#### Enhanced controls for raw milk production: assessment of impact

Evidence Base (for summary sheets)

#### Summary of net costs

	Annual Costs	Total (over 10 years)	Total NPV
FSA	-£1,313	-£1,313	-£1,313
FBO	-£267,979	-£2,528,971	-£2,191,941
Total	-£269,292	-£2,545,366	-£2,193,254

Earned Annual Net Direct Cost to Business	£254,649
---	----------

#### Background

Problem under consideration

- The Food Standard Agency (FSA) is responsible for ensuring that an effective regulatory regime is in place to verify that Food Business Operators (FBOs) meet their obligation to ensure food is safe and is what it says it is. The FSA is the Central Competent Authority (CCA) responsible for the registration of producers of Raw Drinking Milk (RDM), as well as inspecting RDM sites as part of official hygiene controls, through its Dairy Operations unit.
- 2. RDM is milk that has not undergone any form of heat treatment (e.g., pasteurisation) that is sufficient to kill harmful bacteria that may be present in the raw milk. Although the consumption of raw drinking milk is not widespread among the general population, there are some consumers who believe that raw milk possesses particular health properties or attributes, in addition to the existing nutritional components. However, the removal of the pasteurisation step does increase the risk for the microbial load contamination obtained during production to be carried through to the finished product.
- 3. The supply of raw drinking milk is regulated by EU and domestic food hygiene regulations. These regulations place the responsibility for the production and supply of safe food, such as RDM, solely with the FBO. The farmer is the FBO in the case of the supply of the RDM for human consumption. RDM production is subject to additional official controls and requirements on top of standard dairy controls.
- 4. The FSA is proposing a change which seeks to update the internal measures necessarily adopted by RDM producers during production in order to improve the quality assurance of their product. The current requirements have been in place since 2012; however, they have not kept pace with changes in the production, consumption and distribution of RDM over time, thus requiring modification to adapt to this new environment.

Rationale for intervention

5. An internal audit of RDM controls identified a significant rise in the number of producers and volume of production of RDM across England and Wales. This trend has been matched by an increase in the number of outbreaks of illness associated with the consumption of RDM, especially over the period 2016/17. Intervention is required to reduce unacceptable public health risks, whilst protecting consumer choice.

# **Policy options**

## Two options have been identified:

- 6. **Option 1:** 'Do Nothing', and continue with the current registration/inspection system
- 7. **Option 2:** Introduction of a Food Safety Management System (FSMS) which will enable FBOs to demonstrate stronger compliance in the production of RDM in England and Wales.
  - To verify that the FBO has adopted the FSMS (which will likely be based on HACCP<sup>1</sup> principles), it has been identified that frequent sampling of produce will be the most applicable method for verification of internal systems. This is the preferred option.

## **Groups affected**

## The following groups are affected:

## Consumers

8. The requirement to set up and implement a FSMS will ultimately help RDM producers to comply with food hygiene and food standards more effectively. In setting up a robust FSMS RDM producers place themselves in a better position to protect consumers and reduce unacceptable food-related risks. However, should RDM producers pass on the increased cost of production to consumers, the market price of RDM will necessarily rise.

# Food Business Operators (FBOs)

9. RDM producers are the primary focus of this proposed policy update. As of 1<sup>st</sup> January 2019, there are 161 RDM producers in England & Wales<sup>2</sup> that will be affected directly by this proposal. EU and domestic food hygiene regulation stipulates clearly that the responsibility for the production and supply of safe food, such as RDM, lies solely with the producing FBO. As such the proposed policy change will require greater assurance measures to be introduced during the production stage.

<sup>&</sup>lt;sup>1</sup> Hazard Analysis & Critical Control Points.

<sup>&</sup>lt;sup>2</sup> See Figure 1 in Appendix for map of RDM producers across England and Wales.

# The FSA

- 10. The FSA is the CCA responsible for ensuring that an effective regulatory regime is in place that fully enables and clearly demonstrates to FBOs how to meet their obligation to ensure that the food they produce is safe and is what it says it is.
- 11. In additional the FSA is responsible for carrying out official hygiene controls of RDM sites via the 41 (as of January 14<sup>th</sup> 2019) Dairy Hygiene Inspectors (DHIs) the agency directly employs.

#### Wider Economy

12. By helping RDM producers improve the quality assurance associated with its product, the introduction of a FSMS may lead to a reduction in foodborne illnesses that will help relieve pressure on the National Health Service (NHS), reductions in pain & suffering, as well as forgone economic output due to absence from work. However, as this policy update only affects a very small minority of producers and consumers, these wider effects are likely to be minimal when considered on an aggregate basis.

#### **OPTION APPRAISAL**

# Option 1: 'Do Nothing', and continue with current registration/inspection system

#### **Costs and Benefits**

13. Option 1 is the baseline on which all other options are appraised. The FSA currently holds no evidence to suggest that any of the important variables in the baseline will change over time in the absence of intervention. In this baseline, it is presumed that RDM producers are not engaged in sampling for pathogens and/or water supply quality, or have a FSMS in place, based on the HACCP principles.<sup>3</sup> With this in mind, the costs and benefits in the baseline across time assume the current number of RDM producers in England and Wales, overall compliance rates, levels of consumer risk and the number of foodborne illness incidents remain constant. Due to the presumptions made, the policy options measured against this status quo represent a worst-case scenario, resulting in an overestimation of the cost.

# Options 2: Introduction of a Food Safety Management System which will require FBOs to demonstrate stronger compliance in the production of RDM.

#### COSTS

14. All estimated and monetised costs used throughout this assessment are in current prices and are measured over a 10-year appraisal period.

#### **Food Business Costs**

<sup>&</sup>lt;sup>3</sup> In reality this is unlikely to be the case. The FSA lacks the required data to estimate how many farms already have a FSMS in place.

15. There are 161 RDM producers currently operating across England and Wales.<sup>4</sup> The introduction of the FSMS will necessarily increase the required measures taken by each FBO to guarantee the safety and hygiene compliance of its RDM production. These measures will place an additional cost, both of a transitional and recurring annual nature, on each RDM producer. It must be noted however, that this additional cost will vary per RDM producer in accordance with the agreed measures dictated by their bespoke FSMS.

#### Familiarisation costs

16. The proposed policy change will initially require RDM producers to familiarise themselves with the new requirements, so they can fully understand what precautionary measures will have to be adopted into their operation. We anticipate this to take a maximum of 2 hours per FBO and will cost on average £31.23 per FBO and £5,027 in total across all RDM producers.<sup>5</sup>

#### Implementation costs

- 17. The proposed policy change, namely the introduction of a FSMS system, will require a certain amount of time to construct and subsequently implement. As the FSMS is tailored to the specific operations of each RDM producer the amount of time taken to complete this activity will vary across producers. Additionally, many RDM producers may seek to contract this activity out to external contractors, however we do not account for this option within our calculations. In the absence of data, we have estimated that the average time to complete this activity is 4 hours.<sup>6</sup>
- 18. The total cost of constructing and implementing a FSMS is estimated to be  $\pounds 62.45$  per RDM producer and  $\pounds 10,055$  in total for industry.<sup>7</sup>

## Sampling costs

19. The most significant cost placed upon FBOs as a result of this policy change will be activities associated with the necessary sampling requirements. At this stage, sampling has been identified as the most appropriate method for which to verify that FBOs are carrying out the necessary internal steps and procedures as dictated by their bespoke FSMS and that these are effective in providing a safe final product. This process involves the following costs and considerations:

<sup>&</sup>lt;sup>4</sup> Taken from published list of RDM producers on FSA website as at 1<sup>st</sup> January 2019.

<sup>&</sup>lt;sup>5</sup> Using the Annual Survey of Hours and Earnings (ASHE) 2018 data, the median wage of a manager or proprietor in the agriculture or horticulture sector is £15.61 (including an overhead rate of 30% as suggested in the Green Book). £15.61/hour x 161 RDM producers x 2 hours to familiarise = £5,026 cost to industry.

<sup>&</sup>lt;sup>6</sup> This average estimation should be viewed as an approximation. As part of the consultation we encourage any contributions by affected businesses which will enable us to build upon our evidence base on this specific issue.

<sup>&</sup>lt;sup>7</sup> Using the ASHE 2018 data, the median wage of a manager or proprietor in the agriculture or horticulture sector is £15.61 (including overheads). £15.61/hour x 161 RDM producers x 4 hours to implement =  $\pm$ 10,053 cost to industry.

- Loss in productivity: in order to extract, package and dispatch the relevant set of samples to a chosen laboratory it is presumed to take 0.5 hours. This is based on the time taken for a DHI inspection to undertake the same task.
- Courier services: once ready to dispatch the FBO will likely have to pay for a courier service to deliver the relevant set of samples to a chosen laboratory.<sup>8</sup> Transporting samples to a chosen laboratory is a cost that producers will likely seek to minimise. This cost will also vary depending on geographical location and chosen courier service provider.<sup>9</sup> Conversations with a key industry stakeholder suggest that the maximum charge of transporting samples is £20 per set of samples.<sup>10</sup> This covers all identified courier options.
- Laboratory charges: using three quotes from accredited laboratories we were able to calculate an average charge per sample of £81.95. This price covers all required pathogen testing, but not water supply quality testing which would have to be included separately (but would also be required on a less frequent basis).
- **Sampling frequency**: will vary between FBOs that have differing FSMSs and associated risk levels. On average, and in most cases, it is presumed that FBOs will undertake the required pathogen sampling monthly. There may also be scope to reduce sampling frequency if an FBO is able to demonstrate a history of compliance, however this is not accounted for in our estimates.
- 20. Therefore, the total average estimated annual cost of all identified activities associated with sampling is £1,317 per RDM producer and £212,050 in total for industry.<sup>11</sup>

## **General Ongoing Costs**

21. Maintenance and upkeeping of the FSMS will require ongoing record keeping and reporting.<sup>12</sup> These activities are imperative to the ongoing functioning of the FSMS, and record of them will be audited in some form by DHIs as part of official control delivery. As these associated tasks can be incorporated within and alongside other non-related activities, it is difficult to estimate the extra burden of time it will place upon RDM producers. However, in the absence of robust data, we have assumed the average time taken to complete the activities required for record keeping and reporting purposes to take, on average, 0.25 hours per day of

<sup>&</sup>lt;sup>8</sup> Many laboratories (such as the National Milk Laboratory) offer in-house courier services.
<sup>9</sup> Other courier options include (but are not limited to) third-party courier services, through the postal service or bypassing courier services altogether and delivering samples independently. These options would require the set of samples to be ice-packed which would incur an additional cost.

<sup>&</sup>lt;sup>10</sup> This average estimate should be viewed as an approximation. As part of the consultation we encourage any contributions by affected businesses which will enable us to build upon our evidence base on this specific issue.

<sup>&</sup>lt;sup>11</sup> Annual average laboratory cost of £983.40; Annual courier services costs £240; annual sampling processing productivity loss of £93.68 and; 161 RDM producers across England and Wales. Summating these figures provides us with the total cost estimates.

<sup>&</sup>lt;sup>12</sup> Record keeping and reporting will include tasks such as (but not limited to): recording temperatures twice daily and updating training record, on a less frequent basis.

milking.<sup>13</sup> If we assume that RDM producer milk their cows five days a week, then the time spent on completing this activity is 1.25 hours a week or 65 hours a year.<sup>14</sup>

22. Therefore, the estimated total annual record keeping and reporting is £254 per RDM producer and £40,848 in total for industry.<sup>15</sup>

**Official Controls** 

23. The burden of official controls to an FBO as a result of this policy change is net zero.<sup>16</sup> Currently RDM producers are subject to four visits a year which, on average, total four hours.<sup>17</sup> Under this policy proposal, the frequency and duration of visits will change, but the productive time lost to official controls will remain constant at four hours per annum.<sup>18</sup>

## **FSA Costs**

Familiarisation costs

- 24. The proposed FSMS introduction will result in a familiarisation cost to Dairy Health Inspectors (DHIs) who will need to read and familiarise themselves with the changes. FSA enforcement data shows that there are 39 DHIs currently employed on a part-time basis.<sup>19</sup> However, as of January 14<sup>th</sup> 2019, there will be a team of 9 full-time DHIs, supported by 32 existing part-time DHIs.
- 25. The FSA estimates that an authorised DHI will invest approximately two hours reading and familiarising themselves with the FSMS requirements expected of FBOs. The familiarisation cost can be monetised by multiplying the total number of hours needed for DHIs to familiarise themselves with the changes by the average hourly cost of employing those officers. This is estimated at £1,313.<sup>20</sup>

Training costs

<sup>&</sup>lt;sup>13</sup> This assumption should be viewed as an approximation. As part of the consultation we encourage any contributions by affected businesses which will enable us to build upon our evidence base on this specific issue.

<sup>&</sup>lt;sup>14</sup> Based on a 52-week year.

<sup>&</sup>lt;sup>15</sup> Using the ASHE 2018 data, the median wage of a manager or proprietor in the agriculture or horticulture sector is £15.61 (including overheads). Based on the assumption that a RDM producer is producing RDM 5 times a week across 52 weeks of the year. 65 hours/year x 15.61/hour x 161 RDM producers = £39,579

<sup>&</sup>lt;sup>16</sup> Whilst the likely effect to the average RDM producer with regards to the change in official controls is likely to be net-zero, inspection time will vary depending on the level of compliance. Furthermore, it is not understood if the policy change will have any significant impact on overall levels of compliance. <sup>17</sup> Twice to inspect premises and sample produce and twice to sample produce only. Average time taken for an inspection is 1 hour; sampling taking 0.5 hours.

<sup>&</sup>lt;sup>18</sup> Duration will be increased to an average of 2 hours as DHIs will be required to audit the RDM producer's paperwork associated with their bespoke FSMS and; frequency will be reduced to two visits per year, as the requirement for sampling-specific visits will not be required anymore.

<sup>&</sup>lt;sup>19</sup> These DHIs are predominantly Meat Health Inspectors (MHIs); however, they have also been trained in dairy and are back-filled in their red meat plants to go out and deliver dairy inspections, on average of one day a week.

<sup>&</sup>lt;sup>20</sup> Basing an average DHI salary of £25,620 on a 40-hour working week, we calculate the hourly rate as  $\pounds$ 16.01 (including overheads).  $\pounds$ 16.01/hour x 41 DHIs x 2 hours to familiarise =  $\pounds$ 1,313 total cost to FSA.

26. There are no explicit training costs associated with this policy change. Due to the recruitment of a new team of full-time DHIs (see paragraph 24) there will however be a £30,000 cost to the FSA to deliver enhanced training to these individuals. Whilst this training will deliver guidance on all aspects of dairy, it will also have a focus on current RDM controls. Due to the fact that this training is in response to structural changes in the employment of DHIs rather than legislative changes in RDM production requirements, we have discounted this cost (or apportioned any of it) from our cost estimations.

#### **Official Controls**

27. There is a net-zero cost to the FSA with respect to the change in delivery of official controls. As a result of the proposed policy shift, compliant RDM producers can expect less frequent, but longer inspections that amount to the same total annual productive time lost (see paragraph 23). It necessarily follows that the average time spent inspecting sites by DHIs will remain constant. Therefore, there is no change in the costs to deliver official controls.

## **Total Costs**

28. The total costs associated with Policy Option 2 over a 10-year appraisal period are £2,545,366 with a Net Present Value (NPV) of £2,193,254. Industry will assume 99.95% of total costs imposed as a result of this policy. As such, the Earned Annual Net Cost to Business (EANDCB) is £254,649. Benefits were not monetised, therefore the total net cost over the appraisal period is -£2,545,366 with NPV of -£2,193,254.

## BENEFITS

#### **Consumers Benefits**

Improved Confidence

15. No monetised benefits to consumers have been identified. Despite this, the increased measures required of RDM producers will have a positive impact on RDM consumers: they will have greater assurance over the product they are purchasing.

## **FBO Benefits**

**Enhanced Quality Assurance** 

16. No monetised benefits have been identified to RDM producers. However, the change could possibly impact FBOs positively if they demonstrate greater and sustained compliance which may attract more custom, or indeed attract RDM consumers from other non-complying competitors. However, this effect is likely to be somewhat muted, or entirely, by the necessary increases in production costs to the RDM producer associated with this policy change.

## **FSA Benefits**

**Proportional Regulation** 

17. No monetised benefits have been identified to the FSA. As official controls of RDM production are enforced by the FSA, through its Dairy Operations unit, it is the agencies legislative duty to protect consumers by reducing any risk associated with the production, supply or consumption of RDM. The requirement for RDM producers to adopt a bespoke FSMS, along with appropriate verification activities, will demonstrate that the FSA is a modern, flexible and competent regulator.

## WIDER IMPACTS

#### Small and micro business assessment

- 18. The UK food industry is comprised of mainly small and micro businesses (generally greater than 90%) and therefore the greatest impact from new measures in the UK will, in most cases, be on small and micro businesses. For this reason, the FSA assesses the impact on small and micro businesses as standard when undertaking impact assessments.
- 19. Most RDM producers across England and Wales are small or micro businesses. As a result, the FSA does not foresee the policy change to have a significantly disproportionate effect on small or micro businesses.

Unavoidable impact

20. Due to the high density of small and micro businesses in the English and Welsh RDM market, it is unfeasible to exempt said businesses from the proposed policy change as this would fail to achieve the intended effect of reducing unacceptable food-related risks to consumer health. That said, the FSA intends to make every effort to minimise burdens on small or micro businesses through providing clear guidance and general information to RDM producers.

## **Competition Assessment**

Reduction in number of RDM producers

21. The proposed policy change will place an additional burden on RDM producers in the form of increased production costs. If RDM producers are unable to transfer these costs on fully to the consumer, then it may force some producers to drop out of the market. This would lead to a reduction in the number of active RDM producers, which would necessarily reduce competition. As demand for RDM is largely contained locally, any reduction in competition could result in supply imbalances on a per area basis.

# Appendix

Figure 1: Spatial mapping of current RDM producers in England, Wales and Northern Ireland

