



***E. COLI* O157**
CONTROL OF
CROSS-CONTAMINATION

Guidance for
food business operators
and enforcement authorities

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CONTACT TELEPHONE: 020 7276 8449

SUMMARY

Intended audience:	<p>This guidance is for food businesses of all sizes where both raw food and ready-to-eat foods are handled.</p> <p>Raw food in this context means raw meat and any raw ingredients that are potential sources of E. coli O157.</p> <p>Ready-to-eat foods are foods that will not be cooked or reheated before being eaten and include foods such as cooked meats, sandwiches, cheese, salads and desserts.</p>
Regional coverage:	This guidance applies across the UK.
Purpose:	<p>The purpose of this document is to provide guidance on the steps that food businesses need to take in order to control cross-contamination between raw foods and ready-to-eat foods where E. coli O157 is a hazard. Businesses are required to produce safe food and this guidance is intended to assist businesses with meeting that duty.</p>
Legal status:	<p>This document provides guidance on compliance with applicable food hygiene legislation contained in Regulation (EC) No 852/2004 but also contains best practice recommendations.</p>
	<p>Best practice recommendations are highlighted in grey boxes.</p>
Essential actions to comply with regulation(s):	<p>Food business operators must put in place food safety management procedures based on the principles of HACCP (Hazard Analysis Critical Control Point). Where applicable, these must include effective controls to ensure that all ready-to-eat foods are protected against direct or indirect contamination from E. coli O157 arising from raw foods.</p> <p>This contamination can be controlled by:</p> <p>Separation, between equipment, materials and staff involved in handling raw food from those involved in handling ready-to-eat food.</p> <p>Where separation is not physically possible, there are limited circumstances where risks may be reduced through strict and consistent application of cleaning, disinfection and handwashing procedures, which ensure the removal</p>

	<p>of E. coli O157 from surfaces, equipment and hands on every occasion before coming into contact with ready-to-eat foods.</p> <p>These procedures need to ensure that:</p> <ul style="list-style-type: none">• Adequate facilities are provided for handwashing and that staff are trained in handwashing techniques• Appropriate products are selected for cleaning and disinfection of surfaces and are used in accordance with manufacturer's instructions.
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REVIEW OF GUIDANCE

The Agency has, as far as possible, considered the suggestions offered in response to the public consultation in formulating this guidance. The guidance is intended as a source document for both industry and enforcers from which messages can be taken to produce further targeted guidance for specific audiences. This recognises the emerging findings from our work on understanding behaviours which emphasised the need for effective, targeted messages. The Agency will be taking forward a further programme of work to consider how best to target specific audiences and to inform this work. We are seeking feedback from FBOs and enforcers on implementation of this guidance.

Please send your feedback on this guidance either by email to:

controllingecoli@foodstandards.gsi.gov.uk

Or in hardcopy to:

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REVISION HISTORY

This guidance follows the Government Code of Practice on Guidance. If you believe this guidance breaches the Code for any reason, please contact us using the number on the front sheet. If you have any comments on the guidance, again please contact us on the number on the front sheet. This document is scheduled for review by the end of December 2011.

Revision no.	Revision date	Purpose of revision	Revised by
0	15/02/2011	First Issue	

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EXECUTIVE SUMMARY

Background

This guidance sets out the strict precautions needed in food businesses to ensure that consumers are protected from the risk of an isolated instance of low-level contamination of ready-to-eat food with E. coli O157. It applies to all sectors except primary production (e.g. farming) and is therefore applicable to retail, catering, and other processing sectors.

E. coli O157 is a particularly dangerous type of bacteria because it can cause serious, untreatable, illness and even death from very low-levels of contamination of ready-to-eat food. Because E. coli O157 survives at freezer, chill and ambient temperatures, measures to control cross-contamination apply to all of these environments. Although E. coli O157 is the key focus of this guidance, the measures outlined will also help in the control of other food poisoning bacteria, such as campylobacter and salmonella.

The risk of E. coli O157 cross-contamination should be considered wherever raw foods such as raw meat and unwashed vegetables are handled and where ready-to-eat foods are also handled. Without strict controls, E. coli O157 can be spread throughout any food processing environment. It is therefore essential that ready-to-eat foods are at all times handled and stored in clean areas where controls ensure the environment is free from E. coli O157 contamination.

Physical separation

Controls must ensure that surfaces, equipment, hands, clothing etc that are designated as clean will never become contaminated by E. coli O157, because no further controls will prevent that contamination spreading within the clean area. Food premises should be designed to enable adequate separation.

The only reliable way to prevent cross contamination of ready-to-eat foods with E. coli O157 is through strict physical separation of clean environments, where ready-to-eat foods are handled and stored, from any other surfaces or equipment that are not designated for use in the clean area. This will require the use of separate equipment and utensils. Complex equipment such as vacuum packers, slicers and mincing machines should never be used for both raw foods and ready-to-eat foods and separate machines should be provided. These must also be hygienically designed.

Adequate separation requires thorough consideration of everything used in a clean area, including packaging, cleaning materials, cash registers, aprons, gloves, pens etc. If these are overlooked then contamination can enter the clean area and spread without any way of detecting it or controlling the surfaces affected.

Handwashing

The movement of staff from handling raw food to handling ready-to-eat foods should be minimised as far as possible, but where it is unavoidable, handwashing controls must ensure that a proper technique is followed on all occasions. Once hands have been washed, procedures must ensure that they are not re-contaminated by contact with taps. Hygienic hand rubs, such as alcohol gels, can be considered as an additional precaution but should not be used as an alternative to effective hand-washing.

Disinfection

Disinfection by heat using appropriate time/temperature combinations can be effective at destroying *E. coli* O157. The temperatures required are generally achieved in commercial dishwashers and in standard hot wash laundry cycles.

Disinfection using chemical disinfectants or sanitisers should not be substituted for physical separation as a critical control for *E. coli* O157 cross-contamination. However, in the limited cases set out in the guidance (sinks for cleaning and disinfecting food equipment and non-food-contact surfaces such as worktops and walls), it may be the only practicable control measure. In such cases, the use of disinfectants or sanitisers that meet BS EN 1276:1997 or BS EN 13697:2001 can be considered appropriate. This is provided that they are applied to visibly clean surfaces, and are used strictly in accordance with the manufacturer's instructions relating to proper dilution of the chemical, the effective temperature range and the necessary contact time. Since effective chemical disinfection can only be achieved on visibly clean surfaces, a cleaning stage is required first.

Effective chemical disinfection is an essential prerequisite hygiene measure throughout the food industry and the guidance in this document can be used more generally for the selection and use of disinfectants.

Documented procedures

Robust documented procedures are essential for ensuring that measures for controlling *E. coli* O157 cross-contamination are being adhered to. Measures that are critical for control of *E. coli* O157 must be valid and this document provides advice that can be used to draw up valid procedures. These procedures will need to be supported by training of all relevant staff. Training will need to ensure that staff fully understand and implement arrangements for separation and the maintenance of clean areas. Training will also need to ensure that staff are able to carry out proper handwashing technique and fully understand when handwashing is critical to protect ready-to-eat foods and the integrity of designated clean areas. Similarly, training in the correct use of disinfectants and sanitisers is critical to their effectiveness.

Control measures

Supervision must ensure that critical cross-contamination controls are implemented at all times. If a breakdown in procedure is detected, it must be considered a serious incident and the food business operator must take immediate steps to ensure that no food placed at risk from E. coli O157 cross-contamination is supplied for consumption. Effective action must also be taken in respect of any product that has already been placed on the market.

Enforcement

The role of enforcing authorities is to protect consumers where a food business operator has not implemented adequate controls or appropriate corrective actions. Where an enforcing authority identifies that critical cross-contamination controls are inadequate or corrective actions have not been properly implemented, it must intervene and take all appropriate action to protect public health. Enforcing authorities must always consider the use of Hygiene Emergency Prohibition Notices where inadequate control presents a risk of cross-contamination of ready-to-eat foods by E. coli O157. Enforcing authorities should take possession of food intended for use as a ready-to-eat product for the purposes of destruction if it has not been produced, processed or distributed in accordance with statutory hygiene requirements and it has been exposed to the risk of E. coli O157 cross-contamination.

INTRODUCTION

1. This guidance has been developed by the Food Standards Agency in response to the serious foodborne E. coli O157 outbreaks that were reported in Scotland during 1996 and Wales during 2005. Both of these outbreaks resulted in the deaths of some affected individuals and in serious long-term health problems for others. Both the Scotland and Wales outbreaks were attributed to cross-contamination arising from poorly managed food handling practices.

Intended audience

2. This document provides guidance to food business operators (FBOs) and enforcement authorities on the measures required to control cross-contamination involving E. coli O157. It applies to all food businesses that handle raw and ready-to-eat foods, where control measures are necessary to manage the risk of cross-contamination with E. coli O157. This guidance does not apply to primary producers (i.e. farmers and growers).

Purpose of guidance

3. This guidance aims to increase recognition of the threat that E. coli O157 poses to public health and the need for stringent measures required during food production to control the particular cross-contamination risks associated with this pathogen. It should be noted that although E. coli O157 is the key focus of this guidance, the measures outlined will also help in the control of cross-contamination risks posed by other pathogens such as campylobacter and salmonella.
4. The controls set out in this guidance will be necessary in all circumstances where raw foodstuffs, which have the potential to be contaminated with E. coli O157, are handled in the same establishment as ready-to-eat food. Examples of raw foodstuffs known to be potential sources of E. coli O157 are described in paragraph 17 and include the following:
 - Raw meat
 - Raw root vegetables, fruit or other vegetables likely to have been contaminated by soil, excluding products that are specifically sold as ready-to-eat.

5. E. coli O157 outbreaks have also been attributed to the consumption of raw milk and raw milk products, as well as water from untreated supplies. Food businesses using private water supplies will be aware of specialist requirements for ensuring the safety of the supply. Dairy establishments handling raw milk should have well-established systems to control cross-contamination.
6. FBOs should apply the measures set out in this guidance in all circumstances where they have reasonable grounds to believe that E. coli O157 may be present in food ingredients or in any other material entering a food establishment where ready-to-eat foods are also handled.
7. Materials that are used for the wrapping and packaging of foods, which may be contaminated with E. coli O157, are also treated as a potential route for cross-contamination. Guidance is also provided on measures for avoiding the contamination of the outer surfaces of pre-packed foods in order to minimise the potential risk to catering businesses and consumers. Potential indirect routes for cross-contamination via food handlers are also covered.
8. This guidance includes technical control measures in relation to cleaning and decontamination protocols for equipment and surfaces required to reduce the cross-contamination risks associated with E. coli O157 and other foodborne pathogens.
9. The decontamination of foods that may already contain E. coli O157 or other microbiological pathogens is not covered in this document. Such controls through cooking or other processing steps are covered in existing guidance published by the Food Standards Agency.

Legal status of guidance

10. This guidance has been produced to provide advice on how to comply with the legal requirements of Regulation (EC) No 852/2004 where they are applicable to controlling cross-contamination, and what is best practice in this area.
11. The guidance notes on legal requirements cannot cover every situation and you may need to consider the relevant legislation itself to see how it applies in your circumstances. Further information about legal requirements relevant to controlling cross-contamination is provided in Annexe 1. Following the guidance notes will help you to comply with the law. Boxes throughout the text highlight key messages, these have been outlined in green. Compliance with the advice on best practice is not required by law. **To distinguish between the two types of information, all advice on best practice is in grey shaded boxes, with a heading of Best Practice.**
12. Businesses with specific queries may wish to seek the advice of their local enforcement agency that will usually be the environmental health department of the local authority.

GLOSSARY

Asymptomatic	Infection without symptoms.
Bactericidal	Capable of destroying bacteria.
Dual-use	The use of any equipment, at different times, for raw foods and ready-to-eat foods.
CE Mark	A manufacturer's declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation.
Clean area	An area within a food establishment that is specifically managed to ensure that harmful bacteria, including E. coli O157, have been effectively excluded from all surfaces (including hands) that will come into contact with ready-to-eat foods.
Cleaning	The physical removal of food debris, visible dirt, food particles and debris from surfaces, equipment, and fittings using hot water and a detergent.
Clean as you go	The frequent clean up of food waste and debris to avoid accumulation of food residues on equipment and surfaces.
Contact time	The period of time for which a disinfectant should be in contact with a surface to achieve the required level of disinfection.
Cross-contamination	The transfer of harmful bacteria from a contaminated food source to an uncontaminated food item either by direct or indirect contact.
Detergent	A cleansing substance (which does not have disinfectant properties) made from chemical compounds and used for general cleaning.
Disinfectant	A substance that is capable of destroying harmful bacteria when applied at a specified concentration and contact time.
Disinfection	The application, following general cleaning, of a bactericidal disinfecting agent or treatment to facilitate the removal of harmful bacteria from surfaces or equipment.
FBO	Food business operator.
Food safety requirements	The statutory requirements for safe food are defined in European Community food law. Regulation (EC) No 178/2002 requires that food must not be placed on the

market if it does not meet the food safety requirements that are defined within in the regulation.

HACCP	Hazard Analysis and Critical Control Point. An internationally recognised food safety management system that identifies, evaluates, and controls hazards that are significant for food safety. European food law requires every FBO (except primary producers) to implement a food safety management system based on HACCP principles.
Infective dose	The number of pathogenic organisms that will cause infection in susceptible subjects.
Monitoring ¹	The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is under control.
Potable water	Water that is fit for human consumption and free from colour, taint, odour or pathogens.
Raw food	Raw meat and any raw foods that are potential sources of E. coli O157.
Raw meat	Uncooked meat (including mince and sausages), poultry, game and offal.
Ready-to-eat food	Foodstuffs or ingredients that can safely be consumed without further heating or other processing, such as cooked meat, fruit, salads, pies, cheeses and sandwiches.
Sanitiser	A substance that combines disinfectant and detergent in a single product.
Validation ¹	Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome.
Verification ¹	The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended.
Visibly clean	Free from any visible grease or film and solid matter.

¹ Taken from Guidelines for the Validation of food safety control measures CAC/GL-2008 H
http://www.codexalimentarius.net/web/more_info.jsp?id_sta=11022

E. COLI O157 – WHY IS THERE A RISK?

13. Verotoxigenic E. coli (VTEC) is a group of toxin-producing strains of Escherichia coli that occur naturally in the gastrointestinal tract of ruminant animals, including cattle and sheep, which are pathogenic to humans. E. coli O157 is the VTEC strain that has been most commonly implicated in human infection in the UK.
14. E. coli O157 is a particularly dangerous organism because:
 - it is reported to have a very low infective dose (less than 100 bacteria) and can lead to serious illness and death
 - it has the ability to survive during refrigeration and freezing and in environments which have a low pH or reduced water activity
15. E. coli O157 infection can be asymptomatic or can result in symptoms ranging from abdominal pain, mild diarrhoea and bloody diarrhoea (haemorrhagic colitis) to serious conditions including haemolytic uraemic syndrome (HUS). HUS can lead to renal failure, which may be fatal or be associated with long-term complications such as kidney disease, hypertension and neurological disorders. Young children, the elderly and immunocompromised individuals are particularly at risk, and there is no specific treatment for the illness. In a small number of cases VTEC infection may also develop into thrombotic thrombocytopenic purpura (TTP) in adults. TTP is a rare blood condition that causes small clots to form within the circulation. This results in a low platelet count, renal failure and severe neurological complications.

The low infective dose, the severity of the illness, and the lack of effective treatment means that every consumer needs to be protected from the risk of an isolated instance of low-level contamination of food with E. coli O157

This will require food businesses to implement the highest standard of controls to prevent cross-contamination

SOURCES OF E. COLI O157 CONTAMINATION IN FOOD BUSINESSES

16. E. coli O157 is a faecal pathogen and people can become infected through exposure to animal faecal matter via environmental routes. Potential routes include direct contact with ruminant farm animals or livestock, soil and/or manure through farming or recreational activities and exposure to contaminated private water, recreational water or irrigation supplies. As ruminant animals are the key reservoirs for E. coli O157, the raw meat and raw milk from these animals are also potential sources of this organism.
17. Contaminated food is an important vehicle for E. coli O157 infection. The key sources of E. coli O157 within a food production environment are provided below. FBOs concerned with the handling or production of ready-to-eat foods should, at all times, take full account of these risk factors when developing their HACCP-based food safety management systems in order to protect consumers from E. coli O157.

a) Meat

E. coli O157 occurs naturally in the digestive tract of healthy animals and can also be found on the animal's hide, fleece, feathers and skin. The bacteria are shed from the animal in their faecal matter and can contaminate the surfaces of raw meat during slaughter, dressing and packaging. While the pathogen is most commonly associated with red meat from ruminant animals (cattle, sheep and goats), it has also been isolated from pork and chicken. The mincing of meat can spread surface contamination throughout the product and provides an opportunity for the growth of bacteria.

b) Fresh produce

Vegetables and fruits that have been supplied to food businesses as ready-to-eat, should already have been subjected to validated procedures to ensure bacterial load is reduced to levels that do not present a risk to health. The FSA recommends that bagged ready-to-eat fresh produce does not need to be rewashed. In environments where potential sources of E. coli O157 are being handled, the rewashing of products supplied as ready-to-eat could introduce an additional cross-contamination risk.

Leafy and root vegetables that have not been supplied as ready-to-eat will not have been subject to controlled washing procedures and should be classed as a potential hazard in terms of cross-contamination of E. coli O157, particularly if soil or manure is visible.

c) Raw milk

Raw, unpasteurised milk, as well as products made from unpasteurised milk have been implicated in E. coli O157 infection. Therefore, raw milk and raw milk products supplied to a food business should always be treated as a potential source of contamination unless supplied as ready-to-eat. Cheese manufactured from unpasteurised milk and supplied as a ready-to-eat product should be treated accordingly. The processing of raw milk in the manufacture of ready-to-eat foods is beyond the scope of this guidance.

d) Water supplies

Water is an important potential source of microbiological hazards because harmful bacteria may survive in water for months. Water supplied to food businesses, including private supplies, must meet potable water standards.

E. COLI O157 CROSS-CONTAMINATION RISKS IN FOOD BUSINESSES

18. E. coli O157 is not detectable in contaminated foods by the naked eye and does not cause noticeable food spoilage. When establishing controls to prevent cross-contamination between raw foods and ready-to-eat foods it is important to take into account that E. coli O157 is capable of surviving during refrigeration and freezing, and in foods that have a low pH or reduced water activity.
19. Contamination can be spread from one surface, food product or waste product to another, either by direct contact with raw food or indirect contact with contaminated hands, clothing, equipment, or inanimate objects. This spread can only be prevented by adhering to strict food safety management procedures in all areas involving the storing and handling of foods including surfaces, equipment, and the personal hygiene of staff.
20. The following scenarios illustrate some of the potential routes for cross-contamination:

a) Use of contaminated ingredients in foods that are ready-to-eat

FBOs that handle the types of foods listed in paragraph 17 must make themselves aware of the potential risks that they carry and ensure that HACCP-based food safety management procedures are designed to control cross-contamination risks from these foods. The list of key food sources provided in paragraph 17 is not exhaustive and FBOs should maintain an awareness of any new or emerging risks in relation to E. coli O157 in foods through trade bodies or other established sources of advice and guidance relevant to particular industry sectors.

b) Direct contact between raw foods and ready-to-eat foods

Incorrect storage or handling of potentially contaminated raw foods may result in transfer of E. coli O157 by direct contact with the raw food and ready-to-eat food items. Direct contact between foods can occur in a fridge, freezer or on a surface. There is a risk of E. coli O157 contamination if raw and ready-to-eat foods are not adequately separated, wrapped or stored in the correct place. For example, if raw meat is stored above ready-to-eat food in a fridge there is a risk of juice dripping from the raw meat onto food below.

c) Indirect contamination via food contact surfaces (including packaging materials) that come into contact with raw foods and subsequently come into contact with ready-to-eat foods.

E. coli O157 can remain on surfaces following direct contact with contaminated raw foods. Where temperature and environmental

conditions are favourable, E. coli O157 is capable of surviving on a range of surfaces including wood, stainless steel and plastics. The presence of food debris or residues will provide a protective medium for E. coli O157 on surfaces, encouraging it to persist and grow.

Storage of packaging material is often overlooked and if located in areas subject to splashing of blood from raw meat it can present a vehicle for cross-contamination. This applies to all types of packaging such as cling-film, aluminium foil, plastic bags, greaseproof paper, cardboard boxes, vacuum pack bags etc. In addition, outer packaging such as crates, or cardboard boxes, used to transport raw foods may carry a risk of contamination and should be removed before foods are brought into a clean environment where ready-to-eat foods are to be handled.

d) Dual use of equipment and machinery for slicing, mincing or vacuum packing of raw and ready-to-eat foods

There is a major risk of cross-contamination where the same item of equipment, such as vacuum packers, slicing machines and mincers, are used to process raw food and ready-to-eat food. E. coli O157 may contaminate the surfaces of such equipment after use with raw foods. This contamination may not be adequately removed during the cleaning and disinfection process and this can result in any ready-to-eat foods, subsequently processed with the equipment, becoming contaminated.

e) Water spray/aerosols

Water spray resulting from the washing of contaminated food, equipment and hands or the use of running water from a contaminated supply could present a contamination risk for uncovered ready-to-eat foods.

f) Use of contaminated cleaning materials

Cleaning equipment, cloths and chemicals are all potential vehicles for the spread of E. coli O157. The frequency at which cleaning solutions are changed forms a critical part of cross-contamination control. It is also important to ensure that equipment such as mops, brushes, sponges and buckets do not present a cross-contamination risk.

g) Poor personal hygiene practices

Objects that are touched by food handlers, such as money, pens, light switches, door handles, telephones and cash registers may act as vehicles for the spread of E. coli O157 through hand contact with contaminated surfaces.

h) Contamination through clothing, aprons and gloves

Cross-contamination can occur if food handlers handle both raw foods and ready-to-eat foods without adequate washing of hands and/or changing of clothes/aprons/gloves in between.

i) Contamination of foodstuffs by infected individuals

Food handlers infected by E. coli O157 will be a source of the bacteria and can contaminate the food or surfaces the food may come into contact with. No one suffering from or carrying an infection that could be transmitted through food should be allowed to handle food or enter the food-handling area if there is a risk of contaminating food. Staff handling food or working in a food handling area must report an infection or symptoms to management immediately². Further guidance is set out in the Agency's publication Food Handlers: Fitness to Work³.

E. coli O157 is not easily eliminated once contamination has occurred.

It grows well at room temperatures, and is capable of surviving refrigeration and freezing. Effective controls are essential during all stages of food preparation and handling, including during frozen storage and cleaning procedures.

² Annex II, chapter VIII para 2 of Regulation (EC) No 852/2004

³ Food Handlers: Fitness to Work – A Practical Guide for Food Business Operators, <http://www.food.gov.uk/foodindustry/guidancenotes/hygguid/foodhandlersguide>

CONTROLLING THE RISK OF E. COLI O157 CROSS-CONTAMINATION

21. The designation of physically separate surfaces and equipment for raw and ready-to-eat foods is the only reliable means of adequately controlling E. coli O157 cross-contamination. In particular, the dual use of complex equipment, such as vacuum packing machines, for both raw and ready-to-eat foods cannot be implemented safely, even when cleaning and disinfection is applied in accordance with best practice.
22. In certain areas where complete separation is not physically possible, and alternative procedural controls are capable of reducing cross-contamination risks (see paragraphs 30-32), the highest standards of supervision and control are required to ensure that cleaning and disinfection procedures are carried out without fail and in all cases to appropriately high standards.
23. The law requires all food business operators to put in place food safety management procedures based on the principles of HACCP. In order to produce safe food, there must be effective procedures in place at every stage to manage cross-contamination hazards from E. coli O157 and other pathogens.
24. This section of the guidance covers in more detail issues to be considered to control the risk of cross-contamination.

Physical separation

25. The only reliable way to control cross-contamination with E. coli O157 between raw foods and ready-to-eat foods is by implementing physical separation.
26. In some food establishments, complete physical separation of raw and ready-to-eat food during handling and storage will be possible and achievable by the provision of separate working areas/rooms, storage facilities and staff that are physically separated at all times.
27. In food establishments where the above conditions are not achievable, the key to controlling cross-contamination will lie in maintaining designated clean areas for the handling and storage of ready-to-eat foods. A designated clean area is an area within a food establishment that is specifically managed to ensure that harmful bacteria, including E. coli O157, have been effectively excluded from all surfaces (including hands) that will come into contact with ready-to-eat foods. All surfaces, hands, clothing etc in a designated clean area must remain free from any source of contamination so that food handlers can ensure there is no risk of E. coli O157 contamination being spread within the designated clean area. As soon as the critical control represented by a designated clean area is breached, there will be potential for contamination to spread from

successive contacts between clean and contaminated surfaces. A clean area that has been compromised by possible E. coli O157 contamination presents an imminent risk. In these circumstances, operations must cease until all surfaces, equipment etc in the area have been decontaminated or replaced to ensure the risk of cross-contamination has been removed.

28. The following list describes situations when physical separation is always required:
- a) Separation in storage and display accommodation, including refrigerators and freezers, should always be sufficient to ensure that the designated clean areas for ready-to-eat foods are fully protected from the risk of E. coli O157 contamination. Where separate units are not provided, the clean storage areas should be clearly identifiable and sufficiently separated to ensure that the hands and clothing of staff are not exposed to contamination when loading or unloading ready-to-eat foods.
 - b) Under no circumstances should it be considered safe to use the same complex equipment, such as vacuum packing machines, slicers, mincers, etc, for both raw and ready-to-eat foods. Where, for example vacuum packing of ready-to-eat foods is carried out, the vacuum packing machine for this purpose should be located in a designated clean area where there is no risk from cross-contamination via splashes, hands, clothing, packaging or other equipment and should never be used for packing raw foods.

<p>Dual use of complex equipment for raw and ready-to-eat foods should NEVER be regarded as a safe practice</p>
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- c) Separate chopping boards and utensils must be used for raw and ready-to-eat foods unless all such equipment is cleaned and disinfected by heat in a commercial dishwasher meeting the standard set out in paragraph 49, and there is a system in place to ensure that disinfected equipment is not subject to recontamination from raw foods.
- d) Wrapping and packaging materials for ready-to-eat foods should be stored in a designated clean area designed to protect it from cross-contamination and accessible by staff in a way that ensures their clothing and hands are not contaminated when loading or removing materials. Food business operators must ensure that the outside surfaces of any wrapping materials to be used for ready-to-eat food brought into a clean area are free from contamination. It may be possible to establish an assured standard of cleanliness through contractual arrangements with the supplier. In the absence of

commercial guarantees, unpacking of ready-to-eat food should be undertaken in such a way that food is removed safely, without the risk of contaminating a clean area via food packaging.

Best practice:

Food business operators may consider decontaminating the outer surfaces of wrapping as an additional precaution for controlling cross-contamination risks

- e) Cash registers and similar non-food equipment should never present a cross-contamination risk and therefore should not be shared by staff handling ready-to-eat foods or working in clean areas and staff working in other areas. A single cash register can be used if appropriate measures are taken to prevent the spread of bacteria. If the cash register is kept in the clean area, care must be taken to ensure it is not contaminated by staff coming from areas outside the clean area. Similarly if the cash register is kept outside the clean area, staff from the clean area must ensure their hands and clothing are clean after using the cash register.
 - f) Separate cleaning materials including cloths, sponges and mops should be provided, and materials for use in clean areas should be stored in designated clean areas accessible by staff in a way that ensures that their clothing and hands are not contaminated when storing or removing materials
29. Physical separation of the above should be achievable by all businesses involved in the handling of raw and ready-to-eat foods. A commercially desired throughput for an establishment should not constitute a physical limitation that prevents separation. In such cases operations should be scaled-down to a level in the establishment that permits physical separation.
30. It is recognised that in some establishments, there will be particular areas where it is not possible to achieve physical separation, but where it is possible to reduce the risk of cross-contamination through the implementation of alternative procedural controls such as cleaning and disinfection. These areas should be limited to non-food contact surfaces, sinks and staff who handle raw and ready-to-eat foods at different times and FBOs should ensure that their alternative procedural controls are effective in controlling cross-contamination, and are implemented to a consistently high standard:

- a) Non-food contact surfaces such as worktops and walls, which may be subject to splashes from food, provided that all such surfaces are smooth, impervious and easily cleanable and are subject to strict application of cleaning and disinfection procedures, that are effective in removing E. coli O157, before there is any handling of ready-to-eat food in the area concerned.
 - b) The sharing of sinks for disinfection of equipment used for raw and ready-to-eat food, where the sinks and associated fittings and contact surfaces (e.g. taps) are themselves washed and disinfected between use. The flow of cleaning and disinfection should also ensure that utensils etc leaving the disinfection process enter a clean area fully protected against any source of recontamination. When the area is used to clean equipment intended for use in a clean area, staff hands and clothing should be clean at the start of the operation.
 - c) The use of the same staff for handling raw and ready-to-eat foods at different times. In such cases, any movement of staff from an area where raw food is handled into a clean area where ready-to-eat foods can be handled should be kept to an absolute minimum and will only be acceptable if procedures are put in place to monitor and manage strict adherence to documented handwashing procedures and appropriate use of clothing and aprons.
31. Food businesses should be aware that anything less than physical separation will involve a shift towards greater uncertainty regarding the stringency of risk reduction that can be achieved. Therefore, any use of alternative procedural controls in the circumstances listed in a. to c. above must be individually assessed. In particular, it is vital that full consideration is given to the monitoring and management arrangements required to ensure proper implementation of these procedures.
32. The use of alternative procedural controls should not continue if they are not fully and rigorously implemented at all times. If procedural failure is detected, the safety of handling both raw and ready-to-eat foods at the establishment should be reassessed.

Cleaning, disinfection, personal hygiene and handling practices

33. FBOs must ensure that cleaning and disinfection procedures are in place that will ensure effective removal of *E. coli* O157 and other pathogens from all surfaces and equipment involved in food preparation. FBOs must also ensure that personal hygiene and handwashing procedures are implemented to the highest standards to prevent cross-contamination, that staff are trained on these and that all procedures are regularly monitored to ensure they are consistently maintained. It is critical that all procedures are strictly adhered to on every occasion prior to contact with ready-to-eat foods. Management of these procedures is particularly important in situations where it is not possible to achieve complete physical separation. These issues are considered in more detail in the paragraphs below.

Cleaning and disinfection

34. Understanding the processes required to effectively decontaminate surfaces is essential in minimising the cross-contamination risks associated with *E. coli* O157 and other pathogens. This can be carried out using chemical or non-chemical disinfection methods.

Chemical disinfection

35. There are a number of different types of cleaning products on the market and confusion between these types of product and about how they must be used can lead to poor disinfection procedures that allow harmful bacteria to remain on surfaces and equipment. It is important that staff understand what these chemicals do and that the correct products, purchased from reputable suppliers, are always used in accordance with the manufacturer's instructions.
36. As a general guide:
- **Detergents** are products used for general cleaning. These do not have disinfectant properties and, if used on their own, are not capable of destroying harmful bacteria such as *E. coli* O157.
 - **Disinfectants** are products that are capable of destroying harmful bacteria when applied to visibly clean surfaces at a specified dilution and contact time.
 - **Sanitisers** are products that combine a disinfectant and a detergent in a single product. This means that the same product can be used to provide a visibly clean surface and it must be used a second time in order to disinfect the surface.
37. Effective cleaning must use a combination of physical cleaning, using a detergent, followed by a disinfectant used at the correct temperature, contact time and dilution.

38. Chemical disinfection should be carried out using a two-stage process:

Stage 1: General cleaning using a detergent

General cleaning involves the physical removal of visible dirt, food particles and debris from surfaces and equipment that come into contact with food along with the removal of waste from areas where food processing occurs. The detergents selected for use in each situation must be capable of removing all food debris, solids and grease. General cleaning should always be completed by rinsing to ensure thorough removal of all residues from the surface prior to stage 2.

Stage 2: Disinfection

Disinfectants that have been proven capable of destroying disease-causing bacteria should be applied after general cleaning to reduce microbial contamination to an acceptable level. Disinfection can only be successfully carried out on surfaces that have been thoroughly cleaned to remove grease and other dirt, as the effectiveness of disinfection is reduced in the presence of food matter.

39. Different types of disinfectants require different dilutions and contact times. These are specified and validated by the manufacturer and the FBO must follow the manufacturer's instructions for dilution and contact time to ensure the product is effective. Disinfection should be followed by a final rinse of the surface or equipment with potable water to remove any remaining chemical, unless it is formulated for use without a final rinse.

Disinfection will only be effective when carried out on a visibly clean surface that is free from grease, film or solid matter.

For a disinfectant to be effective in destroying bacteria, the correct dilution and contact time must be followed according to the manufacturer's instructions.

Standards for disinfectants

40. There are two officially recognised laboratory standards for assessing the effectiveness of disinfectants against a range of microorganisms, these are:
- BS EN 1276:1997
 - BS EN 13697:2001

41. These standards demonstrate that a disinfectant is capable of reducing the levels of a range of bacteria, including E. coli under a set of specified conditions (e.g. at a particular temperature, dilution and contact time).
42. In order to ensure the adequate decontamination of surfaces, FBOs should ensure that they are using the appropriate disinfectant products by confirming with their suppliers that the products they are using meet, as a minimum, the specifications of these standards. This information may also be obtained from the label of the product, or by contacting the manufacturer directly.
43. It is essential that staff carrying out critical disinfection procedures fully understand instructions they are given for the storage and use of disinfectants and, where necessary, are provided with measuring containers or appropriately marked levels on the vessels used for making up dilutions. Food safety management procedures should not be considered capable of producing safe food where staff responsible for critical disinfection procedures cannot demonstrate how the dilutions are achieved to meet the business' work instructions. In addition, the design of work instructions must be capable of verifying that these will fulfil manufacturers' instructions.

Use of sanitisers

44. Sanitisers combine both cleaning and disinfection properties in a single product, usually as a spray. However, when used in a single stage process these products are only suitable as an interim 'clean-as-you-go' measure and never as a disinfection control for cross-contamination. Single stage use of a sanitiser is not sufficient to ensure thorough and effective disinfection to microbiologically safe standards in relation to controlling E. coli O157 cross-contamination.
45. Many FBOs prefer to purchase a single sanitising product rather than a separate detergent and disinfectant. In these cases a single sanitising product that meets the requirements of the BS EN 1276:1997 or the BS EN 13697:2001 can only be used to achieve the separate general cleaning and disinfection outcomes set out above, where the sanitiser is used in both stages of the cleaning and disinfection processes i.e. in general cleaning to provide a clean surface and then again to disinfect the surface.
46. As with disinfectants, the FBO must follow the manufacturer's instructions for dilution and contact time to ensure the sanitiser is effective.
47. Single use of a sanitiser is not sufficiently effective to ensure thorough disinfection to microbiologically safe standards. If a sanitiser is employed it must be used in both stages of the cleaning and disinfection process, i.e. in general cleaning to provide a clean surface and then again to disinfect the surface.

48. **Additional disinfection considerations for equipment and machinery, including vacuum packing machines:** The cleaning procedures described above are suitable for smooth impervious surfaces in good condition that can be fully inspected to ensure that they are visibly clean before they are disinfected. Although dual use of a complex machine for raw and ready-to-eat foods should never be considered safe, all food equipment should nevertheless be hygienically designed. Machinery supplied for use at work from 1995 should be CE marked to indicate that it was designed to comply with the European Machinery Directive⁴, which includes requirements for hygienic design. Detailed guidance on hygienic design requirements of the Machinery Directive can be found in BS EN 1672-2:2005+A1:2009 Food Processing Machinery Basic Concepts Part 2: Hygiene Requirements, BSI⁵.

⁴ Directive 2006/42/EC, and all previous versions

⁵ Additional requirements for some particular types of food machinery and packaging machinery are set out in more specific standards. Lists of type-specific standards for machinery can be found at:

<http://www.hse.gov.uk/food/standards.htm> for food machinery
<http://www.hse.gov.uk/food/cen.htm> for packaging machinery

Non-chemical disinfection – hot water and steam disinfection

49. The application of heat (thermal disinfection) is one of the most reliable ways of killing bacteria such as E. coli O157, but is not always practical, particularly in small food businesses. Where heat disinfection is being used, food businesses should ensure that the temperature and contact time is sufficient to destroy harmful bacteria. For instance, in certain non-retail establishments that require approval (such as meat cutting establishments), a water temperature of 82°C is legally required for the disinfection of tools⁶. Steam cleaning can be effective for disinfecting the surfaces of certain types of machinery and equipment.
50. **Decontamination of utensils and small equipment:** Properly maintained commercial grade dishwashers in which water reservoirs are maintained at a temperature of more than 80°C providing contact times of at least 15 seconds offer adequate disinfection control. The manufacturer's cleaning and maintenance instructions must be followed and instructions typically include the removal of food debris, plastic wrapping and limescale from the water jets, filters and drains, as well as carrying out regular cleaning.
51. **Decontamination of cloths and mops used for cleaning:** Cleaning materials that were previously used for surfaces, equipment or utensils designated for preparation of raw foods should not subsequently be used for the cleaning of surfaces, equipment or utensils that are used for ready-to-eat foods, or in any designated clean area. Separate cloths must be designated for use only in clean environments (i.e. for cleaning surfaces and equipment used with ready-to-eat foods). In situations where cloths etc are to be re-used in clean areas, the laundering process should be regarded as critical to food safety. Laundering should be carried out at a suitably high temperature. A wash cycle that achieves 82°C or higher, can be considered acceptable. This may be achieved through a standard hot cycle, which typically operates at 90°C. Procedures, including contractual arrangements, must ensure that cycles employed for the washing of cleaning cloths are not changed to lower temperatures as a result of energy efficiency reviews.

⁶ Annex III, Section I, chapter II para 3 of Regulation (EC) No 853/2004

52. The use of disposable, single-use cloths provides a reliable way of ensuring cleaning and disinfection regimes do not present a cross-contamination risk.
53. In order to prevent the re-contamination of cleaning materials, it is imperative that all disinfectants are freshly prepared according to manufacturer's instructions prior to the disinfection of areas used to prepare ready-to-eat foods.

Personal hygiene and handling practices

Effective handwashing practice

54. All staff who work with food must be trained in effective handwashing procedures and ensure that they always wash their hands thoroughly.
55. Effective handwashing is always required prior to handling ready-to-eat foods in order to control cross-contamination. It must also occur after:
- going to the toilet
 - handling any food that may be a potential source of E. coli O157
 - hand contact with shared cash registers, door handles, light switches, aprons or other surfaces that could come into contact with staff handling raw foods
 - handling food and cleaning waste
 - eating
 - cleaning
56. Handwashing should form part of all food handlers working routine and FBOs should ensure all staff are trained in effective handwashing techniques. There must be an adequate supply of handwashing basins with hot water, soap and drying facilities available. Single-use towels or air driers are recommended for drying hands hygienically.

Effective handwashing takes time and requires effective technique

57. Effective handwashing must follow an appropriate technique. Handwashing techniques using soap and water, published by the Department of Health, the NHS, Health Protection Scotland, the Welsh Assembly Government or 'the Department of Health, Social Services and Public Safety Northern Ireland' in relation to infection control for health care workers should be sufficient. Although there may be slight variations, these techniques all include the following stages:
1. Wetting of hands prior to applying soap
 2. A prescribed technique for hand rubbing, aimed at physically removing contamination from all parts of the hands
 3. Rinsing
 4. Hygienic drying

Best Practice:

For extra protection against cross-contamination it is recommended that a liquid hand wash that has disinfectant properties conforming to the European standards BS EN 1499:1997 is used. This information should be available on the label of the product, or may be obtained from the supplier or manufacturer.

58. Hands should not come into contact with taps after they have been washed. Clean single-use towels can be used to prevent contact with taps when turning them off, if taps are designed to be hand operable.

Best Practice:

Use of non-hand operable taps at handwashing facilities is recommended.

59. If, after washing, there is any remaining visible dirt on the skin it should be considered that the method has not been effectively applied and the process should be repeated.
60. It should be noted that hygienic hand rubs do not necessarily remove visible dirt and should never be used as a replacement for handwashing.

Best Practice:

HYGIENIC HAND RUBS

These products can provide an additional level of protection and are recommended following handwashing where there is an increased risk of cross-contamination e.g. when raw foods have been handled prior to handwashing.

Where hygienic hand rubs are being used, FBOs should ensure the products conform to standard BS EN 1500. Again, this information should be available on the label of the product, or may be obtained from the supplier or manufacturer.

Effective handwashing is essential to ensure adequate personal hygiene in all food operations.

Use of gloves and tongs for food handling

61. It is good practice to minimise hand contact with foods, particularly ready-to-eat foods, and many FBOs use gloves, tongs and other utensils to minimise direct hand contact.
62. Hands should always be washed thoroughly before putting gloves on and after taking them off. Gloves should be disposable and should always be changed between the handling of raw and ready-to-eat foods. Gloves should also be changed before handling ready-to-eat food if they have come into contact with any surfaces or objects not designated as clean (e.g. money), and also at every break and when gloves become damaged.
63. The use of separate packs of disposable gloves for different activities will assist with cross-contamination controls, providing care is taken to ensure that gloves are not contaminated by hands when they are being put on. Contaminated gloves must never enter a clean area used for handling or storage of ready-to-eat foods. Before entering a clean area, handwashing must take place before putting on clean gloves.
64. Tongs or other utensils can protect food from contamination but it is essential that equipment used to handle raw food is kept separate from that used for ready-to-eat food. Hand hygiene is also relevant where tongs are used in order to prevent the spread of contamination on handles.

Clothing and aprons

65. Cross-contamination can occur if food handlers handle both raw foods and ready-to-eat foods without adequate changing of clothes and aprons in between. Any contaminated outer clothing worn in a raw food preparation environment (e.g. aprons and overalls) should be changed before handling ready-to-eat foods or entering a clean area. Handwashing should take place after any change out of contaminated clothing and before putting on clean clothing. FBOs may consider using disposable aprons for different activities.

MANAGEMENT CONTROLS FOR E. COLI O157 CROSS-CONTAMINATION IN FOOD BUSINESSES

66. Effective food safety management controls are critical to controlling E. coli O157 cross-contamination hazards.
67. Food hygiene legislation requires food business operators to implement and monitor HACCP-based food safety management procedures⁷. It is not the intention of this guidance to explain those requirements in full, however, a number of the requirements are dealt with more fully in the following paragraphs.
68. FBOs should always ensure that technical controls are appropriately validated, that they are subject to ongoing monitoring, and their effectiveness verified through a system of own checks. Documented procedures should be up to date and cover all aspects of cross-contamination control.

Documented procedures and record keeping

69. Robust documented procedures are essential in ensuring that measures for controlling E. coli O157 cross-contamination hazards are being adhered to, and flexibilities available in some low risk situations should not apply to food control measures that fall within the scope of this guidance. Documented procedures are an essential record of the controls that must take place in an establishment to prevent cross-contamination and they will assist in training staff. Record keeping is essential in ensuring procedures for controlling E. coli O157 cross-contamination hazards are being adhered to.
70. Separation of areas, equipment and staff for handling ready-to-eat food should simplify procedures for control of cross-contamination. Readily identifiable utensils, cleaning equipments, protective clothing etc for use only in designated clean areas should simplify the monitoring of procedures. Use of a specific colour to identify such equipment and materials is commonly used in food businesses for this purpose. The level of monitoring and supervision must be sufficient to ensure complete adherence to critical safety controls.
71. Documented procedures should be based on sound evidence that the procedures are capable of controlling cross-contamination. This guidance document can be used to assist in determining types of control that should be effective if properly implemented. However, following the guidance will still require FBOs to ensure that disinfectants or sanitisers meet the specification recommended in this guidance and that machinery has been

⁷ Article 5 of Regulation (EC) No 852/2004

hygienically designed for its intended purpose and is being maintained, cleaned and disinfected according to manufacturers' instructions.

72. Procedures should be up to date and cover all aspects of cross-contamination control such as:
- methods of separation (e.g. designation of separate clean environments, identification of separate equipment)
 - cleaning procedures for surfaces and utensils, including dishwasher and washing machine temperatures, they should clearly detail the type of disinfection to be used along with the method of cleaning
 - details on the preparation and use of disinfectants and sanitisers
 - personal hygiene (e.g. handwashing requirements and use of protective clothing)
 - training and supervision of staff
 - arrangements for monitoring, verification checks, record keeping and corrective action

This list is not exhaustive and the nature of documentation will vary depending on the type of food operation. All records should be routinely checked and signed off by a competent member of staff.

Training and supervision

73. Food hygiene legislation requires that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity. Training of applicable staff in the specific procedures required to control cross-contamination involving *E. coli* O157 will be crucial to effective cross-contamination control.
74. Effective handwashing technique, set out in this guidance is critical to cross-contamination prevention. Staff must know when handwashing is essential and how to do it properly. It is therefore critical that all relevant staff are trained and verified as competent in handwashing technique before being deployed to work unsupervised in any safety-critical areas.
75. Similarly, the disinfection techniques set out in this guidance will require training of all staff that carry out safety-critical cleaning and disinfection. In particular, it is essential that staff are trained and verified as competent before being deployed to dilute and apply disinfectants, or to undertake hot water or steam disinfection.
76. Supervision of staff is required, as necessary, to ensure food is being safely prepared, where the food business operator cannot rely fully on training. This might be the case where staff are new to a particular duty.

77. Staff responsible for the development or maintenance of the HACCP-based food safety management procedures should have adequate training in the application of HACCP principles.

Verification and review

78. Food hygiene legislation requires food business operators to carry out verification checks to demonstrate that the documented procedures are working reliably. These checks are required in addition to routine monitoring and should be carried out whenever new or amended procedures are put in place. Particular attention should be paid to verification following maintenance work. Verification checks should also be carried out periodically at frequencies sufficient to show that all procedures are operating effectively.
79. FBOs should ensure that the measures applied to control cross-contamination are effective under all conditions of their business, and should not assume that the same procedures will be workable in all situations. The effectiveness of controls should be verified at each critical stage of the operation, during both quiet and busy periods, and particularly so when a new procedure is brought into service.
80. Environmental sampling can assist in verifying that procedures are being properly implemented. However, it is essential that the procedures themselves are demonstrated to be scientifically valid before they are employed as a critical cross-contamination control.
81. Any verification check that establishes loss of control should be considered seriously as a cross-contamination risk and acted on accordingly. 34
82. FBOs are required to review the procedures and make any necessary changes when there is any significant change to the operation of the premises or processes.

It is essential that FBOs can demonstrate procedures to implement valid technical controls described in this document and are able to provide evidence that these are being applied consistently in all relevant parts of the business.

Corrective action

83. The failure to follow any procedure essential to the control of E. coli O157 must always be regarded as a potentially serious incident.
84. Corrective action is always required following any failure in management control, or where a breakdown has been identified in procedures to prevent cross-contamination with E. coli O157.
85. In all cases where a critical cross-contamination control has been lost, the affected food preparation procedures should be stopped until control is re-established. In addition, the following actions must be taken:

a) Quarantine or disposal of affected product

All products potentially affected by a loss of control must be identified and placed under a system of control that will prevent its intended use as, or in, a ready-to-eat food. Action may range from placing the potentially contaminated food in adequately separated storage, with clear identification of its status (prior to reworking), to simply disposing of the potentially affected food.

b) Rework of affected product

In certain circumstances, and where it is practical to do so, it may be possible to subject the ready-to-eat food to further processing (e.g. heat treatment) that will eliminate E. coli O157. In such cases the affected product should be handled, stored and treated as a raw ingredient.

c) Product withdrawal and recall of affected product

Where a product does not meet food safety requirements, an FBO is required by law to organise withdrawal of the product through the supply chain and to notify the appropriate local authority as well as the Food Standards Agency. Where any such product has been sold to consumers, the FBO must also ensure that appropriate information is disseminated to consumers to allow any remaining product to be recalled.

d) Re validation of procedures

Where a technical control has not been properly applied according to the operator's food safety management procedures, the FBO must reconsider the validity of the procedure. Where the FBO is unable to provide assurances that a particular fault will not occur in future, the current procedures cannot be considered to be valid and alternatives, including greater use of physical separation, must be considered.

Where there is a loss or a lack of critical cross-contamination control the operations affected should be stopped immediately until control is re-established.

FBOs should also consider whether quarantine, rework, disposal, withdrawal or recall of affected product is required to make sure potentially contaminated food is not supplied to consumers.

ENFORCEMENT ACTION

86. The scope of this guidance does not include advice to food law enforcing authorities on appropriate sanctions in the case of non-compliance with statutory requirements. However, the role of an enforcing authority is relevant to the overall framework of controls that may be required to protect consumers where an FBO has not implemented adequate controls or appropriate corrective actions.
87. Where the criteria set out in paragraphs 85 relating to corrective action, are found to apply, an enforcing authority must satisfy itself that all appropriate corrective actions are being put in place by the FBO. If there is ever any doubt that an FBO intends to fully implement appropriate corrective actions, the enforcing authority should actively intervene to ensure that any unsafe product is disposed of and, where necessary, withdrawn or recalled.
88. Enforcing authorities should always consider the exposure of ready-to-eat foods to the risk of E. coli O157 contamination as potentially constituting an imminent risk to consumers. Hygiene Emergency Prohibition Notices must therefore be considered where such controls are inadequate.
89. Food hygiene regulations in force throughout the UK provide powers for enforcing authorities to take possession of food for the purposes of destruction if it has not been produced, processed or distributed in accordance with statutory hygiene requirements.⁸

In circumstances where it is identified that critical cross-contamination controls are inadequate, enforcing authorities must intervene and take all appropriate action to protect public health where corrective actions have not been properly implemented by the FBO.

Enforcing authorities must always consider the use of Hygiene Emergency Prohibition Notices where inadequate control presents a risk of direct or indirect contamination of ready-to-eat foods by E. coli O157.

Enforcing authorities should take possession of food intended for use as a ready-to-eat product for the purposes of destruction if it has not been produced, processed or distributed in accordance with statutory hygiene requirements and it has been exposed to the risk of E. coli O157 contamination.

⁸ Food Hygiene (England) Regulations 2006 S.I. 2006/14 as amended
Food Hygiene (Scotland) Regulations 2006 S.S.I. 2006/3 as amended
Food Hygiene (Wales) Regulations 2006 S.I. 2006/31 (W.5) as amended
Food Hygiene Regulations (Northern Ireland) 2006 No. 3 as amended

ANNEXE 1: LEGAL REQUIREMENTS RELEVANT TO CONTROL OF CROSS-CONTAMINATION

Article 5 of Regulation (EC) No 853/2004 requires all food businesses (other than primary producers) to put in place, implement and maintain permanent procedures based on the HACCP principles set out in the table below. This table indicates the way in which this guidance links to the requirements of Article 5 that relate to cross-contamination and E. coli O157:

Article 5	Relevance to E. coli O157 cross-contamination.
(a) identifying any hazards that must be prevented, eliminated or reduced to acceptable levels	This guidance is concerned with controls necessary when E. coli O157 is identified as a hazard that would present a risk to ready-to-eat foods without stringent precautions. Paragraphs 16 and 17 set out types of raw food where E. coli O157 should be assumed to be present but this does not lessen the obligation on food business operators to consider any other sources of E. coli O157 that could be present within an establishment.
(b) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels	This guidance stipulates that full control of cross-contamination will require separation of sources of contamination from any route by which ready-to-eat foods could be exposed to risk of contamination.
(c) establishing critical limits at critical control points that separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards	There is no acceptable critical limit for E. coli O157 contamination in ready-to-eat food due to its low infective dose and the serious and untreatable illness that it can produce. Separation as set out above, is required to reliably achieve acceptable control of cross-contamination.
(d) establishing and implementing effective monitoring procedures at	Monitoring procedures must be capable of ensuring that separation procedures

<p>critical control points</p>	<p>are rigorously implemented. Paragraphs 65 to 77 provide guidance on monitoring and supervision.</p> <p>In any circumstances where disinfection or handwashing is required as a prerequisite hygiene measure or as part of the control measures in an establishment, procedures must be monitored sufficiently to ensure that they are rigorously implemented and effective (see paragraphs 54-60). This must ensure that cleaning and disinfection and handwashing are applied at all junctures set out in the operator's procedures using the correct technique, appropriate dilutions and adequate contact times.</p>
<p>(e) establishing corrective actions when monitoring indicates that a critical control point is not under control</p>	<p>Failure to follow any procedure essential to the control of E. coli O157 must always be regarded as a potentially serious incident. Corrective action is always required following any failure in management control, or where a breakdown has been identified in procedures to prevent cross-contamination with E. coli O157. Paragraphs 82 to 84 in this document provide additional guidance on corrective action.</p> <p>In all cases where a critical cross-contamination control has been lost, the affected food preparation procedures should be stopped until control is re-established. In addition, corrective action must ensure that any products potentially at risk are not placed on the market.</p>
<p>(f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively; and (g) establishing documents and records commensurate</p>	<p>Verification includes initial validation of procedures that are intended to be used. This guidance provides a framework that accepts separation as a valid control measure. It also provides a framework within which food business</p>

<p>with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).</p> <p>When any modification is made in the product, process, or any step, food business operators shall review the procedure and make the necessary changes to it.</p>	<p>operators can develop valid procedures:</p> <ul style="list-style-type: none"> • for the selection and use of disinfectants by reference to European standards and manufacturers' instructions • for effective handwashing technique by reference to existing guidance for health care workers <p>However, the guidance should not be interpreted as accepting the use of disinfection or handwashing as a critical control where separation is physically possible.</p> <p>Paragraphs 77 to 81 in this document provide further advice on periodic checks to verify that the validated procedures are working effectively.</p>
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90. In addition to Article 5, there are certain specific provisions of Regulation (EC) No 852/2004 that are particularly relevant to the control of cross-contamination risks in food premises. The table below provides further guidance on these requirements:

<p>CHAPTER I</p> <p>General requirements for food premises</p>	<p>Relevance to E. coli O157 cross-contamination.</p>
<p>1. Food premises are to be kept clean and maintained in good repair and condition.</p> <p>2. The layout, design, construction, siting and size of food premises are to:</p> <p>(a) permit adequate maintenance, cleaning and/or disinfection, avoid or minimise airborne contamination, and provide adequate working space to allow for the hygienic performance of all operations</p> <p>(b) be such as to protect against the accumulation of dirt, contact with toxic</p>	<p>The size and design of premises must be sufficient to allow good practices in relation to contamination protection. Size of premises should therefore not prevent separation as a necessary practice to protect food against any type of cross-contamination, including protection from E. coli O157.</p>

<p>materials, the shedding of particles into food and the formation of condensation or undesirable mould on surfaces</p> <p>(c) permit good food hygiene practices, including protection against contamination and, in particular, pest control</p>	
<p>CHAPTER II</p> <p>Specific requirements in rooms where foodstuffs are prepared, treated or processed</p>	
<p>1. In rooms where food is prepared, treated or processed...the design and layout are to permit good food hygiene practices, including protection against contamination between and during operations.</p>	<p>The design and layout of food rooms must be sufficient to allow good practices in relation to contamination protection during all operations. The layout of food rooms should therefore not prevent separation as a necessary practice to protect food against any type of cross-contamination, including protection from E. coli O157.</p>
<p>CHAPTER VIII Personal hygiene</p>	
<p>1. Every person working in a food-handling area is to maintain a high degree of personal cleanliness and is to wear suitable, clean and, where necessary, protective clothing.</p>	<p>Personal hygiene requirements apply to every person working in a food handling area (not only to food handlers). The required standard for personal cleanliness is 'high' and must be a higher standard than merely adequate. This means that handwashing must be effective at removing E. coli O157.</p> <p>Any contaminated outer clothing worn in a raw food preparation environment (e.g. aprons and overalls) should be changed before handling ready-to-eat foods or entering a clean area.</p>
<p>Annex II, CHAPTER IX:</p> <p>Provisions applicable to foodstuffs</p>	
<p>2. Raw materials and all ingredients stored in a food business are to be kept</p>	<p>All ready-to-eat foods or ingredients must be protected at all times from E.</p>

<p>in appropriate conditions designed to prevent harmful deterioration and protect them from contamination.</p> <p>3. At all stages of production, processing and distribution, food is to be protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state.</p>	<p>coli O157 contamination by any possible route. Controls must ensure full protection of clean areas for ready-to-eat foods against any general spread of E. coli O157 contamination.</p>
<p>CHAPTER X Provisions applicable to the wrapping and packaging of foodstuffs.</p>	
<p>1. Material used for wrapping and packaging are not to be a source of contamination.</p> <p>2. Wrapping materials are to be stored in such a manner that they are not exposed to a risk of contamination.</p>	<p>Adequate separation is required to ensure that contaminated wrapping materials cannot lead to either direct contamination of food or indirect contamination of clean areas where contamination could subsequently contaminate food.</p>
<p>CHAPTER XII Training</p>	
<p>Food business operators are to ensure:</p> <p>1. That food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity</p>	<p>This guidance provides more detail on areas where training will be critical to ensure that the cleaning and disinfection of surfaces and the washing of hands is effective. The outcome of training, instruction and/or supervision must provide complete assurance that these procedures are carried out on every occasion required and strictly in accordance with the procedures established by the food business operator.</p>

91. Regulation (EC) No 178/2002 prohibits the sale of unsafe food and requires every food business operator to initiate a withdrawal of any food supplied by the business if he believes it is unsafe.