DEVELOPING INNOVATIVE FOOD SAFETY CONTROL MEASURES

A GUIDANCE DOCUMENT FOR FOOD BUSINESSES TO DEMONSTRATE EQUIVALENT FOOD SAFETY OUTCOMES USING AN ALTERNATIVE METHOD OF COMPLIANCE

NSW GOVERNMENT Food Authority

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May 2022
FI385/2205

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Definitions

Term	Definition
Equivalence (of a food safety control measure)	The principle of equivalence is based on the recognition that the alternative control measure/method can achieve the same level of food safety as that achieved by applying an accepted specified measure.
Food safety control measure	Any action or activity that can be used to prevent, eliminate or reduce a significant hazard to an acceptable level. *Cook chill for foodservice and manufacturing (2008)*
Food safety program	A program set out in a written document retained at the food premises of the business, including records of compliance and other related action, that – (a) systematically identifies the potential hazards that may reasonably expected to occur in all food handling operations of the food business; (b) identifies where, in a food handling operation, each hazard identified under paragraph (a) can be controlled and the means of control; (c) provides for the systematic monitoring of those controls; (d) provides for appropriate corrective action when that hazard, or each of those hazards, is found not to be under control; (e) provides for the regular review of the program by the food business to ensure its adequacy; and (f) provides for appropriate records to be made and kept by the food business demonstrating action taken in relation to, or in compliance with the food safety program. *Standard 3.2.2 of the Food Standards Code*
Food Standards Code	It refers to the Australia New Zealand Food Standards Code. It includes standards for food composition, level of contaminants and labelling of the food supply in Australia and New Zealand. These standards are adopted by the States, Territories and New Zealand to form the local food regulations and they are enforced on a local level.
Hazard	A biological, chemical or physical agent in, or condition of, food that has the potential to cause an adverse health effect in humans. *Standard 3.1.1 of the Food Standards Code*
Monitoring	It includes checking, observing or supervising in order to maintain control. [The act of regularly checking to see that food safety hazards are under control, procedures are being correctly implemented and food safety compliance is followed]. *Standard 3.2.1 of the Food Standards Code*

Term	Definition
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. Examples of potentially hazardous foods: • raw and cooked meat/poultry or foods containing raw or cooked meat/poultry (e.g. burgers, curries, kebabs, pate and meat pies), • foods containing eggs (cooked or raw), beans, nuts or other protein-rich food (e.g. batter, mousse, quiche and tofu), • dairy products and foods containing dairy products (e.g. milk, dairy-based desserts, bakery products filled with fresh cream or with fresh custard), • seafood (excluding live seafood) and foods containing seafood (e.g. sushi), • sprouted seeds (e.g. bean sprouts and alfalfa), • prepared fruits and vegetables (e.g. cut melons, salads and unpasteurised juices), • cooked rice and both fresh and cooked pasta, and • foods that contain any of the above foods (e.g. sandwiches, pizzas and rice rolls). *Standard 3.2.2 of the Food Standards Code & Safe Food Australia – Appendix 1 (2016)*
Pre-requisite programs	Practices and conditions needed prior to and during the implementation of HACCP and which are essential for food safety.
Validation	A study to obtain evidence to confirm that a control measure or combination of control measures is complete, effective and will deliver the expected food safety outcomes.
Verification	The application of methods, procedures and tests in addition to monitoring to determine whether a control measure is or has been operating as intended.

Introduction

The NSW Food Authority (the Food Authority) has the legislative responsibility to ensure food businesses in NSW comply with food legislation, including the *Food Standards Code (the Code), Food Act 2003 (NSW)* and *Food Regulation 2015*.

Food legislation contains requirements which can be broadly grouped into two main categories:

- prescriptive processing parameters, such as
  - milk must be pasteurised by heating to a temperature of no less than 72ºC and retaining at such temperature for no less than 15 seconds (*Standard 4.2.4 of the Code*).
  - when cooling cooked potentially hazardous food, cool the food within two hours from 60ºC to 21ºC; and within a further four hours from 21ºC to 5ºC (*Standard 3.2.2 of the Code*).
- outcome-based food safety standards, such as
  - food for sale must be safe and suitable (*Standard 3.1.1 of the Code*).
  - when storing food, store the food in such a way that it is protected from the likelihood of contamination (*Standard 3.2.2 of the Code*)

The major benefit of outcome-based food safety standards is that they provide the opportunity for food businesses to develop innovative solutions to control food safety hazards. Even with some of the prescriptive food standards, more recently, an 'equivalence clause' is often included which allows food businesses to use an alternative, innovative food safety control measure.

The principle of equivalence in food safety is based on the recognition that the same level of food safety can be achieved by applying alternative food safety control measures. In an environment where food regulations are expected to be less prescriptive, demonstration of equivalence becomes a useful tool for the regulators to ensure the safety of food without unnecessarily hindering innovation in the food industry.

The Food Authority encourages businesses to use appropriate alternative control measures, however be aware that the responsibility is on each food business to demonstrate to the Food Authority that it will achieve an equivalent outcome and not adversely affect the safety and suitability of the food.

Although equivalence determinations will be carried out by the Food Authority on a case-by-case basis, there are general principles that apply, such as:

- the assessment is to be based on objective, sound scientific evidence,
- the outcome is to be consistent with national and international approaches where applicable,
- the process is to be transparent, and
- external expert consultation may be sought, if required.

Foods that are subject to prescriptive processing requirements

This category of foods tends to have processing parameters that have been well defined in order to control or reduce a specific hazard. Prescriptive requirements normally relate to the time and temperature of thermal cooking processes (such as pasteurisation or canning), cooling, or storage and display of foods.

The processes contained within the prescriptive regulation are based on historical data to deliver a consistent reduction in the number of microorganisms. An alternative method or process would be considered equivalent if it consistently achieves the same level of safety.

Some common examples:

Process	Alternative compliance
Pasteurisation	According to *Standard 4.2.4* of the Code, any alternative method for pasteurisation must ensure that: (a) the use of any other heating time and temperature combination gives an equivalent or greater lethal effect on any pathogenic microorganisms in the milk; or (b) the use of any other process provides an equivalent or greater lethal effect on any pathogenic micro-organisms. NOTE on (a) With a well characterised process such as pasteurisation of milk, there is sufficient information to facilitate selecting various heating time/temperature combinations to achieve equal or greater lethal effect on pathogenic microorganisms. Such alternative combinations of heating time and temperature are already recognised as equivalent in the pasteurisation requirement in the Code. It is expected that businesses will ensure that alternative production and manufacturing processes are as effective as the conventional processes. A business using an alternative combination of heating time and temperature would **not** need to make an application to the Food Authority, but they would need to have a validated process and have the relevant information to justify that process when asked by a food safety auditor. NOTE on (b) Any other process used would need to be validated by the business and assessed by the Food Authority. The business **must** submit an alternative compliance application.
Temperature control for storage and display of potentially hazardous food	For temperature control for storage and display of potentially hazardous food between 5ºC and 60ºC, the '2-hour / 4-hour rule' is generally regarded as a suitable alternative compliance method. The Food Authority has developed a number of guidelines on this topic (see Appendix 1). If a business wants to use a longer time than 4 hours, the business **must** submit an alternative compliance application and provide evidence that the proposed method will not compromise the safety of the food.

For the use of new technology, a food business may need to rely on published information to demonstrate the effectiveness. In the absence of published validation studies on the alternative method or technology, the business must undertake product development and validation studies under the supervision of a suitably qualified food scientist.

The Food Authority may place specific conditions upon validation trials and the disposition of products resulting from the trials. A report on the trials must be submitted to the Food Authority for technical assessment when it is available.

Foods manufactured under generic food safety requirements

The principal requirement is that all food for sale must be safe and suitable. Food businesses may process food in a number of different ways, but the main outcome is to ensure that it does not adversely affect the microbiological safety of the food.

The Food Authority's role in equivalence determination for the consistent application of the Code is expected to fall largely in this group of issues. Demonstrating the food safety outcome under these generic food safety requirements may be slightly more difficult. Food businesses are encouraged to contact the Food Authority early in the process to determine what type of information is required in an application.

Purpose and scope

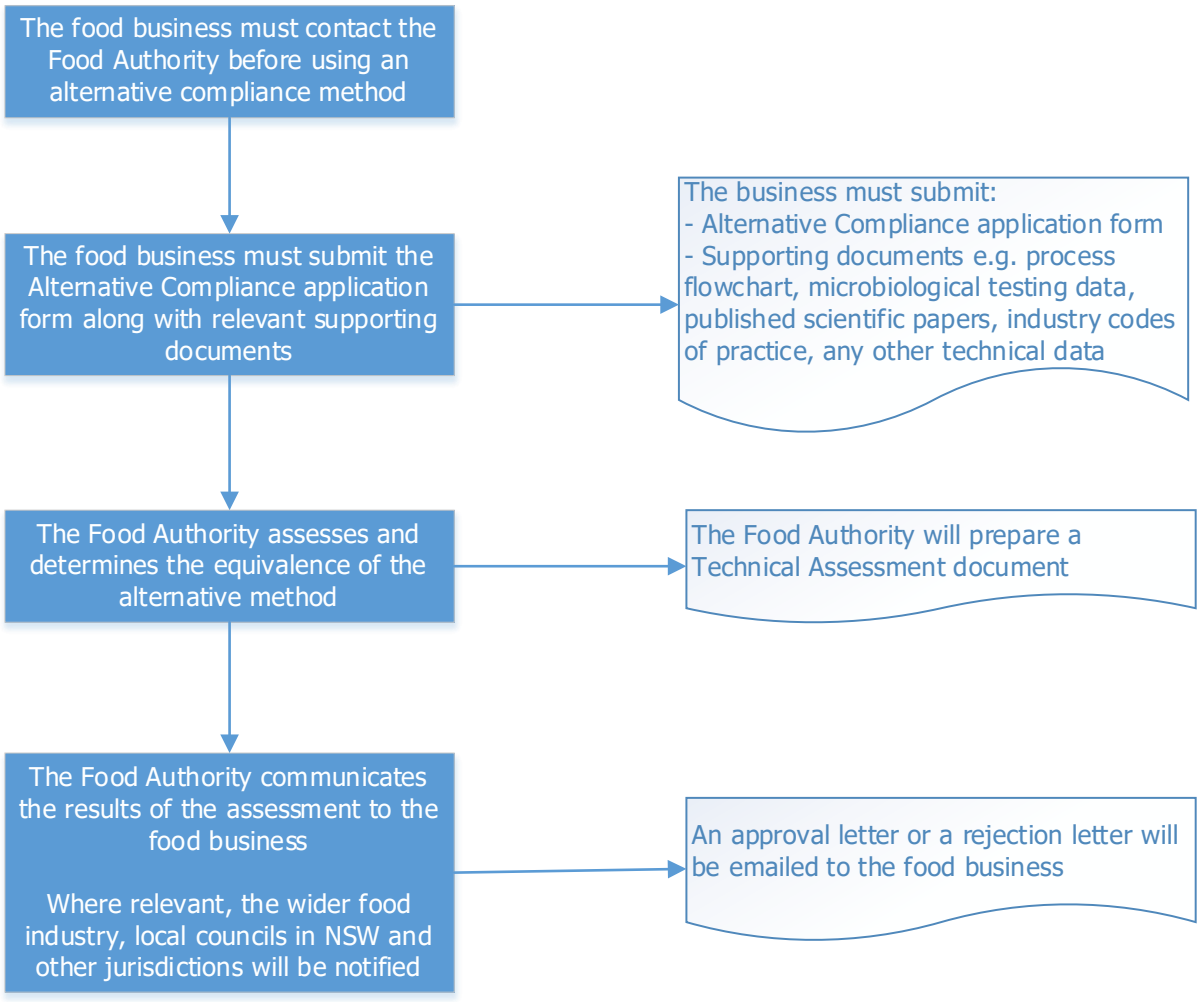
The Food Authority has developed this guideline to provide information on how the Food Authority determines the equivalence of a food safety control measure/alternative compliance method and the type of information that food businesses should collate in order to demonstrate the effectiveness of their alternative method.

Making an application to use an alternative method of compliance

To ensure continued compliance with all relevant food legislation, the Food Authority must be notified **before** the business uses the alternative compliance method. Otherwise the business runs the risk of being found non-compliant with specific regulatory requirements in the Code or other relevant food safety standards.

For all alternative methods of compliance, the food businesses must submit the application form and any supporting evidence. The supporting evidence must demonstrate that the use of the alternative method of compliance will achieve an equivalent outcome to the relevant food safety standard and not adversely affect the safety and suitability of the food.

The flowchart below outlines the process for making an application to use an alternative compliance method.



The assessment process

The process of equivalence determination by the Food Authority is divided into three sequential stages:

Stage 1: a food business makes an application to the Food Authority with the relevant information to support the alternative compliance method.

Stage 2: the application is assessed to identify the food safety issues and any additional scientific evidence that will allow the equivalence determination to be made. A Technical Assessment document will be prepared.

Stage 3: the equivalence determination is communicated to the food business (i.e. accepted or rejected). Where relevant, the wider food industry, local councils in NSW and/or other jurisdictions will be notified of the approved alternative method.

Stage 1 – Application for alternative method of compliance

The food business must contact the Food Authority at food.sciencesupport@dpi.nsw.gov.au before submitting an alternative compliance application. This way, both parties can discuss the type of information the Food Authority needs to conduct the technical assessment. This will save time during the assessment process, as both parties will have already agreed to the information required for the assessment.

Identify the objective basis of comparison

To determine the equivalence of measures in a consistent manner, the business must first identify an objective basis on which to base the comparison of measures and their contribution to safe food, for example the degree of microbial hazard reduction achieved.

To be considered equivalent, the alternative method must achieve at least the same level of acceptable risk as that achieved by the specified measures already in place. The comparison must be carried out objectively utilising all information available on the method currently in place and the alternative method relevant to the equivalence determination.

Information required for establishing an objective basis of comparison includes:

(a) the purpose of the specified measure in place and how it contributes in achieving the acceptable level of risk.

For example, pasteurisation is a specified measure in place with the purpose of controlling the microbial hazards associated with milk. This process operates in a system of hazard control applied consistently by the dairy industry;

(b) an expression of the level of control of the hazard in a food that is achieved by the measure.

For example, pasteurisation achieves at least a 5-log pathogen reduction, so the alternative method/s would be expected to achieve at least the same level of hazard reduction;

(c) the scientific basis for the alternative method including risk assessment as appropriate and any additional information on the system within which the alternative method operates such as quality control, audits and certification.

An objective basis of comparison may be qualitative (e.g. legislation and enforcement) or quantitative (e.g. level of hazard control achieved by the alternative method) or a combination of qualitative and quantitative elements.

Identify the hazards and food safety control measure(s)

All potential hazards associated with the food undergoing the equivalence determination must be taken into account, including those hazards associated with the production/manufacturing environment, the food or ingredients. Information provided must demonstrate (but is not limited to):

(a) the association of the hazard with the food and processing environment,

(b) the levels at which the hazards may be present,

(c) factors which may influence its presence and/or level of contamination, and

(d) the pathogenic characteristics of the organism (including infective dose).

The food safety control measures subject to the equivalence determination must be clearly described. The hazards controlled by each measure should be identified and information provided to demonstrate that the hazards are consistently controlled. The information should include each hazard management step, validation of each step, production flowcharts and performance criteria for processing steps.

It is the responsibility of the food business to provide, or if necessary generate, any comparative data that may be needed for the determination of equivalence. While ideally the equivalence determination should be quantitative rather than qualitative in nature, there may not always be sufficient data or the analytical tools to take this approach; for example the complex nature of microbial pathogenicity and pathogen-matrix interactions may constrain the availability of quantitative information. The analysis may therefore be partially constrained by the lack of supporting scientific data, but the process of conducting the determination will allow these gaps to be identified..

In the submission, the business must also provide scientific information demonstrating the effectiveness of the alternative food safety control measures under consideration. The information should examine the level of each relevant hazard present during various steps in the production/manufacturing chain and an estimate provided of the effectiveness of each step in the process. The information may be derived from the scientific literature, laboratory studies or predictive modelling and should cover a range of conditions that may impact the processing environment in order to demonstrate that the alternative method is consistently effective.

Evidence that may be included to support an application includes (but is not limited to):

(a) temperature profile (e.g. cooking data, cooling data, temperature of products throughout the chain),

(b) microbiological testing data (e.g. food testing results, environmental swabs results),

(c) food characteristics (e.g. pH, water activity, additives, CO_2 level in the packaging),

(d) logs of equipment times and processing temperatures,

(e) shelf life study,

(f) published scientific paper,

(g) industry codes of practice, or

(h) any relevant scientific or technical data.

The data provided to the Food Authority must be for at least two batches to ensure that the batch-to-batch variation can be accounted for.

Submit the application form and supporting documents

Once the food business has all the relevant information, the business must fill in the application form for an alternative method of compliance. The template of the application form can be found on the Food Authority's website.

The application form should precisely define the following:

(a) the hazard(s) to be controlled,

(b) the current food safety control measure and/or legal requirement that the alternative method is replacing,

(c) the alternative method of compliance to be considered, and

(d) the system in place to ensure that the alternative method is working as intended.

It is expected that the application is supported by sufficient scientific and technical data to allow independent evaluation by the Food Authority's officers as appropriate.

The information provided by the food business will be reviewed for its relevance and to identify any major information gaps. At this stage, considerable communication between the Food Authority and the food business is expected to ensure that information is complete and additional information needed is supplied.

For a pre-validated procedure or technology, any existing relevant independent validation data must be provided in the application to the Food Authority. This may mean that a full-scale on-site validation trial may not be needed. It is also recognised that it will not always be practical for an on-site validation trial to be conducted before an alternative method or new technology is introduced. In these circumstances the extent of the trial will be determined by the Food Authority.

Commercial-in-confidence

All information supplied in an alternative compliance application will be treated as commercial-in confidence information. As such, the applicants may be requested to prepare a non-confidential summary for discussion with industry representatives in the Food Authority's consultative committees or independent experts as necessary.

On-site validation trial and ongoing monitoring

The Food Authority may require the food business to undertake an on-site validation trial in conjunction with an independent organisation. The Food Authority may also place specific conditions upon the validation trial and the use of the end products produced during the trial.

The Food Authority cannot design or plan the validation trial as it must be able to evaluate the trial results objectively. The independent organisation nominated will oversee the trial and produce a report of the trial results and an opinion on the success of the validation trial. The results of the validation trial must be included in the application dossier.

After validation is complete, it is essential that any introduced method or technology is monitored on site to verify the validation data and ensure ongoing compliance with the food safety requirements. In its application to the Food Authority, the food business must include a plan specifying the ongoing monitoring of the alternative method of compliance, including what will be monitored, how often, and how (the method).

Stage 2 – Determining the equivalence of measures

Once an application is received, the Food Authority will identify the internal expertise required to undertake the equivalence determination. The expertise required will vary according to the hazards being considered, relevant food safety measures and the public health impact of those measures.

The time taken to complete the assessment depends on the type of alternative method(s) (a pre-validated method already approved somewhere else vs a novel process) and the quality of information provided by the food business. The business is not permitted to use the alternative method(s) until it receives an approval letter from the Food Authority.

The second stage determines the equivalence of the alternative method by evaluating the effectiveness of the proposed alternative method. The determination requires a systematic analysis of the impact of the proposed method on each of the identified hazards and an evaluation of the impact of the proposed method on the overall food safety outcomes. A similar analysis will be performed for the currently used or specified food safety measures.

After considering all relevant information, the Food Authority will make its determination. The outcome of the process may be:

(a) equivalence is determined, conditional on meeting certain requirements,

(b) equivalence not determined because the risk management measures do not provide a level of safety equivalent to the currently permitted measures, or

(c) equivalence not determined because of a specific and identified information gap.

Equivalence can be accepted for a specific method or a combination of methods related to a certain product or categories of products, or on a system-wide basis.

Stage 3 – Communicating the outcome of equivalence determination

The outcome of the equivalence determination will be documented in a letter to the food business. The letter will include identification of the parameters that form the basis of the equivalence determination.

If equivalence is determined, an approval letter will be sent. The approval may include specific conditions under which the alternative method or process is allowed.

Where deemed necessary, the Food Authority will communicate the approval of alternative method to the wider industry through the consultative committee, local councils in NSW and/or other jurisdictions in Australia.

If equivalence is not determined because the risk management measures do not provide a level of safety equivalent to the currently permitted measures or an information gap is identified, a rejection letter will be sent. The business can decide to do further work and re-submit at a later date.

Amendment to the Food Standards Code

If the outcome is that an amendment to the Food Standards Code is required, the food business is referred to Food Standards Australia New Zealand (FSANZ). The process for amending the Food Standards Code is available on the FSANZ website and is outlined in the information for applicants.

http://www.foodstandards.gov.au/code/changes/Pages/default.aspx