

protocol (eg using the EFSA sample size calculation tool) or, if necessary, a 'reinforced'/tightened protocol. If risk factors affect the quality of the stun, EFSA state it will not be necessary to increase the sampling frequency. However, when a conscious animal is detected or when a risk factor (eg employment of new personnel) reduces the sensitivity of an indicator the sampling frequency will need to be increased, and a reinforced protocol adopted. The increase in the sampling frequency is relative to the reduction in sensitivity of monitoring but EFSA report that this value may be unknown and so, testing one-tenth of the slaughter population, in one sampling period may be necessary. Risk factors might include: the outcome of previous checks (particularly if they indicated risks to animal welfare); changes in the type or size of animal slaughtered; personnel working patterns; and the level of competence, experience and/or fatigue of an individual operator, which EFSA suggests can affect the quality of stunning *and* the quality of monitoring of the effectiveness of stunning.

EFSA note that as a result of the "...scarcity of scientific publications reporting correlation between unconsciousness or death ascertained by EEG and the behavioural and physiological indicators to detect unconsciousness and death that could be used in slaughterhouse conditions... Further scientific studies should be carried out to collect valid information on indicator sensitivity and specificity". In December 2013 EFSA published a scientific Opinion on guidance for researchers on the EFSA assessment criteria for studies evaluating the effectiveness of stunning interventions used at slaughter.

EFSA also suggest that the sensitivity, specificity and feasibility of welfare indicators will improve as personnel acquire competence (through relevant knowledge, skill and experience) in monitoring indicators, via education, training and assessment. Hence, EFSA suggests that harmonised training programmes for personnel with responsibility for monitoring and ensuring animal welfare at slaughter, are required throughout the EU, and recommend that: "until such time as any improvement in sensitivity or specificity resulting from personnel training is objectively demonstrated, the values given in [the scientific] Opinion for calculating the sample size should be considered as a minimum requirement" for animals stunned during slaughter.

Sample Size Calculation Tool for Monitoring Stunning at Slaughter (2013). A4, 18 pages. Technical Report, EFSA supporting publication 2013: EN-541. European Food Safety Authority (EFSA), Parma, Italy. Available at: <http://www.efsa.europa.eu/>.

Scientific Opinion on Guidance on the Assessment Criteria for Studies Evaluating the Effectiveness of Stunning Interventions Regarding Animal Protection at the Time of Killing (2013). A4, 41 pages. European Food Safety Authority (EFSA) Panel on Animal Health and Welfare (AHAW), Parma, Italy. Available at: <http://www.efsa.europa.eu/>.

Scientific Opinion on Monitoring Procedures at Slaughterhouses for Bovines (2013). A4, 65 pages. European Food Safety Authority (EFSA) Panel on Animal Health and Welfare (AHAW), Parma, Italy. Available at: <http://www.efsa.europa.eu/>.

Scientific Opinion on Monitoring Procedures at Slaughterhouses for Pigs (2013). A4, 62 pages. European Food Safety Authority (EFSA) Panel on Animal Health and Welfare (AHAW), Parma, Italy. Available at: <http://www.efsa.europa.eu/>.

Scientific Opinion on Monitoring Procedures at Slaughterhouses for Poultry (2013). A4, 65 pages. European Food Safety Authority (EFSA) Panel on Animal Health and Welfare (AHAW), Parma, Italy. Available at: <http://www.efsa.europa.eu/>.

Scientific Opinion on Monitoring Procedures at Slaughterhouses for Sheep and Goats (2013). A4, 65 pages. European Food Safety Authority (EFSA) Panel on Animal Health and Welfare (AHAW), Parma, Italy. Available at: <http://www.efsa.europa.eu/>.

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Cattle, badgers, and achieving bovine TB free status for England

England's cattle have the highest level of bovine tuberculosis in Europe. In the recently updated Strategy for Achieving Officially Bovine Tuberculosis Free Status for England, the Secretary of State for Environment, Food and Rural Affairs, Owen Paterson, states that: "Bovine tuberculosis (bTB) is the most pressing animal health problem in the UK. The crisis facing our cattle farmers, their families and their communities cannot be overstated. It is a devastating zoonosis that threatens our cattle industry and presents risks to other livestock, wildlife species such as badgers, domestic pets and humans".

Bovine tuberculosis (bTB) is a chronic respiratory disease that the farming industry has been battling for decades. Caused by the bacterium *Mycobacterium bovis* (*M. bovis*), cattle are the main host of the infection, but other mammals are also susceptible. Transmission between hosts is usually through breathing in the bacilli aurally, although infection may also occur through ingestion of contaminated feed or water.

Efforts to control bTB include an ongoing countrywide strategy of cattle testing, removal and slaughter of infected animals, movement restrictions of infected herds, and post mortem surveillance of animals at slaughter for bTB lesions. Across Europe, these control and surveillance methods are used and the European Commission has allocated a large amount of money to co-fund bTB control and eradication programmes to assist countries in becoming Officially TB Free (OTF). A number of countries have been successful in achieving OTF status but, so far, the level of bTB in England continues to rise.

It is not clear why bTB is steadily increasing in England, but one theory is that badgers are acting as a reservoir of infection. Over the past few decades numerous reports have been written (eg Zuckerman review, Dunnet review, Krebs report, The Randomised Badger Culling Trial, Independent Scientific Group report), examining the role of badgers in bTB infection of cattle and experimental culls have been carried out to assess

whether reducing the badger population will assist with reducing the overall number of infected cattle. Opinion varies, both within and between, the farming community, veterinarians, government, scientists and the general public.

In 2012, following a period of consultation, Defra announced that culling badgers would, once again, form part of England's bTB control strategy and west Gloucester and west Somerset were to act as pilot areas to test the effectiveness of this policy on reducing overall levels of bTB. Badgers are a protected species (under the Protection of Badgers Act 1992) and a number of conditions needed to be met before a licence, issued by Natural England, could be granted to proceed with the cull.

The culls commenced summer 2013, closely monitored by an Independent Expert Panel (IEP) (appointed by Defra for their expertise in animal welfare, veterinary pathology, badger behaviour and ecology, wildlife population biology, statistics, marksmanship and management of wild animal populations). The IEP's terms of reference were to assess whether the culls could be carried out in an effective, humane and safe way when using controlled shooting as a culling method (although in the field controlled shooting was actually used alongside cage trapping and shooting during the pilots).

The IEP published their findings in March 2014. With regards to the safety aspect of badger culling, the IEP concluded that there was no risk to public safety, even in the presence of local protest. However, a number of concerns were raised over both the effectiveness and humaneness of culling using controlled shooting and the IEP state that "If culling is continued in the pilot areas, or in the event of roll-out to additional areas, standards of effectiveness and humaneness must be improved".

Concerns over the effectiveness of the cull stem from the low number of badgers killed. A previous study found that for a cull to be effective at least 70% of the starting population of badgers must be removed; otherwise the level of bTB may actually rise in animals in surrounding areas due to perturbation. The IEP found that this level of removal was not achieved and estimate (within a 95% confidence interval [CI]) that a combination of both controlled shooting, and cage trapping and shooting, only removed between 34.5 and 48.1% of badgers in Somerset, and 27.5 to 39.1% of badgers in Gloucestershire.

The humaneness of the cull was also questioned. The IEP assumed that "the onset of firearms injury pain in badgers mimics that of people" and "that suffering from marked pain is very likely in badgers that survive more than 5 min after being shot". The number of badgers that took longer than 5 minutes to die was therefore recorded, as were the number of situations in which a badger was believed to have been shot but a body was not recovered (eg due to the contractor being unable to find the badger, or because the badger had entered a sett). Additionally, the IEP suggest that "a threshold of concern for humaneness should be set at 5%, ie it is reasonable to expect that 95% of shot badgers should be dead within 5 min". Contractors were not successful in

meeting this target and the IEP concluded that it was extremely likely (95% CI) that: "between 7.4% and 22.8% of badgers that were shot at were still alive after 5 min, and therefore at risk of experiencing marked pain".

Other key issues raised by the IEP include: problems in identifying the size of the badger population; misidentification of badger setts (1 in 4 badger setts were misidentified in Somerset, and 1 in 10 in Gloucestershire); drop out of contractors; poor knowledge of marksman on field craft, including badger behaviour, sett assessment, pre-baiting and baiting; insufficient use of thermal imaging equipment; and inadequate skill of some marksmen when shooting at night.

The IEP made a number of recommendations to government within their Report and Defra were quick to reply, publishing a response in April 2014. For the most part, Defra accepts the recommendations put forward by the IEP and a brief description is given on how government plans to act on each one. Areas where government is in agreement with the IEP include: the need for improved assessment, monitoring and training of contractors; amendment of the Best Practice Guidance with regard to target area and clarification of shooting distance; the necessity for ensuring that at least 70% of the land included in a cull area may be accessed and that contractors are deployed more uniformly across the land; and the need to improve standards of effectiveness and humaneness. Defra note that "the Panel's report offers useful insights to be taken into account in planning for this year's culls".

Defra does not fully agree with the IEP with regards to how badger population levels may be reliably assessed in cull areas. Assessing the starting population of badgers is important both for the success of any cull (the starting population should be reduced by 70%), and also to ensure that the number of badgers killed does not put the local badger population at risk of extinction (which would contravene the Bern Convention). The IEP advise that a cull-sample-matching approach is used in any future culling operations but Defra proposes instead that they work with Natural England and AHVLA "to adopt more cost-effective methodologies to assess effectiveness of culling, that do not rely solely on measurement of population numbers".

Conclusions of Defra include: "We recognise that even with a combination of cage trapping and controlled shooting, the desired 70% level of control was not achieved in the first year. However, this is only the start of a 4-year culling programme" and "we need to focus on the longer term outcome". Additionally, Defra state that: "We have to recognise that shooting under the circumstances experienced in the field cannot be expected to deliver the same level of precision as that achieved in more controlled environments" and that "We also need to place shooting of badgers in context with the shooting of other wildlife species that is considered normal practice and is not subject to the same level of scrutiny".

As well as responding to the IEP Report in April, Defra also published an updated strategy for tackling bTB entitled: 'The Strategy for achieving Officially Bovine Tuberculosis Free status for England'. The Strategy's objective is for the

whole of England to become officially bTB free (OTF) by 2038, and for large parts of the north and east of England to achieve OTF status by 2025, or sooner (for a member state to be considered officially bTB free, the annual incidence of herds with confirmed *M. bovis* infection must not have exceeded 0.1% and at least 99.9% of the herds within it must have been free from bTB at the end of the year for at least six consecutive years).

Government proposes three key actions for achieving OTF status:

- “establishing three bovine tuberculosis (bTB) management regions or zones (a High Risk Area, a Low Risk Area and a buffer zone (Edge Area) in between);
- applying a range of measures to control the disease within these zones that is practical and proportionate to the disease risk while maintaining an economically sustainable livestock industry;
- ensuring that there is shared governance of the delivery process between the main beneficiaries including the food and farming industry and the taxpayer”.

The Report gives a background of bTB, discusses the rationale for intervention and explains the risk-based approach which is to be utilised for dealing with the disease. Existing measures already in use against bTB within the three management regions are outlined under four main headings: surveillance (find infection early); breakdown management (reduce risk of spread of infection — eliminate infection quickly); dealing with risk of TB from badgers (reduce risk of badger-to-cattle and cattle-to-badger infection); and other disease prevention (reduce risk of infection spread).

Other control methods which may be more widely applied are also expanded upon, including: i) Biosecurity (risk-based trading, on-farm and off-farm biosecurity and using compensation to encourage risk-reduction); ii) improving advice and guidance to farmers; iii) improving compliance and enforcement; and iv) tackling TB in non-bovine species.

Significant funds (approximately £155 million since 1991/92) have been invested into a bTB research programme to further understand the disease and to develop new tools to tackle bTB. In the Strategy, emphasis is placed on current research into developing new diagnostic tests for surveillance (to detect bTB in both cattle and badgers) and also on developing a deployable bTB vaccine (for cattle and badgers). Other areas of future research include investigating alternative strategies for dealing with the risk of TB from badgers and research into genetic resistance of cattle to bTB.

The new Strategy stresses the importance of flexibility when dealing with bTB and that controlling bTB “will require us to apply different sets of interventions according to circumstance because the problem is different in different parts of the country”. It is intended that the Strategy will be “regularly reviewed and refreshed” taking into account field experience and advances in approaches to tackle bTB.

Pilot Badger Culls in Somerset and Gloucestershire (March 2014). A4, 58 pages. Report by the Independent Expert Panel. Available for download from the GOV.UK website: <https://www.gov.uk/government/publications/pilot-badger-culls-in-somerset-and-gloucestershire-report-by-the-independent-expert-panel>.

Pilot Badger Culls in Somerset and Gloucestershire: Report by the Independent Expert Panel: Defra response (April 2014). A4, 12 pages. Department for Environment Food & Rural Affairs. Available for download from the GOV.UK website: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/300424/pb14158-defra-response-independent-expert-panel.pdf. Any enquiries regarding the publication should be sent to: defra.helpline@defra.gsi.gov.uk.

The Strategy for Achieving Officially Bovine Tuberculosis Free status for England (April 2014). A4, 85 pages. Department for Environment Food & Rural Affairs. Available for download from the GOV.UK website: <https://www.gov.uk/government/publications/a-strategy-for-achieving-officially-bovine-tuberculosis-free-status-for-england>.

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Updated operational guidelines published in the UK covering the use of animals in research

To harmonise, strengthen and fully implement the 3Rs principles (Replacement, Reduction and Refinement), legislation covering the use of animals in research throughout the European Union (EU) was updated in 2010. Directive 2010/63/EU replaced Directive 86/609/EEC and took full effect in January 2013. All countries within the EU were required to have translated this Directive into national legislation by this time.

In the UK, The Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 (SI 2012/3039) transpose EU Directive 2010/63/EU and amend the Animals (Scientific Procedures) Act 1986 (ASPAs). Section 21 of ASPA requires the Secretary of State to publish information on the conditions of licences and certificates issued under the Act, and how such licences and certificates may be granted. To comply with this requirement, ‘Guidance on the Operation of the Animals (Scientific Procedures) Act 1986’ was published in March 2014. The Guidance applies to England, Wales, Scotland and Northern Ireland.

The Guidance was developed following a period of consultation with key stakeholders and the Animals in Science Committee and replaces the previous Guidance, published in 2000. Arranged in 14 Sections, and including lengthy appendices (A to I), it is intended that the Guidance acts as a reference document and covers:

- “The scope and main provisions of the amended Act;
- The responsibilities of those with roles under the Act;
- Licences granted under the Act, including the terms and conditions of their issue; and