CONSULTATION DOCUMENT

On the authorisation process, guidance and associated documents for the use of alternative systems for the disinfection of tools in Slaughterhouses, Cutting Plants and Approved Game Handling Establishments.

CONSULTATION SUMMARY PAGE

Date launched:	08 December 2017	Closing date:	12 January 2018

Who will this consultation be of most interest to?

Slaughterhouses / Cutting Plants / Approved Game Handling Establishments/ Food Business Operators (FBO's) / Local Authorities / Service delivery Partners.

What is the subject of this consultation?

The authorisation process, guidance and associated documents for the use of alternative systems for the disinfection of tools in Slaughterhouses, Cutting Plants and Approved Game Handling Establishments.

What is the purpose of this consultation?

The purpose of this consultation is to seek the views on the FSA proposed authorisation process, and associated documents. We would welcome any comment on this prior to the final version being published on our website.

Responses to this consultation should be sent to:

Name Raj Pal
Division/Branch: Corporate Support Unit

FOOD STANDARDS AGENCY
Tel: 0207 276 8083
Email: Raj.pal@food.gsi.gov.uk

Postal address:

Food Standards Agency
Corporate Support Unit
1st Floor
125 Kingsway
London
WC2B 6NH

Impact Assessment	Yes ☐	No ☐ See Annex A for reason.

PROPOSAL:

On the authorisation process, guidance and associated documents for the use of alternative systems for the disinfection of tools in Slaughterhouses, Cutting Plants and Approved Game Handling Establishments.

DETAIL OF CONSULTATION

Introduction

1. Annex III of Regulation (EC) No 853/2004 lays down specific hygiene rules for food of animal origin. It requires that Slaughterhouses and Cutting Plants processing meat of domestic ungulates and poultry, and AGHE, *"have facilities for disinfecting tools with hot water supplied at not less than 82°C, or an alternative system having an equivalent effect."*

2. The Food Standards Agency (FSA) is seeking your views on the process, 'Guidance on the use of alternative systems for the disinfection of tools in Slaughterhouses, Cutting Plants and Approved Game Handling Establishments (AGHEs)'and the attached documents.

3. The guidance sets out the process for authorising and implementing the use of alternative methods for the disinfection of tools in FSA approved meat establishments. The associated documents are intended to support the process.

Background

4. Slaughterhouses and AGHEs use a variety of tools including knives, cleavers, and saws that require cleaning and subsequent disinfection. In addition, Cutting Plants not only use the same cutting tools but also use automatic cutting equipment such as slicers, filleting machines and dicers.

5. One of the difficulties faced by the competent authority in considering a request for an alternative system of disinfection that has an equivalent effect to the use of water at a temperature of not less than 82°C. The purpose of the guidance and associated documents is therefore to clarify the procedure for the submission of an application by a FBO and to provide some guidance on what will be needed by authorised officers to enable them to determine if an alternative system of disinfection of knives and other tools in Slaughterhouses, Cutting Plants and AGHEs is equivalent to the use of water at 82°C.

6. The FSA is responsible for the approval of Slaughterhouses, AGHEs and Cutting plants as well as any procedure that requires authorisation, and on this particular case, it has a duty to ensure that any alternative system of disinfection has an equivalent effect to the use of water at a temperature of not less than 82°C.

7. In setting out the evidence for equivalence, it is essential that the environment in which the alternative method will be used is assessed, as some environments will have higher risks associated with contamination than others. Consequently, this guidance reflects the different risks in Slaughterhouses, AGHEs and Cutting Plants with the process of proving equivalence separated.

8. Whilst slaughterhouses and AGHEs do require a more thorough authorisation process, cutting plants can implement alternative sanitation systems more simply, provided certain basic criteria are met.

Impact Assessment

Evidence from industry on the impact that the proposed authorisation process is needed in order for the FSA to assess the impact of this measure. We would therefore welcome industry input on the impacts of this measure, in particular:

- How likely are you to take advantage of the proposed authorisation process for authorising an alternative system of disinfection?

- What benefit do you perceive from introducing an alternative system of disinfection?

- Do you perceive any significant burdens from the proposed authorisation process for introducing an alternative system of disinfection?

For all questions, please try to explain your responses so that we may fully understand the likely impact of this measure.

Consultation Process

13. This 5 week consultation on the authorisation process, guidance and associated documents for the use of alternative systems for the disinfection of tools in FSA approved meat establishments closes on **12th January 2018**. Please state, in your response whether you are responding as a private individual or on behalf of an organisation / company including details of any stakeholders your organisation represents

14. Response to the consultation received by the closing date on the 12th January, will be taken into account in the final approach taken to the authorisation process and published guidance.

15. Following the consultation, we will review the responses received. A summary of response report will be published on the FSA's website within 3 months following the end of the consultation period.

Thank you on behalf of the FSA for participating in this public consultation.

Yours faithfully,

Henna Safdar,

Meat Hygiene Policy Branch**,** 1st Floor**,** Aviation House **,**125 Kingsway London **,**WC2B 6NH

Enclosed Documents

Annex A: Guidance on the use of alternative systems for the disinfection of tools

Annex B: Application form for the authorisation of the use of alternative systems for the disinfection of cutting tools in abattoirs and game handling establishments

Annex A:

Standard Consultation Information

Publication of personal data and confidentiality of responses

1. In accordance with the FSA principle of openness we shall keep a copy of the completed consultation and responses, to be made available to the public on receipt of a request to the FSA Consultation Coordinator.The FSA will publish a summary of responses, which may include your full name. Disclosure of any other personal data would be made only upon request for the full consultation responses. If you do not want this information to be released, please complete and return the Publication of Personal Data form, which is on the website at **http://www.food.gov.uk/multimedia/worddocs/dataprotection.doc** Return of this form does not mean that we will treat your response to the consultation as confidential, just your personal data.

3. In accordance with the provisions of Freedom of Information Act 2000/Environmental Information Regulations 2004, all information contained in your response may be subject to publication or disclosure. If you consider that some of the information provided in your response should not be disclosed, you should indicate the information concerned, request that it is not disclosed and explain what harm you consider would result from disclosure. The final decision on whether the information should be withheld rests with the FSA. However, we will take into account your views when making this decision.

4. Any automatic confidentiality disclaimer generated by your IT system will not be considered as such a request unless you specifically include a request, with an explanation, in the main text of your response.

Further information

5. An Impact Assessment has not been included in this consultation as this will be developed during the consultation process with industry evidence.

6. Please contact us if you require this consultation in an alternative format such as Braille or large print.

7. **This consultation has been prepared in accordance with HM Government consultation principles[1].**

[1] http://www.bis.gov.uk/policies/bre/consultation-guidance

Guidance on the use of alternative systems for the disinfection of tools in Slaughterhouses, Cutting Plants & Approved Game Handling Establishments

Meat Hygiene Policy
Food Policy Division
August 2017
FSA

Table of Contents

Guidance on the use of alternative systems for the disinfection of tools in Slaughterhouses, Cutting Plants and AGHEs 3
About this Guidance 3
Background 3
Equivalence 4
Animal processing 4
Building design 5
Line Speed 5
Alternative cleaning system Failure 5
Slaughterhouses & AGHEs 6
Process for proving evidence of equivalence 6
Request for alternative method 6
Production of a trial protocol 7
Validation, verification and operation of disinfection procedures 8
Field Trial 9
Assessment and Acceptance 10
Acceptance 10
Refusal 10
Post implementation 10
Future Practice 11
Table 1: Process for requesting the use of an alternative method in SH & AGHE 12
Table 2: Minimum requirements of a draft trial protocol 13
Cutting Plants 15
Process for proving evidence of equivalence 15
Supporting evidence for equivalence and SOP 15
Assessment and Verification Procedure 16
Post implementation 17
Compliance 17
Table 3: Process for the use of an alternative method in cutting plants 18

Examples of chemical disinfection requirements 19

Table 4: Example of a Standard Operating Procedure (SOP) for food grade chemicals for disinfection of tools and equipment 19

Figure 1: Example chemical disinfection process 20

Figure 2: Example Instruction data sheet for a chemical disinfector 21

Examples of ultra violet cleaning requirements 22

Table 5: Example of a Standard Operating Procedure (SOP) for use of ultraviolet light cabins for the disinfection of cutting tools 22

Figure 3.- Example ultraviolet disinfection process 23

Figure 4:- Example instructions datasheet for a UV cabinet 24

Reference Information 25

Table 1: Example daily cleaning schedule and checklist 25

Figure 5 & 6: Example verification forms and certificates 26

Q&A Section 27

Chemicals demonstrated as equivalent in Slaughterhouses. 28

Current 28

Guidance on the use of alternative systems for the disinfection of tools in Slaughterhouses, Cutting Plants and AGHEs

About this Guidance

1. This guidance sets out the process for requesting and implementing the use of alternative methods for the disinfection of tools in a Slaughterhouse, Cutting Plant or Approved Game Handling Establishment (AGHE) in England and Wales. It provides an overview of the assessment processes for Officials and Food Business Operators (FBOs), including details of their roles and responsibilities. The guidance is not intended to detail all possible alternative disinfection methods or highlight how certain methods could be used on the wide variety of tools available. It is the responsibility of the FBO to provide information on the method, the tools that will be disinfected and develop the trial and standard operating procedure (SOP) of for the use of the alternative method that will provide the evidence for equivalence. The FSA Assurance and Approvals Teams together with policy will assess the suitability of the alternative system and the validity of the SOP. It is not the FSAs role to develop the methodology.

Background

2. Annex III of Regulation (EC) No 853/2004 lays down specific hygiene rules for food of animal origin. It requires that Slaughterhouses and Cutting Plants processing meat of domestic ungulates and poultry, and AGHE, *"must have facilities for disinfecting tools with hot water supplied at not less than 82°C, or an alternative system having an equivalent effect."*

3. Slaughterhouses and AGHEs use a variety of tools including knives, cleavers, and saws. In addition, a growing number of modern Cutting Plants not only use the same cutting tools but also use automatic cutting equipment such as slicers, filleting machines and dicers.

4. As new chemical products and processes have been developed for the cleaning and disinfection of tools, interest by FBOs has grown in these pieces of equipment and chemicals as they are seen as safer, cleaner, more consistent and easier to maintain than hot water disinfectors. In addition, alternative disinfection techniques are slowly coming onto the market, such as Ultra Violet (UV) cleaning cabinets.

5. The European Commission adopted an Opinion of the Scientific Committee on Veterinary Measures relating to Public Health on The Cleaning and Disinfection of Knives in the Meat and Poultry Industry in June 2001. The conclusions and

recommendations made in that Opinion have been used as a basis for this paper. The Opinion is available from the Commission website at the following link:

https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scv_out43_en.pdf

6. One of the difficulties faced by the competent authority in considering a request for an alternative system of disinfection that has an equivalent effect to the use of water at a temperature of not less than 82°C, is that there is no EU guidance on how to determine equivalence in this context. The purpose of this guidance is therefore to clarify the procedure for the submission of an application and to provide some guidance on what will be needed by the competent authority to enable it to determine if an alternative system of disinfection of knives and other tools in Slaughterhouses, Cutting Plants and AGHEs is equivalent to the use of water at 82°C.

Equivalence

7. As Competent Authority, the Agency is responsible for the approval of Slaughterhouses and Cutting plants, and has to ensure that any alternative system of disinfection has an equivalent effect to the use of water at a temperature of not less than 82°C.

8. As such it is important to clarify that the FSA's role is not to provide approval for individual chemicals or technical disinfection systems, but to assess the equivalence of the methods/processes and application of these procedures in achieving equivalence in the working environment.

9. In setting out the evidence for equivalence, it is essential that the environment in which the alternative method will be used is assessed as some environments will have higher risks associated with contamination than others. Consequently, this guidance reflects the different risks in Slaughterhouses, AGHEs and Cutting Plants with the process of proving equivalence separated. The reasons for the separation are highlighted below.

Animal processing

10. The first stage of animal processing starts at the Slaughterhouses or AGHEs and potential contamination to carcase surfaces are high, particularly during skinning and evisceration. The risk of cross contamination is higher than in a Cutting Plant as the carcase has already passed post mortem inspection and is considered clean and free from external contamination such as fleece/hair, faecal matter, cysts and abscesses. The latter being related to pathological conditions and potentially containing significant bacterial load.

Building design

11. Slaughterhouses are different in design and set up to Cutting Plants. There are practical issues associated with installation and implementation of alternative disinfection methods in Slaughterhouses which generally have a fixed environment. Cutting Plants tend to have a degree of flexibility when fitting new equipment and there can be more similarity between designs of Cutting Plant.

Line Speed

12. The Slaughterhouse production line can move at pace and as such there is a constant need for tools to be cleaned and disinfected quickly and efficiently to avoid cross contamination. Any method, particularly a novel approach, will have to demonstrate effectiveness at the speed of the line.

Alternative cleaning system Failure

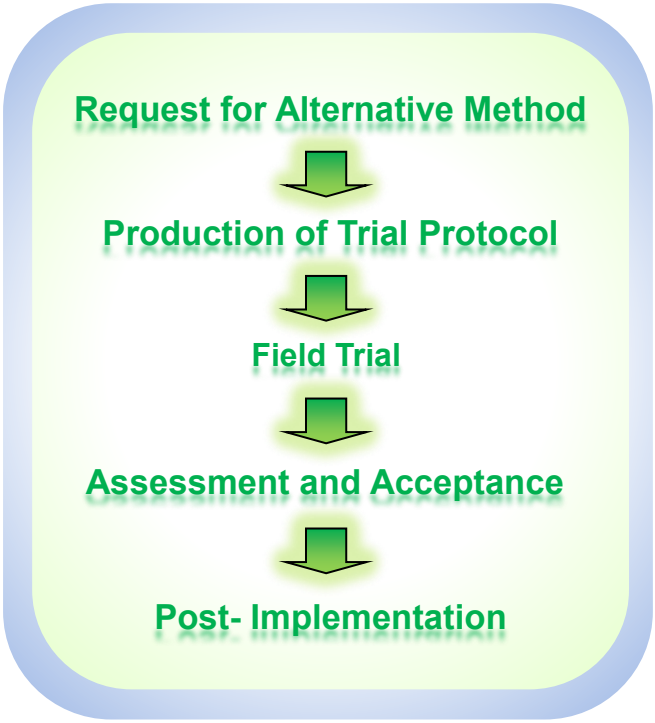
13. Failure in an alternative disinfection system in a Slaughterhouse could have serious implications as finding a quick replacement which complies with legislation might be challenging. This may result in line stoppage and have implications for food safety. A Cutting Plant should have more flexibility to resolve these issues, should a failure in an alternative system occur.

14. Separating the two work streams, Slaughterhouses, AGHEs and Cutting Plants, will allow for each process to focus on the key areas and associated risks when proving equivalence. This ensures that the assessment and supervision are proportionate to the risks associated with the two systems.

Slaughterhouses & AGHEs

Process for proving evidence of equivalence

15. An overview of the process below can be found in Table 1 at the end of this section.



Request for alternative method

16. Before approaching the FSA regarding the use of an alternative disinfection method, the FBO should consider the potential impact it may have on exporting contractual agreements. Although different methods are allowed under EU Legislation, some 3rd countries may not approve the alternative method, which may affect the ability to trade. If in doubt, the FBO can approach the 3rd country exports team at the FSA for advice.

17. Before any formal request to use an alternative method, the FBO wishing to install such a system is advised to discuss this with their Official Veterinarian (OV) or Field Veterinary Leader (FVL). The OV should set out the process highlighted in this guidance and any practical issues they may envisage with the proposed method. After discussions with the OV, if the FBO wishes to continue the FBO should submit a written request to the FSA Approvals Team Approvals@foodstandards.gsi.gov.uk who will coordinate the process of proving equivalence.

Production of a trial protocol

18. The FBO should produce a draft trial protocol detailing exactly how it is proposed that the trial will be carried out This should include proposed dates for the trial and at what points on the slaughter/dressing line the alternative method is to be used and the tools it is to be used on. It should also include any evidence relevant to the use of the alternative method. For example, chemical safety information, supporting evidence of its effectiveness at laboratory level, concentration requirements, and maintenance. It should also include the SOPs for the use of the new alternative system, including the staff training proposals.

19. The trial protocol should then be sent to FSA Approvals team for consideration. If there is uncertainty over scientific method or if the technique proposed is new and novel and therefore may need more involved validation technique, it is important to contact the FSA's Meat Hygiene Policy Team in London for advice. The Approvals team will liaise with the Field Veterinary Lead (FVL) to discuss the suitability of the trial protocol and make a decision on whether a trial can proceed. The trial protocol should be produced to meet the minimum requirements as shown in Table 2 at the end of this section.

20. The trial will need to be undertaken under normal working conditions on the slaughter/dressing line to demonstrate that the system has an equivalent effect to water at not less than 82°C.

21. It is important to note that any trial must not impact on food safety and operate within legislative requirements, i.e. any tool after being swabbed to test the effectiveness of an alternative disinfection method must then be disinfected in 82^{o}c water before coming into contact with a carcase again.

22. Once the trial protocol has been agreed this will be confirmed by the FVL in writing (e.g. by e-mail) which will also confirm the dates during which the trial will take place and the Slaughterhouse(s) or AGHE(s) that will be involved. The OV will be consulted and informed on the proposed dates.

23. Applications for Slaughterhouses and AGHEs from an FBO will only be accepted on a case-by-case basis for use on specific slaughter lines and on specific types of tools. FBOs therefore need to ensure that the trial will include all the types of tools they intend to disinfect using the alternative system.

Validation, verification and operation of disinfection procedures

24. When submitting the trial protocol, evidence should be provided by the manufacturer of an alternative system of its suitability in the food environment, any relevant accreditation such as international/European standards and if necessary appropriateness for use by the Health and Safety Executive. This evidence is in addition to the testing carried out as part of a trial by the FBO in support of the application, and provides the FSA with evidence that the alternative method is viable and can progress to the trial stage.

25. In order to be considered equivalent to disinfection in water at not less than 82°C, an alternative system must have been demonstrated to be effective against a range of bio-indicators. These should reflect those found in the Food Safety and Process Hygiene Criteria of Commission Regulation (EC) No 2073/2005, on microbiological criteria for foodstuffs and typically include (but not exclusively) aerobic colony count, enterobacteriaceae and *Salmonella*. Particular consideration must also be given to *E.coli* if minced meat is intended to be eaten less than thoroughly cooked in the final product, i.e. rare burger or steak tartare.

26. Operators will have to provide documented procedures to verify the effectiveness of the proposed alternative disinfection system on the selected bio-indicators, for example by the microbiological testing of tools. The number and frequency of samples should be proportionate to the type and size of the establishment and the history of test results. Corrective actions must be established and implemented following unsatisfactory results.

27. It may be possible to reduce the number of samples that are subject to microbiological testing in cases where a particular alternative system has already been accepted for use in another similar establishment. However, in such cases, it will be necessary for the applicant to provide details explaining how their system could be considered similar to one currently used, providing evidence that validates and verifies this. This will be reviewed on a case by case basis.

28. Adequate consideration must be given to the required supply of clean tools at each stage in the operation. Any system used must be able to supply satisfactorily disinfected tools whenever necessary. This is particularly important for novel techniques where disinfection times may be extended which may make them impractical. Novel techniques must also be able to withstand the harsh conditions within a Slaughterhouse and not compromise staff safety, this is particularly important if the systems are electrical. Records of maintenance checks, repairs and servicing must be kept.

29. The FBO should have in place procedures based on Good Hygienic Practice to provide the conditions necessary to ensure the effective performance of the disinfection procedure. In particular, operators should have specific tool cleaning procedures in place, including documented instructions for carrying these out effectively and records of checks carried out to verify that these have been carried out. Only tools that have been effectively cleaned should be subject to the disinfection procedures.

30. Equipment and/or chemicals used to disinfect tools must be used in accordance with the manufacturer's instructions. Relevant parameters, such as temperature, time, chemical concentration or frequency and power of a radiant source, should be checked and the results, and corrective actions if necessary, should be recorded.

31. Slaughterhouse staff must be adequately trained in the use of alternative disinfection systems. Existing SOPs should be amended to include each step of the alternative cleaning and disinfection procedure both when a field trial is to take place and following the implementation of the use of an alternative system. Amendments to SOPs must be validated and verified.

Field Trial

32. The purpose of the field trial is to demonstrate the effectiveness of the proposed alternative system under normal working conditions in a slaughterhouse.

33. Once the protocol for the trial is agreed, the FBO must carry out the field trial according to the agreed protocol. It is essential that any trial under working conditions does not compromise food safety and that the protocol ensures that carcases produced during the trial comply with Regulation (EC) No 853/2004. Any tool used in the trial must be disinfected in 82^{o}c water after swabbing before coming into contact with a carcase again.

34. During the trial period, the plant FVL will be responsible for monitoring the trial to ensure that it is carried out according to the agreed protocol with occasional visits. The OV should also be present to ensure they are aware of how the alternative method will operate, although there is no need for 100% supervision. At the end of the trial period, the FVL will inform the Approvals Team that the trial has been carried out.

Assessment and Acceptance

Acceptance

35. Following notification from FVL that the trial was performed in accordance to the protocol, the analytical data gathered by the FBO during the trial will be assessed. A panel made of representatives from the Meat Hygiene Policy team, the Approvals Team, the FVL and an AVL, will undertake an assessment of the results to determine if the system that has been trialled has an equivalent effect to water at not less than 82°C. The FBO will be notified of the result of their request. If the method is accepted as equivalent, confirmation will be provided in writing by the Approvals Team and recorded centrally.

36. Any method accepted by the FSA will be specific to an SOP on a particular slaughter line in a specified plant. Amendments to the accepted procedure can only be made with the agreement of the FVL.

Refusal

37. Use of the proposed equivalent method will be refused if the trial is not carried out in accordance with the agreed protocol and/or if, upon assessment, the trial results are not within the range of results that would be expected to demonstrate equivalent effect to the use of hot water supplied at not less than 82°C.

38. If the alternative method is refused, the FBO may wish to review their trial protocol and make a new request for use of the same or another alternative system of disinfection.

39. Relevant Operational staff will be notified of a failed application of an alternative system of tools disinfection. The FBO will also be notified in writing with the reasons why the system has not been considered to be equivalent.

Post implementation

40. Disinfection equipment must be maintained in good condition, and when necessary be serviced on a regular basis. Records of maintenance checks, repairs and servicing must be kept.

41. Disinfection procedures must be reviewed regularly to verify their continued effectiveness and also when any significant operational changes are introduced.

42. Disinfection procedures will be monitored by the OV and by the competent authority as part of the regular FBO audits at the set risk-based frequency.

Future Practice

43. In future, it is envisaged that if a specific alternative system (for example, use of a particular chemical on knives) has already been accepted for use in a number of different establishments on different slaughter lines, the application for use of this system in other similar establishments and slaughter lines can be streamlined. The FBO would have to demonstrate the efficacy of the alternative system and their ability to operate it consistently with a simplified trial. Microbiological data would be assessed and acceptance for use will be granted if the trial had operated correctly.

Table 1: Process for requesting the use of an alternative method in SH & AGHE

Process Stage	Steps	Responsibility
Request	Hold a discussion with the site OV or FVL to discuss plans.	FBO
	Draft a request and a protocol for the proposed procedure.	FBO
Trial protocol	Submit application and trial protocol to the FSA Approvals Team.	FBO
	Review draft trial protocol to ensure minimum requirements are met and discussed with the FVL for taking forward.	Approvals Team FSA meat hygiene policy (if needed)
	Confirm agreement or request changes of trial protocol with FBO in writing copied to the plant OV.	FVL
Field Trial	Run trial.	FBO
	Monitor compliance with protocol.	FVL with OV presence
	Post-trial. Report findings and recommendations to Approvals Team.	FVL
Assessment and Acceptance	Assess, analyse data and operation of the SOP to work effectively.	Authorisation panel
	Notify FBO of FSA decision.	Approvals Team
Post-implementation	Review/update HACCP based food safety management system to include new procedure (if accepted)	FBO
	Implement new procedure	FBO
	Include in FBO audit at risk-based frequency	FVL/VA

Table 2: Minimum requirements of a draft trial protocol

(This is required to test the procedure and the protocol)

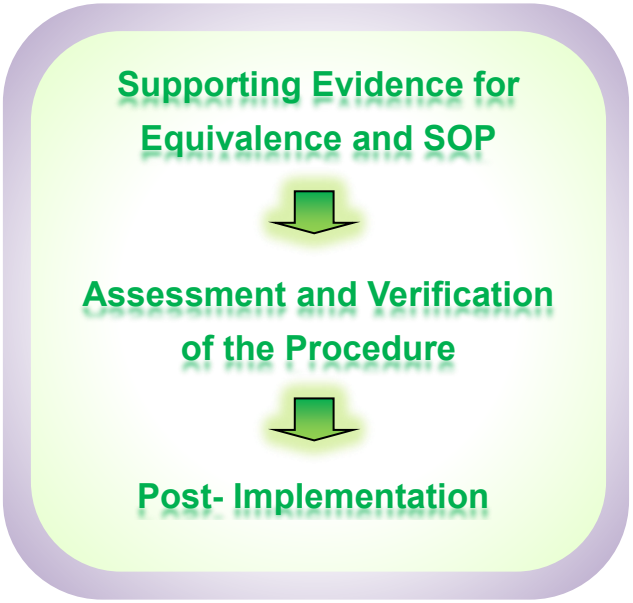
Proposal	**<u>Section 1</u>** This section should include i. An overview of what the objective is, and how the FBO will achieve it, e.g. the use of an alternative method of disinfection to achieve equivalence to water at 82°C. ii. A summary of the existing system as well as a brief outline of methods, chemicals, novel techniques etc. proposed.
Procedure	**<u>Section 2</u>** This section should document i. How the FBO will establish a baseline using their existing system of water at no less than 82°C so that a direct comparison can be made with the proposed alternative ii. The proposed procedure in detail iii. Validation of the chemicals, novel techniques and processes to be used iv. Staff training protocols for the use of the alternative system v. The control measures that will be put in place to ensure efficacy is maintained vi. How control measures will be monitored throughout the process vii. A contingency plan detailing the corrections and corrective actions to be taken in the event that control measures fail
Testing	**<u>Section 3</u>** This section should detail i. The sampling plan (including what, how and how often) ii. The testing laboratory and methodology to be used

Verification	**<u>Section 4</u>** i. This section should describe how the FBO will verify the effectiveness of the system once implemented. ii. The control measures that will be put in place to ensure efficacy is maintained iii. How control measures will be monitored iv. A contingency plan detailing the corrections and corrective actions to be taken in the event that control measures fail

Cutting Plants

Process for proving evidence of equivalence

44. An overview of the process below can be found in Table 3 at the end of this section.



Supporting evidence for equivalence and SOP

45. Before approaching the FSA regarding the use of an alternative disinfection method, the FBO should consider the potential impact it may have on 3rd country exports. Although different methods are allowed under EU Legislation, some 3rd countries may not approve the alternative method, which may affect the ability to trade. If in doubt, the FBO can approach the 3rd country exports team at the FSA for advice.

46. It is the responsibility of the FBO to ensure that if they are using or wish to install an alternative disinfection method, that this does not compromise food safety and is compliant with Legislation requiring it to be an equivalent method. Any method used will be assessed during FBO Audits or unannounced inspections. To ensure the FBO is able to comply with expectations, the FBO may wish to contact the FSA's Approvals Team for more information, particularly if they wish to use a method not covered in this document. For Cutting Plants there is no need for a specific approval process as per slaughterhouses and AGHEs.

47. Before implementation, the FBO must collect evidence regarding the suitability of the alternative system for the disinfection of the relevant tools. This should include information on the chemical or novel method, its efficacy and evidence that the

chemical or novel approach will not impact on food safety. Evidence should be provided by the manufacturer of the equipment, chemical supplier and by testing completed by the FBO which should include evidence that under normal working conditions, that the system can operate effectively and has an equivalent effect to water at not less than 82°C.

48. In order to validate and verify the efficacy *in situ*, the FBO must provide evidence that the disinfection method has been demonstrated to be effective against a range of bio-indicators. These should reflect those found in the Food Safety and Process Hygiene Criteria of Commission Regulation (EC) No 2073/2005, on microbiological criteria for foodstuffs and typically include aerobic colony count, enterobacteriaceae and *Salmonella*. Particular consideration must also be given to *E.coli* if the final product is intended to be eaten less than fully cooked.

49. A Standard Operating Procedure (SOP) for the alternative method should be set out. Examples of these can be seen in Tables 4 & 5 at the end of this section. Figures 1 to 4 show typical manufacturer's instructions.

Assessment and Verification Procedure

50. Operators will have to provide documented procedures to verify the effectiveness of the proposed alternative disinfection system. It is recommended that microbiological testing of tools is used. The number and frequency of samples should be proportionate to the type and size of the establishment and the history of test results. Corrective actions must be established and implemented following unsatisfactory results.

51. Adequate consideration must be given to the required supply of disinfected tools/knives at each stage in the operation. While some premises only need to disinfect knives during breaks others might need it doing more regularly, quickly and close to the working stations. Any system used must be able to supply satisfactorily disinfected tools whenever necessary.

52. The FBO should have in place procedures based on Good Hygiene Practice to provide the conditions necessary to ensure the effective performance of the disinfection procedure. In particular, operators should have specific tool cleaning procedures including instructions and records of checks completed. Only tools that have been effective cleaned should be subject to the disinfection procedures.

53. Equipment and/or chemicals used to disinfect tools must be used in accordance with manufacturer's instructions. Relevant parameters, such as temperature, time,

chemical concentration or frequency and power of a radiant source, should be checked and the results, and corrective actions if necessary, be recorded.

54. Equipment must be maintained in good condition, and when necessary be serviced. Records of maintenance checks, repairs and servicing, such as UV light bulb replacement must be kept.

55. Disinfection procedures must be reviewed regularly and when significant operational changes are introduced.

56. Staff must be adequately trained on the use of alternative disinfection systems.

Post implementation

57. Disinfection equipment must be maintained in good condition, and when necessary be serviced on a regular basis. Records of maintenance checks, repairs and servicing must be kept.

58. Disinfection procedures must be reviewed regularly to verify their continued effectiveness and also when any significant operational changes are introduced.

59. Disinfection procedures will be monitored by the competent authority as part of the FBO audit at a risk-based frequency or at unannounced inspections.

Compliance

60. If during audit or unannounced inspection, the use of the equivalent method is not performing to the correct efficacy or is not being carried out in accordance with the SOP, for example the monitoring results are not within the range of results that would be expected if it were demonstrating equivalence to water supplied at not less than 82°C, then the FBO must stop using this method and revert to hot water sterilisation.

61. At this point the FBO may wish to review their protocol and re-assess its procedures.

62. Any method accepted as equivalent by the FSA during an audit or standard approval visit will be specific to an SOP in a particular Cutting Plant unless otherwise stated.

Table 3: Process for the use of an alternative method in cutting plants

Process Stage	Steps	Responsibility
Supporting Evidence for Equivalence	FBO to ensure that the alternative disinfection method is equivalent to hot water at more than 82^{o}c. The FBO may wish to contact the FSA's Approvals Team for more information.	FBO FSA to be consulted if necessary
	Information on the chemical or novel method should include manufacturing information, efficacy and evidence that the chemical or novel approach will not impact on food safety.	FBO
SOP	FBO to create an SOP on the use of the alternative method in the Cutting Plant.	FBO
	The SOP should include the monitoring procedures to confirm continued compliance and staff training protocols on the SOPs and the new system.	FBO
Assessment and Verification	Microbiological testing of tools should be used as part of a regular sampling plan. This will provide evidence for assessment and verification and continued compliance.	FBO FSA to be consulted if necessary
	Records should be maintained showing that equipment is maintained in good condition.	FBO
Post-implementation	Review/update HACCP based food safety management system to include new procedure.	FBO
	Implement new procedure.	FBO
	The FBO to be audited at risk-based frequency and unannounced inspections.	FSA Audit UAI

Examples of chemical disinfection requirements

Table 4: Example of a Standard Operating Procedure (SOP) for food grade chemicals for disinfection of tools and equipment

1	Only trained personnel will be allowed to carry out the cleaning and disinfection of cutting tools.
2	At break times and/or at the end of the processing day, all cutting tools, equipment surfaces and food contact surfaces (i.e. knives, saws, mincing, dicing, slicing machines, chopping boards) will be washed and cleaned with hot water and a food grade detergent.
3	A dilution bath of an approved food grade odourless disinfectant will be prepared following the instructions in the chemical data sheet (please refer to volumes/concentrations in the datasheet).
4	After washing the tools with detergent and hot water, place utensils and small equipment parts in the bath previously prepared and give sufficient time to ensure the tools have been disinfected (as per the manufacturer instructions).
5	After that time, place the utensils and parts in a rack, rinse with clean potable water using a hand held spray or a clean water bath and allow to dry.
6	Large pieces of equipment and food contact surfaces unable to fit in the bath will be sprayed with the same dilution and allow an exposure time as per the specifications in the datasheet.
7	After that time, equipment will be rinsed with clean potable water and allow to dry.
8	The technical manager will be responsible for monitoring that the process is completed as per the instructions and completing the cleaning check list (doc 1111) to that effect.
9	When pre-cutting inspection is being carried out a colour coded knife must be used.
10	If contamination is found and this need to be trimmed off, steps 1 to 3 must be observed immediately after trimming of contamination.
11	To verify that bacterial growth is kept to the very minimum and the process of cleaning and disinfection is effective, swabs of handles, blades and equipment will be taken on a monthly cycle.

Figure 1: Example chemical disinfection process

Photo 1. Cleaning and disinfection area (i.e. dilution material, washing sink, water spray, disinfection bath, drying/storage area)

Photo 2. Brush washing with hot water and detergent

Photo 3. Dilution equipment. Four full buckets X 1 full measure jar

Photo 4. Disinfection bath

Photo 5. Equipment rinsing with water

Photo 6. Disinfection of equipment

Figure 2: Example Instruction data sheet for a chemical disinfector

KITCHEN CLEANER SANITISER ODOURLESS

Description

Unperfumed, multi purpose cleaner and terminal disinfectant. Recommended for use on a variety of surfaces, including worktops, cutting boards, tables, vending machines, refrigerators, kitchen equipment, shelves, floors and walls.

Laboratory tests have proved it will kill gram positive and gram negative bacteria in 60 seconds.

Features and Benefits

- Unperfumed
- Cleans and disinfects in one operation
- Kills bacteria and helps prevent the spread of infection
- Formulated especially for the Food and Catering Industry
- Passes British and EuropeanTest Method BS EN 1276:1997
- Available in Ready to Use formulation in 750ml trigger spray bottles
- A Microbiology report is available on request

How to Use

FOOD CONTACT SURFACES:
Dilute 500ml of detergent per 5 litres of hot water.
Dilute 50ml of detergent per 500ml of water in a 750ml spray bottle.
Wipe or spray surface. Rinse with clean water

NON FOOD CONTACT SURFACES:
Dilute 100ml of detergent per 5 litres of hot water.
Mop or wipe surface. Allow to air dry.

Composition

Contains a blend of quaternary ammonium compound, glycol ether, sequestering agent, ethoxylated amine, amphoteric and non-ionic surfactants

Typical Product Data

Appearance/ Colour:	Liquid. Pale straw
Odour/Taste:	Faint surfactant
Solubility Description:	Soluble in water
Boiling Pt. (°C):	101 @ 760mmHg
Specific Gravity (Water=1):	1.016 @ 20 °C
Flash Pt. (°C):	Boils without flashing
Melting Point: (°C):	-1
pH-Value, Conc:	11.00

Storage

Store in original sealed container and protect from extremes of temperature

Examples of ultra violet cleaning requirements

Table 5: Example of a Standard Operating Procedure (SOP) for use of ultraviolet light cabins for the disinfection of cutting tools

1	Only trained personnel will be allowed to carry out the cleaning and disinfection of cutting tools.
2	At break times and/or at the end of the processing day knives will be washed and cleaned with hot water and an approved food grade detergent.
3	After rinsing with water, knives will be place in the UV cabinet for a period of time (as per the manufacturer instructions) sufficient to ensure the tools have been disinfected.
4	The technical manager will be responsible for monitoring that the process is completed as per the instructions and completing the cleaning check list (doc 1111) to that effect.
5	When pre-cutting inspection is being carried out a RED handled knife must be used.
6	If contamination is found and this need to be trimmed off, steps 1 to 3 must be observed immediately after trimming of contamination.
7	To verify that bacterial growth is kept to the very minimum and the process of cleaning and disinfection is effective swabs of handles and blades will be taken on a monthly cycle.
8	UV equipment must be regularly checked to make sure it remains compliant with the manufacturers specifications.

Figure 3.- Example ultraviolet disinfection process

Photo 1. Cleaning and disinfection area (i.e. dilution material, washing sink, water spray, disinfection bath, drying/storage area.

Photo 2. Brush washing with hot water and detergent

Photo 3. Open UV cabinet with tools inside

Photo 3. Functioning UV cabinet

Figure 4:- Example instructions datasheet for a UV cabinet

ULTRA VIOLET CLEANER AND DISINFECTOR

Description

This UV knife disinfection cabinet is particularly useful for disinfecting knives and other utensils presenting a risk of contaminating high risk foods. This has proven to be highly effective in eradicating food borne micro-organisms.

Working method

A tube generates ultraviolet germicidal rays transforming oxygen into ozone, thus killing bacteria. The effect of the UV rays (254 nm) is well known, it is a highly effective virucide and germicide. The generated ozone ensures an excellent decontamination of utensils stored within the cupboard. The cupboards, which conform to hygiene standards, are useful in all branches of industry and food trades.

Constructed in brushed 18/10 stainless steel, they are meant to last and can be installed in all kinds of atmospheres including humid environments.

Use

- After cleaning the knives, place them on the magnetic bars and turn the timer from X to X hours/mins.
- The minimum advised time is X hours/mins.
- At the end of this time period, the knives are disinfected and ready for use.

Features

- Disinfect up to X knives at a time;
- Short disinfection time
- Wall mounted

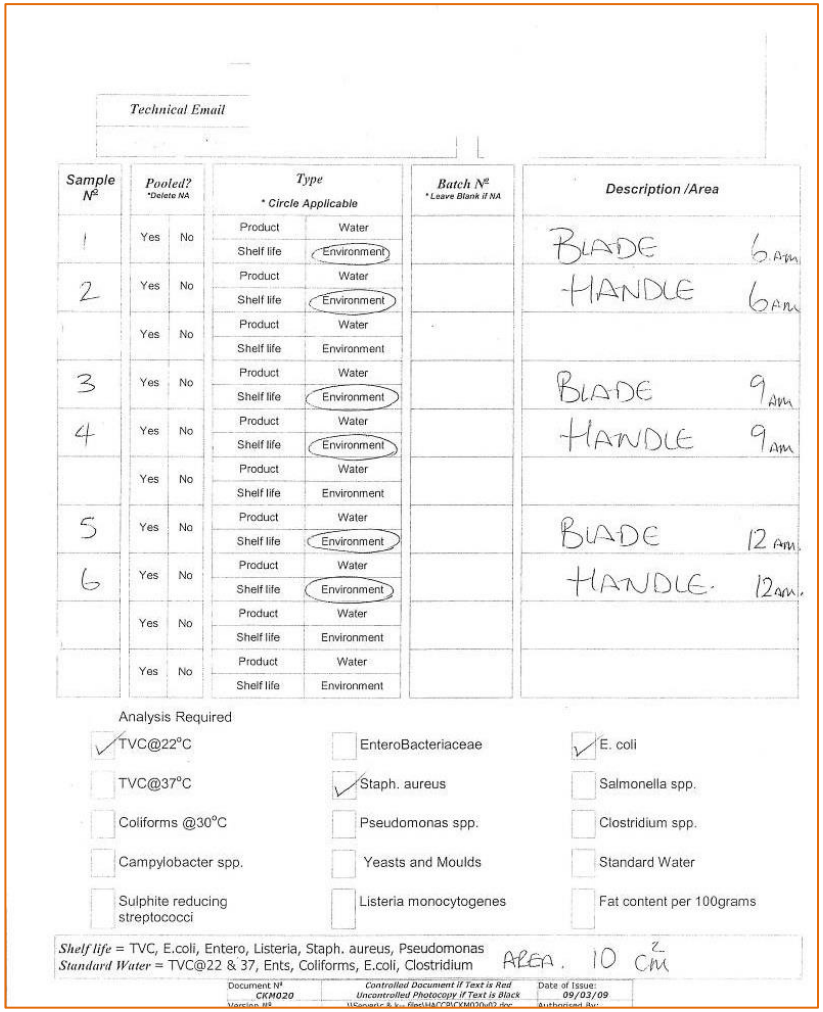
Reference Information

Table 1: Example daily cleaning schedule and checklist

WEEK COMMENCING: .....

Area/Equipment	Frequency of Cleaning	Method of cleaning	Signed by Cleaner							Comments
			S	M	T	W	T	F	S	
Knives	Every break	As per protocol 001								
Knives	End of day									
Mincing machine	End of processing									
Dicer	End of processing									
Slicing machine	End of processing									
Verified by…….										

Figure 5 & 6: Example verification forms and certificates



Technical Email

Sample Nº	Pooled? *Delete NA	Type * Circle Applicable		Batch Nº * Leave Blank if NA	Description /Area
1	Yes No	Product	Water		BLADE 6 AM
		Shelf life	(Environment)		
2	Yes No	Product	Water		HANDLE 6 AM
		Shelf life	(Environment)		
	Yes No	Product	Water		
		Shelf life	Environment		
3	Yes No	Product	Water		BLADE 9 AM
		Shelf life	(Environment)		
4	Yes No	Product	Water		HANDLE 9 AM
		Shelf life	(Environment)		
	Yes No	Product	Water		
		Shelf life	Environment		
5	Yes No	Product	Water		BLADE 12 AM
		Shelf life	(Environment)		
6	Yes No	Product	Water		HANDLE 12 AM
		Shelf life	(Environment)		
	Yes No	Product	Water		
		Shelf life	Environment		
	Yes No	Product	Water		
		Shelf life	Environment		

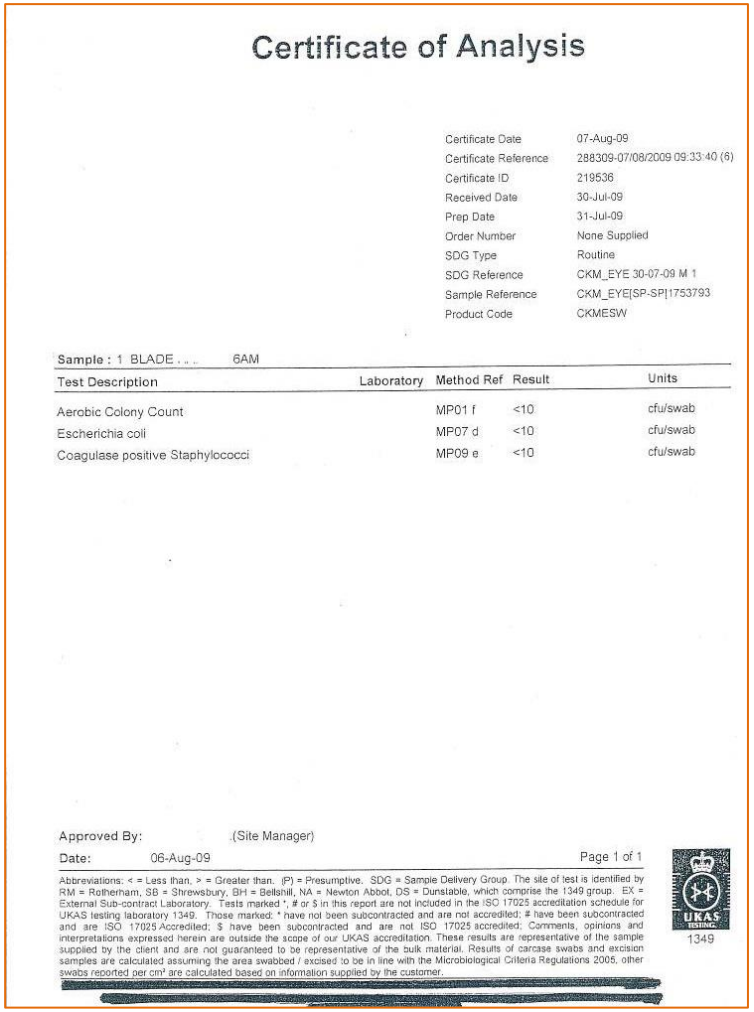
Analysis Required

✓ TVC@22°C	EnteroBacteriaceae	✓ E. coli
TVC@37°C	✓ Staph. aureus	Salmonella spp.
Coliforms @30°C	Pseudomonas spp.	Clostridium spp.
Campylobacter spp.	Yeasts and Moulds	Standard Water
Sulphite reducing streptococci	Listeria monocytogenes	Fat content per 100grams

Shelf life = TVC, E.coli, Entero, Listeria, Staph. aureus, Pseudomonas
Standard Water = TVC@22 & 37, Ents, Coliforms, E.coli, Clostridium
AREA. 10 CM²

Document Nº	Controlled Document if Text is Red	Date of Issue:
CKM020	Uncontrolled Photocopy if Text is Black	09/03/09

Blade and handle microbiological sampling



Certificate of Analysis

Certificate Date	07-Aug-09
Certificate Reference	288309-07/08/2009 09:33:40 (6)
Certificate ID	219536
Received Date	30-Jul-09
Prep Date	31-Jul-09
Order Number	None Supplied
SDG Type	Routine
SDG Reference	CKM_EYE 30-07-09 M 1
Sample Reference	CKM_EYE[SP-SP]1753793
Product Code	CKMESW

Sample : 1 BLADE 6AM

Test Description	Laboratory	Method Ref	Result	Units
Aerobic Colony Count		MP01 f	<10	cfu/swab
Escherichia coli		MP07 d	<10	cfu/swab
Coagulase positive Staphylococci		MP09 e	<10	cfu/swab

Approved By: (Site Manager)
Date: 06-Aug-09
Page 1 of 1

Abbreviations: < = Less than, > = Greater than. (P) = Presumptive. SDG = Sample Delivery Group. The site of test is identified by RM = Rotherham, SB = Shrewsbury, BH = Bellshill, NA = Newton Abbot, DS = Dunstable, which comprise the 1349 group. EX = External Sub-contract Laboratory. Tests marked *, # or $ in this report are not included in the ISO 17025 accreditation schedule for UKAS testing laboratory 1349. Those marked: * have not been subcontracted and are not accredited; # have been subcontracted and are ISO 17025 Accredited; $ have been subcontracted and are not ISO 17025 accredited; Comments, opinions and interpretations expressed herein are outside the scope of our UKAS accreditation. These results are representative of the sample supplied by the client and are not guaranteed to be representative of the bulk material. Results of carcase swabs and excision samples are calculated assuming the area swabbed / excised to be in line with the Microbiological Criteria Regulations 2005, other swabs reported per cm² are calculated based on information supplied by the customer.

UKAS TESTING 1349

Satisfactory test results.

Q&A Section

1.- Why do I need to disinfect cutting tools and contact surfaces

After cleaning cutting equipment, tools or contact surfaces, pathogen bacteria can still be present in these surfaces. These micro-organisms can eventually contaminate food. This is known as cross-contamination. A correctly applied cleaning and disinfection process will kill these pathogens, minimising considerably the risk of cross contamination and subsequent food related outbreak.

2.- How often do I need to disinfect my equipment, tools and contact surfaces?

Every factory has a different working pattern and it is not possible to determine a generic protocol. Whatever disinfection programme you establish at your establishment, should ensure the food processed is safe and fit for human consumption.

As a minimum, knives and cutting tools should be cleaned and disinfected at every break and immediately after they have become contaminated, whereas equipment and contact surfaces should be cleaned at least once a day, at the end of the operations.

3.- Why do I need to carry out a microbiological test on the surfaces that have been disinfected?

In addition to visual examination, this is the best way to verify the effectives of the cleaning and the disinfection processes. The sampling procedure is very simple, and should not take long to complete. This can be paired with other compulsory microbiological testing (i.e. water testing, compulsory food sampling).

4.- Why do I need to wash thoroughly before using the disinfectant?

Chemical or UV disinfectants are only effective on clean surfaces. All organic matter (i.e. meat, fat) has to be removed prior to the application of any chemical or placing the tools in the UV cabinet.

Chemicals demonstrated as equivalent in Slaughterhouses.

Current

INSPEXX 210: Holchem Laboratories Limited

Application form for the authorisation of the use of alternative systems for the disinfection of cutting tools in abattoirs and game handling establishments

Regulation (EC) 853/2004, Annex III, Sections, I, II & IV.

PART 1 – Establishment for which authorisation is sought

Approval number	
Establishment approval name	
Full establishment address (inc. Postcode)	
Telephone number	
Fax number	
Email	

PART 2 – Information and documentation

The following information is required in order to process your application and should be made available to the plant Field Veterinary Leader/Field Veterinary Coordinator.

- A description of the trial protocol, including ☐
  - Details of the trial proposal protocol ☐
  - Details of the trial procedures ☐
  - Details of the trial sampling procedures ☐
  - Details of the verification procedures post-implementation ☐

Name in BLOCK LETTERS		Date	
Signature (not required if emailed)			