Guidance on Temperature Control Legislation in the United Kingdom

EC Regulation 852/2004

The Food Hygiene Regulations 2006 (as amended)

Food Standards Agency

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Contents

Introduction

1. This document gives guidance on the temperature control requirements found in the following hygiene legislation:

    - EC Regulation 852/2004[1]
    - The Food Hygiene Regulations 2006 (as amended)[2]

2. This guidance does not cover the specific temperature control requirements contained within EC Regulation 853/2004[3], EC Regulation 2073/2005[4] and any further product-specific requirements, such as poultrymeat marketing standards regulations. Further information can be found at paragraph 23. Separate guidance on these as well as other regulations and further information, including HACCP and National Guides to Good Practice for Hygiene and for the Application of HACCP Principles, is available from the Food Standards Agency website at

    www.food.gov.uk

3. It is intended that this guidance help explain, for both food business operators and enforcement authorities, the food temperature control requirements of the above legislation in the UK. This guidance contains advice on the types of foods that are required to be held under temperature control. It also gives guidance on the permitted flexibility within the temperature control requirements.

4. While it is intended to be helpful, this guidance does not provide an authoritative interpretation of the law and is no substitute for an understanding of the legal requirements. Any examples given are illustrative and not comprehensive.

5. This guidance is intended to complement best practices in the food industry, which might involve, for example, keeping foods at chill temperatures below the legal maximum and thereby providing additional assurances of food safety. Best practice will vary according to the product concerned.

6. The temperature control requirements should be understood in the general context of the food safety management procedures based on the principles of Hazard Analysis and Critical Control Points (HACCP) requirement contained in Article 5 of EC Regulation 852/2004.

7. Advice on the approach to enforcement of the temperature control requirements of food hygiene legislation is to be found in the Food Law Codes of Practice and

[1] Regulation (EC) No 852/2004 on the hygiene of foodstuffs
[2] Separate legislation applies across the four countries of the UK: The Food Hygiene (England) Regulations 2006 (SI 2006/14); The Food Hygiene (Scotland) Regulations 2006 (SSI 2006/3); The Food Hygiene (Wales) Regulations 2006 (SI 2006/31 (W.5)); and; The Food Hygiene Regulations (Northern Ireland) 2006 (SR 2006 No 3)
[3] Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin
[4] Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs

accompanying Practice Guidance issued to enforcement authorities by the Food Standards Agency.

8. Further guidance on compliance with temperature control legislation, as well as good practice can be found in recognised *National Guides to Good Practice for Hygiene and for the Application of HACCP Principles* as well as European Community Guide equivalents. These Guides are recognised by the Food Standards Agency and the European Commission respectively and have a special status under EU law[5] whereby enforcers are required to consider them when assessing compliance with hygiene legislation.

[5] Article 10(2)(d) of Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

Foods Subject to Temperature Control

9. This paragraph gives some examples of various food types that under normal conditions of storage and use and in the absence of adequate preserving factors should be kept under temperature control (both chill and hot holding) so as not to result in a risk to health. These examples are for general guidance only. There are certain exemptions from the national temperature control regulations, see paragraphs 32-34 for those that apply in England, Wales and Northern Ireland and paragraph 53 for those in Scotland.

a. Dairy products

i. Soft or semi-hard cheeses ripened by moulds and/or bacteria.

The important safety factors for cheese relate primarily to its acidity and water activity. Temperature controls do not apply during the ripening process. However, it is important that once cheese has ripened it is placed under chill holding. During the ripening process, acidity declines until a point is reached where growth of pathogens will no longer be inhibited.

ii. Dairy-based desserts (including milk substitutes), including fromage frais, mousses, creme caramels and products containing whipped cream.

Where the pH of these products (e.g. yoghurt with a pH below 4.5) would prevent the growth of pathogenic micro-organisms or the formation of toxins, or other effective preservative mechanisms (e.g. pasteurisation) are present, the food would not need to be subject to temperature control.

b. Cooked products

There will be a need for temperature control of foods comprising or containing cooked products such as meat, fish, eggs (or substitutes for meat, fish, or eggs), milk, soft cheese, cereals (including rice), pulses and vegetables (whether or not they are intended to be eaten without further re-heating).

The requirement will include ready-to-eat products such as sandwiches containing fillings, toppings, etc. prepared with these foods.

c. Smoked or cured fish which is not ambient shelf-stable

Whilst curing and smoking will inhibit the growth of organisms, the process in itself will not make the fish ambient stable. There is therefore a need for temperature control whether the fish is whole or sliced, in the absence of other preservative factors such as canning. In the case of untreated fish, which is not kept frozen or refrigerated, spoilage organisms (which are obviously detectable through appearance or smell) would likely render the

product unfit for consumption before it became unsafe so temperature control would not always be required for safety reasons.

d. Smoked or cured ready-to-eat meat which is not ambient shelf-stable

Examples may include *sliced* cured cooked meats such as hams, some salamis and other fermented sausages, depending on the method of curing. The method of curing, especially if it does not achieve a low water activity, may mean that foods could not be safely kept at ambient temperatures under defined conditions and within their shelf life.

e. Prepared ready-to-eat foods

Including *prepared* vegetables, or salads containing other products (such as coleslaw), vegetable salads containing fruit and prepared products such as mayonnaise once opened.

f. Uncooked or partly cooked pastry and dough products

Examples include products such as pizzas, sausage rolls, or fresh pasta. These products often contain pre-cooked meat, fish or vegetables (or substitutes for meat or fish) mixed or prepared with raw materials. The subsequent cooking process may be insufficient in some cases to ensure food safety, so temperature control will be necessary. Fresh pasta should normally be temperature controlled, whether or not it contains meat, fish or vegetables.

The General Requirement

10. EC Regulation 852/2004 contains a general requirement for temperature control, as set out in Annex II, Chapter IX, 5

> *Raw materials, ingredients, intermediate products and finished products likely to support the reproduction of pathogenic micro-organisms or the formation of toxins are not to be kept at temperatures that might result in a risk to health. The cold chain is not to be interrupted. However, limited periods outside temperature control are permitted, to accommodate the practicalities of handling during preparation, transport, storage, display and service of food, provided that it does not result in a risk to health...*

11. The general requirement applies to both chill and hot holding. Examples of the types of foods that the requirement applies to can be found in paragraph 9. Food business operators handling specific products of animal origin covered by EC Regulations 853/2004 (see paragraph 23) must also comply with this general requirement. Compliance with the temperature control requirements of EC Regulation 853/2004 may ensure compliance with this general requirement. Compliance with the product specific temperature requirements may require foods to be kept at a temperature below that specified in the national requirements and

may require temperature control of foods to which the general requirement does not apply (see paragraphs 24-26).

12. The temperature of a food may "result in a risk to health" where temperature control is critical to the safety of food. For example, chill holding will not be a requirement where perishable food has been subject to a process that makes is safe to hold at ambient temperatures, e.g. types of canning. Nor will it be a requirement where raw food will be cooked at a later stage to ensure it is fit for human consumption. An exception will be where it is necessary to comply with product specific hygiene regulations that set out specific temperatures at various stages of the food chain, e.g. for some raw meat.

13. It is an offence for a food business operator to contravene the general requirement (see paragraphs 10-16). In most circumstances, food business operators complying with the more specific national requirements (see paragraph 24-26) will also be complying with the general requirements. However, it is possible to breach the general requirement even where the food is kept within chill holding, but only when a maximum lower temperature is critical to food safety. In this case, it would be necessary for an enforcement authority to prove a risk to health for any food alleged to be in breach. This may be demonstrated, for example, by scientific evidence. Observance of temperature recommendations within any special storage conditions on food labels is not automatically mandatory where these relate to food quality rather than food safety. However, if the quality were to deteriorate, there may be an offence committed under Article 14(5) of EC Regulation 178/2002[6], which prohibits the sale of food unfit for human consumption.

14. When considering the permitted limited periods food may be held outside temperature control, it is necessary to take account of the specific national requirements for England, Wales and Northern Ireland that set out times and conditions for this, as described in paragraphs 42-49 and 57-59. No such periods are specified in the Scottish schedule.

15. The general requirement should be taken into account by food manufacturers when specifying storage temperatures and shelf lives for products to be kept at chilled temperatures. For longer shelf life foods, the practical difficulties of ensuring that the cold chain is not interrupted may mean that it is undesirable to rely on a recommended temperature as the *only* controlling factor for food safety.

16. Other food business operators storing products under temperature control should also consider the general requirement. There will be some foods where the general requirement might require them to be stored at temperatures lower than in the national requirements for safety reasons, taking account of the allocated shelf life.

[6] Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

Cooling of Food

17. EC Regulation 852/2004 contains a requirement for the cooling of foodstuffs. Annex II, Chapter IX, 6 states

    Where foodstuffs are to be held or served at chilled temperatures they are to be cooled as quickly as possible following the heat-processing stage, or final preparation stage if no heat process is applied, to a temperature, which does not result in a risk to health.

18. The cooling period for any food would not be regarded as unacceptable merely because other equipment, not present at the business, could have cooled the food quicker. The time taken to achieve cooling must be consistent with food safety. Cooling will always be a step that is critical to food safety.

HACCP

19. Article 5 of EC Regulation 852/2004 requires food business operators to maintain procedures based on HACCP principles. This is so that food safety hazards are identified and monitored and to ensure that controls are in place to eliminate or minimise risks to consumers.

20. There is flexibility in the Regulation, emphasised by guidance from the Commission, on compliance with the requirement for procedures based on HACCP principles. The Agency has developed guidance for businesses; Safer food better business (SFBB) in England and Wales; CookSafe in Scotland; and Safe Catering in Northern Ireland that makes use of this flexibility and in some cases includes limited temperature monitoring and recording, so as not to place undue burdens on smaller businesses.

21. HACCP based procedures have an important role to play in helping to ensure that food is produced safely. Chill holding in particular is very often critical to food safety. This means businesses should understand which foods need to be held under temperature control and be aware of the relationship between temperature and the shelf life of food. Temperature monitoring and logging may be helpful as part of food safety management procedures. A need for monitoring and record keeping (commensurate with the nature and size of the business) is indicated by Article 5.

22. It is also important to remember that changes in food processing practices, such as decreasing the use of preservatives such as salt, may mean that some products may no longer be safe when kept at ambient temperatures.

Product-Specific Food Hygiene Regulations

23. Annex III of EC Regulation 853/2004 contains product-specific hygiene requirements for certain foods of animal origin to be kept at prescribed temperatures, or for the manufacturer to prescribe a temperature. These generally do not apply to retail or catering, except where specified, or in business-to-business sales, subject to exemptions. Whilst the general requirement applies to all businesses, any applicable specific temperature control requirements within the product-specific Regulations would apply in addition to this. This may mean that a different approach to chill holding of some of the products mentioned in this guide will be required, for example, the requirement to chill raw meat in establishments subject to approval as cutting plants. Food business operators should refer to these Regulations for the specific temperature control requirements.

National Requirements

24. Schedule 4 (Temperature Control Requirements) of the 2006 Food Hygiene Regulations requires that in England, Wales and Northern Ireland, foods which are likely to support the growth of pathogenic micro-organisms or the formation of toxins, be held at or below 8°C, or, at or above 63°C. The Schedule allows certain exemptions from the requirements (consistent with the need to ensure food safety) to take into account practical considerations relating, for example, to processing or handling.

25. Schedule 4 (Temperature Control Requirements) of the 2006 Food Hygiene Regulations for Scotland applies to food that is being kept for commercial operations and allows specific exemptions from the regulations. The general obligation to avoid keeping foods at temperatures, which would result in a risk to health, applies in Scotland as in the rest of the UK. Similarly, the types of food described as '*foods subject to temperature control*' are the same throughout the UK (see paragraph 9). However, the details of temperature control measures in Scotland do differ significantly from those applying elsewhere in the UK; primarily that no exact chill temperature is given; that food reheated must reach a temperature of 82°C; and that there are no specified tolerance periods for either the chill or hot holding of food.

26. Schedule 4 does not apply to any food business operation that requires approval under EC Regulation 853/2004. In addition, they specifically do not apply to ships and aircraft, which should comply with the General Requirement rather than those in the Schedule. The only exception is for permanently moored ships that contain a food business, to which the Schedule does apply.

Chill Holding

England, Wales and Northern Ireland

Chill Holding Requirements

27. Food that is likely to support the growth of pathogenic micro-organisms or the formation of toxins must be kept at a temperature of 8°C or below. Paragraph 9 gives some examples of various food types, which, under normal conditions of storage and use and in the absence of adequate preserving factors, should be kept under temperature control to help secure food safety. Schedule 4 does however contain a number of specific exemptions, which are described in paragraphs 32-34. The requirement is for the temperature of the food, not the surrounding air.

28. The requirement applies to foods, including raw materials and ingredients, at all stages of preparation, processing, transport, storage and display for sale within the manufacture, retail and catering sectors.

29. Foods that are not likely to support the growth of pathogenic micro-organisms or the formation of toxins are not covered by the requirement. There may be other reasons to keep such foods cool, for example yoghurts with a pH below 4.5, hard cheeses and butter may be held under chilled conditions for *quality*, rather than for safety reasons.

30. In any legal proceedings where food had not been kept at or below 8°C, the burden of proof would be on the enforcement authority to demonstrate that a food is likely to support the growth of pathogenic micro-organisms or the formation of toxins.

31. The requirement does not apply to cooked or reheated foods to be sold hot, which should be kept at or above 63°C.

Exemptions from Chill Holding Requirements

32. Schedule 4 provides exemptions from the chill holding requirement in defined circumstances for some foods even though they are inherently likely to support the growth of pathogenic micro-organisms or the formation of toxins. The exemptions recognise that a limited period outside chill holding would not have adverse consequences for human health and that there is a link between time and temperature in the growth of micro-organisms. It also exempts raw foods that are intended to be processed, e.g. by cooking.

33. In any legal proceedings, the enforcement authority would be required to prove beyond reasonable doubt that there has been a contravention of Schedule 4 of the national requirements, having taken into account the exemptions listed as appropriate.

34. The exemptions are:

i. Food, which, for the duration of its shelf life, may be kept at ambient temperatures with no risk to health.

The inherent properties of the product or the way in which it has been treated or packed may be important in securing the stability of the product. Examples include certain pickles or jams, which may be safely kept at ambient temperatures, provided that their packaging remains intact and they are within their shelf life. Some cured or smoked products, such as air-dried, cured hams with low water activity, may be safely kept at ambient temperatures under defined conditions and within their shelf life.

Other foods are normally sold to consumers with a short shelf life, as the quality of the product is not acceptable at a later stage. This would include certain bakery products and sandwiches (although not those containing cooked products described in paragraph 9b), which are sold within a short period of being produced or prepared. Bakery products would include, for example; uncut baked egg and milk pastry products, e.g. custard tarts; or cooked pies and pasties that are completely encased in pastry to which nothing has been added after baking.

Under these circumstances, all of these products can be safely sold to consumers without any need for chill holding, even though they are not ambient shelf stable. Other examples might include certain types of cake and products that have already undergone a treatment, such as pasteurised milk (including both shop bought and doorstep deliveries).

ii. Food, which is being or has been subjected to a process such as dehydration or canning, intended to prevent the growth of pathogenic micro-organisms at ambient temperatures.

Once foods that may support the growth of pathogenic micro-organisms or the formation of toxins are processed (such as dehydration or canning) they may be ambient stable until they are re-hydrated or the seal of the packaging is broken. For example, re-hydrated pasta would be likely to support the growth of micro-organisms or toxin formation. Rehydrated pasta would therefore normally require temperature control.

iii. Food, which must be ripened or matured at ambient temperatures, but not when the process of ripening or maturation is completed.

This exemption is intended to allow foods such as soft or mould-ripened cheeses to ripen at ambient temperatures. The exemption applies *only* where

the ripening cannot take place at or below 8°C or a recommended higher temperature - see paragraphs 35-41 for further explanation.

The exemption would not normally apply to soft or mould-ripened cheeses, which are on retail display. Although the ripening process may not have stopped, the primary ripening which secures the quality of the product would be expected to have taken place at an earlier stage in manufacture.

iv. *Raw food intended for further processing (including cooking) before human consumption, but only if that processing, if undertaken correctly, will render that food fit for human consumption.*

Some foods may support the growth of pathogenic micro-organisms or the formation of toxins but adverse consequences for human health, for products such as raw meat, can be prevented by thorough cooking or other heat treatment before consumption. Fresh meat and fish would fall into this category. However, fresh meat or fish intended to be eaten raw, for example as steak tartare, carpaccio or sushi, would not be exempt from the 8°C requirement.

v. *Any food, which is being sent as part of a mail-order transaction to a consumer.*

Although such foods are exempt from the 8°C control they are subject to the general requirement that the product must not be supplied by the mail-order business at a temperature that might result in a risk to health. For further information on mail-order transactions, see the *Food Industry Guide to Good Hygiene Practice: Mail Order Food*.

Upward Variation from the 8°C Maximum Chill Temperature

35. This is relevant for the application of the legislation in England, Wales and Northern Ireland. It is not directly relevant to Scotland. This section aims to help anyone using the facility for certain food business operators to recommend holding temperatures higher than 8ºC. It helps them think through the steps to be considered in developing the necessary scientific assessment. It also provides guidance for food business operators holding foods at or below temperatures recommended by the food manufacturer, but where they are higher than 8°C.

36. A food business operator may offer a defence against failure to observe the requirement for foods to be kept at or below 8°C, by proving that:

a. The food business manufacturing, preparing, or processing the food has recommended that it is kept:

i. at or below a specified temperature between 8°C and ambient temperatures, and

ii. for a period not exceeding a specified shelf life

b. That recommendation has, unless the accused is that food business, been communicated to the accused either by means of a label on the packaging of the food or by means of some other appropriate form of written instruction

c. The food was not kept by the accused at a temperature above the specified temperature and

d. *The specified shelf life has not been exceeded.*

37. A food business responsible for manufacturing, preparing or processing food shall not recommend that any food is kept

- at or below a specified temperature between 8°C and ambient temperatures and

- for a period not exceeding a specified shelf life

unless that recommendation is supported by a well–founded scientific assessment of the safety of the food at the specified temperature.

38. A microbiologically unsafe food is one that contains levels of pathogens or their toxins, which would be injurious to health when eaten. All foods must be held under conditions conducive to maintaining their safety. The scientific assessment must clearly demonstrate that the microbiological safety of the food will not be compromised by storage and handling at the higher temperature.

39. The recommended temperature will be between 8°C and the ambient temperature and will generally require some form of refrigeration if it is to be achieved over any extended period.

40. Schedule 4 allows food business operators manufacturing, preparing, or processing food to recommend a temperature higher than 8°C. The food business operator involved in the manufacture of the food should be best placed to know its microbiological and other safety characteristics, in the light of any processing it may have undergone. Food business operators cooking or preparing food, e.g. running a catering business, may also make the recommendation for a higher temperature. Such food business operators should check with the manufacturer first, where this is relevant, before deciding whether changes can be made without compromising food safety.

41. Food business operators who are only retailing and/or wholesaling may not themselves recommend a higher temperature. They may keep food at a temperature higher than 8°C, for a specified shelf life, where this is recommended by the manufacturer or processor. They can then rely on a defence, in any proceedings, that they had kept the food at or below the recommended temperature and, that the specified shelf life had not been exceeded. Food business operators seeking to use this defence must comply with all parts of the

provision to be able to use the defence. The burden of proof in any proceedings would be with the food business operator wishing to show that these defences can be used.

Chill Holding Tolerance Period

4-hour exemption

42. A food business operator may offer a defence against failure to observe the requirement for foods to be kept at or below 8°C by proving that the food:

    - *was for service or on display for sale*

    - *had not previously been kept for service or display for sale outside temperature control, or, above a recommended temperature (as described in paragraphs 35-41) and*

    - *had been kept for service or on display for sale for a period of less than four hours.*

43. This tolerance would allow, for example, for display outside chill holding in catering premises in respect of self-service food, buffets, cheese boards and in retail premises for service and display.

44. The exemption only permits a single period outside temperature control. Foods displayed outside chill holding under this tolerance should subsequently be placed under chill holding until they are served, sold, or discarded. Alternatively, they should be discarded immediately after the tolerance period.

45. The defence applies to foods that are ‘for service or on display for sale’. These terms are not defined by the regulations, but the intention is that they are synonymous with a period outside any form of temperature control.

46. The requirements of Article 5 of Regulation 852/2004, relating to putting in place HACCP based procedures, mean that any hazards associated with the display and service of foods outside the specific temperature control requirements must still be controlled.

Exemption for practicalities

47. A defence against failure to observe the requirement for foods to be kept at or below 8°C may also be offered by proving that the food was kept for a limited period only, that was consistent with food safety, outside temperature control or above a recommended higher temperature, and

    - the food was being loaded or unloaded from a vehicle for transfer to or from a food premises or

- there were unavoidable reasons, such as to accommodate the practicalities of handling during and after processing or preparation; defrosting of equipment; or temporary breakdown of equipment.

48. The "limited periods" and permitted rises in food temperature for these purposes are not specified in Schedule 4, but must be consistent with food safety. In normal circumstances, a single limited period of up to two hours outside temperature control is unlikely to be questioned. For longer periods, some justification and a hazard analysis based on the HACCP principles may be expected.

49. As with other defence provisions, the burden of proof rests with the food business operator to show that these defences can be used.

Scotland

Chill Holding Requirements

50. Any person in respect of any commercial operation or food premises who keeps food outwith a refrigerator, a refrigerated chamber or a cool ventilated place is guilty of an offence unless the food is held at over 63ºC. Food that is being held above 63ºC is covered by the hot holding requirements and more details on these requirements are outlined in paragraph 60.

51. As there is no specific temperature mentioned for the chilling of foods that are likely to support bacterial growth it is recommended that if the food storage place chosen exceeds 8°C then the shelf life of the foodstuff may need to be reduced. Food should be kept at ambient temperature for the shortest time possible.

52. Schedule 4 does however contain a number of specific exemptions for chill holding as outlined below.

Exemptions from Chill Holding in Scotland

53. Schedule 4 recognises that some variation from usual temperature control is necessary to accommodate aspects such as handling and preparation, these exemptions are;

    i. *Food which is undergoing preparation for sale*

    The practicalities of food preparation allow for food to be outwith a refrigerator, a refrigerated chamber or a cool ventilated place as long as it being prepared for sale.

    ii. *Food which is exposed for sale or has been sold to a consumer whether for immediate consumption or otherwise.*

The requirement to keep food cool does not apply to food that has been sold or that is exposed for the purpose of sale.

iii. *Food which, in order that it may be conveniently available for sale on the premises to consumers, it is reasonable to keep otherwise than in a refrigerator or refrigerating chamber or in a cool ventilated place*

The requirement to keep food cool does not apply to a product kept for sale where it is not reasonably practicable to keep cool.

iv. Food which for the duration of its shelf life may be kept at ambient temperatures with no risk to health

The inherent properties of the product or the way in which it has been treated or packed may be important in securing the stability of the product. Examples include certain pickles or jams, which may be safely kept at ambient temperatures, provided that their packaging remains intact and they are within their shelf life. Some cured or smoked products, such as air-dried, cured hams with low water activity, may be safely kept at ambient temperatures under defined conditions and within their shelf life.

Hot Holding

England, Wales and Northern Ireland

Hot Holding Requirements

54. Food which is for service or on display for sale, that has been cooked or reheated and needs to be kept hot to control the growth of pathogenic micro-organisms or the formation of toxins must be kept at a temperature at or above 63°C. The foods this would apply to are broadly similar in nature to the food types described in paragraph 9.

55. Similar considerations apply as for scientific assessments of the safety of foods at chill temperatures, e.g. on the use of competent and expert advice, the use of generic recommendations and the nature of the scientific assessment. However, unlike the chill temperature variation provisions, there is no requirement for written instructions.

Downward Variation from the 63°C Minimum Hot Holding Temperature

56. A food business operator may offer a defence against failure to observe this requirement by proving that

    - *a well founded scientific assessment of the safety of the food at temperatures below 63°C has concluded that the food can be kept safely at that temperature for a specified period and*

    - *the food was held in a manner that was justified in the light of the scientific assessment*

    Further information on what constitutes a scientific assessment can be found in paragraphs 67-80.

Hot Holding Tolerance Period

57. A food business operator may offer a defence against failure to observe the requirement to keep foods at or above 63°C by proving that the food:

    - had been kept for service or on display for sale for a single period of less that 2 hours.

58. This tolerance would also apply to a recommended temperature for hot holding lower than 63°C. At the end of the period of up to 2 hours, the food should be as quickly as possible cooled to a temperature of 8°C or below or discarded.

59. As with other defence provisions, the burden of proof rests with the food business operator to show that these defences can be used.

Scotland

Hot Holding Requirements

60. Food that is being kept for commercial operations, which is for service or on display for sale and has been cooked or reheated must be kept at a temperature above 63°C. Any person who keeps food otherwise than at a temperature above 63°C is guilty of an offence unless it is kept in a refrigerator, a refrigerated chamber or a cool ventilated place. More details on chill holding requirements are outlined in paragraphs 50-52. Schedule 4 does however contain a number of specific exemptions for hot holding requirements as outlined below.

Exemptions from hot holding requirements

61. Schedule 4 recognises that some variation from usual temperature control is necessary to accommodate aspects such as handling and preparation, these exemptions are;

i. *Food which is undergoing preparation for sale*

The practicalities of food preparation allow for food to be at a temperature below 63ºC as long as it being prepared for sale.

ii. *Food which is exposed for sale or has been sold to a consumer whether for immediate consumption or otherwise.*

The requirement to keep food above 63ºC does not apply to food that has been sold or that is exposed for the purpose of sale.

iii. *Food which immediately following any process of cooking to which it is subjected or the final processing stage if no cooking process is applied is being cooled under hygienic conditions as quickly as possible to a temperature which would not result in a risk to health.*

Food, which has been heat processed or prepared is not to be treated as in breach of Schedule 4 if it is immediately after processing or preparation being cooled as quickly as possible to a 'safe' temperature.

iv. *Food, which, in order that it may be conveniently available for sale on the premises to consumers, it is reasonable to keep otherwise than above 63ºC.*

The requirement to keep food cool does not apply to a product kept for sale where it is not reasonably practicable to keep above 63ºC.

v. Food which for the duration of its shelf life may be kept at ambient temperatures with no risk to health

The inherent properties of the product or the way in which it has been treated or packed may be important in securing the stability of the product. Examples include certain pickles or jams, which may be safely kept at ambient temperatures, provided that their packaging remains intact and they are within their shelf life. Some cured or smoked products, such as air-dried, cured hams with low water activity, may be safely kept at ambient temperatures under defined conditions and within their shelf life.

Reheating of Foods

62. In Scotland, reheated foods must be raised to a temperature of not less than 82ºC; any person who does not is guilty of an offence.

> *Food which in the course of a commercial operation has been heated and which is thereafter reheated before being served for immediate consumption or exposed for sale shall, on being reheated, be raised to a temperature of not less than 82ºC.*

63. Foods, which are cooked on the premises, must be reheated to a temperature of not less than 82ºC before being displayed or served. There is no equivalent requirement in the rest of the U.K.

64. Once food exceeds 82ºC, it may then be kept at over 63ºC. The whole of this food must reach 82ºC and care must be taken that the temperature and time of heating are sufficient to do this.

65. There is however an exemption from this requirement on the basis that the quality of the food would be adversely affected.

> *It shall be a defence for the accused to prove that the food could not have been raised to a temperature of not less than 82ºC without a deterioration of its qualities.*

66. The 82ºC re-heating temperature need not be achieved if to do so would cause the food to deteriorate, including deterioration of the quality of the food.

Scientific Assessment Supporting a Recommended Temperature Variation

67. This section is not directly relevant to Scotland. A scientific assessment should include the microbiological examination of a food under controlled conditions that represent expected real life conditions. A suitably qualified scientist should undertake the assessment. The report of the assessment will require an evaluation by that scientist of the effects of time and temperature of storage (including distribution and retail display) on the safety of the food as it will be consumed. The use of a theoretically based modelling approach, e.g. ComBase, may be helpful in defining the safety factors but is not considered in itself to provide a sufficient assurance of food safety.

68. It is common practice within businesses manufacturing foods to use a range of sources of raw material to allow for factors such as cost, availability, seasonal variation and quality to make the manufacturing process more cost effective. In some instances, the raw material may vary on a day-to-day basis. The justification for the use of a higher temperature than 8°C must take into consideration the

effects of raw material variation on the microbiological status of the food so that the effects on safety can be fully evaluated.

69. The scientific justification must be fully developed for each product or group of products for which a specific controlling factor has been established. That justification will need to be reviewed in the light of changes to any process (e.g. preparation of ingredients, cooking etc.), ingredients, product characteristics or the product life.

70. It is not possible, within this guidance, to list all the parameters that must be considered in a scientific assessment. The parameters will depend on the type of ingredients and processing involved the nature of the food itself, its packaging and the intended end-use by the consumer. In most cases due consideration will need to be given to:

- pH
- type of acidulants
- water activity
- type of solutes and
- the combined effects of preservative factors.

This is not an exhaustive list and each case must be given careful consideration.

The Specified Shelf-life

71. The scientific assessment in support of the use of a higher temperature than 8°C must show how the safe product life has been established. It must also provide the necessary evidence that the product will not be microbiologically compromised if consumed within the use-by period, allowing for reasonable handling by the consumer following retail sale. Consideration must be given to limited periods of exposure to temperatures higher than the new prescribed control temperature, which may arise during loading and unloading of delivery vehicles or during defrosting periods of refrigeration equipment.

72. Shelf-life assessments may relate to quality as well as food safety. There are separate legal obligations relating to deterioration of the quality of food and the information that must be given about this to the consumer. The scientific assessment needed to justify a variation from the maximum temperature of 8°C must relate *only* to safety issues.

73. Guidance on ‘shelf life’ means the period up to and including the ‘best before’ or ‘use by’ date, as appropriate, where these are required to be given under the Food Labelling Regulations 1996[7] (as amended). If no, ‘best before or ‘use by’ date is given, the shelf life is the period during which the food can be expected to remain fit for sale if it is kept in a manner which is consistent with food safety.

[7] SI 1996/1499 - The Food Labelling Regulations 1996 and SR 1996 No 383 - Food Labelling Regulations (Northern Ireland) 1996

Generic Temperature Recommendations

74. Generic recommendations may be made for variations of chill temperature. The scientific assessment must tightly define the foods in all aspects from raw materials to finished products. The handling and storage regimes must also be fully described and allow for the "worst case" scenario for the industry concerned. For example, a trade association recommended temperature for a fully defined product, based on a scientific assessment of fully defined preparation and handling practices and defined storage conditions that provide evidence of safety for that product.

75. It is most important that food business operators using such generic recommendations have access to the appropriate definitions of the product used for the scientific assessment. This is to enable them to use the facility for a higher temperature correctly and follow the handling and storage regimes that are consistent with those used in the original scientific assessment. A food business making use of a generic recommendation when putting a temperature on a food label is responsible for ensuring that this is consistent with food safety.

76. Generic recommendations may be included in National Guides to Good Practice for Hygiene and for the Application of HACCP Principles that have been recognised as complying with the Regulations. A scientific assessment justifying such a recommendation, where this is included in a recognised Guide, will normally be regarded as a sound scientific assessment.

Communication of the variation of temperature

77. Food business operators manufacturing, preparing or processing food are required to communicate the variation of temperature either by means of the food label, or by another appropriate form of written instruction. Without one of these forms of communication, the variation of temperature cannot be used by a food business operator other than one manufacturing, preparing or processing the food.

78. The two essential items of information to be communicated are the new maximum temperature and the specified shelf life. Food items, which are pre-packed, will also be covered by the Food Labelling Regulations, which require most foods to indicate "Use-by" or "Best-before" date(s) on the food label. Where this is so, this information will be taken as the shelf life for temperature control purposes and should be calculated with this in mind. The new temperature must be stated clearly with an instruction to other food business operators in the food chain to store at or below this temperature. It is helpful to distinguish between recommendations made for food safety purposes and those made for quality reasons.

79. The option of using the food label to communicate storage information will not apply in the case of unpackaged food. Written instructions must accompany each batch of food to which the variation applies. Most unpackaged food for which the

variation of temperature might be employed would be expected to be short shelf-life products, in many cases manufactured and sold on the same premises. Where foods are manufactured and sold on the same premises, use of a general written instruction on storage temperature and shelf life of a specified product would be good practice if the variation of temperature is to be employed, but it is not a requirement.

Who can advise on scientific assessments?

80. While large businesses may be able to undertake this type of scientific assessment in-house, it is unlikely that many small businesses would have the necessary technical competence to carry out such an exercise. In such cases, it will be necessary to seek outside advice and assistance, perhaps through a trade association. It is of the utmost importance that advice is sought from suitably qualified scientists or bodies employing such scientists who are in a position to provide sound, unbiased and practical help. Examples of bodies employing such people are public analysts, food examiners, food research associations and the Health Protection Agency (HPA).

Further Information

81. For further information on the legal requirements or this guidance, please contact:

Simon Petty
Primary Production Division 1
Food Standards Agency
125 Kingsway
London
WC2B 6NH
Tel: +44 (0)20 7276 8976
Email: simon.petty@foodstandards.gsi.gov.uk

In Scotland:

Elaine McLaughlin
Food Standards Agency Scotland
Contaminants, Hygiene, Additives & Shellfish Branch
6th Floor, St Magnus House
25 Guild Street
Aberdeen
AB11 6NJ
Telephone 01224 288 356
E-mail: elaine.mclaughlin@foodstandards.gsi.gov.uk

In Wales:

Keith Blake
LA Enforcement & Emergency Planning
Food Standards Agency Wales
11th Floor
Southgate House
Wood Street
Cardiff CF10 1EW
Tel: 029 2067 8902
E-mail: keith.blake@foodstandards.gsi.gov.uk

In Northern Ireland:

Trevor Williamson
General Food Hygiene and Incidents Unit
Food Standards Agency Northern Ireland
10c Clarendon Road
Belfast BT1 3BG
Tel: 028 9041 7713
E-mail: trevor.williamson@foodstandards.gsi.gov.uk