

Food Standards Australia New Zealand

FSANZ Guidelines Determining the Equivalence of Food Safety Measures

1. Foreword

Food Standards Australia New Zealand (FSANZ), in cooperation with the Commonwealth, State and Territory Governments and the New Zealand Government, develops food standards for Australia and, in some cases for New Zealand, in the form of the *Australia New Zealand Food Standards Code* (FSC). FSANZ's primary objective in developing food standards is to protect public health and safety.

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 hazard control measures. The objective is to determine if these measures, when applied to a food, achieve the same level of food safety as that achieved by applying specified measures. In an environment where food regulations are expected to be less prescriptive, equivalence becomes a useful tool for the regulators to ensure the health and safety of consumers without unnecessarily hindering innovation in the food industry. To this end, FSANZ has developed guidelines for determining the equivalence of food safety measures in a reliable, consistent and transparent manner.

Food standards that address public health and safety are separate from animal and plant health quarantine requirements. Under the *Imported Food Control Act 1992*, The Australian Quarantine and Inspection Service (AQIS) is responsible for ensuring that imported food comply with quarantine requirements as well as national food standards, as set out in the FSC.

Equivalence of food safety measures is recognised in the World Trade Organisation (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures¹ (SPS Agreement) and the WTO Agreement on Technical Barriers to Trade² (TBT Agreement). These agreements require member countries to ensure their measures are objective, science-based and consistent. They should also conform with international standards, where they exist, unless they are considered to be an ineffective or inappropriate means for the fulfilment of a country's legitimate policy objectives (TBT) or insufficient to achieve what the country determines to be an appropriate level of sanitary or phytosanitary protection (SPS). Because measures can take many forms, member countries are encouraged to accept as equivalent, measures and regulations of other members, provided they are satisfied these alternative measures and regulations meet their appropriate level of protection. The articles relevant to

¹ http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm

² http://www.wto.org/english/tratop_e/tbt_e/tbtagr_e.htm#Agreement

equivalence in these Agreements are Article 4 of the SPS Agreement, and Article 2.7 of the TBT Agreement as well as Article 6.1, which deals with conformity assessment procedures.

In October 2001, the SPS committee published a decision (G/SPS/19)³ outlining principles to facilitate the application of equivalence provisions of the SPS Agreement for all WTO members. The decision is supported by a 3-year programme to further the implementation of Article 4 of the SPS Agreement.

The Codex Alimentarius Commission, the international food standard setting body is aiming to better articulate the concept of equivalence and its application to food safety. In particular, the Codex Committee for Food Inspection and Certification Systems (CCFICS) has developed guidelines on the judgement of equivalence of sanitary measures associated with food inspection and certification systems⁴. In relation to TBT measures, CCFICS has also initiated the development of a discussion paper on the judgement of equivalence of technical regulations associated with food inspection and certification systems.

2. Purpose

The purpose of these guidelines is to provide guidance to FSANZ for determining the equivalence of alternative measures applied to achieve the safety of imported and domestically produced foods for sale in Australia and, where relevant, in New Zealand. Measures subject to equivalence determination, as discussed in this document, are the measures which fall within FSANZ's responsibility, primarily food standards. The guidelines will assist FSANZ in determining equivalence in a reliable, consistent and transparent manner.

3. Scope

These guidelines provide a general framework for determining the equivalence of food safety measures in a wide range of imported or domestically produced foods. Food-related health risks can arise from microbial or chemical hazards associated with foods and from poor nutrition, which can adversely affect health and may enhance susceptibility to the effects of food-borne hazards. The guidelines focus on SPS measures and draw largely on examples of microbial hazards in food, however, the framework could be applied to other types of food hazards. Therefore, in these guidelines the term "food safety" is used in the general sense, to indicate the safety of food from microbial as well as non-microbial hazards.

To ensure consistency with the international approach to equivalence in relation to food safety measures, the guidelines incorporate many elements of the CCFICS guidelines⁴

The scope of these guidelines does not cover issues around compliance. However, it is understood that equivalence should be considered within the context of a broader food control system that is in compliance with the relevant regulations.

³ http://www.wto.org/english/tratop_e/sps_e/equivalence2001_e.htm

⁴ Draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (at Step 8). Alinorm 03/30A -Appendix II, December 2002.

The FSANZ process for developing or amending food standards is prescribed in *the Food Standards Australia New Zealand Act 1991* (FSANZ Act 1991). A determination of equivalence must be made within this context as it may require an amendment to the FSC. The guidelines propose steps that FSANZ will undertake to determine equivalence in response to an external application or a proposal from FSANZ itself to amend the FSC (summarised in Figure 1). The process for amending the FSC is outlined in the information for applicants⁵.

These guidelines outline the procedures, and the information needed, for determining the equivalence of food safety measures. The guidelines divide the process of equivalence determination into three sequential stages which are discussed in detail in section 7. The three stages are: preliminary stage, equivalence determination and outcome.

- *The preliminary stage* commences at the time the application is made and involves information gathering and dialogue within FSANZ and with the applicant on the scope and objectives of the determination.
- *The second stage* of the process requires food safety issues to be identified and collation of the scientific evidence that will allow the equivalence determination to be made. Information that must be submitted to support the application may relate to hazard control measures, infrastructure and efficacy of the hazard control measures, as discussed below.
- *The final stage* is the documentation of the equivalence determination and recommendation that may result in a variation to the FSC. Any variation to the FSC approved by the FSANZ Board is notified to the Australian New Zealand Food Regulation Ministerial Council who may request that FSANZ review the variation.

In general, the guidelines will apply to both imported food as well as domestically produced food. However, clearly the infrastructure of food production systems that may be subject to equivalence determination will vary. Therefore, information requirements, for example, of the infrastructure associated with hazard control may vary based on the level of knowledge of the system that is in place.

4. General principles for determining the equivalence of food safety measures

Although equivalence determinations will be carried out on a case-by-case basis, there are general principles that would apply. These are:

- Scientific basis and objectivity.
- Harmonisation with international approach to equivalence determination.
- Consistency of safety requirements in food produced in Australia and, where relevant, New Zealand with food imported from other countries.
- Transparency of process.
- Expert and community consultation.

These principles are consistent with Australia's and New Zealand's international obligations and with domestic policies and legislation.

⁵ <http://www.foodstandards.gov.au/standardsdevelopment/informationforapplicants/index.cfm>

5. The context of equivalence determination in food safety

The purpose of equivalence determination is to ensure that alternative food safety measure(s) achieve at least the same level of consumer health and safety as that achieved by applying the standard/traditional measures.

An equivalence determination can be sought for any measure or set of measures relevant to a food product or group of food products within FSANZ's responsibilities for food standards. Generally, food safety measures/systems can be categorised as:

- Infrastructure including legislation (e.g., food law and enforcement law) and administration (e.g., organisation of national and regional authorities and enforcement systems).
- Program design, implementation and monitoring (including documentation, laboratory capability, decision criteria and audit).
- Specific requirements including premises and equipment requirements, process-related requirements (e.g. HACCP plans) and product-related requirements (e.g. microbiological limits).

In this context, a measure or a set of measures can be allocated to a particular category to simplify the extent of the equivalence determination and to assist in developing a common view on how to objectively compare alternative measures.

6. Objective basis of comparison

In order to determine the equivalence of measures in a consistent manner, an objective basis on which to base the comparison of measures and their contribution to safe food must be identified. The level of food safety achieved by the measures being compared, for example the degree of microbial hazard reduction achieved, may be used as the objective basis of comparison. Different hazard control measures will only be judged as equivalent if they can be demonstrated to achieve the required level of food safety consistently.

Food safety measures that are in place are presumed to achieve a level of risk acceptable to the community and provide a benchmark against which alternative measures are compared. To be equivalent, alternative measures must be demonstrated to achieve at least the same level of acceptable risk as that achieved by the measures in place. The comparison must be carried out objectively utilising all information available on measures currently in place and alternative measures relevant to the equivalence determination. The process of comparing the alternative measure with the benchmark of the current measure using all relevant information is termed the objective basis of comparison.

An objective basis of comparison may be qualitative (legislation and enforcement) or quantitative (level of hazard control achieved by the measure) or a combination of qualitative and quantitative elements. Information required for establishing an objective basis of comparison may include:

- the purpose of the measure in place and how it contributes to achieving the acceptable level of risk. As an example, pasteurisation is a measure in place with the purpose of

controlling the microbial hazards associated with milk. The measure operates in a system of hazard control applied consistently by the industry;

- 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 and alternative measure(s) would be expected to achieve or contribute to achieving the same level of hazard reduction;
- the scientific basis for the measure including risk analysis as appropriate; and
- any additional information on the system within which the measure operates such as quality control, audits and certification.

7. FSANZ's process for determining the equivalence of food safety measures

FSANZ will be working within the framework of risk analysis to determine the equivalence of food safety outcomes. The risk analysis framework emphasises the risk and evidence based approach to establish a scientific basis for equivalence determinations. Each of the three stages of the equivalence determination is outlined below.

It is the responsibility of the applicant 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. This will facilitate more focused research and information gathering in the future which will lead to the process in time becoming more robust.

7.1. Stage 1 – Preliminary stage

An equivalence determination may be initiated by either an application submitted by an external applicant or a proposal prepared by FSANZ to amend the FSC. In general, the application should precisely define the food hazards to be addressed, the food safety measures to be considered, and the food safety outcome achieved by the alternative measure(s) as the objective basis for comparing the alternative measures with the currently applied measures. However, in some instances where equivalence is being determined for a specific measure applied at a particular point in the food chain the requirements may be less comprehensive, but still adequate to ensure food safety.

It is expected that the application will be supported by sufficient scientific and technical data to allow independent evaluation by expert analysts. The information submitted should be in the form of both raw and analysed data. All experimental methodologies and statistical procedures should be explained and evidence provided that studies have been performed in accordance with good laboratory practice. For further information on general application requirements, please refer to FSANZ's information for applicants document.

FSANZ will identify the scope of the equivalence determination and issues to be considered. Information provided by the applicant will be reviewed for general relevance and to identify any major information gaps. This stage is expected to be highly iterative and interactive between FSANZ and the applicant to ensure that information is exchanged in a timely manner.

FSANZ will identify the 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 outcome of this stage will be the development of the initial assessment report which will outline the scope of the application to amend the FSC and the approach to be taken (i.e., determination of equivalence in relation to traditional or currently used food safety measures). This report will provide the basis for FSANZ's initial assessment of the application/ proposal to make an equivalence determination. As with the normal FSANZ process, the initial assessment report will be released for public comment.

7.2. Stage 2 – Determining the equivalence of measures

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

The food safety outcomes of the two alternative food safety measures will be compared. While ideally these outcomes will be measured in terms of public health, it is recognised that the comparison may actually be based on the impact of the measures on the level of the hazards. Therefore, the analysis of the efficacy of the food safety measures may focus on determining if the level of the hazards is reduced and the extent of the reduction.

The comparison of the impact of the alternative food safety measures will lead to a determination of the similarity of food safety outcomes. The determination may be expressed in terms of health outcomes or impact on food hazards and may relate to any of the categories of measures.

The outcome of this stage will be the draft assessment report which will include identification of the parameters that form the basis of the equivalence determination, in particular definition of the food safety outcomes that will need to be met by the determination, and a preferred regulatory option including any associated drafting of an amendment to the FSC. It will outline the evidence on which the determination was made. This report will provide the basis for ANZFA's draft assessment of the application/ proposal for equivalence determination. The draft assessment report will be provided for public consultation and input received will be considered in the completion of the equivalence determination.

7.3. Stage 3 – Outcome

The determination of equivalence will be finalised following consideration of any further scientific and technical information that is provided and relevant submissions from stakeholders. The outcome of the process may be:

- Equivalence is determined, conditional on meeting certain requirements;
- Equivalence not determined because the risk management measures do not provide a level of safety equivalent to the currently permitted measures; or
- Equivalence not determined because of a specific and identified information gap.

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

The outcome of the equivalence determination will be documented in the final assessment report. The FSANZ Board will consider the outcome of the final assessment, and if appropriate, approve an amendment to the relevant food standard. The amendment may include specific conditions under which the alternative measures or processes are allowed such as relevant legislation or processing criteria/ limits. The FSANZ Board will notify its decision to the Australia and New Zealand Food Regulation Ministerial Council.

8. Information considered in determining the equivalence of food safety measures

There are 3 major elements to the information that should be considered during an equivalence determination. These are:

- the infrastructure associated with the hazard control measures including mandatory regulations and advisory requirements;
- hazards and the measures to control these hazards, and
- information that demonstrates the effectiveness of the hazard control measures in meeting the required food safety outcome.

8.1. Infrastructure

An evaluation of the product-related infrastructure will provide insights into the effective implementation of the hazard control measures. Information should be provided on both mandatory requirements and industry agreed standards (including good manufacturing and good agricultural practices). The mandatory requirements may include relevant legislation, compliance and enforcement activities, such as audit systems, functional hazard monitoring and surveillance programs, validated performance criteria and inspection and certification activities. Evidence should be provided to demonstrate that infrastructure requirements are implemented through the provision of, for example, audit reports, and outcomes of monitoring and surveillance programs.

Any hazard management programs applied to the in-going ingredients will also be considered. This may be particularly important for raw ingredients.

8.2. Hazards and hazard control measures

All potential hazards associated with the food undergoing the equivalence determination should be taken into account, including those hazards associated with the production/ manufacturing environment or food or ingredients. Information should be provided to demonstrate the association of the hazard with the food, and processing environment, the levels at which the hazards may be present and factors which may influence its presence and/ or level of contamination and the pathogenic characteristics of the organism (including

infective dose). Each hazard should also be characterised in terms of the health impact, and particularly impact on susceptible sub-populations in the community.

The hazard control measures subject to the equivalence determination should 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.

Some estimate of the exposure to the hazard through the diet should be considered by identifying the foods in which the hazard may be present. The intakes of those foods should be estimated, for example, by drawing on information from national nutrition surveys. The presence of the same hazards in other foods and the subpopulation expected to consume the food should also be considered.

8.3. Efficacy of hazard control measures

Scientific information demonstrating the effectiveness of the alternative hazards control measures under consideration should be provided. 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 modelling studies and should cover a range of conditions that may impact on the processing environment in order to demonstrate that the alternative hazard control measures are consistently efficacious. The information provided may take the form, for example, of levels of pathogen contamination after each major processing step. Wherever possible, epidemiological studies should be provided linking pathogens in specific foods with health effects.

9. Equivalence determinations in developing and revising food regulatory measures

The philosophy underpinning FSANZ's role in food regulation in Australia and, where applicable, New Zealand, recognises two main food categories in relation to risk.

9.1 Foods manufactured under generic requirements to produce safe food

Foods in the first category are not subjected to specified regulatory measures because the hazards are likely to be known and well-characterised, the hazards are of low health impact and/ or are limited in number. This category includes foods with established history of safe use and collective community knowledge that is applied to address the hazards, making the food safe for consumption. This category may also include foods produced using established and consistent processes - such as canning.

The application of equivalence in this category will be outside FSANZ's role, however, it is expected that manufacturers will ensure that alternative production and manufacturing processes are as effective as the conventional processes. Alternative measures/processes would be considered equivalent if they consistently achieve the same level of safety. An example of these foods is tetra-packed soups available to consumers that are considered equivalent in terms of health and safety to canned soups.

9.2 *Foods that are subject to specific regulatory requirements*

The second category includes foods and food ingredients for which FSANZ develops and varies regulatory measures. This category includes medium/high risk foods mainly associated with a higher number of hazards many of which maybe of high impact (e.g. dairy products). This category also includes foods for which the risks are unknown as in the case of foods that do not have a long history of safe use and/ or there is little community knowledge about their safe use (e.g. novel foods and irradiated foods).

Within this category, food maybe produced by a well-established and consistent process such as pasteurisation. Milk pasteurisation is commonly applied using a specific time/ temperature combination (e.g. heating to no less than 72°C and retaining at such temperature for no less than 15 seconds). However, there is sufficient information to facilitate selecting various time/ temperature combinations to achieve equal or greater lethal effect on pathogens. Such alternative combinations of time and temperature are already recognised as equivalent in the pasteurisation requirement in the FSC.

Also within this category are foods produced by less well-established or more complex processes. These processes may have a high number of variables and their effect on hazard reduction may be less predictable. Because many of these processes are not well established in the Australia and New Zealand context, and the potential variability of the multiple steps, FSANZ has previously considered each process for equivalence before giving permission for its use. As an example, an alternative may be proposed for pasteurisation of milk used to make cheese (e.g. cheeses made from raw milk) where a multi-step process would be assessed for achieving an acceptable level of risk as that achieved by pasteurisation of milk. FSANZ's role in equivalence determination is expected to fall largely in this group of issues.

FSANZ will apply the guidelines for equivalence determination when alternative measures are considered in relation to foods of medium/high risk. Application of the guidelines will be in the context of amending the FSC which will follow due process.

Food manufacturers and other participants in the food supply chain have an important role in the application of equivalence as discussed in low risk foods and in medium/high risk foods produced using well-established processes with limited variability in the safety measures.

10. Equivalence determination within the process for amending the Food Standards Code

The process of amending the FSC, as prescribed in the FSANZ Act 1991, must be followed when making an equivalence determination.

10.1. Public consultation

Two rounds of public consultation will generally take place during the assessment of the application/ proposal seeking an equivalence determination:

- The initial assessment report, providing preliminary information on the issues, will be released for comment.

- The draft assessment report and the draft amendment to the FSC will be released for a second round of consultation. FSANZ will have regard to any submissions in preparing the final assessment of the application/ proposal seeking an equivalence determination.

10.2. Outcome of equivalence determination

After considering all relevant information and any submissions, the FSANZ Board makes its assessment, taking into account FSANZ's objectives set down in the FSANZ Act. The FSANZ Board must consider any relevant New Zealand standards and any other matters pertinent to the particular standard. The Board notifies its decision to the Ministerial Council which may request that FSANZ review of the amendment to the standards.

After the Ministerial Council process is finalised, FSANZ gazettes the amendment and it becomes part of the FSC.

10.3. Confidentiality

Applicants may ask FSANZ to regard commercial information supplied with an application as confidential commercial information. FSANZ will consider such requests in accordance with the FSANZ Act 1991, and may, in part or in total, refuse this request. If it does, applicants have the option of withdrawing their application or its relevant sections. Unless the applicant requests, justifies and is granted confidentiality, material provided in the application will be placed on the public record.

11. Definitions

The definitions presented in this document relate to the process of equivalence determination by FSANZ, and are derived from, and are consistent with, those of the Codex Alimentarius Commission and the SPS and TBT Agreements of the WTO.

Equivalence (of food safety measure): Equivalence is the state wherein the measures applied in one food production system, though different from the measures applied in another system, achieve, as determined by FSANZ, the required food safety outcome for Australia and New Zealand. Equivalence determination may be based on qualitative or quantitative information.

Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Measure: Any measure applied in the context of food safety to protect consumers from risks arising from hazards in food.

Figure 1- Proposed diagram for the process of equivalence determination

