

Intervention Protocol for FSS approved meat establishments

Introduction

1. This document provides guidance to the Head of Operational Delivery (HOD), Operations Managers (OMs), Veterinary Managers (VM), Official Veterinarians (OVs) and frontline teams on:
 - Monitoring performance of approved meat establishments; and
 - Action that should be taken in the event that a Food Business Operator (FBO) does **not** put in place measures to raise levels of compliance with legal requirements.
2. Food Business Operators can access this protocol at <http://www.foodstandards.gov.scot/>

Strategic Aims

3. The goal of the Intervention Protocol is to protect consumers and safeguard public health by improving overall business compliance through:
 - Targeting high impact intervention where risks to public health exist.
 - Seeking prompt compliance in high risk areas of non-compliance and targeting intervention.
 - Provide a graduated and proportionate response to legislative non-compliance ensuring advisory and deterrent elements, along with the escalation of sanctions, where necessary, based on the level of non-compliance risk at individual establishments.

Background

4. As part of the intervention protocol, we want to ensure that all FBOs of FSS approved establishments are complying with legal requirements and are taking responsibility for the production of safe food. FSS resources will be directed to non-compliant establishments identified during Official Control (OC) activities outlined below:
 - Results of FBO audits;
 - Findings from unannounced inspections (e.g. routine or investigating complaints etc.); and
 - Establishment level of inspection, enforcement and audit findings (serious deficiencies or where evidence of repeated stoppage exists.)
5. The protocol includes a process for recommending the prompt withdrawal of plant approvals as the ultimate sanction for sustained non-compliance, whilst taking

an open and transparent approach to informing FBOs about what we are doing and why, in accordance with risk-based assessment methodology. FSS must take action quickly in the event of non-compliances which may impact on public health or animal welfare and provide clarity to operational staff on when and what action to take. Where an FBO fails to put in place the necessary measures leading to public health, animal health and welfare improvement, FSS officials may recommend that their approval status is reviewed. This could lead to their approval being withdrawn or suspended.

6. By gathering high quality evidence at the earliest stage via audits, unannounced inspections and regular Official Control activities, prompt intervention will be taken with the appropriate enforcement actions.
7. Providing advice and education will often secure sustained compliance as well as delivering a more cost-effective enforcement regime. Voluntary compliance is likely to be more sustainable in the long term than formal enforcement action as outlined in the following illustration:



Summary of risk rating

8. Actions taken by FSS staff will be driven by findings from audits, unannounced inspections and other OC activities. FSS will use results from inspections and audit of FBOs to support informed tactical actions. Following evaluation of supporting evidence, decisions will be:

- Where necessary, quickly escalate the enforcement activity for high risk and/or sustained non-compliances; and
 - Identify and prioritise criteria to assess risk-based planning and delivery of Official Controls.
9. Educational approaches should be considered at low and medium risk establishments.

10. Table 1 presents a summary of tactical information on required actions, using the audit outcomes as a guide to plant level characteristics of compliance.

Table 1 - Risk analysis utilising audit outcomes

Compliance Category	FBO status	Intervention
Serious Risk Urgent Improvement Necessary (2 month audit category)	Recurrent deficiencies and/or failure to permanently resolve deficiencies within a reasonable time frame, and/or new deficiencies considered to have a critical impact on public health, or animal health and welfare. (Reasonable is relative to the nature and magnitude of the deficiencies present and will be consistent with enforcement timelines and any written correspondence from FSS)	<p>Establish appropriate enforcement action.</p> <p>Schedule formal meeting with FBO to request an action plan for addressing the deficiencies.</p> <p>Explore the option of increased / additional controls.</p> <p>Review approval if there are serious deficiencies or repeated stoppage of the line.</p> <p>Monitor via unannounced inspections (UAI) in cutting plants and game handling establishments (GHEs) and routine attendance in slaughterhouses and follow up audit visits. The frequency of UAIs will be increased accordingly to reflect the risk of sustained non-compliance.</p>
Medium risk Improvement Necessary (3 month)	New or recurrent deficiencies that result in "Improvement Necessary" category for three or more consecutive audits	If an establishment is in the "Improvement Necessary" category for three consecutive audits, the FBO will be required to produce an action plan for addressing the deficiencies.

Compliance Category audit category)	FBO status	Intervention
	Deficiencies / Repeated deficiencies	<p>Explore the option of increased / additional controls.</p> <p>Monitor via unannounced inspections in cutting plants and GHEs and routine attendance in slaughterhouses and follow up audit visits. Advise FBO on educational programmes aimed at improving compliance (Meat Industry Guide, FSS guidance -package).</p> <p>Reasonable timelines to correct deficiencies.</p> <p>Review approval if there are serious deficiencies or repeated stoppage of the line.</p>
Low Risk Generally Satisfactory / Good (12 – 18 month audit category)	Low risk deficiencies	<p>Monitor via Unannounced Inspections in Cutting Plants and game handling establishments (GHEs) and routine attendance in slaughterhouses and follow up visits.</p>
	Compliant	<p>Advise FBO on educational programs aimed at improving compliance (Meat Industry Guide, FSS guidance package) where conditions are deteriorating during interim audit period.</p> <p>Reasonable timelines to correct deficiencies.</p>

Approvals

11. Approval of establishments must be kept under review by the competent authority whilst carrying out Official Controls, including initiating action to withdraw or suspend the approval in certain circumstances as described in Article 31(2) (e) of Regulation (EC) No 882/2004. Criteria for the review of approval can be found at <https://www.food.gov.uk/sites/default/files/multimedia/pdfs/oppolicy-meatestablishments.pdf>
12. More information regarding approval of establishments are available at the following link: <http://www.foodstandards.gov.scot/food-safety-standards/regulation-and-enforcement-food-and-feed-law/approval-meat-plants>. In this intervention protocol FSS is strengthening the links between OC - activities, enforcement, and review of approvals. Linking these activities along with quality audits/unannounced inspections and enforcement action, the competent authority can be assured the right evidence is available when reviewing an approval. Audits/unannounced inspections provide a useful tool in risk-profiling where concerns around non-compliance, repeated stoppages and/or deficiencies are identified.

Table 2 – Activities/enforcement/approvals cycle



Referral for review of approval

13. Drawing on findings from the carrying out of Official Controls, or as a result of local intelligence, the VM will have responsibility for initially assessing whether to undertake the process to initiate suspension/withdrawal in accordance with this protocol. Other matters which trigger a review of approvals are outlined in the approvals policy e.g. *force majeure*, such as a flooding or fire. The Director of Operations (DO) has an overarching responsibility to make sure that appropriate action is being taken.
14. The VM will arrange or supervise the collation of evidence packs to assist in any review of approval liaising with the relevant contractor where applicable. These evidence packs **must** include but are not limited to:
 - a. current **approval documentation** and approval history;
 - b. latest copy of **Business Agreement**
 - c. latest **FBO audit report and unannounced inspection results** and a comparison of trends over recent audits
 - d. latest **enforcement programme**, any **supporting intervention; records and pictures or any other evidence of the deficiencies**
 - e. an **overview** of activity, including reports of meetings held with the FBO (e.g. following an establishment being identified as Urgent Improvement Necessary); and
 - f. any **other relevant information**.
15. The “Operational Policy for the Approval of Meat Establishments” gives details to FBOs of the process that will occur after the VM submits his/her recommendation to the Director of Operations. This policy is currently available at: <https://www.food.gov.uk/sites/default/files/multimedia/pdfs/oppolicy-meatestablishments.pdf>. Local Authorities will be informed in the event of revocation of approval by FSS to establish an appropriate handover of responsibilities.

Additional controls

16. Introducing additional controls may provide an effective incentive to the FBO and deliver improvements in compliance. The HOD and VM should consider whether additional Official Controls are required (up until generally satisfactory compliance is achieved). For example, an additional OV may be brought in to focus upon enforcement and hygienic production and practice, allowing the resident OV to continue to carry out daily duties.
17. Charges for additional controls will be made under Regulation (EC) 882/2004 and the Meat (Official Control Charges) (Scotland) Regulations 2009.
18. The HOD has ultimate responsibility for determining where additional controls should be put in place. FSS will draft a notice of additional resource to inform the

FBO of additional controls being introduced, and if required, revise the Business Agreement. The OM will explain reasons for this action and that charges for these additional controls will be levied at full cost.

19. When reviewing corrective actions taken by the FBO the following considerations must be taken into account:

- confirm what actions were taken and why,
- the appropriateness of the actions,
- review any records that demonstrate the effectiveness of the corrective actions,
- observe the changes. A follow-up inspection may be needed to confirm that the corrective action has been completed and is effective.

20. Once appropriate action has been taken to address non-compliances and the improvements have been sustained, FSS will consider whether it is appropriate that the additional resource should be reviewed and the Business Agreement amended.

Low Risk Establishments

21. Low risk establishments will have audit outcomes of Good and Generally Satisfactory, with audit frequencies of 12 and 18 months (18 months for slaughterhouses only).

22. All premises must have at least one interim unannounced inspection (UAI). Generally Satisfactory plants will also have a partial audit and VMs will monitor or supervise the monitoring of the results by Service Delivery Partners (SDP) of all UAIs and partial audits and ensure enforcement action and/or Official Control activities are escalated accordingly and as per the Intervention Protocol.

23. Whilst FSS reserves the right to carry out a chargeable re-audit should this be necessary, prompt action is required to ensure that appropriate action is taken immediately should conditions at the premises significantly worsen from the last audit outcome.

Table 3 – Low risk, tactical approach

Compliance Category	FBO status	Intervention
Low Risk Good / Generally Satisfactory	Compliant	Monitor via unannounced inspections and follow up visit. Advise FBO on educational programs aimed at improving compliance (MIG, FSS

(18 & 12 month audit frequencies)	Low risk deficiencies	guidance package) any minor non-compliances with reasonable timelines to correct deficiencies in line with FSS enforcement policy.
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Medium risk establishments – Improvement Necessary

24. Improvement Necessary establishments will be subject to more frequent audits (3 monthly) and intervention than those that are demonstrating compliance. Audit outcomes are designed to drive improvement in lower compliance premises by linking audit outcomes to follow-up action.

25. Improvement Necessary establishments will be those which are exhibiting major non-compliances that are likely to compromise public health (including food safety), animal health and welfare, or which may lead to the production and handling of unsafe food if remedial action is not taken.

26. FSS as a regulator will work with FBOs to facilitate compliance. The key to a successful working relationship is communication. There is nowhere that this is more important than in relation to guiding the FBO on compliance with legal requirements.

27. Improvement Necessary premises have the following audit outcome profile:

Table 4 – Improvement Necessary defined

Audit outcome	Definition	Non-compliance threshold
Improvement necessary	Major non-compliances identified at audit and/or non-compliances during the audit period not always responded to and corrected promptly.	3-6 majors during audit or during audit period No critical during audit period

28. The approach for first time and repeat offenders is the same as outlined in the table below; however the default position is to tactically address non-compliance concerns should conditions significantly worsen during the interim audit period.

29. An FBO receiving three consecutive Improvement Necessary audits is required to present an action plan to FSS with the aim of rectifying the non-compliances. A letter (Annex 4) will be issued by the Director of Operations to the FBO.

Table 5 – Definition and Approach

Compliance Category	FBO status	Intervention
Medium risk Improvement Necessary	New or recurrent deficiencies that result in “Improvement Necessary” category for three or more consecutive audits	If an establishment is in the “Improvement Necessary” category for three consecutive audits, the FBO will be required to produce an action plan for addressing the deficiencies. Explore the option of increased / additional controls . Monitor via unannounced inspections and follow up visits. Advise FBO on educational programs aimed at improving compliance (Meat Industry Guide, FSS guidance package)
	Deficiencies/ Persistent deficiencies	Reasonable timelines to correct deficiencies Review approval where conditions are worsening resulting in serious deficiencies

30. Medium risk establishments should be identified utilising OC - activities and dealt with in order of non-compliance e.g. by prioritising premises which are demonstrating significant enforcement.

Audit outcomes – Serious risk establishments – Urgent Improvement Necessary

31. In line with audit outcomes, establishments can be identified as **Urgent Improvement Necessary** based on the severity and quantity of non-compliances.

32. Urgent Improvement Necessary establishments may have a **critical** non-compliance where the contravention poses an imminent and serious risk to public health (including food safety), animal health and welfare and/or **multiple major** non-compliances which are likely to compromise public health, animal health and welfare or may lead to the production and handling of unsafe or unsuitable food if no remedial action is taken.

Table 6 – Urgent Improvement Necessary defined (as above)

Audit outcome	Definition	Non-compliance threshold
Urgent Improvement necessary	Multiple major non-compliances or a critical non-compliance identified during audit visit or interim audit period. Official intervention required to ensure public health safeguards.	1 critical or >6 major non-compliances during audit or during audit period

33. Urgent Improvement Necessary interventions and procedures are of paramount importance and FSS will escalate enforcement activity quickly to influence food business perceptions around risk and consequences of non-compliance.

34. An FBO receiving an Urgent Improvement Necessary audit is required to immediately produce an action plan and present it to FSS with the aim of rectifying the non-compliances. A letter (Annex 3) will be issued by the Director of Operations to the FBO.

Approach to FBOs identified as Urgent Improvement Necessary and support to frontline teams

35. Following an audit which places (or keeps) an establishment in the Urgent Improvement Necessary outcome, a letter of notification will be sent to the FBO by the Director of Operations to emphasise the seriousness of the FBOs current position following audit. The wording is provided at **Annex 3**.

NB: Where it is considered that activities are of serious risk to public health these activities must be addressed using appropriate enforcement and a review of approval initiated. More than 6 Major non-compliances which have not been rectified within reasonable time periods (e.g. interim audit period), will also trigger a review of approval. It is important to differentiate between historical NCs (even if major or critical) which have been closed and those which are still open, or where FBOs have not shown willingness to cooperate.

36. As soon as an establishment is identified as Urgent Improvement Necessary, the VM will ensure that a meeting with the FBO is arranged to carry out a thorough assessment of enforcement action and any response by the FBO which has been taken in the premises, and to discuss the action that will follow.

37. Where audit scores trigger an FBO going into Urgent Improvement Necessary, the VM should carefully monitor action being taken, also interpreting the following:

- patterns of **non-compliances**
- **frequency** of moving in to this compliance rating

- the need for **additional controls**, or
- more formal **escalation of enforcement**
- **Timelines** for improvement or for referral for a review of approval.

38. As a starting point, the FBO has a responsibility to operate in compliance with the Regulations and should be encouraged to look at their most recent audit report and/or unannounced inspection report (where applicable) and in particular the Corrective Action Report and Enforcement Programme. These should identify key areas where the FBO needs to take action or make improvements. In addressing corrective actions, it may also be helpful to refer the FBO to relevant sections of the Meat Industry Guide, for clarification on legal obligations and advice on how these may be met. **Of course, an FBO may determine other ways of achieving compliance with the law as these may be equally valid.**
39. FSS VM will supervise the SDP's work with the FBO to help them draw up an action plan of steps that they can take and timescales to improve compliance offering ideas of the actions that the FBO may take. FBOs should agree a reasonable timescale for any actions with the veterinarian, so that they can show satisfactory progress. Where necessary, the VM will intervene more directly into this work.
40. FSS VMs will have an important role to play in overseeing the consistency and actions taken by the SDP's OV. In particular, FSS VMs should increase their visibility within the slaughterhouse. In standalone cutting establishments, the FSS VM will oversee OC - attendance and actively liaise with contractors and FSS staff who have been allocated to the premises.
41. It is important that a brief report of any meetings with the FBO is produced. This should summarise discussions held, and particularly any education and support provided to the FBO. These meeting reports (together with any subsequent progress updates) will serve as a useful reminder of the approach taken and may form part of the evidence base in the event that a referral for review of approval is made. **The FBO should be given opportunity to comment and agree the content of the meeting record.**
42. The HOD should consider and authorise any additional controls recommended by the VM.
43. During these inspections FSS VMs should receive assurance that the FBO is making progress against any agreed timescales and the action plan.

Dealing with adverse behaviour by the FBO

44. It is appreciated that, whilst many FBOs will respond positively and will want to put in place measures for improvement, others may react in a negative way. There is a wealth of resources available on Saltire on avoiding confrontation or aggression in the workplace, and what to do when an incident happens. The Bullying and Harassment Policy can be found on Saltire:

<http://intranet/InExec/AboutUs/Agencies/FoodStandardsScotland/HumanResources/BullyingandHarassment>

Routine monitoring

45. The HOD and VM along with SDP should review action taken at establishments at their Operations Management Team meetings.

Support available

46. The VMs and OM's will ensure that support is in place for frontline teams, and will liaise with the SDP where relevant to ensure a consistent approach is taken.

47. The VM will compile a submission to the Director of Operations. This submission will provide a background to the case, referencing the Veterinarian report and accompanying evidence.

Routine publication of audits on FSS website

FSS publishes results of FBO audits on the FSS website:

The most recent audits for FSS approved meat establishments in Scotland are published on the FSS website at the link below. These are, as issued to the food business operator, but potentially sensitive information is removed (such as personal details) and detailed technical information, establishments are listed by their approval number. Dependant on frequency of audit for individual food businesses, these are uploaded to the FSS website on a regular basis and replaced with the most recent audit undertaken. <http://www.foodstandards.gov.scot/food-safety-standards/regulation-and-enforcement-food-laws-scotland/audit-and-monitoring>

Review

48. This protocol will be kept under review - and will be updated as required

Annex content

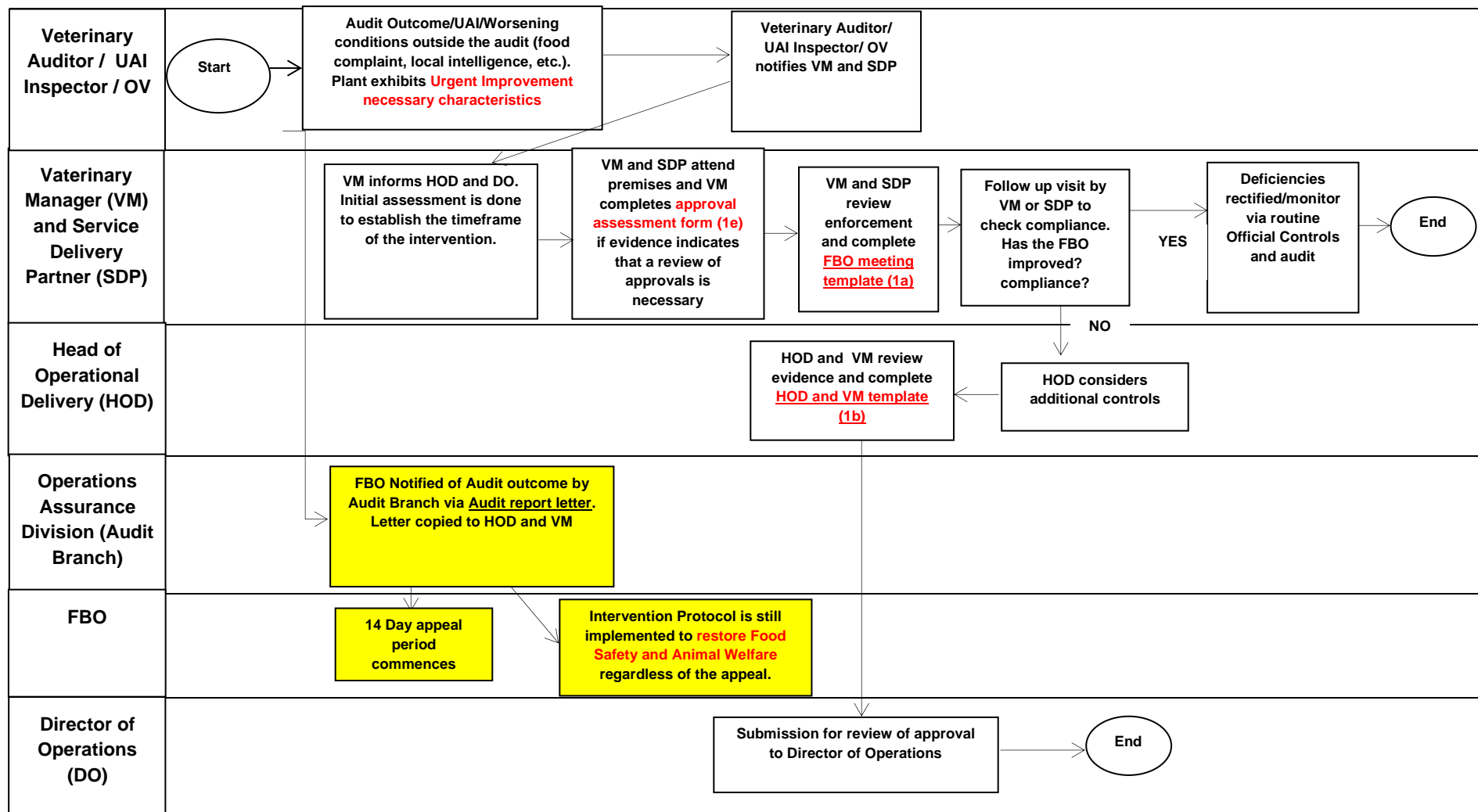
Annex 1 – Stand alone cutting plant intervention flow chart

Annex 2 – Slaughterhouse and co-located cutting plant intervention flow chart

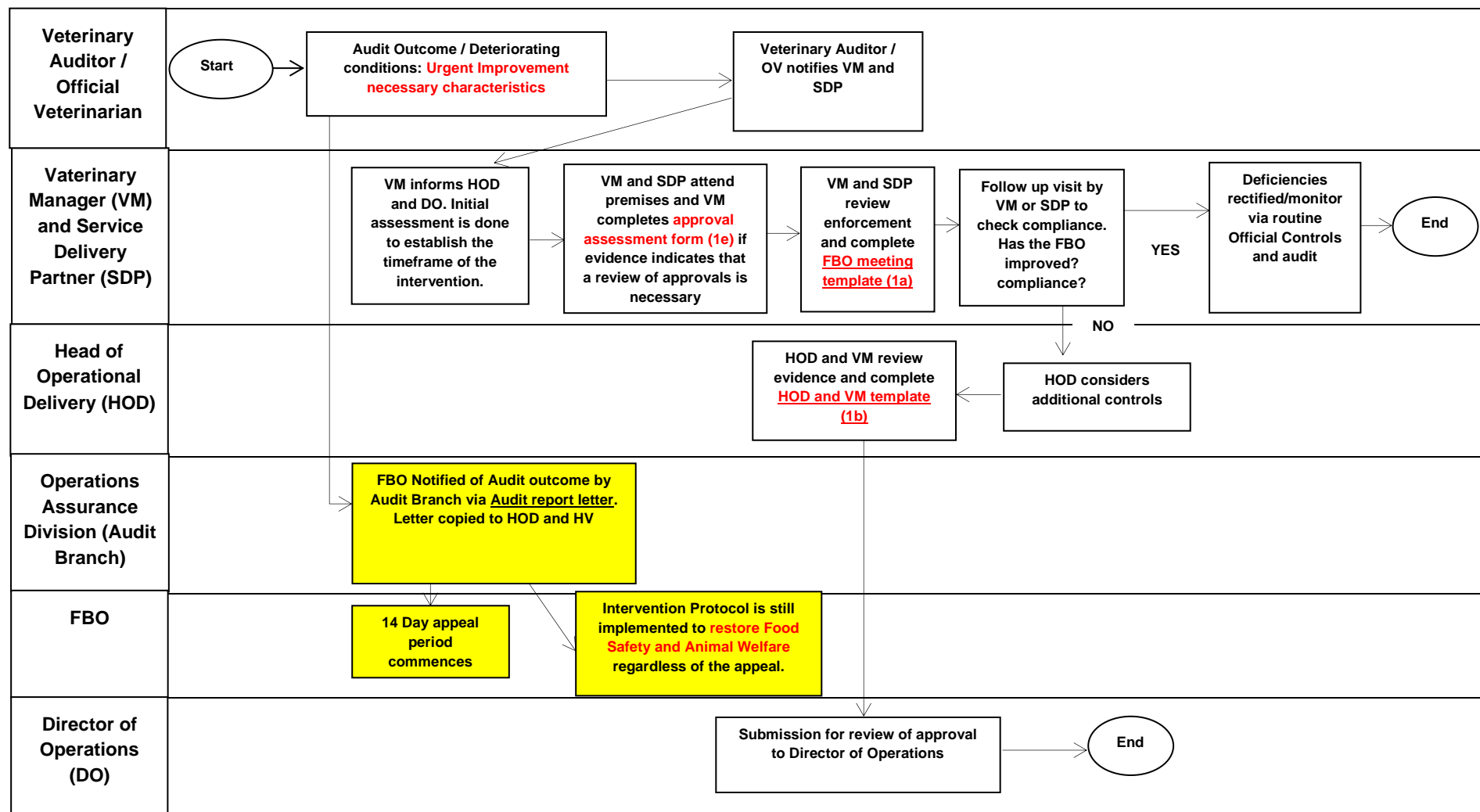
Annex 3 – Urgent Improvement Necessary – additional text for FBO audit notification letter

Annex 4 – 3rd Improvement Necessary audit – additional text for FBO audit notification letter at the 3rd consecutive audit in the Improvement Necessary category.

ANNEX - 1 - Stand Alone Cutting Plant intervention flow (chart)



ANNEX- 2 Slaughterhouse, GHE and co located cutting plant intervention flow (chart)



ANNEX 3 – Addition to FBO audit outcome letters

Dear [Name]

URGENT IMPROVEMENT NECESSARY: FOR YOUR IMMEDIATE ACTION

Further to your most recent audit, I can confirm that Food Standards Scotland (FSS) regards the level of compliance at your establishment as needing urgent improvement. Our assessment indicates that more than six major and/or at least one critical non-compliances have been identified throughout the last audit period and require your immediate attention in order to safeguard public health. Following the categorisation of your establishment as “Urgent Improvement Necessary” we consider that you are not demonstrating a consistent and sustained approach to compliance with food hygiene and other relevant legislation.

In view of the risks you have placed upon public health, it is the responsibility of FSS to ensure the relevant safeguards are restored. This will be done through a significant increase of enforcement and attendance which may ultimately lead to increased charges and the review of your approval.

You are required to produce an action plan with the aim of rectifying the non-compliances identified.

FSS is concerned regarding this level of poor compliance and would request you attend a meeting with FSS Operations management to present your action plan to secure sustainable improvement and an acceptable level of compliance. Depending on the outcome of this meeting FSS may also review any additional actions needed such as increasing the level of Official Control resources deployed in your plant.

You may find it helpful to talk to your Official Veterinarian (OV) or FSS Veterinary Manager who are willing to discuss how FSS can continue to work co-operatively with you to improve your compliance levels and negate the possibility of reviewing your approval.

Finally, please do not hesitate to contact me should you wish to discuss the contents of this correspondence in further detail.

What can I do to prevent further enforcement action and the possible review of the establishment's approval?

You should work with the OV to develop and implement an action plan for swift and sustained improvement to rectify these non-compliances. Any such action plan must immediately address the issues raised within the last audit, along with ensuring a longer term strategy for the continued protection of public health through the application of best practice.

Current enforcement activity at your establishment will not be stopped as a result of being categorised as “Urgent Improvement Necessary”. If you have already been served with a formal enforcement notice, you must comply with its contents and within the agreed timeframe.

The Meat Industry Guide is available to all Food Business Operators (FBOs) and will guide you by offering further advice around the provision of best practice.

What happens if I don't comply?

You should not ignore this letter. It is not too late to work with FSS to make improvements in your levels of compliance but failure to take appropriate action may result in FSS officials recommending that your approval status is reviewed, which could ultimately lead to your approval being withdrawn or suspended.

Additionally, FSS may decide to implement an increased regime of activities through the application of unannounced inspections and or additional controls. Both of which may be chargeable to you as the FBO.

Do I have a right of appeal?

The decision to categorise your premises as "Urgent Improvement Necessary" is based on the outcome of Official Control activities and audit findings, therefore it does not in itself hold the right of appeal. However, any FBO that is not satisfied with the outcome of an audit does have the right of appeal.

Publication on the FSS website

You should note that, once the appeal period relating to an official audit has elapsed and the audit finalised, we will publish details of all FSS approved meat establishments which is accessible by the general public.

Yours sincerely (Director of Operations)

ANNEX 4 – Addition to FBO audit outcome letters

Dear [Name]

THREE CONSECUTIVE IMPROVEMENT NECESSARY AUDIT OUTCOMES: FOR YOUR IMMEDIATE ACTION

Further to your most recent audit, I can confirm that Food Standards Scotland (FSS) regards the level of compliance at your establishment as needing improvement. Our assessment indicates that three or more major non-compliances have been identified throughout the last audit period and require your immediate attention in order to safeguard public health. Following the categorisation of your establishment as “Improvement Necessary” for the past three consecutive audits, FSS consider that you are not demonstrating a consistent and sustained approach to compliance with food hygiene and other relevant legislation.

FSS is concerned regarding this sustained poor compliance record and would request you attend a meeting with FSS Operations management to present your action plan to secure sustainable improvement and an acceptable level of compliance. Depending on the outcome of this meeting FSS may also review the level of Official Control resources deployed in your plant.

You will already be aware that FSS takes a graduated approach to enforcement and further failure to take the necessary steps to improving compliance will most likely result in an escalation of enforcement action.

In advance of presenting your action plan you may find it helpful to talk to your Official Veterinarian (OV) or FSS Veterinary Manager who are willing to discuss how FSS can continue to work co-operatively with you to improve your compliance levels.

Finally, please do not hesitate to contact me should you wish to discuss the contents of this correspondence in further detail.

What can I do to prevent further enforcement action?

You should work with the OV to develop and implement an action plan for swift and sustained improvement to rectify these non-compliances. Any such action plan must immediately address the issues raised within the last audit, along with ensuring a longer term strategy for the continued protection of public health.

Do I have a right of appeal?

The decision to categorise your premises as “Improvement Necessary” is based on the outcome of Official Control activities and audit findings, therefore it does not in itself hold the right of appeal. However, any food business operator that is not satisfied with the outcome of an audit does have the right of appeal.

The Meat Industry Guide is available to all Food Business Operators and will guide you by offering further advice around the provision of best practice.

Yours sincerely (Director of Operations)