ANNEX A

Title: **Impact Assessment for Amendments to the Labelling Provisions to Protect Vulnerable Consumers from Risks Associated with Consumption of Raw Drinking Milk** **IA No: FOOD0157** **Lead department or agency:** **FOOD STANDARDS AGENCY** **Other departments or agencies:**	Impact Assessment (IA)
	Date: July 2017
	Stage: Consultation
	Source of intervention: Domestic
	Type of measure: Secondary legislation
	Contact for enquiries: Solomon Okoruwa

Summary: Intervention and Options

RPC Opinion: GREEN

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANDCB on 2015 prices)	**In scope of One-In, Two-Out?**	**Measure qualifies as**
-£0.09	-£0.09	£0.01m	Yes	Zero Net Cost

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

Following a review of the controls on raw drinking milk (RDM) the FSA Board expressed a need to strengthen the requirements for the labelling of RDM in England and Northern Ireland in order to protect vulnerable groups (i.e. pregnant women, infants, children, the elderly and those with a weakened immune system). Government intervention is necessary to ensure that adequate controls are in place to protect vulnerable groups[1], through mandatory health labelling for milk from all species including buffalo milk. The market fails to deliver adequate protection because food business operators (FBOs) do not have sufficient incentives to communicate the full extent of the risks faced by consumers. This is a problem of asymmetric information, where FBOs are more informed than consumers about the characteristics of the product being sold.

What are the policy objectives and the intended effects?

- The statutory objective is to protect public health in relation to food and consumers' other interests in relation to food.
- The new health labelling provisions will provide increased protection for vulnerable consumers of RDM, which will ensure that they are adequately protected and are able to make an informed choice about the food they eat.

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

Option 1: Do Nothing – This option will not provide the necessary public health measures required to protect vulnerable consumers from the risks associated with the consumption of RDM.

Option 2: Amend existing national Regulations to enhance the current labelling provisions to protect vulnerable consumers of the risks associated with consumption of RDM.

Option 3: Seek to introduce sector specific assurance schemes/guidance through industry collaboration; and or Voluntary Code of Practice

Option 2 is the preferred option.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** 07/2019

Does implementation go beyond minimum EU requirements?			No		
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.

[1] For listeriosis, vulnerability is considerably increased with the following groups: elderly, unborn and newly delivered infants, pregnant women, diabetics, alcoholics and a variety of other conditions. https://www.food.gov.uk/sites/default/files/multimedia/pdfs/committee/acmsflisteria.pdf

Signed by the responsible SELECT SIGNATORY: ***Date:***

Summary: Analysis & Evidence

Policy Option 1

Description: Do Nothing – This option will not provide the necessary public health measures required to protect vulnerable consumers of the risks associated with the consumption of RDM.

FULL ECONOMIC ASSESSMENT

Price Base Year 2016	**PV Base Year** 2016	**Time Period Years** 10	**Net Benefit (Present Value (PV)) (£m)**		
			Low: Optional	**High:** Optional	**Best Estimate:** 0

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	0		0	**0**

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

This is the baseline which all other options are appraised against.

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

This is the baseline which all other options are appraised against.

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				

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

This is the baseline which all other options are appraised against.

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

This is the baseline which all other options are appraised against.

Key assumptions/sensitivities/risks

Discount rate 3

Do nothing represents the current policy situation, without intervention.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			**In scope of OITO?**	**Measure qualifies as**
Costs: 0.0	**Benefits:** 0.0	**Net:** 0.0	Yes	Zero net cost

Summary: Analysis & Evidence

Policy Option 2

Description: amend existing national Regulations to enhance the current labelling provisions to protect vulnerable consumers of the risks associated with consumption of RDM.

FULL ECONOMIC ASSESSMENT

Price Base Year 2016	PV Base Year 2016	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate: -** 0.09

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	0.0			**0. 1**

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

Familiarisation costs to farmers: £790 (present value)
Familiarisation costs to local authorities: £349 (present value)
Re-labelling costs to industry: £84k (present value)

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

No non-monetised costs have been identified.

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			**0.0**

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

No monetised benefits have been identified.

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

Health benefits to consumers: new labelling provisions will provide protection to vulnerable consumers who may consume raw drinking milk, which will ensure that they are adequately protected and are able to make an informed choice about the food they eat.

Key assumptions/sensitivities/risks — **Discount rate** 3.5

A key assumption is that the re-labelling costs to industry only occur in years four and five of the 10 year assessment period. This is because it is assumed that farms will change their labelling every 2-5 years for non-regulatory reasons. Moreover, this regulatory change will only be put in place after a three year period.

BUSINESS ASSESSMENT (Option2)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: 0.01	**Benefits:** 0.0	**Net:** 0.0	Yes	Zero net cost

Evidence Base (for summary sheets)

Problem under consideration and rational for intervention

1. In 2012, the Food Standards Agency (FSA) Board agreed to review the current controls and possible approaches to managing the risks associated with the consumption of raw drinking milk (RDM) and cream from all species in England, Wales and Northern Ireland. In January 2014, the FSA carried out a public consultation on an Impact Assessment, which looked at a number of options, ranging from a requirement to pasteurise all milk prior to sale through to removal of all sales restrictions. The options were reviewed following consultation responses, and evidence gathered from wider stakeholder engagement activity. Initial proposals for the development of RDM controls were presented to the Board for consideration in July 2014.
2. One of the main hazards associated with RDM is Shiga toxin-producing *E. coli* (STEC)[1]. *E.coli* O157 is the most common of the toxin-producing *E.coli* responsible for human infection in the UK. The incidence of *E.coli* O157 is highest in children aged 1-4 years[2].
3. In autumn 2014, an outbreak of *E.coli*, which involved nine cases (seven out nine cases were children), was linked microbiologically and epidemiologically to the consumption of raw cows' drinking milk.
4. In July 2015, the FSA Board considered the FSA review of RDM controls and recommended alignment of the Regulations on RDM in England and Northern Ireland with the Welsh Regulations in making the labelling of RDM more stringent to protect vulnerable groups (i.e. pregnant women, infants, children, the elderly and those with a weakened immune system). In making this decision, the Board recognised that whilst this was a difficult issue, there was a need to balance consumer choice alongside public health protection and wider consumer interests.
5. In England and Northern Ireland, RDM from all species (except buffalo) must be labelled with the words "This milk has not been heat-treated and may therefore contain organisms harmful to health."
6. The national Regulations in Wales have enhanced labelling, which states:
   - "This milk has not been heat-treated and may therefore contain organisms harmful to health.
7. The Welsh Regulations apply to all species, including buffalo. Sales of RDM are banned in Scotland.
8. Therefore it has been proposed that the following sentence: 'the FSA strongly advises that it should not be consumed by children, pregnant women, older people and those who are unwell or have chronic illness', is added to the labelling of RDM in England and Northern Ireland.
9. Government intervention is necessary to ensure that adequate controls are in place to protect vulnerable groups, through mandatory health labelling for RDM in England and Northern Ireland which mirrors that in Wales and also to ensure requirements apply to all species, including buffalo. This will also enable consistency in consumer health protection associated with consumption of RDM throughout those UK countries where the sale of RDM is permitted.
10. National legislation does not require raw cream to bear a health warning. Although there are no restrictions on the sale of raw cream the raw cream market is very small (only 18 producers in the country).
11. No cases of illness associated with the consumption of raw cream have been reported in the last 15 years. However, it is not possible to quantify the risk fully due to lack of data. Whilst the health marking requirement could be extended to raw cream, it is considered that introducing statutory safety labelling requirements for such a small market may be disproportionate. Equivalent public health outcomes may be achieved through the availability of FSA advice to consumers on consumption of RDM and cream.

Evidence for the review of RDM controls

[1] European Food Safety Authority Scientific Opinion on the public health risks related to the consumption of raw drinking milk (http://www.efsa.europa.eu/en/efsajournal/pub/3940)

[2] Byrne et al (2015)

12. Vulnerable consumers such as the young, elderly, pregnant women or those with weakened immune systems are at greatest risk from infection. There is no specific data on consumption by vulnerable groups. Consumer feedback from the 2013 consultation indicated that 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 indicated that RDM may be consumed by children in the family sometimes for perceived health benefits. The health warning currently used in England and Northern Ireland does not specifically caution against consumption by vulnerable consumers, who are most at risk. Hence the need to enhance the labelling requirements so that consumers understand the risk and can make informed choices.

Policy objective

13. The FSA has statutory responsibility for protecting consumer health and consumers' other interests in relation to food. Each of the three options has been considered in accordance with this objective, the FSA's core principles and policy making framework.

14. The main policy objective is to protect public health by enhancing the existing labelling provisions in England and Northern Ireland for the consumption of RDM by vulnerable groups and ensures labelling advice is consistent across species. This will also ensure that vulnerable consumers and those providing food for vulnerable consumers are adequately informed of the risks associated with consumption of RDM, should they decide to consume it. The FSA's view is that this option supports a balance between food safety and consumer choice.

15. To this end, the FSA recommends amendment of the Food Safety and Hygiene (England) Regulations 2013 and the Food Hygiene Regulations (Northern Ireland) 2006 (as amended) to enable the necessary labelling provisions. This will align the labelling requirements with the Welsh Regulations, ensuring labelling consistency across the three countries.

Groups effected

16. All producers of RDM, about 130 as at 1 December 2016, will be affected by the proposed labelling change including one buffalo milk producer who previously has been excluded from any health labelling provisions. Additional health labelling requirements could place a burden on producers as they will need to adapt their existing labelling or produce new labelling. However, in order to minimise the impact of this measure on producers, a transitional period of three years is proposed to allow producers to incorporate the labelling change into their routine business cycle; this is in line with the usual provisions for changes to labelling. This will allow existing packaging stocks to be used up before the new requirements come into effect.

17. The Welsh IA noted that costs to industry in changes to RDM labelling were cost neutral as industry typically change their product labelling every three years. Evidence from a report conducted by Campden BRI on behalf of Defra in 2010 found that "For dynamic products, the packaging / label lifecycle may be as short as 12 months; however, for other products, it may be 2 - 5 years (and possibly longer in the case of well-established products)"[3]. Taking a cautious approach, this assessment has assumed a five year label lifecycle.

18. The proposal will also affect the enforcement bodies and others with an interest in RDM. There may also be one-off costs associated with familiarisation and learning of the labelling change.

Evidence base

19. In January 2014, the FSA undertook a public consultation on an Impact Assessment on the review of the controls governing the sale and marketing of unpasteurised, or raw drinking milk and raw cream in England, Wales and Northern Ireland. The overall objectives of the review were to ensure that existing controls in place were sufficient in managing the food safety risk associated with RDM and are proportionate and risk-based, taking into account the latest scientific evidence and information and views from producers, consumers and other interested parties with an interest in this sector. The consultation identified 4 options: 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; and, Option 4: Introduce measures to harmonise and clarify current controls.

[3] **"Developing a Framework for Assessing the Costs of Labelling Changes in the UK"** by Campden BRI, 2010 on behalf of Defra, p34: http://webarchive.nationalarchives.gov.uk/20130402151656/http://archive.defra.gov.uk/evidence/economics/foodfarm/reports/documents/labelling-changes.pdf

20. Details of the consultation and stakeholder responses are published on the FSA's website at:

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

Autumn 2014 Outbreak

21. The first UK reported outbreak of *E.coli* O157 associated with consumption of RDM in 12 years occurred in autumn 2014. There were a total of nine cases (seven primary and two secondary). One case was also infected with *Salmonella* Mbandaka which was an identical strain to one isolated from a RDM sample taken from one producer. The FSA suspended the sales of RDM from a farm involved and product recalls were issued.

22. Prior to this, no outbreaks of human illness associated with RDM or raw cream had been reported in England and Wales since 2002. This outbreak provided direct evidence of the risks associated with RDM and severity of the disease that can occur. It also indicated that foodborne disease surveillance systems are capable of identifying small numbers of cases of illness associated with a particular product, particularly if symptoms are severe.

23. The cases were linked microbiologically and epidemiologically to the consumption of RDM. Of the nine primary and secondary cases, seven were male and two female. Seven cases were children. The median age was 5 years (Range1-49 years, Mean 11 years)[4]. The duration of symptoms ranged from two to seventeen days (median six days). Two cases of Haemolytic Uremic Syndrome (HUS)[5] in children were reported. This supported the established view that there is a heightened risk for vulnerable consumers which is also noted in a scientific opinion on this topic published by the European Food Safety Authority (EFSA)[6]. The opinion highlighted that "there should be improved risk communication to consumers, particularly susceptible/high risk populations, regarding the hazards and control methods associated with consumption of RDM".

Recommendations to the FSA Board

24. On 15 July 2015 a paper was presented to the FSA Board[7],[8],[9], which provided an update on the FSA's review of controls for RDM. The Board was asked to agree that the FSA review of RDM controls should be concluded with a significant degree of certainty, that hazards associated with RDM consumption by consumers except those who are vulnerable by virtue of underlying health conditions, is acceptable when appropriate hygiene controls are applied throughout the chain. And risks to those who are vulnerable are heightened and action is needed to increase awareness of those risks.

25. The Board was also asked to agree the current restrictions on the sales of RDM should remain in place in the absence of a quantitative risk assessment and limitations in the evidence base. There is uncertainty that the same level of consumer protection could be maintained if the current restrictions were relaxed to allow wider access to RDM.

26. The Board was also asked to agree that in the absence a quantitative risk assessment, any future consideration of extending sales should; i) use principles that already exist in EU legislation, ii) balance any extension to new routes or supply with tighter regulatory controls that would manage the risk to an acceptable level.

27. The Board was also asked to agree that given the current evidence on compliance, focus should be to ensure RDM producers are implementing current controls and meeting required standards. Any relaxation of current sales restrictions could only be considered when there is evidence to indicate a high level of compliance across the sector. The Board was further asked to agree that communications of the associated risk with consumption of RDM at the point of sale or equivalent should be improved and, as a first step, labelling requirements in England and Northern Ireland should be extended to include a warning for vulnerable groups, as currently exists for Wales.

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[4] http://www.food.gov.uk/sites/default/files/phebartonfarmoctreport.pdf

[5] A severe, life-threatening complication of *E. coli* infection that can lead to acute renal failure and chronic kidney disease.

[6] http://www.efsa.europa.eu/en/efsajournal/pub/3940.htm

[7] http://www.food.gov.uk/sites/default/files/multimedia/pdfs/board/fsa120305.pdf

[8] http://www.food.gov.uk/sites/default/files/multimedia/pdfs/board/board-papers2014/fsa-140704.pdf

[9] http://www.food.gov.uk/sites/default/files/fsa150704.pd f

28. The Board generally accepted the recommendations of the review and acknowledged that the level of risk associated with RDM consumption was acceptable when appropriate hygiene controls are applied, except for vulnerable groups.

29. In terms of current restrictions on RDM sales, the Board recommended that these should remain in place in the absence of a quantitative risk assessment and limitations in the evidence base. There is uncertainty that the same level of consumer protection could be maintained if the current restrictions were relaxed to allow wider access to RDM. The Board was particularly concerned about reports of non-compliance in the industry and agreed that supporting improvements in compliance, in addition to risk communication, should be a focus for FSA action. The Board also highlighted that there was a clear public health interest in consumers knowing where to find appropriately registered RDM providers (from all species including goats, sheep and buffalo). For this reason, on 1 March 2016, the FSA published a list of all registered RDM producers and their compliance level on its website at www.food.gov.uk/science/raw-drinking-milk-and-cream .

Risk Communication

30. The FSA has made it clear in its 2016 -2020 strategy that consumers have responsibilities as well as rights. Those responsibilities extend to the people they care for, and are balanced by a right to be informed and supported taking on those responsibilities and a right to make informed choices about what they eat. Furthermore, the EFSA opinion recommends improved risk communications to consumers, particularly those in vulnerable groups, on the hazards and controls that should be applied.

31. The FSA advice on consumption of raw milk is clear and indicates that RDM should not be consumed by vulnerable groups as it may contain harmful microorganisms as it has not been heat treated. This is more fully reflected in labelling requirements for RDM sold in Wales.

Other evidence

32. There are public health arguments for highlighting specific risks for vulnerable groups as required by legislation in Wales, as the FSA is aware the impact of illness could be greater with that sector of the population. This is also consistent with the approach the FSA takes in providing advice to consumers on consumption of other foods**.**

33. There is therefore, sufficient evidence to justify measures to ensure labelling on RDM sold in England and Northern Ireland highlights the specific risks to vulnerable groups and align the labelling for RDM for those vulnerable consumers with the Welsh Regulations.

Legislation and compliance

EU hygiene legislation provides general and specific controls for the production of RDM and allows for further controls to be introduced by Member States. The domestic hygiene legislation in England, Wales and Northern Ireland builds on these and provides additional requirements for RDM.

34. Domestic legislation for England, Wales and Northern Ireland sets out different RDM labelling provisions in each country, so consumers are not provided with the same information to support their choices.

35. In addition to the EU labelling requirements for raw milk, national legislation (the Food Labelling Regulations 1996[10] (the FLRs)) in England and Northern Ireland required additional labelling of RDM from all species except buffalo (buffalo milk is thought to have been excluded due to historically low consumption levels) 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 was not prepacked and was sold in an on-farm catering establishment, the following had to be clearly stated: 'milk supplied in this establishment has not been heat-treated and may therefore contain organisms harmful to health'. Changes to EU and domestic legislation on food labelling resulted in the revocation of the FLR's in December 2014. The Food Safety and Hygiene (England) Regulations 2013 and the Food Hygiene Regulations (Northern Ireland) 2006 in Northern Ireland were amended[11], to maintain the labelling requirements for RDM, previously contained in the FLR's until the review was concluded and any changes to controls over RDM were agreed.

SI 1996/1499[11] SI 2013 No. 2996; and SR 2006 No. 3

[11] SI 2013 No. 2996; and SR 2006 No. 3

36. Furthermore, national legislation in Wales requires 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 illnesses'. The Welsh Regulations apply to all species.

37. All RDM producers are subject to 6 monthly official control inspection visits and quarterly sampling and testing (cows' milk) or local authority (DAERA in Northern Ireland) sampling checks (for other species) against criteria in the domestic legislation. In practice, this means enforcement officials visit production holdings quarterly. If the milk fails to comply with the microbiological criteria, this prompts an inspection visit and follow-up testing.

38. The principles underpinning enforcement of controls for RDM are consistent with establishments in other sectors producing high risk foods.

Options considered

Option 1: Do nothing - do not introduce new labelling provisions for at risk vulnerable consumers

39. This option will not provide the necessary public health protection measures required to protect vulnerable consumers of the risks associated with consumption of RDM and will fail to meet the FSA's statutory objective to protect consumer health and consumers' other interests in relation to food.

Option 2: amend existing national Regulations to enhance the current labelling provisions to protect vulnerable consumers of the risks associated with consumption of RDM.

40. This option provides adequate health protection for vulnerable consumers who may be at higher risk from consuming RDM, while preserving consumer choice. This option will also align the labelling provisions in England and Northern Ireland to those in Wales and introduce consistency in labelling across all species.

41. This option also meets the FSA's statutory objective to protect consumer health and consumers' other interests in relation to food.

Option 3: - Seek to introduce sector specific assurance schemes/guidance through industry collaboration; and/or Voluntary Code of Practice

42. The FSA has an obligation to consider non-legislative approaches to achieve its aims, such as the introduction of sector specific guidance, voluntary measures or Codes of Practice.

43. Consumer research carried out in 2013 highlighted that 66% of those in England and 56% of those in Northern Ireland thought that the existing raw milk label contained such information. The information missing from the current labelling 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.

44. Regulation and advice was subsequently explored in greater detail during the consumer discussions in 2014. Consumers recognised the need for regulation and were concerned that without regulation, farmers with poor hygiene standards could enter the market and sell products that were unsafe for consumption.

45. The option of introduction of voluntary measures (e.g. a voluntary Code of Practice) was fully considered in the 2014 consultation. The FSA received 536 responses, which included views from RDM producers and RDM producer representatives. In general RDM producers opposed the introduction of additional labelling. Therefore, the FSA felt that requesting voluntary labelling would not be followed by sufficient producers to be considered a viable option.

46. The FSA's long standing message has been that vulnerable groups should not consume RDM. However, the 2014 outbreak, where seven children (out of nine cases) were taken ill due to consumption of RDM, brought to the fore the need for additional advice for vulnerable consumer groups at the point of sale.

    The FSA remains of the view that the implementation of voluntary labelling cannot guarantee enhanced protection for vulnerable consumers, since the common view among producers is that additional labelling is not required.

    Consumer research – online survey

47. 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

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

Consumer engagement (Feb 13)

49. 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 FSA would be favourable to demonstrate that 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 that farms are compliant, and are therefore able to sell RDM.

Option Appraisal

Costs and Benefits

Option 1: Do Nothing – do not introduce new labelling provisions for at risk vulnerable consumers

50. There are no costs or benefits associated with this option as it is a baseline against which all other policy options are appraised. The baseline assumes that doing nothing will put vulnerable consumers at risk from RDM.

51. The labelling in Wales carries a specific warning for vulnerable groups, but this is not required in England and Northern Ireland and this inconsistency would also continue under this option. There would also be inconsistent labelling requirements across species.

Option 2: amend existing national Regulations to enhance the current labelling provisions to protect vulnerable consumers of the risks associated with consumption of RDM.

52. This option would address the inconsistencies in labelling of RDM to protect vulnerable consumers across the UK against risks associated with RDM consumption; this option would also harmonise the labelling provisions across the UK countries.

Costs

Costs to Industry

Familiarisation Costs to Farmers (One-off Cost)

53. Under Option 2, there will be a familiarisation cost to industry from reading and familiarising themselves with the changes to enhanced RDM labelling. Familiarisation costs can be monetised by multiplying the wage rate of the person carrying out the familiarisation with the time required for familiarisation. We envisage that it will be a farmer responsible for familiarisation and that it will take one farmer per farm/business 30 minutes for familiarisation.[12] The median hourly wage rate of a business manager is £9.97. This is uprated by 20 percent to take account of overhead costs, leading to an adjusted wage rate of £11.96. Given that there are 132 relevant farms (those which sell RDM) in England and Northern Ireland, this generates a total familiarisation cost to farmers of £763[13](see Table 1).

Table 1: Familiarisation costs to farmers

[12] Based on the Regulator Appraisal Subgroup of the Cross Whitehall Group on the Economics of Regulation draft guidance on the appraisal of guidance 30 minutes was considered to the best estimate.

[13] Wage rate obtained from Annual Survey of Hours and Earnings 2016.(provisional). https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation4digitsoc2010ashetable14 Earnings-by: occupation. Median hourly wage rate of farmer directors' was used, £9.96, plus 20% overheads, totalling £11.96. A 2016 base year is used.

	Number of farms in the UK selling Raw Drinking Milk	Familiarisation costs
England	**127**	**£760**
NI	**5**	**£30**
England & NI	**132***	**£790**

*Figures correct as at March 2017

54. 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[14]. The total one-off familiarisation cost to farmers in this proposal is £790, which yields a total equivalent annual cost of £92 over a ten year period.

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

55. Under Option 2 there will be a cost to business from labelling changes as a result of the harmonisation of the labelling requirements on RDM for all species. This will impact on all producers of RDM 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 (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)[15]. We currently do not have information on exactly what an SKU is in the context of RDM. However, if we assume that the product itself, RDM 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 quantify this cost by multiplying the number of SKUs per farmer with the total number of farmers selling RDM (132). This generates a total indicative estimated cost to farmers of £238k. However, if we assume that the re-labelling cycle for this product is five years, this implies that this figure should apply to a full five year period.

56. However, it is the intention of the FSA to minimise this cost to farmers of amending the labelling. We would therefore intend to introduce a transitional period for farmers of three years, so that the labelling changes can be introduced as part of the normal re-labelling cycle.

57. Evidence suggests that the re-labelling cycle can be up to 5 years.[16] Assuming a five year re-labelling cycle (so as to be cautious) means that re-labelling costs will only be incurred in years four and five of the 10 year policy period. This is because there is also a three year transitional period before the regulation takes effect. Averaging the total cost of the re-labelling change over the five years of a re-labelling cycle leads to an annual cost of £47.5k, in nominal terms. Hence, the total nominal cost will be £95k, leading to a present value figure of £84k; with an associated EAC of £10k.

[14] 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:

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

[15] "Developing a Framework for Assessing the Costs of Labelling Changes in the UK" by Campden BRI, 2010 on behalf of Defra, p46: http://webarchive.nationalarchives.gov.uk/20130402151656/http://archive.defra.gov.uk/evidence/economics/foodfarm/reports/documents/labelling-changes.pdf

[16] "Developing a Framework for Assessing the Costs of Labelling Changes in the UK" by Campden BRI, 2010 on behalf of Defra, p34: http://webarchive.nationalarchives.gov.uk/20130402151656/http://archive.defra.gov.uk/evidence/economics/foodfarm/reports/documents/labelling-changes.pdf

Table 2

	Number of farms	Re-labelling costs
England	127	£91,440
NI	5	£3,600
England & NI	**132**	**£95,040**

Costs to Enforcement Authorities

Familiarisation Costs (one-Off Cost)

58. There will be a one-off familiarisation cost to the FSA's Dairy Hygiene Inspectorate under Option 2. Familiarisation costs can be monetised by multiplying the wage rate of the person carrying out the familiarisation with the time required for familiarisation. We envisage that it will be a Dairy Industry Inspector (DHI) that will be responsible for familiarisation and that it will take DHIs 30 minutes[17] for familiarisation and dissemination. The median hourly wage rate for Inspectors of standards and regulations DHI is £14.90[18], which after being uprated by 20 percent for overheads this is £17.88. There are 39 relevant officials in England and Northern Ireland. This leads to a total familiarisation cost to in England and Northern Ireland of £349. See Table 3.

Table 3

	Number of Dairy Industry Inspectors	Familiarisation costs
England	31	£277
NI	8	£72
England & NI	**39**	**£349**

Benefits – Industry

Option 2

Monetised Benefits

59. No monetised benefits have been identified.

Non-Monetised Benefits

Consumers

Public health *(non-monetised)*

60. The FSA Strategic Plan to 2020 makes it clear that FSA science should focus on the biggest risks and challenges to consumers' current and future interests and be focused on areas where it can make the biggest impacts. The potential hazards associated with consumption of RDM are well characterised. There is a potential for severe illness – particularly for vulnerable groups - and illness may be under-reported. Also RDM is a niche product consumed by small groups of consumers[19].

[17] Based on the Regulator Appraisal Subgroup of the Cross Whitehall Group on the Economics of Regulation draft guidance on the appraisal of guidance 30 minutes was considered to the best estimate.

[18] Wage rate obtained from Annual Survey of Hours and Earnings 2016 (provisional) https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation4digitsoc2010ashetable14. Median hourly wage rate of a farmer directors' was used, £14.90, plus 20% percent overheads, totalling £17.76..

[19] This research indicates that 2% of the population have consumed RDM in the past six months, with 1% of the population reporting consumption on a daily basis. Questions on purchase and consumption of raw drinking milk and cream (RDM) were included in random probability omnibus surveys in England, Wales and Northern Ireland to provide robust estimates of the proportion of the population who purchase and consume RDM (based on reported only). http://tna.europarchive.org/20141103165934/http://www.foodbase.org.uk//admintools/reportdocuments/867-1-1611_RDM_Omnibus_Report_FINAL.pdf

61. The amended labelling provisions will provide additional information to vulnerable consumers of RDM, which will ensure that they are aware of the risks associated with consumption of this product and are therefore able to make an informed choice about the food they eat.

Consultation

There has been an extensive formal consultation and informal stakeholder engagement since the review was initiated and as the FSA has implemented Board recommendations.

Consumer Engagement

62. There has been extensive consumer engagement over the course of the review, including specific focus groups, wider consumer research and a face to face consumer engagement event, as well as several communications directly with RDM producers.

63. The consultation carried out in January 2014 included an option (Option 1), in the Impact Assessment[20] for enhanced labelling in England and Northern Ireland; additional warning in Wales, highlighting specific risks to vulnerable groups on the associated risks of RDM consumptions.

64. The FSA received 536 responses; these were from individual consumers and consumer groups, local authorities, other government departments, retailers, trade bodies, RDM producers, artisan cheesemakers, healthcare professionals, the ACMSF, focus groups members and a charity organisation.

65. Of the 536 responses received, the vast majority of them were from individual consumers (493), who supported continued access to sales of RDM, with the focus on individuals being allowed to make informed choices and having the freedom to choose to consume RDM. Many consumers indicated the need for greater accessibility to RDM, and many cited perceived health benefits as the reason for consuming RDM. RDM producers, as well as consumers recognised the need for the stringent regulation to safeguard consumers and the industry. There were four responses (which included a charity organisation representing 99 individuals, pressed for all milk to be pasteurised prior to sale, the main reason cited as being the inherent risk associated with the RDM and the need to protect public health.

66. The published responses to the 2014 consultation can be found at:

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

67. The current consultation on this Impact Assessment, takes into consideration the Board recommendations, the EFSA opinion, outbreaks associated with RDM and evidence of risk associated with RDM and comments received from the earlier consultation. Evidence shows that risk communication, including labelling must be improved. This is more apparent in relation to vulnerable consumer groups who, by virtue of age or underlying health conditions, are more vulnerable. The new labelling provisions are designed to protect vulnerable consumers from risk associated with RDM and provide more fully informed consumer choice for those consumers who choose to consume RDM.

Devolution Implications

68. The new labelling provisions to protect vulnerable consumers from risks associated with RDM consumption, which are the subject of this IA, cover England and Northern Ireland only. Wales already has these labelling provisions in place. Sales for RDM in Scotland are banned and controls in Scotland are outside of this review.

[20] http://www.food.gov.uk/news-updates/consultations/2014/rawmilk-consult