The Control of Salmonella in Poultry
(Breeding, Laying and Broiler Flocks) (Scotland) Order 2009
The Animal By-Products (Enforcement) (Scotland) Regulations 2013

The Scottish Government

Guidance on Application for Laboratory Approval

Introduction

These notes explain the application and other procedures you must follow if you wish your laboratory to be approved under:

- The Control of Salmonella in Poultry (Breeding, Laying and Broiler Flocks) (Scotland) Order 2009 (CSPO)
- The Animal By-Products (Enforcement) (Scotland) Regulations 2013 (ABPR)

Laboratories which meet these criteria are placed on the Scottish Government list of approved laboratories.

Background

European Union regulations require competent authorities to designate or approve laboratories that carry out the analysis of samples during official controls and the analysis of operator samples taken under the requirements of the *Salmonella* National Control Programmes. These include the following:

(a) CSPO implements EU Regulation 2160/2003 on the control of *Salmonella* at primary production and throughout the food chain. Producers are required to take samples during rearing and production from all their commercial poultry flocks to test for the presence of *Salmonella*, with the primary focus on *Salmonella* of public health significance[1]. The sampling, preparation and testing requirements are set by Regulations made under Regulation 2160/2003 as amended. These implementing regulations are periodically reviewed and repealed by legislation amending Regulation 2160/2003. The legislation requires that the method of detection is ISO 6579:2002/Amd1:2007 (Annex D) where a semi solid medium (MSRV) is used as a single selective medium.

(b) Regulation (EC) 1069/2009 and its accompanying implementing Regulation (EC) 142/2011 are directly applicable and are enforced in Scotland by ABPR. These require microbiological testing of product samples from composting plants, biogas plants, rendering and other processing plants and petfood plants for the purposes of process validation and/ to ensure that the product complies with certain microbiological standards before it is placed on the market. The sampling requirements are laid out in EU Regulation (EC) 142/2011. The new legislation does not specifically require laboratories wishing to carry out this testing to be approved/designated by the national competent authority, although there may be specific circumstances where approval is required e.g. as an export condition. Therefore Scottish Government approved laboratory status for general sampling under ABPR is **optional**. These guidance notes therefore apply only to laboratories who wish to apply for or maintain Scottish Government approved status for testing under ABPR regulations on a voluntary basis or in a specific circumstance where approval is required for export purposes. However, all laboratories wishing to test samples under ABPR must be ISO 17025 accredited

[1] The regulated Salmonella serovars are *S*. Enteritidis, *S.* Typhimurium, *S*. Hadar, *S*. Infantis , *S.* Virchow and the monophasic strains of S. Typhimurium with the antigenic formulae 1,4,[5],12:i:-

To obtain Scottish Government approved laboratory status requires the following criteria to be met:

(i) Accreditation to ISO 17025
(ii) Participation in a quality assessment/proficiency testing system
(iii) Compliance with the requirements laid out in this guidance note.

Further information is given in Annex 1

The statutory instruments relevant to the approval of laboratories are listed in Annex 3. Approved laboratories are expected to hold hard- or electronic copies of the relevant legislation and key staff should be able to demonstrate familiarity with them in so far as they affect the work of the laboratory. Copies of the legislation are available from the Stationery Office Scotland, 26 Rutland Square, Edinburgh EH1 2BW (tel: 0131 659 7020, fax: 0131 659 7040, e-mail: enquiries@tsoscotland.com).

The approval procedure

Approval is for one year and is renewable. The application for approval is considered subject to:

(i) Receipt of a completed application form (SG Lab Application)
(ii) Receipt of a copy of a valid accreditation certificate ISO 17025 and a schedule (scope) for all those tests for which approval is required (the testing methods for which approval is sought must be in scope and follow methodology as required by specific legislation)
(iii) Proof of participation in a Proficiency Testing (Quality Assessment) scheme for ABPR if another provider is used. (**Not required** for CSPO because participation in the AHVLA National Proficiency Testing scheme is mandatory for approval)
(iv) Provision of data as specified under the Regulations and/or Orders

Provision of this evidence is sufficient for a laboratory to be included on the list of approved laboratories without Scottish Government inspection. You should note, however, that the schedule of tests attached to the accreditation certificate must include any new methodology. For those testing for *Salmonella* under the CSPO the scope needs to include the ISO 6579 (2002) Annex D MSRV testing method. The main requirements relating to the testing of samples, including those that are statutory, are listed in **Annex 1** of this guidance.

For annual renewal of approval status you may apply 3 months prior to the expiry of your approval for renewal of your approval for a further year.

The above should be sent to The Scottish Government, Animal Health & Welfare Division, Saughton House, P Spur, Broomhouse Drive, Edinburgh, EH11 3XD.

CSPO applicants only. If the Scottish Government is satisfied with the information given in the application form, a fee to cover the administrative costs of handling your application will be requested. This fee for annual registration is non-refundable. Fees can be found in the Animal Health (Miscellaneous Fees and Amendments) (Scotland) Regulations 2013.

The Scottish Government will issue your laboratory with a certificate of approval valid for twelve months from the date of issue. The name and contact details of your laboratory will be put onto the register of approved laboratories. This register will be made publicly available on the Scottish Government website.

Should the information in your application form cease to be accurate in any way you must notify the Department in writing immediately. This is particularly important if the named applicant leaves the laboratory or there is a change in the status of ISO 17025 accreditation.

Revocation or suspension of approvals

Suspension or revocation of approvals will normally arise only after unsatisfactory inspections, suspension of ISO 17025 accreditation, refusal to submit to Scottish Government inspection, failure to pay requested fee, or a change in your laboratory which means that you can no longer meet the standards required in the application form.

If a Scottish Government inspection reveals a problem, the inspector will consider whether suspension is appropriate depending on the severity of the problem and the ease of its correction. Should a serious problem be revealed, an inspector can recommend suspension of an approval with immediate effect. If an inspection by an accreditation body, such as UKAS, reveals a serious problem further action will be taken by the accreditation body. If this matter affects the status of your accreditation (including a change in your schedule) **you are required to inform us** and it will not be possible for your laboratory to remain on the list of approved laboratories for the tests concerned until any problems have been rectified.

A suspension would continue pending review of either a report from a Scottish Government inspection or receipt of a valid ISO 17025 certificate for the tests for which approval is sought. We may require written assurances, including any remedial action taken on the failures, and if necessary a further inspection of your premises. This could lead to lifting of the suspension of if the matter is not resolved satisfactorily revocation of the laboratory's approval.

Following revocation, you may opt to stay off the approved list or you may apply gain for approval. If you wish to reapply, we will normally require:

- A detailed review from you of your laboratory's practices, identifying possible reasons for the failures and proposed remedies;
- Your acceptance of a chargeable inspection; and
- Your payment of the fee for a further PT test
- Provision of a valid ISO 17025 certificate

When a laboratory whose approval has previously been suspended or revoked is reinstated, it will resume at the point in the annual cycle of PT tests/renewal applications that it had reached before the suspension/revocation took place.

Fees

Fees for services provided in relation to the Laboratory Approval schemes are made under the Zoonoses and Animal By-Products (Fees) (Scotland) Regulations 2009.

Enquiries

Please direct any enquiries you may have to the Scottish Government, Rural and Environment Directorate, Animal Health & Welfare Division, P-Spur, Saughton House, Broomhouse Drive, Edinburgh, EH11 3DX or Tel: 0131 556 8400

Complaints procedure

It is important to the Scottish Government that complaints about service are dealt with by the right person at the right time.

If you have a complaint about the service you have received from a department or official, the Government will work with you to resolve the complaint in a full and fair way, keeping you informed of progress.

First, you must speak to the officials in the business area or department that your complaint is about. Working with you, they will aim to resolve your complaint. You can reach officials through the Main Addresses and Contact Points of the Scottish Government.

If, working together, you are unable to resolve the issue, the officials will ask you to confirm if you wish to move on to the next stage. A senior official will appoint a Complaints Officer who is completely independent of the business area involved in the stage above. They will look into your complaint and aim to help you resolve it. If your complaint is still not resolved it will be subject to a final review by the relevant Director. If you remain dissatisfied, you then have the option of taking up your complaint with the Ombudsman.

Guidance on how to complain to the Scottish Government is available at www.scotland.gov.uk/Publications/2008/06/11133639/2.

The Scottish public Services Ombudsman is independent of the Scottish Government, and may be able to take up a complaint on your behalf. The Ombudsman will normally only be able to act if you have followed the steps above.

To find out about the Ombudsman's work, visit the Scottish Public Services Ombudsman website (www.spso.org.uk/), or contact the office at 4 Melville Street, Edinburgh, EH3 7NS, Tel: 0800 377 7330, Email: ask@spso.org.uk

Details of the requirements for Scottish Government approved laboratory status

Accreditation to ISO 17025

The Official Feed and Food Controls (EU Regulation 882/2004) requires that all laboratories conducting official tests for zoonoses and zoonotic agents are accredited to ISO 17025 standards by an organisation that is itself accredited to ISO 17011 (EN 45002/3). Regulation 2160/2003 also lays down this requirement for laboratories testing operator NCP samples to conform to EN ISO 17025 standards.

In the UK this currently means that laboratories testing under CSPO and ABPR will have to be accredited to ISO 17025 by the United Kingdom Accreditation Service (UKAS)[2] in order to be eligible for Scottish Government approved status and be included on the list of approved laboratories to conduct testing. (http://www.european-accreditation.org/n1/doc/EA-1-08.pdf).

Following successful assessment, test methods subject to the requirement for Scottish Government approval will be clearly indicated on the laboratory's schedule of accreditation. The accreditation process is concerned fundamentally with assuring technical competence and 'fitness for purpose'. Specific requirements regarding sample type, handling and storage etc are therefore all within the scope of the ISO 17025 accreditation process as compliance with the criteria laid out in the legislation determine the sample's fitness for purpose.

It is the responsibility of the person in charge of the laboratory to arrange for UKAS accreditation directly with UKAS. In the event of full suspension/withdrawal of a laboratory's accreditation status, the laboratory is removed from the accredited institutions/bodies list on the public-access UKAS website. Partial suspension of accreditation (e.g. for a specific diagnostic test) results in removal of that specific test from the laboratory's accreditation schedule. **The person in charge of the laboratory must notify the Scottish Government in the event that accreditation is withdrawn or suspended.**

Proficiency Testing (Quality Assessment)

All laboratories on the approved list for CSPO are required to participate in a national Proficiency Test (PT) scheme coordinated by the National Reference Laboratory for the examination of samples for the required micro-organisms. Laboratories approved to test under ABPR may use an alternative accredited PT provider. Failure to return results for a PT distribution without good reason may lead to the suspension of a laboratory from the list of approved laboratories.

PT tests are designed to assess the laboratory's ability to correctly isolate and identify micro-organisms related to the category applied. In the case of the ABPR they are also designed to assess the laboratory's ability to interpret results accurately in terms of the pass/fail standards.

The scheme takes the following form:

- Each laboratory is assigned a confidential and unique PT identification number;
- PT for ABPR and CSPO will be issued on four occasions during the year at 3-monthly intervals;

They are issued in three different batches:

[2] UKAS is a signatory to the European Co-operation for Accreditation of Laboratories Multilateral Agreement (EAL) and is the only body in the UK that meets this requirement of ISO 17011 (EN45002/3) that is nominated to carry out accreditation according to Regulation (EC) No 765/2008

- Salmonella under CSPO
- Salmonella under ABPR
- Enterobacteriaceae/Clostridium perfringens under ABPR

Laboratories are allowed a specified time period in which to report back results of the PT testing – the deadline date for receipt of results via the computerised system is indicated on the result entry page. Result entry pages will then be locked and results will not be included in the tabulations. Final reports will be published electronically by AHVLA Quality Assurance Unit, Sutton Bonington, to all participants and made available to the Scottish Government.

Failure to analyse or interpret a Proficiency Test correctly

If your laboratory fails a PT test, we will expect you to carry out the procedure for the control of a non-conforming product as specified in the standard. Should there be two consecutive PT failures within the same scheme, we will notify the accreditation body who will investigate. They are likely to undertake an unannounced inspection.

All laboratories may, as part of any internal investigation into a PT failure, request a chargeable repeat set of PT samples from the Scottish Government to help identify any problems. **Laboratories should approach AHVLA Quality Assurance Unit directly to request repeat samples and will be invoiced directly by the QA Unit, AHVLA Sutton Bonnington for these samples.** This second set of samples would be for your laboratory's use only and would not form part of the Scottish government's official testing records. Although the re-testing of these samples would add time to your investigation we would still require an initial written report within the 10 working days.

If, after a reasonable period, the laboratory has not resolved the problem and a panel of PT samples have not being correctly analysed and reported, revocation of the laboratory's approval will normally result.

Tests under CSPO

As a condition of approval you are required to comply with the Zoonoses Order 1989. If as a result of an examination in your laboratory a culture of *Salmonella* is isolated from a sample you should make a written or oral report of the isolation, containing the particulars specified in Schedule 2 to the Order to a regional laboratory of the AHVLA and send a subculture.

The results of the testing should be reported in writing or electronically as soon as practicable to the operator who submitted the sample or the nominated person/company representative. Under the conditions of approval, *Salmonella* isolates should be reported to the AHVLA as soon as they have been confirmed.

This should be done on the next working day after the isolate has been identified. **Group B and Group D isolates are considered priority cases and must be sent to the AHVLA within 3 working days**. **Other *Salmonella* serogroups may be batched and dispatched to AHVLA within 7 working days. Laboratories who do not undertake serogrouping to identify Groups B and D should submit all their isolates within 3 working days**

At the end of each calendar month, send a report of tests carried out during the month to The Scottish Government, Animal Health & Welfare Division, Saughton House, P Spur, Broomhouse Drive, Edinburgh, EH11 3XD or email animal.health@scotland.gsi.gov.uk. This should be done on form **SG CSPO LAB**.

The person in charge of a laboratory must ensure that all laboratory staff who receive and handle samples do so according to the requirements of the legislation and ensure that the sample is

refrigerated and that the examination begins within 48 hours of receipt. The sample must be tested **within 4 days** of being taken by the operator for the breeding chicken, laying chicken and turkey NCPs. This requirement will also apply to the broiler chicken NCP from the beginning of 2012. The sample type, weight and time period since sampling must comply with the relevant requirements included in the EU legislation.

Tests under ABPR

Tests must be carried out in accordance with Regulation (EC) 142/2011. In order to meet the requirement for the Competent Authority to monitor compliance of operators with EU Regulation (EC) 1069/2009 (when tests establish that the material does not comply with the microbiological standards in the ABPR, in addition to informing the plant/operator of the results) you should notify the Regional Veterinary Lead at the AHVLA Office responsible for supervising the plant.

EU Regulation 142/2011 requires that five samples are tested for *E. Coli, Enterococcaceae, Enterobacteriaceae* and *Salmonella,* therefore, laboratories should provide 5 sets of results for each submitted sample. Further guidance on testing under the ABPR is available at: http://animalhealth.defra.gov.uk/managing-disease/animalbyproducts/reg-tran-hand-storage/laboratory-requirements-for-testing-abp.htm

At the end of each calendar month you must send a report of tests carried out during the month, including nil returns, to The Scottish Government, Animal Health & Welfare Division, Saughton House, P Spur, Broomhouse Drive, Edinburgh, EH11 3XD or email animal.health@scotland.gsi.gov.uk. This should be done on form **SG ABPO LAB.**

Report any *Salmonella* isolated by private laboratories from feed samples to the AHVLA Regional Laboratory local to the private laboratory that has isolated the *Salmonella*, and send a sub-culture. The reporting requirements are the same as for the Control of *Salmonella* in poultry orders above. The AHVLA Regional Laboratory will then send the sub-culture to one of the AHVLA serotyping centres for further identification.

Requirements to be met by all laboratories testing for Salmonella under the Control of Salmonella in Poultry (Breeding, Laying and Broiler Flocks) (Scotland) Order 2009

Some samples submitted under CSPO require post mortem work to be carried out upon them. Therefore there are some additional requirements for laboratories wishing to be approved under CSPO. These are detailed below.

Premises

Location and construction of post mortem facilities (See Section C of the application form).

- **Purpose**

That the laboratory premises shall be of a suitable size, construction and location for the purpose of testing samples for Salmonella without cross contamination or sample miss-identification.

(a) The post mortem facilities and testing laboratory must be located away from livestock of any kind and if livestock are kept on the premises there must be restricted laboratory access to specialist staff only and with suitable gowning and personal cleaning facilities provided.

(b) The laboratory must be of a size and design which allows reasonable separation of sample reception; post mortem examinations; processing; microbiological plate reading and identification; and culture media and reagent preparation.

(c) Post mortem facilities should be separate from other laboratory areas and have restricted entry. Working surface must be impervious and capable of being disinfected. Sterilisation facilities for instruments should be available. Protective clothing should be available for use, together with washing facilities. Arrangements for the disposal of biological waste must be such that there is no cross contamination of samples, equipment or the environment.

Personnel

Requirements to employ a Member of the Royal College of Veterinary Surgeons (See Section C of application form).

- **Purpose**

Paragraph 12 of the Schedule of the Order requires the Scottish Ministers to be satisfied that a laboratory has the necessary facilities and personnel to carry out the test before the laboratory is authorised; breeding flock operators required to collect samples under CSPO have a right to expect the Scottish Government to take reasonable steps to ensure that approved laboratories can do the testing work specified under the Order.

Among the duties of the laboratory is the dissection of chicks and the removal of 'the yolk sac, liver and terminal intestines to include portions of small intestines, large intestines and caecal tonsil'. The Scottish Government therefore asks laboratories applying for approval under this Order to have a veterinary surgeon, under whose direction the dissection of chicks should take place.

A veterinary surgeon can be assumed to have knowledge of the anatomy of a chick and to take professional responsibility for ensuring that work is carried out correctly; therefore if the laboratory can advice us that a veterinary surgeon carries out training and is satisfied that any person who does the dissection is competent to do it properly, The Scottish Ministers can be satisfied that this aspect of the work is being carried out correctly.

It is not necessary to have a MRCVS in your full time employ to satisfy this requirement. The conditions could be met through a consultancy arrangement.

Annex 3

Relevant legislation

Search engine for legislation available at: http://eur-lex.europa.eu/RECH_legislation.do

Salmonella National Control Programme legislation available at:
http://ec.europa.eu/food/food/biosafety/salmonella/index_en.htm

Number	Title
178/2002	REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
2160/2003	REGULATION (EC) No 2160/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 November 2003 on the control of salmonella and other specified foodborne zoonotic agents
1177/2006	COMMISSION REGULATION (EC) No 1177/2006 of 1 August 2006 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards requirements for the use of specific control methods in the framework of the national programmes for the control of salmonella in poultry
200/2010	COMMISSION REGULATION (EC) No 200/2010 of 10th March 2010 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Union target for the reduction of the prevalence of *Salmonella* serotypes in adult breeding flocks of *Gallus*
517/2011	COMMISSION REGULATION (EC) No 517/2011 of 25th May 2011 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Union target for the reduction of the prevalence of certain *Salmonella* serotypes in laying hens of *Gallus gallus* and amending Regulation (EC) No 2160/2003 and Commission Regulation (EU) 200/2010
646/2007	COMMISSION REGULATION (EC) No 646/2007 of 12 June 2007 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Community target for the reduction of the prevalence of *Salmonella enteritidis* and *Salmonella typhimurium* in broilers and repealing Regulation (EC) No 1091/2005
584/2008	COMMISSION REGULATION (EC) No 584/2008 of 20 June 2008 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Community target for the reduction of the prevalence of *Salmonella enteritidis* and *Salmonella typhimurium* in turkeys
199/2009	COMMISSION REGULATION (EC) No 199/2009 of 13 March 2009 laying down a transitional measure derogating from Regulation (EC) No 2160/2003 of the European Parliament and of the Council, as regards direct supply of small quantities of fresh meat derived from flocks of broilers and turkeys
213/2009	COMMISSION REGULATION (EC) No 213/2009 of 18 March 2009 amending Regulation (EC) No 2160/2003 of the European Parliament and of the Council and Regulation (EC) No 1003/2005 as regards the control and testing of *Salmonella* in breeding flocks of *Gallus gallus* and turkeys
1069/2009	REGULATION (EC) No 1069/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)

142/2011	REGULATION (EC) No 142/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 February 2011 implementing Regulation (EC) No 1069/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive
2009/158	COUNCIL DIRECTIVE 2009/158/EC of 30 November 2009 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs
765/2008	REGULATION (EC) No 765/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93