

Final Business and Regulatory Impact Assessment

Title of Proposal

Bulk Milk Sampling for Brucella Abortus – Amendment to The Brucellosis (Scotland) Order 2009 enabling a change to the Brucellosis Milk Sampling Regime for producer retailers.

Purpose and intended effect

• Background

Although Great Britain has had Officially Free Status (OFS) for Brucellosis since 1985, EU Directive 64/432/EEC requires the operation of a monitoring and testing programme to maintain that status. The Brucellosis (Scotland) Order 2009, as amended, implements the provisions of Council Directive 64/432/EEC and specifically details the requirements for the national surveillance programme including; investigations of reported abortions in cattle and for sampling and testing of milk for sale or resale as milk or milk products. Milk samples are submitted quarterly to a Government approved laboratory by all primary milk purchasers at their own expense. For producer retailers AHVLA currently collect the bulk milk samples and submits them to the approved lab for testing. All milk testing is currently undertaken in Scotland by National Milk Laboratories as part of an agreed contract with Scottish Government and costs for this work are charged to the devolved budget for Animal Health and Welfare.

A GB-wide review of brucellosis surveillance carried out in 2011 highlighted disproportionately high costs and resource associated with AHVLA undertaking collection of milk samples from producer retailers. Recommendations were made that the responsibility and costs should be transferred to industry bringing producer retailers in line with arrangements already undertaken by primary milk purchasers for all other milk samples. It is considered that in practice this will not impose a significant burden on producer-retailers and will have the added benefit of reducing the biosecurity risk to producers with removal of the need for AHVLA visits and at the same time maintaining a robust disease surveillance regime at a negligible cost to Industry.

• Objective

To transfer costs and responsibility for collection and submission of milk samples to Producer Retailers (PR) of milk. This is to bring them in line with primary milk purchasers who already have a statutory responsibility under The Brucellosis (Scotland) Order 2009, as amended, to supply bulk milk samples on a quarterly basis to an approved laboratory for testing at their own expense and to bring surveillance testing for this small number of dairy herds to a more proportionate and cost effective level.

The amendment to the Brucellosis (Scotland) Order 2009 will support the Government's Economic Strategy and the strategic priority of Effective Government through increasing the public sector's direct contribution to the economy through smart use of the public purse. Additionally, the amendment will bring producer retailers in line with primary purchasers of milk thereby ensuring equality of treatment within the Dairy Sector with regards to Brucellosis disease surveillance.

- **Rationale for Government intervention**

Council Directive 64/432/EEC on animal health problems affecting intra-community trade in bovine animals and swine, defines the requirements for a monitoring and testing programme for Brucellosis to ensure that animals intended for intra-community trade are not a source of contagious or infectious disease. A recent GB-wide review of brucellosis surveillance highlighted disproportionately high costs and resource associated with AHVLA undertaking collection of bulk milk samples from producer retailers in satisfying this EU requirement. This practice is inconsistent with the arrangements for the rest of industry where sampling is undertaken through primary milk purchasers. There are also benefits to producer retailers in submitting their own samples with the removal of the biosecurity risk posed by AHVLA collecting samples. It is therefore recommended that PR's submit their own milk samples in future.

Consultation

- **Within Government**

The Food Standards Agency (FSA) was consulted in relation to any possible public health issues. They advised that the need to pasteurise all drinking milk before sale in Scotland (Dairy Products (Hygiene) (Scotland) Regulations 1995, as amended) would address any risk of Brucellosis infection from a public health perspective. Where products made from raw milk are sold direct to the consumer, PRs are required to produce a HACCP plan (Hazard Analysis and Critical Control Point) which also takes Brucellosis infection into account and therefore the FSA have no concerns about transferring responsibility for submitting samples to the PRs.

Devolved Administrations

The issue has been discussed with colleagues in Defra and Welsh Assembly Government who are fully in agreement with this proposal. A consistent approach to implementation throughout GB is preferable and Defra are to consult shortly on amending their legislation to reflect a similar change in approach.

- **Public Consultation**

There will be no public consultation as there is no direct effect on the public.

- **Business**

The possibility of transferring responsibility for this testing was raised informally with stakeholders at one of the regular Stakeholder Meetings on 30 April 2012. There were no objections raised at that time and it was advised that there would be further consultation if a legislative approach was to be taken.

We understand that there are approximately 17 producer retailers in Scotland. Most of these are classified as micro businesses having less than 10 employees.

All 17 Producer Retailers in Scotland and the industry bodies listed below were consulted by means of discussion paper. The discussion paper was issued on the 1 November 2013 and included both the BRIA and a questionnaire for responses, which were requested by 13 December 2013.

1. Dairy Co
2. Dairy UK
3. Scottish Dairy Cattle Association
4. Scottish Dairy Association
5. Food Standards Agency Scotland
6. Royal Association of British Dairy Farmers
7. National Farming Union Scotland

We received very limited feedback (2 responses from individual Producer Retailers - one in favour and one against – none from industry) on the discussion paper and have, on balance, taken this to signify that the consensus is acceptance of the Scottish Government proposal to bring both primary purchasers and producer retailers of milk in line by placing the statutory obligation for collection and supply of samples for Brucellosis testing across the dairy industry.

Options

1. Do Nothing – AHVLA continue to collect samples from the producer retailers and submit them for testing.

2. Option 1 - Voluntary Approach – Agreement from PRs would be sought that they would voluntarily supply milk samples to an approved laboratory for testing each quarter. Sample pots and dippers would be provided to them by AHVLA for this purpose and postage would be prepaid.

With no enforcement procedure available, AHVLA would still need to monitor the situation and provide back up if necessary to ensure samples were being received. This option would have no cost implications for the PRs.

3. Option 2 - Legislative Approach – A new statutory obligation would be introduced, this would require an amendment to the extant Brucellosis (Scotland) Order and consultation with those affected would also be undertaken.

PRs would have to supply bulk milk samples on a quarterly basis to an approved laboratory for testing at their own expense. Sample pots and dippers for this purpose could be purchased by them from the approved laboratory (currently National Milk Laboratories). Test costs will continue to be met by Scottish Government and charged to the devolved budget for Animal Health as is the case for primary purchasers.

This approach would allow costs to be recovered in the event of non-compliance and although there would be a small financial increase for PRs it would ensure consistency with current requirements for primary milk purchasers.

- **Sectors and groups affected**

The proposed changes will only affect Producer Retailers of Milk within Scotland, of which there are around 17.

- **Benefits**

Do Nothing

With no change in the current situation there would be no cost increases for PRs, and the surveillance programme would be effectively maintained ensuring any re-emergence of the disease is quickly identified.

Option 1 - Voluntary Approach

There would be no additional cost to PRs as all costs for testing, equipment and postage to send samples to the laboratory would still be met by Scottish Government.

Removal of biosecurity risk with no visit required from AHVLA representative to collect sample. More flexibility over when milk is sampled should also benefit business operations by reducing any associated disruption to the daily routine.

Option 2 - Legislative Approach

Costs to Scottish Government would be reduced through the removal of the need for an AHVLA representative to visit premises to take a milk sample.

Removal of biosecurity risk with no visit required from AHVLA representative to collect sample. More flexibility over when milk is sampled should also benefit business operations by reducing any associated disruption to the daily routine.

Legislation would enable recovery of costs from PRs in the event of non-compliance.

Transferral of collection cost and responsibility to PRs will bring them in line with primary purchasers of milk for whom it is already a legislative requirement to submit, at their own expense, a quarterly sample for testing at an approved laboratory.

Current surveillance levels would be effectively maintained enabling timely identification of any disease incursion and under statutory conditions surveillance is likely to achieve greater compliance than under a voluntary requirement.

- **Costs**

Do Nothing

The cost to Government of collecting quarterly samples from PR's is estimated to be £8846 per annum. Costs are associated with time to arrange and carry out the farm visit, including travel time, collection of the sample and submission to the laboratory and test costs.

Costs to PR's are associated with the time to arrange and supervise AHVLA visits to collect the bulk milk samples. On average time to arrange and supervise a visit is estimated at approximately 25 minutes, at a cost of £4.72 per visit.¹

¹ This cost has been calculated using the "Skilled agricultural and related trades" hourly wage figure from the 2012 Survey of Hours and Earnings (provisional results, ONS) and adding 30% for leave, absence and employer NI contributions. This is a standard method for deriving the labour costs to business.

Option 1 - Voluntary Approach

The £128 cost of an AHVLA representative to collect each sample would be removed for Scottish Government under this option but the £17pa cost of the testing kits would remain. Postage costs estimated at £693 would also be incurred by SG under this option. The test cost of £121pa also remains under this option.

Costs to PR's would only be in the time taken to collect the sample itself and which is considered to be negligible, as it can be done at the time of emptying the bulk milk tanks.

With no mechanism to enforce the requirement to supply samples under a voluntary approach, any failure to supply the required sample significantly raises the risk of re-emergence of the disease thus enabling an incursion of the disease to remain undetected.

Additionally, AHVLA resource may on occasions still be required where samples were not being submitted.

Option 2 - Legislative Approach

The £128 cost of an AHVLA representative to collect a sample would be removed for Scottish government under this option and the £3.60 cost of the testing kit and £8.64 postage would be passed on to the PRs per sample. The test cost of £121pa for Government also remains under this option.

Costs to PR's would include the time taken to collect the sample itself which is considered to be negligible, as it can be done at the time of emptying the bulk milk tanks. There would be a potential additional cost of £2 per sample which would only apply for missed samples to cover the cost where follow up action with PR's to submit samples had to be taken by the approved laboratory.

Scottish Firms Impact Test

As previously mentioned, an informal consultation with all 17 Producer Retailers in Scotland was undertaken by discussion paper which was issued on 1 November 2013 with responses to be submitted by 13 December 2013. The introduction of a requirement for producer retailers (most falling under the definition of micro businesses) to submit bulk milk samples themselves would impose a new statutory responsibility with an associated minimal cost increase of £7.52 per sample. However, this has already been effectively offset by a related cost saving in 2011 when a change was made to the Brucellosis Order reducing testing frequency from monthly to quarterly. Costs to supervise AHVLA sampling visits is estimated at £4.72 per visit² with resulting savings of £37.76 per year. There is also an option for PRs to further reduce milk sampling costs by using quarterly bulk milk samples submitted for Brucellosis for other mandatory microbiological testing, such as BVD.

There was limited feedback from the discussion paper received with only two questionnaires returned. Both responses received were from individual producer retailers and are summarised below.

² This cost has been calculated using the "Skilled agricultural and related trades" hourly wage figure from the 2012 Survey of Hours and Earnings (provisional results, ONS) and adding 30% for leave, absence and employer NI contributions. This is a standard method for deriving the labour costs to business.

Response 1 – Happy with current system which they felt worked well – unhappy about undertaking bulk milk sampling in line with primary milk purchasers in terms of both cost and time – concerns about refrigeration /spoilage issues. Concerns on refrigeration/spoilage were addressed directly in writing.

Response 2 – Content to undertake bulk milk sampling responsibility in line with primary milk purchasers although would still be preferable to have AHVLA do it – agreed this would bring about greater fairness within the dairy industry with regard to Brucellosis disease surveillance – content that the estimated cost increase was fair and reasonable- agreed that a legislative approach was the best option for maintaining a robust disease surveillance regime – did not foresee any problems with the proposed new process.

There were no face to face discussions carried out as these were considered to be disproportionate in relation to the overall impact of this change.

Competition Assessment

- Will the proposal directly limit the number or range of suppliers? e.g. will it award exclusive rights to a supplier or create closed procurement or licensing programmes?

The proposed amendment will have no effect on competition within the Dairy Industry as the scale of the additional costs is very small if not negligible. Additionally, conditions for surveillance testing will be made equal across the Dairy Industry as a result of the proposed amendment. This will rectify the situation where currently producer retailers enjoy somewhat of a privileged position over primary purchasers who already have a statutory obligation to collect and supply samples for disease surveillance at their own cost. Scottish Government will continue to be responsible for the brucellosis milk testing costs, and the current testing contract is held by National Milk Laboratories. This was awarded after the required invitation to tender was published on the Public Contracts Scotland website. The current contract is due for renewal in March 2014. Options for return postage of items are limited as Royal Mail is the only current universal service supplier. Other mail suppliers do not cover all parts of Scotland.³

- Will the proposal indirectly limit the number or range of suppliers? e.g. will it raise costs to smaller entrants relative to larger existing suppliers?

Costs and sample numbers per year will be the same for all producer retailers regardless of business size but the cost is considered to be minimal.

- Will the proposal limit the ability of suppliers to compete? e.g. will it reduce the channels suppliers can use or geographic area they can operate in?

The requirements for submitting a bulk milk sample can be met during the normal practices of milk producers. Additionally, PRs will benefit from being able to take samples at a time that suits their individual practices as opposed to fitting in with an AHVLA visit.

In terms of market capability for laboratories offering the brucellosis testing, this is a specialised service which receives limited interest from those laboratories with the capability and capacity to take on this testing work. Geographic area is not an issue for laboratories as the samples will be posted.

³ Information taken from the AHVLA ops manual for return of samples to AHVLA under current process.

- Will the proposal reduce suppliers' incentives to compete vigorously? e.g. will it encourage or enable the exchange of information on prices, costs, sales or outputs between suppliers? No

Test run of business forms

- Are the proposals likely to introduce any new forms for business to fill in?

No, test kits will be supplied already containing barcode information specific to each producer retailer.

Legal Aid Impact Test

The Scottish Government's Legal Aid Team have confirmed that this policy should not impact upon the legal aid fund.

Enforcement, sanctions and monitoring

National Milk Laboratories (NML) currently carry out, under contract, all milk testing for Brucellosis in Scotland and invoices are submitted for payment on a quarterly basis. As part of the agreed contract they operate a monitoring process and submit to Scottish Government quarterly management reports detailing all samples tested, any positive samples recorded and any that have been missed, including the reasons why. This management information already includes samples for producer retailers as currently submitted by AHVLA and would continue to do so. This would be used to monitor PR samples were being submitted and any that are missing would be followed up as they are now. A legislative approach would allow AHVLA intervention and subsequent cost recovery in cases of non-compliance. Local authorities would be responsible for enforcement due to potential significant health risk to both humans and animals for non-compliance.

We are amending the existing Brucellosis (Scotland) Order 2009 to transfer costs and responsibility for collection and submission of milk samples from AHVLA to the producer retailers by extending existing provisions under Article 7(1) of the above Order to include section 7(1A) and this amendment will come into force on 1 April 2014.

The offence provisions that will apply should a person fail to take the action referred to in Article 7 (4) of the above Order will also be extended to include section 7(1A) and will be set out in section 7(6) with penalties detailed in section 7(9).

Powers for Article 7 of the 2009 Order were provided by section 2 (2) of the European Communities Act 1972 but the penalties applied reflect those in Section 75(2) of the 1981 Act, which apply to the rest of the 2009 Order, in that persons guilty of an offence are liable on summary conviction to imprisonment for a term not exceeding 6 months or to a fine not exceeding level 5 on the standard scale or both. These penalties were referred to and agreed by the Criminal Law and Sentencing Branch.

Implementation and delivery plan

The amendment to the current Brucellosis Order is intended to come into force on 1 April 2014.

The intention will also be to issue a guidance note to all producer retailers making clear the new process required of them to submit samples and will detail contact details of National

Milk Laboratories, etc. This document would also be published on the Scottish Government Website.

- **Post-implementation review**

As stated previously National Milk Laboratories currently produce quarterly spread sheets for the Scottish Government detailing samples tested. This would also include producer retailers and could be used to monitor the effectiveness of the new legislation and identify any further improvements required to increase submission rates should there be any issues with these. Therefore, review will be on-going on a quarterly basis.

Summary and recommendation

In summary, a change to the current Brucellosis legislation to transfer responsibility and costs for brucellosis testing of milk samples from AHVLA to producer retailers (PRs) is being pursued due to the disproportionately high costs and resource associated with AHVLA undertaking collection of milk samples.

Option 2 is the preferred option – By introducing a statutory requirement for PR's to submit bulk milk samples in future, this represents a far more cost effective option than AHVLA continuing to conduct visits including those to remote Island locations to collect samples. A legislative requirement will ensure that requirements are clear, enforceable and in line with requirements for primary milk purchasers and will maintain the status quo with regards to surveillance at a minimal additional cost. Discussion with the other devolved governments have shown that making this change through legislation is also their preferred option

- **Summary costs and benefits table**

Tables outlining costs & benefits of each option considered.

1. Current Costs to Scottish Government

		Per sample	Total per quarter @17 Samples	Total per annum @ 68 samples
AHVLA Field Costs ⁴		64.74	1100.58	4402.32
AHVLA Core/Hard Costs		63.33	1076.61	4306.44
AHVLA Equipment Costs	Pots	0.13	2.21	8.84
	Dippers	0.12	2.04	8.16
NML Test cost		1.78	30.26	121.04
Totals		130.10	2211.7	8846.80

2. Current Costs to Industry

		Per sample	Total per PR @ 4 Samples	Industry per annum @ 68 samples
AHVLA sample collection supervision ⁵		4.72	18.88	320.96
Totals		4.72	18.88	320.96

⁴ This cost includes travel, subsistence, hours, postage and packaging for the current AHVLA sample collection

⁵ This cost has been calculated using the "Skilled agricultural and related trades" hourly wage figure from the 2012 Survey of Hours and Earnings (provisional results, ONS) and adding 30% for leave, absence and employer NI contributions. This is a standard method for deriving the labour costs to business.

3. Option 1 - Proposed costs to Scottish Government - Voluntary approach

AHVLA		Per sample	Total per quarter @17 Samples	Total per annum @ 68 samples
Equipment costs	Pots	0.13	2.21	8.84
	Dippers	0.12	2.04	8.16
Packaging & dispatch costs	Outward P&P	3 ⁶	51	204
	Return P&P	7.2 ⁷	122.4	489.6
NML Test cost		1.78	30.26	121.04
Total		12.23	207.91	831.64

4. Option 2 - Proposed costs to Scottish Government – Legislative approach

	Per sample	Total per quarter @17 Samples	Total per annum @ 68 samples
NML Test cost	1.78	30.26	121.04

5. Option 2 - Proposed increase to Industry – Legislative approach

NML	Per sample	Total per PR @ 4 Samples	Industry per annum @ 68 samples
Equipment costs	3.6	14.4	244.8
Postage costs	8.64	34.56	587.52
Cost to supervise sample collection	-4.72	-18.88	-320.96
Cost to chase samples	2	8	136
Total (including charge to chase samples)	9.52	38.08	647.36
Total (excluding charge to chase samples)	7.52	30.08	511.36

⁶ This cost is based on the size dimensions of a Safebox being sent to PR through Royal Mail small packet service.

⁷ Royal Mail Safebox – box of 12 currently priced at £72 +VAT

