult to quantify this risk based on available data. The Committee also noted that no new data were available that would suggest that raw milk and cream were safer than previously. The lack of recent reported outbreaks linked to raw milk could be a result of reduced consumer exposure to raw milk and cream. The presence of faecal contamination in raw milk was apparent from available data on microbiological quality of raw milk and the Committee noted that the link between faecal contamination and the presence of pathogens has been demonstrated previously. The Committee concluded that given the evidence available, it could not justify a change to its recommendation that pasteurisation is an important control measure for reducing the risks associated with RDM.
15. In September 2011⁵ the ACMSF considered the specific risks associated with *Mycobacterium bovis* (*M. bovis*) from RDM and products derived from raw milk. The Committee concluded that the risk to human health from *M. bovis* in unpasteurised cows' milk and milk products is 'very low'. The ACMSF also concluded that the risk to human health from *M. bovis* in unpasteurised sheep, goat and buffalo milk is 'likely to be low', however, due to the lack of data on these species there are more uncertainties associated with the assessment.

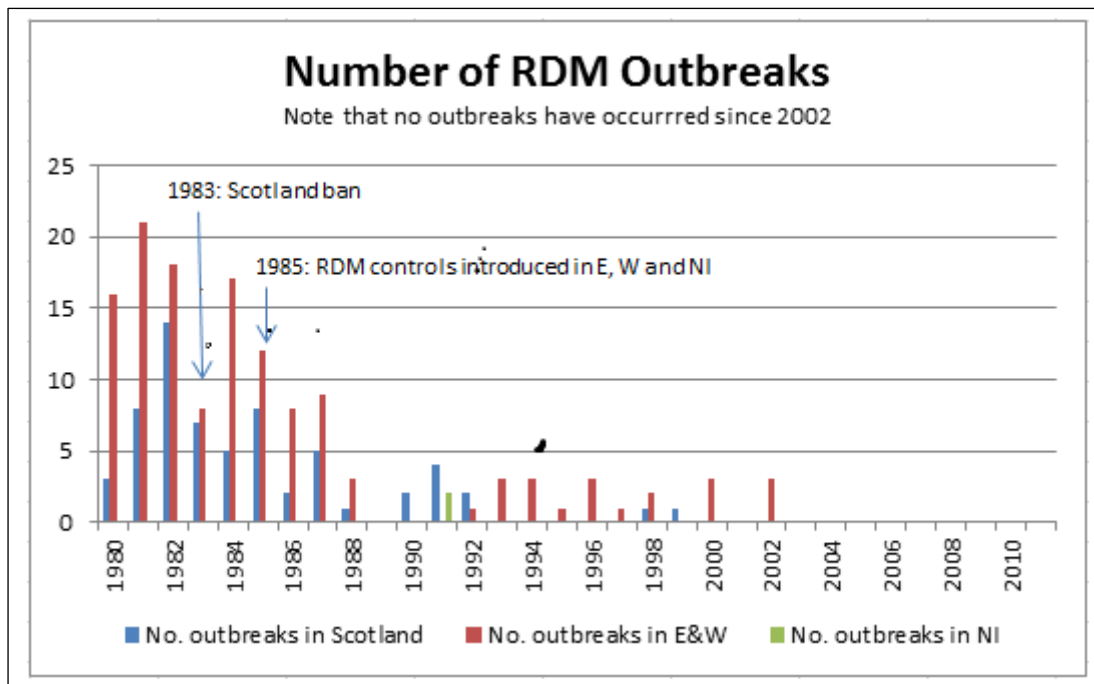
Science and Risk Assessment

Outbreak data mapped to the introduction of RDM controls

16. Data on outbreaks of illness linked to unpasteurised milk in the UK between 1980 and 2011 were mapped against the introduction of the Scottish ban on sales of raw milk in 1983 and the introduction of RDM controls in England, Wales and Northern Ireland (NI) in 1985 (see Annex 1 for the full set of controls introduced). This data is presented in Figure 1 below.

Figure 1: Number of reported outbreaks associated with Raw Drinking Milk and Cream in England & Wales, Scotland and NI between 1980 and 2011

⁵. <http://www.food.gov.uk/multimedia/pdfs/committee/acm1047a.pdf>



17. As Figure 1 shows, there have been no reported outbreaks linked to raw milk consumption in England, Wales and NI since 2002 and in Scotland since 1999. The figure shows that the number of outbreaks was consistently higher during the 1980s than in the 1990s. For England and Wales, the number of outbreaks flattened out during the 1990s, to tail off completely in the 2000s. For Scotland, the number of outbreaks fell after the introduction of the ban in 1983, with some sporadic outbreaks during the 1990s, and no outbreaks in the 2000s.
18. The pattern of outbreaks following the ban on sales in Scotland in 1983 was similar to the pattern seen in England, Wales and NI following the restrictions placed on the market in 1985, where outbreaks continued in the years following the introduction of controls and then there was a significant reduction in the number and scale of outbreaks. It should be noted that the outbreaks which occurred during the 1990s and 2000s were very small in comparison to earlier outbreaks. It should also be noted that the size and frequency of outbreaks may be under-reported and single sporadic cases of illness associated with RDM may remain undetected.
19. Active national surveillance systems for Verotoxigenic *E. coli* (VTEC) infection have been established in Wales (1990), NI (1998) Scotland (1999) and England (2009). These systems assemble a comprehensive clinical, epidemiological and microbiological data-set for laboratory confirmed VTEC cases, covering exposure to various possible risk factors, including the consumption of unpasteurised milk. This data has been reviewed to explore the role consumption of raw milk may have in contributing to VTEC illness. Analysis of the data from enhanced VTEC

surveillance shows that the majority (97-99%) of VTEC cases included in UK enhanced surveillance do not report raw milk consumption, suggesting that raw milk is not causing a significant proportion of VTEC cases in the UK (see table 2 of science review paper at Annex 2). A small number of VTEC cases (1-3% or 51/2384 in England, 9/1151 in Wales, 18/583 in NI and 14/2313 in Scotland) do report raw milk consumption; however they may also have been exposed to other sources of infection. Cases often report multiple risk factors including contact with farm animals, handling raw meat or consuming water from private water supplies. Due to the serious nature of the disease it is likely that most cases are reported. A relatively small number of consumers are exposed to RDM (up to 3%) so it could be argued that low numbers of VTEC cases with a potential association to RDM are of greater significance than if the product were consumed by the wider population. It is however not possible to test this argument due to confounding factors such as the identification of other risk factors in cases that identify an association with RDM.

International data

20. The controls for RDM vary across different countries around the world with some countries prohibiting sales while others restrict sales in a similar way to England, Wales and Northern Ireland or permit wider sales. Data and risk assessments from a selection of countries (US, Australia, New Zealand, Italy and Germany) reporting different controls were assessed (see science paper review at Annex 2).
21. Of the countries reviewed internationally and in the EU, where raw milk sales are permitted, outbreaks of illness have been reported to varying extents. The size, frequency and seriousness of the reported outbreaks vary due to many underlying factors that differ between the countries such as differences in consumer exposure, microbiological quality of milk, on-farm controls, animal health and husbandry practices and differing systems for collecting and reporting data on illness associated with food. This makes direct comparisons of the effect of different control measures and an assessment of the anticipated effect if these were implemented in the UK difficult.
22. The data does however show that outbreaks of illness continue to occur in many countries where sales of RDM are allowed. A published⁶ analysis of data from the US shows that the incidence of outbreaks caused by unpasteurised milk was higher in States that permitted sales than in States where sales were not allowed. This suggests that increased exposure could increase the risk of illness associated with RDM.

⁶ Langer AJ, Ayers T, Grass J, Lynch M, Angulo FJ, Mahon BE. (2012) Nonpasteurized dairy products, disease outbreaks, and state laws—United States, 1993–2006. *Emerg Infect Dis*.

23. Sales are currently banned across all states and territories in Australia and quantitative risk assessment⁷ by the Food Standards Australia New Zealand determined that access to raw cows' milk would result in increased likelihood of foodborne illness in Australia. Again it is difficult to apply this directly to the UK situation. However, it could be interpreted to indicate that increased sales, and therefore increased exposure, could result in an increase in the number of cases of illness associated with RDM. There is also data to show that even in countries where sales are not permitted outbreaks linked to raw milk do occur due to illegal sales or personal consumption.

Other species

24. There is also the potential for pathogens to be present in raw milk from other species and outbreaks of illness linked to consumption of milk from other species do occur but are less frequently reported, possibly due to the lower levels of consumption. In the UK outbreaks linked to non-bovine raw milk consumption have only been reported twice, in 1983 and 1984, where both outbreaks were associated with goat's milk. It is not possible, without a quantitative risk assessment, to say how the risk from raw milk from other species compares with the risk from cows' raw milk.

25. There is little data on the microbiological quality of raw milk from other species. The available data in the UK was reviewed by ACMSF in January 2011 when they reviewed the health risks associated with raw milk consumption¹. ACMSF didn't make any distinction between species in their conclusion that pasteurisation is an important control measure for milk safety.

26. Since there is limited data on the microbiological status of raw milk from sheep, goat and buffalo in the UK, more recent data from other countries has also been reviewed (see science paper review at Annex 2). Surveys in other countries have found varying levels of pathogens and indicator organisms in raw milk from non-bovines. It is likely that the main pathogens of concern in cows' raw milk are similar to those of concern in non-bovine raw milk as goats and sheep are susceptible to infection with most of the organisms that affect cows and the potential routes of milk contamination, via udder or faecal contamination are the same. However, the prevalence of infection and clinical symptoms in non-bovine species may differ and there are differences in husbandry practices, milking practices and farm environment that will also affect the microbiological status of raw milk from different species.

27. The limited number of recorded outbreaks linked to raw milk from non-bovines in the UK could also reflect the lower level of consumption of raw milk from these species. Consumption volumes are not known but there are currently 28 registered producers in the UK of milk from other species (25 goats, 2 sheep and

⁷ Microbiological Risk Assessment of Raw Cow Milk Dec 2009, FSANZ

1 buffalo) compared with 74 registered cow's milk producers. Herds of cows producing raw milk also tend to be larger in size than herds of other animals producing raw milk.

Development of Allergic disease

28. It has been suggested that consumption of unpasteurised milk during infancy may protect against the development of allergic conditions in later life. While epidemiological studies have provided conflicting data, there is some evidence to suggest there may be an association between raw milk consumption in infancy and a reduced prevalence of allergic disease later in life. However, further research is required to confirm this effect and whether it is independent of other factors. Until it is known what mechanisms underlie this possible protective effect it is not possible to recommend consumption of unpasteurised milk to prevent the development of allergic condition. There are many reasons why people develop allergies. Therefore, given the uncertainty in the evidence base and in the absence of supporting data, it is not possible to quantify any benefits that may be associated with consumption of unpasteurised milk in infancy and the reduction in allergic disease. If a protective effect were to be confirmed, consideration would need to be given as to whether the potential benefits would outweigh the risks associated with increased pathogen consumption in unpasteurised milk particularly for vulnerable groups such as young children (see science paper at Annex 2).

Nutritional benefits

29. The enhanced nutritional quality of RDM is one of the perceived benefits associated with consumption. As part of this review, the current scientific evidence has been reviewed to determine whether there are any confirmed nutritional benefits associated with the consumption of unpasteurised milk (see Annex 2). Our conclusion, however, is that there is a lack of scientific evidence to support the potential nutritional and health benefits of raw milk consumption.

30. There is little current scientific evidence to indicate that pasteurising milk substantially alters its nutritional composition and insufficient evidence to determine the effect of pasteurisation on the functional properties of nutrients in milk. Research suggests there is little or no impact of pasteurisation on the macronutrients, carbohydrates, fat and protein with only 1% decrease in the biological value of protein observed following pasteurisation. There are no major nutritional changes in milk fat known to result from pasteurisation and there is minimal mineral loss. Some water soluble vitamins are relatively stable during pasteurisation while losses to varying degrees up to around 25% (Vitamin C) of others during the process have been reported. The fat soluble vitamins A, D, E and K seem to be relatively stable. A recent systematic review and meta-analysis of the effects of pasteurisation in Canada showed pasteurisation appeared to qualitatively reduce concentrations of vitamins B12 and E and increase concentrations of vitamin A. The review showed how results varied

between studies and that the effect of pasteurisation on vitamins could not be measured quantitatively.

31. Differences in cow breed, age, feeding regime as well as seasonal changes, lead to wide variations in nutritional composition of milk whether raw or pasteurised. Variation in reported nutritional compositional values of raw milk is also likely to be due to analytical difficulties and differences. This appears to be especially the case for micronutrients.
32. The review focussed on the effect of pasteurisation on the nutritional composition of milk and on functional properties of the nutrients in milk. The effect of homogenisation has not been extensively reviewed as it is widely accepted that there is limited scientific evidence to indicate whether homogenisation alters the nutritional content or function of milk. See Science review paper at Annex 2.

Summary of stakeholder views gathered through the engagement programme

Consumer Focus Groups (See Annex 3 for full report)

33. Seven focus group meetings (in urban and rural areas) with over 50 raw milk consumers were held across England between October and December 2012. Discussions in these meetings focussed on purchasing, motivation, awareness and Regulation. The key findings were:
 - There were 3 types of consumer – the local supporter (generally rural areas, purchase from local source), artisanal (generally urban where purchase is a lifestyle decision and there is a wish for increased knowledge of provenance) and health conscious (purchase due to perceived health benefits). All tend to be well informed and decisions are made on an understanding of the risks and perceived benefits. The support for consumer choice was a key driver in their participation in the focus groups.
 - Consumers' purchasing patterns generally depended on their geographical location. Consumers living in rural areas generally made purchases at the farm or had milk delivered via a milk round; they were also likely to know the farmer/farm they were buying from. Consumers living in more urban areas indicated that they used either a farmers' market or travelled to a farm to make their purchases.
 - Consumers of RDM generally viewed this product as a staple item on their shopping list and not a luxury purchase.
 - Perceived health benefits were considered as one of the main reasons for consuming RDM; consumers generally thought that pasteurisation of milk was an unnecessary and harmful process.
 - Generally consumers had good knowledge of the milking process but some did not accept that there are health risks associated with the product.

- Participants recognised the need for regulation and highlighted that without it unsafe RDM could potentially enter the market
- Restricting sales to the farm gate was seen as out-dated and penalising consumers living in non-rural areas. However, consumers also stated that knowledge of the provenance of the product is very important and this may be lost if longer supply chains became the norm following the removal of sales restrictions.

Online survey (consumers who consume pasteurised milk or cream) (See details at Annex 4)

34. The report is based on 1,333 interviews across the UK with boosted numbers in Wales and NI to give confidence in the analysis of the results. The sample⁸ was nationally representative in terms of age, gender and region. Screening ensured all respondents were consumers of milk or cream with 3% of respondents indicating that they currently consume/buy RDM. The majority of respondents were also aware of RDM with 72% (81% after prompting) being able to describe the product.
35. The majority (58%) of consumers had limited or no interest in consuming raw milk or cream with 19% indicating they had some interest in trying this, mainly due to curiosity. Health risk was the main reason cited for those who had no interest.
36. Views were varied on the responsibility of Government to protect consumers (37%) versus freedom of choice (29%) with the remainder unsure. There was however a very clear majority support for sales of raw milk to continue (77%). The majority of those who supported continued sales (70%) consider this should be through farms, farm shops and farmers' markets and 48% also considered sales should be allowed from supermarkets. Internet sales (18%), mail order/delivery (20%) and department stores scored low (8%). However, consumers in urban areas want more easy access to RDM and feel the current regulations penalise them on the basis of their location.
37. Consumers were also asked to consider labelling. Around two thirds considered current labelling provides sufficient information but two thirds of consumers expressed a preference for specific information to be included on the types of bacteria that might be present.

Stakeholder Discussions (See Annex 3 for full details)

38. A meeting with stakeholders in England, Wales and Northern Ireland was held early on in the Review process to provide an update on progress of the Review

⁸ The survey took place online using the Harris Interactive panel. The Harris Poll Online Panel consists of members of the general public who have opted-in and voluntarily agreed to participate in online research studies. Through careful recruitment and management, Harris Interactive are able to rapidly survey large numbers of the general population and accurately represent the views of the nation. They have over 100,000 active panellists in the UK and their panel is used solely for market & opinion research. Members are contacted at random and invited to take part in a survey.

and an opportunity for discussions on the way forward. This was well attended, and well received, with constructive discussion by a wide range of stakeholders representing differing views e.g. National Farmers Union (NFU), Dairy UK, Specialist Cheesemakers' Association, Campaign for Real Milk, Association of Unpasteurised milk producers and consumers, Chartered Institute of Environmental Health (CIEH), Defra and Health Protection Agency (HPA).

39. The engagement plan included a discussion with a producer in Wales during which the main issue highlighted was the labelling requirements in Wales being different from England and Northern Ireland. The information required in Wales was thought to be excessive and could be restrictive to acquiring new customers. The need for regulation was understood and it was accepted that regulation was necessary; however, it was hoped that there would be no further additions to the current regulations.
40. Informing consumers of the testing regime and the current FSA guidelines on producing and selling RDM was felt to be important. A suggested option from the producer was for the FSA to actively publicise that RDM is allowed to be sold only when strict criteria are met. This would provide consumers with confidence that RDM is a controlled and regulated product.
41. A stakeholder/consumer discussion group was held in Belfast for Northern Ireland producers and their customers. A key point that came from this meeting was the need for clarification on what the legal requirements for the sale of RDM are. There was some confusion about what producers were required to do in order to sell RDM and as a result they were hesitant to do so. There was support for the testing regimes required to sell RDM as this was thought to provide customers with a sense of confidence in the RDM product.

The Market for RDM

Questionnaire to RDM producers

42. The Agency developed a short questionnaire, in consultation with the stakeholder group, in order to gather information to improve our understanding of the volume of RDM produced and the sales routes used by producers and to inform RDM producers of the main drivers for the review. This was sent to all registered RDM producers in England, Wales and Northern Ireland in December 2012.
43. Sixty five producers (63%) of the 104 registered producers of RDM responded to the questionnaire. A summary of responses is below:
- 62 farms from those who responded are currently selling either raw milk or cream or both. 91% sell raw milk, and 9% raw cream totalling 382,903 litres a year.
 - The majority (90%) of farms sell cows' RDM, 6% sell goats' RDM and 3% sell sheep's RDM. None of those who responded sold buffalo RDM.

- The majority (65%) of the milk is sold at the farm, 7% from farmers markets, 5% from a distributor, 4% from vending machines, and 15% from other routes. One farmer indicated it sold RDM via the internet but it is unknown how much milk is sold via this route.

44. England and Wales: The number of registered producers who provide cows' RDM for direct human consumption in England and Wales has fallen from around 570 in 1997 to 102 in 2009 and further still to 74 in 2012. There are also 25 producers of goats' RDM and two of sheep's RDM and one buffalo which is sold for direct consumption or processing. There are no separate data on raw cream producers but surveillance in 1997 identified 11 producers in England and Wales.

45. Northern Ireland: There are currently no known sales of cows' RDM in Northern Ireland. There are two low-output producers of goats' RDM milk (18 and 24 goats) selling from the farm.

New Sales Routes

46. In recent years new routes have been established through which RDM is being offered for sale such as via the internet. Direct internet sales (i.e. not involving a 3rd party) are permitted under current domestic controls (see Annex 1), although this is not explicitly mentioned in the legislation and is possibly not within the intention of the legislation as these controls were developed to allow restricted sales to a local market. Some producers are also exploring sales through vending machines; sales from vending machines on farm premises and at farmers' markets would be permitted under current legislation but sales from vending machines located remotely to the farm would not be permitted. The public health risks associated with these developments in the market have been considered to ensure the legal provisions provide appropriate public health protection.

Labelling

47. In addition to the EU labelling requirements for raw milk, national legislation (the Food Labelling Regulations 1996, as amended (FLR)) in England and Northern Ireland requires additional labelling of RDM from all species except buffalo with the following statement 'this milk has not been heat-treated and may therefore contain organisms harmful to health'. In the case where the RDM is not pre-packed and is sold at a catering establishment the following must be clearly stated 'milk supplied in this establishment has not been heat-treated and may therefore contain organisms harmful to health'. National legislation in Wales requires additional enhanced labelling: 'This milk has not been heat-treated and may therefore contain organisms harmful to health. The FSA strongly advises that it should not be consumed by children, pregnant women, older people or those who are unwell or have chronic illness'. The Welsh legislation is applicable to all species, including buffaloes (See Annex 1 for Summary).

48. The FLR are due to be revoked in their entirety in December 2014 and all EU labelling requirements will be replaced by the EU Food Information Regulation. Where there are additional national labelling requirements these will be replaced in national legislation as appropriate. Therefore, it is timely to review the national RDM labelling provisions currently contained in the FLR and those requirements that need to be preserved and/or amended be incorporated into Schedule 6 of the Food Hygiene Regulations 2006 together with the other RDM provisions.
49. The labelling of RDM was explored through the on-line questionnaire. In England and Northern Ireland around two thirds of consumers considered current labelling provides sufficient information but there was a preference for specific information on the types of bacteria that might be present to be included. In Wales, where labels are more detailed, 76% people thought the labels were sufficient. The more specific information that consumers indicated they would like to see on labels was to do with details of health risks and specific details of bacteria that may be present, along with the fact that it is not recommended for vulnerable groups of consumers.

Consultation Question 1

Do stakeholders have any comments on the available evidence considered to assess this issue and is there other evidence available that should be considered?

Description of Options

50. Four options have been identified providing a range of alternatives from removing restrictions on sales through to introducing a requirement for all milk to be pasteurised prior to sale.
51. The FSA has a statutory objective to protect consumer health and consumers' other interests in relation to food. Each of the options has been considered in accordance with this objective, the FSA's core principles and policy making framework. The preferred option has been selected on the balance of available evidence and represents the FSA's pre-consultation opinion. However, the scientific data on public health risks associated with raw milk and recommendations of the independent expert committee has had the greatest influence in the identification of the preferred option as consumer health protection must be given priority. Other information, such as consumer preferences and the impact on businesses, has also been considered to ensure the preferred option represents a proportionate approach. The FSA Board will make final recommendations on the way ahead after consideration of the available evidence and the consultation responses.

OPTION 1 – DO NOTHING

Cows' RDM	Sales restricted to direct sales between farmer and consumer
RDM other species	No sales restrictions
Labelling	Health warning in England/Northern Ireland; Additional warning in Wales highlighting specific risks for vulnerable groups
Other sales routes permitted	Direct internet sales from the farm/farmer, vending machines only on farm premises

52. Under this option the majority of milk sold to consumers in the UK would continue to be pasteurised before consumption. Restricted sales would continue to allow a relatively small number of consumers to drink RDM.

Science

53. The ACMSF reviewed the available surveillance and monitoring data most recently in 2011 and highlighted the potential for pathogens such as *Salmonella* spp, *Campylobacter* spp, *E.coli* O157 to be present in RDM. These bacteria can cause serious illness and vulnerable consumers such as the young, elderly and pregnant or immune-compromised individuals are at greatest risk from infection. Therefore the potential public health impact of any illness associated with the presence of pathogens in RDM is high.
54. However, the likelihood of illness occurring from RDM consumption is considered to be low with the current controls for the following reasons:
- There have been no reported outbreaks of illness associated with raw drinking milk in the UK since 2002. It is, however, recognised that some

cases of food poisoning are not reported and sporadic cases of illness in particular will not be detected.

- Data from national surveillance systems for VTEC infection provides additional evidence on the public health risks associated with RDM particularly as, given the severity of the disease, illness associated with VTEC is more likely to be reported. The majority of cases (97-99%) do not report raw milk consumption and the small number (1-3% or 51/2384 in England, 9/1151 in Wales, 18/583 in NI and 14/2313 in Scotland) that do report raw milk consumption also report exposure to other sources of infection such as contact with farm animals, handling raw meat or consuming water from private water supplies. This suggests RDM is not causing significant numbers of cases of VTEC illness in the UK.

55. However, absence of reported illness does not guarantee that illness will not occur in the future, so other data need to be considered to provide additional assurances that the likelihood of illness occurring is low. This is provided to some extent by the ACMSF assessment of the specific risks from milk and milk products associated with the rise in bovine TB in cattle which concluded that the risk of *M. Bovis* infection in humans following consumption of unpasteurised cows' milk is very low and that the risk associated with RDM from other species is also likely to be very low. The Committee noted that the limited data created more uncertainty about the risk associated with RDM from other species.

56. Surveillance data on RDM was considered by the ACMSF and data from surveys carried out between 1995 and 1999 on raw milk and cream from cows and other species indicated *Campylobacter spp*, *E.coli* O157, *Salmonella spp* and *L.monocytogenes* were present in up to 2, 0.5, 0.5 and 3% of samples respectively. There is no more recent data and these levels may not represent the current situation but, if the pathogens were still present at the levels found in the surveys, this would support the view that the likelihood consumers being exposed to RDM containing pathogens is low. It is not unusual for large surveys of ready to eat foods to find occasional presence of pathogens similar to the levels seen here. In those instances action would be taken at a local level to address the risks in individual cases. Appropriate actions may include removing product from sale and investigations to identify and eliminate the source of contamination.

57. The data on illness associated with RDM shows that there has been a reduction in the number and size of outbreaks since the 1980s and these are no longer being reported. This effect is likely to be due to a combination of contributing factors. Mapping the data on outbreaks of illness in the UK between 1980 and 2011 against the different controls introduced across the UK did not provide a direct correlation between the introduction of the controls and reduction in outbreaks, but it showed the number and size of outbreaks has reduced following their introduction. A similar pattern is seen in Scotland where a requirement to pasteurise all milk was introduced and the rest of the UK where sales were restricted. This would seem to suggest the current controls for RDM are at least a contributing factor in the reduction of illness associated with RDM. There are no data on the volume of raw drinking milk consumed during this time but, it is a reasonable assumption that restricting sales has possibly reduced consumption and thereby consumer exposure to raw milk and, as noted by ACMSF this could

be a key factor in reducing the number of reported cases of illness associated with RDM. Other factors such as hygiene controls introduced through EU legislation and improvements in microbiological quality of raw drinking milk sold could also be contributing to the decline.

58. In summary, the potential public health impact of pathogens being present in RDM is high but evidence suggests that the current EU and domestic controls are effective in improving the conditions under which RDM is produced, as well as controlling the number of people exposed to these risks, and are reducing the likelihood of illness associated with RDM occurring.

Consultation Question 2

We invite stakeholders to provide information on the current volume of RDM sold on an annual basis and, if possible, how this has changed since sales restrictions were introduced in 1985.

Consultation Question 3

We invite stakeholders to comment on the impact of current sales restrictions and or other contributing factors on the reduction in illness associated with RDM

Other Evidence

Legislation and enforcement

59. EU hygiene legislation provides general and specific controls for production of RDM and allows for further controls to be introduced by Member States (Annex 1). The domestic hygiene legislation in England, Wales and Northern Ireland builds on EU legislative controls and provides additional requirements for RDM. Compliance with these legislative provisions helps reduce the risk associated with RDM, particularly the requirements concerning disease status of the herd (EU legislation) and the microbiological criteria (domestic legislation). These legislative requirements for RDM would continue to apply under Option 1.
60. The current enforcement regime of twice-yearly inspection of the farms and quarterly testing of RDM against the microbiological criteria will continue to provide information on the microbiological quality of the RDM, where a pass indicates lower likelihood of pathogens being present. Analysis of monitoring data shows that around 12-18% of samples fail to meet the microbiological criteria, although this includes repeat samples on farms that have previously failed to meet the criteria. While failure to meet the criteria does not directly correspond to the presence of pathogens, this does indicate presence of faecal contamination and pathogens are more likely to be present as levels of faecal contamination increase. There are no specific standards for pathogens in RDM, although to meet the general obligation for supply of safe food producers need to ensure pathogens are not present at levels that could cause illness. Where there is a failure to meet the criteria, the producer is advised to stop selling their product, farm hygiene is inspected and follow-up samples are taken. Sampling continues until the inspector is content that the criteria are being met. Effective enforcement of the controls for RDM provides a level of public health protection, but cannot remove completely the risk associated with the unpasteurised commodity.

Consumers

61. Consumer feedback (reported behaviour) from an online survey of milk/cream consumers (See Annex 5) indicates that 3% (25/1333) of those who responded to the survey currently buy and/or consume RDM. This figure for RDM consumption is higher than anticipated and further work with consumers may provide more specific information on the numbers of consumers who drink RDM regularly. However, the feedback still indicates that a relatively small proportion of consumers will consume RDM. Option 1 would allow controlled sales to continue to the small proportion of consumers who wish to consume RDM. This would be consistent with consumer views expressed during previous consultations showing very strong support for those who wish to consume raw milk to be allowed to continue to do so. More recently, feedback from the online survey supports this view as 77% respondents believe that the sales of RDM should be allowed to continue. It is also consistent with feedback from some raw milk consumers who consider an element of regulation is required to maintain high standards among producers and safety of the product.
62. Vulnerable consumers such as the young, elderly and pregnant or immune-compromised individuals are at greatest risk from infection. There is no specific data on consumption by vulnerable groups. Consumer feedback indicates RDM is consumed for a variety of reasons, and it is likely that at least some consumers who do so will fall within a vulnerable group. For example, feedback from consumers has indicated RDM may be consumed by children in the family. The health warning currently in use in England and Northern Ireland does not caution against consumption by vulnerable consumers.

Impact on businesses and wider better regulation issues

63. This option does not provide businesses with significant opportunity for growth but it maintains provisions that support rural communities by allowing the farmer to sell milk direct to local consumers.
64. There are inconsistencies in the current controls for sales of RDM from different species and labelling requirements differ in different UK countries. These would remain under Option 1. The labelling in Wales carries a specific warning for vulnerable groups but this is not required in England and NI and this inconsistency would also continue under Option 1. These issues are discussed further under Option 4.
65. Experience has shown there are difficulties in interpreting some aspects of the controls, particularly their application to new sales routes that were not envisaged when the EU and domestic regulations were introduced. New sales routes such as internet sales and vending machines are allowed where these comply with the controls for RDM sales, i.e. sales are permitted direct to the consumer by the farmer. These requirements would continue under the Option 1 but no clarification would be provided. The current difficulties in interpreting the legislation would continue. This is discussed further under Option 4.

OPTION 2 - ALL MILK TO BE PASTEURISED PRIOR TO SALE

Cows' RDM	No sales of RDM permitted
RDM other species	No sales of RDM permitted
Labelling	N/A
Other sales routes permitted	N/A

66. This option would require all milk to be pasteurised prior to sale so no sales of RDM would be permitted. However, consumption of RDM through personal consumption could continue legally by the farmer and farmer's family and there is also the potential that occasional informal farm-gate sales direct to consumers would continue.

Science

67. This option is consistent with the ACMSF recommendation that pasteurisation is an important control measure when considering measures to reduce the risks of illness associated with raw drinking milk.

68. As noted in Option 1, whilst the likelihood of illness occurring from RDM consumption with the current controls in place would seem to be low due to restrictions on production and sales and therefore restricted consumption, the potential public health impact of pathogens being present in raw drinking milk is high. Pasteurisation, when carried out effectively, destroys pathogens that could be present in raw milk and so introducing measures to require all milk to be pasteurised prior to sale would minimise the risk associated with the product sold to consumers. This is therefore the most effective option for protecting public health.

69. The requirement to pasteurise milk would lead to a further and significant reduction in consumption of raw milk, so the likelihood of illness associated with raw milk occurring would be lower than in Option 1. Removing raw milk from sale would not however completely remove the risk that illness might occur as this would not prevent personal consumption by the farmer and the farmer's family, or occasional informal (illegal) farm-gate supply. Data from other countries such as the US show that outbreaks of illness associated with raw milk still occur where sales are prohibited.

70. It is difficult to quantify the potential public health benefit that would be associated with introducing the requirement for all milk to be pasteurised. There is the potential for pathogens to be present in RDM, and pasteurisation would remove that potential risk and give assurance that illness will not occur in the future. Data on the prevalence of pathogens in raw milk indicates these may be present in a small number of samples and the absence of reported cases of illness would seem to indicate that current controls are preventing illness by controlling consumption and are sufficient to manage the potential risks associated with RDM. The increase in quantifiable public health benefits, compared to Option 1, therefore seems to be low. However, it must be acknowledged that while we cannot quantify the potential for illness to occur, the impact of that illness

occurring could be severe and this could be prevented by the additional controls requiring pasteurisation of RDM.

71. There is anecdotal evidence on the nutritional and allergenicity benefits associated with raw drinking milk with many believing in wider health benefits. The scientific data on these issues is incomplete, but the available evidence does not support the view that pasteurisation causes either significant nutrient losses or that consumption of raw milk reduces the risk of developing allergies. This suggests that there would be no negative impact on public health if pasteurisation of all milk was required.

Other evidence

Legislation and enforcement

72. EU hygiene legislation provides general and specific controls for production of raw milk and allows Member States to establish national provisions for RDM. The legal framework therefore exists for the introduction of a range of risk management options, including a requirement for all RDM to be pasteurised before sale. The enforcement of RDM controls would be simplified as there would no longer be a need to enforce specific provisions for RDM.

Consumers

73. This option would remove choice from consumers and prevent sales of RDM. This is inconsistent with the very strong support for those who wish to consume raw milk to be allowed to do so and views of raw milk consumers who wish to retain the ability to purchase the product (supported by the online survey in which 77% of respondents believe that the sales of RDM should be allowed to continue). Also, there would be a negative reception from those consumers who perceive there are health benefits in consuming RDM, especially where personal experience suggests consumption RDM may be linked to improvements in health.

Impact on business and wider better regulation issues.

74. This option could have a negative impact on businesses, relative to option 1, and would have a disproportionate impact on small businesses and rural communities (both producers and consumers). There are around 100 registered producers of RDM. The market for RDM is small and this is unlikely to be the sole source of income for farmers but in preventing sales of RDM the current premium attached to RDM when compared to pasteurised milk would be lost. It is also noted that there is a production cost associated with the pasteurisation process that is not incurred in the sale of RDM. For producers that may not have the ability to undertake their own on-farm processing, this option would remove the freedom to market their product directly to consumers and would result in it being subject to stipulated market prices by milk purchasers. For very small producers of milk there may also be a disproportionate impact if their sales of RDM make up a significant quantity of their total milk sales.
75. EU legislation allows MS to establish national provisions for RDM. The additional controls currently provided within UK legislation are justified by the additional public health protection they provide. Option 2 would extend current controls by requiring all milk to be pasteurised. Current UK Government policy requires that any domestic legislation which goes beyond the minimum requirements of EU

legislation must have clear justification to do so. Therefore, option 2 would only be considered consistent with this policy if the potential increase in public health protection can be clearly demonstrated and that is difficult with the current data.

OPTION 3 – ALLOW SALES OF RAW DRINKING MILK FROM ALL OUTLETS

Cows' RDM	No sales restrictions
RDM other species	No sales restrictions
Labelling	Health warning in England/Northern Ireland; Addition warning in Wales highlighting specific risks for vulnerable groups
Other sales routes permitted	No sales restrictions

76. This option removes the current restrictions on sales of RDM from cows and, as is currently the case with other species, would allow sales of cows' RDM from any outlet. RDM would become more available to consumers and we would expect this to increase the proportion of milk sold without pasteurisation.

Science

77. As noted in Option 1, the potential public health impact of pathogens being present in raw drinking milk is high but evidence suggests that the current EU and domestic controls are effective in controlling the number of people exposed to those risks and are reducing the likelihood of illness associated with RDM occurring. ACMSF noted that the absence of reported outbreaks could be due to reduced consumer exposure to RDM. This suggests that increasing consumer exposure could increase the likelihood of illness occurring and data and risk assessments from other countries (see Annex 2) also indicate that this could be the case.

Consultation Question 4

Stakeholders are invited to comment on whether our assessment that increased exposure to raw drinking milk could increase the risk of illness associated with RDM seems reasonable or not. If not, please provide as detailed information and data as possible for us to be able to assess the risk and monetise this cost more robustly.

Other Evidence

Legislation and enforcement

78. EU hygiene legislation provides general and specific controls for production of raw milk and allows for further controls to be introduced by Member States (Annex 1). The domestic hygiene legislation in England, Wales and Northern Ireland builds on these and provides additional requirements for RDM. Compliance with these provisions and increased inspection frequency in

comparison to pasteurised milk helps reduce the risk associated with RDM, particularly the requirements concerning disease status of the herd (EU) and compliance with the microbiological criteria (domestic). However, as stated under option 1, it is a reasonable assumption that restricting sales has possibly reduced consumption and thereby consumer exposure to raw milk and, as noted by ACMSF this could be a key factor in reducing the number of reported cases of illness associated with RDM. Under Option 3 those aspects of the legislation that assure safer production methods would continue to apply and the current enforcement regime of twice-yearly inspection of the farms and quarterly testing against the microbiological criteria will help ensure compliance. The only change that would be made is that RDM would be made more widely available through other outlets.

Consumers

79. Consumer choice would be liberalised with this option. Feedback, based on reported behaviour, indicates around 20% of milk consumers would be interested in buying or consuming RDM and, while it is unlikely that these will all become regular RDM consumers, opening up the market would provide increased opportunities for these consumers to source RDM. It is also consistent with feedback from some raw milk consumers who would support wider sales.

Impact on business and wider better regulation issues

80. This option may have a positive impact on rural communities as small businesses in particular could benefit from increased opportunities for growth in the RDM market. However, with wider availability consumers would no longer need to rely on local suppliers and this could lead to a negative local impact. It is not possible to quantify potential growth but, as noted above, increased availability would allow those consumers interested in trying RDM to do so. This could however be offset by a reduction in sales in pasteurised milk as consumers might move from pasteurised to raw milk consumption.

Alternative Approach

81. There is support from some consumers for sales via smaller, local retail outlets only and this presents an alternative to allowing sales from all outlets. Similar arguments apply to those above although on a smaller scale. There is the potential for increased sales opportunities and increased availability of RDM, although these increases would be less than if sales were allowed from all outlets. It is reasonable to assume under this alternative approach that there could be an increase in exposure to the risks associated with RDM and an increase in illness, although that increase would be expected to be lower than if sales were allowed from all outlets.

Consultation Question 5

We invite stakeholders to provide views and evidence that will inform our final view on whether an appropriate level of public health protection could be maintained if wider sales were allowed either through all outlets or through local retailers.

OPTION 4 – INTRODUCE MEASURES TO HARMONISE AND CLARIFY CURRENT CONTROLS

Cows' RDM	Sales restricted to direct sales between farmer and consumer – as with Option 1
RDM other species	New measures to harmonise controls with sales restricted to direct sales between farmer and consumer
Labelling	New labelling in England, Wales and Northern Ireland to provide consistent advice across countries that highlights specific risks associated with RDM
Other sales routes permitted	Direct internet sales from the farm, and vending machines on farm premises only as with Option 1
Interpretation of legislation	New guidance provided so that legal provisions are clear for enforcers and producers

82. This option builds on Option 1 to introduce measures to harmonise labelling requirements and controls on RDM for all species, and issue guidance so that legal provisions are understood by enforcers and producers. This represents a modest change from the current situation, aimed at introducing greater consistency in controls and labelling whilst retaining current restrictions on sale in England, Wales and Northern Ireland. Under this option, and as with Option 1, the majority of milk in the UK would continue to be pasteurised before consumption and there would be provisions allowing restricted sales of RDM to continue to a relatively small number of consumers who wish to consume RDM (see paragraphs 60 and 61).

83. A review of the domestic legislation for England, Wales and NI has shown that:

- There are different controls for different species producing RDM and only RDM from cows is subject to sales restrictions.
- There are different RDM labelling provisions in England, Wales and NI so consumers are not provided with the same information to support their choices.
- There are no specific legal provisions for new sales routes such as internet sales and vending machines as these were not envisaged when the current controls were introduced.

84. Option 4 would seek to address these issues by either legislative or non-legislative means or a combination of these. The FSA has an obligation to consider non-legislative approaches to achieve its aims, for example self-regulation and introduction of sector specific assurance schemes or Codes of Practice. In this instance it is possible that a voluntary Code of Practice developed by producers rather than changes to the legislation could introduce effective measures for other species.

85. Evidence presented under Option 1 in relation to the controls on cows' RDM also applies to Option 4. Arguments regarding the three additional elements of Option 4 are presented below.

Controls on production of RDM from species other than cows

Science

86. Evidence indicates it is likely that the pathogens of concern for raw cows' milk are similar to those of concern in other species such as sheep, goats and buffalos (Annex 2). The impact of illness associated with other species RDM is therefore likely to be high. However, only limited information is available on prevalence of pathogens in milk from these species. ACMSF considered the *M.bovis* risks associated with RDM from species other than cows and concluded that while there were fewer data on other species and more uncertainty associated with the risk assessment, the risk was very likely to be low.

Other evidence

Consumers, impact on business and wider better regulation issues

87. Stakeholder feedback indicates there are few producers of raw goats, sheep and buffalo milk in England, Wales and NI (27, 2 and 1 respectively) as compared to cows' milk producers (74). Herds of these species tend to be smaller than herds of cows producing RDM. There is the potential that introducing sales restrictions on RDM from other species would place additional burdens on producers. However, feedback suggests there are limited or no retail sales of goat and sheep RDM with sales made directly to the consumer at the farm. Impact on current businesses and consumers may therefore be minimal in practice. The impact of restricted sales on new producers and farmers seeking to provide milk from other more diverse species is recognised but again this is likely to be limited due to the small market involved.

Consultation Question 6

Stakeholders are invited to provide information, quantitative where possible, about the volumes of other species RDM that is sold via different routes (for example, at farm, by internet, retail).

Consultation Question 7

Stakeholders are invited to provide evidence that would inform the risk assessment for RDM from species other than cows, and information on potential burdens that would be imposed by the extension of controls to RDM from species other than cows.

Consultation Question 8

Stakeholders are invited to indicate whether the intended FSA policy objectives (as stated at paragraph 4) could be achieved through introduction of a voluntary Code of Practice which provides controls for RDM from species other than cows which are similar to the legislative controls for cows' RDM.

88. The FSA will consider the most appropriate approach (legislative vs voluntary) taking into account the evidence available, including that which is collated through this consultation exercise. In making that decision the FSA will apply its statutory objectives to protect public health and to regulate in a risk-based and

proportionate manner. It will also take into account its obligations under the wider Government better regulation agenda.

89. The FSA's initial view is that it would be preferable to harmonise the legislation across all species. However, whilst arguments such as ensuring equal controls for all species and taking into account future market developments based on current trends may be advanced to support this change it may be difficult to provide clear evidence as required by the Government's Better Regulation agenda. A Code of Practice, which would be developed by producers, could provide an alternative approach and include general husbandry and hygiene controls that would help address the risks associated with RDM from individual species and introduce sales restrictions consistent to those applying to raw cow's drinking milk. The likelihood of a voluntary Code of Practice achieving the desired policy outcomes will be a factor in determining the most appropriate option.

Consultation question 9

Stakeholders are asked to comment on which approach, legislative or a voluntary Code of Practice, would provide proportionate controls for RDM from species other than cows. Please provide supporting evidence.

Consultation Question 10

Stakeholders are asked to comment on what they would consider appropriate content for a voluntary Code of Practice, bearing in mind the policy objective.

Labelling provisions

90. There are different labelling provisions for different species in England and NI with all species other than buffalos carrying labelling indicating that the milk has not been heat treated and may therefore contain organisms harmful to health. Producers in Wales are required to provide additional labelling on milk from buffalos and for vulnerable groups. This Option would address those inconsistencies and provide consistent labelling for all consumers to allow them to make more informed choices.

Science

91. There are public health arguments for highlighting specific risks for vulnerable Groups as required by legislation in Wales as we know the impact of illness could be greater with this sector of the population. This is also consistent with the approach the FSA takes in providing advice for consumers on consumption of other commodities.

Consumers

92. The consumer engagement work (see Annex 3) indicates 66%, 56% and 75% of RDM consumers in England, NI and Wales respectively feel the current labelling provides enough information. However, there is also some consumer support for changes to the labelling provided. The main criticism was that the current labelling does not give enough specifics on the potential health risks and there was a preference for labelling that highlighted the specific pathogens that could be present.

93. The domestic Food Labelling Regulations will be revoked in December 2014 and the labelling provisions for RDM must transfer to the domestic Food Hygiene Regulations if they are to be retained. This provides an opportunity to refine the existing labelling requirements to ensure the information provided to consumers purchasing RDM is consistent and sufficient information is provided to allow them to make informed choices.

Impact on businesses and wider better regulation issue

94. Introducing new labelling requirements could place a burden on businesses as they would need to change their packaging to comply with new requirements. However, this negative impact could be minimised by allowing a transitional period for old packaging to be used before the new requirements were introduced. It is therefore considered that a legislative approach is appropriate for these provisions.

New sales routes

95. Producers are exploring new sales routes for RDM such as internet sales and vending machines. Stakeholder feedback indicates the majority of RDM is sold at the farm. Data from producers indicates that the majority of sales occur at or from the farm gate with only 7% of sales from farmers markets, 5% from a distributor operating from the farm, 4% from vending machines at the farm and 15% from other routes. There is a low level of internet sales (with 1 farmer indicating this as a sales route).
96. Experience has shown there are difficulties in interpreting some aspects of the current RDM controls, particularly their application to new sales routes (internet and vending machine sales) that were not envisaged when the Regulations were introduced. These new sales routes are allowed where they comply with the conditions associated with RDM sales, i.e. where sales are direct to the consumer from the farm. Under Option 4 it is envisaged that guidance would be provided for enforcement authorities and producers to clarify the legislation on different sales routes. This would support the FSA's commitment to effective Regulation.
97. Public health risks associated with internet sales and vending machines have been considered to determine whether there would be any additional risks to consumers. There are potential food safety risks associated with handling and storage of RDM where these routes are used but there is no evidence to suggest these risks are any different to those posed by other food products sold via the internet or vending machines. These risks can be controlled by the application of good hygienic practices including appropriate temperature control, and should be addressed by the food safety management plans businesses should already be implementing to meet their obligations to produce and supply safe food.
98. There is the potential that continuing to allow new sales routes will lead to increased distribution and availability of RDM. Internet sales allow those consumers who do not have easy access to a local supplier to source RDM. The impact on availability of vending machines is likely to be less as, under the existing legislation, these can only be located at the farm or at farmers markets. Consumer feedback suggests growth in the market is likely to be minimal with few indicating a preference for buying RDM via the internet. This feedback also indicates that the market will be self-limiting due to the costs associated with

distribution and that consumers will carry out extensive research on producers before making an informed purchase. There is therefore the potential for consumer exposure to risks associated with RDM to increase but available evidence indicates this will be limited.

Consultation Question 11

Stakeholders are invited to comment on the proposals to enhance current controls for RDM for species other than cows and to harmonise RDM labelling.

Consultation Question 12

Option 4 envisages guidance on the interpretation of the legislation on permitted sales routes for RDM. Stakeholders are invited to highlight other aspects of the legislation that would benefit from clarification.

SECTORS AND GROUPS AFFECTED

Producers of Raw Drinking Milk

99. Producers of RDM will be affected by any changes to current policy. Potential impact varies with costs and benefits associated with each option. Under all options farmers would need to familiarise themselves with these changes. Under **Option 2** (all milk to be pasteurised) farmers will no longer be able to produce and sell RDM, which could constitute a cost to farmers. It may be that at least some producers of RDM could choose to divert milk for pasteurisation or as an ingredient for raw milk products and continue to sell it. However, as stated at paragraph 74 there are other issues to consider. Under **Option 3** (no sales restrictions), farmers may benefit from increased sales. Under **Option 4** (harmonisation of measures and guidance), there may be additional costs to producers of RDM from other species as these will be subject to restricted sales and to producers of all species of RDM from labelling changes.

100. Table 1 below shows the number of producers of raw drinking milk by country and firm size, whilst Table 2 shows the number of these producers by species. These numbers were determined using the number of registered producers in 2012. Throughout this impact assessment, all of the costs related to production figures have been based on the responses to the questionnaire sent out by the FSA during the evidence gathering phase, to which we had a 63% response rate. Costs and benefits have then been extrapolated to include all 104 registered producers of raw milk.

Table 1: All Producers of Raw Drinking Milk, by Country

	Micro	Small	Medium	Large	Total
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England					95
Wales					7
NI					2
UK	N/A	N/A	N/A	N/A	104

Table 2: All Producers of Raw Drinking Milk, by Species

	Cows	Sheep	Goats	Buffalo	Total
England	69	2	23	1	95
Wales	5	0	2	0	7
NI	0	0	2	0	2
UK	74	2	27	1	104

Consultation Question 13

(a) Stakeholders are invited to comment on whether we have managed to capture all producers of raw milk in England, Wales and Northern Ireland.

(b) Stakeholders are also invited to comment on what is the likely distribution of producers of RDM between micro (<10 employees), small (<50 employees), medium (<250 employees) and large (+250 employees) businesses.

(c) We have assumed that all registered producers are actively producing raw milk for sale to the consumer. Is that a reasonable assumption? If not, please provide information which will allow us to better calculate the costs.

Food Standards Agency

101. **Option 4** will introduce guidance to clarify legal provisions to enforcement and producers. The FSA will incur costs of producing this guidance.

Enforcement Authorities

102. Under all policy options, enforcement authorities will need to read and familiarise themselves with the changes in policy and will therefore incur familiarisation costs. **Option 2** would mean that the extra dairy hygiene inspections currently carried out for RDM producers would no longer need to be carried out so inspection burden is likely to reduce. **Option 3** could mean that the number of inspections increases as the number of producers choosing to sell RDM could increase although provisions for RDM would be simplified as sales from all outlets would be allowed. There would be limited change under **Option 4** but, there are benefits associated with the clarification of the legislation through guidance and the harmonisation of legislation across the UK and across species.

Table 3: Number of enforcement Authorities by Country

	England	Wales	NI	UK
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LAs & PHAs	354	23	26	403
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Consumers

103. Consumers will be affected under all options that introduce a change in current policy. **Option 2** requires all milk to be pasteurised, which means that current consumers of RDM would no longer have access to a product that they find attractive. There may also be a negative impact on individual consumers who believe consumption of RDM is having a positive effect on their health. **Option 3** relaxes sales restrictions, which may have benefits to consumers in terms of increased access. **Option 4** potentially extends sales restrictions to producers of RDM from other species, which may have the effect of reducing access of these products although in practice these may be limited.

Consultation Question 14

Can you identify any other groups that will be affected? If so, please list these and explain what the potential impact would be. Please provide detailed information and evidence to support your position and to allow us to monetise any impact.

OPTION APPRAISAL

Option 1 – Do nothing - leave current RDM requirements unchanged

COSTS AND BENEFITS

104. There are no costs or benefits associated with this option as it is the baseline against which all other policy options are appraised. The baseline assumes that all other variables in the baseline remain unchanged for the lifetime of the policy, including current levels of consumer awareness of the risks associated with raw drinking milk; the number of outbreaks associated with RDM and the level of business compliance with raw milk requirements and general food hygiene law. We have no evidence to suggest the contrary.

Option 2 – All milk to be pasteurised prior to sale

COSTS

Costs to Industry

Familiarisation Costs to Farmers (One-Off Cost)

105. There will be a familiarisation cost to industry from reading and familiarising themselves with the changes to raw milk policy under Option 2. Familiarisation costs can be monetised by multiplying the wage rate of the person carrying out familiarisation with the time required for familiarisation. We envisage that it will be

the business manager that will be responsible for familiarisation and that it will take one manager per business one hour for familiarisation. The median hourly wage rate of a business manager is £25.8⁹, which generates a total familiarisation cost to farmers of £2,683.

Table 4: Familiarisation Costs to Industry by UK country and firm size

	Micro	Small	Medium	Large	Total
England					2,451
Wales					181
NI					52
Total					2,683

106. In order for one-off costs to be compared to annual costs on an equivalent basis across the time span of the policy, one-off costs are converted into Equivalent Annual Costs (EACs) by dividing the one-off cost by an annuity factor.¹⁰ The total one-off familiarisation cost to farmers in this proposal is £2,683 which yields a total equivalent annual cost of £312 over a ten year period and Table 5 shows the EAC by country.

Table 5: Familiarisation Equivalent Annual Costs to Industry by UK country and firm size

	England	Wales	NI	Total
EAC	285	21	6	312

Consultation Question 15

Stakeholders are invited to comment on whether our assumption on the time required for businesses for familiarisation (1hr) seems reasonable or not. If not, please provide detailed information and data for us to be able to monetise this cost more robustly.

Lost Sales/ Lost Premium and Distortion of the Market (Ongoing)

⁹ Wage rate obtained from Annual Survey of Hours and Earnings 2012, <http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcm%3A77-280149>. Median hourly wage rate of a 'production managers and directors' was used, £19.83, plus 30% overheads, totalling £25.8.

¹⁰ The annuity factor is essentially the sum of the discount factors across the time period over which the policy is appraised. The equivalent annual cost formula is as follows:

$$a_{t,r} = \sum_{j=0}^{t-1} \prod_{i=0}^j \left(\frac{1}{1+r_i} \right)$$

107. This option requires all RDM to be pasteurised, which could have cost implications to farmers in terms of lost sales. At this stage we are uncertain about the exact impact of such a requirement.
108. We envisage that some producers would choose to pasteurise the milk that they currently sell raw and continue to sell it or divert to supplying raw milk for use in production of raw milk products. To these farmers, the requirement to pasteurise would impose a cost in terms of a lost premium, as we assume that RDM carries a higher price than pasteurised milk, or raw milk as an ingredient.
109. However, after the introduction of a ban, not all farmers may be able to source new alternative markets for their products. This group might include farmers that keep a very small herd. To these farmers, a move to a requirement for all drinking milk to be pasteurised might involve additional costs that would outweigh any benefits. To these farmers the requirement to pasteurise would then result in the loss of total sales and therefore all current profit from selling RDM.
110. We currently do not have any certain estimates of the price of RDM as the price of RDM is not published in any established datasets. To provide an indicative estimate of that price we carried out an internet search which gave us the following estimates: £1.8, £2 and £3 per litre of raw drinking milk.¹¹ Due to lack of other information, we have assumed that the average of these estimates (£2.3 per litre) is representative for the average market price of this product.
111. We do not have the information to allow us to determine the proportion of farmers who would or would not be able to source alternative markets for the RDM. If we were to assume that 100% of farmers would be able to source alternative markets we can calculate the lost premium to farmers by first subtracting the average UK farm gate price of one litre of pasteurised milk (£0.34 per litre¹²) from our estimate of the average price of raw milk, which generates a premium per litre of £1.96. We can then estimate the cost of the lost premium by multiplying the premium by the number of litres of RDM sold in the UK per annum (558,584L¹³). This generates a total cost per annum to farmers of £1,094,825.
112. If we instead would assume that 100% of farmers would be unable to move to pasteurisation, we can calculate the cost of lost sales to the sector by multiplying

¹¹ Estimates of the price of raw drinking milk obtained from (no year supplied for the data): <http://organicrawmilk.co.uk/buyfreshmilk/>; <http://localfoodnews.wordpress.com/tag/raw-milk/>

¹² Average UK farm gate price of milk (October 2013) obtained from: <http://www.dairyco.org.uk/market-information/milk-prices-contracts/farmgate-prices/uk,-gb-and-ni-farmgate-prices/>

¹³ Estimate extrapolated from responses to an industry questionnaire sent out to all registered producers of RDM, which had a response rate of 63% (65 of 104 registered RDM producers responded). Based on responses to this questionnaire, total sales of RDM was 349,099 litres. Extrapolating this to all producers generates an estimate of 558,584 litres sold (based on the average litres sold per respondent). This estimate should be treated with caution as we presently do not know if all registered producers are still in the market for RDM – it could therefore be an overestimate. In addition, we do not know the actual average number of litres sold per producer across the market.

our estimate of the average price of 1 litre of raw drinking milk (£2.3) by the number of litres of RDM sold in the UK per annum. This generates a total cost per annum to farmers of £1,284,743.

113. Since we do not know the distribution of producers between these two groups and consider it unlikely that the impact on all producers will be the same, we have assumed a 50-50 split, which means that the total cost to the sector is equal to the average of the two estimates, £1,189,784.

Consultation Question 16

We invite stakeholders to comment on our assumptions on the potential cost of lost sales under Option (2), in particular:

- (a) Does our estimate of the price per litre of raw drinking milk seem reasonable?
- (b) What would be the likely outcome of the requirement to pasteurise all milk – would producers chose to pasteurise the milk and continue to sell it, or would sales be lost to some producers? What would be a reasonable estimate of the distribution of farmers between these two groups?
- (c) Are there any other costs associated with the requirement to pasteurise all milk?

Please provide us with as much detailed information and evidence as possible for us to be able to monetise these potential costs.

Costs to Enforcement

Familiarisation Costs (One-Off Cost)

114. There will be a one-off familiarisation costs to Local Authorities under Option 2. Familiarisation costs can be monetised by multiplying the wage rate of the person carrying out familiarisation with the time required for familiarisation. We envisage that it will be an Environmental Health Officer (EHO) that will be responsible for familiarisation and that it will take one EHO per LA one hour for familiarisation and dissemination within the organisation. The median hourly wage rate of an EHO is £21.1¹⁴, which generates a total familiarisation cost to Local Authorities of £8,503, with an associated total EAC (see paragraph 106 above) to industry of £988. Table 6 below shows these costs.

Table 6: Familiarisation Costs to Enforcement Authorities

	England	Wales	Ni	UK
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¹⁴ Wage rate obtained from Annual Survey of Hours and Earnings 2012, <http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcm%3A77-280149>. Median hourly wage rate of a 'health and safety officers' was used, £16.25, plus 30% overheads, totalling £21.1.

LAs & PHAs	7,469	485	549	8,503
EACs	868	56	64	988

Consultation Question 17

Stakeholders are invited to comment on whether our assumption on the time required for enforcement for familiarisation (1hr) seems reasonable or not. If not, please provide as much detailed information and data as possible for us to be able to monetise this cost more robustly.

Costs to Consumers

Loss of Access to an Attractive Product (Ongoing Cost)

115. This option introduces a requirement for all milk to be pasteurised. This constitutes a cost to consumers who no longer can access a product that they find attractive and a loss of consumer choice. This cost can be monetised as a loss of consumer surplus by assuming that consumers value the raw milk they purchase at the price at which they purchase the milk. There is uncertainty about the total number of litres of RDM currently sold, but extrapolation of information obtained from industry (see paragraph 100) has given us an estimate of approximately 558,584 litres of raw drinking milk sold per annum. This estimate includes all species, i.e. cows', sheep, and goats' milk.

116. We currently do not have any certain estimates of the price of raw drinking milk, but if we assume (based on an internet search) that the cost of one litre of raw drinking milk is around £2.30, compared to the cost of one litre of pasteurised milk (55.9 pence per litre ¹⁵), we can monetise this impact. Multiplying the number of litres sold by the cost per litre generates a total cost to consumers of £1,284,743 per annum.

117. Due to the uncertainties we can carry out some sensitivity analysis, using the low estimate (£1.8) and the high estimate (£3) of the price of raw drinking milk. This generates a low estimate of the total cost to consumers of lost access of £1,005,451 per annum, and a high estimate of the cost of £1,675,752 per annum.

Table 7: Sensitivity Analysis of the Cost to Consumers of Lost Access

Lost Access	Year 0	1	2	3	4	5	6	7	8	9	Total	PV
CONSUMERS												
Low estimate	1,005,451	1,005,451	1,005,451	1,005,451	1,005,451	1,005,451	1,005,451	1,005,451	1,005,451	1,005,451	10,054,512	8,654,609
Best estimate	1,284,743	1,284,743	1,284,743	1,284,743	1,284,743	1,284,743	1,284,743	1,284,743	1,284,743	1,284,743	12,847,432	11,058,667
High estimate	1,675,752	1,675,752	1,675,752	1,675,752	1,675,752	1,675,752	1,675,752	1,675,752	1,675,752	1,675,752	16,757,520	14,424,348

¹⁵ Retail price of liquid milk obtained from: <http://www.dairyco.org.uk/market-information/dairy-sales-consumption/uk-retail-prices/uk-retail-prices/>, accessed on 05/09/2013, the price of milk on 28/08/13, 4 pints costs 127, converted into pence per litre

Wider Impacts

Potential Rise of an Illegal Economy (Non-Monetised Cost)

118. Preventing the sales of products that consumers find attractive, and businesses want to trade in, may give rise to an illegal economy, in which participants continue to trade now illegal products. This can, for example, have consequences on tax revenue. For RDM we would expect this to be limited to occasional informal sales but, there could potentially be an increase in the risk with RDM if the production of raw drinking milk is no longer controlled by hygiene criteria and other requirements. It is however very difficult to monetise this potential cost so this is not included.

BENEFITS

Benefits to Consumers

Potential Reduction in the Risk of RDM associated Outbreak (Non-Monetised Benefit)

119. We currently do not have sufficient evidence to ascertain the contribution individual factors have made to the decrease in outbreaks associated with RDM over the past decade. While the likelihood of illness occurring is considered low, the risks and potential for severe illness associated with RDM are recognised. In this case, banning all sales of raw drinking milk could therefore potentially reduce the risk of future outbreaks associated with RDM (although this effect might be offset to some extent by personal consumption and occasional illegal sales). However, since there have been no outbreaks associated with RDM over the past ten years, the costs of this option may be disproportionate to the benefits.

Summary of all Costs and Benefits under Option 2 (pasteurisation of all milk)

120. Table 8 shows that Option 2 would generate a total cost to society in of £21,311,140 (PV, ten years). The total cost to industry is £10,243,970 (PV, ten years). Since we have been unable to monetise any health benefits associated with a potential reduction in the risk of a future outbreak of illness associated with RDM consumption, or the potential cost of a rise in illegal sales, the net impact is a cost to the economy of £21,311,140 (NPV, ten years) and a total cost to industry of £10,243,970 (NPV, ten years).

Table 8 Summary of All Costs and Benefits under Option 2

COSTS	Year 0	1	2	3	4	5	6	7	8	9	Total	EAC/p.a.	PV
INDUSTRY													
Familiarisation	2,683	0	0	0	0	0	0	0	0	0	2,683	312	2,683
Lost premium/ Lost sales	1,189,784	1,189,784	1,189,784	1,189,784	1,189,784	1,189,784	1,189,784	1,189,784	1,189,784	1,189,784	11,897,839	1,189,784	10,241,287
ENFORCEMENT													
Familiarisation	8,503	0	0	0	0	0	0	0	0	0	8,503	988	8,503
CONSUMERS													
Lost access	1,284,743	1,284,743	1,284,743	1,284,743	1,284,743	1,284,743	1,284,743	1,284,743	1,284,743	1,284,743	12,847,432	1,284,743	11,058,667
WIDER IMPACTS													
Illegal economy	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
TOTAL COSTS	2,485,714	2,474,527	2,474,527	2,474,527	2,474,527	2,474,527	2,474,527	2,474,527	2,474,527	2,474,527	24,756,458	2,475,827	21,311,140
BENEFITS													
CONSUMERS													
Health benefits	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
NET IMPACT													NPV
Net cost	2,485,714	2,474,527	2,474,527	2,474,527	2,474,527	2,474,527	2,474,527	2,474,527	2,474,527	2,474,527	24,756,458	2,475,827	21,311,140
Net cost industry	1,192,467	1,189,784	1,189,784	1,189,784	1,189,784	1,189,784	1,189,784	1,189,784	1,189,784	1,189,784	11,900,522	1,190,096	10,243,970

Option 3 – Allow sales of raw drinking milk from all outlets

COSTS

Costs to Industry

Familiarisation Costs to Farmers (One-Off Cost)

121. As under Option 2 there will be familiarisation costs to industry, see paragraph 105.

Costs to Enforcement

Familiarisation Costs (One-Off Cost)

122. As under Option 2 there will be familiarisation costs to enforcement, see paragraph 114.

Costs to Consumers

Potential increased Risk of Disease associated with RDM (Ongoing Cost)

123. Option 3 relaxes sales restrictions on raw milk and could therefore lead to an increase in the production of raw milk, which in turn could increase consumer exposure to raw milk. As with all higher risk products, increased exposure could lead to an increased risk of illness.

124. It is very difficult to monetise any impact on consumer health from the removal of sales restrictions as it is not possible to estimate the likelihood of illness occurring as a result. We do not have any UK evidence on the impact of sales restrictions on the risks of an outbreak of disease associated with unpasteurised milk. However, there is some data from the USA (see paragraph 22) and other countries (see paragraph 23) that seems to suggest that increased exposure to raw drinking milk could increase this risk, and that restricting sales of non-pasteurised products could reduce this risk.

125. If we assume that sales restrictions do have an impact on the risk of outbreaks associated with RDM, we can compare data from the period before, to the period after, the introduction of sales controls. Using estimates from the HSE on the willingness to pay (WTP) to prevent contracting foodborne disease of various severity and the DfT estimate of the willingness to prevent death, we can calculate the average per annum cost of RDM associated illness before and after the introduction of controls. However, it is difficult to conclude with any certainty exactly which controls that might have contributed to the reduction in outbreaks that we have seen in the late 1980s and in the 1990s as several hygiene controls were introduced alongside the sales restrictions for RDM.
126. Using HSE and DfT estimates we have calculated that the average cost per annum of food borne illness caused by raw drinking milk was £3,895,786 during the period 1980 to 1984, whilst the average costs per annum was £614,834 during the period 1985 to 1989. This is based on outbreak data from England and Wales. This represents a reduction in the costs of illness associated with RDM between the periods of £3.2m per annum (84%). For details of the calculations, please see Annex 5.
127. If we believe that the sales restrictions are the critical measure that led to the reduction in illness associated with RDM, we can use this estimate of £3.2m per annum as a measure of the cost of relaxing sales restrictions. It should be noted however, and as stated above, that we cannot be certain exactly which controls or other factors may have contributed to the decline and this may overestimate the costs.

Consultation Question 18

Stakeholders are invited to comment on whether they find it reasonable that relaxed sales restrictions are likely to increase the risk of illness associated with RDM. Please support your arguments with evidence and provide us with detailed information and data for us to be able to monetise this cost.

Other Costs

Consumer confidence in food safety controls following a Potential Outbreak associated with RDM (Non-Monetised Cost)

128. If relaxed sales restrictions lead to increased exposure to consumers of raw drinking milk this could potentially increase the risk of illness associated with RDM (see paragraph 77). If there is an outbreak of illness associated with RDM after relaxed sales restrictions this could lead to a reduction in consumer confidence in food safety controls more generally. There may be an impact on the wider dairy industry producing pasteurised milk and milk products and raw milk products. We have, however, been unable to monetise this potential cost.

BENEFITS

Benefits to Industry

Benefits from expanded sales (Non-Monetised)

129. If sales restrictions are relaxed, more producers may start producing raw drinking milk, and may therefore benefit from expanded sales. It is however very difficult to determine exactly what effect relaxed sales restrictions would have on production and sales, and we have therefore not been able to monetise this potential benefit.

Benefits to Consumers

Benefits from increased consumer choice and accessibility (Non-Monetised)

130. Relaxing sales restrictions could generate benefits to consumers from increased accessibility as, following the change, raw milk could be sold in a wider range of outlets such as retail and vending machines. As it is difficult to determine exactly how the consumption would change as result of relaxed restrictions, we have been unable to monetise this potential benefit

Summary of All Costs and Benefits under Option 3

131. As can be seen in Table 9 below, Option 3 generates a total cost of £28,252,591 (PV over ten years). We have been unable to monetise any benefits in terms of increased sales to producers, or increased access to consumers, and the option therefore generates a net cost of £28,252,591 (NPV, ten years). The net cost to industry is £2,683 (NPV, ten years).

Table 9: Total Costs and Benefits under Option 3

COSTS	Year 0	1	2	3	4	5	6	7	8	9	Total	EAC/p.a.	PV
INDUSTRY													
Familiarisation	2,683	0	0	0	0	0	0	0	0	0	2,683	312	2,683
ENFORCEMENT													
Familiarisation	8,503	0	0	0	0	0	0	0	0	0	8,503	988	8,503
CONSUMERS													
Risk of illness	3,280,952	3,280,952	3,280,952	3,280,952	3,280,952	3,280,952	3,280,952	3,280,952	3,280,952	3,280,952	32,809,518	3,280,952	28,241,404
TOTAL COSTS	3,292,138	3,280,952	3,280,952	3,280,952	3,280,952	3,280,952	3,280,952	3,280,952	3,280,952	3,280,952	32,820,704	3,282,251	28,252,591
BENEFITS	Year 0	1	2	3	4	5	6	7	8	9	Total	EAC/p.a.	PV
INDUSTRY													
Increased Sales	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
CONSUMERS													
Increased Access	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
NET IMPACT													NPV
Net cost	3,292,138	3,280,952	3,280,952	3,280,952	3,280,952	3,280,952	3,280,952	3,280,952	3,280,952	3,280,952	32,820,704	3,282,251	28,252,591
Net cost industry	2,683	0	0	0	0	0	0	0	0	0	2,683	312	2,683

Option 4 – Harmonise and clarify current legislation

COSTS

Costs to Industry

Familiarisation Costs to Farmers (One-Off Cost)

132. As under Options 2 and 3 there will be familiarisation costs to industry, see paragraph 105.

Re-labelling Costs from the Harmonisation of Labelling requirements (One-Off Cost)

133. Under Option 4 there will be a cost to businesses from re-labelling changes as a result of the harmonisation of the labelling requirements on raw drinking milk for all species. This will impact on all producers of raw milk regardless of species. We envisage this to be a minor labelling change. Campden BRI has carried out research on the costs to businesses from labelling changes, and has estimated that the average cost of a minor labelling change (only changes to text, on a single face of the label and no packaging size modification) is approximately £1,800 per stock keeping unit (SKU)¹⁶. We currently do not have information on exactly what an SKU is in the context of raw drinking milk. However, if we assume that the product in itself, raw drinking milk, would constitute an SKU for farmers, this would mean that each farmer would incur a cost of re-labelling their product of £1,800. We can then quantify this cost by multiplying the number of SKUs per farmer with the total number of farmers selling raw drinking milk (104, see Table 1). This generates a total cost to farmers of £187,200.

134. It is the intention of the FSA to minimise this cost of re-labelling to farmers. We would therefore aim to introduce a transition period for farmers of three years, so that labelling changes can be introduced as part of the normal re-labelling cycle. Previous analysis of labelling changes shows that a normal labelling cycle is around two to three years. Due to uncertainties around these potential costs we have opted to monetise the full cost to farmers. As a result of the aim to introduce a transition period, the costs presented in this section are therefore likely to be an overestimate.

135. Table 10 below shows the costs associated with the labelling change, together with their associated EACs (see paragraph 106).

Table 10: Re-labelling Costs to Farmers in England, Wales and NI

	Micro	Small	Medium	Large	Total	EAC
England					171,000	19,866
Wales					12,600	1,464
NI					3,600	418
UK					187,200	21,748

Consultation Question 19

Stakeholders are invited to comment on whether our assumptions on the costs of re-labelling and appropriate transition period (3 years) seem reasonable. If not, please provide as detailed information and data as possible for us to be able to monetise

¹⁶ Developing a framework from Assessing the Cost of Labelling Changes in the UK, <http://archive.defra.gov.uk/evidence/economics/foodfarm/reports/documents/labelling-changes.pdf>

this cost more robustly.

Consultation Question 20

The Agency would welcome views and evidence from industry about any other costs that this IA might have overlooked and which would be incurred as a result of the new labelling requirements.

Extension of sales restrictions to all species (Ongoing Cost)

136. This option extends existing sales restrictions on cows' raw drinking milk to all species. In the UK, we are aware of sales of raw drinking milk from goats and sheep, in addition to the sales of cows' raw drinking milk, although there may be sales of RDM from other species such as camel that we are currently unaware of. Through consultation with the industry we have identified two producers of sheep raw drinking milk, and 27 producers of raw milk from goats (see Table 2). There is one registered producer of buffalo milk but communications with industry has indicated that this producer currently does not sell any raw drinking milk.
137. Of the 20 responses from goat RDM producers to the industry questionnaire, the majority (16) indicated that they only sell their milk directly from the farm, via farmers' markets or via on-farm catering and will therefore not be affected by the extension of sales restrictions. The four remaining goat producers sell via different channels and the changes would therefore affect them. Out of the 2 sheep producers, one only sells its products direct from farm and would therefore not be affected, whilst the remaining one sells via a distributor, and would therefore be affected. Table 11 below shows the routes of sales of the four goat producers (top four rows) and the one sheep producer (fifth row):

Table 11: Producers of Goat and Sheep RDM

	Via distributor	Internet	Retail
producer 1	10% (500 L)		
producer 2	25% (50 L)		
producer 3	10% (n/a)	5% (n/a)	40% (n/a)
producer 4	10% (1000 L)		
producer 5	10% (1000 L)		

138. These five producers will be affected by the change in policy. At this stage we are uncertain about exactly what effect this policy would have, but we have assumed the worst case scenario, i.e. that sales via these routes are lost. We have limited information on price of raw milk from other species, but an internet

search, based on a very small number of goats milk producers has indicated it would be reasonable to calculate an indicative cost based on our best estimate of the average price of 1 litre of cows' raw drinking milk (£1.96, see paragraph 111 above). We do not know whether this estimate is representative for the average cost of RDM from other species and acknowledge that milk from some species is likely to be more expensive, for example camel's milk can be bought for around £7 per litre.

139. For the goat producer that we do not have data on litres sold we assume that he sells the average across the three other goat producers, i.e. 517 L. Multiplying the litres sold per producer with the price per litre then gives a total indicative cost to industry of £7,054 per annum from extended sales restrictions. To note is that this estimate is uncertain and should only be treated as an indicative cost.

Table 12: Indicative Cost to Goat and Sheep Producers from Lost Sales

	Litres	Cost
Producer 1	500	1,150
Producer 2	50	115
Producer 3	517	1,189
Producer 4	1000	2,300
Producer 5	1000	2,300
Totals	3,067	7,054

Consultation Question 21

Stakeholders are invited to comment on our assumptions with regards to the extension of sales to other species. In particular:

- (1) What is a reasonable estimate of the average price of RDM from other species? Is it reasonable to assume that this would be similar to the average price of 1 litre of cows' raw drinking milk?
- (2) What is the most likely impact from extended sales restrictions to other species – would producers of RDM from other species lose all their sales, or would they be able to continue to sell their milk via other channels?

Please provide us with as detailed information and data as possible for us to be able to monetise this cost.

Costs to Enforcement

Familiarisation Costs (One-Off Cost)

140. As under Option 3 there will be familiarisation costs to enforcement, see paragraph 114.

Costs to Food Standards Agency

141. Costs of producing guidance (One-Off Cost) This option also introduces guidance to help industry and enforcement officers with the interpretation of the controls on RDM, and the FSA will therefore incur a cost from producing this guidance.

BENEFITS

Benefits to Industry

Greater Clarity of Requirements on Raw Drinking Milk (Non-Monetised)

142. Introducing guidance is likely to generate benefits to farmers in terms of a greater clarity of the rules governing the production and sales of raw drinking milk. Due to uncertainties about the number of farmers that would find the guidance beneficial, we have been unable to monetise this potential benefit.

Consultation Question 22

Stakeholders are invited to comment on our assumption that guidance would increase the clarity of current legislation to farmers, and whether this benefit could potentially be monetised as a time saving. We would also welcome comments on the assumption that new entrants into the market may find current legislation more accessible. Please support your arguments with information and data, if possible. If you agree, please provide an estimate of how much time could potentially be saved.

Benefits to Enforcement

Greater Clarity of Requirements on Raw Drinking Milk (Non-Monetised)

143. Introducing guidance is likely to generate benefits to enforcement officers in terms of a greater clarity of the rules governing the production and sales of raw drinking milk and how to enforce these rules. Due to uncertainties about whether enforcement authorities would find the guidance beneficial and the numbers affected we have been unable to monetise this potential benefit.

Consultation Question 23

Stakeholders are invited to comment on our assumption that guidance would increase the clarity of current legislation to enforcement officers, and whether this benefit could potentially be monetised as a time saving. Please support your arguments with information and data, if possible. If you agree, please provide an estimate of how much time could potentially be saved.

Summary of All Costs and Benefits under Option 4

144. As can be seen in Table 13 below, Option 4 generates a total cost to the economy of £259,106 (PV over ten years) (total cost to business is £250,603, PV over ten years). We have been unable to monetise any benefits in terms of greater clarity arising from guidance, and the option therefore generates a net

cost to the economy of £259,106 (NPV), and a net cost to business of £250,603 (NPV over ten years).

Table 13: Total Costs and Benefits under Option 4

COSTS	Year 0	1	2	3	4	5	6	7	8	9	Total	EAC/p.a.	PV
INDUSTRY													
Familiarisation	2,683	0	0	0	0	0	0	0	0	0	2,683	312	2,683
Re-labelling	187,200	0	0	0	0	0	0	0	0	0	187,200	21,748	187,200
Sales restriction	7,054	7,054	7,054	7,054	7,054	7,054	7,054	7,054	7,054	7,054	70,541	7,054	60,719
ENFORCEMENT													
Familiarisation	8,503	0	0	0	0	0	0	0	0	0	8,503	988	8,503
FSA													
Guidance	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
TOTAL COSTS	205,441	7,054	7,054	7,054	7,054	7,054	7,054	7,054	7,054	7,054	268,928	30,102	259,106
BENEFITS	Year 0	1	2	3	4	5	6	7	8	9	Total	EAC/p.a.	PV
INDUSTRY													
Greater clarity	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
ENFORCEMENT													
Greater clarity	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
NET IMPACT													NPV
Net cost	205,441	7,054	7,054	7,054	7,054	7,054	7,054	7,054	7,054	7,054	268,928	30,102	259,106
Net cost industry	196,937	7,054	7,054	7,054	7,054	7,054	7,054	7,054	7,054	7,054	260,424	29,114	250,603

SUMMARY OF OPTIONS AND THE PREFERRED OPTION

145. Under **Option 1** (Do Nothing), the majority (at least 97% based on consumer feedback) of consumers in England, Wales and NI would continue to consume pasteurised milk. There have been no reported outbreaks of illness related to consumption of RDM since 2002 and analysis of the available scientific data seem to indicate that the current EU and domestic controls (**Option 1**) are controlling the risks associated with RDM and preventing illness from occurring. The data also shows introduction of the requirement for all milk in Scotland to be pasteurised before sale had a similar impact to the restrictions on sales applied to the rest of the UK. It is likely that **Option 2** will provide increased consumer protection over **Option 1**, but this is likely be marginal. However, the option does not provide any further clarity about rules governing the sales of RDM, and under this option there are different rules for different species which leads to inconsistencies both in application of the current law and across species.
146. **Option 2** (all milk to be pasteurised) would be consistent with the advice of the ACMSF that the most effective option for managing the risks associated with raw drinking milk is to pasteurise all milk before sale. The public health benefits of **Option 2** would be potentially preventing future outbreaks that may occur under the other options. The pathogens that could be present in raw milk can have severe public health consequences, but the likelihood of illness occurring is considered low under current controls, particularly given the absence of confirmed cases of illness associated with RDM and the relatively small number of consumers exposed to the product. The evidence on microbiological safety will carry significant weight in the final assessment by the FSA, consistent with the introductory statement of our strategy to 2015 that “we will put the health of the consumer first”. We will also weigh other evidence, in line with our statutory

duty to consider all risks, costs and benefits before reaching a decision. Consideration of other evidence shows **Option 2** would have a negative impact on some consumers, and a disproportionate impact on small business. As such, this option would be contrary to wider Government policies on growth and localism. It would also be inconsistent with consumer feedback that indicates a very strong support for consumer choice and therefore potentially fails to look after consumers' other interests in relation to food as required of the FSA in the Food Standards Act 1999. **Option 2** would also raise questions of consistency of risk management with other foods that consumers choose to consume raw such as steak tartare, eggs and raw shellfish. In these cases, the FSA provides advice to consumers highlighting risks, including increased risk for vulnerable groups, so they can make informed choices.

147. There is no data to allow us to estimate the impact of **Option 3** (no sales restrictions on sales of raw milk) but it is reasonable to assume that increased availability would lead to an increase in RDM consumption. Some evidence seems to suggest that increasing consumer exposure to raw milk could increase the likelihood of illness occurring. Given the severity of the disease that could be caused by any pathogens present it would be difficult to justify measures that could lead to an increased risk of the disease occurring. This would suggest that **Option 3** is not appropriate on public health risk grounds, although it is recognised that the risk of allowing sales from local retail outlets only is likely to be lower than removing all sales restrictions.

148. **Option 4** (clarification and guidance) offers scope to enhance the existing controls. Microbiological and epidemiological data seem to indicate that the current combination of EU and domestic controls is managing the risks associated with raw drinking milk to a low level and is preventing detectable outbreaks of illness associated with this commodity. However, there are aspects of the legislation that would benefit from clarification (new sales routes) and harmonisation (sales provisions for species other than cows and labelling). Doing so would be consistent with the majority view from consumers. It would also continue to allow local provision of RDM and such provision would be in line with Government policies on growth and localism.

Conclusion

149. The preferred option represents a preliminary view, and is without prejudice to the final decision of the FSA Board following consideration of the consultation responses and wider engagement activity. Further evidence may become available during the consultation process that would strengthen the evidence base and influence assessment of each option. The FSA Board will therefore make final recommendations on the way ahead at an open Board meeting later in 2014 after consideration of the available evidence and the consultation responses.

150. The preferred Option is **Option 4**, to enhance current controls through harmonising controls for all species and the labelling provided to consumers. The limitations in the evidence base and uncertainties associated with the risk assessments mean it is difficult to present compelling scientific evidence to support significant changes to the current controls to either introduce more or less restrictions on the sale of RDM. There are however reasonable and logical arguments to support the relatively small changes proposed by **Option 4** so that current controls are harmonised and clarified.
151. **Option 1** (do nothing) provides similar provisions to **Option 4** and similar levels of public health protection but ambiguity and inconsistency in the Regulations would not be addressed. In particular, no controls would be applied to RDM for species other than cows, and consumers would be subject to different advice on product labels.
152. **Option 2** (requirement for pasteurisation) would offer the highest level public health protection. However, given the absence of reported illness and the low level of consumer exposure, the additional public health benefits this approach would provide seems likely to be low. This Option would have a negative impact on consumers by removing consumer choice and a disproportionate impact on small business.
153. **Option 3** (remove sales restrictions) could introduce increased risks to the consumer and, given the severity of disease, this is not appropriate even though there are wider regulatory considerations such as support for economic growth which could be made in favour of this option.

Consultation Question 24

Stakeholders are invited to indicate whether or not they agree that the available evidence supports Option 4 as the preferred option? It would be helpful if an explanation could be provided to support opinions, particularly where other options are preferred.

SUMMARY OF EVIDENCE ASSOCIATED WITH EACH OPTION FOR CONTROLS FOR RAW DRINKING MILK

Evidence	Option 1 Do nothing	Option 2 All milk to be pasteurised	Option 3 Remove restrictions on sales of raw drinking milk	Option 4 Introduce measures to harmonise and clarify current controls
Risk Assessment	<p>Majority of milk sold in the UK would be pasteurised.</p> <p>Available data indicates pathogens could be present in RDM which are known to cause severe illness. The potential public health impact of illness associated with RDM is therefore high.</p> <p>Data on reported outbreaks of foodborne disease and VTEC illness indicate the likelihood of illness occurring is currently low.</p> <p>There have been no reported outbreaks of illness associated with RDM for over 10 years. VTEC surveillance data shows the majority of VTEC cases are not associated with RDM. A small number report RDM consumption alongside exposure to other known VTEC risk factors.</p> <p>Likelihood of illness is related to consumer exposure and it</p>	<p>All milk sold in UK would be pasteurised.</p> <p>Available data indicates pathogens could be present in RDM which are known to cause severe illness. The potential public health impact of illness associated with RDM is therefore high.</p> <p>Data on reported outbreaks of foodborne disease and VTEC illness indicate the likelihood of illness occurring is currently low.</p> <p>Likelihood of illness is related to consumer exposure. Consumer exposure would be reduced further and limited to personal consumption by the farmer and farmer's family and illegal sales.</p> <p>Public health benefits arise from prevention illness that may (or may not) occur in future. The potential for illness to occur would be</p>	<p>Majority of milk sold in the UK would be pasteurised.</p> <p>Available data indicates pathogens could be present in RDM which are known to cause severe illness. The potential public health impact of illness associated with RDM is therefore high.</p> <p>Data on reported outbreaks of foodborne disease and VTEC illness indicate the likelihood of illness occurring is currently low.</p> <p>Likelihood of illness is related to consumer exposure and this likely to increase with increased availability of RDM.</p> <p>Public health risks are associated with the potential for illness to occur in future which could increase with increased consumer exposure. The potential presence of pathogens and the severity of disease this might cause is also</p>	<p>Majority of milk sold in the UK would be pasteurised.</p> <p>Available data indicates pathogens could be present in RDM which are known to cause severe illness. The potential public health impact of illness associated with all RDM is therefore high.</p> <p>There is limited data on RDM from species other than cows but the pathogens that may be present are similar.</p> <p>Data on reported outbreaks of foodborne disease and VTEC illness indicate the likelihood of illness occurring is currently low.</p> <p>There have been no reported outbreaks of illness associated with RDM for over 10 years. VTEC surveillance data shows the majority of VTEC cases are not associated with RDM. A small number report RDM consumption alongside</p>

	<p>is reasonable to assume that consumer exposure is restricted by current controls.</p> <p>Public health risks are associated with the potential for illness to occur in future. Historical data indicates likelihood of illness occurring is low but it is not possible to quantify the public health risks associated with the current controls.</p>	<p>reduced, but not completely removed. It is however not possible to quantify the public health benefits associated with a requirement for all milk to be pasteurised.</p> <p>Scientific evidence on nutritional and allergenicity benefits are incomplete but there is no evidence support the view that pasteurisation leads to nutrient losses or RDM consumption reduces the risk of developing allergies</p>	<p>recognised but it is not possible to quantify the public health risks associated with wider RDM sales.</p>	<p>exposure to other known VTEC risk factors.</p> <p>Likelihood of illness is related to consumer exposure and it is reasonable to assume that consumer exposure is restricted by current controls. It is possible restrictions on sales of milk from other species will reduce consumer exposure to RDM slightly.</p>
Consumers	<p>Allows supply of RDM to a relatively small proportion of consumers.</p> <p>Previous consultations and more recent consumer feedback indicates there is strong support for continued sales of RDM by RDM consumers and the wider population.</p> <p>Consumers also support continued sales with an element of Regulation to maintain quality and safety of RDM.</p>	<p>Consumers would no longer be able to purchase RDM.</p> <p>Consumer choice is removed but there is strong support for that to be maintained.</p> <p>Many consumers perceive there are wider public health benefits associated with the consumption of RDM so potential perceived negative impact on individuals.</p>	<p>Opportunities for increased supply of RDM to consumers.</p> <p>Consumers feedback suggests some support for wider sales.</p> <p>Consumer interests other than food safety are protected with the potential for increased consumer choice</p>	<p>Allows RDM consumption by small proportion of consumers.</p> <p>Previous consultations and more recent consumer feedback indicates there is strong support for continued sales of RDM by RDM consumers and the wider population.</p> <p>Introduces consistent labelling for all consumers with increased information highlighting risks to vulnerable groups.</p>
Impact on business	<p>Supports rural economy and allows producers access to a</p>	<p>Potential negative impact on rural economy as limited</p>	<p>Provides potential to strengthen rural economy</p>	<p>Supports rural economy by allowing producers access to</p>

	limited market.	<p>market no longer available.</p> <p>Value of sales likely to be variable. RDM is unlikely to be sole source of income for farmers and potential loss of market could be offset by diverting to pasteurisation or as an ingredient for raw milk products.</p> <p>Could have a disproportionate impact on small businesses.</p>	<p>and growth in the RDM market, although potential benefits cannot be quantified.</p> <p>P.</p>	a limited local market.
Impact on enforcement authorities	Enforcement authorities will continue to carry out controls for a relatively low number of RDM producers.	Potential to reduce burden on enforcement authorities as inspection of RDM producers will no longer be required.	Potential to increase burden on Enforcement authorities due to the likely increase in producers placing RDM on the market.	Minimal impact on Enforcement Authorities.
Better regulation	<p>Difficulties in interpreting some aspects of the legislation, particularly potential sales routes remain.</p> <p>Inconsistent controls and labelling for different species and in consumers in different countries of the UK remain.</p>	Simplifies and harmonises controls as prevents sales of RDM	<p>Simplifies, clarifies and harmonises controls as removes sales restrictions.</p> <p>Inconsistent labelling for different species and consumers in different countries of the UK</p>	<p>Clarifies interpretation of controls through provision of guidance.</p> <p>Introduces consistent controls across all species.</p>

Preferred Option – Option 4

It is difficult to present compelling evidence to support significant change to the current controls for RDM. There are logical and reasonable arguments to support the limited change presented in **Option 4** which would harmonise and clarify current provisions. **Option 1** provides similar provisions but ambiguities and inconsistencies would not be addressed. **Option 2** would offer the highest level of public health protection but, given the absence of reported illness and low level of exposure, the additional public health benefits would seem to be low. There is also potential negative impact on consumers through the removal of consumer choice and disproportionate impact on small businesses. **Option 3** has the potential to increase public health risks and, given the potential severity of disease, this is not appropriate.

Annex 1: Current controls on RDM

EU legislation:

1. EU food hygiene rules that came into force on 1 January 2006 provide both general hygiene controls (Regulations 852/2004, 853/2004 and 854/2004) and some specific controls on RDM and cream (Regulation 853/2004 and Regulation 2073/2005 on the microbiological criteria of foodstuffs), which are applicable across all Member States. This legislation also allows Member States to introduce such national measures governing the sale of these commodities in domestic markets as are necessary to ensure the potential risks associated with RDM are controlled.

National legislation:

2. National regulations on raw milk intended for direct human consumption (RDM) are in place in England, Wales and Northern Ireland.
 - The Food Hygiene (England) Regulations 2006 (as amended);
 - Food Hygiene (Wales) Regulations 2006 (as amended) and
 - Food Hygiene (Northern Ireland) Regulations 2006 (as amended),
 - The Food Labelling (England) Regulations 1996 (as amended),
 - The Food Labelling (Wales) Regulations 1996 (as amended),
 - The Food Labelling (Northern Ireland) Regulations 1996 (as amended).
3. These regulations include requirements related to microbiological criteria, labelling and sales restrictions with different combinations applying to RDM from different species (see Table 1 below for a summary of current regulations). An outline of the current controls is set out below. These regulations do not apply to products made from RDM (see paragraph 2).

Microbiological criteria:

4. In addition to controls set down in EU legislation, all RDM must also meet the microbiological criteria for levels of bacteria set down in national legislation. These provide an indication of the microbiological quality of raw milk and are more stringent than those in the EU legislation so as to provide additional protection against risks associated with RDM. The microbiological criteria are not under review.

Sales restrictions:

5. Raw cows' drinking milk can only be sold directly by the farmer to consumers. This includes sales direct from the farm premises (including by the farmer at a farmer's market), in a farmhouse catering operation (e.g. bed and breakfast on farm) or by a distributor from a vehicle (e.g. a lorry or milk float) used as a shop premises. Sales through other outlets have been prohibited since 1985. Direct internet sales (i.e. sales not involving a third party) are permitted under current legislation. Sales from vending machines on farm premises are permitted where they are manned by the farmer or their representative but sales from vending machines located in retail outlets away from the farm are not permitted. Milk from other species (e.g. goats, sheep and buffalo) are not subject to these restrictions.

Labelling requirements:

6. In addition to the EU legislative requirement to label all RDM as 'raw milk', since 1996, legislation in England, Wales and Northern Ireland requires the additional statement- ***'this milk has not been heat-treated and may therefore contain organisms harmful to health'*** to appear on the label. In the case where the RDM is not pre-packed and is sold at a catering establishment there must be a clear display saying ***'milk supplied in this establishment has not been heat-treated and may therefore contain organisms harmful to health'***. In England and Northern Ireland these labelling requirements apply to RDM from all species except buffalo RDM which is not required to carry the additional labelling. From 2006, legislation in Wales requires the following enhanced labelling for RDM from all species ***'This milk has not been heat-treated and may therefore contain organisms harmful to health. 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 illnesses.'***

Inspections and sampling

7. Cows' RDM producers are subject to twice-yearly inspections which verify they are complying with the requirements of the hygiene legislation for the production and handling of the milk. These inspections are carried out by the FSA in England and Wales and by the Department of Agriculture and Rural Development's Agri-food Inspection Branch (DARD AfIB), on behalf of the FSA, in Northern Ireland. Official control samples of cows' milk are taken and tested quarterly to verify compliance with microbiological standards that are indicators of the quality of the milk. While failure to meet the current microbiological standards does not directly imply the presence of pathogens, this does indicate higher levels of faecal contamination and/or microbiological contamination, either from livestock or during production, and pathogens are more likely to be present as bacterial counts increase. There are no specific standards for pathogens in RDM in national legislation above the requirements set down in EU legislation but to meet the general obligation for supply of safe food, producers need to ensure that pathogens are not present at levels that could cause illness. Similar inspections are carried out, on a risk basis, for producers of other species' RDM by the relevant local authority in England & Wales and by DARD AFBI in NI.

Table 1:
CONTROLS ON RAW DRINKING MILK IN ENGLAND, WALES, NORTHERN IRELAND AND SCOTLAND

	<u>England</u>	<u>Wales</u>	<u>Northern Ireland</u>	<u>Scotland</u>
Raw Cows Drinking Milk				
Sales	Sales allowed direct to consumers at the farm gate, in a farmhouse catering operation or through milk roundsmen. Sales by farmers at farmers market and internet sales allowed. All other sales including vending machines in retail establishments prohibited			Sales prohibited since 1983
Specific controls	Herd must be officially tuberculosis free, and brucellosis free and comply with EU hygiene rules ¹ and with microbiological standards in domestic Food Hygiene Regulations ² .			N/A
Labelling requirements	Must comply with requirements in domestic Food	Must comply with requirements in domestic Food	Must comply with requirements in domestic Food	

¹ Regulation EC No. 853/2004, Annex III, Section IX, Chapter 1, 2

² The Food Hygiene Regulations 2006, Schedule 6, 5 (similar requirements apply in England, Wales and Northern Ireland)

Annex 1: current controls on RDM

	Labelling Regulations ³ and state: “This milk has not been heat-treated and may therefore contain organisms harmful to health”	Labelling Regulations and state: “This milk has not been heat-treated and may therefore contain organisms harmful to health. 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”	Labelling Regulations and state: “This milk has not been heat-treated and may therefore contain organisms harmful to health”	
Official controls	Twice yearly inspections Quarterly sampling and testing			
Raw milk from other species				
Sales	No restrictions on sales			Sales prohibited since 2005
Specific controls	Buffaloes milk must come from a tuberculosis and brucellosis free herd. Sheep and goat milk must come from a brucellosis-free herd. RDM from buffaloes, sheep and goats must comply with EU hygiene rules and microbiological standards in domestic Food Hygiene Regulations.			N/A
Labelling requirements	Sheep and goat RDM must be labelled to state: “This milk has not been heat-treated and may therefore contain organisms harmful to health” No requirements in Food Labelling Regulations 1996 for buffaloes RDM, but EU food hygiene rules on labelling for raw milk apply.	Sheep, goat and buffalo RDM must be labelled to state: “This milk has not been heat-treated and may therefore contain organisms harmful to health. 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”	Sheep and goat RDM must be labelled to state: “This milk has not been heat-treated and may therefore contain organisms harmful to health” No requirements in Food Labelling Regulations 1996 for buffaloes RDM, but EU food hygiene rules on labelling for raw milk apply.	
Official controls	Twice-yearly inspections Sampling subject to Food Authority checks			

³ The Food Labelling Regulations 1996 (equivalent legislation applies in Northern Ireland).

POLICY REVIEW ON RAW DRINKING MILK CONTROLS SCIENCE WORKSTREAM

1. Scope

Scientific evidence on the microbiological safety of raw milk was assessed by ACMSF in January 2011 and presented as part of the March 2012 Board paper on the microbiological safety of raw drinking milk.

This paper considers additional scientific data to provide evidence to support options developed as part of the review of current controls on raw drinking milk. The science workstream covers scientific evidence in relation to microbiology, epidemiology, nutrition and allergy.

2. Microbiology & epidemiology of unpasteurised milk consumption

Aims:

- To review the effect of the differing raw milk controls in the UK on outbreaks of illness.
- Further analysis of the enhanced Verotoxigenic *E.coli* (VTEC) surveillance in the UK.
- To review data on the human health impacts of raw milk consumption and controls in other EU countries and internationally.

Findings:

- Prior to the introduction of a ban on sales of raw drinking milk in Scotland and restrictions on sales in England, Wales and N. Ireland large outbreaks of illness associated with raw milk consumption were seen fairly frequently. It appears that both the ban and the restriction on sales had a significant effect on reducing the number of outbreaks and illness linked to raw drinking milk consumption, although in both cases it took a couple of years before the effects were seen. There may be other underlying factors that have contributed to the decline in outbreaks such as reduced production, and therefore exposure to, raw milk and improved microbiological quality of raw milk. No outbreaks linked to raw milk consumption have been reported in England, Wales and N. Ireland since 2002 and in Scotland since 1999.
- The majority of VTEC cases included in UK enhanced surveillance do not report raw milk consumption (97-99%) suggesting that raw milk is not causing a significant proportion of VTEC cases in the UK. A small number of VTEC cases (1-3%) do report raw milk consumption, however they may also have been exposed to other sources of infection. It is not possible to identify from this data, what the impact on VTEC case numbers would be, if the current control measures were not in place.

- There is some production of raw milk from non-bovine species in the UK (sheep, goat and buffalo) although the total number of such producers is less than 1/3 of the number of raw cow's milk producers. There is the potential for pathogens to be present in milk from non-bovine species and outbreaks of illness linked to non-bovine milk consumption do occur but are less frequently reported, possibly due to the lower levels of consumption. In the UK outbreaks linked to non-bovine milk consumption have only been reported twice, in 1983 and 1984, both outbreaks were associated with goat's milk. It is not possible, without a quantitative risk assessment, to say how the risk from raw milk from non-bovine species compares with the risk from raw cows' milk.
- Of the countries reviewed, internationally and in the EU, where raw milk sales are permitted outbreaks of illness of varying size, frequency and seriousness linked to raw milk consumption have been reported. The variations are due to many underlying factors that differ between the countries, making direct comparisons of the effect of different control measures difficult. Even in countries where sales are not permitted outbreaks linked to raw milk have been seen due to illegal sales or personal consumption.
- The full referenced review of data can be found in annex 1.

3. Consumption of unpasteurised milk and development of allergic disease

Aims:

- To review the current scientific evidence on consumption of unpasteurised milk and the risk of developing allergy and intolerance.

Findings:

- There is some evidence to suggest there may be an association between raw milk consumption in infancy and a reduced prevalence of allergic disease later in life. However, further research is required to confirm this effect, and whether it is independent of other factors.
- Until it is known what mechanisms may underlie this possible protective effect and the risks that may be associated with them, it is not possible to recommend consumption of unpasteurised milk to prevent the development of allergic disease.
- There are many reasons why people develop allergies. Given the uncertainty in the evidence base, and in the absence of supporting data, it is not possible to quantify any benefits that may be associated with consumption of unpasteurised milk in infancy and the reduction in allergic disease.
- If a protective effect were to be confirmed, consideration would need to be given as to whether the potential benefits would outweigh the risks associated with increased pathogen consumption in unpasteurised milk.
- Consumption of unpasteurised milk is not recommended to prevent or treat lactose intolerance or cows' milk allergy.
- The full referenced review of data can be found in annex 2.

4. Nutritional implications of unpasteurised milk consumption

Aims:

- To review the current scientific evidence on nutritional differences between unpasteurised and pasteurised milk including evidence on any nutritional benefits associated with consumption of unpasteurised milk.

Findings:

- There is little current scientific evidence to indicate that pasteurising milk substantially alters its nutritional composition. Differences in cow breed, age, feeding regime as well as seasonal changes, lead to variations in nutritional composition of milk whether raw or pasteurised. Wide variation in reported nutritional compositional values of raw milk is likely to be due to analytical difficulties and differences. This appears to be especially the case for micronutrients. Given that milk is a rich source of many vitamins and minerals it would be advisable to monitor the effect any processing techniques have on vitamin and mineral levels both in terms of content and bioavailability.
- There is insufficient evidence to show the effect of pasteurisation on the functional properties of nutrients in milk. Further research is needed to consider changes in nutrient function resulting from milk processing.
- There is a lack of scientific evidence to support potential nutritional and health benefits of raw milk consumption. Further research is recommended into the effect of raw milk consumption on health and disease.
- The full referenced review of data can be found in annex 3

Annex 1**MICROBIOLOGY AND EPIDEMIOLOGY OF UNPASTEURISED MILK CONSUMPTION****Issue**

1. ACMSF considered data on the microbiological safety of raw drinking milk in January 2011. They reviewed UK data on human illness and outbreaks linked to raw drinking milk and cream, surveys of pathogens and hygiene indicator species in raw milk/cream and results of the raw cows' milk sampling programme. The details can be found in paper ACM 1008¹. The ACMSF concluded that pasteurisation is an important control measure for milk safety.
2. Additional microbiological and epidemiological data to help support development of control options is considered here.

Timeline of outbreaks linked to raw milk in the UK

3. To assist in assessing the impact of the differing controls in Scotland with England, Wales and N. Ireland, data on outbreaks linked to unpasteurised milk in the UK have been mapped against the introduction of control measures. Table 1 presents data on reported outbreaks of infectious intestinal disease linked to raw milk and cream consumption in England and Wales, Scotland and N. Ireland from 1980 to 2011. A comparison of the number of confirmed outbreaks each year in the four countries is shown in figure 1 and a comparison of the number of individuals affected in outbreaks each year in the four countries is shown in figure 2.
4. Prior to the 1983 ban on sales of raw milk in Scotland there were a number of large outbreaks of illness linked to raw milk consumption. From 1980-1983 there were 32 outbreaks involving 1448 people with 8 deaths. After the 1983 ban a number of raw milk associated outbreaks were still seen in Scotland but fewer people were affected. From 1984-1985 there were 13 outbreaks in Scotland linked to raw milk consumption with 101 individuals affected. After 1985 the incidence of outbreaks declined significantly over time with fewer much smaller outbreaks reported and the last recorded Scottish outbreak was in 1999.
5. The picture is similar in England and Wales with large outbreaks affecting hundreds of individuals reported before sales were restricted in 1985. Between 1980 and 1985 there were 92 outbreaks linked to raw milk consumption in England and Wales involving 2035 people. In the years following the restriction on sales a number of serious outbreaks were still seen (from 1986-87 17 outbreaks affecting 713 individuals were recorded) but since then there has been a significant decline in the number of outbreaks

¹ <http://www.food.gov.uk/multimedia/pdfs/committee/acm1008rawmilk.pdf>

with generally fewer affected individuals, although it is noted there were 2 larger outbreaks in 1992 and 1995. No outbreaks of illness linked to raw milk have been reported since 2002 in England and Wales. In N. Ireland only 2 outbreaks linked to raw milk have been reported, both in 1991.

6. From the reported incident data it appears that both the ban on raw milk sales in Scotland and the restricted sales in England, Wales and N. Ireland had a significant effect on reducing the number of outbreaks and illness linked to raw drinking milk consumption, to the point that none have been detected since 1999 in Scotland and 2002 in England and Wales. However, in both cases it took a couple of years before the effects were seen. There may be other underlying factors that have contributed to the decline in outbreaks such as reduced production, and therefore exposure to, raw milk and improved microbiological quality of raw milk. It should be noted that the size and frequency of outbreaks may be under-reported and single, sporadic cases of illness linked to raw milk may remain undetected.

Table 1: General outbreaks of infectious intestinal disease linked to raw milk and cream consumption in Scotland, England & Wales, and N Ireland 1980 – 2011.

Year	Scotland		England & Wales		N. Ireland	
	No. outbreaks	No. affected	No. outbreaks	No. affected	No. outbreaks	No. affected
1980	3	98	16	210	0	0
1981	8	782	21	294	0	0
1982	14	539	18	612	0	0
1983	7	29	8	283	0	0
1984	5	27	17	404	0	0
1985	8	74	12	232	0	0
1986	2	10	8	347	0	0
1987	5	30	9	366	0	0
1988	1	4	3	27	0	0
1989	0	0	0	0	0	0
1990	2	6	na	na	0	0
1991	4	17	na	na	2	7
1992	2	6	1	72	0	0
1993	0	0	3	41	0	0
1994	0	0	3	38	0	0
1995	na	na	1	26	0	0
1996	na	na	3	16	0	0
1997	na	na	1	8	0	0
1998	1	4	2	10	0	0
1999	1	3	0	0	0	0
2000	0	0	3	9	0	0
2001	0	0	0	0	0	0
2002	0	0	3	22	0	0
2003	0	0	0	0	0	0
2004	0	0	0	0	0	0
2005	0	0	0	0	0	0
2006	0	0	0	0	0	0
2007	0	0	0	0	0	0
2008	0	0	0	0	0	0
2009	0	0	0	0	0	0
2010	0	0	0	0	0	0
2011	0	0	0	0	0	0

Figure 1: A comparison of the number of reported outbreaks linked to raw milk and cream consumption in Scotland, N. Ireland, England & Wales between 1980 and 2011. The introduction of the ban on sales in Scotland and restriction of sales in N. Ireland, England & Wales is shown

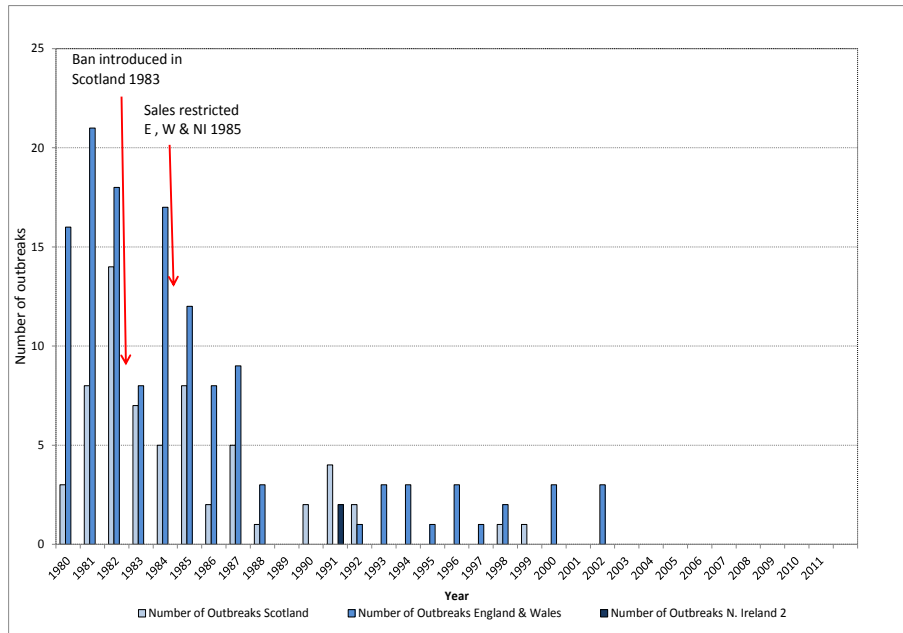
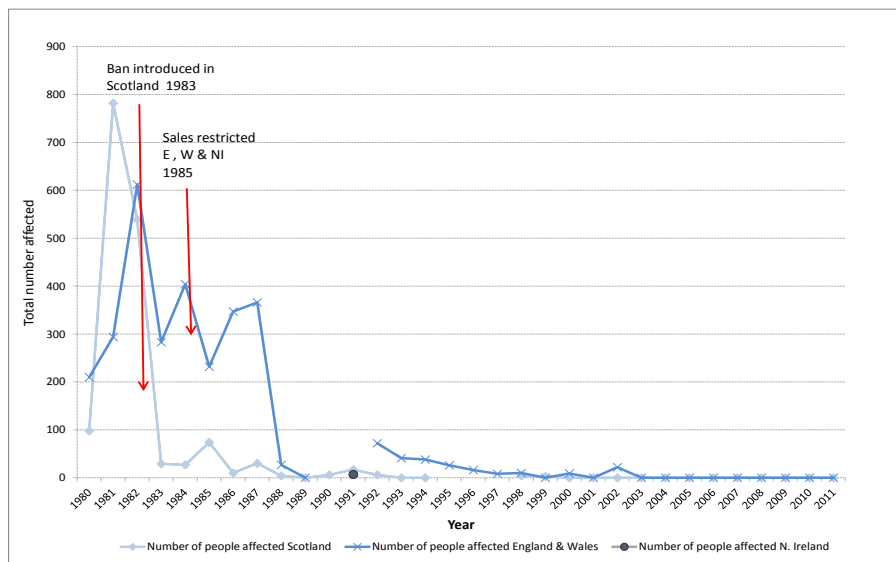


Figure 2: A comparison of the numbers of individuals affected in outbreaks linked to raw milk and cream consumption in Scotland, N. Ireland, England and Wales between 1980 and 2011. The introduction of the ban on sales in Scotland and restriction of sales in N. Ireland, England and Wales is shown.



Note for figures 1 & 2 and table 1. Outbreaks linked to raw cows' and goats' milk and cream are included. There were 2 outbreaks in England (1981 and 83) linked to cream and 1 outbreak (1989) linked to milk where it was not recorded whether the product was raw or pasteurised. These have been excluded from the analysis. No data are available for Scotland in 1995, 1996, 1997. No data are available for England in 1990 and 1991. Data from 1980 –1989 were confirmed reports to PHLS Communicable Disease Surveillance Centre and the Communicable Disease (Scotland) Unit. Data taken from the Report on the Committee on the Microbiological Safety of Food, Department of Health, 1991. Data from 1990 to 2011 are from Health Protection Scotland (HPS) and Health Protection Agency (HPA).

Enhanced VTEC surveillance in the UK

7. Active national surveillance systems for Verotoxigenic *E.coli* (VTEC) infection were established in Wales, Scotland, England and N. Ireland in 1990, 1999, 2009 and 1998 respectively. The systems assemble a comprehensive clinical, epidemiological and microbiological dataset for laboratory-confirmed VTEC cases, covering their exposures to various biologically plausible risk factors, including consumption of unpasteurised milk.
8. Data from enhanced VTEC surveillance in the UK has been reviewed to explore the role consumption of raw milk may have in contributing to illness.
9. The data show that between 1-3% of VTEC cases in the UK report having consumed unpasteurised milk (Table 2).
10. This does not mean that these individuals became infected solely as a result of consuming unpasteurised milk. Cases often report multiple risk factors, including contact with farm animals, handling raw meat, or consuming private water supplies, and may have been exposed to more than one potential source of infection. It should also be noted that the systems do not have access to data allowing them to compare the frequency of potential exposures in cases compared to the general population.

Table 2: Proportion of laboratory-confirmed, UK cases from enhanced VTEC surveillance who report having consumed raw milk¹

	England 2009-2012	Wales ⁴ 1991-2012	NI 1998 - 2011	Scotland ⁵ 1999-2012
Total number of laboratory-confirmed VTEC ^{2,3} cases	2384	1151	583	2313
Number who reported consuming unpasteurised milk	51 (2%)	9 (1%)	18 (3%)	14 (1%)

England data from Health Protection Agency, Wales data from Public Health Wales, N. Ireland data from Public Health Agency Northern Ireland, and Scotland data from Health Protection Scotland

1. *Data for 2012 are provisional. Data for Wales in 2011 are also provisional.*
2. *Data include sporadic cases and general outbreak cases (sporadic cases are cases in single households who were not linked to general outbreaks, outbreaks are defined as involving the members of more than one household, or institutions).*
3. *VTEC includes cases with non-O157 serogroups of verotoxin-producing E. coli, as well as serogroup O157 cases, except in Wales and N. Ireland which are O157 serogroup cases only.*
4. *Wales data includes cases confirmed from specimens sent to HPAs Laboratory for Gastrointestinal Pathogens from patients with Welsh addresses in addition to cases identified through enhanced VTEC surveillance in Wales.*
5. *Scotland data is for primary, UK acquired VTEC cases only (i.e. those who acquired infection by exposure to a source rather than by person- to person spread). Data from the other countries includes primary and secondary cases.*

11. The enhanced VTEC surveillance data are analysed by the national Health Protection organisations for each country to identify potentially linked cases or clusters. In England, Wales and N. Ireland no outbreaks linked to raw milk consumption were identified from the data collected. In Scotland, two of the 14 cases included above, were part of a general outbreak linked to the consumption of raw milk.

12. It should be noted that whilst VTEC is statutorily notifiable in Scotland, the reporting of both outbreaks, and of detailed exposures for VTEC cases, is voluntary. The comprehensive data validation undertaken by HPS indicates that ascertainment of VTEC outbreaks is robust, but the under-reporting of raw milk consumption by sporadic/single household cases cannot be ruled out. The potential under-reporting of raw milk consumption also applies to England, Wales and N. Ireland.

13. The majority of VTEC cases included in the enhanced surveillance do not report raw milk consumption (97-99%) suggesting raw milk is not the cause of a significant proportion of laboratory-confirmed VTEC cases in the UK.

14. It is not possible to identify from this data, what the impact on VTEC case numbers would be, if the current raw milk control measures were not in place or to compare the effects of different control measures in place in Scotland,

England, Wales and N. Ireland. The time period covered by VTEC enhanced surveillance must also be considered when estimating the potential risk from raw milk consumption. Legislation banning raw milk sales was introduced in Scotland in 1983. The first report of a laboratory-confirmed VTEC case did not occur in Scotland until 1984, and when enhanced surveillance began in 1999, the ban had been in place for 16 years.

15. Further analysis of the VTEC data could be performed if desired, to analyse the VTEC subtypes and/or demographics of patients that report raw milk exposure. In Scotland, for instance, all 14 cases included above, involved infection with VTEC serogroup O157.

Milk from non-bovine species

16. The outbreak data summarised in table 1 and discussed above includes outbreaks linked to milk from non-bovine species. However, there has only been one reported outbreak where the vehicle of infection was non-bovine milk in England and Wales from 1980 to the present. This was an outbreak of Campylobacteriosis affecting three individuals in 1984 linked to consumption of raw goat's milk. In Scotland there has also been only one recorded outbreak where the vehicle of infection was non-bovine milk from 1980 to present. This was in 1983 and was linked to raw goat's milk contaminated with Staphylococcal enterotoxin, affecting two individuals. This occurred before the ban on the sale of raw milk in Scotland was extended to all species in 2005. "Since 1984 none of the outbreaks or sporadic cases that were reported to Health Protection Scotland (HPS) as having involved people who consumed raw drinking milk, were reported to have involved milk of non-bovine origin. Although the reports on some of these incidents did not specifically state the species origin, and HPS cannot therefore categorically say they involved bovine milk, the information that was provided to HPS does not suggest non-bovine sources.
17. No outbreaks linked to raw drinking milk consumption from other species (sheep, buffalo, etc) have been recorded in the UK.
18. Outbreaks linked to raw milk from non-bovine species have been recorded more recently in other countries. For example in the U.S there have been two Campylobacteriosis outbreaks linked to raw goats' milk consumption since 2010. Outbreaks linked to raw milk from non-bovine species in other countries have not been reviewed for this paper in a systematic way. However, a brief search did not find any reported outbreaks linked to raw sheep milk or raw buffalo milk consumption but outbreaks linked to raw sheep milk products were found, both in the UK and other countries. For example in France an outbreak of Salmonellosis in 2012 was linked to raw sheep milk cheese (*Salmonella* was also detected in the sheep milk).
19. There is little data on the microbiological quality of raw milk from non-bovine species. The available data in the UK was reviewed by ACMSF in January 2011 when they reviewed the health risks associated with raw milk

consumption¹. Two microbiological surveys which sampled goat, sheep and buffalo milk were carried out between 1997 and 1999. Some pathogens were detected in very low numbers in some of the samples of raw milk but the frequency of detection varied between the two surveys. In the 1997 survey no *Campylobacter*, *Salmonella* or *E. coli* O157 were detected in any samples. ACMSF didn't make any distinction between species in their conclusion that pasteurisation is an important control measure for milk safety.

20. Since there is limited data on the microbiological status of raw sheep, goat and buffalo milk in the UK more recent data from other countries has also been reviewed^{2,3,4,5}. Surveys in other countries have found varying levels of pathogens and indicator organisms in raw milk from non-bovines. Surveys have detected VTEC, *Campylobacter*, *Listeria monocytogenes* and *Staphylococcus aureus* in sheep and goats' milk, although some of the surveys found no pathogens in any samples. It is difficult to make meaningful comparisons of the microbiological status of non-bovine and bovine milk using this data, as these are "snap-shot" surveys and sample numbers are small in some of the surveys (e.g. 48 samples). The main pathogens of concern in raw cow's milk are probably similar to those of concern in non-bovine milk as goats and sheep are susceptible to infection with most of the organisms that affect cows and the potential routes of milk contamination, via udder or faeces are the same. However, the prevalence of infection and clinical symptoms in non-bovine species may differ and there are differences in husbandry practices, milking practices and farm environment which will also affect the microbiological status of raw milk from different species.
21. The limited number of recorded outbreaks linked to raw milk from non-bovines in the UK is probably in part a reflection of the lower level of consumption of milk from these species. Consumption volumes are not known but there are currently 28 registered producers of milk from non-bovines (25 goats, 2 sheep and 1 buffalo) compared with 74 registered cow's milk producers. Raw cow's milk producing herds also tend to be larger in size.
22. The data reviewed shows the potential for pathogens to be present in milk from non-bovine species. Contaminated milk from non-bovine species has the potential to cause human illness as evidenced by recent outbreaks of IID linked to goats' milk and sheep's milk cheese in other countries. However in the UK outbreaks linked to non-bovine milk have only been reported twice since 1980. It is not possible without a quantitative risk assessment to say

² Cupakova Š, Pospišilova M, Karpišková R, Janšтова B, Vorlova L. Microbiological quality and safety of goat's milk from one farm. Acta Univ. Agric. Silv. Mendel. Brun. 2012; 60(6): 33-38

³ Eglezos S, Huang B, Dykes G A, Fegan N, Bell K, Stuttard E. A survey of the microbiological quality of frozen unpasteurized goats' milk in Queensland, Australia. Aus. J. Dairy Tech. 2008; 63 (3): 79-81.

⁴ Klinger I, Rosenthal I. Public health and the safety of milk and milk products from sheep and goats. Rev. sci. tech. Off. Int. Epiz. 1997; 16(2): 482-488.

⁵ Muehlherr J E, Zweifel C, Corti S, Blanco J E, Stephan R. Microbiological Quality of Raw Goat's and Ewe's Bulk Tank Milk in Switzerland. J. Dairy Sci. 2003; 86: 3849-3856.

how the risk from raw milk from non-bovine species compares with the risk from raw cows' milk.

Data on illness and outbreaks linked to raw drinking milk in other countries

23. The regulation of the sale of raw drinking milk varies across different countries. In some countries sales are banned completely and in other countries restricted sales are allowed. EU legislation permits Member States to introduce national controls on raw drinking milk and therefore, even within the EU, controls relating to raw milk vary. A review of the raw milk controls in place in other Member States has been compiled as part of the policy workstream.
24. The section below does not attempt to review data on outbreaks and illness linked to raw milk in all countries but reports data and risk assessments from a selection of countries which apply different controls on raw drinking milk.

United States

25. Restrictions vary in different US states. Sales between states are not permitted. In 2011 it was estimated that raw drinking milk sales were permitted in 30 states and banned in 20⁶. Where sales are permitted the rules can vary and include requirements such as warning labels, licensing, restriction of sales to the farm gate etc. The US Food and Drug Administration (FDA) support the use of pasteurisation and their position is that it is not safe to consume raw milk.
26. Between 1998 and 2008, 85 outbreaks of human infection resulting from consumption of raw milk were reported to the Centres for Disease Control and prevention (CDC). These outbreaks included a total of 1,614 reported illnesses, 187 hospitalizations and 2 deaths. Analysis of outbreak data has shown the incidence of outbreaks caused by unpasteurised milk was higher in states that permitted the sale of unpasteurized milk than in states that prohibited such sale⁷.
27. Outbreaks linked to raw milk have occurred in states where sale of raw milk is not permitted. For example in Oregon an outbreak involving *E.coli* O157 occurred in April 2012 affecting 19 people, including 15 children, several of whom developed Haemolytic Uraemic Syndrome (HUS) and were hospitalised⁸. Sales of raw milk are not permitted in Oregon but the outbreak occurred amongst members of a cow-share agreement where those who want to consume raw milk buy a share in a herd and drink its milk.

⁶<http://www.fda.gov/Food/FoodSafety/ProductSpecificInformation/MilkSafety/ucm277854.htm>

⁷ Langer AJ, Ayers T, Grass J, Lynch M, Angulo FJ, Mahon BE. (2012) Nonpasteurized dairy products, disease outbreaks, and state laws—United States, 1993–2006. *Emerg Infect Dis*.

⁸http://public.health.oregon.gov/DiseasesConditions/DiseasesAZ/ecoli/Documents/foundationfarm2012_outbreak.pdf

Canada

28. Sale of unpasteurised milk is prohibited in Canada. There is, however, consumption of raw milk by dairy producers and it is permitted to bring milk for personal consumption into Canada from US states that permit it.
29. A recent presentation (May 2013) at the BC Centre for Disease Control reviewed the evidence around health and safety claims for raw milk⁹. The presentation reviewed quantitative risk assessments for raw milk and different pathogens to see whether raw milk should be considered a high risk food when the risk per serving was compared with other food types. For *Campylobacter* the risk per serving for raw milk was lower than the risk estimated for home cooked chicken. For *E.coli* O157 the risk per serving for raw milk was lower than the risk estimated for home cooked beef burgers and leafy green salads from salad bars. It was noted that the figures given in the quantitative risk assessment outputs would ideally be validated with epidemiological data. The risk assessments compared were from several different countries and differences in the models used may affect the validity of comparing risk estimates. The data is not yet published in the peer-reviewed literature although the risk assessments reviewed are published.

Australia

30. Sales of raw cows' milk are banned across all states and territories of Australia. Ongoing illegal sales and consumption amongst dairy producers exist but it is thought there is very limited consumption. Between 1998 and 2003 eight outbreaks were identified comprising 101 cases of illness (and 4 hospitalisations) associated with the consumption of raw cows' milk in Australia. Four outbreaks occurred on school camps, two on farms and one in a school.
31. In order to assess the risk to Australian consumers from consumption of raw cows' milk, a quantitative microbiological risk assessment was undertaken by Food Standards Australia New Zealand (FSANZ) in 2009 which determined that access to raw cows' milk would result in an increased likelihood of foodborne illness in Australia. The risk assessment modelling determined that per 100,000 servings of a mean daily intake of 540 ml of milk to a child the probability of illness was less than 1 case of campylobacteriosis, 97 cases of Enterohaemorrhagic *E. Coli* and 153 cases of salmonellosis in the general population for children. In a susceptible sub-population 170 cases of listeriosis were predicted.
32. The risk assessment also sought to identify ways of reducing the burden of illness and determined that the capacity to make a significant impact on the burden of illness was limited. The assessment noted that current animal

⁹ Ijaz, N., 2013. Unpasteurised milk: myths and evidence.
http://www.bccdc.ca/NR/rdonlyres/00E8757C-99E4-4414-8C54-2C92BB776567/0/RevisedPresentationJuly8RawmilkmythsandvidenceNadineljaz_PROTECTED.pdf

management structures were based on best practice for controlling mastitis and limiting the contamination of milk with spoilage and pathogenic microorganisms through the hygienic operation of the milking environment. Other measures such as testing of animals for carrier status, or analysis of raw milk were concluded unlikely to detect low levels of pathogens.¹⁰

New Zealand

33. In New Zealand raw milk sales are restricted to farm gate sales by producers to a maximum of 5 litres. Two outbreaks associated with raw milk consumption have been reported, one campylobacteriosis outbreak in 2009 due to raw milk affected 16 people (primary school children visiting a dairy farm) and one in May/June 2011 which involved eight people.¹¹
34. A New Zealand Ministry of Agriculture and Forestry (MAF) paper on proposals for continuing to legally provide for farm gate sales of raw drinking milk suggests the lower number of documented outbreaks in New Zealand might reflect their smaller population and that the sale of raw drinking milk is limited by the farm gate sale restriction. They also note there is likely to be under-reporting for short term less severe illnesses and sporadic cases where it can be difficult to trace the source.¹²

Italy

35. Raw milk sales through self-service vending machines have been permitted in Italy since 2004 and around 1500 machines are registered. Several outbreaks of illness due to *E. coli* O157 and *Campylobacter* have been reported in Italy, linked to raw milk consumption, in the last five years and as recently as 2009⁹. However it is difficult to find complete published data on outbreaks since there is no official reporting system for VTEC or *Campylobacter* infections. Since 2008 the Ministry for Health has advised that all raw milk should be boiled before consumption and signs are put on raw milk vending machines to state this, although research suggests that around 40% of people do not follow this advice. A letter to the Clinical Infectious Disease journal in 2009 reports that preliminary findings of a case control study in Italian children with HUS found the only food significantly associated with development of HUS was raw milk¹³.
36. A recent quantitative risk assessment to estimate the number of cases of illness linked to raw milk vending machines in Northern Italy estimated that for every 10 000 to 20 000 consumers each year there would be 2.12 to 1.14

¹⁰ Microbiological Risk Assessment of Raw Cow Milk Dec 2009, FSANZ.

¹¹ <http://www.foodsmart.govt.nz/food-safety/high-risk-foods/raw-milk/rawmilk.htm>

¹² Proposals for continuing to legally provide for farm gate sales of raw drinking milk, MAF Public Discussion Paper No: 2011/11, October 2011.

¹³ Scavia G, Escher M, Baldinelli F, *et al* (2009). Consumption of Unpasteurized Milk as a Risk Factor for Hemolytic Uremic Syndrome in Italian Children *Clin Infect Dis.* 48 (11): 1637-1638.

Campylobacter cases and 0.02 to 0.09 HUS cases in 0-5 year olds with 0.1 to 0.5 HUS cases in those over 5 years¹⁴.

Germany

37. In Germany, only licensed producers are permitted to sell raw milk in retail outlets under a certified scheme and the product has to be packed and labelled before vending. The distribution license for retail sale contains certain production requirements, around 80 farmers in Germany are licensed. Unpackaged raw milk can only be sold through farm gate sales and is labelled "Raw Milk - boil before usage".

38. Between 2007 and 2011 there were 9 confirmed outbreaks linked to consumption of raw milk in Germany affecting 156 people. The majority were caused by *Campylobacter* with one VTEC outbreak reported in 2008.¹⁵

Europe-wide

39. A recent review of the risks and benefits of raw and heated cow's milk consumption reviewed reported outbreaks linked to raw milk consumption in Europe and worldwide¹⁶. The three most frequently reported pathogens as sources of human outbreaks, in order of decreasing reporting frequency, were found to be *Campylobacter* spp, *Salmonella* spp and Verotoxigenic *E. coli*. The presence of these pathogens in raw cow's milk in Europe was estimated at 0-2.9% for *Salmonella* spp, 0-6.0% for *Campylobacter* spp and 0-5.7% for human pathogenic *E. coli*, based on data from a number of surveys and studies. The significance of *L. monocytogenes* and *S. aureus* in relation to illness linked to raw cow's milk consumption was reported to be very low. The review suggests this is because growth of these organisms is limited by commensal flora present in raw milk and a high infectious dose is required to cause illness.

Discussion

40. Of the countries reviewed, where raw milk sales are permitted, outbreaks of illness linked to raw drinking milk have been reported to varying extents. The frequency, size and seriousness of the reported outbreaks vary due to many factors that differ between these countries including:

- Differences in consumer exposure to the product –e.g. the number of consumers, volumes consumed, age and health status of consumers and how the milk is consumed (e.g. is it boiled)
- The microbiological quality of the milk produced

¹⁴ Giacometti F, Serraino A, Bonilauri P, et al (2012) Quantitative risk assessment of verocytotoxin-producing *Escherichia coli* 0157 and *Campylobacter jejuni* related to consumption of raw milk in a province in northern Italy. *Journal of Food Protection*, 75, (11), 2031-2038.

¹⁵ Personal communication BfR (Federal Institute for Risk Assessment), Berlin, Germany.

¹⁶ Claeys, W. L., Cardoen, S., Daude, G., et al (2013). Raw or heated cow milk consumption: Review of risks and benefits. *Food Control*. 31, 251-262.

- On farm controls, inspections and enforcement
 - Animal health and animal husbandry practices
 - Differing systems for collecting and reporting data on illnesses and outbreaks linked to food.
41. Because of these underlying variations it is difficult to make direct comparisons between countries to assess the effectiveness of different controls or anticipate the effect they would have if applied to the UK. Several countries have undertaken quantitative risk assessments to predict the number of cases of illness that may be expected if different controls are implemented, to help inform their policy development. Comparison of quantitative risk assessments from different countries has suggested the risk per serving from raw milk is less than the risk per serving from chicken, burgers and green leafy salads with respect to *Campylobacter* and *E.coli* O157.
42. Even in countries where raw milk sales are not permitted outbreaks linked to raw milk have been seen due to illegal or personal consumption.

Conclusions

43. Prior to the introduction of a ban on sales of raw drinking milk in Scotland and restrictions to sales in England, Wales and N. Ireland large outbreaks of illness associated with consumption were seen fairly frequently. From the reported incident data it appears that both the ban on raw milk sales in Scotland and the restricted sales in England, Wales and N. Ireland had a significant effect on reducing the number of outbreaks and illness linked to raw drinking milk consumption, although in both cases it took a couple of years before the effects were seen. There may be other underlying factors that have contributed to the decline in outbreaks such as reduced production, and therefore exposure to, raw milk and improved microbiological quality of raw milk. No outbreaks linked to raw milk consumption have been reported in England, Wales and N. Ireland since 2002 and in Scotland since 1999. It should be noted that the size and frequency of outbreaks may be under-reported and single, sporadic cases of illness linked to raw milk may remain undetected.
44. The data show that between 1-3% of UK VTEC cases report having consumed unpasteurised milk, however they may also have been exposed to other sources of infection. It is therefore not possible to conclude these cases became infected solely as a results of raw milk consumption. The majority of VTEC cases included in UK enhanced surveillance do not report raw milk consumption (97-99%) suggesting that raw milk is not causing a significant proportion of VTEC cases in the UK. It is not possible to identify from this data, what the impact on VTEC case numbers would be, if the current control measures were not in place.
45. There is some production of raw milk from non-bovine species in the UK (sheep, goat and buffalo) although the total number of such producers is less

than 1/3 of the number of raw cow's milk producers. There is the potential for pathogens to be present in milk from non-bovine species and outbreaks of illness linked to non-bovine milk consumption do occur but are less frequently reported, possibly due to the lower levels of these products consumed. In the UK outbreaks linked to non-bovine milk consumption have only been reported twice, in 1983 and 1984 (associated with goat's milk). It is not possible without a quantitative risk assessment to say how the risk from raw milk from non-bovine species compares with the risk from raw cows' milk.

46. Of the countries reviewed, where raw milk sales are permitted, outbreaks of illness of varying size, frequency and seriousness linked to raw milk consumption have been reported. The variations are due to many underlying factors that differ between the countries, making direct comparisons of the effect of different control measures difficult. Even in countries where sales are not permitted outbreaks linked to raw milk have been seen due to illegal or personal consumption.

Annex 2**SCIENTIFIC ANALYSIS AND RECOMMENDATIONS FOR CONSUMPTION OF UNPASTEURISED MILK AND DEVELOPMENT OF ALLERGIC DISEASE****Issue**

1. The Agency is undertaking a review of controls on raw drinking milk and cream. It has been suggested that consumption of unpasteurised milk during infancy may protect against the development of allergic disease in later life. This paper outlines the current scientific evidence and the key recommendations that can be drawn regarding consumption of unpasteurised milk and the risk of developing allergy and intolerance.

Key Recommendations

2. There is some evidence to suggest there may be an association between raw milk consumption in infancy and a reduced prevalence of allergic disease later in life. However, further research is required to confirm this effect, and whether it is independent of other factors.
3. Until it is known what mechanisms underlie this possible protective effect and the risks that may be associated with them, it is not possible to recommend consumption of unpasteurised milk to prevent the development of allergic disease.
4. There are many reasons why people develop allergies. Given the uncertainty in the evidence base, and in the absence of supporting data, it is not possible to quantify any benefits that may be associated with consumption of unpasteurised milk in infancy and the reduction in allergic disease.
5. If a protective effect were to be confirmed, consideration would need to be given as to whether the potential benefits would outweigh the risks associated with increased pathogen consumption in unpasteurised milk.
6. Consumption of unpasteurised milk is not recommended to prevent or treat lactose intolerance or cows' milk allergy.

Background

1. Childhood asthma and allergies are major health problems in industrialised countries¹⁷. Studies demonstrate that children growing up on farms are at a reduced risk of developing allergic diseases such as asthma, hayfever, food allergy and atopic dermatitis¹⁸. The effect observed is likely to be

¹⁷ Eder W, Ege MJ, von Mutis E. (2006) The asthma epidemic. *N Engl J Med.* **355**, 2226 - 2235

¹⁸ Genuneit J. (2012) Exposure to farming environments in childhood and asthma and wheeze in rural population: a systematic review with meta-analysis. *Pediatr Allergy Immunol.* DOI: 10.1111/j.1399-3038.2012.01312.x

multifactorial and no single specific factor has been consistently identified in conferring this protection¹⁹. However, it is suggested that consumption of unpasteurised milk in infancy is one of the factors that contributes towards this protection.^{20,21}

2. Several epidemiological studies have been conducted which have consistently demonstrated that consumption of unpasteurised milk during the first year of life is significantly inversely associated with the development of allergic disease and this effect has been shown to be independent of other farm exposures.^{14,22,23,24} In addition, a recently published paper from the GABRIEL study (a multidisciplinary study to identify the genetic and environmental causes of asthma in the European Community) has provided additional support for this conclusion by demonstrating that consumption of unpasteurised milk was associated with a reduced risk of childhood allergies, including asthma, hayfever and atopic sensitisation, although it was not shown to be significantly protective against atopic dermatitis.
3. However, in contrast studies by Radon et al and Remes et al did not find consumption of unpasteurised milk was independently protective against the development of atopic disease^{25, 26}. In addition, a recently published study by Roduit,²⁷ found that the association between unpasteurised milk consumption in the first year of life and the risk of developing allergic disease was limited. Although there was a decreased risk of an infant developing atopic dermatitis when consuming unpasteurised milk, this was only among children with parents without allergy. The introduction of yoghurt and pasteurised cows' milk within the first year of life was shown to have more of a protective effect.
4. Overall, currently available data are conflicting and it is difficult to draw conclusions about the effect that consumption of unpasteurised milk may have on allergic disease. There is a need for high quality prospective studies.

¹⁹ Lili S, Depner M, Gennuneit J (2012) Protection from childhood asthmas and allergy in Alpine farm environments – the GABRIEL Advanced studies. *American Academy of Allergy & Asthma & Immunology*. doi:10.1016/j.jaci.2012.03.013

²⁰ Waser M, Michelse KB, Bieli C et al (2007) Inverse association of farm milk consumption with asthma and allergy in rural and suburban populations across Europe. *Clinical Exp Allergy*, **37**, 661 - 670

²¹ MacDonald L, Brett J et al (2011) A systematic review and meta analysis of the effects of pasteurisation on Milk Vitamins, and evidence for raw milk consumption and other health-related outcomes. *J Food Prot.* **74**:1814-32.

²² Riedler J, Braun-Fahrlander C, Eder W et al (2001) Exposure to farming in early life and development of asthma and allergy: a cross sectional survey. *Lancet* **358**, 1129 – 33.

²³ Perkin MR, Strachan DP.(2006) Which aspects of the farming lifestyle explain the inverse association with childhood allergy? *J Allergy Clin Immunol*; **117**:1374–81.

²⁴ Barnes M, Cullinan P, Athanasaki P et al. Crete (2001) does farming explain urban and rural differences in atopy? *Clin Exp Allergy* **31**:1822–8.

²⁵ Radon K, Windstetter D, Eckart J et al (2004). Farming exposure in childhood, exposure to markers of infections and the development of atopy in rural subjects. *Clin Exp Allergy*; **34**:1178–83.

²⁶ Remes ST, Livanainen K, Koskela H, Pekkanen J (2003). Which factors explain the lower prevalence of atopy amongst farmers' children? *Clin Exp Allergy* **33**:427-34

²⁷ Roduit C, et al. (2012) Development of atopic dermatitis according to age of onset and association with early-life exposures. *Journal of Allergy & Clinical Immunology*, **130**: 130-136

Ideally intervention studies need to be conducted to establish whether there is a protective effect independent of other factors. Mechanisms for such an effect would also need to be characterised before recommendations could be made.

5. Currently there is considerable speculation about possible mechanisms by which consumption of unpasteurised milk may confer protection against the development of allergic disease. Possibilities include: -
 - It is speculated under the hygiene hypothesis that the protective effect on allergic disease that appears to be observed from consumption of unpasteurised milk may be a consequence of the increase in exposure to a diversity of pathogenic and non-pathogenic microbes that are present in raw milk.^{28,29} It is hypothesised that these bacteria mediate the functioning a healthy gut and of the immune system which prevents the development of allergic disease.
 - The levels of certain nutritional factors such as vitamin A and omega 3 fatty acids are thought to be reduced through the pasteurisation process. It is hypothesised that consumption of these factors during both pregnancy and early life may confer protection to infants against allergic disease (although there is a lack of high quality evidence which demonstrates this effect and the possible mechanisms by which this effect is mediated is unknown).^{23, 17}
 - It is hypothesised that pasteurisation may alter the milk proteins and influence the way in which the allergenic epitopes are presented. This processing may influence the allergenic potential of the milk proteins.^{23,17}
6. It has also been proposed that unpasteurised milk could be a possible treatment for lactose intolerance as the milk contains natural lactase enzymes and lactobacteria which are normally destroyed during the pasteurisation process. However evidence to support these types of suppositions are limited with only one study found which investigated associations between raw milk and lactose intolerance. No significant associations were found between consumption of unpasteurised milk and risk reduction or treatment of lactose intolerance.³⁰
7. There is also some discussion as to whether pasteurised milk contributes to the initial sensitisation step in the development of milk allergy and/or that it exacerbates milk allergic symptoms in susceptible individuals. However

²⁸ Braun-Fahrlander C, von Mutius E (2010) Can farm milk prevent allergic disease, *Clinical & Experimental Allergy* 41: 29-35.

²⁹ Flohr C, Yeo L. (2011) Atopic dermatitis and the hygiene hypothesis revisited. *Current Problems in Dermatology*. 41: 1-34.

³⁰ Kim HS, Gilliland SE (1983) *Lactobacillus acidophilus* as a dietary adjunct for milk to aid lacto digestion in humans. *J. Dairy Sci.* 66:959-966

evidence suggests that milk allergy development and reactions are independent of milk pasteurisation.³¹

Conclusions

8. Additional research is required (particularly prospective and intervention studies) to confirm conclusions reached in some epidemiological studies, and to provide robust evidence on whether consumption of unpasteurised milk in infancy is protective against the development of allergic disease and whether this is independent of other factors.
9. Before the consumption of unpasteurised milk could be recommended to reduce the risk of developing allergic disease it would be important to establish the relevant mechanisms that underlie this possible protective effect and whether the potential risks that may be associated with its consumption can be isolated.³²
10. Consumption of unpasteurised milk is not recommended to prevent or treat lactose intolerance or cows' milk allergy.

³¹ Claeys WL, Cardoen S, et al (2013) Raw or heated cow milk consumption: Review of risks and benefits. *Food Control*, 31, 251-262

³² Perkin MR (2007) Unpasteurized milk: health or hazard? *Clinical and Experimental Allergy*, **37**, 627 - 630

Annex 3

REVIEW OF CURRENT SCIENTIFIC EVIDENCE ON NUTRITION BENEFITS ASSOCIATED WITH CONSUMPTION OF UNPASTEURISED MILK COMPARED WITH CONSUMPTION OF PASTEURISED MILK

Issue

1. The Agency is undertaking a review of controls on raw drinking milk and cream. Claims have been made that raw milk is nutritionally superior to pasteurised milk. This paper outlines and reviews the current scientific evidence on whether there are any nutritional benefits associated with the consumption of unpasteurised milk compared with consumption of pasteurised milk.

Outcome

2. There is little current scientific evidence to indicate that pasteurising milk substantially alters its nutritional composition.
3. There is insufficient evidence to show the effect of pasteurisation on the functional properties of nutrients in milk.

Recommendations

4. Differences in cow breed, age, feeding regime as well as seasonal changes, lead to variations in nutritional composition of milk whether raw or pasteurised. Wide variation in reported nutritional compositional values of raw milk is likely to be due to analytical difficulties and differences. This appears to be especially the case for micronutrients. Given that milk is a rich source of many vitamins and minerals it would be advisable to monitor the effect any processing techniques have on vitamin and mineral levels both in terms of content and bioavailability.
5. Further research is needed to consider changes in nutrient function resulting from milk processing.
6. There is a lack of scientific evidence to support potential nutritional and health benefits of raw milk consumption. Further research is recommended into the effect of raw milk consumption on health and disease.

Background

1. Research suggests there is little or no impact of pasteurisation on the macronutrients carbohydrates, fat and protein,³³ with only a 1% decrease in biological value of protein observed following pasteurisation.³⁴
2. Lactose is the predominate carbohydrate found in milk. Pasteurisation does not change the concentration of lactose but can destroy lactase producing bacteria that may be present. This reduction in lactase production may exacerbate intolerance to dairy products among some lactase deficient individuals. With heating, lactose in milk can be degraded to indigestible carbohydrates including lactulose. Pasteurisation does not lead to detectable levels of lactulose being present in milk.^{26,35}
3. The nutritive value of proteins are largely unaffected by pasteurisation. Milk casein proteins are stable to heat treatment.²⁶ Pasteurisation does not affect the functional and nutritional properties of casein proteins. Milk whey proteins are more sensitive to heat. Heat treatments cause the denaturation of whey proteins. Pasteurisation has been shown to lead to denaturation of immunoglobulin and serum albumin in milk. This denaturation causes a change in the physical structure of the proteins, but does not affect the nutritional composition.³⁶ However, heat treatment applied during processing can alter the structure of the protein and thereby contribute to lower digestibility and changing the biological activity of the protein.³⁷ Further research is needed to consider the effect this has on nutrient function.
4. Milk fat is relatively stable towards heating. There are no major nutritional changes in fat known to result from pasteurisation.²⁹ Changes do take place in milk lipids physical properties during heating, however pasteurisation does not appear to affect the nutritional properties of milk fat.³⁸
5. There is minimal mineral loss following pasteurisation.^{27,39} There are no reported significant differences in the total amount and bioavailability of

³³ Cifelli CJ, Maples IS, Millar GD (2010) Pasteurisation implications for food safety and nutrition. *Nutrition Today*, 45 (5), 207-213

³⁴ White FM, McCarthy ME (1982) Raw milk and health in humans. *Can Med Assoc J*, 126 (11), 1260-1262

³⁵ Aragon IB, Sabat P, Gouti N (2001) A method for discriminating milk heat treatment. *International Dairy Journal*, 12, 59-67

³⁶ Ullmann's Encyclopedia of Industrial Chemistry (2012) Milk and milk products. Wiley online library, on line ISBN: 9783527306732

³⁷ Chatterton DEW, Smithers G, Roupas P et al (2006) Bioactivity of beta-lactoglobulin and alpha-lactalbumin, technical implications for processing. *International Dairy Journal*, 16, 1229-1240

³⁸ Fox PF, McSweeney PLH (1998) *Dairy Chemistry and Biochemistry*. Published by Thomson Science, ISBN 0412720000

³⁹ Savage WG (1933) The effect of pasteurisation upon the nutritive properties of milk. *Lancet*, 221 (5713), 429-431

calcium following pasteurisation.⁴⁰ The iodine content of milk varies greatly. One study showed an average loss of 20% in iodine with pasteurisation.³² A more recent study showed that pasteurisation did not change significantly the concentration of iodine of milk.⁴¹ The authors of this study explain the variance in the earlier work being due to difficulty in measuring iodine concentration of milk accurately. They recommend a more comprehensive evaluation of methods for measurement of iodine in milk is required.

6. Milk contains the water soluble vitamins thiamine (vitamin B1), riboflavin (vitamin B2), niacin (vitamin B3), pantothenic acid (vitamin B5), pyridoxine (vitamin B6), folate, vitamin B12 and vitamin C.
 - McCance and Widdowson report 0-10% loss of B vitamins due to pasteurisation and up to 25% loss of vitamin C. They explain these values have been calculated using measured losses report in literature.⁴²
 - Thiamine (vitamin B1) is relatively unstable with 9-20% losses reported with pasteurisation.⁴³
 - Riboflavin, niacin, biotin, and pantothenic acid are all reported to be stable and relatively unaffected by pasteurisation.
 - PF Fox indicates pasteurisation leads to a considerable decrease in the ability of the vitamin B12 binding proteins to bind the vitamin.⁴⁴ The importance of this is unknown. A Swedish study suggests that pasteurisation results in significant losses of the most predominate folate form, 5-CH₃THF.⁴⁵ This research showed heat processing of milk also changed the concentration and capacity of folate binding protein, which may have implications on the bioavailability of milk folates. The authors concluded since the physiological function of milk folate binding proteins is unclear, further studies on milk processing and the bioavailability of folates are important.
 - Loss of pyridoxine is reported to be 0-8% with pasteurisation and losses of folate and vitamin B12, 0-10%³⁶
 - The vitamin C content of milk varies with a cow's diet. Pasteurisation is reported to result in a loss of 0-25% vitamin C present.³⁷ It should be recognised though that milk and dairy foods are not considered rich

⁴⁰ Weeks CE, King RL (1985) Bioavailability of calcium in heat processed milk. *J Food Sci*, 50, 1101-1105

⁴¹ Wheeler SM, Fleet GH, Ashley RJ (1983) Effect of processing upon concentration and distribution of natural and iodophor-derived iodine in milk. *J Dairy Sci*, 66 (2), 187-195

⁴² Paul AA, Southgate DAT (1978) *McCance and Widdowson's The Composition of Foods*. ISBN HMSO 0114500363

⁴³ Fox PF, McSweeney PLH (2009) *Advanced Dairy Chemistry, Volume 3, Lactose, Water, Salts and Minor Constituents*, Third Edition. Published by Springer, ISBN 9780387848648

⁴⁴ Fox PF (1995) *Heat Induced Changes in Milk*. Second edition. International Dairy Federation. ISBN 9290980179

⁴⁵ Wigertz K, Hansen I, Hoier-Maden M et al (1996) Effect of milk processing on the concentration of folate binding protein folate binding capacity and retention of 5-methyltetrahydrofolate. *Int J Food Sci and Nutr*, 47, 315-322

sources of vitamin C, instead this vitamin is found in significant amounts in fruit and vegetables.

7. Pasteurisation is reported not to cause significant losses of the fat soluble vitamins A, D, E and K.^{27,31,37}
8. Milk contains antioxidant factors, for example, vitamins A, C and E as well as antioxidant enzymes. Some research suggests that short heat treatments can be responsible for depletion in the overall antioxidant properties of milk. Current knowledge is not sufficient to identify the technological conditions which promote or inhibit antioxidant activity in milk.⁴⁶
9. A recent systematic review and meta-analysis of the effects of pasteurisation carried out in Canada showed pasteurisation appeared to qualitatively reduce concentrations of vitamins B12 and E and increase concentrations of vitamin A. The review demonstrated how levels of vitamins A, B12 and E varied significantly between studies although with the available literature included in this review it was not possible to quantitatively measure the effect of pasteurisation on vitamins A, B12 and E. In the review results on vitamin A were inconsistent, with an increase reported in two studies but a slight decrease reported in two other studies. Of the forty studies assessed, random effects meta-analysis revealed no significant effect of pasteurisation on vitamin B6 concentrations but a significant decrease in concentrations of vitamin B1 (Thiamin), vitamin B2 (Riboflavin), vitamin C and folate. Milk is not considered to be an important dietary source of vitamins B12, C or E. However, milk consumption contributes significantly to intakes of vitamin B2. The authors of the review recommend the impact of heat treatment on vitamin B2 is further considered.⁴⁷
10. One of the most consistent findings within the studies included within the Canadian review, was the reduced incidence of allergic hypersensitivities and diseases among children raised on farms, however the reasons for this association remain speculative. The authors of the review suggest the protective influence of farm living on allergic risk is likely to be multifactorial.⁴⁰
11. The results of the Canadian systematic review do not support an association between raw milk consumption and cancer. One of the studies indicated a protective effect of raw milk consumption for rectal cancer but there were a number of experimental flaws in the study.⁴⁰
12. Raw milk has been cited as a 'cure' for lactose intolerance. The authors of the Canadian review did not find a significant association. The review

⁴⁶ Calligaris S, Manzocco L, Anese M et al (2004) Effect of heat treatment on the antioxidant and pro-oxidant activity of milk. *Int Dairy J*, 14, 421-427

⁴⁷ MacDonald LE, Brett J, Kelton D et al (2011) A systematic review and meta-analysis of the effects of pasteurisation on milk vitamins, and evidence for raw milk consumption and other health related outcomes. *Journal of Food Protection*, 74(11), 1814-1832

concluded there is a lack of high quality scientific evidence to support potential benefits of raw milk consumption. They recommend further research into the effect of raw milk consumption on disease, for example, allergy, cancer and lactose intolerance.⁴⁰

13. This paper has focused on the effect of pasteurisation on the nutrient composition of milk as well as considering effect on nutrient function. The effect of homogenisation has not been extensively reviewed as it is widely accepted there is limited scientific evidence to indicate homogenisation alters the nutritional content or function of milk. A review carried out by Michalski and Janual, reports there is no strong evidence that dairy products, including homogenised milk, increases the risk of coronary heart disease. The studies they reviewed did not show any impact of homogenisation on milk allergy or intolerance. Michalski and Janual conclude by stating the structure of milk is greatly altered depending on the various mechanical and thermal steps of the processing chain. They recommend interdisciplinary studies should be carried out on the impact of processing on the nutritional and health value of milk.⁴⁸

⁴⁸ Michalski MC, Januel C (2006) Does homogenisation affect the human health properties of cow's milk? *Trends in Food Science and Technology*, 17 (8), 423-437

Consumer Engagement: Raw Drinking Milk

Consumer Engagement Team

February 2013

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KEY FINDINGS

1. Consumer choice was a theme heard in all groups and was a key driver for the consumers that participated in these discussions. Exercising choice was often based on having knowledge, understanding risk and an expectation of receiving perceived benefits that derived from the consumption of Raw Drinking Milk (RDM).
2. Consumers often spoke about their rights to buy RDM and were concerned that the Food Standards Agency (FSA) had a hidden agenda and wanted a ban on RDM. At the start of each group discussion reassuring consumers that there was not a hidden agenda and a decision had not been made to ban RDM was important to gain trust and openness of consumers. There appeared to be a lack of trust and suspicion of Government generally and a sense that the FSA was working on behalf of the dairy industry. (This will need to be recognised in the communication of the consultation that will take place.)
3. There was a high level of knowledge around the production processes of RDM and Pasteurised Milk (PM). This indicates that the consumers of RDM we spoke to have either done research or have asked questions from producers about the production process. These consumers believe they are making an informed choice in consuming RDM.
4. In all groups anecdotal evidence of health benefits were discussed and many of the consumers talked about a reduction in allergies and other skin complaints. Nutritional benefits were often mentioned as a reason for consuming RDM with the comment that RDM contained good bacteria and pasteurisation removes the good bacteria from milk.
5. The availability of RDM was another key issue that was raised in all groups. Consumers generally understood the current regulations and the restrictions on where RDM could be sold. There was strong feeling that the restrictions were inconsistent with other regulations on sales of food or other products known to have health risks e.g. shellfish, fizzy drinks and tobacco.

6. RDM being sold through vending machines was a topic introduced by participants at several groups. Experiences while on holiday in other EU Member States were often quoted as the only times vending machines had been used for RDM. The use of a vending machine in small, rural parts of France and Italy appeared to work in those countries however, there were concerns raised by participants that there were too many risks associated with this route of sale to make it a sensible option in England.
7. The lack of control and potential for cross contamination was mentioned as the biggest risk to the vending machine approach. Where this had been experienced consumers brought their own containers to the vending machine and filled the containers themselves. Consumers quickly identified the increased risk of cross contamination and were not supportive of this method of sale.
8. The unrestricted sale of RDM in other Member States was quoted and highlighted the apparent negative view that was held in the UK towards RDM. Other Member States appeared to have a more relaxed and accepting view of RDM as an alternative to PM. Consumers felt the negative perception in the UK was due to the influence of the dairy industry and their lobbying for a ban on RDM.
9. Across all groups of consumers, there was a strong and passionate plea for the choice not to be taken away from consumers in choosing the milk they purchased.

INTRODUCTION

Background

The FSA Board at their meeting in March 2012 discussed the current controls and safety risks associated with RDM and cream. The discussion at the Board was as a result of previous Advisory Committee of the Microbiological Safety of Food (ACMSF) discussions on RDM and new developments in the marketing and sale of RDM. The Board agreed to a review to look at control options for managing the food safety risks associated with RDM and cream. Any new options would be developed in consultation with consumers and stakeholders.

Approach

Focus groups with consumers of RDM were held in England between October and December 2012 and followed a discussion guide (see Annexe A). Each group was approximately 90mins long. The number of people attending each discussion group ranged from 4–29 (See Annex B for more detail) and were carried out in seven locations across England (See Figure 1).

In Northern Ireland and Wales a different approach was used to capture views of consumers. In Northern Ireland, there are a limited number of outlets selling RDM, therefore, a meeting was arranged in Belfast to speak to producers who voiced an interest in selling RDM and their potential customers. A note of the meeting is available in Annex C.

A similar sales situation exists in Wales with a limited number of identified producers selling RDM. It was possible however to speak to one producer (in Flintshire, North Wales) who provided their perception of customer behaviour and attitude towards RDM in Wales. A note of this discussion is available in Annex D.

Participants in each group were recruited via a combination of methods:

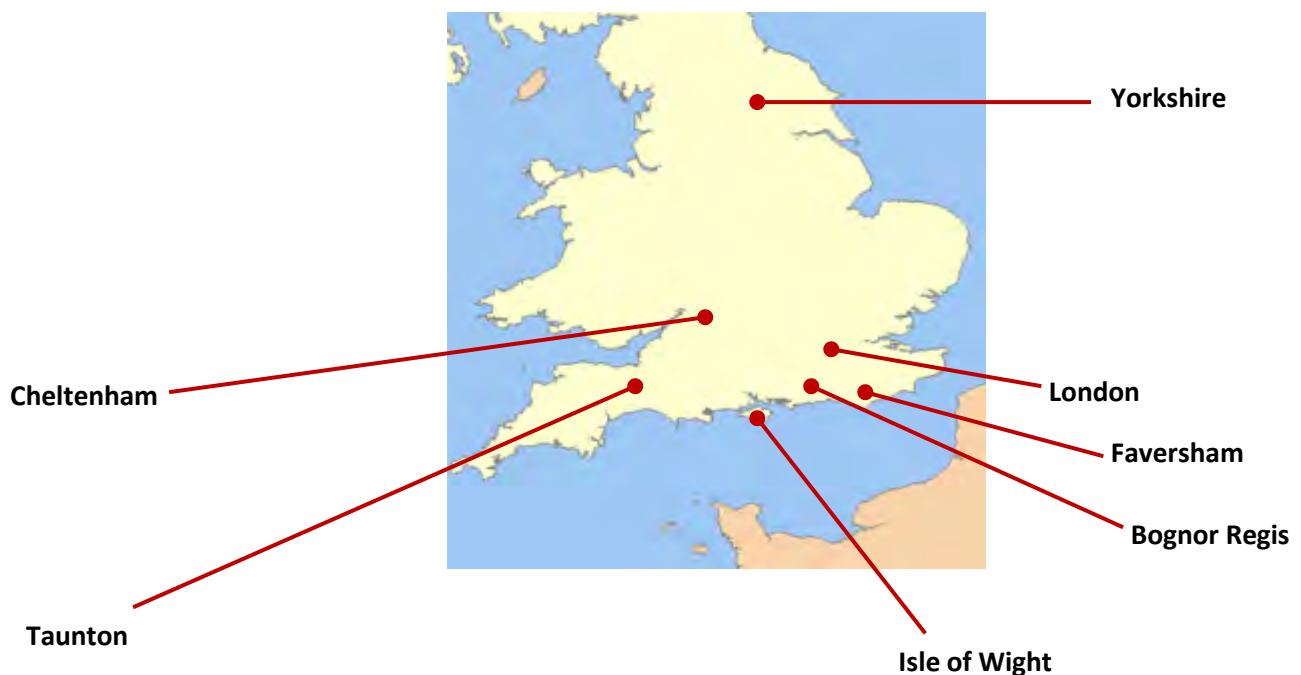
- Word of mouth between RDM consumers
- Networks of RDM consumers using social media
- Producers of RDM asking their customers to attend

Note the participants in the focus groups were consumers who regularly purchased and consumed RDM and were selected on this criterion. Their views may not be representative of general consumers of pasteurised milk who were not part of this research.

The groups were facilitated by members of the FSA's Consumer Engagement Team. Members of the FSA RDM policy team were present to explain current policies on controls for RDM.

This consumer research was one of four work streams undertaken by the FSA to inform policy on RDM. The other work-streams considered science and risk assessment, delivery and enforcement , and policy development including exploring how RDM is currently regulated in other EU Member States.

Figure 1. Locations across England



FINDINGS

This Report focuses on four key elements identified as important in the consumer journey:

1. Purchasing – how RDM is bought
2. Motivation – why RDM is consumed
3. Consumer Awareness – consumer knowledge about risk and perceived benefits
4. Regulation – consumer views on current and future regulation

Analysis of the findings suggest three RDM consumer types:

- **The Local Supporter** – in some areas where RDM is sold, consumers wanted to support local producers. RDM was just one of many products bought at the farm shop. Pricing was not a factor as the price of RDM was the same or the difference was negligible to that of PM. The generational tie to RDM was also stronger with these consumers. Often they had been drinking RDM from their childhood. Buying RDM was not difficult as it was available on the ‘doorstep’ metaphorically and sometimes literally, it was almost the default option. By definition these consumers were more rurally based.
- **The Artisan** – for this group of consumers RDM was more about lifestyle. There was a desire to know the provenance of food and this was the most important factor in the purchasing decision. Locally sourced food including RDM was thought to be of a higher quality and therefore better than highly processed foods. These consumers are willing to pay a premium for RDM. Where availability is more difficult they are prepared to make more effort to source and buy RDM including buying via the internet. These consumers tend to live in urban areas and are more likely to live further away from RDM producers. RDM tends to be purchased once a week from a farmers’ market.
- **Health Conscious** – for these consumers RDM is consumed primarily for health reasons. The benefits perceived from consuming RDM far outweighed the extra cost and any risks. RDM was not seen as a luxury but as part of the weekly

'shopping list'. It was also used as an ingredient to make other products like Kefir or yoghurt. These consumers had anecdotal evidence of improvements to their or their family's health as a result of consuming RDM. Purchase was carried out in a variety of ways including farm shops, farmers' markets and internet delivery.

Purchasing

This is an important consideration as the review in part has been triggered by the new methods in the sale of RDM. For example the current regulations do not cover sale of RDM via the internet.

In discussions there were several methods used to purchase RDM. Geography and proximity to a producer of RDM shape the general methods in which RDM is bought.

Typically in more rural areas or where door step deliveries take place the farmer and their farm are known by the consumer. This has created a stronger relationship between the consumer and the producer and there is an element of trust that exists between the two parties. In the urban towns/cities consumers indicated that RDM is purchased either at a Farmers' Market or via driving to a farm shop. One participant in the discussions indicated they drove over 30 miles to collect their supply of milk.

The cost of RDM also varied depending on proximity to the farm. For some consumers the cost differential between RDM and PM was negligible, in most cases this occurred where the supplying farm was part of the village community. However, the cost of RDM for consumers living in towns/cities was considerably higher. This was whether purchase was from a Farmers' Market or having it delivered to the door via a courier.

Sales via the internet were also explored with participants. This was not a very popular way of purchasing RDM with participants. The consumers that used the internet used it as more of a service to find the closest producer of raw milk. Perhaps an analogy is using the internet as a Yellow Pages rather than the Amazon website.

A theme around RDM being a luxury purchase or 'staple' was explored. For the majority of participants, RDM was viewed as part of the weekly shopping list and not a luxury, although for some consumers it was expensive. This aspect of RDM

being a luxury developed into a discussion about choice and how consumers made their choices and prioritised.

For the Health Conscious and Artisan consumers cost was not seen as prohibitive, their health and the provenance of their food were seen as an over-riding factor to the cost. The Local Supporters were more pragmatic when it came to the cost of RDM. They benefited from a marginal price differential between RDM and PM. Purchasing RDM was equally as convenient as purchasing PM for the Local Supporter. In the same way that PM is delivered to the doorstep, RDM was also delivered as part of their weekly shopping list from the local farm shop.

Motivation

Across all three identified consumer segments perceived health benefits were mentioned as part of their motivation. Some participants spoke confidently about the microbiological aspects of pasteurised and un-pasteurised milk. The process of pasteurisation was seen as depleting essential bacteria from milk. The desire for RDM was therefore based on having the 'best' form of milk possible.

It was clear that the majority of participants had done a reasonable amount of research before making the choice to purchase and consume RDM. The length of time that RDM had been consumed varied, for some it was a fairly recent change – this tended to be the Artisan Consumer – others had been purchasing RDM for most of their adult life. Local Supporters in the majority of cases had been consuming RDM for longer.

The discussions also highlighted that Local Supporters also had a good knowledge of past issues with RDM and the improvements that had been made in farm practices that minimised the risks. Anecdotal evidence was offered about practices in the past that were less than desirable and more 'risky'. There was a general feeling that producers selling RDM are now all of a high standard. The general sense was that producers had so much more to lose if anything went wrong as they risked their reputation not just on RDM but on their whole farming business.

The Artisan and Health Conscious consumers focused on the pasteurisation of milk and felt it removed the good bacteria and all the 'goodness' from milk. PM was therefore purchased only in exceptional circumstances. Interestingly for some Local Supporters PM was not seen inherently as 'bad' and organic PM or PM was purchased as well as RDM.

The connection between food, farming and a deeper understanding of where food comes from was often discussed as being important for the Artisan and the Health Conscious. The Local Supporters were less vocal about this connection, this could be as a result of their approach to food in general and the automatic links they

make between food and farming production. Purchasing from the local farm was seen as the 'right thing to do' and as RDM was sold there that too was the 'right thing to do'.

Consumer knowledge

Overall, participants' knowledge of raw milk was high across all three identified consumer groups. A number of the participants were able to talk in detail about perceived nutritional and health benefits experienced personally or observed. They had knowledge of the farms and some participants had visited a farm to see the setting, animals, understand the milking procedure, farm inspections and testing regimes and being satisfied with what they had seen. This was a significant component in the perceived risks of raw milk.

Sources of information mentioned by consumers were restricted and included organisations such as The Weston A Price Foundation, various internet sites, books and other published literature and information from the producers themselves. However, outside of London, there was a sense of sharing information within the local community; where there is a close network of consumers. As a result, word of mouth (friends/family/through farm shop advertisements etc.) was the main source of sharing information.

The Artisan and Health Conscious participants had knowledge and awareness of the process involved, often knew the farm where the milk was produced and the farmer they purchased the milk from. More importantly they trusted the farmers to produce milk that was safe for consumption. The source i.e. the farm, of the RDM was a significant consideration for many participants. When probed, it was revealed that the underlying reason for this is to know that the animals have been looked after and are healthy, but essentially, knowing what the animals have been fed. For certain participants, this was an important factor in driving their usage.

Generally, across all consumer groups, particularly amongst Local Supporters and the Artisan group of consumers, there was trust in suppliers, therefore consumers accepted the risks. Particularly, amongst the Health Conscious group of consumers, there is a perception that the benefits of RDM outweigh the risks of consuming raw milk. When consumers were challenged on where their knowledge on the benefits of RDM originated from, the majority drew on their personal and observed health benefits to promote its characteristics. Others had a general sense of benefits, but

through no personal experiences. The specific health benefits sought or observed included reduced digestive problems (such as bloating and lactose intolerance), improved skin conditions such as eczema and other allergies and management of diabetes.

The perceived risks of RDM were very low. Consumers, the Health Conscious group in particular, drew attention to the fact that they had no knowledge of any outbreaks in the last 10 years, and did not necessarily identify any risks involved in consuming RDM. Amongst this group of consumers there was a belief that riskier foods (such as fizzy drinks) were available on the market. Moreover, many consumers perceived the nutritional content of the raw milk to be more balanced, natural and healthy than that of pasteurised milk. Most consumers considered the risk of RDM to be reduced if handled and refrigerated correctly. Additionally, some consumers noted that due to its bacterial content raw milk does not 'go off' in the same way that PM does – it sours and separates, but it can still be used and consumed in other forms of dairy product such as yogurt.

Regulations

Regulation and advice was discussed in some detail during the consumer discussions. Consumers recognised the need for regulation, and highlighted that without regulation, farmers with poor hygiene standards could enter the market and sell products that were unsafe for consumption. Moreover, most consumers spontaneously indicated that certification approved by the Agency would be favourable to demonstrate the raw milk sold by farmers was safe for consumption. Additionally, the consensus on regulations of RDM from other species was that it lacked clarity. Certification from FSA for farms producing/selling RDM would be sufficient to demonstrate the farms are compliant, and are therefore able to sell RDM.

Some consumers were aware of the current inspection process that farms are subject to. Others were unsure or had very limited knowledge of the inspection process. They assumed an inspection would take place, but were unsure what the inspection process entailed. Those aware of the inspection process were mainly aware of the inspection directly through the farmer, as the farms are required to close for a period of time when inspection is taking place.

Consumers were aware of Government advice (from various government websites as well as hearsay) around RDM and had general knowledge of what the advice entailed (i.e. for pregnant women and babies to avoid RDM). However, there was confusion with regards to regulations on where raw milk could be sold; they had an understanding of where raw milk could be sold, i.e. at the farm gate or through farm shops and farmers markets, but were unclear about internet sales and sales through other retailers.

The overall feeling from consumers was that the regulatory system should be used as a 'guarantee' that producers were using the right processes to ensure safety of their product and therefore the sale of raw milk could be expanded to smaller independent specialist shops.

There was often a contradictory discussion around the sale of RDM. On one hand consumers wanted RDM to be more widely available and sold in conventional shops. There was recognition however, that increased availability and the removal of the sales restriction could lead to the 'commercialisation' of RDM. Commercialisation in this context meant the interventions and involvement of large retailers and large dairy companies, which consumers thought would be a negative step. This aspect of the discussion highlighted a wider issue of concern, the monopoly on milk production and the detrimental effect this was having on smaller farmers.

Regulation of RDM was discussed in detail and consumers had mixed views on whether the current system was adequate or too restrictive. There was universal recognition that regulation was needed, without it, farmers with poor hygiene standards could start to sell RDM. A suggestion was made in several groups that the regulatory system should be used as a 'guarantee' to reassure consumers that producers were using the right processes to ensure safety of their product.

With a guarantee to endorse the safety of RDM, there was a question on why it could not be sold by smaller independent specialist shops. Most consumers unprompted suggested the Government should introduce having a certification system supported by the FSA to provide consumers with reassurance that the RDM they were buying was safe.

CONCLUSION

The level of participation in all the discussion groups was high and the demand for more discussion groups continued after the final group discussion was held.

Consumers appreciated the opportunity to contribute and welcomed the FSA's willingness to attend discussions in a range of locations and outside of the normal working day.

There was a level of scepticism about the driver for the review of RDM and the initial comment was that a decision to ban RDM had already been taken by the FSA. Once consumers had been reassured that this was not the case they were happy to articulate their feelings on the issues around consuming RDM.

Consumers that attended the discussion groups were passionate about their choice and their rights to buy, use and consume RDM in their daily lives. RDM was not a luxury item purchased occasionally, it was bought and used in a way that other consumers used PM.

Where RDM could be bought was a key issue for a high proportion of the consumers that attended the discussion groups. The restricting of sales to the farm shop was seen as out-dated and penalised consumers living in a non-rural or urban location.

Consumers saw the need for RDM to be regulated and were not anti-regulation. A system that recognises the checks and the inspection process that a producer is subject to in selling RDM and 'certifies' their RDM was suggested. This was unanimously supported by all consumers that attended the discussion groups. Consumers argued that if such a system was in place the regulation restricting sales could be relaxed and more consumer choice exercised.

Across all groups of consumers, there was a strong and passionate plea for the choice not to be taken away from consumers in choosing the milk they purchased.

In taking forward a full consultation it will be important to keep in mind:

- The high level of knowledge about the production process of RDM that exists across the networks of RDM consumers;

- The interest and likely mobilisation of responses from a wide and vocal consumer base; and
- The importance of demonstrating that a decision on how to regulate RDM has not already been made

Annex A

Discussion Guide Raw Drinking Milk

Discussion Theme		Timing
<p>FSA Introductions :</p> <ul style="list-style-type: none"> • Who we are, what the FSA is and what it does • Why we are discussing RDM with them • How the information from them will be used • Offer to send them the final report 		10 mins
<p>Group Introductions</p> <ul style="list-style-type: none"> • Who they are • Something about their family situation • Shopping patterns • Role of milk in their lives 		5 mins
<p>RDM purchasing</p> <ul style="list-style-type: none"> • Talk about how RDM is purchased • Is it bought weekly, daily? • Is PM bought as well? • IS RDM a luxury, additional purchase or is it a 'staple', regular part of the grocery list? 		10 mins
<p>Where purchased</p> <ul style="list-style-type: none"> • Currently purchased from x producer, can they see any benefits in this? • Are there specific reasons they buy from this producer? • Would they buy from 		15 mins

<p>anywhere else? Why/why not</p> <ul style="list-style-type: none"> • What are their thoughts on buying from a – Farmers Market or on the internet (especially if the web was cheaper)? • What information is provided by the farm? • Talk about the current restrictions on RDM sales 		
<p>How is RDM being used</p> <ul style="list-style-type: none"> • Is RDM used instead of PM? • Is it being used as a supplement to PM • Is it used for cooking or making other dairy based products like cheese etc? 		5–7 mins
<p>Why</p> <ul style="list-style-type: none"> • RDM is more expensive than PM, so why is it being purchased? • Do they think there are health benefits? • Allergies/intolerances etc <p>Expand & explore on the reasons given</p>		15 mins
<p>What they know about RDM</p> <ul style="list-style-type: none"> • Where does their knowledge on RDM come from? • Information on labels is this helpful, understood or ignored? • Are they aware of any risks in consuming RDM? • Do they think there are any precautions they 		10–15 mins

<p>should take in consuming RDM?</p> <ul style="list-style-type: none"> • What about vulnerable groups & RDM? (pregnant/children/ill) • Do you encourage/tell others about RDM benefits? 		
<ul style="list-style-type: none"> • Views on regulation of RDM 		
<p>Any Other Points</p> <p>Top 3 things for the FSA</p>		5mins

Annex B

Discussion Groups

Location	Number of Attendees	Recruitment Methods	Producers Attending
London	8	RDM Network Word of Mouth	No
Cheltenham	7	RDM Network Local User Group	Yes
Faversham	11	RDM Network Word of Mouth Local Producers	Yes
Isle of Wight	7	RDM Network Word of Mouth	No
Bognor Regis	14	RDM Network Word of Mouth	No
Charlton Musgrove, Somerset	29	Local Producers Stakeholder Group Word of Mouth	Yes
Hebden Bridge, W.Yorks	4	Social Media - Twitter & Facebook	No

Annex C

A note of the findings from the discussions in Northern Ireland

FSA in NI Raw Milk Citizen Forum

Friday 22 February 2013

Conference Rooms 1, FSA in NI, 10a-c Clarendon Road, Belfast, BT1 3BG

The background to the raw milk citizen forums and the FSA review of the controls in place for raw drinking milk were outlined and Review's three work streams were explained

The following questions and comments were discussed:

Why is Raw Milk important and why would consumers want to buy Raw Milk?

- Consumers should have the choice
- Milk doesn't have to be pasteurised to be safe
- Health benefits – which outweigh the associated 'dangers'
- Processing of raw milk removes the 'goodness'
- Raw milk is naturally low in fat and better in quality/taste

The group also discussed the confusion surrounding the legal requirements for producing and selling raw milk. There was an apparent lack of understanding about the regulations of selling RDM and this led to an element of concern by potential producers of RDM

What changes would they like to see to the sale of Raw Milk?

- Hygiene on the farm and testing of product is most important for producer and this should continue under any changes to regulation
- Shortened food chains – which decreases the risk
- Trust is paramount from a consumer perspective – knowing standards are in place would help provide consumers with assurance that RDM was safe
- More information is needed – farmers are not anti-regulation just require clarification of legal requirements

What are the appropriate mechanisms for selling raw milk?

- Consumers would welcome good accessibility of buying raw milk – would prefer to get from farm gate or from health shops
- Possible objections could arise to sale at health shops from supermarket chains
- Supermarkets would not sell raw milk due to shelf life issues

In summary, key message from the discussion:

- Consumers want choice
- More information for producers regarding legislation
- Regulation is needed, but it should be proportionate to risk and size of the market
- Changes to the wider food system are needed to encourage healthier eating

Annex D

A note of the findings from the discussion in Wales

Raw Drinking Milk Producer Discussion, Wales

A telephone call was made to a Raw Drinking Milk (RDM) producer in Flintshire North Wales to organise a focus group with customers who bought RDM. The producer indicated that customers travelled from North Wales, Merseyside and Anglesey to collect and purchase milk and was therefore concerned about where a meeting would be held.

A decision was taken to continue the discussion as the producer began to talk about the issues from his perspective and also from the viewpoint of his customers.

The views and opinions outlined below are from the producer, he did comment on the perspectives of his customers, while these opinions have been included they have not been verified.

Purchasing

Customers travelled up to 70 miles to purchase RDM and customers would often buy a supply that would last a week. RDM would be frozen by some customers and used over a longer period of time. Most customers purchased RDM because of the perceived health benefits they received. They were also customers with allergies to pasteurised milk (PM) that had no adverse reaction to RDM. The producer pointed out that his customers had a comprehensive knowledge about RDM and its benefits in comparison to PM.

Labelling

This was an issue the producer had strong feelings on, he commented on the current labelling regulations in Wales was like putting 'this is a poison' on a product. As there has not been any foodborne disease caused by contaminated RDM in recent history it was felt that the current labelling regulations are too stringent.

There was also an anomaly with the labelling requirements being different in Wales to England. Many customers travelled to his farm from England to purchase RDM. The labels in Wales with different information to that required in England seemed to be more 'alarming' than necessary and could be considered to be anti-competitive.

Regulation

The producer accepted that regulation was necessary however, it was hoped that there would be no further additions to the current regulations.

Informing consumers of the testing regime and the current FSA guidelines on producing and selling RDM was felt to be an important aspect of the regulatory guidelines for RDM. The FSA should actively publicise that RDM is allowed to be sold only when this criteria is met. This would provide consumers with confidence that RDM is a controlled and regulated product.

Top 3 Messages

1. Keep the current controls with no additional features
2. Publicise controls to consumers to increase their confidence
3. Examine ways to broaden the potential to sell RDM e.g. in restaurants and cafes.

AHEAD OF WHAT'S NEXT.

Raw Milk Report

Delivered : December 2012



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- **Understanding and experiences of Raw Milk/Cream**
- **Level of interest in Raw Milk/Cream**
- **Importance of freedom of choice versus government protection in relation to Raw Milk/Cream**
- **Labelling options for Raw Milk/Cream**
- **What do people think is the best scenario moving forwards with regards to Raw Milk/Cream**
- **Conclusions**
- **Appendix**

The majority *know what 'raw milk' is* (72% unprompted and 81% prompted)

Looking at the sale of raw milk/cream - more people feel the *Government should protect us* (37%) than those that favour freedom of choice (29%) and the rest are unsure (35%)

23% think raw milk/cream should be banned, whereas 77% believe it *should remain for sale*

People see the advantages of raw milk/cream split between *naturalness* (11%), *nutrients and vitamins* (10%), *lack of additives/preservatives* (8%) and *taste* (7%). The dominating disadvantage is the possibility of *bacteria/infections* (45%)

Triple the proportion of those interested in trying raw milk/cream (19% - mostly due to curiosity and taste) are *not interested in trying it* (58% - safety and health issues being the main barrier)

The majority in England (66%), NI (56%), Wales (75%) feel the *current labelling provides enough information*. The main criticism is that the labelling *does not give enough specifics on potential health risks*

Label 3 has come out the overall most favourable



This product may contain harmful bacteria such as E.coli, Listeria and Salmonella. It has not undergone heat-treatment that would destroy harmful bacteria.

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

Introduction





Background to Research

- In March 2012, the Food Standards Agency's (FSA) Board agreed to a review of the current **controls of raw drinking milk and cream** in England, Wales and Northern Ireland*
- The review aims to explore the potential options for **managing the public health risks** from the consumption of these products
- As part of the review, the agency is looking at :
 - Current statutory controls to ensure they provide **clear, consistent and appropriate guidelines**
 - Recent **developments in the sale** of raw milk (such as the Internet, vending machines etc)
 - Variation in **labelling requirements**
 - Controls for raw milk from **other farmed species** (i.e. sheep, goats and buffalo)
- To understand the above the Food Standards Agency commissioned Harris Interactive to conduct research with the general population to understand their views on raw drinking milk and cream.

** Please note that Scotland wasn't included, since the sale of raw milk has been banned in Scotland since 1983.*



The Review's Overall Research Objectives

- The key objective was to *better understand the market for Raw Milk and Cream* and seek a *balanced view from stakeholders and consumers on the sale and consumption* of these products, as well as *options for further controls*
- The entire review includes:
 1. Engagement with producers of both raw and pasteurised milk to better understand the market
 2. Face-to-face discussion with consumers of raw milk
 3. Research to understand what consumers of pasteurised milk think about consuming Raw Milk/Cream
- This report specifically addresses the third objective shown above:

“To understand what consumers of pasteurised milk think about consuming Raw Milk/Cream”



Approach & Panel

- We conducted an online survey with 1,333 people across England, Wales and Northern Ireland between the dates of 15th to 20th November 2012.
- The survey took place online using the Harris Interactive panel
- The Harris Poll Online Panel consists of members of the general public who have opted-in and voluntarily agreed to participate in online research studies. Through careful recruitment and management, we are able to rapidly survey large numbers of the general population and accurately represent the views of the nation.
- We have over 100,000 active panellists in the UK and our panel is used solely for market & opinion research. Members are contacted at random and invited to take part in a survey.



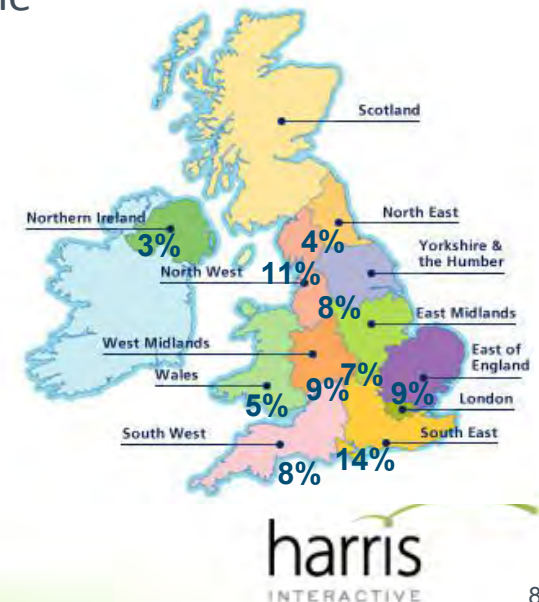


Audience – a representative sample

- The results of the study are weighted to reflect the size and shape of the UK population (exc. Scotland as this was not part of this study)
- Because we needed to have robust numbers in Wales and Northern Ireland we boosted the sample size in the study to 202 people in Wales and 201 in Northern Ireland and then down-weighted their size to reflect the true proportions as per the map below
- This means that the results in this report reflect an audience that is as true as possible of the population with the same age, gender and regional profile
- Of course not everyone in the UK has internet access, but online panel research results are considered to be extremely accurate. In fact, according to the British Polling Council, Harris Interactive was the most accurate *online* polling company during the UK elections:

<http://www.britishpollingcouncil.org/press100508.html>

- Screening ensured that the people we spoke to were **consumers of milk or cream** (see slide 10), this represents **94% of the population (exc Scotland)**

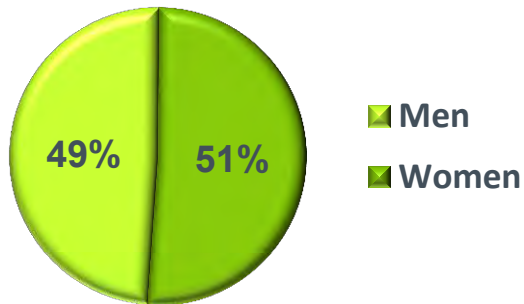




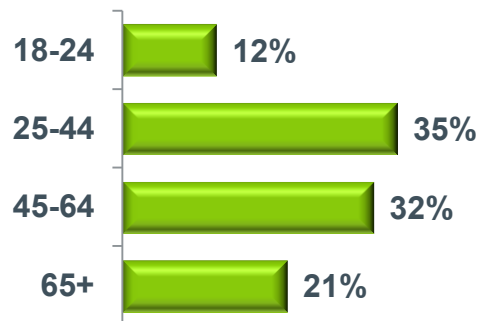
A closer look at the audience

- The people who took part in the survey were a nationally representative sample in terms of **Gender**, **Age** and **Region** as detailed below

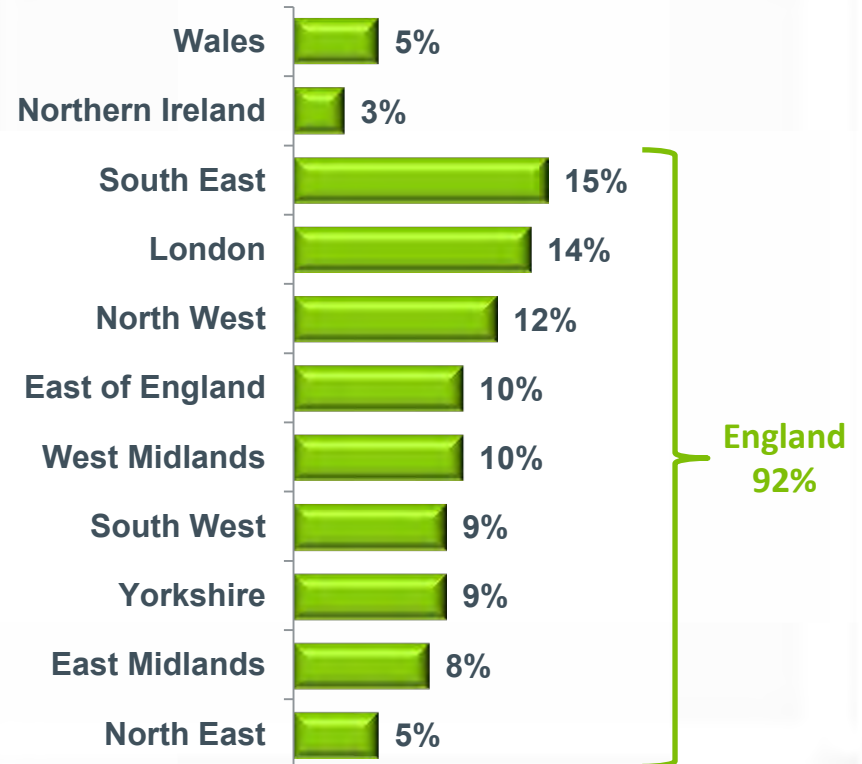
Gender



Age



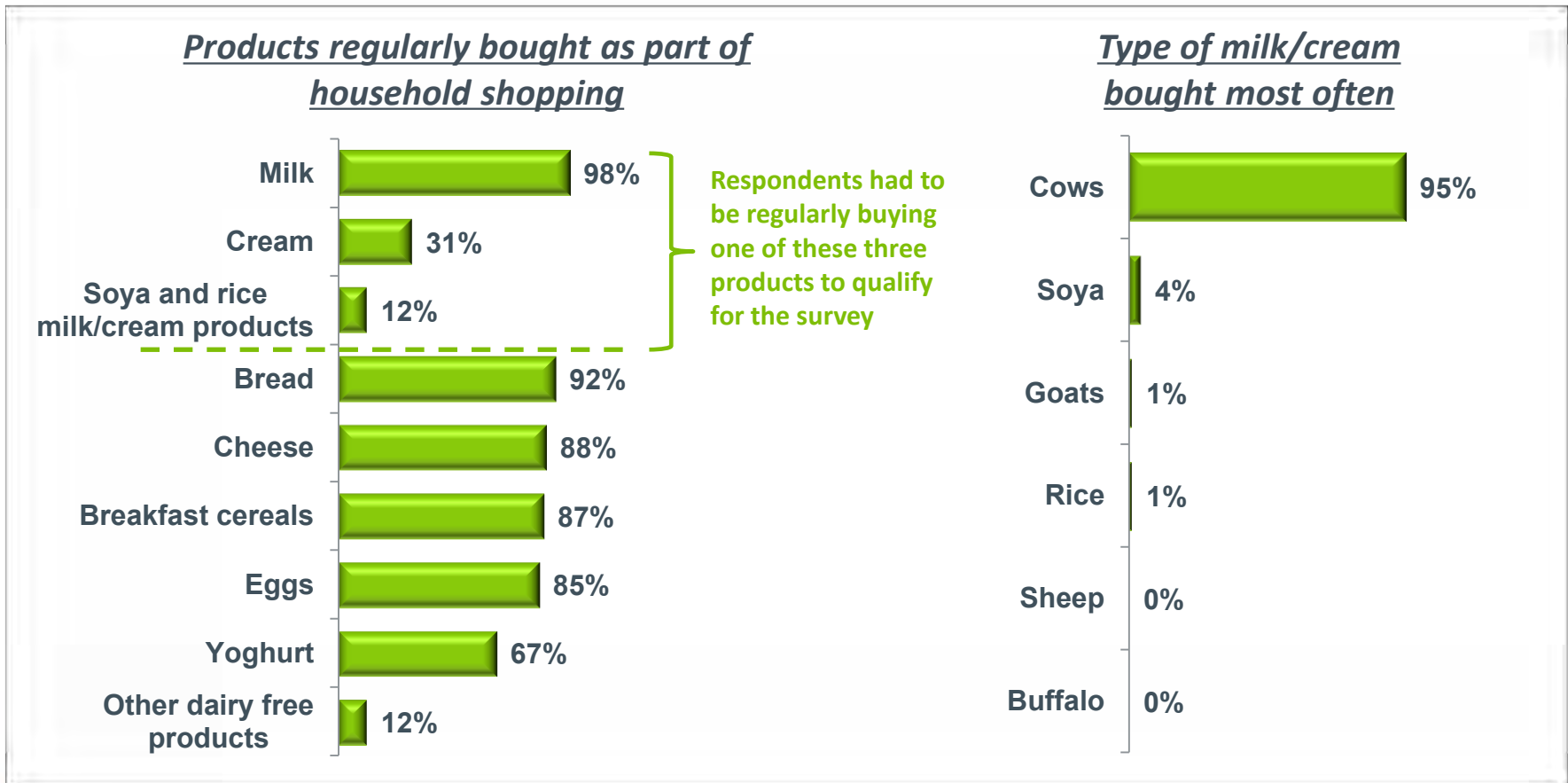
Region





Everyone who took part in the survey was a regular milk or cream buyer

- Screening ensured that everyone we spoke to currently bought **milk or cream** as part of their regular household shopping. This is 94% of the population (exc Scotland)



For further detail on the demographics of respondents, please see Appendix 2

Raw Milk Study Quality Assurance



How we ensure quality responses

- Each survey invite sent out was unique which means it could only be taken once
- A 'Minimum Length of Online Interview' was defined – this prevented people rushing through without proper consideration of their responses
- We also put in place automatic logic checks to ensure responses make sense and don't contradict
- Anyone who fails two or more quality checks within a survey is excluded from the results

Privacy & Data Protection

- Harris Interactive has a privacy policy. The purpose of this privacy policy is to clearly communicate; the nature of the data we collect, how we manage personally identifiable information (PII), what panelist can do to update their information or be removed from our panel. We comply with all governmental and industry regulations with respect to handling data.
- Harris Interactive's Privacy Policy: <http://www.harrisinteractive.com/about/privacy.asp>
- Additionally, Harris Interactive conforms to the European Commission Directive on Data Protection
- Harris Interactive provides security measures against unauthorized access to our systems including programs, files and information. All data is subject to stringent data backup policies and practices.

Membership of professional bodies

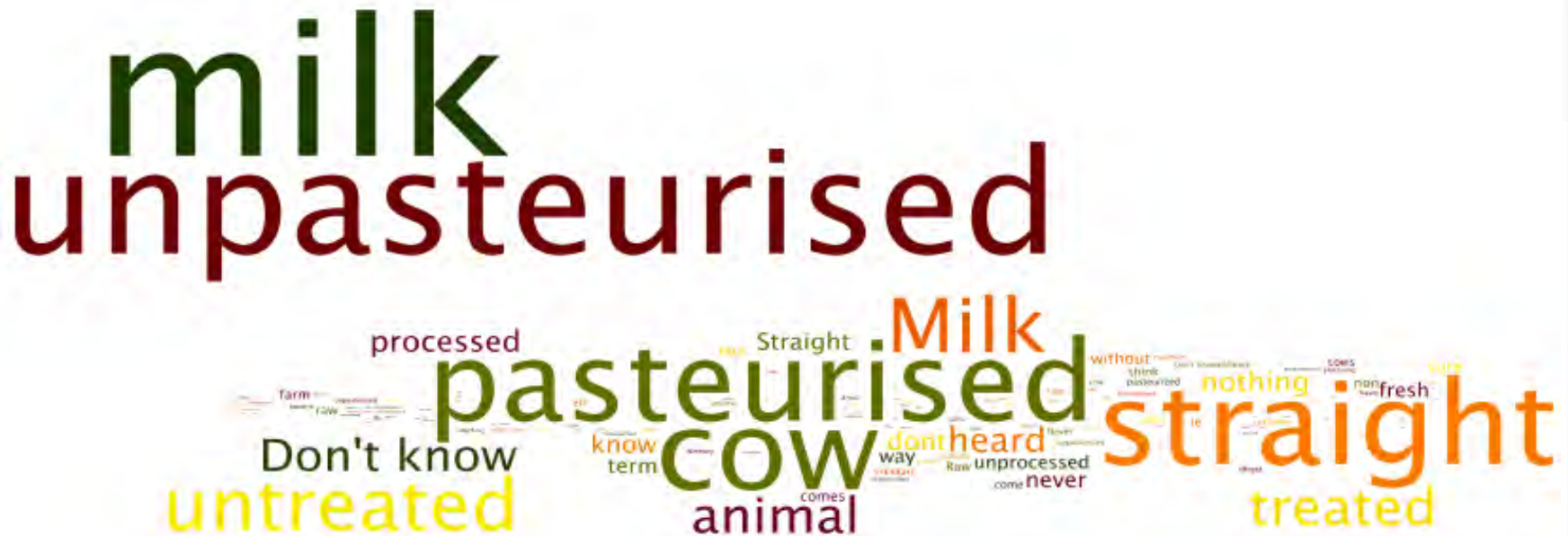
- We are an MRS (Market Research Society) Company Partner and are also an MRS Accredited Training Centre so we take our responsibilities seriously. Further, we enforce best practice on a global basis – making sure that our activities fall within, and where possible exceed the standards set by market research bodies around the world. These include, although are not limited to ESOMAR and CASRO.

Understanding and experiences of raw milk/cream



Seven out of ten (70%) correctly understand what is meant by the term 'Raw Milk' – the remaining 30% are not sure

What is understood by the term Raw Milk (Unprompted)



Unprompted...



70% correctly understand what is meant by raw milk



30% did not know or were unable to give an explanation

Understanding of raw milk – a selection of verbatim comments

What's understood by the term Raw Milk (Unprompted)



Means nothing to me...
Female, aged 28, never tasted and never bought raw milk



I assume that the term relates to milk that has come straight from the cow and has not been treated in any way i.e. Pasteurised.
Male, 45, never tasted and never bought raw milk



I would guess it would mean unpasteurised milk, which would be milk straight from the cow with no pasteurisation to kill bacteria, no skimming of cream and fat and no additives to prolong life. I would imagine it would taste great but be a bit more risky in terms of cholesterol and food poisoning.

Male, aged 37, never tasted and never bought raw milk



Milk fresh from the dairy?
Female, aged 36, never tasted and never bought raw milk

Not sure, probably milk that has come directly from the cow without being processed.

Female aged 30, never tasted and never bought raw milk

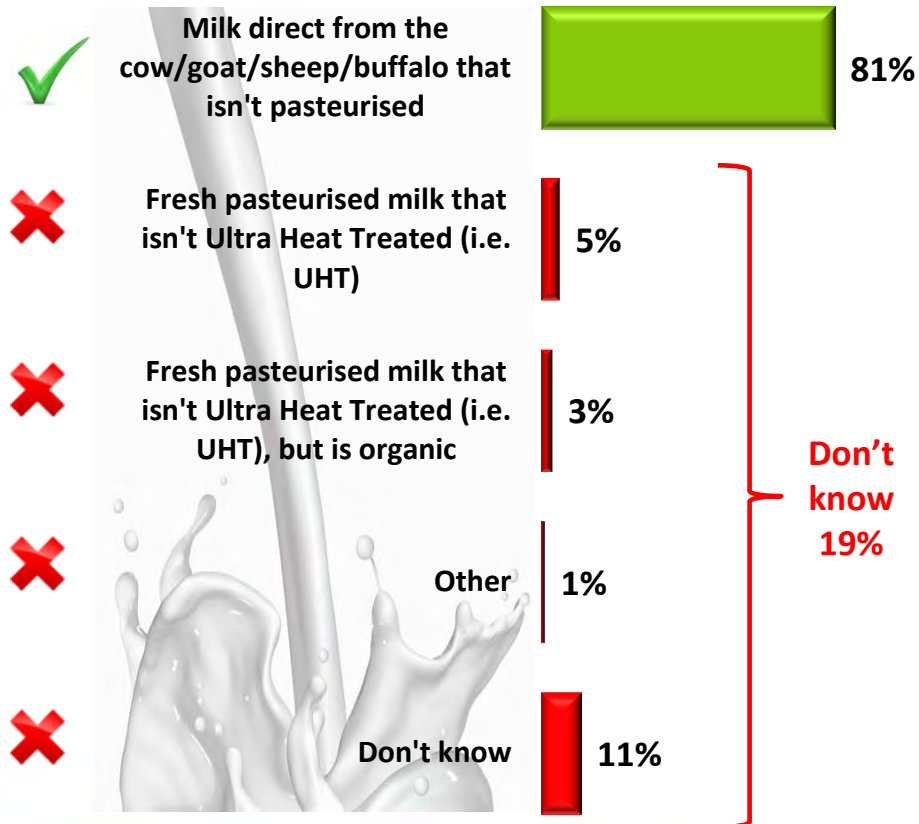


Straight from the cow, un-pasteurised. Not normally available for the consumer.
Male, aged 77, never tasted and never bought raw milk

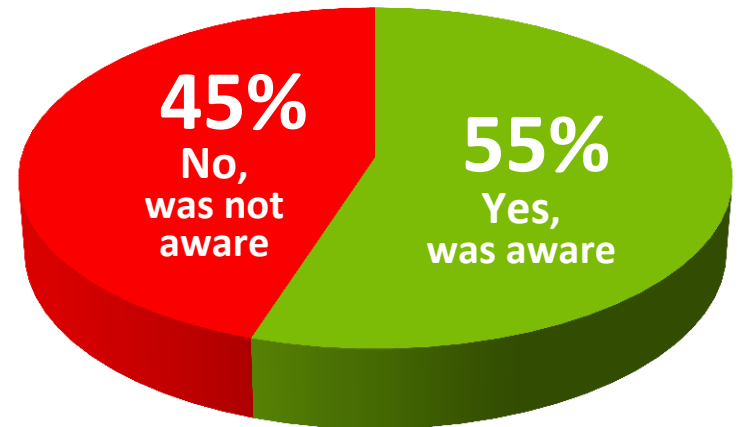


When prompted, four out of five (81%) correctly understood the term 'Raw Milk', but just under half (45%) were not aware that some people choose to consume it...

What's understood by Raw Milk (Prompted)



Level of awareness that some people choose to consume raw milk/cream



Q815. Which of the following descriptions do you think most accurately describes raw milk?

Q820. Were you aware that some people choose to consume raw milk and cream?

Base: All qualified respondents (1,333)

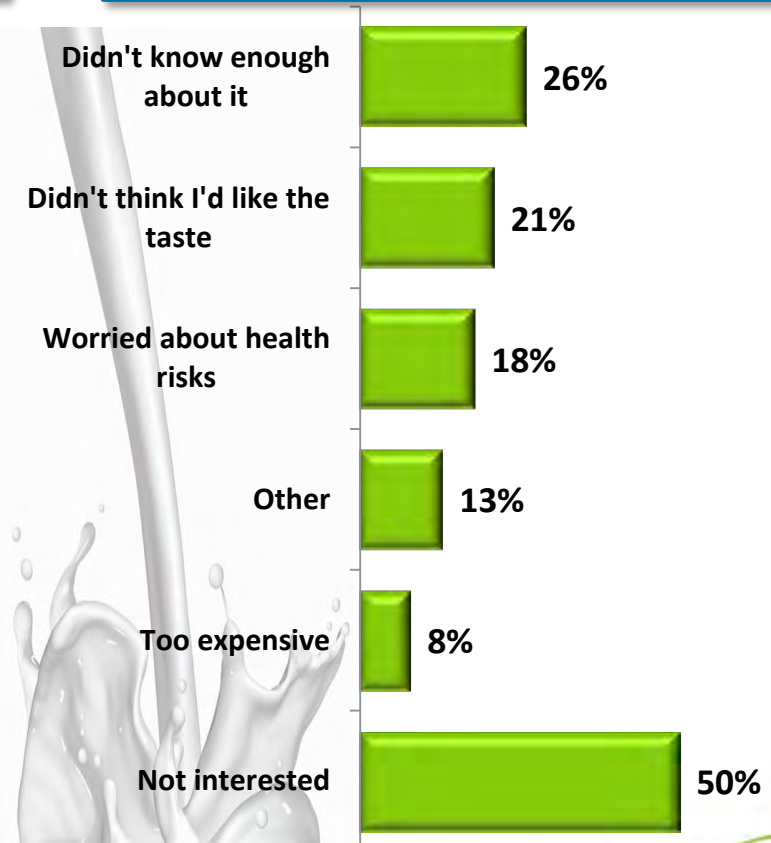
Amongst those who are aware of raw milk/cream, 92% have never seen it for sale. Amongst the 8% who have seen it for sale, half were not interested in buying it with many not knowing enough about it or expecting to dislike the taste.

You said you were aware that some people choose to consume raw milk and cream, but you haven't ever bought or tasted it. Why is this?

8% have seen it for sale but choose not to buy/try it

92% have not seen it for sale so haven't been able to buy

Why did you choose not to buy/try raw milk/cream?



Q860. have you ever seen raw milk/cream for sale?

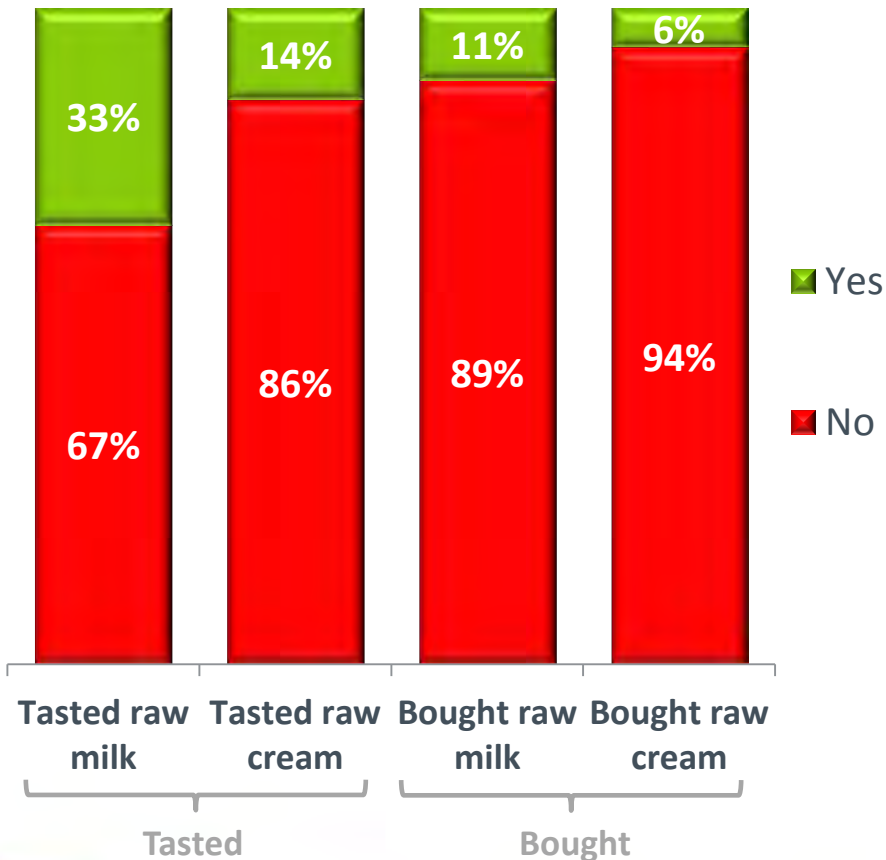
Base: All qualified respondents aware that some choose raw milk/cream but have never tried/bought themselves (373)

Q865. Why did you choose not to buy/try raw milk/cream?

Base: All qualified respondents aware that some choose raw milk/cream but have never tried/bought themselves and have seen for sale (25)

More have tasted raw milk/cream than have bought it. The proportion of those currently buying/consuming is low (3%).

Ever bought/consumed raw milk or cream



Currently buying/consuming raw milk/cream
(amongst all qualified respondents)



Please note : The 3% that report consuming raw milk/cream is 3% of all milk/cream consumers. In this study non-milk/cream consumers were excluded. If non-milk/cream consumers had been included, the proportion of raw milk drinkers would be less than 3%.




Q825. And to the best of your knowledge, have you ever...?

Q830. Do you currently buy and/or consume raw milk or cream?

Base: All qualified respondents (1,333)

Those in Northern Ireland appear to have a slightly better understanding of the term 'Raw Milk'. The proportion purchasing/consuming is similar across all countries.

Understanding and experiences of raw milk, by country

	 England	 Wales	 Northern Ireland
base size:	930	202	201
Understand what is meant by the terms Raw Milk (Unprompted)	71%	64%	77%
Understand what is meant by the terms Raw Milk (Prompted)	81%	76%	84%
Ever bought/tried	34%	32%	33%
Currently buying/consuming	2%	4%	3%

Q810. What do you understand by the term Raw milk?

Q815. Which of the following descriptions do you think most accurately describes raw milk?





Q825. And to the best of your knowledge, have you ever...?

Q830. Do you currently buy and/or consume raw milk or cream?

Base: All qualified respondents (1,333) – see above

Older people are more likely to understand what is meant by the term 'Raw Milk' and to have ever bought/tried. However, current consumers/buyers are more likely to be younger.

Understanding and experiences of raw milk, by age

	 18-24	 25-44	 45-64	 65+
base size:	115	450	479	289
Understand what is meant by the terms Raw Milk (Unprompted)	50%	65%	78%	80%
Understand what is meant by the terms Raw Milk (Prompted)	70%	79%	86%	82%
Ever bought/tried	31%	28%	38%	40%
Currently buying/consuming	7%	4%	1%	1%

Q810. What do you understand by the term Raw milk?

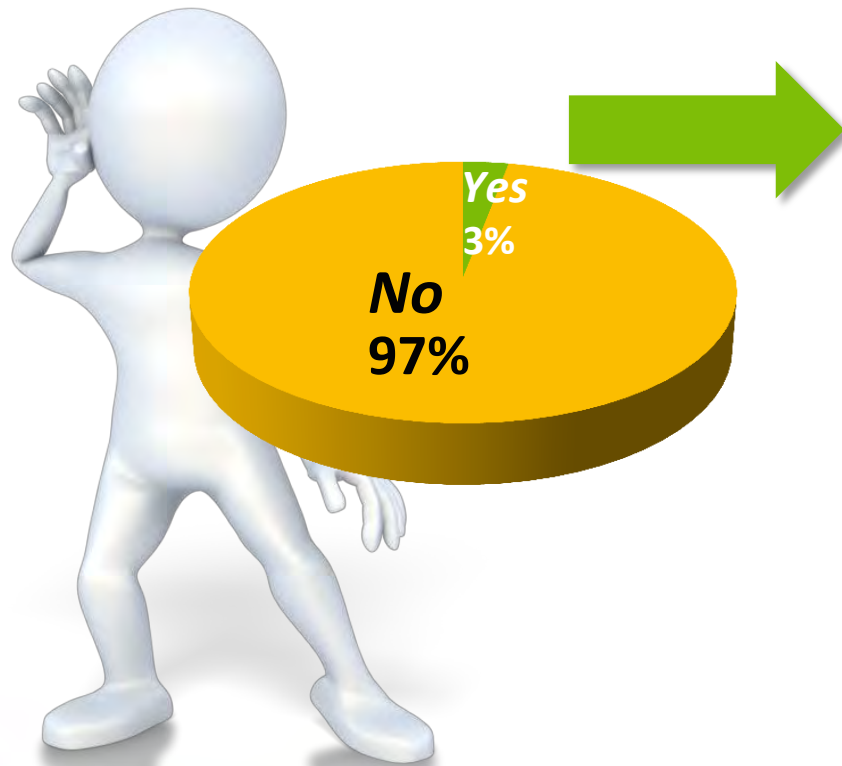
Q815. Which of the following descriptions do you think most accurately describes raw milk?

Q825. And to the best of your knowledge, have you ever...?

Q830. Do you currently buy and/or consume raw milk or cream?

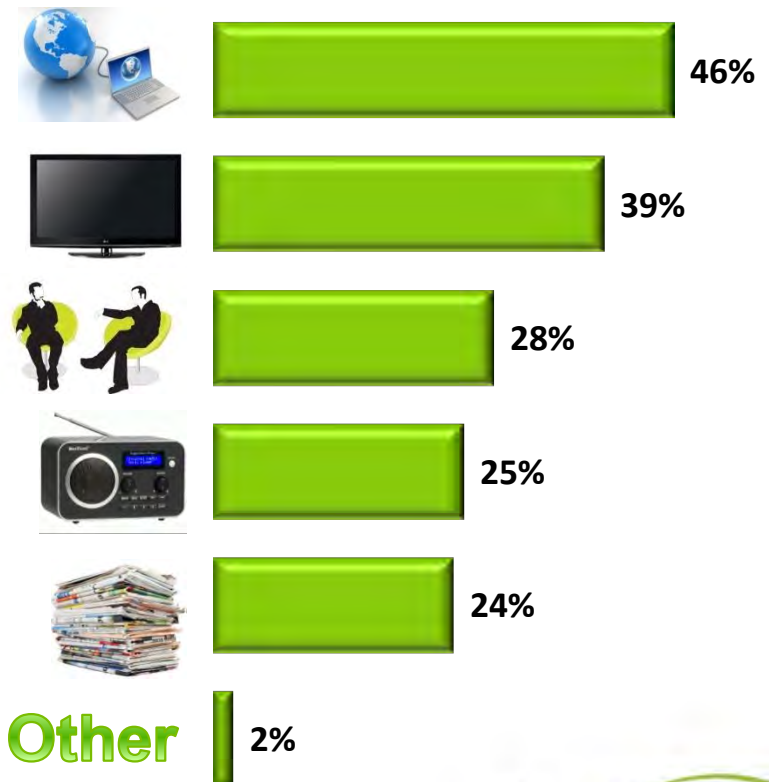
Base: All qualified respondents (1,333) – see above

3% of the UK population (excluding Scotland) buying milk/cream (excluding Scotland) have recently heard something relating to raw milk/cream – most commonly on the Internet (46%) or TV (39%) *Heard anything about raw milk or cream*



Where did you hear about raw milk or cream?

 Caution – low base size



930. Have you heard anything about raw milk or cream anywhere recently?

Base: All qualified respondents (1,333)

Q935. Where did you hear about raw milk/cream?
Base: All qualified respondents who have heard about raw milk or cream recently (42)

What has recently been heard about Raw Milk/Cream? – a selection of verbatim comments



“I read the Wikipedia article on raw milk and other related articles there, and various opinions on both sides of the Atlantic” (*Internet*)

Female, aged 26, England



“Think it was farmers being interviewed about it and the benefits/drawbacks were discussed” (*TV*)

Female, aged 65, England



“A friend from the USA was telling me about controversy over the use of raw milk there and we discussed the dangers and benefits” (*Talking to someone*)

Female, aged 26, England



“Excellent milk by cows who eat natural food” (*Radio*)

Male, 27, England



“Dangers of disease transmission; TB in the old days, Salmonella etc. nowadays. Also the danger to mothers during pregnancy” (*Magazines/newspapers*)

Male, aged 75, England

“Not good for you” (*Magazines/newspapers*)

Male, aged 47, England



Caution – low base size

Q945. What did you hear?

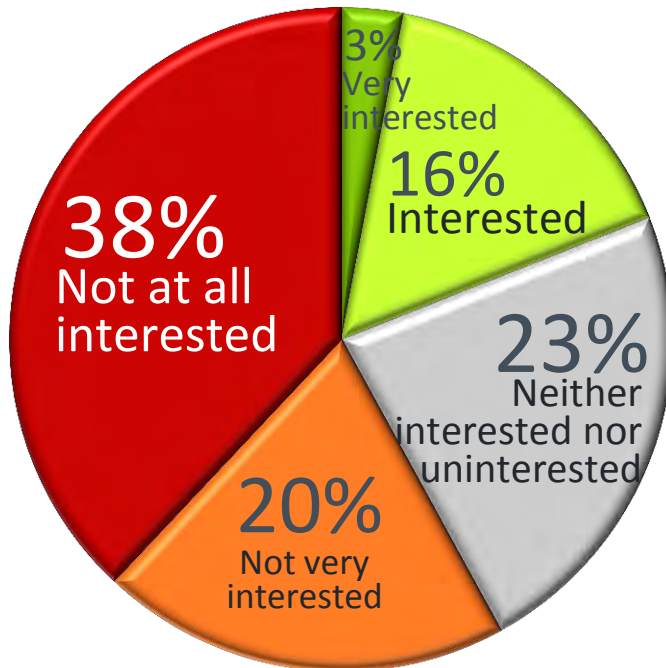
Base: All qualified respondents who heard about raw milk/cream recently, magazines or newspapers (8), TV (16), Radio (7), Internet (16), Talking to someone (10)

Level of interest in raw milk/cream



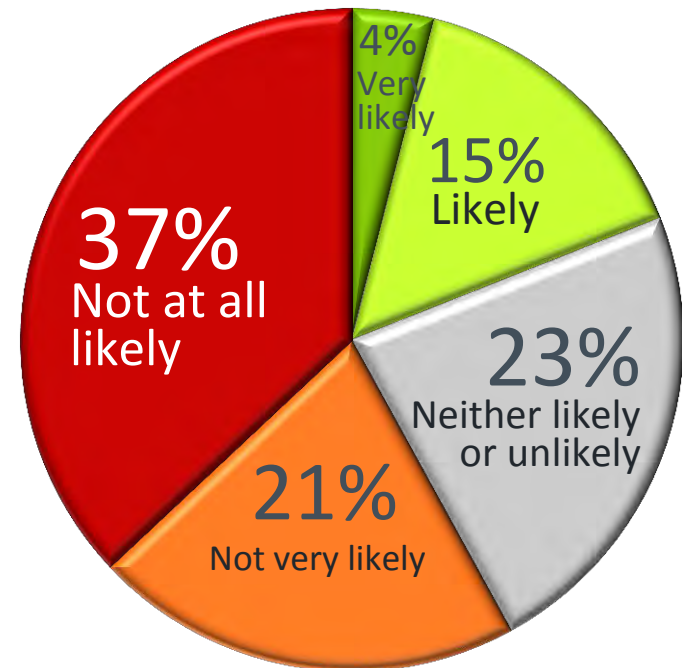
Almost a fifth (19%) of the UK (excluding Scotland) population buying milk/cream (excluding Scotland) would be interested in buying/consuming raw milk or cream, with the same proportion (19%) likely to buy it if it were available at a price they considered acceptable.

Level of interest in buying/consuming



Interested (NET): 19%

Likelihood to buy



Likely to buy (NET): 19%

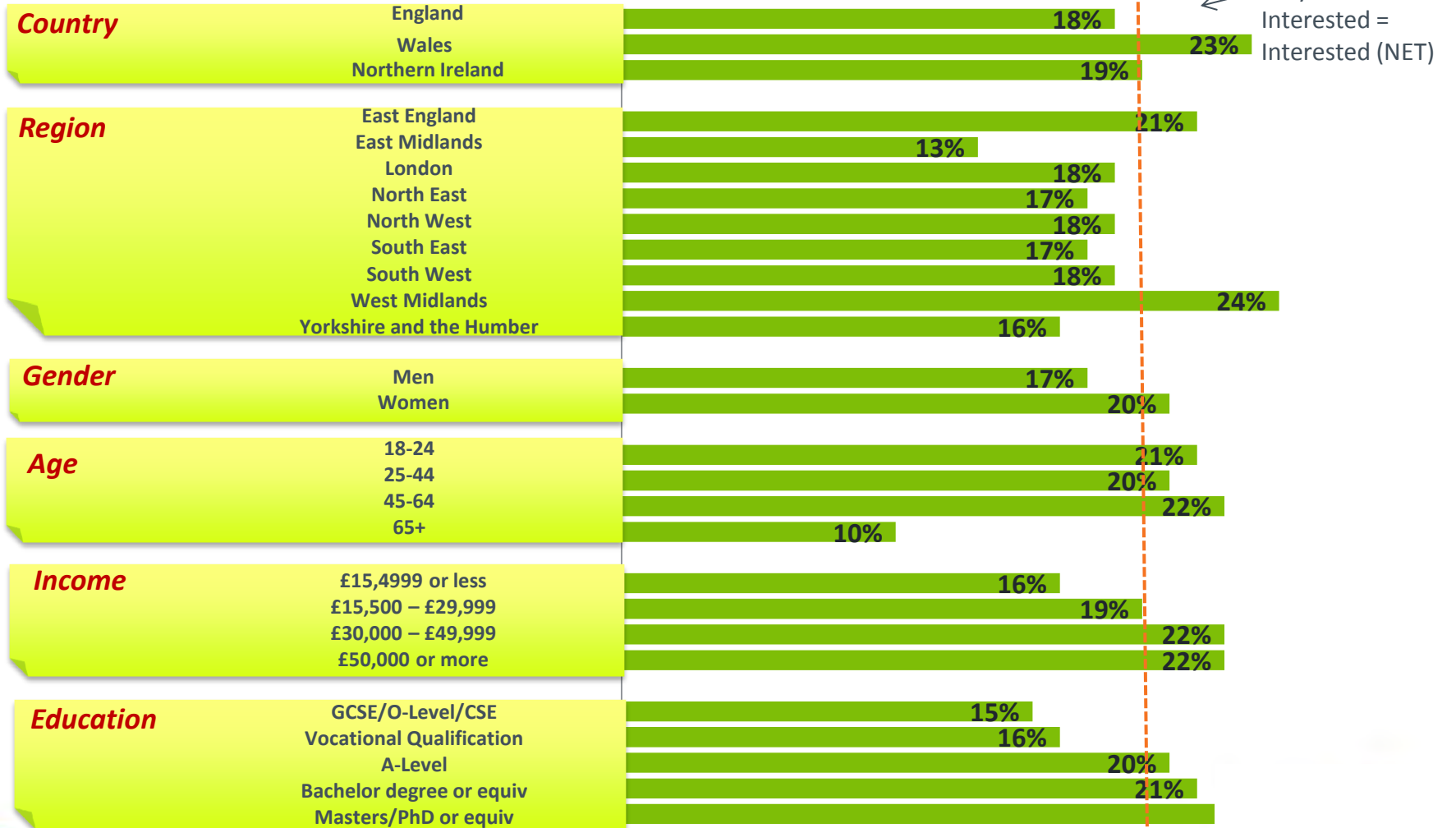
Q900. Regardless of whether you have bought or consumed, how interested would you be in buying/consuming raw milk?

Q905. If Raw Milk/Cream was available where you shopped at a price you considered acceptable, how likely would you be to buy for you and your family?

Base: All qualified respondents (1,333)

Those most highly educated are more interested in buying/consuming Raw Milk/Cream (26%) and aged 65+ are least interested (10%).

% who would be interested



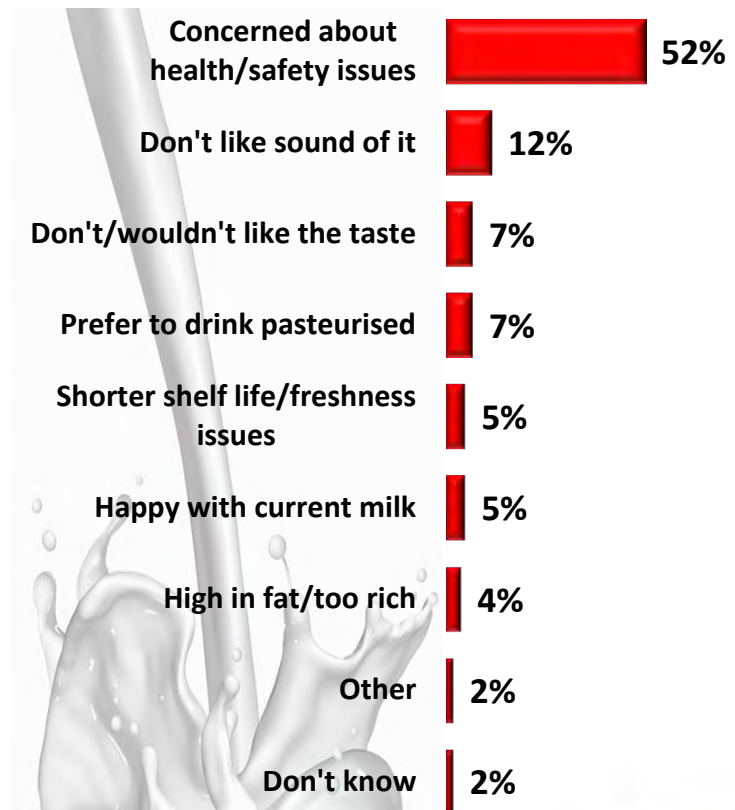
average 19%

The top reason for interest is to do with curiosity. Safety issues are by far the main reason for people to not express an interest.

*Reasons why interested in raw milk
(amongst the 19% expressing interest)*



*Reasons why not interested in raw milk
(amongst the 58% not interested)*



Q902. You said you would be interested. Can you tell us a bit more about why?

Q903. You said you would not be interested. Can you tell us a bit more about why not?

Base: All interested (252), not interested (776)

Reasons for interest in Raw Milk/Cream – a selection of verbatim comments

Verbatim comments amongst those who would be interested

Concerned that we are not getting food as it should be. Would like to try this if there was a local producer

Female, aged 56, tasted but never bought raw milk

I just like to try different things.

Male, 51, never bought, never tasted raw milk

I am keen to encourage food production that has not been mucked about with. I would like to set an example - make a point.

Female, aged 64, tasted but never bought Raw milk

I would be curious to know if it tasted different from pasteurised milk, and I'm interested in what I've heard about its health benefits.

Female aged 26, never bought, never tasted raw milk

It offers full flavour!

Male, aged 22, tasted and bought raw milk

Reasons for lack of interest in Raw Milk/Cream – a selection of verbatim comments

Verbatim comments amongst those who would not be interested



It's a food fad and I'm not interested in those.

Male, 55, never bought, never tasted raw milk



I prefer pasteurised as it has less infection risk.

Male, aged 22, tasted, but never bought raw milk



Concerned about bacteria – we have pasteurised for years for a reason!

Female aged 32, never bought, never tasted raw milk



I would want to know more about it, have some knowledge about the production criteria etc.

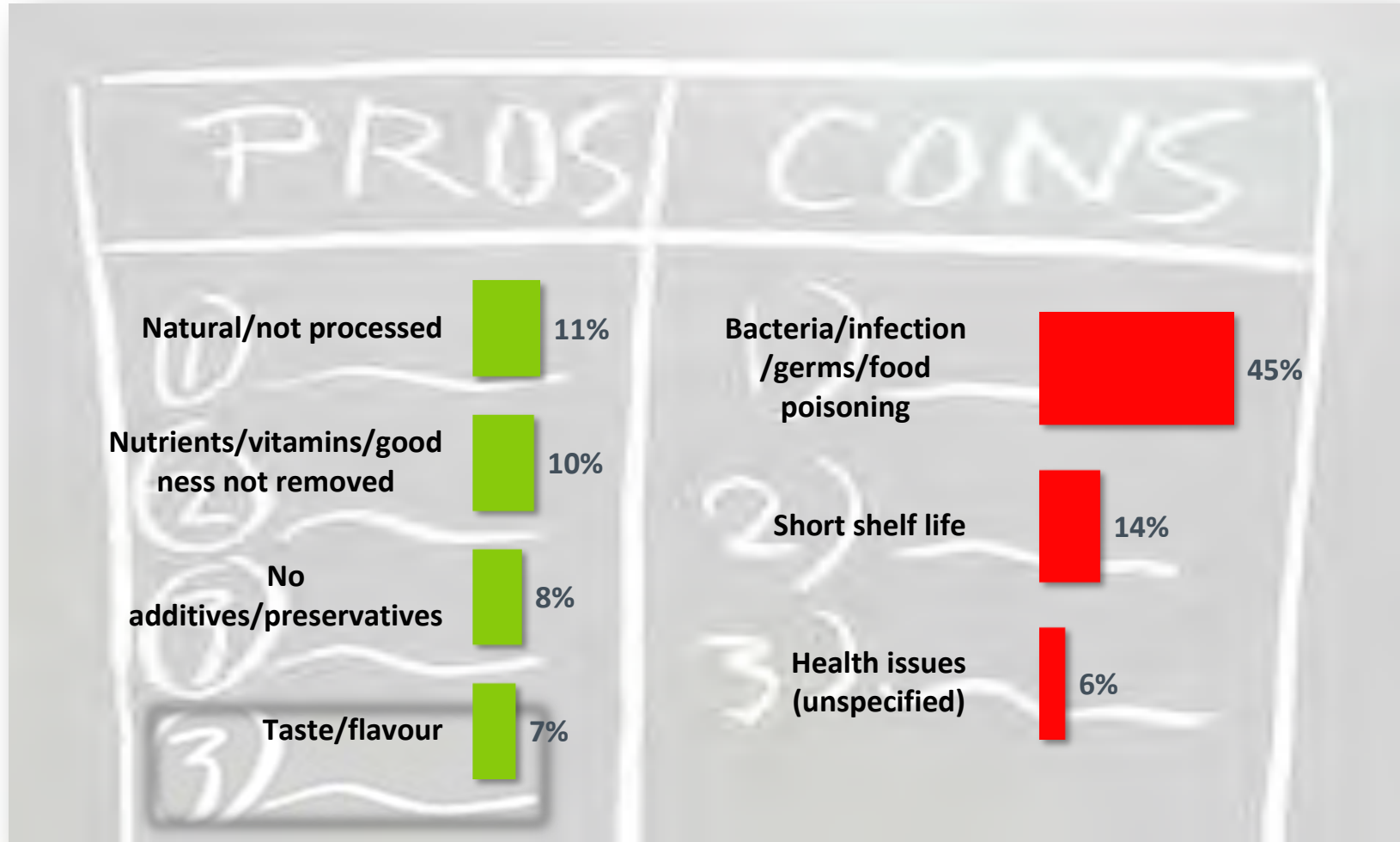
Female, aged 67, never bought, never tasted Raw milk

I didn't find it very nice; warm with an unpleasant consistency i.e. Creamy in parts and watery in others.

Female, aged 68, tasted, never bought raw milk



Respondents are clearer on the disadvantages than the advantages – the key disadvantage is perceived to be the health risk.



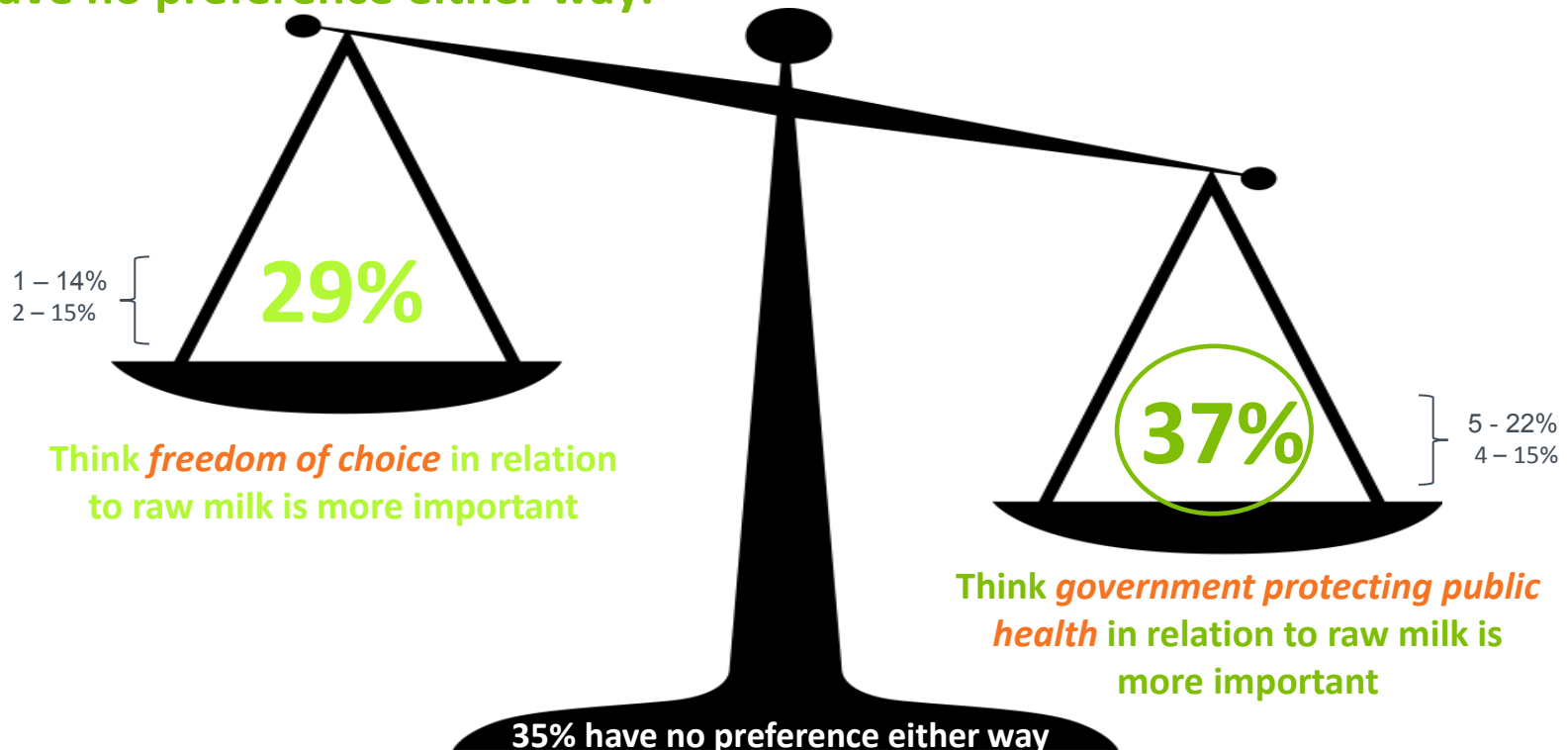
Q910. What do you think the main benefits associated with Raw Milk/Cream might be?
 Q915. What do you think the main drawbacks associated with raw milk/cream might be?

Base: All qualified respondents (1,333)

Importance of freedom of choice versus government protection in relation to raw milk/cream



The UK population (excluding Scotland) who buy milk/cream are more likely to agree that the government protecting public health in relation to Raw Milk/Cream is more important than freedom of choice. However 35% have no preference either way.



Scale Used

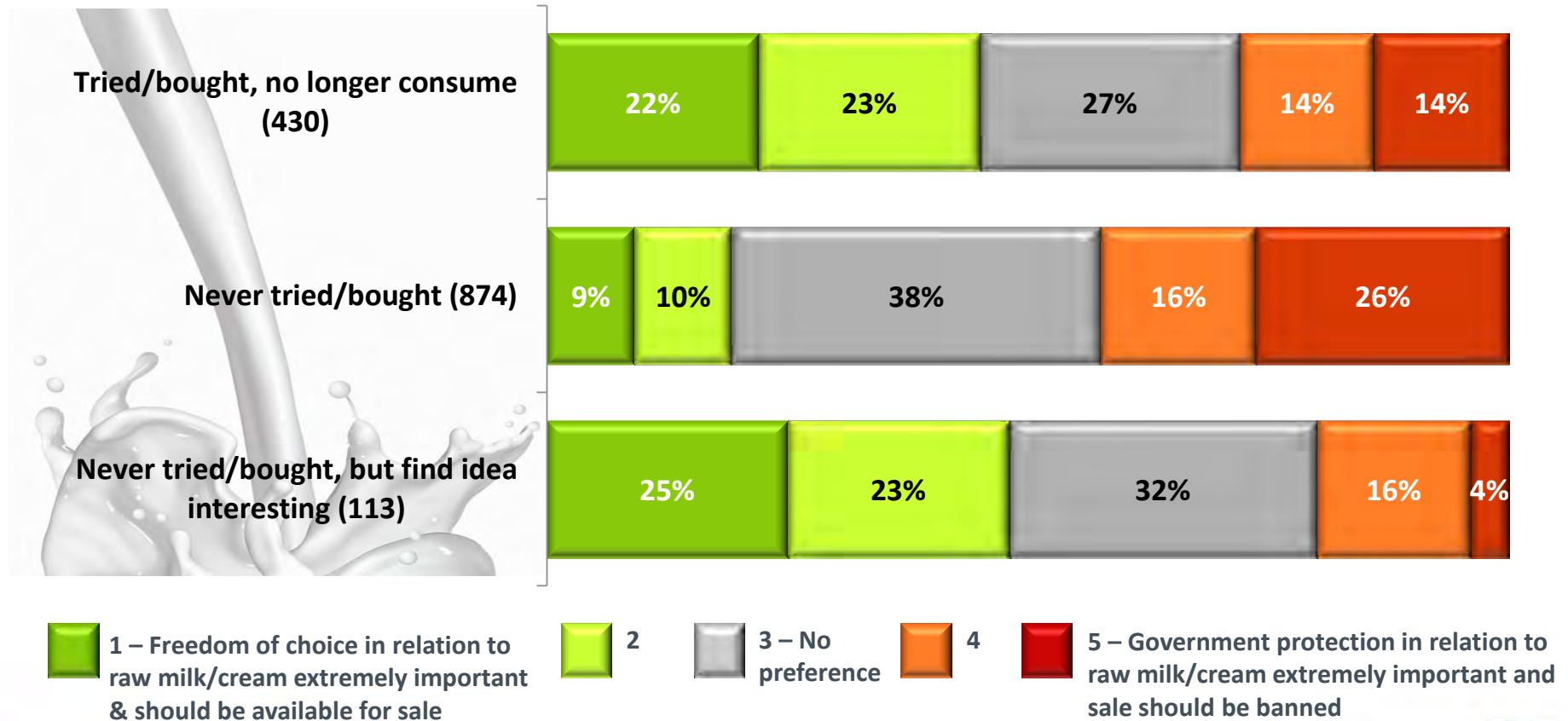
- 1 – Freedom of choice in relation to raw milk/cream extremely important & should be available for sale
- 3 – No preference
- 5 – Government protection in relation to raw milk/cream extremely important and sale should be banned

Q920. Some people think that freedom of choice in relation to raw milk is extremely important and it should be available for sale, others think it is extremely important that the government should protect public health and the sale should be banned. Using the scale, please indicate where you sit....

Base: All qualified respondents (1,333)

Those that have never tried/never bought but find the idea interesting are more likely to be favourable towards freedom of choice than those who have never tried/bought overall.

Freedom of choice in relation to raw milk versus government protecting public health

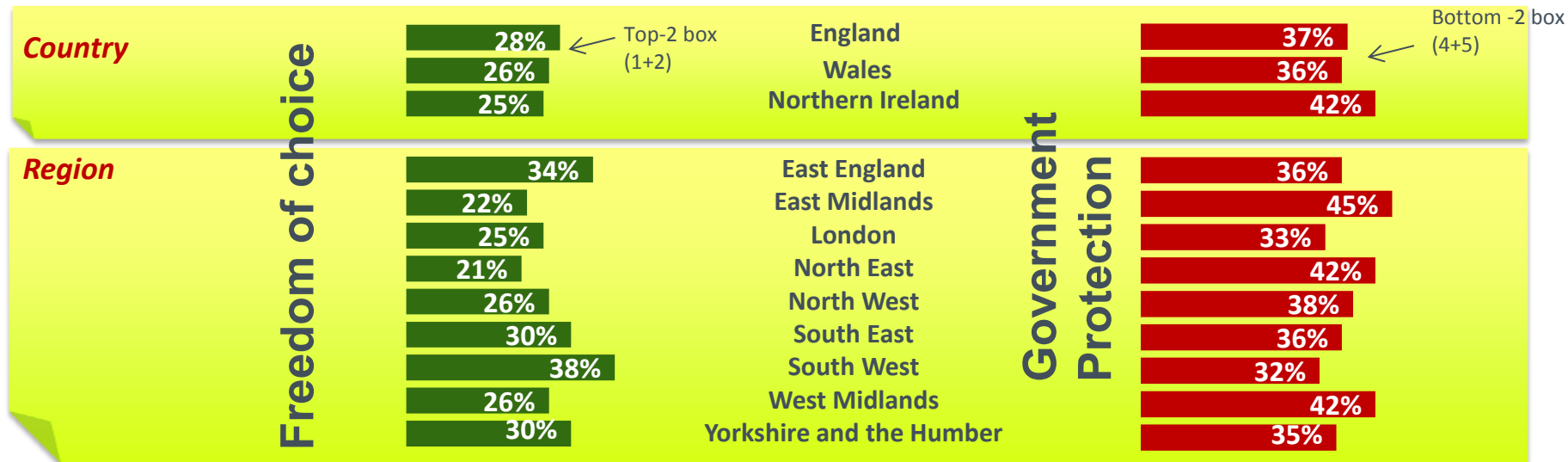


Q920. Some people think that freedom of choice in relation to raw milk is extremely important and it should be available for sale, others think it is extremely important that the government should protect public health and the sale should be banned. Using the scale, please indicate where you sit....

Base: All qualified respondents (1333) – see above

Those living in East Midlands, North East and West Midlands feel stronger about Government Protection (caution - please note low base sizes!).

Freedom of choice in relation to raw milk versus government protecting public health



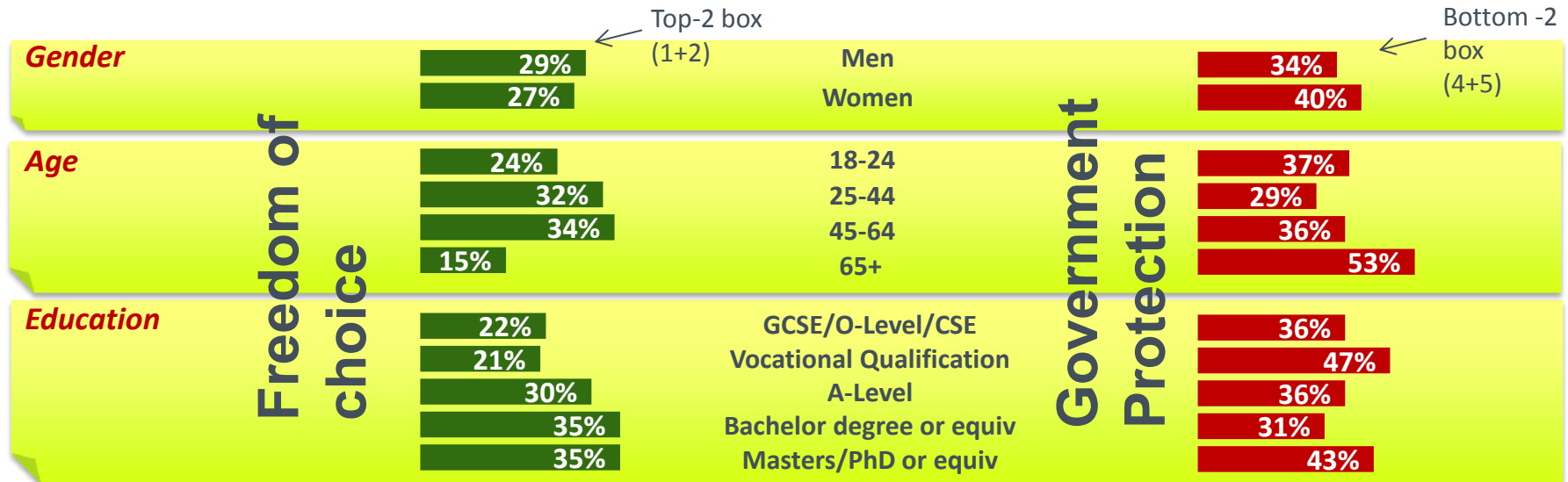
1 – Freedom of choice in relation to raw milk/cream extremely important & should be available for sale

5 – Government protection in relation to raw milk/cream extremely important and sale should be banned

Q920. Some people think that freedom of choice in relation to raw milk is extremely important and it should be available for sale, others think it is extremely important that the government should protect public health and the sale should be banned. Using the scale, please indicate where you sit....
Base sizes range from 60 to 930

Women feel more strongly about government protection than men and those aged 65+ are less inclined towards freedom of choice compared to the younger groups.

Freedom of choice in relation to raw milk versus government protecting public health



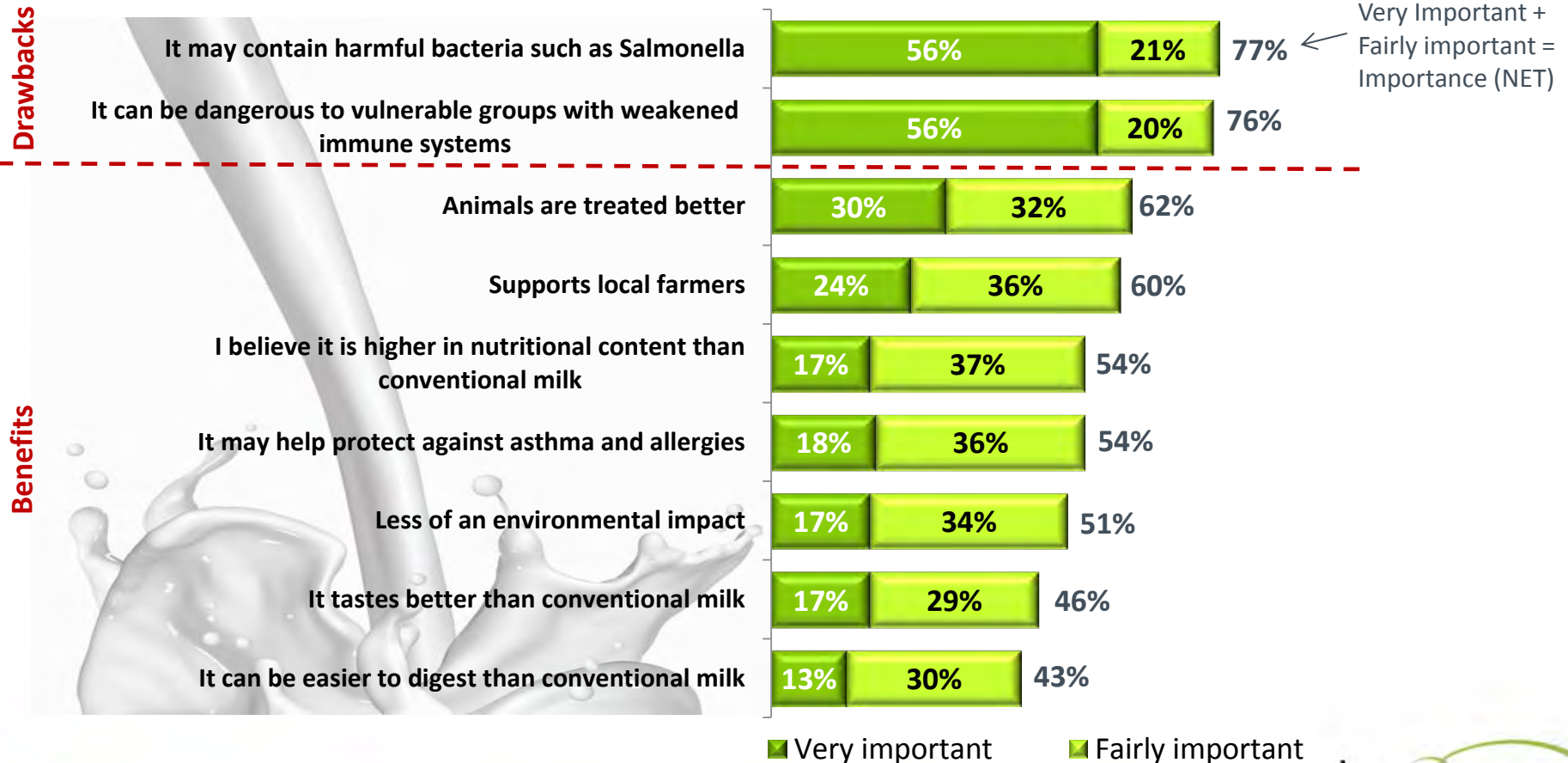
1 – Freedom of choice in relation to raw milk/cream extremely important & should be available for sale

5 – Government protection in relation to raw milk/cream extremely important and sale should be banned

Q920. Some people think that freedom of choice in relation to raw milk is extremely important and it should be available for sale, others think it is extremely important that the government should protect public health and the sale should be banned. Using the scale, please indicate where you sit....
Base sizes range from 60 to 930

The perception that Raw Milk/Cream may contain harmful bacteria and could be dangerous to vulnerable groups makes it an important consideration for people.

Importance of benefits and drawbacks associated with raw milk



Q950. Please can you indicate how important each of these would be when considering whether to buy raw milk/cream for you and your family? List of prompted responses provided as above.

Base: All qualified respondents (1,333)

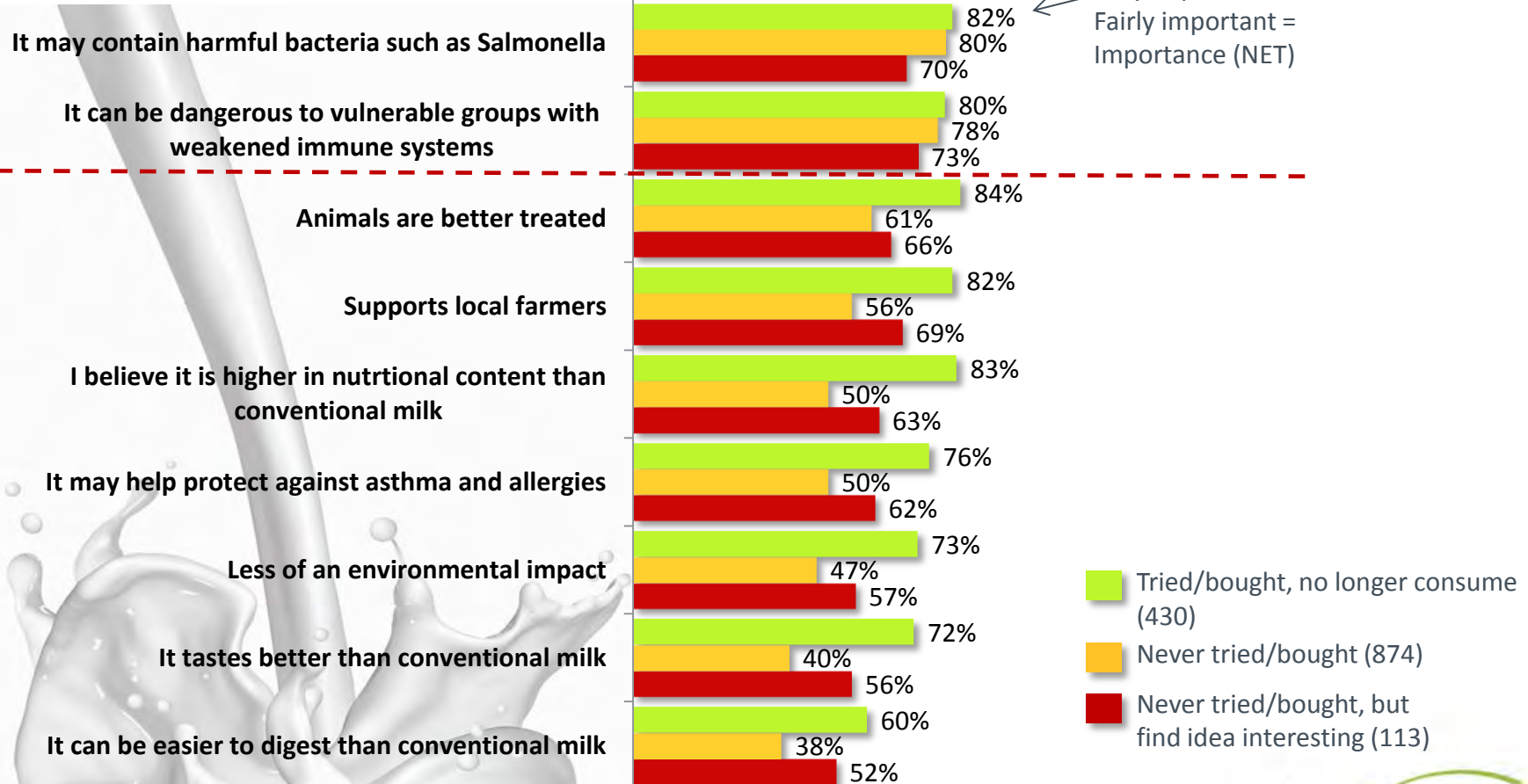
Those who have tried/bought but no longer consume raw milk have much higher importance scores across all benefits. They also feel stronger in regards to the drawbacks, which is closely followed by those that have never tried/bought raw milk.

Importance of benefits and drawbacks associated with raw milk

Drawbacks

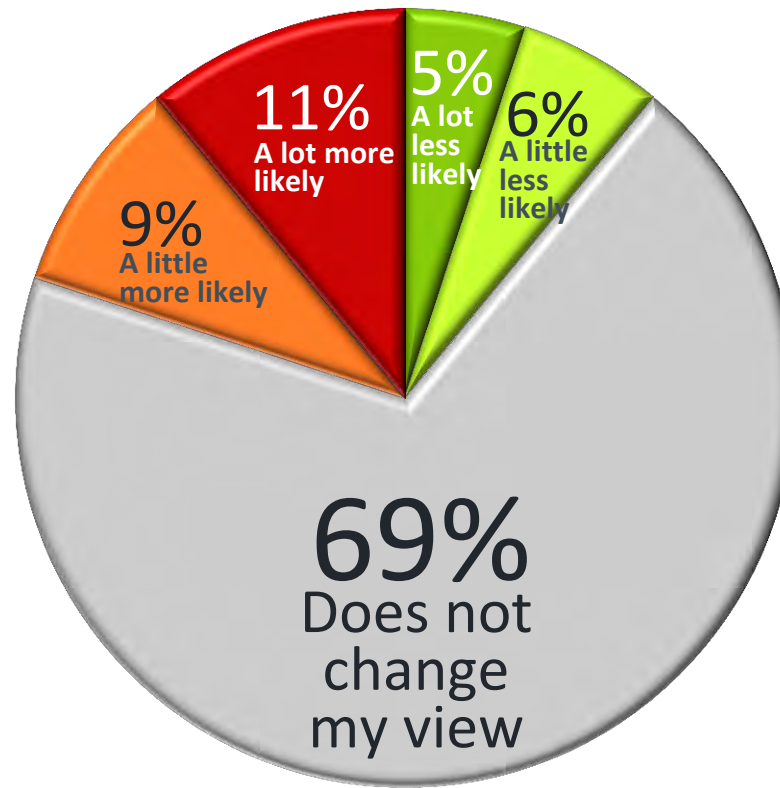
Very Important +
Fairly important =
Importance (NET)

Benefits



Knowing Raw Milk/Cream is banned in Scotland doesn't change the view of most people (69%). A fifth (20%) meanwhile would be more likely to say it should be banned, while a tenth (11%) would be less likely.

Does knowing Raw Milk/Cream is banned in Scotland change your view?



Q955. The sale of raw milk has been banned in Scotland since 1983, although it is still available in England, Wales and Northern Ireland. Does this change your view on whether or not raw milk and cream should be banned?

Base: All qualified respondents (1,333)

Labelling options for raw milk/cream



66% of those in England and 56% of those in Northern Ireland think the existing raw milk/cream label contains enough information. In Wales (where the existing label is more detailed), people are more likely (76%) to think it contains sufficient information.

Existing raw milk/cream label in England and Northern Ireland

E

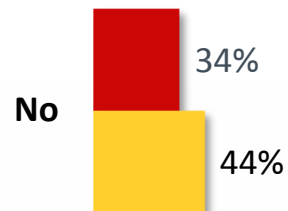
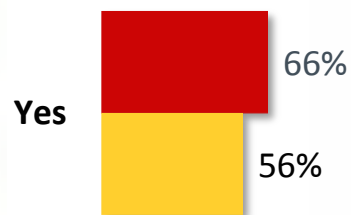
England

NI

Northern Ireland



Does this provide enough information about the risks associated with raw milk/cream?



■ England ■ N. Ireland

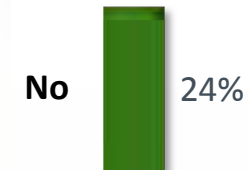
Existing raw milk/cream label in Wales

W

Wales

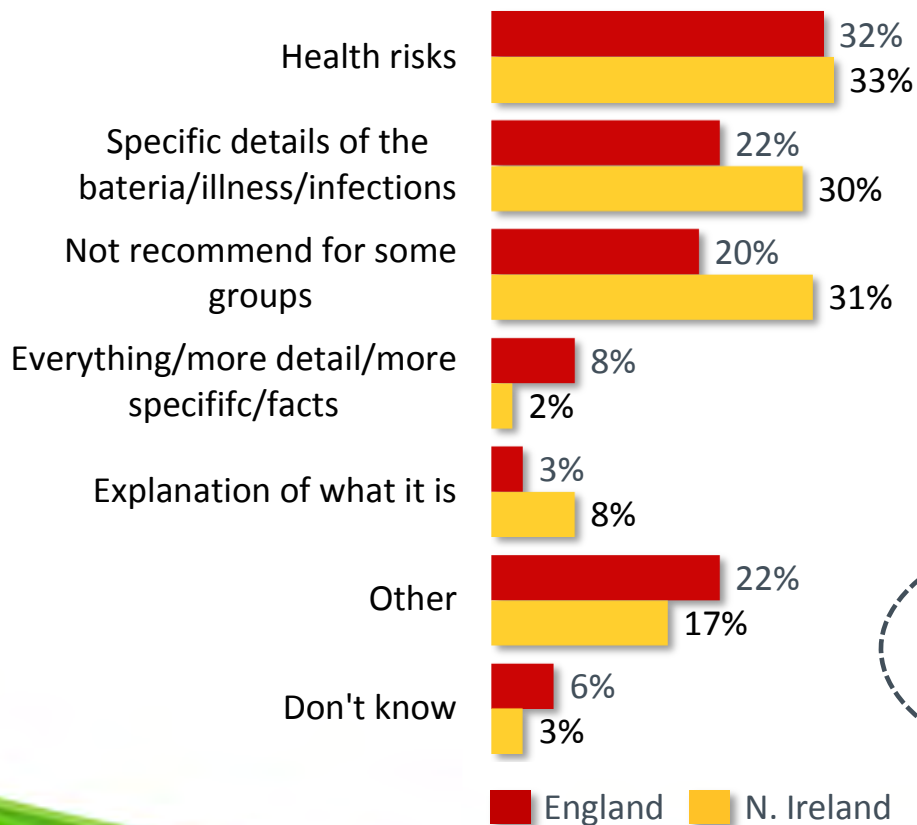


Does this provide enough information about the risks associated with raw milk/cream?



The information that is considered to be missing from the current labelling in England and Northern Ireland is to do with the health risks and specific details of bacteria that may be present, alongside the fact that it is not recommended for some groups.

*What is missing from current labelling?
(England and Northern Ireland)*



It should clearly say which groups of people it could be harmful to i.e. could be harmful if pregnant.

Male aged 43, England

The nature of the problem, not just a bland statement.

Male aged 75, England

The fact that you could get salmonella etc. from it should also be on the label.

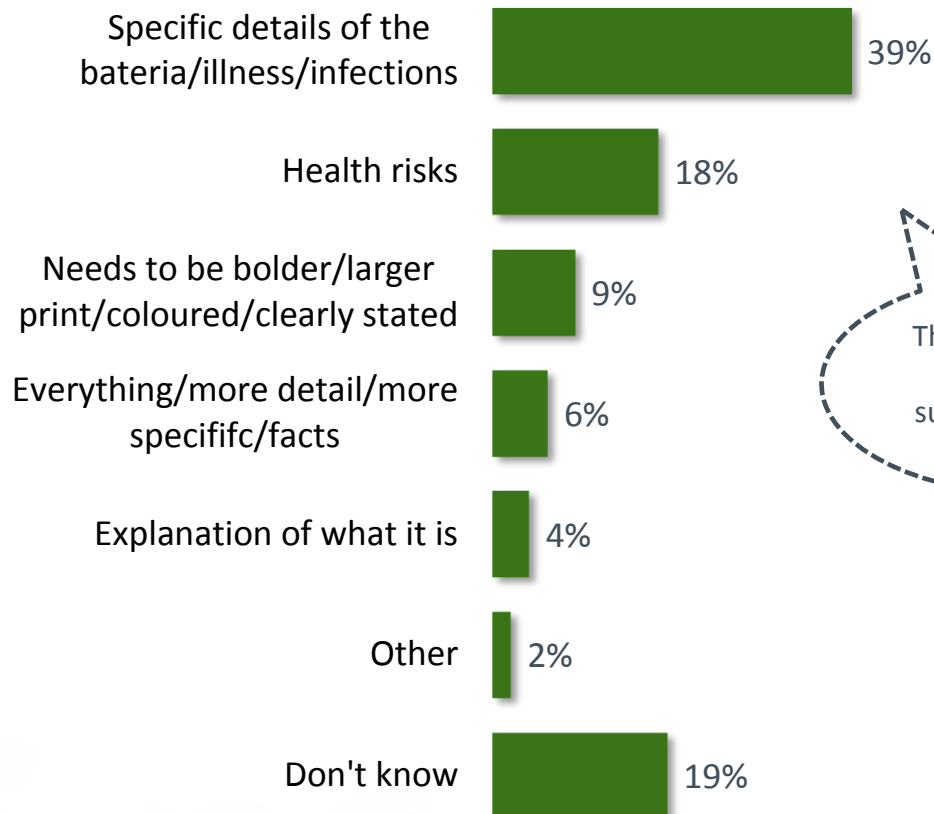
Female aged 46, Northern Ireland

More of a list of all the drawbacks and health issues, so consumers have all the information available to choose.

Female, aged 28, England

Likewise, in Wales, the information that is considered to be missing from the current labelling covers the health risks and specific details of bacteria that may be present.

*What is missing from current labelling?
(Wales)*



There is a risk of death.
Look at the warnings on
cigarette packets
Male aged 68, Wales

The diseases which
could be caught
such as Salmonella
Male aged 28, Wales

The sort of microbes
and what could
happen to you.
Female, aged 19, Wales

That it has not been treated and
the names of some of the diseases
that can be contracted through the
consumption of raw milk.
Female aged 59, Wales

Ransom Note Exercise

During the survey, we introduced four proposed new labelling options and asked respondents to assess each of these using the Harris Ransom Note tool. As part of this exercise, respondents were shown each of the four labels and asked firstly to review, highlighting any words they found **helpful** and then review for a second time, highlighting any words they found **confusing**.

We are now going to show you four proposed new labelling options for Raw Milk/Cream products. Using your mouse, please point and click on key words or short phrases in the statement that are most helpful. This will highlight each word you select. If there is nothing you find helpful in the statement, please click to move forward to the next screen

Label option 1

This product has not been heat-treated and may therefore contain organisms harmful to health.

The Food Standards Agency strongly advises that it should not be consumed by **children, pregnant women** or **older people** or those who are unwell or have chronic illness.

1 Respondent asked to click on the word or words that they find helpful

2 Task repeated to identify which word or words they find confusing

The four proposed new labelling options

Please note that the second sentence stays the same in all four labels, so we only asked respondents to review this once



Label option 1*

This product has not been heat-treated and may therefore contain organisms harmful to health.

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.



Label option 2

This product has not been heat-treated and may contain organisms harmful to health, such as E.coli, Listeria and Salmonella.

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



Label option 3

This product may contain harmful bacteria such as E.coli, Listeria and Salmonella. It has not undergone heat-treatment that would destroy harmful bacteria.

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



Label option 4

This product may contain bacteria which cause serious human illness.

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

** Note that label option 1 is the existing label currently being used in Wales*

Organisms is a word that people find helpful, but confusing at the same time. It is considered helpful to know that raw milk/cream has not been heat-treated and may be harmful to health. The warning about who it should not be consumed by is considered helpful.



Label option 1

This product has **not been heat-treated** and may therefore **contain organisms harmful** to health.

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**.

Ransom Note exercise:



Helpful words/statements selected by more than 20% of the sample are highlighted in green



Confusing words/statements selected by more than 15% of the sample are highlighted in orange



Words that were considered both helpful and confusing are highlighted in light brown

Note: The larger the font size, the more frequently the word was selected

In the first sentence, specifically naming E-coli, Listeria and Salmonella is considered very helpful to respondents.
(Note, the second sentence stays the same for all four labels)






Label option 2

This product has **not been heat-treated** and may contain organisms **harmful to health**, such as **E.coli, Listeria** and **Salmonella**.

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**.

Please note: no words were found confusing by >15% of respondents

Ransom Note exercise:

-  Helpful words/statements selected by more than 20% of the sample are highlighted in green
-  Confusing words/statements selected by more than 15% of the sample are highlighted in orange
-  Words that were considered both helpful and confusing are highlighted in light brown

Note: The larger the font size, the more frequently the word was selected

In the first sentence, telling people that raw milk may contain harmful bacteria and specifically naming E-coli, Listeria and Salmonella is considered very helpful. *(Note, the second sentence stays the same for all four labels)*



Label option 3

This product **may contain harmful bacteria** such as **E.coli, Listeria** and **Salmonella**. It has **not undergone heat-treatment** that would **destroy harmful bacteria**.

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**.

Please note: no words were found confusing by >15% of respondents

Ransom Note exercise:



Helpful words/statements selected by more than 20% of the sample are highlighted in green



Confusing words/statements selected by more than 15% of the sample are highlighted in orange



Words that were considered both helpful and confusing are highlighted in light brown

Note: The larger the font size, the more frequently the word was selected

Q1014. We are now going to show you four proposed new labelling options for raw milk/cream products being sold in England and Northern Ireland/Wales. Using your mouse, please point and click on key words or short phrases that are most helpful/confusing; Base: All qualified respondents (1,333)

There are some words in label option 4 which are considered both confusing and helpful. While a high proportion of respondents find the phrase 'serious human illness' confusing, a similar proportion find this helpful. *(Note, the second sentence stays the same for all four labels)*






Label option 4

This product **may contain bacteria** which cause **serious human illness**.

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**.

Ransom Note exercise:

-  Helpful words/statements selected by more than 20% of the sample are highlighted in green
-  Confusing words/statements selected by more than 15% of the sample are highlighted in orange
-  Words that were considered both helpful and confusing are highlighted in light brown

Note: The larger the font size, the more frequently the word was selected

The labelling options that people in England and Northern Ireland prefer are labelling options 2 and 3 (the ones containing most detail and specifically naming the harmful bacteria).

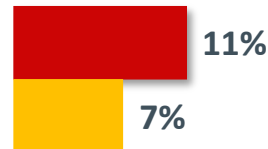
Preferred labelling option (England and Northern Ireland)

Combined score –
England & NI

11%

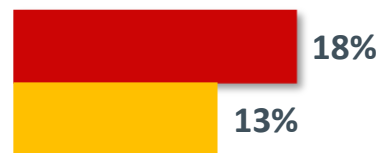
[EXISTING LABELLING IN ENGLAND AND NORTHERN IRELAND]

This product has not been heat treated and may therefore contain organisms harmful to health



This product has not been heat-treated and may therefore contain organisms harmful to health.

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



18%



This product has not been heat-treated and may contain organisms harmful to health, such as E.coli, Listeria and Salmonella.

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



27%



This product may contain harmful bacteria such as E.coli, Listeria and Salmonella. It has not undergone heat-treatment that would destroy harmful bacteria.

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



30%



This product may contain bacteria which cause serious human illness.

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



14%

England
N. Ireland



Likewise in Wales, the preferred labelling option is label 3, followed by label 2.

Preferred labelling option (Wales)



This product has not been heat-treated and may therefore contain organisms harmful to health.

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*

22%



This product has not been heat-treated and may contain organisms harmful to health, such as E.coli, Listeria and Salmonella.

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

27%



This product may contain harmful bacteria such as E.coli, Listeria and Salmonella. It has not undergone heat-treatment that would destroy harmful bacteria.

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

36%



This product may contain bacteria which cause serious human illness.

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

15%

** Note that label option 1 is the existing label currently being used in Wales*



Label Option 1 – preferred by 18% of people in England and Northern Ireland and 22% of people in Wales

Annex 4: presentation - Raw Milk report

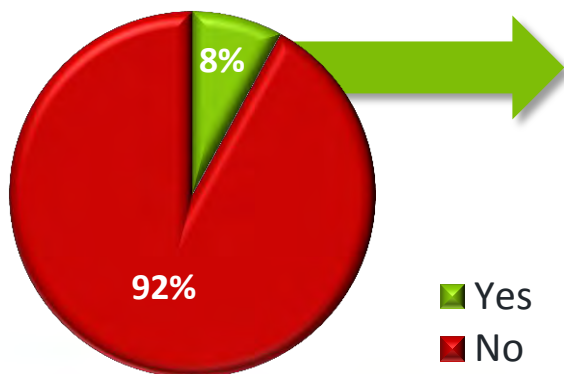


Why do you like this label?

(top-5 reasons shown)



Is there anything you feel is missing?



What do you feel is missing?



Q1030. Why do you say that?

Q1035. Is there anything that you feel is missing from this label?

Q1040. What do you feel is missing from the labelling?

Base: All qualified respondents saying label 1 (229)



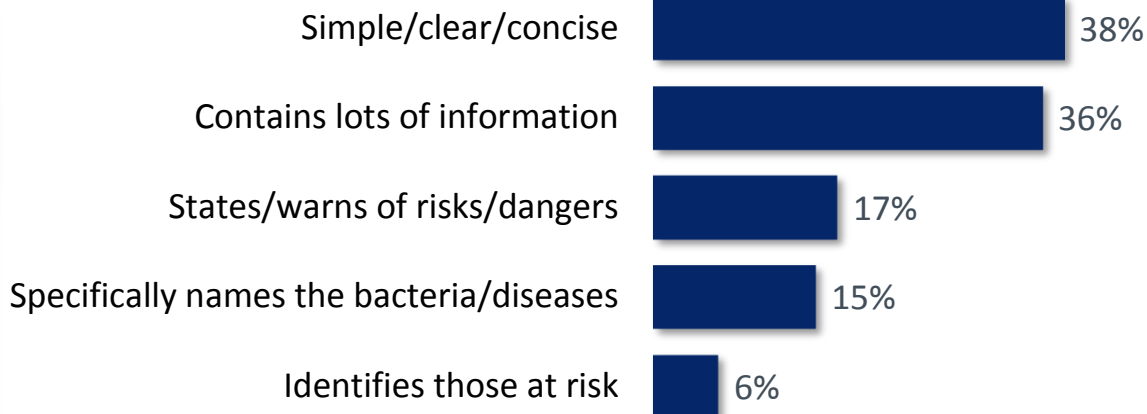
Label Option 2 – preferred by 27% of people in England and Northern Ireland and 27% of people in Wales

Annex 4: presentation - Raw Milk report

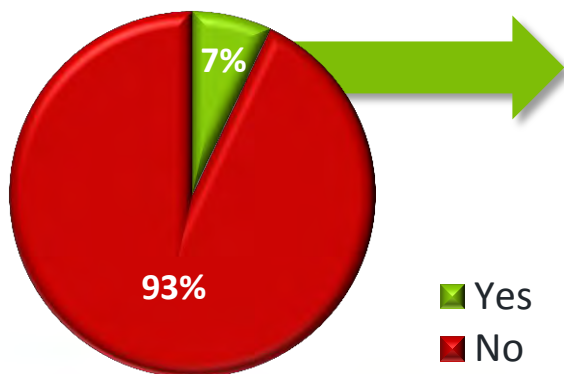


Why do you like this label?

(top-5 reasons shown)



Is there anything you feel is missing?



What do you feel is missing?



Q1030. Why do you say that? Q1035. Is there anything that you feel is missing from this label?

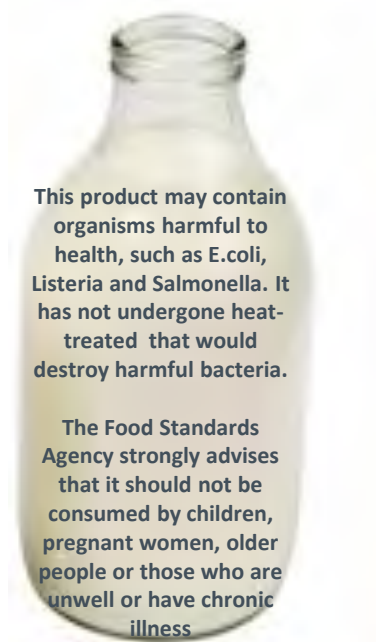
Q1040. What do you feel is missing from the labelling?

Base: All qualified respondents saying label 2 (362)



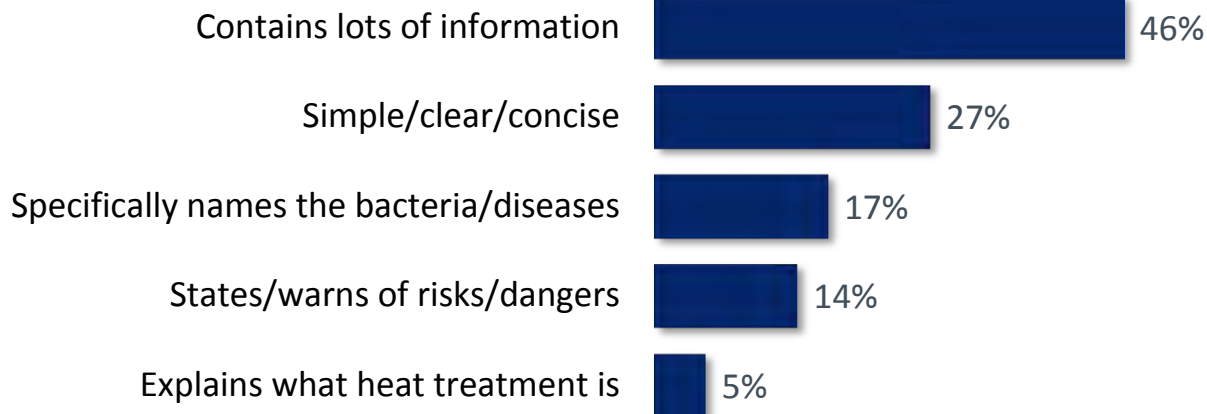
Label Option 3 – preferred by 30% of people in England and Northern Ireland and 36% of people in Wales

Annex 4: presentation - Raw Milk report

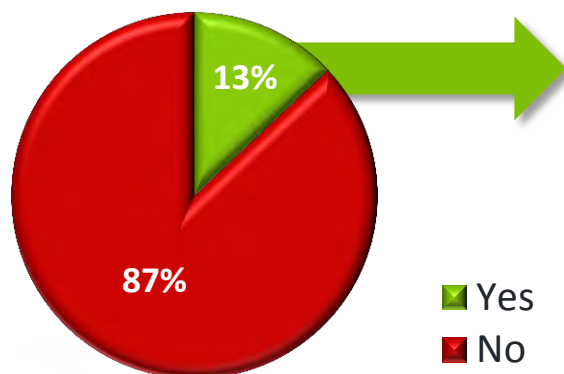


Why do you like this label?

(top-5 reasons shown)



Is there anything you feel is missing?



What do you feel is missing?



Q1030. Why do you say that? Q1035. Is there anything that you feel is missing from this label?

Q1040. What do you feel is missing from the labelling?

Base: All qualified respondents saying label 3 (433)



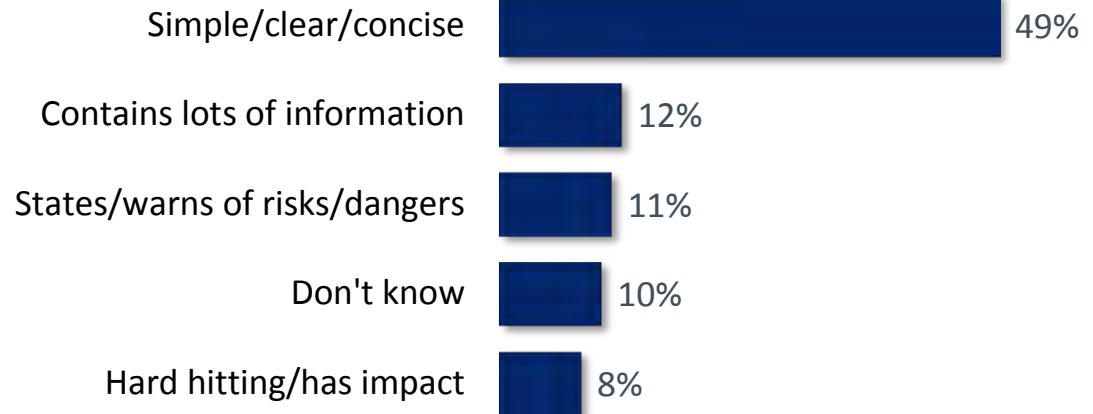
Label Option 4 – preferred by 14% of people in England and Northern Ireland and 15% of people in Wales

Annex 4: presentation - Raw Milk report

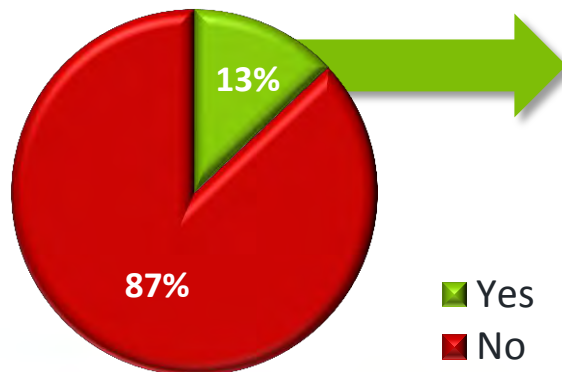


Why do you like this label?

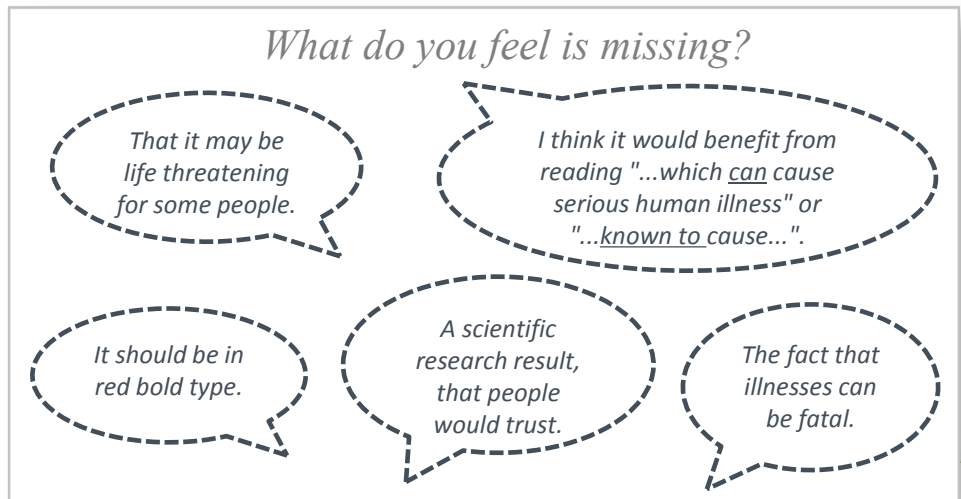
(top-5 reasons shown)



Is there anything you feel is missing?



What do you feel is missing?



Q1030. Why do you say that? Q1035. Is there anything that you feel is missing from this label?

Q1040. What do you feel is missing from the labelling?

Base: All qualified respondents saying label 4 (188)

What do people think is the best scenario moving forwards with regards to raw milk/cream



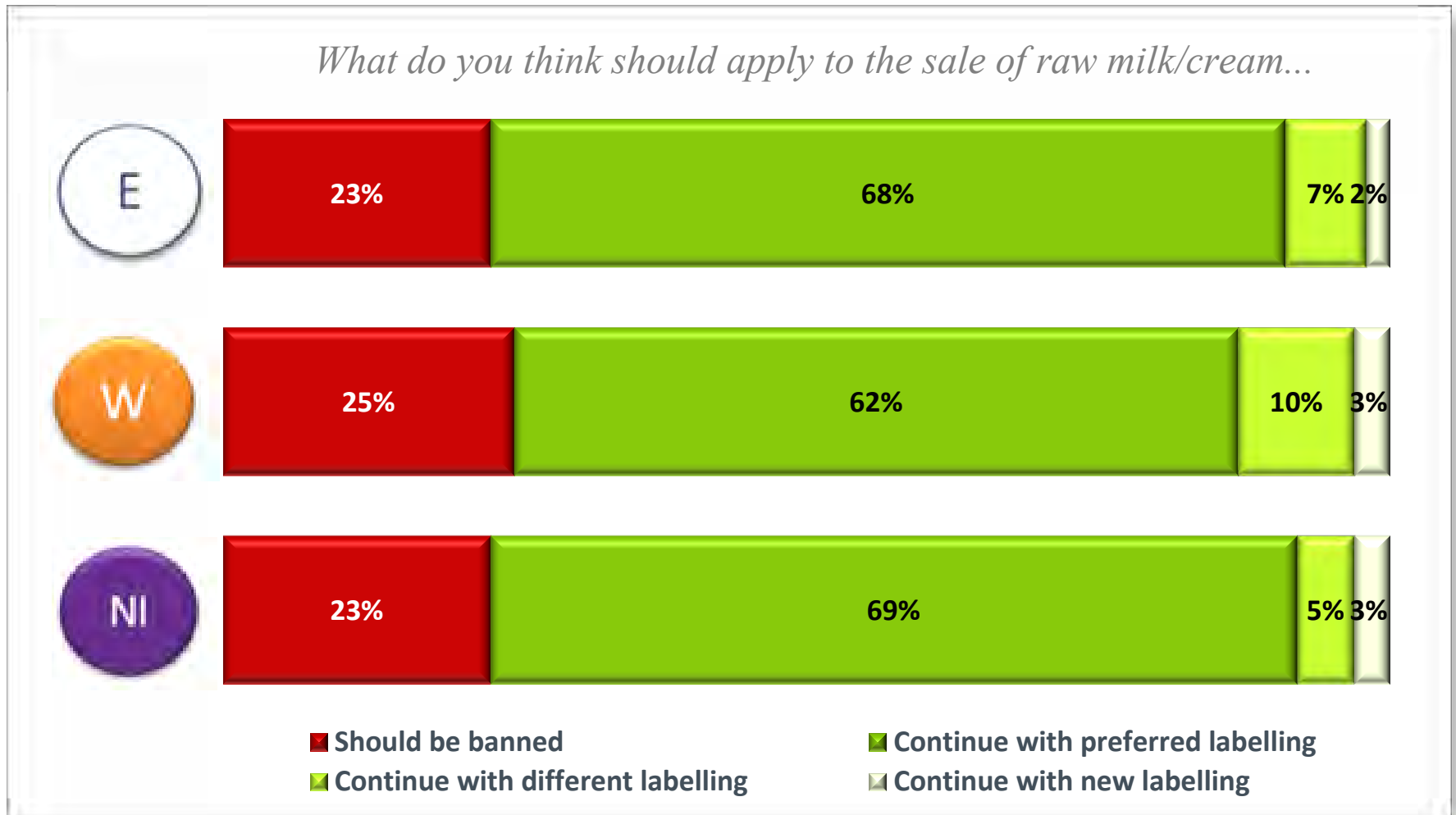
Just over two-thirds (68%) believe that the sale of Raw Milk/Cream should continue, but with one of the new labelling options. Just under a quarter (23%) believe the sale should be banned.



Q1105. In the future, which of the following options do you think should apply to the sale of raw milk and cream?

Base: All qualified respondents (1,333)

By country, there are only small differences...



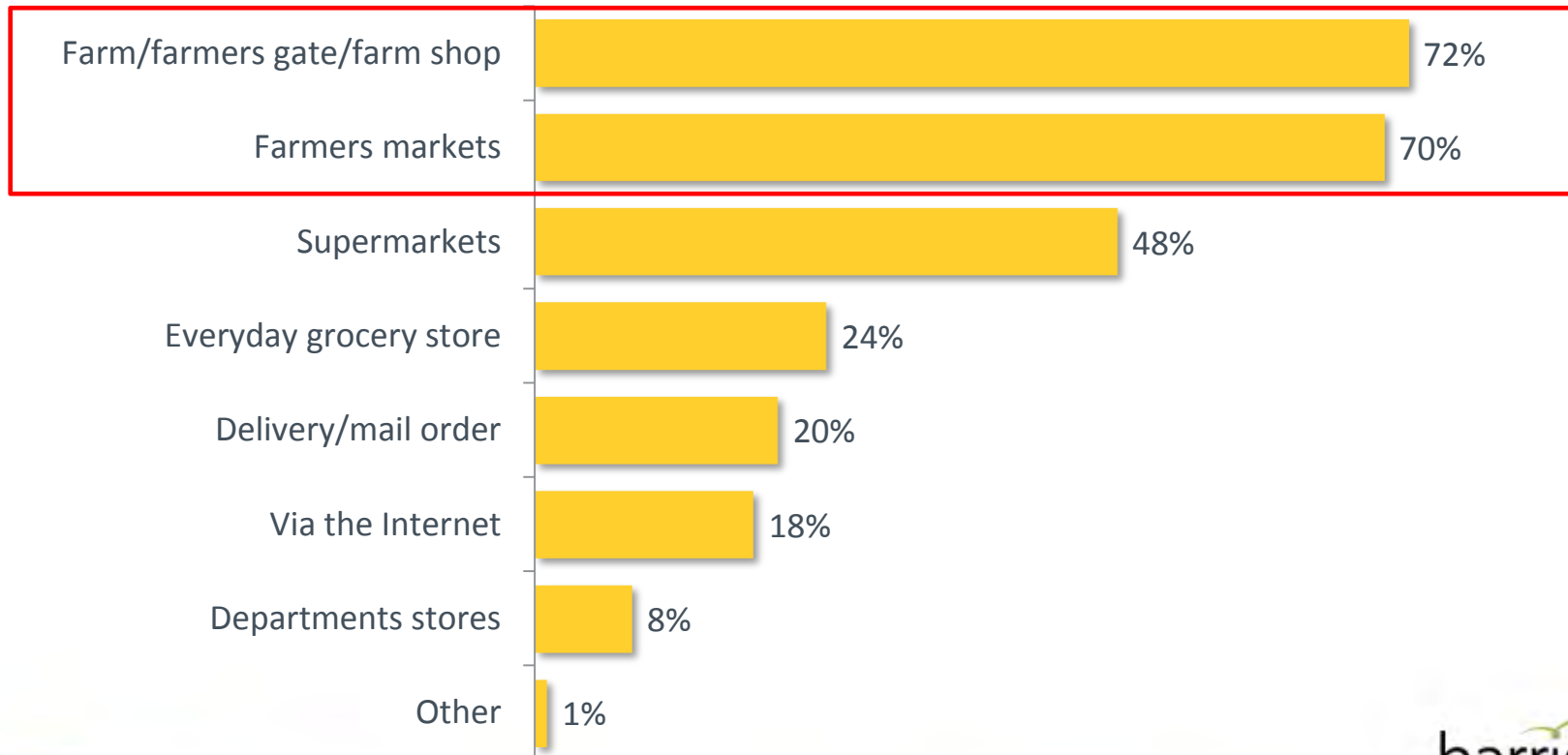
Q1105. In the future, which of the following options do you think should apply to the sale of raw milk and cream?

Base: All qualified respondents , England (930), Wales (202), Northern Ireland (201)

Amongst those who do think raw milk should be available for sale, the majority think it should be available in Farms/Farm shops/Farmers markets. After this, around half (48%) think it should be available in Supermarkets and less think it should be available via other channels.

Where Raw Milk/Cream should be available for sale.....

(amongst those who think it should be available for sale)



Q1100. Where do you think raw milk and cream should be available for sale?

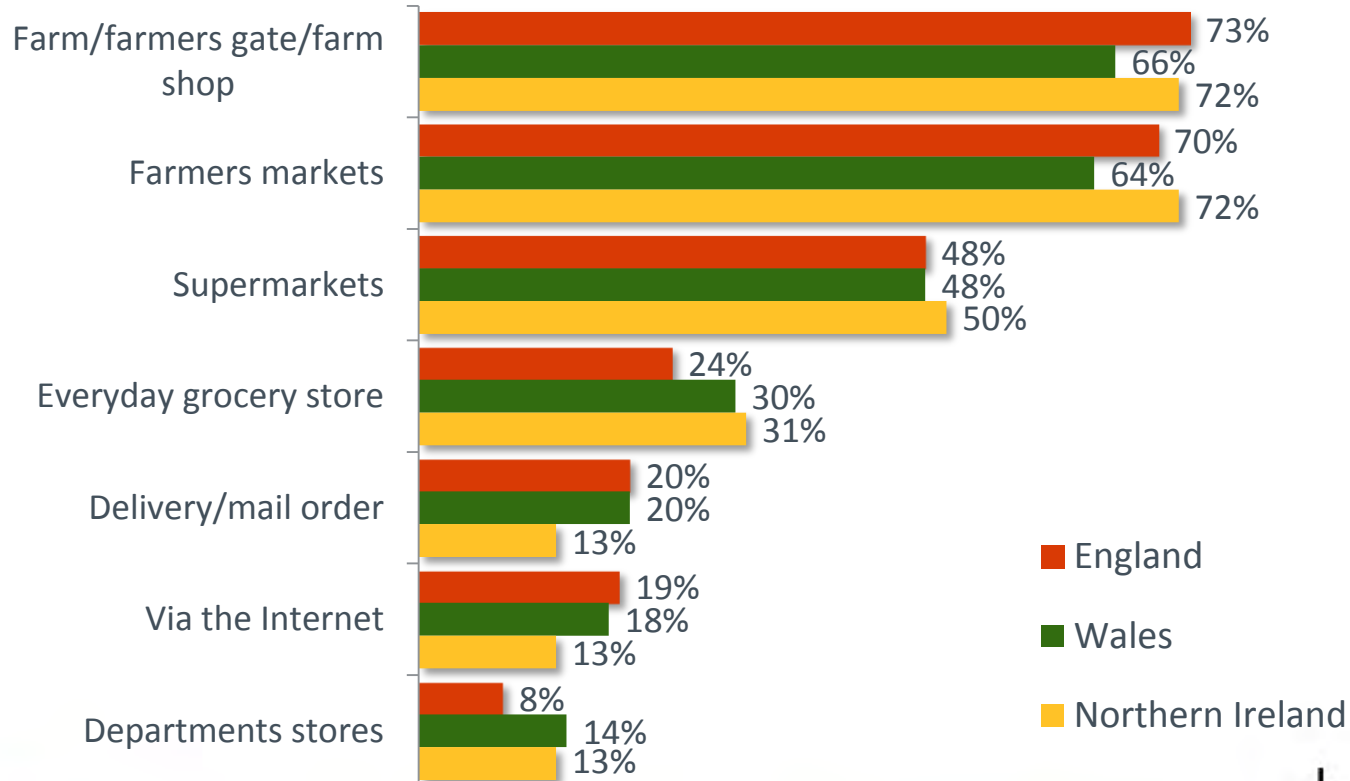
List of prompted responses provided as above.

Base: All qualified respondents who think raw milk should be available for sale (690)

People in Wales are slightly less likely to think that raw milk/cream should be available in farms/farm shops/farmers markets. They are just as likely to think it should be available through other retail channels though.

Where Raw Milk/Cream should be available for sale.....

(amongst those who think it should be available for sale)



Q1100. Where do you think raw milk and cream should be available for sale?

List of prompted responses provided as above.

Base: All qualified respondents who think raw milk should be available for sale, England (930), Wales (202), Northern Ireland (201)

Conclusions

Amongst consumers of milk and cream products in the UK (excluding Scotland), what do people understand by Raw Milk/Cream and what are their experiences of it?

- Most do understand what is meant by 'Raw Milk/Cream'
 - 72% understood before prompting and this increased to 81% when prompted
 - However, younger people are much less likely to understand what is meant by raw milk/cream (and also those in Wales are a little less likely)

“ I don't know what it is ”
Aged 18



- Despite most understanding what raw milk/cream is, only just over half (55%) were aware that some people choose to consume raw milk/cream
- 3% of milk consumers are currently buying/consuming Raw Milk or Cream.

Are milk and cream consumers interested in consuming Raw Milk/ Cream?

- Just under a fifth (19%) express some level of interest in raw milk/cream. However, only a very low proportion (3%) are 'very interested'



- Curiosity is the main reason for interest
- Those with higher incomes and higher education levels would be much more likely to express an interest in raw milk/cream

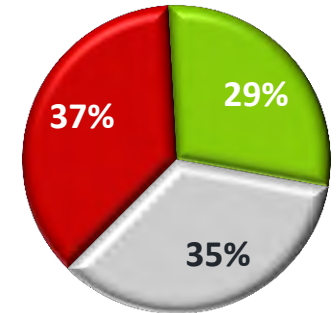
“ I just like to try different things ”
Aged 51

- 58% are not interested in the idea of Raw Milk/Cream, with three-quarters (75%) of these citing health risks as the main reason.

How do people balance freedom of choice versus government protection in relation to Raw Milk/Cream?



- When asked about the importance of government protection versus freedom of choice with regards to Raw Milk/Cream, the public are split – 29% think freedom of choice is more important, 37% think government protection is more important and the remainder (35%) just are not sure!
 - There were some demographic differences – those in higher education groups were much more likely to agree that freedom of choice was important, as were men.



- Government protection
- Freedom of choice
- No preference

- When we asked people to rate the importance of a selection of benefits and drawbacks associated with Raw Milk/Cream, perceptions of the drawbacks were considered much more important than the benefits.

What do people think would be the best case scenario for Raw Milk/Cream moving forwards?



- A minority – almost one-in-four (23%) think the sale of Raw Milk/Cream should be banned.
- The remainder (just over three-quarters – 77%) think it should continue
 - No notable differences by country

- Amongst those who think it should be available for sale, while a high proportion think it should be available on farms/at farmers markets/in farm shops, fewer think it should be available through other channels (with Internet, mail order/delivery and department stores scoring particularly low).

What do people feel about the current labelling of Raw Milk/Cream?

Existing labelling

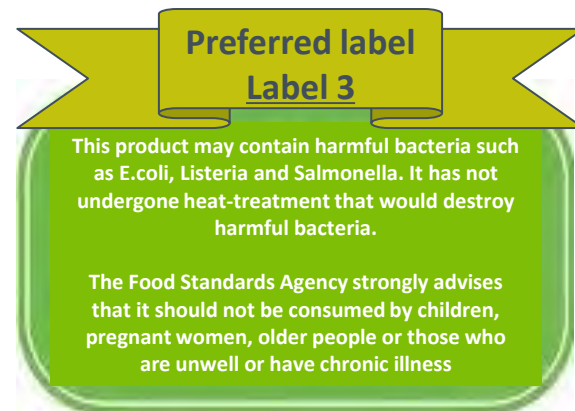


- Two-thirds (66%) of pasteurised milk/cream consumers in England feel the current labelling provides enough information about the risks.
 - Slightly lower in Northern Ireland (56%)

....this indicates there does seem to be room for improvement
- In Wales, where the existing labelling is more detailed, three-quarters (75%) think that it does provide enough information.
- The main criticisms of both existing labels are that they do not clearly communicate what the health risks are, or provide detail regarding the specific bacteria/illness/infection.

What labelling do people think should be used going forwards?

- Current milk/cream consumers in England like labels 2 & 3 best, while those in Northern Ireland and Wales clearly favour label 3.
- Labels 2 & 3 contain most detail and it is this that people appear to like...the Ransom Note exercise demonstrated that people find it helpful when the actual bacteria that might be contained in Raw Milk/Cream is named.
- Label 4, on the other hand, appears to contain too much ambiguity, particularly around 'serious human illness'.
- Our recommendation would be to use label 3 going forwards, as it contains the level of detail that people are looking for to make an informed decision and it sits marginally ahead of label 2 overall (but notably ahead in Northern Ireland and Wales).



Appendix 1: Consumers of Raw Milk

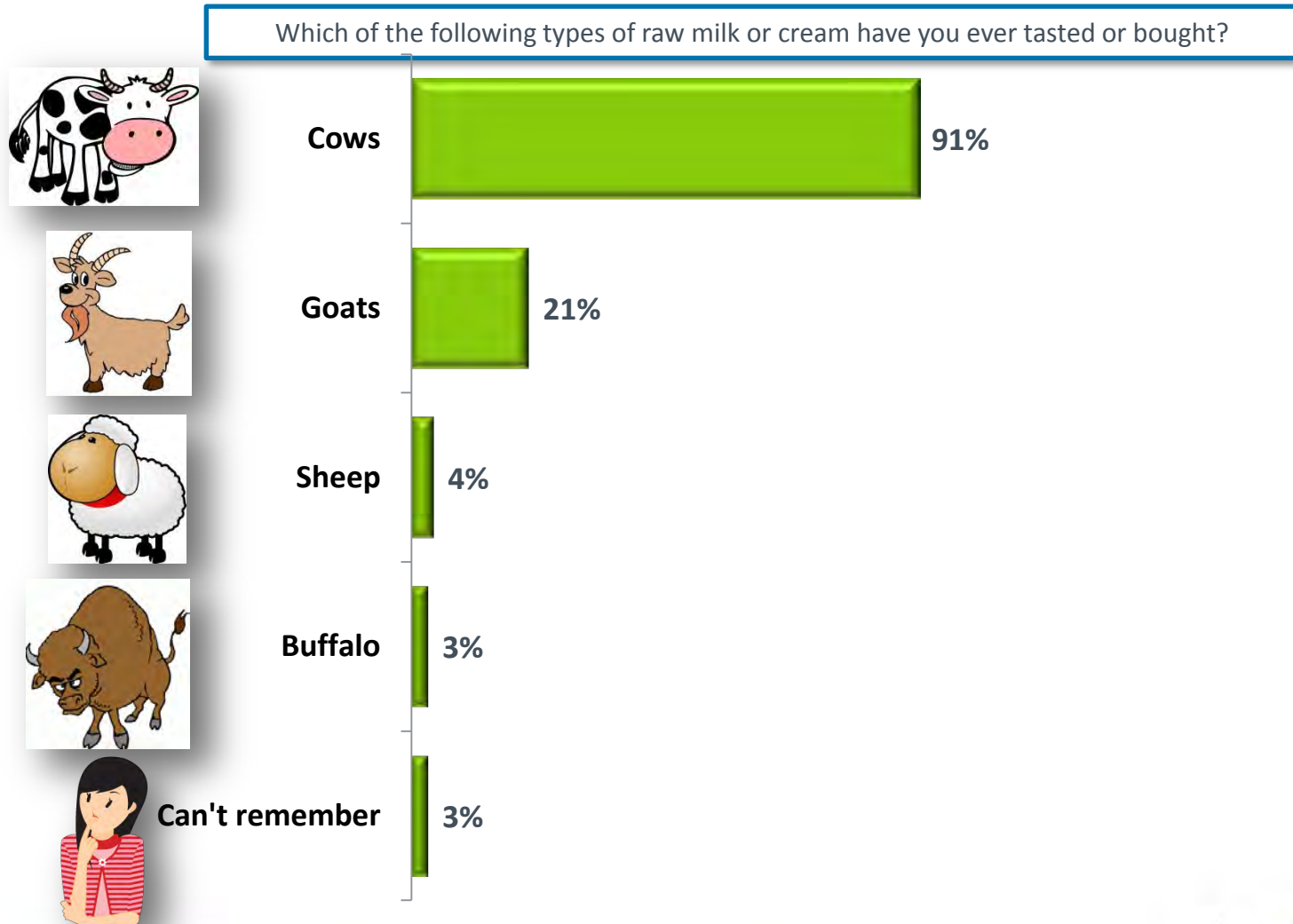
The following slides focus on the responses of people who have ever tasted raw milk/cream (459 people).

Some questions only look at the 3% of people (29 individuals) who currently buy/consume raw milk. The 29 people is for indicative purposes only and is not statistically robust – these people were found naturally as part of the random sampling process.

The 3% that report consuming raw milk/cream is 3% of all milk/cream consumers. In this study non-milk/cream consumers were excluded. If non-milk/cream consumers had been included, the proportion of raw milk drinkers would be less than 3%.

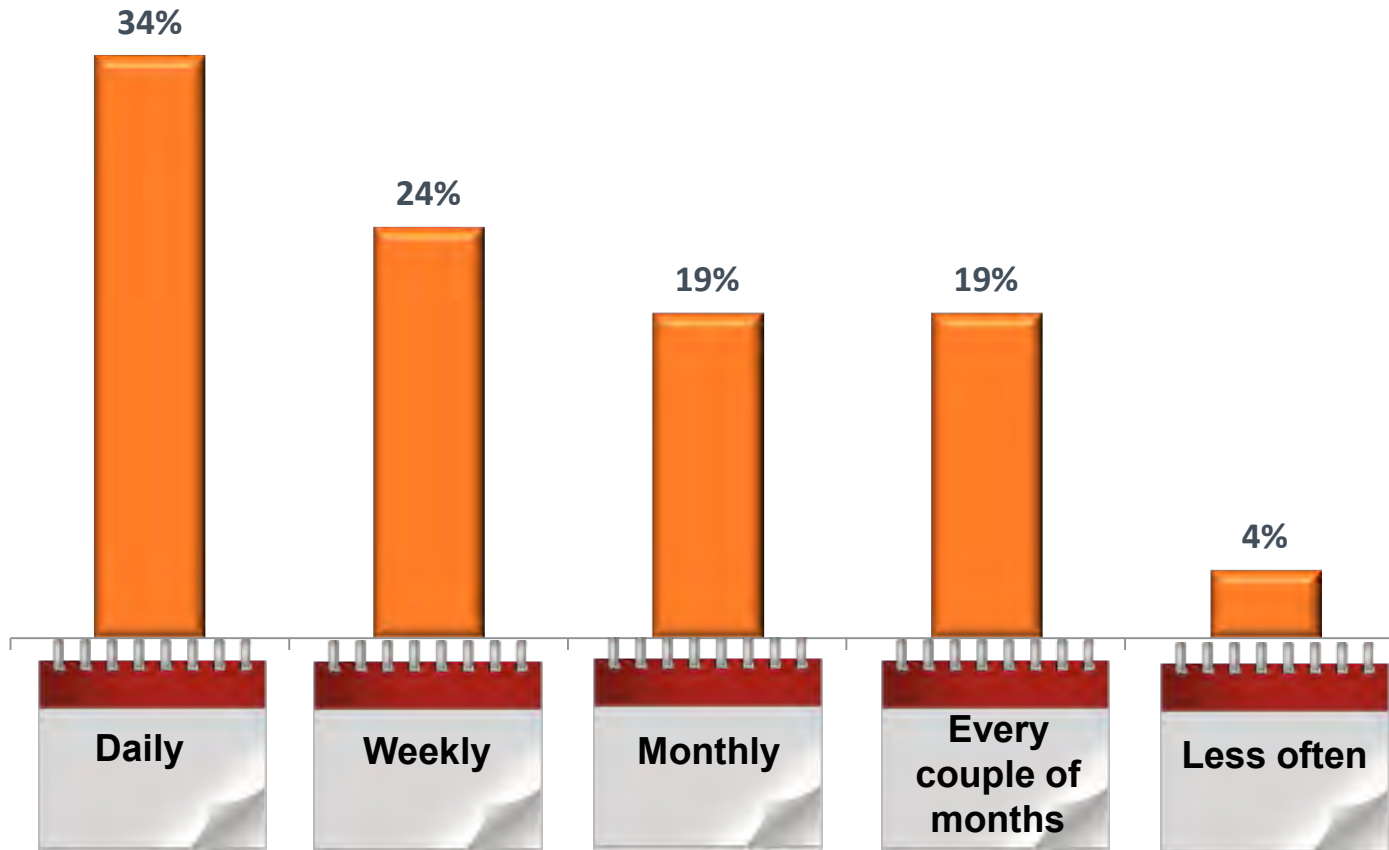


Amongst people who have ever tasted or bought raw milk/cream, cow's milk is the most popular having been tasted/ bought by 91%



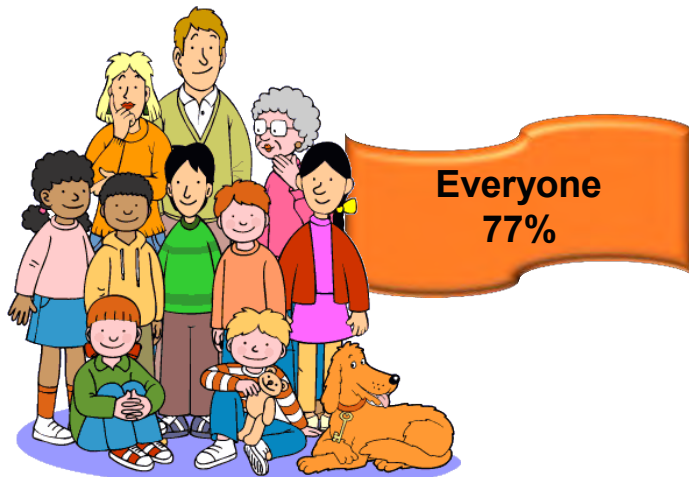
Those currently buying/consuming Raw Milk/Cream do so on a regular basis

Which of the following best describe how often you buy/drink raw milk or cream?

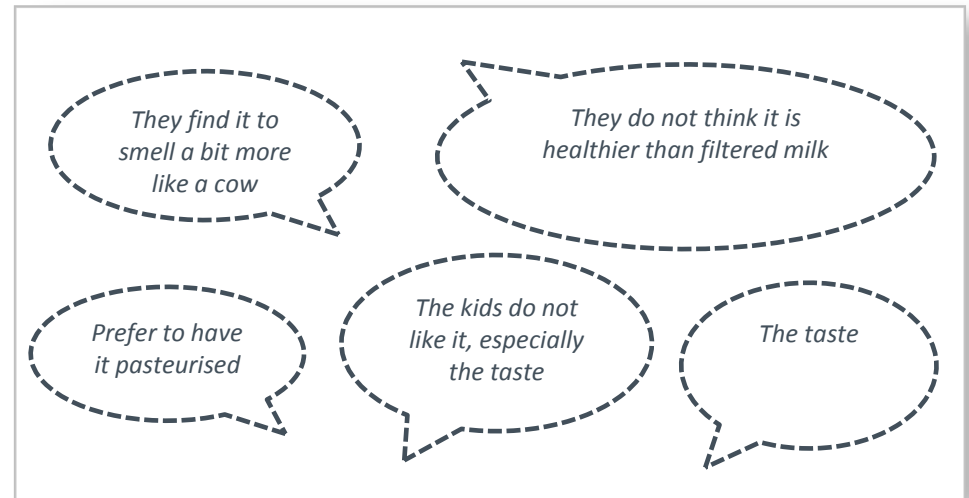


Those consuming raw milk/cream are much more likely to have everyone in their household also consuming rather than only some.

Who in your household consumes raw milk and cream?

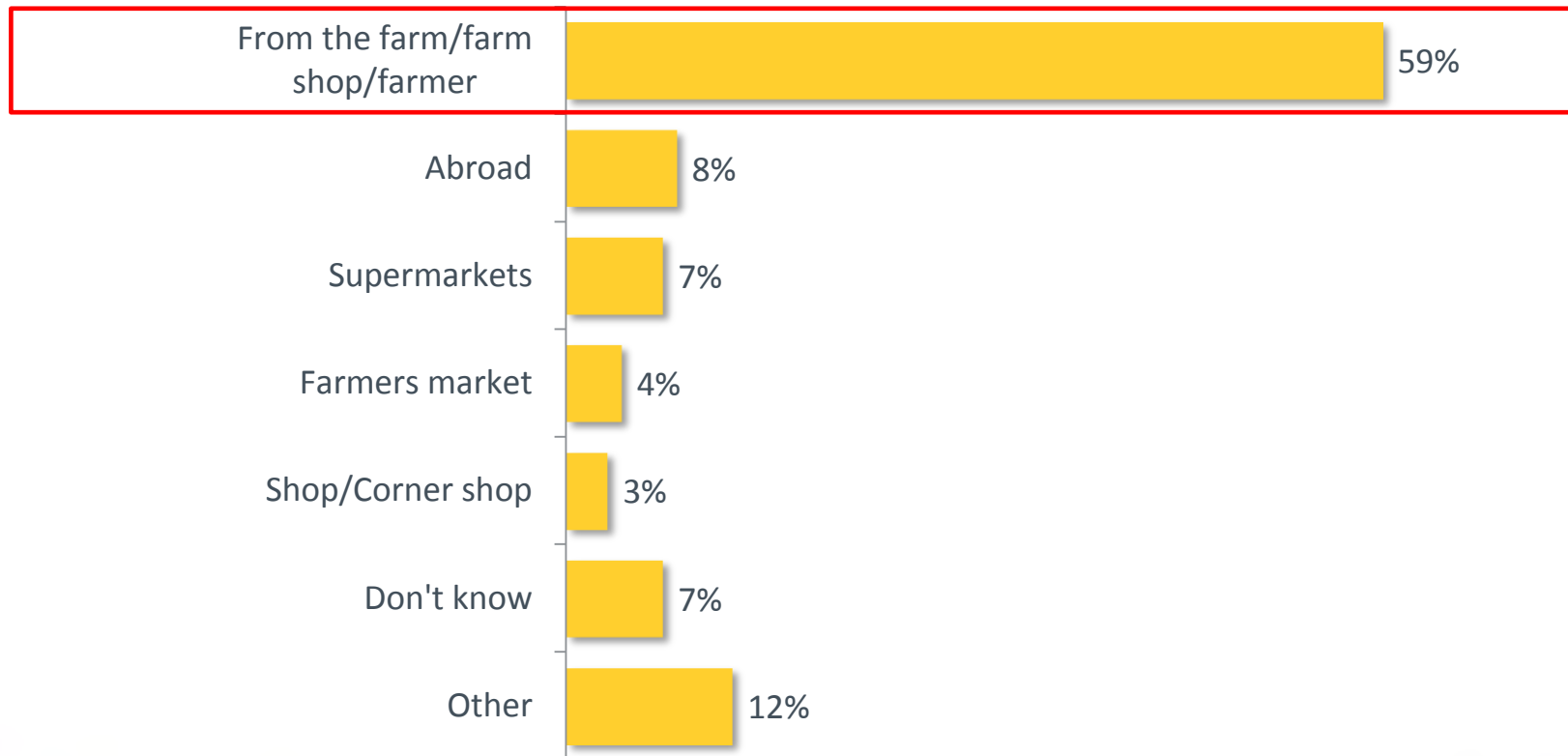


For what reason do some people in your household not consume raw milk and/or cream?



Three out of five (61%) purchased raw milk/cream from a farm/farm shop/farmer.

Where have you bought raw milk or cream from?

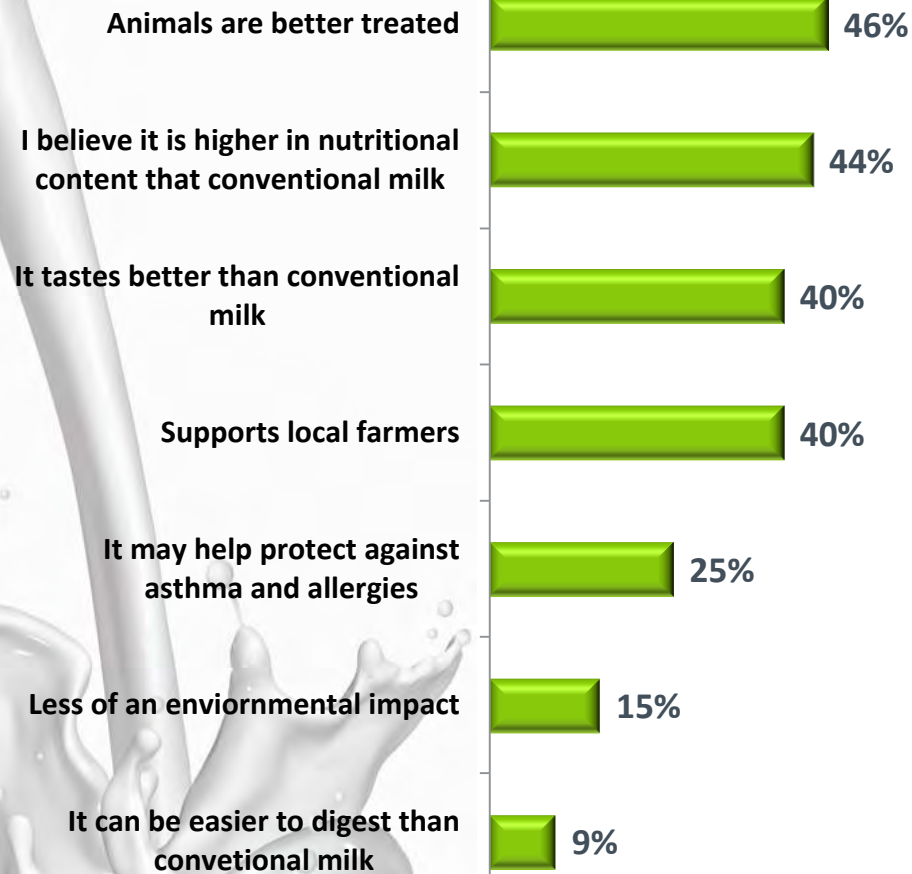


Q832. Where have you bought raw milk or cream from?

Base: All qualified respondents who have ever bought raw milk/raw cream (144)

The treatment of animal welfare is the highest purchase driver, followed by the nutritional content.

For what reason(s) do you buy/drink raw milk or cream?



Appendix 2:

Details about respondents

Detailed demographics...

Working Status	
Working full time	49%
Working part time	12%
Housewife / husband	3%
Unemployed	5%
Retired	23%
Full time education	3%
Disabled	6%

Education	
Still studying	2%
GCSE/O Level/CSE	23%
Vocational	10%
A Level / Scottish Higher	20%
Bachelor degree or equivalent	28%
Masters/PhD or equivalent	8%
None/Other	9%

Household Income	
Less than £13,500	19%
£13,500 - £24,999	26%
£25,000 - £39,999	24%
£40,000 - £74,999	15%
£75,000 - £99,999	2%
£100,000 +	2%

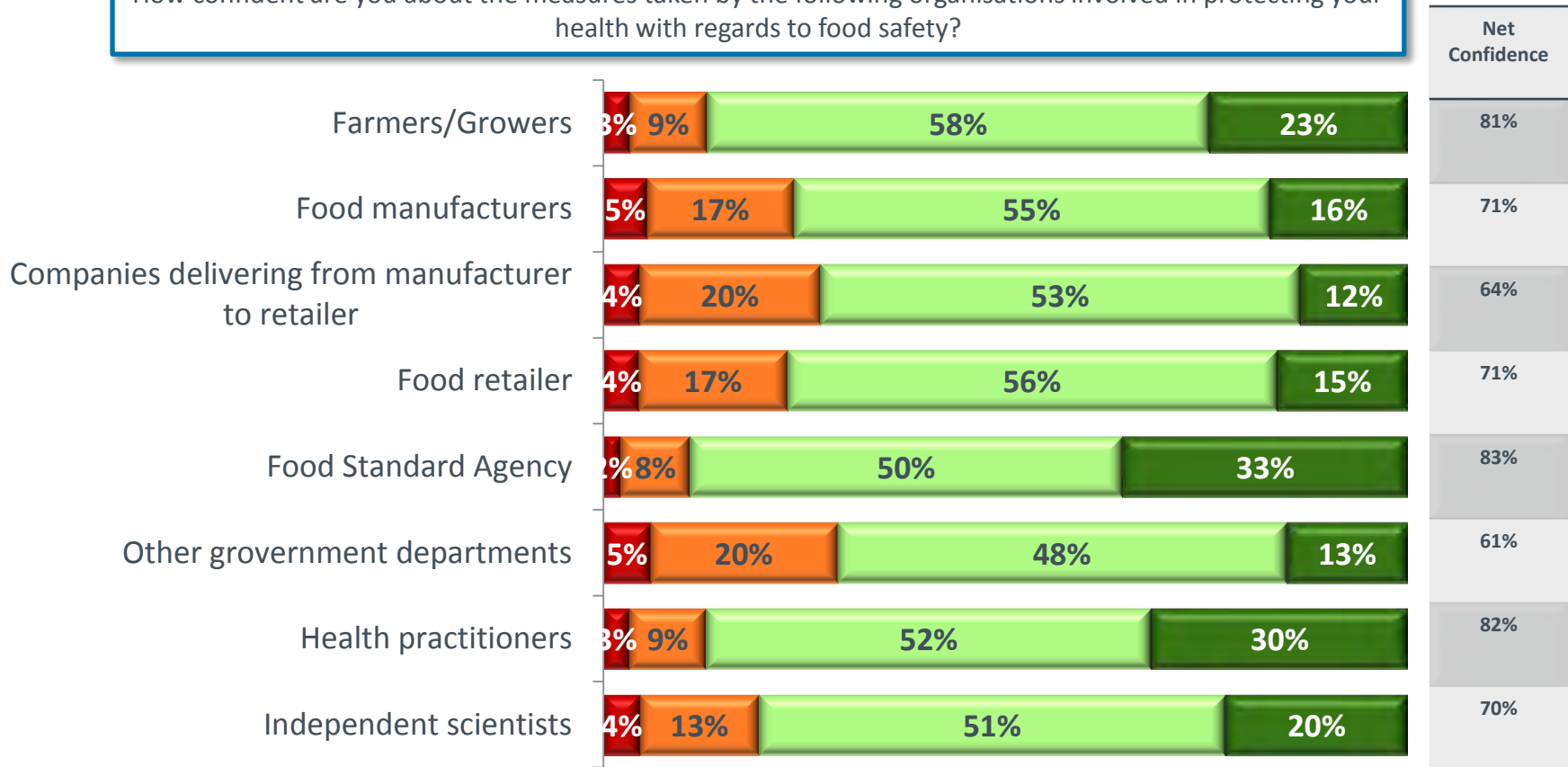
Further detail on our sample...

Dietary requirements	
Vegetarian	6%
Vegan	1%
Pescatarian	4%
No dietary requirements	88%

Food intolerances	
Milk/lactose	3%
Wheat/gluten	3%
Fish/seafood	3%
Nuts	2%
Other	4%
No food intolerances	88%

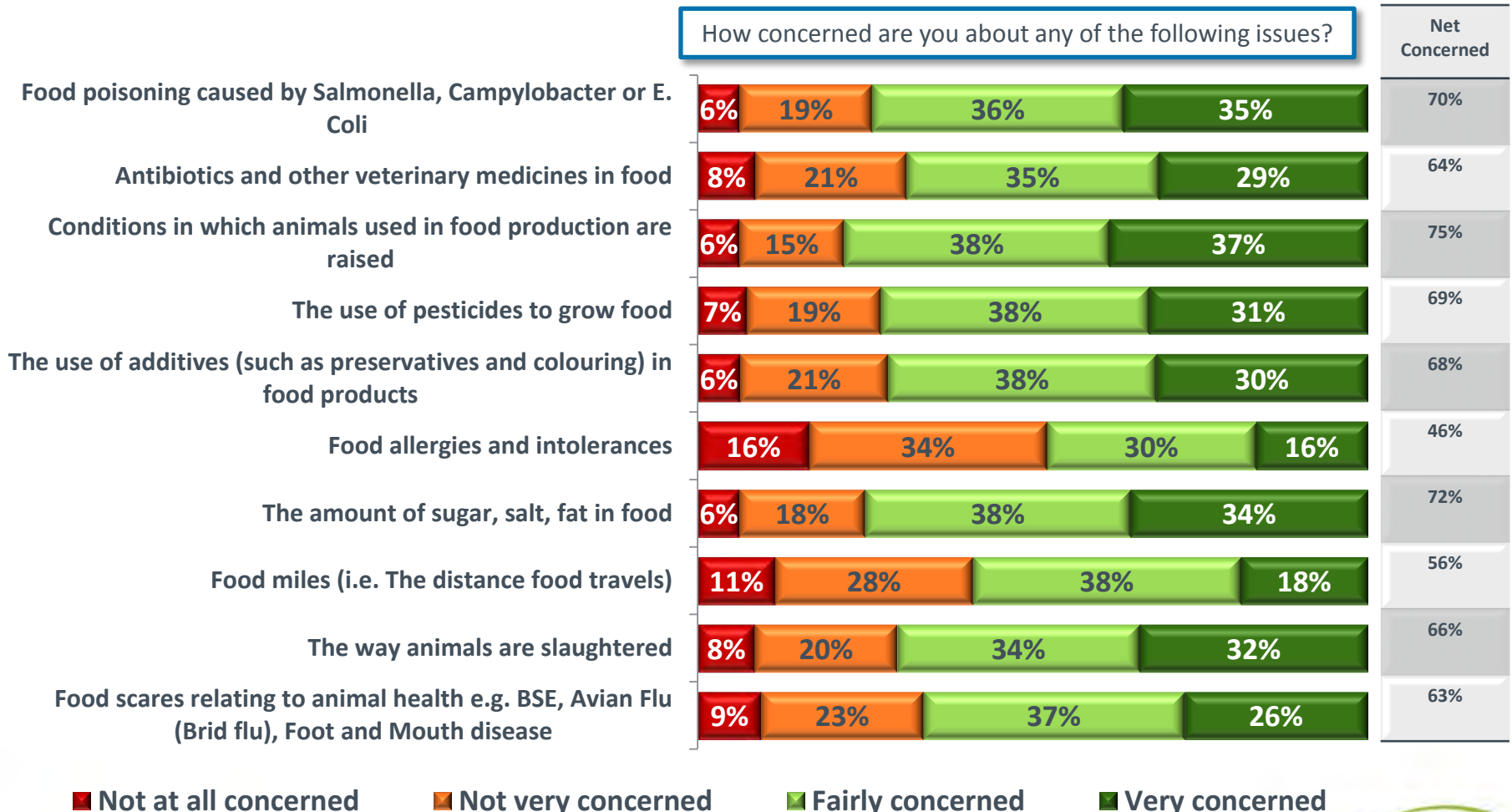
FSA comes out on top for food safety, with a confidence rating of 83% closely followed by health practitioners and farmers/growers.

How confident are you about the measures taken by the following organisations involved in protecting your health with regards to food safety?



■ Not at all confident
 ■ Not very confident
 ■ Fairly confident
 ■ Very confident

Animal welfare is the issue raising most concern (75%) and food allergies and intolerances holds the least amount of concern (46%).



Q705. How concerned are you about the following issues?
 Base: All qualified respondents (1,333)

Around a third (35%) sometimes buy organic and more people never buy organic (22%) than buy it when they can (13%).

How frequently do you buy organic food and drink products?



Annex 5: Calculation of an indicative estimate of the cost of disease associated with RDM

1. We currently do not have sufficient UK data to be able to discern exactly which factors underlie the decline in illness associated with RDM that we have seen since the late 1980s. There is an argument that restricting the sales of raw drinking milk could reduce the risk of an outbreak associated with RDM, and some data from the US suggests that this might be the case (see paragraph 29). If we assume that this is the case, we can compare data from the period before, to the period after, the introduction of sales controls. Sales restrictions were introduced in England and Wales in 1985.
2. In order to calculate an indicative estimate of the reduction in cost from illness associated with RDM after controls were introduced, we have used data published by the CDSC on outbreaks of foodborne disease associated with raw drinking milk in England and Wales between 1980 and 1989. This data, which is summarised in Table A below, shows that, for the period of 1980 to 1984, the average number of outbreaks per annum was 16, the average number of affected individuals per annum was 361, and the average number of deaths per annum was 2. For the period 1985 to 1989 the average number of outbreaks per annum was 8, the average number of affected individuals per annum was 243, and the average number of deaths per annum was 0.3.
3. For these periods we do not have data on the number of hospitalisations from outbreaks associated with RDM, but we have looked at data from the Advisory Committee on Microbiological Safety of Foods between 1992 and 2002, and this data shows an average hospitalisation rate of 0.26. Multiplying the hospitalisation rate by the average per annum number of affected individuals for each time period then gives us an estimate of the average per annum number of hospitalised individuals. This gives a value of 95 for the period between 1980 and 1984, and a value of 64 for the time period between 1985 and 1989. Table 1 below shows these numbers.

Table 1: Outbreak data on disease associated with RDM, England and Wales (1980 to 1989)

Period 1980-1984				
	No. outbreaks	No. affected	No. deaths	No. hospitalisations
Total	80	1,803	11	473
av p.a.	16	361	2	95
Period 1985-89				
	No. outbreaks	No. affected	No. deaths	No. hospitalisations
Total	32	972	1	255
av p.a.	8	243	0.3	64

4. Health and Safety Executive (HSE) has published estimates on the willingness to pay (WTP)⁴ for preventing illness from foodborne disease of different severity. HSE also used the DfT value to prevent fatalities to calculate a measure of the WTP to prevent death from foodborne illness. Table 2 below shows these estimates, uprated to 2013 prices.

Table 2: Willingness to prevent foodborne disease of different severities

Value to prevent illness	£2013
Illness up to 7 days	210
Illness longer than 7 days	2,657
Permanent incapacity	256,077
Value to prevent death	1,631,365

⁴ Quoted in "Full Regulatory Impact Assessment - Proposals to Consolidate EU Food Hygiene Regulation", <http://www.food.gov.uk/multimedia/pdfs/euhygiene2004riafull.pdf>

5. We have used these values to calculate the cost of an outbreak associated with RDM for the two time periods by assuming that mild illness (up to 7 days) is the number of affected individuals minus the number of deaths, minus the number of hospitalisations. We have assumed that severe illness (longer than 7 days) equals the number of hospitalisations. We do not have any numbers on the number of individuals that might have experienced permanent incapacity (for example, after contracting HUS). The data gives us the number of deaths for the time periods.
6. Multiplying the WTP estimates in Table 2 with the corresponding numbers in Table 1 then gives an average per annum cost of outbreaks associated with RDM in the period between 1980 and 1984 of £3.9m, and in the period between 1985 and 1989 of £614k. This represents an average per annum cost saving of £3.3m (84%).

Acorn Farm
Active Health Clinics
ADAS
Aeron Jersey Dairy Products
Albany Homes International Ltd
Aldi stores Ltd
Aller Farm
Alliance for Natural Health International
Anaphylaxis Campaign
Anaphylaxis Campaign/Food Allergy Support Ltd
ARC Healthcare
Arla Foods
Association of Convenience Stores
Association of Port Health
Association of Public Analysts
Association of Unpasteurised Milk Producers and Consumers
Baby Milk Action
Ballyrashane CA and DS Ltd
Bassetlaw District Council
Belfast Health and Social Care Trust
Blackburne and Hayes
Boydells Dairy Farm
Bridgend Creamery - Dairy Farmers of Britain
British Angora Goat Society
British Bison Association
British Cattle Veterinary Association
British Cheese Board
British Dietetic Association
British Essence Manufacturers Association
British Frozen Food Federation
British Goat Society
British Hospitality Association
British Importers Association
British Medical Association
British Milk Sheep Society
British Nutritional Foundation
British Pig Association
British Retail Consortium
British Soft Drinks Association
British Specialist Nutrition Association Ltd
British Veterinary Association
Brookes Wye Valley Dairy Co Ltd
Buffalo Dairy Limited
Burger King
Campaign for Real Milk UK
Campden BRI
Charlemar

Chartered Institute of Environmental Health
Chilled Food Association
College of Agricultural Food and Rural Enterprise
CLG and J Wadman and Sons
Countryside Alliance
Cross Hall Farm
CWF Hughes and Son
Dairy Co
Dairy Crest
Dairy Crest Group plc.
Dairy Development Centre
Dairy Produce Packers Ltd
Dairy UK
Dairy UK Scotland
Dansco Dairy Products Ltd
Dee Dairy Services
Defra
Department of Health
DJ, MJ, and PW House
Dreames Farm
Duchy of Cornwall
E and D E Horn
E and S Carr
Ellie's Dairy
Emma's Organic Dairy Farm
European Dairy Association
European Food Law Association UK
Federation of Small Businesses
Feld Fere Produce
First Milk Limited
Food Alliance
Food and Drink Federation
Food Commission
Food Standards Agency - Advisory Committee on the Microbiological Safety of Food
Food Standards Agency - Better Regulation Advisory Group
Food Standards Agency - Consumer Advisory Panel
Foulgers Dairy
Fred W Read
GD and M Rogers and Sons
Goat Advisory Bureau
Goat Dairy Trade Association
Goat Veterinary Society
Goat's Milk Processors Federation
Golden Acre Dairy Foods Ltd
Half Moon Farm
Hargreaves Fold Farms
Heart of Mersey

Henchclose Organic Farm Produce
HF Capon and Son
High Farm
Hinton Farm Ltd Red Barn Farm Shop
HK Oultram and Co
Hollypark Organics
Hook and Son
HorsePool Farm
HS Fletcher and Son
HUSH UK
Ice Cream Alliance
Ice Fresh Food
Imperial College
Institute of Food Science and Technology
Institute of Grocery Distribution
Institute of Refrigeration
Jacmar Dairy Goats
Jan P Cavill
JD Farms Ltd
J K Blackburn and Son (Buffers Coffee Shop)
John's Jerseys
JT and E Thornber
Kings College London
Little Acres Goat Products
Little Arthur Farm
London Farmers Markets
Long Clawson Dairy Limited
Loseley Dairy Ice Cream Ltd
Lowna Dairy Ltd
M Tyrrer
Malvern Cheesewrights
Marcassie Farm Partnership
Margarine and Spreads Association
Mario's Luxury Dairy Ice Cream Fecci's Ice Cream Ltd
Messrs Hughes
Middle Farm
Milk Link Limited
Ministry for Primary Industries in NZ
ML and JM Richardson and sons
Modbury Farm
Mount Pleasant Farm
Muller Dairy (UK) Limited
National Association of Health Stores Ltd
National Association of Master Bakers
National Cattle Association (Dairy)
National Consumer Council

National Consumer Federation
National Dairy Council
National Farmers' Markets Association (FARMA)
National Farmers Union
National Federation of Women's Institutes
National Sheep Association
NFU National Dairy Board
Norsworthy Dairy Goats
Pengoon Farm
Peteen Home Farm
Plas Wilkin
Provision Trade Federation
Public Health England
Public Health Scotland
Pure Body Balance
Quality Milk Producers Ltd
Queenbower Dairy
R and A Galbraith
R and LA Briggs
R C Cook and Co
Raw Living
RCGP Clinical Champion for Allergy
Red Tractor Assurance Dairy (formally ADF)
Royal Association of British Dairy Farmers
Scoriton Farm
Soil Association
Specialist Cheese Makers Association
St Georges Hospital
Storm Hall Farm
Stowford Manor Farm
Strathroy Dairy Ltd
Stilton Cheesemakers' Association
Sustain : the Alliance for better food and farming
SVA Ltd
T Parkinson, Cliftons Farm
TD Prince Beechenhill Farm
Tenant Farmers Association
The General Council and Register of Naturopathy
The Goodwood Estate Co.Ltd
The Nutrition Society
TMC Dairies NI Ltd
United Dairy Farmers Ltd
University College Cork
Trading Standards Institute
Tremedda Farm
University of Brunel
University of Cambridge

University College Cork
University of Leicester
University of London
University of Manchester
University of Manchester
University of Sussex
University of Southampton
Waitrose Limited
Wellies
Weston A Price
Which?
Windmill Dairy
Withybush Farm
Women's Food and Farming Union

Local Authority's in England

Individual consumers