

Business and Regulatory Impact Assessment

04 November 2022

Final Business and Regulatory Impact Assessment

Title of Proposal

The Tuberculosis (Scotland) Amendment Order 2022

Purpose and intended effect

Background

Bovine Tuberculosis (bTB) is a serious infectious disease of cattle, caused by the bacterium *Mycobacterium bovis* (*M. bovis*) and a major challenge currently facing large parts of the UK cattle farming industry. The disease is characterised by the development of “tuberculosis” lesions in any organ of the body. It mainly affects cattle but can be passed between most mammals. It is also a zoonotic disease which means it can be passed from infected animals to people, causing an illness similar to human TB. The risk of people contracting TB from cattle in Great Britain (GB) is however considered to be very low.

Scotland achieved Officially Tuberculosis Free Status (OTF) in September 2009, in recognition of the relatively low and stable incidence of TB found in Scottish herds, and this pattern is consistent with sporadic introductions of disease which are eradicated through testing and removal of infected cattle.

The current [Tuberculosis \(Scotland\) Order](#) came into force in 2007 and has been amended a number of times since, most recently to make amendments arising from the withdrawal of the United Kingdom from the EU. The proposal is to make an amendment to the current order, prior to consolidating the Order and making further amendments in 2023.

- **Objective**

The main objective of this proposal is to amend the Tuberculosis (Scotland) Order to ensure that when samples are taken with the intention of applying a diagnostic test for TB, permission must be sought from Scottish Ministers. This will enable conditions to be set, such as a requirement to report any results, to make Scottish Ministers aware of the number of cattle tested, the locations of the participating farms.

It is recognised that scientific and technological advances may bring benefits through reducing time taken to sample, reduce costs and bring greater confidence in tests. However, in the event of samples being tested by third parties with an unvalidated TB test, there is the potential for cattle to be reported inaccurately as testing positive for TB. Any unvalidated claims of infected cattle, even though these could be false positives, could bring our recognised low infection rates into question and impact negatively on Scotland’s OTF status, as numbers of herds infected with TB needs to meet specific criteria. Losing our OTF status would have a negative effect on the cattle industry and could disrupt trade. This is a serious and urgent concern, and we want to urgently take forward the policy to manage

this risk.

The objective of this proposal is to ensure that TB controls in Scotland continue to be effective and fit for purpose. The legislative changes being introduced by this amendment aim to support the maintenance of our low and stable levels of TB in Scotland. These changes are intended to further safeguard our OTF status and to facilitate continued trade with EU Member States.

Scottish Government are of the view that this is a necessary amendment to effectively deliver effective TB disease control policy in Scotland.

- **Rationale for Government intervention**

Scotland was recognised as being officially TB free (OTF) by the European Commission in September 2009. This status is currently a unique position within Great Britain and recognises the low and stable incidence of TB and the high standards of animal welfare achieved in Scottish herds. Maintaining that OTF status and Scotland's reputation for high quality produce is crucial to the continuing success of the Scottish cattle industry. Losing our OTF status would impact on Scotland's international reputation as having healthy cattle which are free from infection, which may affect trade. It would also mean that more TB testing would have to be undertaken, at the cost of the taxpayer, as currently with OTF status you can exempt herds from testing if they are low risk and consequently 60.4% of Scottish herds do not need to be routinely tested for TB. Returning to this routine testing would be time consuming and costly for Scottish farmers. This would also draw upon more government resources, such as veterinary and laboratory time, and time to report results, all of which would divert resource away from other key priorities.

The Scottish Government (SG) is committed to a comprehensive, practical and proportionate programme of measures to maintain the current low levels of TB in cattle and other species and to safeguard our OTF status. This includes minimising the risks from all potential sources of infection and reducing the risk of disease spread as far as possible.

National Performance Framework

The policy change meets the following outcomes from the National Performance Framework:

- *value, enjoy, protect and enhance their environment*
- *have a globally competitive, entrepreneurial, inclusive and sustainable economy*
- *are healthy and active*

Reducing endemic disease can have significant advantages for reducing the carbon footprint associated with livestock production, as healthier animals tend to grow faster and require fewer inputs, all of which will reduce the emissions intensity per kg of meat or litre that they produce. This will also improve the

welfare of animals and protect public health by reducing the number of cows which become affected by TB (and then compulsorily slaughtered as a result) by putting in stricter legislation that protects Scottish cattle.

In making these changes now the aim is to continue to safeguard our low levels of TB and in doing so contribute to Scotland's National Performance Framework by maintaining Scotland's reputation for high quality produce and helping to increase Scotland's economic growth by increasing exports of healthy cattle and beef.

Consultation

Within Government

SG have consulted with the Animal & Plant Health Agency (APHA) as our lead operational delivery partner for implementing Scottish Government's TB control policy and implementation of the proposed changes consulted on in 2022.

Initially the plan was to consolidate the current legislation and bring in a number of amendments in 2022, however, APHA will need time to implement the changes to operational instructions. As such only one amendment is being taken forward at this time as a priority. A full consolidation with a more complete set of changes will be introduced in Spring next year to ensure APHA can deliver the legislative changes made at an operational level. This will also provide sufficient time for Scottish Government to update industry stakeholders on the forthcoming changes. Consolidating and bringing in a number of further amendments to this instrument remains a top priority, as consolidation will make the legislation more accessible and the amendments will further strengthen disease control policy.

SG also consulted with colleagues in Defra and the Welsh Government at an early stage to review both current provisions and recent disease control amendments for bovine TB within their jurisdictions and to identify what other changes are being considered for the future. Colleagues in the devolved administrations have been kept up to date through groups such as the TB Liaison Group, the Cattle Vaccination group and the Badger Vaccination group.

Both Defra and the Welsh Government have run consultations within the last year relating to legislative changes and the outcomes of these consultations have been considered as part of these proposals.

Public Consultation

The consultation on changes to the TB Order ran from 9th May 2022 until 1st August 2022 on Citizens Space, a total period of 12 weeks. This consultation was on the proposals to introduce changes to disease control measures and compensation arrangements for TB in Scotland.

The consultation received 19 responses and this included 7 key stakeholder organisations, such as National Farmers Union Scotland (NFUS), the Scottish Beef Association (SBA), the British Veterinary Association (BVA) and British Cattle Veterinary Association (BCVA). Disease control for Bovine TB is a specialised subject, and so a limited number of responses is not entirely unexpected.

The consultation helped to gauge attitudes towards these proposals and make informed and proportionate decisions on whether proposals should be taken forward or not. It also helped to identify any unanticipated impacts that these changes would have on the farming industry.

The responses provided useful feedback which has been used to inform decisions on how Scotland's TB policy will be developed. It was clear that there is support among the various respondent groups for the changes proposed. SG has therefore decided to take forward six out of the eight changes consulted on.

Changes being implemented at this time (Amendment Order 2022)

- Amend the provisions for the application of diagnostic tests, to include a requirement for the prior written permission of Scottish Ministers where non-statutory and private samples are taken with the intention of applying a diagnostic test for TB. – *The majority of respondents agreed with this proposal (73.68%), with many supporting on the grounds that this provides a full picture of disease surveillance. Of those who disagreed there was some misunderstanding that this may impact on the work of vets undertaking testing, or those who wish to test to dispute their results. It will be made clear in the consultation response that this is not the case and the purpose is to target third parties / private companies who are sampling with the intention of applying TB tests, and rather that conditions will be applied which will give an awareness of the results in Scotland to ensure that the government has a full disease picture.*

Changes being implemented in 2023 Consolidation

- End the practice of accepting a clear final short interval test (SIT) at the end of all TB breakdowns as a valid pre-movement test.
- Shorten the period during which a pre-movement test with negative results remains valid, from the current 60 days to 30 days after tuberculin injection.
- Reduce compensation for unclean cattle at slaughter by 50%.
- Include requirements for 'isolation' in legislation to ensure that proper isolation of reactors and inconclusive reactors is undertaken.
- Reduce compensation for reactors or IRs which are not properly isolated.

Changes **not** being implemented

- Strengthen the TB isolation requirements by specifying a location for isolation to take place – *Although a small majority (52.63%) agreed with this proposal, this would require a significant amount of resource to action and the benefit was not considered to be great enough to change this from the status quo. Instead, a*

more appropriate route would be to provide clear guidance on the isolation requirements, in tandem with the requirements which will be provided through the legislation as a result of the change outlined above within the measures that will be taken forward in 2023.

- Include a reduction in compensation where subsequent reactors in the herd are found as a result of a failure to properly isolate a reactor or IR . – *The majority of respondents disagreed with this proposal (52.63%) with many noting that this would be very difficult to prove and infection could occur for a number of reasons other than insufficient isolation of a reactor. Following internal discussion on the consultation result, it was agreed that proving the source would be difficult and as a result it was decided not to take the proposal forward.*

Business

As well as being made publically available on the Scottish Government website, the consultation was issued directly to a wide range of stakeholder groups including livestock businesses and associations, enforcement agencies and animal health organisations with a potential interest.

The proposals outlined in the consultation were discussed with a range of stakeholder groups at the SG Animal Health and Welfare General Stakeholder Meetings, with regular reminders of where members could respond to the consultation. This group contains members with an active interest in this consultation from a range of organisations, such as the British Cattle Veterinary Association (BCVA), the British Veterinary Association (BVA), Scotland's Rural College (SRUC), Quality Meat Scotland (QMS) and also many individual farmers. This was followed up with written correspondence to encourage these stakeholders to provide their views to the consultation.

Communications

The consultation was advertised through the SG website and through regular posts on the SG social media channels. In addition, the audience of these posts was boosted by organising retweets from the Chief Veterinary Officer Scotland and APHA.

Options

Option 1 - Do Nothing – (Status Quo) – No legislative changes

Under this option further regulation would not be introduced and current arrangements in relation to bovine TB controls provided by the Tuberculosis (Scotland) Order 2007 as amended would continue as they are now.

The early identification and removal of test positive cattle under the existing disease control policy has kept Scotland Officially TB free since 2009.

OTF status is recognition of the relatively low and stable incidence of TB found in Scottish herds. This does not mean that Scotland has no cases of bovine

tuberculosis, but recognises that there are relatively few cases, below the threshold for that designation. Each year there are a small number of new confirmed breakdowns which can generally be attributed in the most part to imported infection from other parts of the UK where TB continues to be a significant problem for both the cattle industry and Government alike.

To do nothing could therefore potentially put Scotland's OTF status and the future of the Scottish cattle industry at risk and would result in strong criticism from the cattle industry for appearing complacent in not taking strong enough action to incentivise compliance and best practice to keep disease out of Scotland.

Option 2 – Introduce changes to TB controls - amend the Tuberculosis (Scotland) Order 2007

The second option is to make an amendment to the Order to bring in changes to diagnostic testing permissions for those taking samples, and then in 2023 consolidate the legislation and bring in legislative changes related to pre-movement testing, compensation for unclean cattle at slaughter, and isolation requirements.

This option would provide the opportunity to enact the following policy:

- Amend the provisions for the application of diagnostic tests, to include a requirement for the prior written permission of Scottish Ministers where non-statutory and private samples are taken with the intention of applying a diagnostic test for TB.

Sectors and groups affected

The main group affected by this change will be research and test development companies who will now need permission to test blood and milk samples outside of Scotland, and may be subject to reporting back on certain conditions set by Scottish Ministers. Also affected would be those who own or keep bovine animals on a premises in Scotland, as they may wish to be involved in these trials.

Occasionally cattle keepers, research companies, or other third parties, seek permission to take samples from Scottish herds to undertake TB testing in private laboratories, however permission is not required to take samples and test these in a country which is not Scotland. What happens to these samples in other countries cannot be controlled by the Scottish Government, so the policy change will require permission to be sought where samples are taken with the intention of undertaking TB testing. This policy change will mainly affect those who seek to undertake diagnostic testing/validation studies for TB tests, as it will require that they must seek permission to take any samples and there may be conditions related to this where they must report certain information to Scottish Ministers, such as sample types, the number of cattle tested, farm locations, and results.

Benefits

Option 1 – Do Nothing (Status Quo)

The current system generally works well and livestock keepers are familiar with the existing requirements for TB testing and control.

Doing nothing would not however be in the best interest of the cattle industry as a whole, and there is not considered to be any real financial or disease control benefits for either Government or industry by taking no action.

The risk of not putting through this legislation is that if there are trials where TB samples are taken and tested, and these samples show to be positive, there would be no clear path on how to manage these results and control disease. Information on where disease was present or how many cattle were affected would not be provided. If many cattle are disclosed as testing positive this could put our officially TB free status at risk, which would have a negative effect on the cattle industry and could result in disruption to trade.

Option 2 - Introduce changes to TB controls - amend the Tuberculosis (Scotland) Order 2007

Under this option there will be the opportunity to strengthen our existing TB controls that will help to maintain our current low levels of TB in cattle and safeguard our valuable OTF status.

In situations where TB samples will be taken in Scotland to test with a diagnostic tool which has not been validated, the Scottish Government would not have access to any information relating to test positive cattle. In positive cases the government would have no access to any information on the number of cattle affected, the location of these cattle etc. If many cattle are disclosed as testing positive, even if this is through an invalidated test, this could put our officially TB free status at risk, which would have a negative effect on the cattle industry and could result in disruption to trade.

These legislative changes will allow conditions to be set in cases of samples being taken for diagnostic testing, which would allow access to information such as which cattle are reactors and where these are. This would ensure that the government have full awareness of any testing carried out, and the results of this testing, and can consider what implications this has for TB control in Scotland.

Costs

Option 1- Do Nothing (Status Quo)

No additional costs or savings are anticipated with this option.

Option 2 - Introduce changes to TB controls - amend the Tuberculosis (Scotland) Order 2007

Amend the provisions for the application of diagnostic tests, to include a requirement for the prior written permission of Scottish Ministers where non-statutory and private samples are taken with the intention of applying a diagnostic test for TB

This policy is to extend a current policy where applying a diagnostic test for tuberculosis is not permitted without consent from the Scottish Ministers. This would simply extend this policy to include taking samples with the intention of applying a diagnostic test. This means if samples are sent to other countries for testing there would be a requirement to report results to Scottish Ministers, who would set the conditions of the information required in relation to these tests. There are no additional costs anticipated in making this change. It is expected there will be some minimal additional costs to the third parties who are undertaking the sampling, as those which are approved to sample and test will need to report their findings to the Scottish Government. This will result in a cost to the company undertaking the research, as they will need to provide time resource through the operational cost of putting in place reporting requirements.

Scottish Firms Impact Test

These legislative changes could potentially have an impact on international trade if they are not taken forward, however they are unlikely to have an impact on international investment.

If many cattle are disclosed as testing positive this could put our officially TB free status at risk, which would have a negative effect on the cattle industry and could result in disruption to trade. Without this policy, there would be no means for the government to request the details of the affected cattle and this would mean that the full disease picture for TB would not be available.

Competition Assessment

These amendments to the Tuberculosis Order will not impact negatively on competition within the sector.

Question	Answer
Will the measures directly or indirectly limit the number or range of suppliers?	No
Will the measures limit the ability of suppliers to compete?	No
Will the measures limit suppliers' incentives to compete vigorously?	No
Will the measure limit the choices and information available to consumers?	No

Consumer Assessment

This amendment will not have any impact on consumers.

Test run of business forms

No new business forms are required to be completed by herd owners affected by these legislative amendments.

Digital Impact Test

It is not anticipated that there will be any digital impact with these legislative changes.

Legal Aid Impact Test

It is not anticipated that these changes will give rise to any additional need for legal aid.

Enforcement, sanctions and monitoring

APHA, as Scottish Government's operational delivery partner, are responsible for all aspects of disease control for bovine TB for reported or suspected cases of disease (inspections, test notifications, testing, reactor removal, valuation and payment of compensation) including any follow up in relation to non-compliance and all activity associated with the judicial process.

Local authorities are responsible for enforcement of the Tuberculosis (Scotland) Order 2007 under the Animal Health Act 1981 due to the potential health risk to both humans and animals as a result of non-compliance with the rules.

Scottish Ministers are required to pay compensation for any bovine animals slaughtered in relation to bovine TB under section 32 of the Animal Health Act. Where a keeper has acted illegally or failed to comply with the statutory testing requirements for their herd, and powers would be available to either withhold (£1 nominal payment) or reduce the amount of compensation paid, depending on the circumstances. It is considered only fair and reasonable that where a keeper has knowingly broken the rules, they should not then be able to recover the full market value for animals that become diseased and are slaughtered as a result of their poor farming practices or non-compliance.

This TB Order is made under the Animal Health Act and so inspector powers of entry, testing, seizure and slaughter are all contained in that Act. Obstruction of inspectors in exercise of their duties and non-compliance with any requirements of the Order will be prosecuted under the Animal Health Act. A person guilty of an offence under the Animal Health Act is liable on summary conviction to a term not exceeding 6 months imprisonment or to a fine not exceeding level 5 on the standard scale or to both.

For this change, there would be an amendment to article 26 of the TB order to require those who are taking samples with the intention of applying a diagnostic test for TB to request consent from the Scottish Ministers.

Implementation and delivery plan

Implementation

The making date for this legislation will be the 10th November 2022, with the laying date as 14th November 2022 and then a subsequent coming into force date on 28th November 2022.

Delivery Plan

TB controls in Scotland are already well established and delivered by APHA as our operational delivery partners. APHA have carried out the required Request for Policy Driven Change and Response form for this proposed change and which are now in the process of being adopted into "business as usual" by the APHA project delivery team.

For communications, a letter will go out to general stakeholders, and those who responded to the consultation to make them aware of this change and the further upcoming proposed changes in 2023. An SG news release will also be published and this will be promoted on social media. This will summarise the policy, stressing that currently permission is already required to apply a private diagnostic test for TB on a bovine animal, and this policy is being expanded so that going forward permission is also required for taking samples for the purpose of applying a diagnostic test for tuberculosis. An Official Veterinarian (OV) briefing note will also be provided to update on these changes.

As part of the agreed communications plan APHA will write a briefing for Official Veterinarians (OVs), which will also cover communication with labs in Scotland to make them aware of this change. A letter to Scottish Government stakeholders and a Scottish Government news release will also be issued.

- **Post-implementation review**

Disease Control measures for bovine TB are subject to continuous monitoring and review. More changes are planned next year, when further amendments will be made under the Tuberculosis (Scotland) Order 2023, and at this point any legislation which is not considered fit for purpose will be remedied.

Summary and recommendation

Scotland was recognised as being officially TB free (OTF) by the European Commission in September 2009. This status is a unique position within Great Britain and recognises the low and stable incidence of TB and the high standards of animal welfare achieved in Scottish herds.

Defra and the Welsh Government have both recently introduced substantial changes to their respective TB Programmes. In also reviewing and updating our TB legislation, this will ensure that our policies continue to be fit for purpose, incentivise compliance and best practice, and ensure these policies are financially sustainable in the future. This will occur between this amendment, and the full consolidation and amendments which will take place in 2023.

Maintaining Scotland's OTF status and reputation for high quality produce is crucial to the continuing success of the Scottish cattle industry. For this reason the recommended option is:

- **Option 2 – Introduce changes to TB controls - amend the Tuberculosis (Scotland) Order 2007**

Responses to the consultation provided useful feedback on the proposals and gave a clear indication that there is support among the various respondent groups for the changes proposed and the importance attached to maintaining the OTF status by the Scottish cattle industry. That is why at this stage a change will be made to require

permission for samples taken with the intention of applying a diagnostic test for TB, followed by a number of further amendments and a consolidation in 2023. It was assessed that this amendment is a priority which is why this is being taken forward at this time, with further policy changes in 2023. The further changes will include a consolidation of the current legislation, and this will require more time to allow APHA to make the necessary changes to documentation, and for clear communications to be distributed to cattle keepers, which is why these changes are being delayed until next year.

• **Summary costs and benefits table**

Option	Total benefit per annum: - economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
<p>Option 1 Do Nothing (Status Quo)</p>	<p>The current system generally works well and livestock keepers are familiar with the existing requirements for TB testing and control.</p> <p>To do nothing would not be in the best interest of the cattle industry as that could potentially put Scotland's OTF status at risk</p>	<p>No additional costs or savings are anticipated with this option.</p> <p>Compensation would continue to be paid at full market value for all cattle that become diseased even as a result of poor farming practices, such as presenting unclean cattle at slaughter or non-compliance in relation to areas such as isolation.</p>
<p>Option 2 Introduce changes to TB controls - amend the Tuberculosis (Scotland) Order 2007</p>	<p>This options provides the opportunity to:</p> <ul style="list-style-type: none"> • Amend the provisions for the application of diagnostic tests, to include a requirement for the prior written permission of Scottish Ministers where non-statutory and private samples are taken with the intention of applying a diagnostic test for TB. 	<p>This change will not result in any additional costs to SG. It is difficult to accurately assess what the total savings would be.</p> <p>It is expected there will be some minimal additional costs to the third parties who are undertaking the sampling, as those which are approved to sample and test will need to report their findings to the Scottish Government. This will result in a cost to the company undertaking the research, as they will need to provide time resource through the operational cost of putting in place reporting requirements.</p> <p>As our operational delivery</p>

		<p>partners, APHA have carried out a Change Management Assessment for all proposals and do not anticipate any significant costs to implement any of the proposed changes.</p>
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Declaration and publication

I have read the Business and Regulatory Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs. I am satisfied that business impact has been assessed with the support of businesses in Scotland.

Signed: Mairi Gougeon

Date: 10 November 2022

Minister's name - Mairi Gougeon

Minister's title – Cabinet Secretary for Rural Affairs and Islands

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