Food Authority

NSW GOVERNMENT

Potentially hazardous foods

Foods that require temperature control for safety

Table of Contents

Definitions

Term	Definition
2-hour/4-hour rule	An alternative method of satisfying the temperature control requirements specified in the Food Standards Code. The principal concepts of the 2-hour/4-hour rule are that when potentially hazardous ready-to-eat food has been kept between 5°C and 60°C for: • up to 2 hours, it can be refrigerated below 5°C, or kept hot above 60°C, or used immediately • between 2 and 4 hours, it must be used immediately • up to a total of 4 hours or more, it must be thrown out. Safe Food Australia – Appendix 2 (2023)
Authorised Officer	A definition of an Authorised Officer is included in the Food Standards Code (Standard 1.1.2) and also defined in the NSW Food Act 2003 Part 1. The appointment of Authorised Officers and Certificates of Authority are set out in NSW Food Act 2003 Part 9 Division 3.
Demonstrate	Means demonstrate to the satisfaction of the NSW Food Authority Food Regulation 2015, Part 6, Clause 38
Pathogenic bacteria	Bacteria capable of causing food poisoning. Some examples: *Salmonella, Listeria monocytogenes, Bacillus cereus*, and *Staphylococcus aureus*.
Potentially hazardous food	Food that has to be kept at certain temperatures to minimise the growth of any pathogenic microorganisms that may be present in the food or to prevent the formation of toxins in the food Food Standards Code 3.2.2, Division 1, Clause 1
Process	Activity conducted to prepare food for sale including chopping, cooking, drying, fermenting, heating, pasteurising, thawing and washing, or a combination of these activities Food Standards Code 3.2.2, Division 1, Clause 1
Ready-to-eat food	Food that is ordinarily consumed in the same state as that in which it is sold and does not include nuts in the shell and whole raw fruits and vegetables that are intended for hulling, peeling or washing by the consumer. Food Standards Code 3.2.2, Division 1, Clause 1

Term	Definition
Temperature control	Maintaining food at a temperature of: • 5°C or below if this is necessary to minimise the growth of pathogenic microorganisms in the food, so that the microbiological safety of the food will not be adversely affected for the time the food is at that temperature, or • 60°C or above, or • another temperature - if the food business demonstrates that maintenance of the food at this temperature for the period of time for which it will be so maintained, will not adversely affect the microbiological safety of the food. Food Standards Code 3.2.2, Division 1, Clause 1
Temperature danger zone	Between 5°C and 60°C

Introduction

Standard 3.2.2 of the Australia New Zealand Food Standards Code (Food Standards Code) defines potentially hazardous food (PHF) as “food that has to be kept at certain temperatures to minimise the growth of any pathogenic microorganisms that may be present in the food or to prevent the formation of toxins in the food”. Potentially hazardous foods are also referred to as ‘Time/temperature control for safety (TCS) foods’ in other reference documents. The phrase does not mean a naturally dangerous food such as a poisonous mushroom.

The need for time/temperature control is primarily determined by the potential for contamination with and survival of pathogenic microorganisms of concern and the potential for subsequent growth and/or toxin production. Factors affecting microbial growth include moisture content (water activity, aw), acidity (pH), nutrient content, antimicrobials, atmosphere of packaging, processing steps and storage conditions. If the combination of these factors creates a favourable environment and the food is not kept under temperature control, microorganisms can grow, and some may form toxins. If the levels of pathogenic microorganisms or toxins reach unsafe levels, foodborne illness may occur.

Clause 8 of Standard 3.2.2 requires that a food business, when displaying potentially hazardous food, display it under temperature control. This clause is simple and logical. However, when it comes to inspecting food on display the situation is not always as simple. In some cases, it is not possible to determine whether a food is potentially hazardous during an inspection. While the food business has the responsibility to demonstrate that it is handling food safely, many small businesses are not equipped to do so.

This document includes information on factors that can be used to assess the hazard, lists of food types where the nature of the hazard can be determined and provides information on what laboratory work can be done to provide clarity when the nature of the hazard is not clear.

What food is potentially hazardous?

Potentially hazardous foods are generally moist, nutrient-rich foods with a neutral pH. Examples of foods that are normally considered potentially hazardous include:

Food type[1]	Examples
Raw and cooked meat/poultry	
Foods containing raw or cooked meat/poultry	Burgers, curries, kebabs, pate, meat pies
Foods containing eggs (cooked or raw), beans, nuts or other protein-rich food	Batter, mousse, quiche, tofu
Dairy products and foods containing dairy products	Milk, dairy-based desserts, bakery products filled with fresh cream or with fresh custard (yoghurt is not included here as it is an acidified product)
Seafood (excluding live seafood) and foods containing seafood	Sushi
Sprouted seeds	Bean sprouts, alfalfa
Prepared fruits and vegetables	Cut melons, salads, unpasteurised juices
Cooked rice, fresh and cooked pasta	
Foods that contain any of the above foods	Sandwiches, pizzas, rice rolls

Note:

1. Some of the types of food listed will not be considered potentially hazardous if they have been processed in certain ways, for example, if a food contains certain additives or has been commercially sterilised.
2. Any food that contains a potentially hazardous ingredient must also be considered a potentially hazardous food. For example, sushi rice correctly prepared with vinegar may be acidic enough to prevent pathogen growth, but adding fillings such as raw fish, cooked chicken or vegetables would make the end product potentially hazardous.

[1] FSANZ Safe Food Australia – Appendix 1: Potentially hazardous food (FSANZ, 2023)

What food is not potentially hazardous?

If a food does not support the growth of a pathogen or toxin production, then it is not potentially hazardous.

Some foods in their natural state do not support pathogen growth because their intrinsic properties create an unfavourable environment, for example, foods that are naturally acidic. Other foods may have been processed in a way that minimises microbial growth (for example, dried, salted, acidified) or has eliminated microorganisms in the food (such as commercially sterilised food). In addition, the use of certain chemical additives such as nitrites, sulphites or specialised packaging may minimise microbial growth in food.

Examples of food types considered to be not potentially hazardous[1]

Biscuits and crackers	Fruit cake	Plain cakes
Bottled marinades (before opening)	Fruit juices	Raw whole fruit and vegetables
Bottled pasta sauces (before opening)	Hard cheeses	Salad dressings
Bottled salsas (before opening)	Honey and jam	Sauces – Asian/soy, ketchup style
Confectionery	Nuts in the shell	Salted dried meats
Dried fruit	Peanut butter	Unopened canned foods
Dry goods	Pickles	Yoghurts
Fermented dried meats	Plain breads and bread rolls	

Note:

Foods in the above list do not support the growth of pathogenic bacteria or the formation of toxins in the food. However:

1. Many of the products require refrigerated storage to prevent food spoilage or maintain quality to achieve the stated shelf-life.
2. Some foods might contain certain pathogenic microorganisms but not support their growth. Although by definition such foods are not “potentially hazardous”, they can still be a food safety hazard. For example, food contaminated with viruses such as hepatitis A or norovirus can cause foodborne illness even though the pathogen does not multiply in the food.
3. The above foods might become potentially hazardous when the food is opened or altered in some ways. For example, opening a can of food, cutting up a whole melon, slicing cured meat, cooking vegetables or reconstituting dry foods.

[1] FSANZ Safe Food Australia – Appendix 1: Potentially hazardous food (FSANZ, 2023)

Regulations and Guidelines

The Australia New Zealand Food Standards Code

Standard 3.2.2 – Food Safety Practices and General Requirements defines potentially hazardous food (PHF) as "food that has to be kept at certain temperatures to minimise the growth of any pathogenic microorganisms that may be present in the food or to prevent the formation of toxins in the food".

The associated definition of temperature control is important. Standard 3.2.2 defines temperature control as maintaining food as a temperature of –

a. 5°C, or below if this is necessary to minimise the growth of infectious or toxigenic microorganisms in the food so that the microbiological safety of the food will not be adversely affected for the time the food is at that temperature; or

b. 60°C or above; or

c. Another temperature – if the food business demonstrates that maintenance of the food at this temperature for the period of time for which it will be so maintained, will not adversely affect the microbiological safety of the food.

The 2-hour/4-hour rule

The 2-hour/4-hour rule is an alternative method that has been designed to help businesses deal with some of the practicalities of handling refrigerated potentially hazardous ready-to-eat food. Studies have been done to show that food can be held out of temperature control for short periods of time without significantly increasing the risk of food poisoning.

The principal concepts of the 2-hour/4-hour rule are that when potentially hazardous ready-to-eat food has been kept between 5°C and 60°C for:

- up to 2 hours, it can be refrigerated below 5°C, or kept hot above 60°C, or used immediately.
- between 2 and 4 hours, it must be used immediately.
- up to a total of 4 hours or more, it must be thrown out.

It is important to note that the time is cumulative; all time periods where the food is at temperatures between 5°C and 60°C need to be counted.

If a food business wishes to maintain potentially hazardous food between the temperatures of 5°C and 60°C for time periods longer than the two hours and four hours specified above, the food business must demonstrate that the extension of time will not compromise the safety of the food.

For more information on the use of the 2-hour/4-hour rule, please refer to the '*Guidance on the 2-hour/4-hour rule*' document on the Food Authority's website foodauthority.nsw.gov.au/resource-centre.

Institute of Food Technologists/United States Food and Drug Administration suggested definition of Potentially Hazardous Food

The Institute of Food Technologists/US Food and Drug Administration (IFT/FDA) report on *Evaluation and Definition of Potentially Hazardous Foods* suggests adopting the term "temperature controlled for safety (TCS)" with the definition "foods that require time/temperature control to limit pathogen growth or toxin formation that constitutes a threat to public health". This definition has similar intent to that used in the Standard 3.2.2.

The report goes on to consider factors that influence microbial growth and provides useful guidance on determining whether a product requires TCS. Given the similarities in definitions, the IFT/FDA guidance also addresses Australian Code requirements. Much of the analysis that follows is based on the IFT/FDA model.

How to determine if foods are potentially hazardous

Water activity (aw) as the control factor for pathogen growth

The water activity of a food describes the degree to which water is “bound” in the food, its availability to participate in chemical/biochemical reactions and its ability to make possible the growth of microorganisms (IFT/FDA, 2001). In foods, it ranges from 0.10 (dry products, like crackers) to 1.00 (very moist). Most fresh foods have aw values that are close to the optimum growth level of most microorganisms (0.97 to 0.99) (Appendix 1).

Appendix 2 shows the minimum aw at which foodborne pathogenic bacteria can grow or produce toxin. The benchmark organism is *Staphylococcus aureus* which can grow at aw 0.83 and produce toxin at 0.88.

pH as the control factor for pathogen growth

The pH of a food relates to its acidity. Most foods such as meat, fish and vegetables are slightly acidic, while most fruits are moderately acidic. It is well known that groups of microorganisms have a pH optimum, minimum and maximum for growth in foods.

Appendix 3 shows the minimum pH at which foodborne pathogenic bacteria can grow or produce toxin. The benchmark vegetative bacteria are *S. aureus* which can grow at pH 4.0 and produce toxin at 4.6 and *Yersinia enterocolitica* and *Salmonella* spp. both of which can grow at pH 4.2. The spore-forming bacteria of interest is *Clostridium botulinum* which can grow and produce toxin down to pH 4.6.

Interactions between aw and pH

The tables below (IFT/FDA, 2001) provide a useful advice on some combinations of pH and water activity which, taken together, will prevent microbial growth or spore outgrowth. Those combinations that lead to “non-TCS” are also not PHF. If the combination is denoted by a “?”, it indicates that the product is potentially unsafe without refrigeration. Note that some individual foods have characteristics that prevent pathogen growth at conditions of pH and water activity that are less severe than those indicated in the tables.

Care should be taken when analysing multicomponent foods because measurements of aw, pH, or antimicrobials of the whole food may not reflect the actual value of the components or at the interface among the different components. In these cases, the parameters should be measured at the interface areas of the food, as well as in the component itself.

If the product of interest has been heat treated to destroy vegetative microbial cells and has been packaged to avoid recontamination, use Table 1 (IFT/FDA Table A) to ascertain the need for temperature control. If the product has not been heat-treated or heat-treated but not packaged, use Table 2 (IFT/FDA Table B).

Table 1 IFT/FDA Table A – Product treated to control spores and protected from recontamination.

Water activity	<4.2	4.2 - 4.6	>4.6 - 5.0	>5.0 - 5.6	>5.6
<0.85					
>0.85 - <0.88					
0.88 - 0.90					
>0.90 - 0.92					
>0.92 - 0.95					?
>0.95			?	?	?

Table 2 IFT/FDA Table B – Product not treated to control spores or treated but not protected from recontamination.

Water activity	<4.2	4.2 - 4.6	>4.6 - 5.0	>5.0 - 5.6	>5.6
<0.85					
>0.85 - <0.88					
0.88 - 0.90				?	?
>0.90 - 0.92			?	?	?
>0.92 - 0.95		?	?	?	?
>0.95		?	?	?	?

	Non-TCS / not PHF
?	Query area - Possible TCS - Individual product assessment required

If the food is classified as a non-TCS food, it may be stored and held safely without regard to time or temperature.

However, if the need for time/temperature control is questionable, the food should be held either hot or cold for safety, or subjected to a product assessment as outlined in Figure 1 as the next step in determining the appropriate classification.

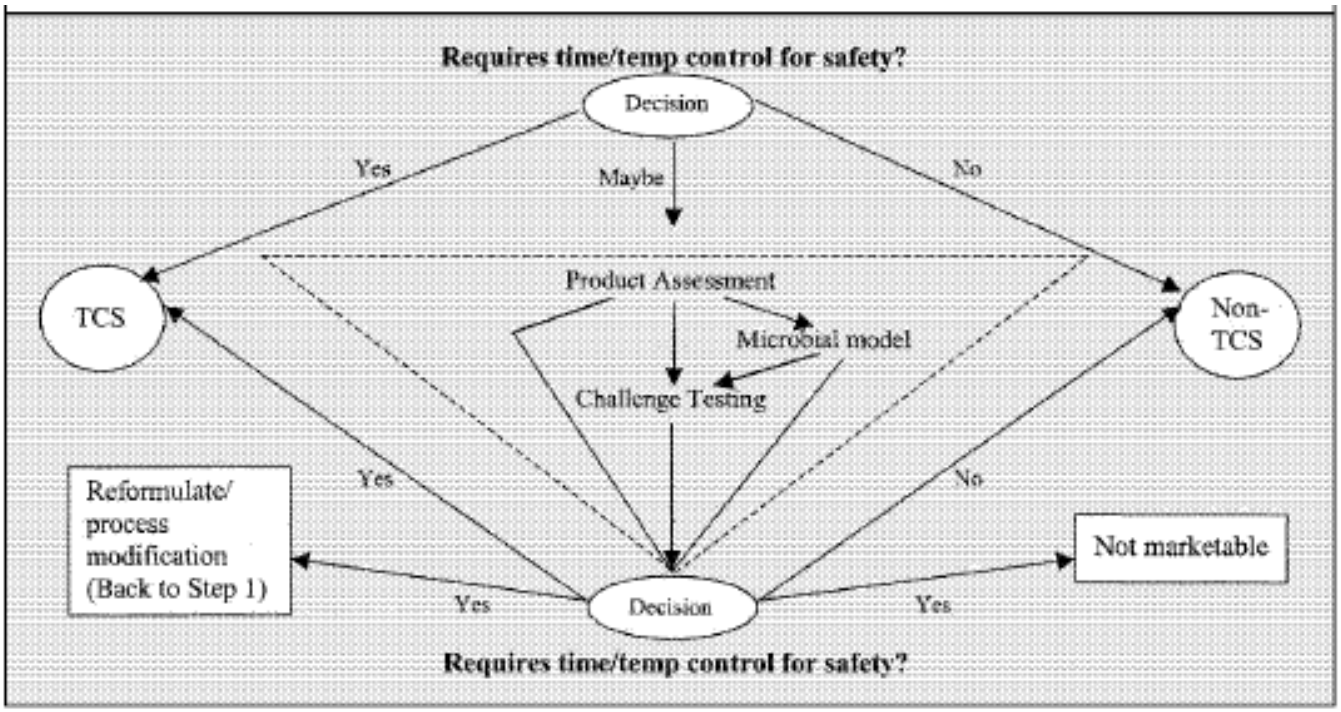

Figure 1 A flowchart to determine whether a product requires time/temperature control for safety (IFT/FDA, 2001)

Individual product assessment

The IFT/FDA report includes details of individual product assessment. The steps set out in the report should be undertaken under the guidance of a trained food technologist or food scientist. Laboratory analysis is required to complete the assessment.

Step 1

Conduct a pH and water activity (aw) testing. If the product is not homogeneous, measurements of pH and aw are required in triplicate for each component. The assessment of a food that is not homogenous will be based on the “weakest link” (i.e. the highest risk).

Step 2

Evaluate the results of testing according to the appropriate IFT/FDA table (see page 10).

- Use Table 1 if the product is processed (e.g. cooked) to control vegetative cells and protected from recontamination.
- Use Table 2 if the product is not treated to control vegetative cells or treated but not protected from recontamination.

If the product is classified as non-TCS the assessment is complete.

Step 3

If the product is in the query area, then time or temperature-controlled display is required. Further studies can be undertaken, if necessary, but time or temperature controls are often better options. The studies are complex and expensive and require input from an experienced food technologist/scientist. Product assessment should consider factors such as:

- Potential pathogens
- Intrinsic factors such as preservatives, acidulants, nutrients, humectants
- Extrinsic factors such as packaging, modified atmosphere, shelf life
- Effectiveness of the processing control of pathogens
- Possible post-process recontamination
- Historical information on the safety of similar or related products
- The consultant could also use microbial growth models to evaluate the likely success of challenge studies.

Step 4

Microbial challenge studies tests should be undertaken if there is a reasonable likelihood of success. ISO 20976-1:2019 specifies protocols for conducting microbiological challenge tests for growth studies on vegetative and spore-forming bacteria in raw materials and intermediate or end products. Products passing a properly designed challenge test are considered to have demonstrated alternative compliance as long as controlled display times and temperatures do not exceed those employed in a successful challenge trial.

Note 1: The results of microbiological testing of the food product are useful for verification of the assessment but they do not stand alone. Good results might provide a level of comfort about product safety, but they do not necessarily address all the inherent risks.

Note 2: The history of the product alone does not confirm product safety. The history must be underpinned by a sound scientific evaluation.

Verifying that foods are not potentially hazardous

Food businesses are responsible to determine which foods they serve, or sell are potentially hazardous. Authorised officers require evidence of the determination, for example (but not limited to) a validation study, analytical testing results or the result of a challenge testing.

Food businesses are also required to substantiate food safety controls when handling PHF.

Common issues

Warm food (less than 60°C) in a bain marie

A correctly adjusted bain marie can hold food at 60°to 65°C without generating too much steam. If food on display is less than 60°C, the unit could be set too low, or the operator might have used the bain marie to reheat food. Bain marie is not designed for reheating food. If attempted, the food typically spends many hours at a perfect temperature for bacterial growth. Food must be freshly cooked or reheated prior to display in a bain marie.

If the business is worried that food may lose quality at the temperature of greater than 60°C, the business must use time as a control (such as the 2-hour/4-hour rule). Records of the times and temperatures that food is displayed must be kept to ensure that the food is safe.

Salads and cut meats displayed above 5°C

It is common for salad and sandwich bars to display cold food at 5 to 10°C and it can be difficult to rectify the issue without significant investment. Brightly lit displays, with “cold plate” refrigeration, stacked high with food to be more appetising, are more difficult to manage than compact displays with overhead cooling.

Sometimes the problem can be traced to operator actions, such as placing spacers (cardboard, foam or bread) between the cold plate and the food tray to avoid freezing. In this case the use of plastic trays might be a better option.

Often the only solution available to operators is to display suitable quantities of food and to remove food from display consistent with the “2-hour/4-hour rule”. Condiments, sauces and other non PHF do not have to follow the rule.

Pre-cut sandwiches and rolls

Sandwich shops sometimes prepare sandwiches ahead of the lunch rush hour. Sandwiches are a potentially hazardous food, and time or temperature control is necessary. If adequate refrigeration is not available, then sandwiches must be sold within the 4-hour time frame and time control must be evident.

Ambient or cool display of sushi

Sushi businesses are reluctant to refrigerate their products because changes to rice starch can result in a firmer texture and starchy taste. Even though the rice is acidified, some components of the sushi remain potentially hazardous, which causes the RTE sushi to be categorised as PHF.

The NSW Food Authority permits retail sushi businesses to display sushi at temperatures up to 25°C for no more than 4 hours provided:

- The Food Standards Code's requirements are followed during the receipt, preparation and storage of sushi and raw materials;
- Proper acidification of the rice (to a pH less than or equal to 4.6) takes place to inhibit the growth of food poisoning bacteria. The pH must be recorded; and
- Sushi businesses implement a system for monitoring the length of time sushi is displayed at 5°C to 25°C.

Further information can be found in the '*Food safety guidelines for the preparation and display of sushi*' on the Food Authority's website www.foodauthority.nsw.gov.au/resource-centre.

Ambient display of seemingly perishable Asian foods

Anecdotally, Asian communities have a tradition of "cook–serve" food service and equate refrigerated products to old or stale food. However, many Asian specialties "cook–serve" has been replaced by a longer supply chain that includes centralised processing, overnight (or early morning) delivery and extended display times often with no temperature control. Even when foods are prepared at the retail premises, if temperature and time controls are lacking, it is not possible to comply with the Food Standards Code requirements for display of potentially hazardous foods.

The wide variety of often unfamiliar foods might present a challenge for Authorised Officers. Most products will be exactly as they seem — potentially hazardous. A small number of foods appear potentially hazardous but previous studies have revealed that they are low risk foods.

Chinese-style roast meats (such as roast duck, roast chicken, roast pork, BBQ pork)

Despite the concerns about lack of temperature control, Chinese-style roast meats have rarely been implicated in foodborne illness incidents. The conventional cooking method for these products produce internal temperatures high enough to destroy all vegetative pathogens resulting in the absence or very low levels of microbial load on the products immediately after cooking. The products are then promptly moved to the display cabinet, away from the main kitchen, which is vital in avoiding cross-contamination between the cooked and raw meat (Ying, 2000).

NSW Health previously reviewed these products and established a tolerance for BBQ shop practices. The Department of Health Victoria also studied Chinese roast meats and established specific food safety plans for the products. A study in Canada (Lao, Sidhu & Shaw, 2014) also found roast pork to have water activity much lower than 0.85 (0.7 for the skin and 0.81 for the cavity).

The NSW Food Authority's position is that traditionally prepared BBQ pork, duck and chicken on the day of preparation are low risk products until they are cut up for sale. After cutting, the protection provided by scalding, surface drying and roasting in a salty-sugary glaze is lost and the products become perishable and potentially hazardous. The products then must follow the "2-hour/4-hour rule".

The Department of Health Victoria's document includes additional information on other BBQ shop products. It is important to note that the "low risk" status does not extend to the miscellaneous products sold by the BBQ shops such as gizzard, squid and tongue.

Some BBQ shops prepare large batches of roast meats early in the day and sell them until the shop closes. Other shops prepare smaller batches several times throughout the day. The latter practice is recommended by the NSW Food Authority.

Asian cakes and desserts

A number of products look potentially hazardous and like many other cakes, under the IFT/FDA model they are in the query zone. However, the high sugar content and the processing steps may make them not potentially hazardous.

The Department of Health Victoria published FoodAtlas (www.foodatlas.health.vic.gov.au) which provides information about the physical, chemical and compositional properties, their associated food safety risk and the processes they undergo for culturally diverse foods.

In 2017, the NSW Food Authority conducted a survey of rice-based desserts, commonly known as rice cakes and found that steam cooking was effective in destroying any vegetative microorganisms and these products should be safe to be stored at room temperature until the end of the next day (day of manufacturing +1). These products are more likely to spoil before they become unsafe. Further information can be found in '*Rice based desserts*' document on the Food Authority's website www.foodauthority.nsw.gov.au/resource-centre.

Asian fresh noodles and rice rolls

Some types of fresh, Asian-style noodles are potentially hazardous because they have a high-water activity level and a near neutral pH. Contaminated or spoiled products may not look deteriorated, so they must be refrigerated at all times to minimise the risk to consumers.

Retailers sometimes reluctant to put these products in the refrigerator because they harden when refrigerated and some customers may think that the noodles are not fresh. The 'use-by' or 'best-before' date, production date (if it is included), and storage and cooking instructions on the packaging should reassure consumers that the products are fresh. Noodles will soften once they are reheated. The packaging should provide instructions on how to do this.

Note that some types of fresh noodles have been specifically treated and vacuum packaged so they can be stored on the shelf.

Baked goods

Products with fresh cream or custard filled bakery products generally have pH and aw which causes them to be categorised as potentially hazardous. As a result, they need the temperature or time control for safety. This is supported by a history of food poisoning (caused primarily by *Salmonella* and less frequently *S. aureus* and *Bacillus cereus*) attributed to these products.

Mock cream filled products, tarts, cookies, plain cakes, and muffins are typically stored at ambient temperature on the day for which they are manufactured. The products have a relatively low aw, a much drier protective crust and a long-established history of safe ambient storage.

The pH or aw of bread products are generally not low enough to classify the products as not potentially hazardous. However, other characteristics such as the dry protective crust mean that plain bread does not require refrigeration for food safety reasons. The same reason applies to bread rolls with baked-on toppings. However, products that have recently been introduced to the market with readily perishable fillings or fillings/toppings added after baking have been classified as potentially hazardous. They are generally displayed in display cases under time control (the 2-hour/4-hour rule).

Alternative Methods of Compliance

Clause 25 of Food Standard 3.2.2 outlines how food businesses can demonstrate that an alternative system of time or temperature control will not adversely affect the microbiological safety of the food.

Food Regulation 2015 establishes how the use of the word “demonstrate” in the Food Standards Code is to be interpreted:

> Part 6 Clause 38 (1) (d) ‘to demonstrate is to be read as a reference to demonstrate to the satisfaction of the Food Authority’.

Demonstrating alternative compliance

Companies may demonstrate alternative compliance by having validated food safety plans. However, food safety plans are not routinely used in the food sectors where the common issues (identified above) are encountered. If a food safety program is used to demonstrate compliance it must identify the risks inherent in food display. If the food is potentially hazardous then the controls employed for safe display must be validated and systematically monitored. This approach has been used by the Victorian Department of Health for Chinese roast meats.

Companies may also demonstrate compliance based on sound scientific evidence or written guidelines published by the relevant food industry. In both cases there must be documented evidence of the completion of a suitable study. This will often be a challenge study, which is discussed in the previous section, but could also be based on microbiological growth models or an expert report.

For more information on alternative compliance, please refer to the ‘*Developing Innovative Food Safety Control Measures’* document on the Food Authority’s website.

Conclusion

There are a number of important questions that a business must answer when deciding if temperature or time control is required for food on display:

1. Could the food contain a pathogen that can cause foodborne illness if it multiplies? With a few exceptions, such as commercially canned foods, the answer to this question is “yes”. Cooked foods can have residual contamination in the form of heat resistant spores. Foods handled after cooking are exposed to further contamination by pathogenic bacteria.
2. Will the food support the growth of pathogenic bacteria? The tables and charts on page 11 and in the Appendices provide guidance on this question. All or parts of most meals will readily support pathogen growth and their safety is dependent on temperature or time-controlled display.
3. Is the food too dry to support pathogen growth? The answer is “yes” for a few ready-to-eat foods such as jerky and fruit cake. For most foods the answer is “no”, and pathogen growth can occur. A laboratory test for water activity can provide an answer but the most perishable components of the food must be tested.
4. Is the food too acidic to support pathogen growth? For some products such as pickles, some sauces and fruit juices the answer is “yes”. For most ready-to-eat foods the answer is “no”. A laboratory test for pH can provide an answer but again the most perishable components must be tested.
5. Are there other factors that might make the food safe?

The final question leads businesses into food technology, expert advice and laboratory testing. If there are sound technical reasons that make temperature or time control unworkable, then the business might have no choice other than to seek an answer to this question.

This protocol is a guide and does not replace good science or good judgment applied by the business to their product and process. Furthermore, this protocol does not limit the ability of the business to develop additional data beyond those described in this protocol to demonstrate the safety of their food product.

The NSW Food Authority considers that any food product that fails to meet the definition of “not potentially hazardous” is subject to the temperature control requirements of the Food Standards Code.

References and further reading

Department of Health Victoria. (2022). FoodAtlas. Retrieved 21 April 2023 from https://www.foodatlas.health.vic.gov.au/

Department of Health and Human Services Tasmania. (n.d.). Food safety program template supplementary practices section for retail and food service businesses – Safe water and food, Sushi, Chinese-style roast meats. Retrieved 21 April 2023 from https://www.health.tas.gov.au/sites/default/files/2021-12/Food_Safety_Program_Template_Supplementary_Practices_Section_DoHTasmania2014.pdf

Food Standards Australia New Zealand. (FSANZ). (2023). Safe Food Australia – A guide to the Food Safety Standards. Retrieved 21 April 2023 from https://www.foodstandards.gov.au/publications/pages/safefoodaustralia3rd16.aspx

Institute of Food Technologists for the Food and Drug Administration of the United States Department of Health and Human Services (IFT/FDA). (2001) Evaluation and Definition of Potentially Hazardous Foods. Comprehensive Reviews in Food Science and Food Safety, April 2003 - Vol. 2 Issue s2 Page 3-109. Retrieved 21 April 2023 from https://www.fda.gov/files/food/published/Evaluation-and-Definition-of-Potentially-Hazardous-Foods.pdf

Lao, W., Sidhu, B. & Shaw, F. (2014). Safety of Chinese roast pork as determined by the water activity of the skin and cavity. BCIT Environmental Public Health Journal. https://doi.org/10.47339/ephj.2014.159

NSW Food Authority. (2017). Rice based desserts. Retrieved 21 April 2023 from https://www.foodauthority.nsw.gov.au/sites/default/files/_Documents/scienceandtechnical/rice_based_desserts_survey.pdf

NSW Food Authority. (2020). Food safety guidelines for the preparation and display of sushi. Retrieved 21 April 2023 from https://www.foodauthority.nsw.gov.au/sites/default/files/2021-01/FI366%202011_%20Food%20Safety%20Guidelines%20for%20the%20Preparation%20and%20Display%20of%20Sushi.pdf

NSW Food Authority. (2022). Developing innovative food safety control measures. Retrieved 21 April 2023 from https://www.foodauthority.nsw.gov.au/sites/default/files/2022-06/developing-innovative-fs-control-measures.pdf

NSW Food Authority. (2023). Guidance on the 2-hour/4-hour rule. Retrieved 21 April 2023 from https://www.foodauthority.nsw.gov.au/sites/default/files/2023-02/guidance-2-4-hour-rule.pdf

United States Food & Drug Administration (FDA). (2017). Food Code. Retrieved 21 April 2023 from https://www.fda.gov/food/fda-food-code/food-code-2017

Ying, J. (2000). Chinese-style barbecued meats: A public health challenge. Canadian Journal of Public Health, 91(5), 386 – 389.

Appendices

Appendix 1. Water activity as the control factor for pathogen growth

Approximate water activity (aw) values for growth of selected pathogens in food (adapted from IFT/FDA, 2001).

Organism	Minimum aw for growth
Campylobacter spp.	0.98
Clostridium botulinum type E	0.97
Shigella spp.	0.97
Yersinia enterocolitica	0.97
Vibrio vulnificus	0.96
Enterohaemorrhagic *Escherichia coli*	0.95
Salmonella spp.	0.94
Vibrio parahaemolyticus	0.94
Bacillus cereus	0.93
Clostridium botulinum types A and B	0.93
Clostridium perfringens	0.943
Listeria monocytogenes	0.92
Staphylococcus aureus	
toxin production	0.88
growth	0.83

Appendix 2. Estimation of water activity during an inspection

Battery powered instruments are available for aw estimation. The instruments can cost several thousand dollars. They are good for screening products, but borderline results should be confirmed by a NATA accredited laboratory.

With mixed foods it is important to test the most perishable component. This is usually the moist component such as cream or custard fillings rather than the cake or pastry case.

Calibration is important and the manufacturer's instructions must be followed.

Product	a_w
Fresh meat, poultry fish	0.99 to 1.00
Fresh fruit, vegetable	0.97 to 1.00
Pudding	0.97 to 0.99
Cured meat	0.97 to 0.95
Eggs	0.97
Natural cheese	0.95 to 1.00
Bread – white	0.94 to 0.97
Baked cake	0.90 to 0.94
Sweetened condensed milk	0.83
Uncooked rice	0.80 to 0.87
Cake icing	0.76 to 0.84
Jam	0.75 to 0.80

Product	a_w
Honey	0.75
Fruit cake	0.73 to 0.83
Parmesan cheese	0.68 to 0.76
Flour	0.67 to 0.87
Dried fruit	0.55 to 0.80
Dried whole egg	0.40
Bread – crust	0.30
Dried whole milk	0.20
Sugar	0.19
Cereal	0.10 to 0.20
Crackers	0.10

Appendix 3. pH as the control factor for pathogen growth

Approximate pH values for growth of selected pathogens in food (adapted from IFT/FDA, 2001).

Organism	Minimum pH for growth
Clostridium perfringens	5.5 – 5.8
Vibrio vulnificus	5.0
Campylobacter spp.	4.9
Shigella spp.	4.9
Bacillus cereus	4.9
Vibrio parahaemolyticus	4.8
Clostridium botulinum	
toxin production	4.6
growth	4.6
Staphylococcus aureus	
toxin production	4.6
growth	4.0
Enterohaemorrhagic *Escherichia coli*	4.4
Listeria monocytogenes	4.39
Yersinia enterocolitica	4.2
Salmonella spp.	4.2

Appendix 4. Estimation of pH during an inspection

Battery powered instruments are available for pH estimation. Unlike aw instruments they are relatively inexpensive. The most economical instruments use a glass electrode and these are not suitable for use adjacent to exposed food. Non-glass probes are available and these are clearly preferable in food service areas. pH meters must be calibrated. Borderline results should be verified by a NATA accredited laboratory.

pH paper or strips can also be used with caution in foods. Narrow range strips that cover about pH 3 to pH 7 are preferred. Results in the critical range between pH 4 and pH 5 should be confirmed by a NATA accredited laboratory.

Product	pH
Camembert cheese	7.4
Cake chocolate	7.2 to 7.6
Egg white	7.0 to 9.0
Fish fresh (most)	6.6 to 6.8
Chicken	6.5 to 6.7
Egg yolk	6.4
Potatoes	6.1
Corn	6.0 to 7.5
Rice cooked	6.0 to 6.7
Ham	5.9 to 6.1
Cheddar cheese	5.9

Product	pH
Peas	5.8 to 7.0
Lamb	5.4 to 6.7
Bread	5.3 to 5.8
Papaya	5.2 to 5.7
Beef minced	5.1 to 6.2
Cottage cheese	5.0
Carrots	4.9 to 5.2
Mayonnaise	4.2 to 4.5
Oranges	3.1 to 4.1
Jam	3.1 to 3.5

Appendix 5. United States Food and Drug Administration definition of Time/Temperature Control for Safety Food (formerly "potentially hazardous food" (PHF)) (US FDA, 2017)

1. "Time/temperature control for safety food" means a food that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation.
2. "Time/temperature control for safety food" includes:
    a. An animal food that is raw or heat-treated; a plant food that is heat-treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation;

    and

    b. Except as specified in Subparagraph (3)(d) of this definition, a food that because of the interaction of its aw and pH values is designated as Product Assessment Required (PA) in Table A or B of this definition:

Table 3 Interaction of pH and aw for control of spores in food heat-treated to destroy vegetative cells and subsequently packaged.

A_w values	pH: 4.6 or less	pH: > 4.6 – 5.6	pH: > 5.6
≤ 0.92	non-TCS food*	non-TCS food	non-TCS food
> 0.92 – 0.95	non-TCS food	non-TCS food	PA**
> 0.95	non-TCS food	PA	PA

* TCS food means Time/Temperature Control for Safety Food

** PA means Product Assessment required

Table 4 Interaction of pH and aw for control of vegetative cells and spores in food not heat-treated or heat-treated but not packaged.

Aw values	pH: < 4.2	pH: 4.2 – 4.6	pH: > 4.6 – 5.0	pH: > 5.0
< 0.88	non-TCS food	non-TCS food	non-TCS food	non-TCS food
0.88 – 0.90	non-TCS food	non-TCS food	non-TCS food	PA
> 0.90 – 0.92	non-TCS food	non-TCS food	PA	PA
> 0.92	non-TCS food	PA	PA	PA

3. “Time/temperature control for safety food” does not include:

(a) An air-cooled hard-boiled egg with shell intact, or an egg with shell intact that is not hard-boiled, but has been pasteurized to destroy all viable salmonellae;

(b) A food in an unopened hermetically sealed container that is commercially processed to achieve and maintain commercial sterility under conditions of non-refrigerated storage and distribution;

(c) A food that because of its pH or aw value, or interaction of aw and pH values, is designated as a non-TCS food in Table A or B of this definition;

(d) A food that is designated as Product Assessment Required (PA) in Table A or B of this definition and has undergone a Product Assessment showing that the growth or toxin formation of pathogenic microorganisms that are reasonably likely to occur in that food is precluded due to:

(i) Intrinsic factors including added or natural characteristics of the food such as preservatives, antimicrobials, humectants, acidulants, or nutrients,

(ii) Extrinsic factors including environmental or operational factors that affect the food such as packaging, modified atmosphere such as reduced oxygen packaging, shelf life and use, or temperature range of storage and use, or

(iii) A combination of intrinsic and extrinsic factors; or

(e) A food that does not support the growth or toxin formation of pathogenic microorganisms in accordance with one of the Subparagraphs (3)(a) - (3)(d) of this definition even though the food may contain a pathogenic microorganism or chemical or physical contaminant at a level sufficient to cause illness or injury.

More information

- Visit the Food Authority's website at www.foodauthority.nsw.gov.au
- Email the Helpline at food.contact@dpi.nsw.gov.au
- Phone the Helpline on 1300 552 406.