



NZFSA Policy on Food Safety Equivalence:

A Background Paper

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1 What is Equivalence

When considered in relation to food safety the primary point of reference as to what is equivalence is the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). Article 4 of the SPS Agreement deals specifically with equivalence (see Annex A).

The SPS Agreement clearly recognises that an importing country's food safety requirements (the SPS Agreement uses the term 'appropriate level of sanitary or phytosanitary protection' or ALOP) can be achieved in alternative ways. Further, if a country can objectively demonstrate that the measures it applies provide the same level of health protection another country requires for the product or products in question, even if the measures are different, they should be accepted as equivalent. This approach helps ensure that consumer protection is maintained while providing the greatest quantity and variety of safe foodstuffs for consumers, the best availability of safe inputs for producers, and healthy economic competition.

The concept of equivalence therefore allows exporters to adopt different ways of reaching the required level of food safety protection. Equivalence allows the competent authority in the exporting country to determine the most cost-effective and efficient way to fulfil the agreed food safety requirements of the importing country.

2 Why have we sought equivalence agreements

Some importing countries may specify not only the sanitary outcomes must be met but also how these outcomes are to be achieved, or shown to be achieved, by the exporting country. This might require wholesale re-engineering of systems and processes and the loss of efficiency and innovation for little or no gain in food safety. Through the addition of industry costs, it is also likely to add cost to consumer purchases of the product.

Recognition of equivalence (and acceptance that the importing country food safety requirements are being met) can result in reduced requirements for products entering a foreign market, whilst maintaining food safety as required by the importing country. For example, checks undertaken during process might reduce, at the point of import, sampling and physical checks. This in turn reduces costs without compromising in food safety.

Another reason for seeking equivalence is that trade relationships develop over time and with it there is increased knowledge and confidence in an exporting country's food control systems. This can lead to an importing country accepting or recognising, first, the robustness of the overarching design and performance of the food control system in the exporting country and second, the modus operandi of the competent authority with oversight and control of that system. The importing country needs to be assured that the exporting country's competent authority exercises systems and controls across the entire food chain such that the foods produced within the system can be considered to have met the importing country's food safety requirements. Such an approach can be viewed as an acceptance or recognition of the equivalence of a food control system rather than just focusing on a specific measure(s) or individual components within a food control system.

3 New Zealand's involvement in equivalence arrangements

New Zealand has for many years, been involved in the negotiation of bilateral and regional arrangements (some as part of free trade agreements) that apply the principle of equivalence. The agreements and arrangements with Australia (which began with the Closer Economic Relations Trade Agreement in the early 1980's, saw the Joint Food Standard Agreement signed in 1995 and later the Trans Tasman Mutual Recognition Agreement of the late 1990's) are the most comprehensive example of this for New Zealand, in that food that can be legally sold in one country can be sold in the other without any additional measures applying. The New Zealand - European Union Agreement, signed in 1996, at its highest level recognises the equivalence of the food control systems and sets out a process for determining equivalence of specific commodity / measures as well. New Zealand and the United States of America have also reached agreements focussed at the specific commodity / control measures level largely in relation to microbiological monitoring.

In recent years, New Zealand has also entered into a number of free trade agreements (FTAs) that include a specific SPS chapter. Examples include the Trans-Pacific Strategic Economic Partnership Agreement ('P4') between Brunei Darussalam, Chile, New Zealand and Singapore signed in 2005; the New Zealand - China FTA signed in 2008; the New Zealand - Malaysia FTA signed in 2009; and the ASEAN - Australia and New Zealand Free Trade Area Agreement signed in 2010 and the New Zealand - Hong Kong, China Closer Economic Partnership Agreement also signed in 2010.

New Zealand applies principles of transparency in all cases where food safety equivalence is applied – both when New Zealand seeks recognition from another country, and when another country seeks recognition from New Zealand.

4 Equivalence Determination

Expression to the SPS Agreement's article 4 is given through a number of sources.

4.1 WTO SPS Committee Guidance on the Implementation of Article 4: Equivalence

In October 2001 the WTO Committee on Sanitary and Phytosanitary Measure (SPS Committee) adopted a Decision on the Implementation of Article 4: Equivalence of the SPS Agreement (G/SPS/19). This decision was agreed in response to a request from the General Council to examine the concerns of developing country members regarding equivalence and the difficulty some had experienced in having their sanitary or phytosanitary measures accepted as equivalent.

The Committee subsequently provided clarification on some of the paragraphs in that original decision and in July 2004 issued a revised document incorporating all of the advice (G/SPS/19/Rev 2).

The decision provides guidance for WTO members on:

- the concept of equivalence – that equivalence requires "acceptance of alternative measures that meet an importing Member's appropriate level of sanitary or phytosanitary protection", but not duplication or "sameness" of measures;
- the need for an importing country to explain (including the provision of copies of risk assessments and other relevant documents) the objective and rationale for a sanitary or phytosanitary measure, the risks that the relevant measure is intended to address, and the appropriate level of protection it is designed to achieve;
- the expectation that importing countries will respond in a timely manner to any request for a determination of equivalence, normally within six months;
- the provision by the exporting country of appropriate science-based and technical information to support its objective demonstration of equivalence;
- use by the importing country of an accelerated process for determining equivalence for products which have a history of trade between the two countries;
- a request for a determination of equivalence not being a reason to disrupt or suspend trade in the relevant product(s);
- the use of an objective basis of comparison (as proposed in the CCFICS text CAC/GL 53-2003) as a way to facilitate the analysis of the science-based and technical information presented by the

exporting country to demonstrate it is able to achieve the importing country's required level of protection;

- requests for assistance by developing countries; and
- encouraging WTO members to participate in the work of Codex and OIE where these bodies undertake work on equivalence and to bear in mind the difficulties faced by developing country members in participating in these bodies.

The full document may be accessed on the WTO website:

http://www.wto.org/english/docs_e/docs_e.htm

New Zealand participated in the discussions of the SPS Committee in the development of this decision. In doing so, New Zealand placed particular emphasis on the importance of the work being undertaken in the international standard setting bodies – Codex and OIE – in developing standards, guidelines and procedures that would support the implementation of the concept of equivalence.

4.2 Codex Alimentarius Guidance

Guidance is available in documents developed by the Codex Committee for Food Import and Export Inspection and Certification Systems (CCFICS). CCFICS has developed two documents directly relating to Equivalence:

- Guidelines for Development of Equivalence Agreements regarding Food Import & Export Inspection & Certification adopted by Codex Commission (CAC/GL/34 – 1999); and
- Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Import & Export Inspection & Certification adopted by the Codex Commission (CAC/GL/53 – 2003), and an Appendix – Additional guidance to assist exporting and importing countries in undertaking an equivalence determination adopted in 2008.

A short description of the content of these two guidelines is provided at Annex B while the full documents may be viewed on the Codex website:

http://www.codexalimentarius.net/web/standard_list.do?lang=en

New Zealand actively participated in the development of the CCFICS guidelines and led the working group that developed the guidelines on the judgement of equivalence which were eventually adopted in 2003. Development of specific guidance from Codex was seen as a valuable step towards a better understanding of how the concept of equivalence could be applied and were intended to provide practical guidance for governments. The CCFICS guidelines also recognised that equivalence agreements could take various forms and might cover bilateral or multi-lateral trade. It was understood that countries may wish to enter such agreements to:

- provide an enhanced means of assuring that exported food products conform to importing country requirements;
- eliminate duplication of activities and use collective resources more efficiently and effectively; and/or
- provide a mechanism for the cooperative exchange of expertise, assistance and information to help assure and enhance conformity with food safety requirements.

A particularly important concept that is developed in the CCFICS Guideline on Judgement of Equivalence is the need to identify an objective basis for comparison to facilitate the judgement process.

4.3 Summary of steps involved when New Zealand seeks equivalence

When New Zealand seeks to develop an equivalence arrangement, the steps usually involved can be summarised as follows:

1. Identify the sanitary measure or group of sanitary measures at issue.
2. Document the New Zealand requirements, including inspection and certification systems for the identified measure(s).
3. Gain an understanding of the importing country's measure(s) by assessing regulatory requirements and discussions with the competent authority about what outcome the measure(s) are intended to achieve. Identify how the importing country's domestic requirement achieves this level of protection.
4. Identify the history of compliance of New Zealand product exported against the measure(s).
5. Consider any political or legal constraints that may prevent the importing country from granting equivalence.
6. If available request a copy of the importing country's risk assessment on which the measure(s) are based.
7. Discuss with the importing country's competent authority criteria for assessing equivalence of the measure(s), preferably based on internationally accepted principles developed by CCFICS (i.e. an objective basis for comparison).
8. Determine which measure(s) are the same and will therefore be met by 'compliance with the importing country requirements' and which measure(s) require an equivalence determination, where necessary by undertake a side by side comparison of each country's regulatory requirements associated with the measure(s).
9. Share assessment with the importing country.
10. If an equivalence determination is granted, develop a process for ongoing maintenance and review of the relevant control systems.

Progress through these steps also involves discussion between the competent authorities and to a certain extent will therefore be iterative. It is also possible for a determination of equivalence to be made at any point in the process, in which case some of the steps will be shortened or not require completion.

5 Annex A: SPS Agreement Text

Article 4: Equivalence

1. Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.
2. Members shall, upon request, enter into consultations with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures.

6 Annex B: CCFICS guidelines on equivalence

Guidelines for Development of Equivalence Agreements regarding Food Import & Export Inspection & Certification adopted by Codex Commission (CAC/GL/34 – 1999)

The CCFICS guidelines on the development of equivalence agreements is intended to provide practical guidance for governments desiring to enter into bilateral or multilateral equivalence agreements concerning food import and export inspection and certification systems. Such agreements may be binding instruments taking the form of “international agreements” under the Vienna Convention on the Law of Treaties, or they may be other less formal arrangements such as memoranda of understanding.

It is often the case that importing and exporting countries operate different food inspection and certification systems. The reasons for such differences include differences in prevalence of particular food safety hazards, national choice about management of food safety risks and differences in the historical development of food control systems.

Equivalence agreements are not generally intended as a condition for trade but rather as a means for ensuring that importing country requirements are met with minimal trade impediments. For example, such agreements may result in reducing the importing country’s rate of physical checks or sampling to test against standards or to avoid additional certification in the country of origin.

The CCFICS guidelines are intended to cover both bilateral and multi-lateral arrangements. Such arrangements may cover trade in one or both directions between trading partners. An equivalence agreement covering control and certification systems may relate to any aspect of food safety or other relevant requirement for food. Such agreements may be limited to specific areas of trade or specific products. Such agreements may be entered into where equivalence has been established in respect of some or all requirements.

Equivalence agreements may include provisions for certificates or other forms of certification of particular traded products or may provide for dispensing with certification altogether.

The guidelines devote several sections to suggestions on how to go about initiating discussions, the range of information that might be exchanged during consultation discussions. The key aspect is that both parties should get to know each other and develop an understanding of how each party goes about protecting their consumers and ensuring that only ‘safe’ or ‘fit for purpose’ products are traded and sold. This includes what systems are in place to prevent unfit product being sold or consumed.

Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Import & Export Inspection & Certification adopted by Codex Commission (CAC/GL/53 – 2003)

CCFICS has developed Guidelines on Judgement of equivalence of sanitary measures associated with import and export inspections and certification systems. The intention is to assist exporting and importing countries to work together to facilitate trade while protecting the health of consumers, an exporting and an importing country may work together to consider the effectiveness of sanitary measures of the exporting country in achieving the appropriate level of sanitary protection of the importing country, consistent with the principle of equivalence as provided for in the WTO SPS Agreement.

This guideline sets out the principles that should be applied when making a Judgement and also provided guidance on the context within which an agreement rests.

How involved the determination process will be will depend on the prior experience, knowledge and confidence the importing country has in the food control measures of the exporting country.

When an importing country has prior experience, knowledge, and confidence in food control measures relevant to those being evaluated for equivalence and the countries agree that import requirements are being fully met, e.g. where trade experience exists, determination of the equivalence of sanitary measures may be made without further consideration of those other relevant measures making up the food control system.

When an importing country does not have prior experience, knowledge, and confidence in food control measures relevant to those being evaluated for equivalence and the countries have not determined that import requirements are being fully met, e.g., where trade in a food product or group of food products is being proposed for the first time, determination of the equivalence of sanitary measures will require further consideration of those other relevant measures making up the food control system.

A key concept for enabling a judgement to be made is that of agreeing on an objective basis of comparison – need to be able to find the basis for comparing systems that may appear quite different. The key point is that the exporting country needs to be able to show that their system can deliver the level of protection that the importing country has set for that product (or similar products) produced or manufactured in the importing country.

Supporting information to be provided by the importing country may include:

- a) the reason/purpose for the sanitary measure, including identification of the specific risks that the measure is intended to address;
- b) the relationship of the sanitary measure to the ALOP, i.e., how the sanitary measure achieves the ALOP;

- c) where appropriate, an expression of the level of control of the hazard in a food that is achieved by the sanitary measure;
- d) the scientific basis for the sanitary measure under consideration, including risk assessment where appropriate;
- e) any additional information that may assist the exporting country in presenting an objective demonstration of equivalence.

The guidelines note that the determination of equivalence is facilitated by both the importing and exporting country following a sequence of steps, with the parties working through these steps in a co-operative manner. A flow diagram of these steps is also provided in the guideline.

Appendix to CAC/GL 53-2003 – Additional guidance to assist exporting and importing countries in undertaking an equivalence determination

This appendix was added to the Guidelines in 2008. The appendix lists a number of factors that may facilitate the undertaking of an equivalence determination. These are:

- a) The experience, knowledge and confidence the importing country has with the exporting country's food control system (see paragraphs 9 to 14 below);
- b) The prior history in food trade between the importing and exporting countries;
- c) The level of compliance of the exporting country's food products with the importing country's requirements;
- d) The level of cooperation that exists between the food safety competent authorities of the importing and exporting countries;
- e) The extent to which importing and exporting countries' food control systems are similar (e.g., the similarity of food laws and regulations, the capabilities of professional staff and laboratories, the similarity of inspection and monitoring programs);
- f) Being well prepared to undertake an equivalence determination, including that the importing and exporting countries have access to the necessary resources such as the scientific and technical capabilities;
- g) Consideration of the relevance of any previous equivalence determinations made by the importing country.

It lists a number of preparatory steps that should be considered including considering the benefit and cost/resource implication of an equivalence determination in comparison to other arrangements; and

whether the importing and exporting country have access to the necessary scientific and technical resources to carry out a determination.

The importance of correctly scoping of the equivalence determination is highlighted.

The appendix also expands on and gives examples of the factors that can contribute to experience, knowledge and confidence that an importing country may have in an exporting country. Similarly additional guidance relating to what constitutes the development of an objective basis of comparison is provided. Also noted is that depending on the scope of the equivalence determination there may be more than one objective basis for comparison.

The information that may need to be included in a country's submission for a determination of equivalence is expanded on. The importance of confining the necessary information and documentation requirements to essential information is highlighted, as is that the process should be undertaken in a planned and co-ordinated manner.

Further details on the Judgement process are discussed. It is noted that ongoing communication between the importing and export countries can assist the judgement process particularly in the area of clarifying technical points and providing any additional information. If the preliminary assessment indicates that the application is likely to be unsuccessful it is suggested that this should be communicated to the importing country at the earliest opportunity. It is noted that a favourable decision can be made at any point during the determination process.

The appendix also notes that on-site visits may be useful in clarifying information provided by the exporting country and in improving knowledge and confidence in the food control systems of the exporting country.

Finally some examples of when the provision of technical assistance may be needed or be beneficial are provided.