



EQUIVALENCE IN FOOD SAFETY MANAGEMENT

The principle of equivalence in food safety management is based on the premise that the same level of food safety can be achieved by employing alternative hazard control measures. Hence any equivalence determination seeks to establish if these alternative control measures achieve the same level of food safety as that achieved by the original measures.

With the global trend towards food regulations which are less prescriptive and provide opportunities for product innovation, equivalence becomes a useful tool for food safety regulators to ensure that the health and safety of consumers is protected without unnecessarily hindering technological advances in food processing (FSANZ 2004).

Background

Food safety has long been recognised as a mandatory requirement in the production and marketing of foods. Traditional approaches to food safety management have relied upon end product sampling and laboratory testing. Detailed procedures were developed to set specifications for foods in regard to chemical and microbiological levels, and also levels of physical contamination. Such specifications were originally derived from knowledge of Good Manufacturing Practice (GMP) requirements and more recently from detailed risk assessments which determined the likelihood of hazards presenting a risk to public health and safety.

Food product specifications and end product testing have traditionally formed the primary basis for regulatory oversight of food safety. In some areas this is still the case today. A major change in approach arose when it was demonstrated that hazard identification and control could be used to manage food safety across the entire agri-food supply chain, rather than at some endpoint. This approach led to the adoption of the now well accepted Hazard Analysis and Critical Control Point (HACCP) system which emphasised preventative approaches. Whereas the initial research relating to food product hazard control was undertaken several decades ago, the impetus for its adoption in the food sector became very significant in the 1990s.

A second area of development is the concept of “hurdle technology” where a series of food safety measures are used, sometimes in steps, to gain synergy in the interaction and effectiveness of several food safety measures. The correct application of a series of hurdles can achieve the same product safety as a single food safety measure such as a kill step.

Continuing research underpinning food safety management has provided a number of new approaches, and tools, which have strengthened risk assessment capability, and allowed a clearer

delineation between risk assessment and risk management. This has enabled a transition from end product specification and testing to a focus on establishing new measures of food safety such as Food Safety Objectives and associated metrics (ICMSF 2002). This allows the food industry greater flexibility when examining approaches to food safety management.

Development of new approaches to food safety management

There are several factors which have led to the need to consider new approaches in food safety management. Consumer trends in food choice have given rise to new food safety challenges. Consumers are seeking foods which are fresher, minimally processed, and with less reliance on preservatives. At the same time, a focus on reducing salt levels in processed foods has been an additional challenge. While new food preservation technologies have enabled food manufacturers to make improvements in sensory quality and in particular in colour and flavour retention, such conditions may favour the survival and/or growth of pathogenic microorganisms.

Examples of recent developments in food preservation technology are high pressure processing, food irradiation, pulsed electric fields and pulsed light. These new technologies enable manufacturers to provide innovative products as well as meet food safety objectives.

Of these new technologies, food irradiation and high pressure processing are at the most advanced stage in regard to commercial application. High pressure processing is successful in improving flavour retention and sensory quality in a range of foods, for example fruit juices, fruit and vegetable purees, processed meat products, and seafood. The technology is successful also in controlling microbial levels in many situations, and it provides a good example of “equivalence” to traditional high temperature heat treatment.

Consumer acceptance of new preservation technologies is a critical issue. Food irradiation is a technology that has the capacity to play an important role in food safety management, but consumer acceptance has been until recently quite low in some countries.

New technologies do have particular limitations, for example high pressure processing alone does not deal effectively with spore-forming organisms. However such technologies can be most effective in combination with other measures where synergy comes into play, for example preservation technologies in combination with HACCP, or as part of a set of “hurdle” technologies.

Advances in predictive microbiology have also contributed significantly to food safety management (McMeekin *et al.*, 1993). Predictive microbiology, where the effects of food formulation, processing conditions, packaging, and storage on the survival and growth of microorganisms in foods can be measured and assessed, has enhanced the potential to apply “equivalence” assessments in food safety management. *ComBase* is a database where data and predictive tools on microbial responses to food environments are freely available via web-based software. The database contains information about how microorganisms respond to different food properties and environments.

The ability to apply the principles of equivalence in food safety management has been made possible by new approaches to food safety risk assessment, and by the availability of new food safety risk management tools, e.g. the Food Safety Toolkit™, an educational and implementation tool that enables food companies to meet their food safety obligations, and Risk Ranger™, a spreadsheet based risk assessment tool, intended as an aid to determining relative risks from different food product, pathogen and processing combinations. Both tools were developed by the Australian Food Safety Centre of Excellence (now the Food Safety Centre).

Equivalence in food safety management - international trade

The principle of equivalence in food safety has become an important issue, impacting on international trade in foods. At this level, considerable effort is being directed to achieving agreement on the concept of equivalence as it applies to food safety management systems, i.e. does the management

of food safety in one country achieve or ensure the same level of protection as the food safety management system in a second country?

Equivalence of food safety measures is recognised in the World Trade Organization (WTO) *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement) and the *Agreement on Technical Barriers to Trade* (TBT Agreement). Both agreements require member countries to ensure their food safety measures are objective, science-based, consistent, and harmonised with international standards, where they exist. Because measures can take many forms, WTO member countries are encouraged to accept other countries' measures and regulations as being equivalent, provided they are satisfied these alternative measures and regulations meet their appropriate level of protection (ALOP) or public health goals. The ALOP which is the responsibility of national legislators, may not be the same for all countries. Article 4 of the SPS Agreement and Article 2.7 of the TBT Agreement relate to equivalence (FSANZ 2004).

The WTO has recently created the SPS Information Management System (SPS IMS), a database for searching for information on WTO member governments' sanitary and phytosanitary measures which includes food safety and animal and plant health and safety.

The Codex Alimentarius Commission, the international food standards setting body, is moving to better articulate the concept of equivalence and its application to food safety. The Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) has developed guidelines for the judgement and development of equivalence of sanitary measures associated with food inspection and certification systems. The CCFICS guidelines were adopted by the Codex Alimentarius Commission at its meeting in July 2003. CCFICS has recently drafted a discussion paper on the judgement of equivalence of technical regulations associated with food inspection and certification systems and this is being progressing through a CCFICS Working Group.

Equivalence in food safety measures

For food processors and food regulation authorities, there is also the need to determine the equivalence of different food safety measures, i.e. the ability of alternative technologies to achieve the same level of health protection by destroying or inhibiting pathogenic microorganisms. The focus is on comparing existing approved measures, which are presumed to achieve a level of risk acceptable to the community, with alternative food safety measures. This is achieved by reviewing the kinetics and efficacy of pathogen reduction, and all other pre- and post- processing measures that impact on food safety. Alternative hazard control measures will only be judged as equivalent if they can be demonstrated to consistently achieve the required level of food safety.

Examples of foods where an evaluation of the equivalence of measures is important include dairy products, when a processor seeks to use an alternative to pasteurisation for the treatment of liquid milk, or an alternative to the 12D process for hermetically sealed low-acid food products. Such determinations are difficult when the measure uses non-thermal processes and the kinetics of death are different and/or poorly understood.

Dairy products

High-temperature short- time pasteurisation of milk at not less than 72°C for at least 15 seconds achieves a significant kill of typical vegetative pathogens encountered in raw milk . While pasteurisation has served the industry well for a prolonged period of time, dairy processors continue to explore other techniques for producing safe raw milk (Mahoney 2007).

To meet the benchmark established by pasteurisation, any alternative technology would need to achieve at least a 7 log reduction in pathogens typically encountered in raw milk. This will ensure an equivalent public health outcome for consumers of non-pasteurised dairy products.

An equivalence determination would therefore need to demonstrate to the competent authority that the number of pathogenic bacteria typically encountered in raw milk is reduced by 7 log. Such a determination would need to quantify pathogen numbers found in typical raw inputs, demonstrate the efficacy of a kill step, and validate the management of post-treatment packaging and handling to

prevent recontamination and/or outgrowth of any surviving pathogenic microorganisms. Where non-thermal processes are utilised, the lethal or inhibitory impact of the technology on the range of pathogens (Gram negative, Gram positive, heat sensitive, sporeformers, etc) typically encountered in raw milk inputs would need to be demonstrated.

Comminuted fermented meat products

Comminuted fermented meat products are typically heated to temperatures in excess of 65°C for at least 10 minutes to render them safe by destroying pathogenic bacteria which may be encountered in the raw materials, e.g. enterohaemorrhagic *Escherichia coli*, *Salmonella* spp., and *Listeria monocytogenes*. There is significant concern about the presence of enterohaemorrhagic *E. coli* in this type of meat product because of its virulence, survival in this type of product, impact on vulnerable consumers, and recent evidence of disease outbreaks.

A separate class of comminuted fermented meat products is prepared from uncooked raw materials, and this may represent a risk to public health unless the product is subjected to processes and handling practices which achieve an equivalent level of health protection. In the absence of a cooking step, the effective combination of fermentation, smoking, maturation and desiccation steps are critical in achieving at least a 5 log reduction in pathogen numbers. This can be achieved by monitoring of incoming ingredients for *E. coli*, the use of fecund starter cultures, control of the fermentation process, and the monitoring of pathogen numbers in raw materials and final products. Competent authorities usually require processors to establish food safety management systems to administer product safety control steps and to validate the efficacy of control measures.

Conclusion

Scientific advances in the food industry will see the ongoing development of exciting new technologies for the processing of foods. Traditional methods of food processing have focused on product safety and have generally served the industry well. For this reason, it is essential that new technologies achieve equivalent pathogen control and enable competent authorities to achieve the same public health goals. Equivalence determinations enable the food industry to quantify the efficacy of new technologies in pathogen control and benchmark them against traditional methods.

References

FSANZ (2004) *Guidelines for Determining the Equivalence of Food Safety Measures*. Food Standards Australia New Zealand, Canberra, Australia. 15 pp.

ICMSF (2002) *Microorganisms in Foods. 7. Microbiological Testing in Food Safety Management*. Kluwer Academic / Plenum. New York, USA. 362 pp.

Mahoney, D.B. (2007) Establishing the equivalence of new technologies. *Aust. J. Dairy Technol.* 62 (2): 64-66.

McMeekin, T.A., Olley, J. and Ross, T. (1993) *Predictive Microbiology : Theory and Application*. John Wiley & Sons, Taunton, UK

IUFoST recommended websites on equivalence

ComBase

A combined database for predictive microbiology.

<http://www.combase.cc/>

Codex Alimentarius Commission

Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems. Codex Alimentarius Commission, Rome, Italy. CAC/GL 53-2003. 7 pp..

<http://www.codex.org/>

Food Safety Centre

Risk Ranger™ (a spreadsheet-based risk assessment tool).

<http://www.foodsafetycentre.com.au/tools.php>

Food Standards Australia New Zealand (FSANZ)

Guidelines for Determining the Equivalence of Food Safety Measures. Food Standards Australia New Zealand, 2004, Canberra, Australia. 15 pp.

http://www.foodstandards.gov.au/srcfiles/Equivalence%20Determination%20Guidelines_jan04.pdf

World Trade Organization

Agreement on the Application of Sanitary and Phytosanitary Measures [SPS Agreement].

http://www.wto.org/english/docs_e/legal_e/15-sps.pdf

Agreement on Technical Barriers to Trade [TBT Agreement].

http://www.wto.org/english/docs_e/legal_e/17-tbt.pdf

SPS Information Management System

A database for searching for information on WTO member governments' sanitary and phytosanitary measures.

<http://spsims.wto.org>

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The International Union of Food Science and Technology (IUFoST) is the global scientific organisation representing over 200,000 food scientists and technologists from more than 60 countries. It is a voluntary, non-profit association of national food science organisations linking the world's food scientists and technologists.

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