

Appendix 2: The use of time as a control for potentially hazardous food

Potentially hazardous food must be kept under temperature control to minimise the growth of foodborne pathogens and prevent the formation of toxins in the food. Toxin formation is not limited to toxins produced by pathogens; toxins may also be formed in foods through compositional degradation.

In practice in general terms, food must be kept at or below 5°C, or at or above 60°C, unless the food business can demonstrate that another practice it uses is safe (as per clause 25 of Standard 3.2.2). The temperature range between 5°C and 60°C is often referred to as the 'temperature danger zone' because food poisoning bacteria can grow rapidly in this range. However, short periods in this temperature range are unlikely to allow foodborne pathogens to grow (or produce toxins) to unsafe levels.

This appendix provides science-based guidance on the use of time as an alternative control for potentially hazardous food.

General guidance on using time as an alternative control

If a business uses time to control potentially hazardous food, it must ensure food handlers have and apply the appropriate skills and knowledge to use time correctly. This skills and knowledge would include, for example:

- knowledge that a type of food is potentially hazardous and able to support the growth of pathogenic microorganisms at temperatures between 5°C and 60°C
- knowledge that certain pathogens may be associated with certain foods
- knowledge that the time potentially hazardous food is kept between 5°C and 60°C is important because bacteria multiply faster (exponentially) as this time extends
- skill to monitor the time that potentially hazardous food is between 5°C and 60°C, which may accumulate over multiple steps (e.g. over receipt, transport and display periods)
- skill to manage the food correctly (e.g. use, refrigerate or discard it) depending on the times and temperatures that have been used during food handling operations.

The business will need to carefully consider any risks of pathogen growth or toxin production during its food handling practices. The growth rate of pathogens in potentially hazardous food depends on the:

- pathogen of concern in the particular food — some pathogens may be intrinsically present in the food because of its origins and other pathogens may have been introduced by cross contamination. Each pathogen has its own temperature tolerance and optimum growth temperature.
- characteristics of the food — its pH, water activity, solidity, complexity of ingredients, etc. will determine how favourable the food environment is for each pathogen to multiply or produce toxins
- starting temperature that food is brought out of temperature control — that is, whether it is refrigerated (5°C) or has been cooked (60°C)
- temperature of the environment — for example, temperatures greater than 21°C would allow most foodborne pathogenic bacteria to grow faster than at 10°C.

Taking these factors into account, the final level of pathogens (or toxins they may produce) will depend on the initial number of pathogens present in the food and the total time the food is between 5°C and 60°C (note that food safety risks may be greater if pathogen levels are higher to start with). The business will need to demonstrate that the time it has kept food between 5°C and 60°C has not allowed pathogen or toxin levels to adversely affect the safety of the food.

Ready-to-eat potentially hazardous food

As a general rule, the total time that a ready-to-eat potentially hazardous food can be kept at temperatures between 5°C and 60°C is **4 hours**. After this time the food needs to be discarded.

Generally, cooked potentially hazardous foods should be either served immediately, hot held at temperatures of 60°C or above, or cooled for later use as per subclause 7(3) of Standard 3.2.2. However, it is recognised that there are some circumstances where cooked food is kept at temperatures below 60°C; for example during further food preparation or transport, or when displaying food for service for short periods (e.g. at a temporary stall). In these circumstances, the food can be used or sold up to 4 hours but once 4 hours has passed, it needs to be thrown out.

It is important to note that the total time is the **sum** of any periods that the hot food is at temperatures below 60°C (i.e. the time is cumulative). For example, the time includes any transport and display time at temperatures between 5°C and 60°C.

How does this work in practice for hot food?

- Timing should start from when the temperature of the cooked ready-to-eat potentially hazardous food drops below 60°C (e.g. as checked with a probe thermometer).
- The cooked food can be used, sold or discarded within 4 hours.
- Once cooked food has been held for a total of 4 hours below 60°C, the time limit is exceeded and the food needs to be discarded.

Displaying hot food below 60°C

A food business owner prepares a variety of cooked meat and vegetarian dishes and transports them to a market stall to display and sell over lunch. To keep the food safe, the business does the following:

- The food is cooked in the morning and immediately placed in insulated containers to keep it hot.
- The food is transported to the stall and placed in display units.
- The display units at the stall can keep food warm, but cannot hold the food at temperatures of 60°C or above. Because of this, the business knows that the food should not be kept for more than 4 hours.
- The business needs to monitor when the food first cools below 60°C (e.g. 11 a.m.). The business adds 4 hours to this time so it knows when the 4-hour period will be up (3 p.m.), and makes a note of this time.
- Once the 4-hour limit is reached (3 p.m.) any remaining food is removed from display and discarded.

Example

The 2-hour/4-hour rule for ready-to-eat potentially hazardous food brought out of refrigeration

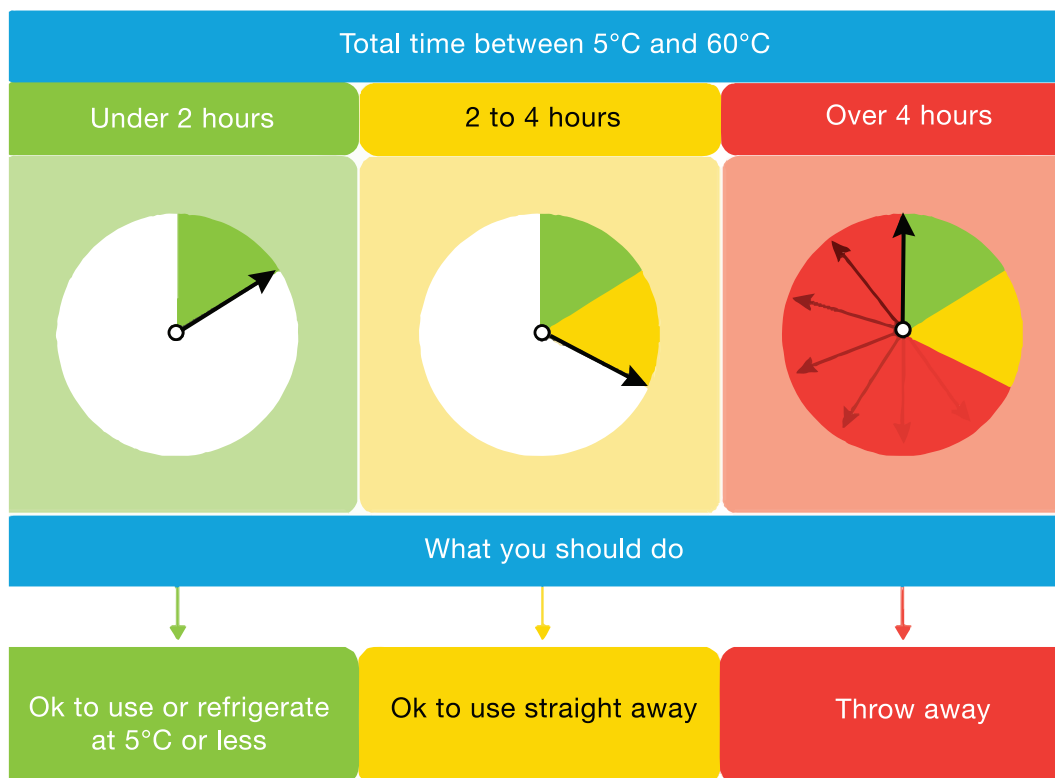
The 2-hour/4-hour rule is a rule of thumb that has been designed to help businesses deal with some of the practicalities of handling refrigerated ready-to-eat potentially hazardous food. It recognises there may be several circumstances where this type of food is brought out of refrigeration and held at temperatures above 5°C for convenience; for example while preparing food at a kitchen bench or displaying food for service for short periods.

The rule provides options for what can be safely done with ready-to-eat potentially hazardous food **brought out of refrigeration**, depending on how long it has been at temperatures above 5°C.

If the total time is:

- less than 2 hours, the food may be used, or refrigerated for later use
- between 2 and 4 hours, the food may still be used
- 4 hours or longer, the food needs to be thrown out.

Figure: The 2-hour/4-hour rule for potentially hazardous food brought out of refrigeration (image provided courtesy of SA Health)



The rule is designed so that once the 2-hour mark has been passed, the food cannot be re-refrigerated for later use: the business must use it or discard it before the total 4-hour time limit.

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. This includes food preparation time (e.g. making sandwiches or sushi), any subsequent transport time (e.g. transferring from a caterer's business to the place of consumption, or from a preparation kitchen to a market stall) and any time periods that food is held for service or display between 5°C and 60°C.

How does the 2-hour/4-hour rule work in practice?

- Timing should start from when ready-to-eat potentially hazardous food is brought out of refrigeration (at 5°C or below).
- If food is held for no more than 2 hours above 5°C, it can be put back in the refrigerator to use later.
- Once food is held for more than 2 hours above 5°C, it needs to be used, sold or discarded before the total time of 4 hours is exceeded.
- Once food has been held for a total of 4 hours above 5°C, the time limit is exceeded and it must be discarded.
- An example template that may be helpful for logging time as a control is provided in Appendix 8.

Extra caution may be necessary in some cases. Some foods should not be kept at higher ambient temperatures (e.g. > 25°C) for 4 hours; a maximum of 2 hours is advised. For example, the Australian Egg Corporation (AECL) recommends that egg products that are to be held warm (e.g. foods with a hollandaise or béarnaise sauce) are prepared just before service and held only for that service period (generally up to 2 hours) (AECL 2015). See also Appendix 4. Extra caution is advised with foods served to vulnerable people (young, elderly, ill or pregnant).

Food prepared and displayed at ambient temperature

A business prepares sushi and displays it for sale at ambient temperature on a conveyor belt. The sushi rice the business uses has been acidified to pH 4.6 so is not in itself a potentially hazardous food. However, meat, seafood and vegetable fillings are added to this rice, so the final product is potentially hazardous. To display the food safely, the business uses the 2-hour/4-hour rule as follows:

- The time the fillings are removed from refrigeration is noted, as this is the start of the 2-hour/4-hour period (e.g. 11 a.m.). The fillings are added to the sushi rice and the final products displayed for sale.
- Before the 2-hour mark (1 p.m.) the business assesses how well the sushi is selling, and decides whether to put some sushi back into refrigeration for later use.*
- At the 4-hour mark (3 p.m.), the business discards any remaining sushi on display.

*If leftover, re-refrigerated sushi is brought out to display later, the business needs to sell this sushi within 2 hours (since this makes a total of 4 hours out of refrigeration) or discard it.

Example

Applying time as a control for potentially hazardous food

How can businesses keep track of the time?

It is a good idea to keep records of the times that food is out of temperature control, and/or to identify displayed food with time stickers or colour-coded plates, etc. These measures will help the business keep track of how long food has been held in the temperature danger zone, and also to demonstrate the safety of their practice with potentially hazardous foods as per clause 25 of Standard 3.2.2.

An example template for logging the time that ready-to-eat potentially hazardous food is out of refrigeration is provided in Appendix 8.

What if cooked food has been cooled – does the cooling time count?

No, cooling is a separate process. The 2-hour/4-hour rule only applies to ready-to-eat potentially hazardous food once it has been removed from refrigeration. It can be applied to previously cooked foods that have been cooled according to clause 7(3) of Standard 3.2.2, because this cooling process ensures pathogens that survived the cooking process will not be able to multiply to dangerous levels as the food cools. So, when this food is removed from refrigeration it can still be safe for up to 4 hours.

What if the food has been prepared by another business?

If a food business wishes to use the 2-hour/4-hour rule for ready-to-eat potentially hazardous food it has not itself cooked or otherwise processed to ensure its safety, they will need to know the temperature history of the food; for example, whether the food spent any time in the temperature danger zone during storage, preparation, or transport. If any of the available time has been 'used up' before the business receives the food, this time needs to be counted towards the total 4-hour period. If the business does not know this history, it should not make use of the 2-hour/4-hour rule and the food will need to be kept at or below 5°C or at or above 60°C.

Example

Preparing food using cooked ingredients from another supplier

A café purchases precooked and chilled meats from a supplier to make salads and wraps that will be displayed at ambient temperature over the lunch period. To demonstrate this practice is safe, the café receives advice from the meat supplier that the cooked meat was cooled as per subclause 7(3), and has spent less than 30 minutes between 5°C and 60°C by the time it is delivered. The café notes that it takes another 30 minutes to prepare the salads and wraps, leaving less than 3 hours for safe display for sale at ambient temperature. The salads and wraps are identified with stickers on wrapped food or on the display platters that indicate they are to be sold within 3 hours' time or discarded.

Can food be brought in and out of temperature control more than once?

Yes, as long as the periods are for less than 2 hours each and the total time out of temperature control is no longer than 4 hours. The business should keep track of each time period the food is between 5°C and 60°C so it is sure when the total 4 hours is used up. A sample template for logging times is provided in Appendix 8.

Displaying potentially hazardous food at room temperature more than once

A café cooks and cools chickens the day before they are used to make sandwiches. It then prepares the sandwiches with the cold chicken and displays them at ambient temperature (about 21°C) over the lunch period. If sales are slow, the business would like to refrigerate some sandwiches for sale the following day. To make sure this practice is safe, the business:

- cools the cooked chickens according to the temperatures and times specified in Standard 3.2.2 subclause 7(3) (this cooling period does not count towards the 2-hour/4-hour rule);
- records the time when the cooled chicken is first removed from refrigeration on the next day to make the sandwiches (this is when the 2-hour/4-hour rule starts);
- adds 2 hours to this time and notes that this will be the time the chicken sandwiches are to be put back into refrigeration for use the next day (using the 2-hour part of the rule);
- adds a further 2 hours to note that this will be the time any remaining chicken sandwiches are to be discarded (using the 4-hour part of the rule).

If the business chooses to keep any sandwiches for use the following day, the chicken must not have been out of refrigeration for more than 2 hours the first day. When the chicken sandwiches are removed from refrigeration for sale the following day, they need to be sold or discarded within 2 hours (so the total is less than 4 hours).

What if a business uses time periods other than those specified in this appendix?

A business may still use any temperature/time combination with any potentially hazardous food if it can demonstrate the practice it uses is safe (as per clause 25 of Standard 3.2.2).

What is the origin and science behind using time as a control?

The advice on using time as a control provided in this appendix was originally developed from information in the US Food Code 1999 and the UK Food Safety (Temperature Control) Regulations 1995. The US and UK guidance has been more recently incorporated into, respectively, the US Food Code 2013 edition (US FDA 2013) and 2007 guidance from UKFSA accompanying European EC Regulation 852/2004 The Food Hygiene Regulations 2006 (UK FSA 2007).

The guidance is largely based on scientific modelling and food experiments conducted in the US. This research included looking at worst-case scenarios, to predict the growth of target pathogens in food allowed to sit at ambient temperatures, and in hot foods removed from 60°C control. Recently, FSANZ conducted modelling on pathogen growth in foods brought out of refrigeration. Details are provided below.

A. Cold foods held out of refrigeration:

- US modelling simulated *Listeria monocytogenes* growth in food held constantly at a range of temperatures including ambient (23.9°C) and warmer (35°C). Results showed that growth of this pathogen is slow enough over 4 hours to not adversely affect the food's safety.
- FSANZ modelling simulated *Salmonella* growth in chilled food exposed to a range of temperatures from 5°C up to 30°C, for 2 hours and for 4 hours. For most temperature scenarios the growth was considered slow and low risk. However, as temperatures rose and times extended, the growth of *Salmonella* significantly increased. These results indicate some high-risk foods may need to be treated with extra caution when applying the 4-hour limit at warmer temperatures.
- The US and FSANZ worst-case modelling scenarios were based on liquid broths held constantly at warm temperatures, so the results exaggerate the pathogen growth rate in actual food. In most cases, foods would equilibrate more gradually with the surrounding environment's temperature, so generally pathogen growth is likely to be slower than modelling suggests.

B. Hot foods held below 60°C:

- The US Food and Drug Administration conducted in-house laboratory experiments with *Clostridium perfringens* as the pathogen of concern in cooked foods allowed to cool to ambient conditions.
- *C. perfringens* spores were inoculated into foods that were cooked and then cooled to temperatures that promote rapid pathogen growth. The growth data indicated that food should remain safe in these conditions over 4 hours.

The 2-hour component of the 2-hour/4-hour rule in Safe Food Australia has been incorporated to allow for the practicalities of businesses displaying refrigerated ready-to-eat food for short periods. It provides a safe, science-based option of re-refrigerating the food for later use.

Further information

Information on the US scientific work is available in Annex 3 of US Food Code 2013. Enquiries on the FSANZ modelling work may be made by contacting FSANZ.

For recommendations on the use of eggs, refer to AECL 2015 *The Culinary Uses of Eggs. Identification of Raw/Low-Cooked Egg Dishes that May be of Food Safety Concern*.