ELSEVIER

Food Control 12 (2001) 339–346

FOOD CONTROL

www.elsevier.com/locate/foodcont

Future challenges in global harmonization of food safety legislation

Y. Motarjemi [a], M. vanSchothorst [b], F. Käferstein [c,*]

[a] *Food Safety Unit, World Health Organisation, Geneva, Switzerland*
[b] *Nestlé, Vevey, Swizerland*
[c] *Food and Drug Administration and Food Safety and Inspection Service, Washington, DC, USA*

Received 11 December 2000; received in revised form 23 March 2001; accepted 26 March 2001

1. Introduction

Society is in the midst of a profound transition period. Increasingly, food safety policies are the subject of public health concern. At the same time, driven by technological and economic developments, the moving of people, goods, images, values and financial transactions across national borders is causing social, political and economic interdependence between countries, unprecedented in human history. The globalization aspect, which characterized the end of the 20th century, influences different aspects of human life, including the safety of food supply and, consequently, human health.

As the world becomes more interconnected, the need for harmonization of food safety regulations, and for reaching international agreement on the principles for establishing such regulations, grows.

This paper explains why global harmonization of food safety regulations is important to the 21st century and outlines progress made in this regard, future challenges awaiting public health authorities, and difficulties that have to be overcome.

2. Why global harmonization of food safety legislation?

When asked what he thought of Western civilization, Mahatma Gandhi (1869–1948) replied: "*I think it would be a good idea.*" Certainly, global harmonization of food safety regulations will be a challenging task for the world leaders of tomorrow. However, in the globalized world of the 21st century, it would perhaps not only be a good idea, but also a necessity. There are different reasons for this.

2.1. Right to safe food

Perhaps one of the fundamental reasons for a global harmonization of food safety regulations is the moral obligation that human beings have towards each other and towards the observation of the *Universal Declaration of Human Rights (1948)*. Article 1 of this Declaration proclaims that:

> All human beings are born free and equal in dignity. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood.

Article 25 stipulates:

> Everyone has the right to a standard of living adequate for the health and well being of himself and of his family, including food, clothing, housing, medical care and necessary social services.

Although the term "safety" was not explicitly mentioned at the time, it was implicitly understood that safety is an intrinsic quality of the food and thus, the term "food" means "safe food".

Recognizing the role of food in the transmission of diseases, and taking note of the increased incidence of foodborne diseases observed in many countries during the last 2 to 3 decades as well as of other problems which have emerged in connection with the food supply, the Food and Agriculture Organization (FAO)/World Health Organization (WHO) International Conference on Nutrition (ICN, 1991) recognized in 1992 the importance of food safety and made explicit reference to it in its "World Declaration on Nutrition":

> Access to nutritionally adequate and safe food is the right of each individual.

* Corresponding author.
E-mail address: fritz.kaferstein@cfsan.fda.gov (F. Käferstein).

PII: S0956-7135(01)00036-6

Considering that all human beings, regardless of race, colour, sex, language, religion and social origin, have equal rights, the above statements could be interpreted to mean that every one has the right to the same standard of food safety and the same degree of health protection from foodborne hazards.

Global harmonization of food safety regulations is a major step in recognizing and implementing this right. It also contributes to ensuring that populations around the world benefit from the same degree of health protection from foodborne hazards and the same standard of food safety.

On the outset, it should however be stressed that harmonized food safety legislation per se will not automatically provide the same degree of health protection. To protect consumers, any food safety legislation should be supported by an adequate enforcement infrastructure, responsibly operating food industries and appropriate food handlers training and consumer education programmes. The latter is particularly important when considering biological hazards.

2.2. Globalization and food safety

There are also practical and economical reasons why global harmonization of food safety regulations is important.

In the late 20th century, and certainly even more so in the 21st century, the world is becoming increasingly globalized. This will have implications for food safety. Due to the factors mentioned below (as shown in Fig. 1), food safety problems are becoming globalized, which means that the food safety problems of one country can easily become the problems of other countries.

There are many factors that contribute to the globalization of food safety problems:

Globalization of the food supply system and international trade in food. Advances in food science and technology in tandem with transport technologies have made it possible for foods to be transported to distant places and have facilitated globalization of the food supply. The opening of the world market as a result of the successful finalization of the Uruguay Round of Multilateral Trade Negotiations has also allowed international trade in food to flourish. The value of food trade is growing rapidly. In 1997, it was estimated to be around US $458 billion, which was 4 to 5 times more than 10 years earlier. As food may be a vehicle for foodborne pathogens, food trade may be a mechanism for the spread of foodborne pathogens. Indeed many outbreaks have been traced to imported foods, including in countries with sophisticated control systems at their borders. In addition to trade in food, trade in animal feed is also substantial; animal feed may also be contaminated with hazards, thus contributing in no small way to their transnational spread and introduction into the human food chain.

International travel and migration. Advances in transport technologies have facilitated the movement of people. Be it for business, tourism, or migration, international travel has increased in recent years. It was estimated that about 597 million people crossed international boarders in 1995. By the year 2010 the figure may have doubled. Depending on the destination, it is estimated that up to 60% of travellers may acquire a

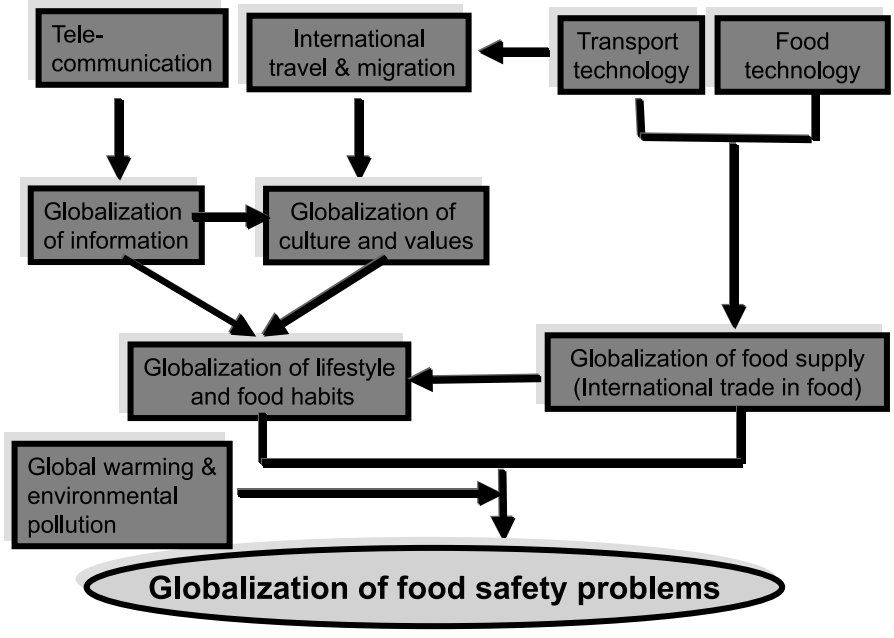

Fig. 1. Factors influencing globalization of food safety.

traveller's diarrhoea during their travel (Cartwright & Chahed, 1997). In other words, a substantial number of people are affected by food safety problems in other places than their own country. In Scandinavia, 80–90% of cases of salmonellosis have been shown to be imported cases.

Globalization of lifestyle, food habits, values and cultures. International travel and migration jointly with advances in telecommunication contribute to globalization of information, cultures, and values and may lead to changes in lifestyles and food habits. Today, populations in distant countries may experience similar food safety problems or may share the same concern with regard to their food supply. For example, the concern of consumers in Europe in connection with Genetically Modified Organisms (GMOs) is spreading to countries where consumers may already have accepted the technology.

There is no doubt that globalization raises a number of food safety problems, e.g., the increased risk of spread of foodborne diseases. However, globalization also provides many benefits. It opens the doors to new markets and opportunities for trade. In this way, it contributes to economic growth and subsequently to improvements in standards of living and health. It also contributes to the improved supply of populations with micronutrients by the provision of foods containing for instance vitamins at times when the vitamin content of local foods is insufficient. Finally, a globalized food trade adds to the variety of food available in many parts of the world, thus contributing to the pleasure of eating. A major challenge in the 21st century is to harness globalization in such way that risks to food safety and health are minimized, at the same time taking advantage of the opportunities that globalization presents from nutritional, gastronomic and economic point of view. *Global harmonization of food safety regulations will help ensure fair competition among countries in terms of trade and at the same time it will help ensure that all populations enjoy the same degree of food safety.* This is also the idea behind the Uruguay Round of Multilateral Trade Negotiations, which resulted in the creation of the World Trade Organization (WTO) in 1995, including a number of agreements, e.g., the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and the Agreement on Technical Barriers to Trade (TBT).

3. Progress in global harmonization of food safety regulations

The history of harmonization of food safety legislation goes perhaps back to ancient times, when certain religions spread to many countries. Many of these religions established rules of a hygienic nature.

In more recent history, some of the earliest international standards were those for milk and milk products elaborated by the International Dairy Federation. The years 1945 and 1948 are important milestones in the elaboration of international standards since the FAO of the United Nations and the WHO were established in those years. The former is responsible for setting standards related to quality and composition while the latter has the mandate of establishing food standards relevant to health. In the late 1940s, there were many attempts to establish regional food codes. In 1949, Argentina proposed a regional Latin American food code, the "*Código Latino–Americano de Alimentos*". Between 1954 and 1958, Austria actively pursued the creation of a regional food code, the Codex Alimentarius Europaeus or the European Codex Alimentarius. The Codex Alimentarius Commission (CAC), as we know it today, was created during the period 1961–1963. In 1961, the FAO Conference decided to establish a CAC and requested an early endorsement by WHO of a joint FAO/WHO Food Standards Programme. In 1962, a Joint FAO/WHO Food Standards Conference requested the CAC to implement a joint FAO/WHO food standards programme and to create the Codex Alimentarius. In 1963, the World Health Assembly approved the establishment of the Joint FAO/WHO Programme on Food Standards and adopted the statutes of the CAC.

In 1994, the Uruguay Round of Multilateral Trade Negotiations were concluded in Marrakech. Subsequently, as mentioned above, the World Trade Organization was created and the SPS and TBT agreements came into force.

The SPS and TBT Agreements are particularly important for food safety as they have had a major impact on the harmonization of food safety regulations. The SPS Agreement recognizes the governments' rights to take sanitary measures, but specifies that the measures should be based on science and applied to the extent necessary to protect human health and should not discriminate arbitrarily or unjustifiably between members where identical or similar conditions prevail. Both agreements also encourage WTO Member States to base their measures on international standards, guidelines and recommendations where such exist. With regard to food safety, the SPS agreement recognizes the standards, guidelines and recommendations of the CAC as a benchmark for health protection requirements. It is also expected that WTO Member States accept the sanitary and phytosanitary measures of others as being *equivalent* if the exporting country demonstrates to the importing country that its measures meet the importing *countries appropriate level of health protection*. A question that comes to mind in this context is "what is the appropriate level of health protection?" Debates at international level on this subject have led to the development of new concepts such *as food safety objectives*.

There is no doubt that the SPS Agreement opens the door to new questions such as equivalence, appropriate level of health protection and food safety objectives. *The SPS Agreement has nevertheless played a major role in encouraging countries to bring their legislation in line with international food standards, guidelines and recommendations, i.e., the work of the* CAC *and in this way contributing to the harmonization of food safety regulations. It has also been a catalyst in starting debates on the scientific validity of certain regulations and underlining the need for re-visiting the principles of decision making. It has also encouraged countries to actively participate in the work of the CAC.*

The TBT Agreement is also important to food trade. It provides WTO Member States with the right to consider other legitimate factors in their decision-making process. Examples of such factors are considerations regarding environment, animal welfare, consumer interests, etc.

Box 1. Achievements in the harmonization of food safety regulations

> Today, there has been great progress in the global harmonization of food safety regulations. The CAC, an intergovernmental body operating under the auspices of FAO and WHO, has so far established some 237 commodity food standards, 41 codes of hygienic or technological practice, evaluated some 54 veterinary drugs, 185 pesticides and 1005 food additives.
>
> It has also established Maximum Residue Limits for some 3274 pesticides and guideline values for some 25 contaminants. Furthermore, it has provided guidance on food labelling, nutrition, sampling and analysis, import and export certification, general principles of food hygiene and HACCP.

During the last decade, food safety and its management including the principles for establishing food safety regulations have been in continuous evolution. A turning point in this evolution was the 1991 FAO/WHO Conference on Food Standards, Chemicals in Food and Food Trade, which recommended that the CAC should place greater emphasis on science in its norm-setting work. As a followup to this Conference, FAO and WHO organized jointly three consecutive consultations in 1995, 1997 and 1998 where the concept of risk analysis was introduced at the international level (FAO/WHO, 1995, 1997, 1998, 1999).

In this context, the need for adoption of rational and logical principles of food safety management based on scientific data as well as on considerations of a cultural and socioeconomic nature was emphasized.

These trends have resulted in the fact that the entire approach to food safety has been revisited and has led to the development of the concept of *risk analysis* as a basis for food safety decisions.

Risk analysis consists of three interrelated areas of work: risk assessment, risk management and risk communication. Food legislation is a risk management option and as such it relies heavily on data collected through risk assessment but also on risk communication. It is thus not possible to discuss future challenges in harmonization of food safety regulations without addressing issues related to risk assessment and risk communication. Therefore, in addition to future challenges in risk management, which legislation makes part of it, the paper also addresses the future challenges in risk assessment and risk communication.

4. Future challenges in the harmonization of food safety legislation

There are two types of challenges with which the world's food safety authorities are confronted: scientific and societal challenges.

4.1. Scientific challenges

Scientific challenges refer in this context to all the tasks and endeavours needed to collect the necessary scientific data for making appropriate and transparent decisions.

In terms of *risk management*, one of the key decisions to be taken is the establishment of an appropriate level of health protection or in other words acceptable levels of risk. With respect to global harmonization of food safety regulations, this means the establishment of an internationally agreed appropriate level of health protection. An internationally agreed appropriate level of health protection is very much in line with the principles of the Universal Declaration of Human Rights which accords the same rights to all people regardless of their origin, thus the same rights in terms of health protection from hazardous foods. Thus the establishment of such an agreement including the corresponding food safety legislation is desirable and has so far been feasible mainly for certain chemical hazards, such as food additives and pesticide residues. The relative ease of harmonizing food safety legislation in respect of certain chemical hazards compared to biological hazards is due to mainly the following factors:

1. the presence of chemical hazards in foods is by and large easier to control than biological hazards which are dependent on a number of environmental and human factors;
2. there are already internationally agreed principles for the risk assessment of chemical hazards;

3. the risk assessment of chemicals is based on toxicological studies in animals and, sometimes, even on human data; and
4. there is international agreement that the presence of such chemical hazards should not present any appreciable risk to human health.

With regard to biological hazards, the situation is more complex and difficult. One difficulty arises from the definition of an appropriate level of health protection and how this is to be measured. While, in the SPS Agreement, the WTO provides a definition for appropriate level of sanitary or phytosanitary protection, [1] it does not explain how it should be established or measured. The ICMSF has suggested that the highest acceptable number of foodborne illnesses per 100 000 population could be considered as a criterion for establishing an appropriate level of health protection (van Schothorst, 1998). While not contesting the soundness of such an approach, there are a number of impeding problems to be addressed. Firstly, accurate and reliable data on the incidence of foodborne diseases in different parts of the world are difficult to obtain, if at all possible considering the weakness in programmes for surveillance of foodborne illnesses. Secondly, it should be borne in mind that the control of foodborne illnesses or foodborne hazards of biological origin is difficult since different types of factors (including human, technological and climatic) intervene (Box 2) and means to control these factors in different countries vary considerably.

As a result, protecting consumers from foodborne hazards is not merely a matter of establishing food safety legislation, but also strengthening the necessary infrastructure and providing adequate education to people to control as many of these factors as possible.

A major barrier to global harmonization of food safety regulations is naturally the differences between countries in terms of feasibility to meet certain regulations. One of the principles in risk management is that decisions regarding the acceptable level of risk should be determined primarily from a human health point of view, and that arbitrary or unjustified differences in risk levels should be avoided. However, other factors such as economic costs, perceived benefits, technical feasibility and societal preferences, need to be taken into consideration, particularly in the determination of measures to be taken. It is clear that these factors vary considerably from country to country and, in particular, between the industrialized and the developing countries. The reactions of consumers to GMOs in Europe and how these have influenced food safety regulations show how difficult this is.

[1] The level of protection deemed as appropriate by the member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.

Risk assessment consists of four tasks: hazard identification, hazard characterization, exposure assessment and risk characterization. For hazard identification, there is a need for data on foodborne hazards. Presently, the source and the causative agent of many foodborne disease incidences remains unclear. In this context, the developing countries are in a particularly disadvantageous situation as most of them lack a foodborne disease surveillance programme and their methods of investigation of foodborne disease outbreaks and dissemination of the information are weak. In this regard, there is a need to strengthen the investigation of foodborne disease outbreaks, collecting and analysing the information in databases and disseminating the information widely.

With regard to the hazard characterization of many foodborne pathogens, dose–response data are limited or non-existent. The difficulty of establishing dose–response is due to the fact that

(a) host susceptibility to pathogens is highly variable;
(b) attack rates from a specific pathogen may in different foods vary considerably;
(c) virulence of pathogenic species is highly variable;
(d) pathogenicity is subject to genetic variations resulting from frequent mutation, antagonism from other bacteria in foods or the digestive tract.

There is thus a need for research on the dose–response relationships of various foodborne pathogens. Animal and human volunteer studies need to be carried out to have a better understanding of some underlying factors to these issues.

Investigation of foodborne disease outbreaks should be strengthened and expanded to include collection of data on the level of contamination of foods implicated in outbreaks, the predisposing factors involved and all factors determining human response.

With regard to the assessment of the exposure to foodborne pathogens, the challenge relates to the quantitative evaluation of the likely intake of pathogens. In the case of pathogenic bacteria, this is particularly difficult as the bacterial population may increase or decrease during preparation and/or storage of foods.

The difficulty related to risk characterization is the cumulation of the difficulties encountered during the first three steps of risk assessment, including all the attendant uncertainties.

Risk communication is part of the decision-making process. However, populations around the world differ a lot in terms of their perception, values, culture, religion and lifestyle, needs and motivation, and level of education. Countries have also different means of communication. The language and terminology are main barriers to adequate risk communication and may sometimes create confusion and misperception.

Box 2. Factors contributing to the spread or increase of foodborne diseases

Food supply system
Mass production and distribution, leading to opportunities for contamination and larger foodborne disease outbreaks;
intensive agriculture and animal husbandry practices leading, to increased contamination of the raw foodstuffs, increased use of pesticides and veterinary drugs;
international trade and importation of potentially contaminated food;
longer food chain as a result of urbanization, leading to greater opportunities for contamination, survival and growth; and
blooming food service establishments where food handlers do not necessarily have any training in food safety.

Health and demographic situation
Population growth;
increase in the numbers of the vulnerable population, such as the elderly, immunocompromised individuals, malnourished persons;
increase in number of displaced people and refugees, often with poor health and nutritional status, as a result of man-made or natural disasters, such as wars, floods, earthquakes, etc., and
rapid urbanization, in some areas without necessary water supply and sanitation infrastructure.

Health system and infrastructure
A decrease in resources with a simultaneous increase in the number of food businesses which require supervision, guidance and control;
inadequate water supply and sanitation, as well as fuel for cooking in some parts of the world;
Inadequate education and training of health workers in food safety, with subsequent incapacity of the country to implement adequate and relevant health education activities in the area of food safety;
weaknesses in the investigation and surveillance of foodborne diseases and monitoring contaminants leading to a consequential chain of problems, such as lack of information about food safety problems and priorities, incapacity to evaluate impact of food safety interventions, and
lack of awareness on the part of public health authorities about the magnitude and the consequences of foodborne diseases; and
availability and access to health technologies, including food technologies, telecommunication.

Social situation, behaviour and lifestyle
Increased consumption of food outside home, with a subsequent increase in the number of food service establishments;
increased travel and exposure to unsafe food;
change in food preparation habits as a consequence of the change in the family structure;
Poverty and lack of education;
social and cultural behaviour leading to predilection for certain types of hazardous food;
lack of time and ambition to strive to increase economic profit; and
lack of training and education of food handlers and consumers in food safety.

Environmental conditions
Environmental pollution;
climatic conditions and its changes; and
changes in ecological systems resulting in shrinking fresh water and adequate food supplies.

4.2. Societal challenges

In global harmonization of food safety regulations there are a number of challenges which we can refer to as societal challenges (see Fig. 2). Some of these challenges are:

1. *Balancing the interests of the industrialized and the developing countries*. It is certain that globally harmonized food safety legislation should provide for adequate health protection for people in all countries of the world. However, it should not be unnecessarily stringent and discriminatory towards the developing

Fig. 2. Balancing the needs, interests, risks, benefits, rights and responsibilities of all stakeholders.

countries. International cooperation, particularly assistance of the more well-to-do countries to developing countries is of vital importance.

2. *Balancing the interests of large vs. small industries*. It is important to ensure that food safety regulations do not put small enterprises out of business. To meet this challenge, it is essential that governments recognize the limitations of small businesses and provide assistance to small industries in order that they may meet the food safety regulatory requirements.
3. *Balancing the risks posed by biological and chemical hazards*. To ensure that foods are safe from the point of view of biological as well as chemical hazards, it is essential to consider risks of all hazards in an integrated way and to consider the risk–benefits of measures for control of these hazards.
4. *Balancing consumer concerns and advances in sciences and technology*. It is important to address consumer concerns. However, the challenge is to ensure that consumer concerns do not unjustifiably prevent advances in science and technology.
5. *Balancing efforts for economic growth and food safety considerations*. Trade in goods including foods is an important source of foreign income and thus important for economic growth. Furthermore, food production, manufacturing and processing provide job opportunities and are the backbone of economies of many countries. However, it is important to ensure that these considerations are not at the cost of compromising food safety and the nutritional requirements of the population.
6. *Balancing the interests of consumers and industry*. In the industrialized world, industry is the engine of the economy and it is in their interest to respond to market demands. However, the consumers have also the right to be protected from fraud and unsafe food put on the market intentionally or unintentionally. Therefore, a major challenge is balancing the interest of industry and the rights of consumers.
7. *Balancing globalization and localization*. As mentioned before, globalization is important for economic growth, but it is a major challenge to ensure that globalization is not at the cost of losing national or local identities and culture.
8. *Balancing animal welfare and environmental considerations with the need for new food production methods and innovations*. To meet the needs of a growing world population, continuous innovations in food production, processing and preparation are essential and are of vital importance for meeting the food supply requirements of the 21st century. However, it is important that these innovations do not jeopardize animal welfare and damage the environment.

5. Conclusion

Global harmonization of food safety regulations is certainly a major challenge to the 21st century. In the globalized world of the 21st century, it is indeed an overriding necessity. It is also very much in line with the spirit of the Universal Declaration of Human Rights.

However, a key challenge in global harmonization of food safety regulations is to achieve agreements that provide for adequate health protection and consumer acceptance (including concerns for the environment and animal welfare). Such agreements should, however, not compromise the benefits that can be drawn from economic growth, progress in science and technological development, or penalize the developing countries, small industries and the weakest in society. Some of the key measures in meeting these challenges is the increased participation of the public health sector in the work of the CAC, dialogue and communication with consumers and their education in food safety. Last, but not the least, is the sharing of information, experience and knowledge found in academia, industry, governments and consumer unions in order that a concerted effort to improve food safety can be made at the global level.

Acknowledgements

The authors would like to acknowledge with thanks the contribution of Mr. João Magalhães, WTO, and Dr. Maged Younes, WHO and Dr. Ed Scargorough, US Department of Agriculture for reviewing this article.

References

Cartwright, R. Y., & Chahed, M. (1997). Foodborne diseases in travellers. *World Health Statistics Quarterly*, *50*(1/2), 102–110.

FAO/WHO. (1995). Application of risk analysis to food standards issues. *Report of a joint FAO/WHO expert consultation*, Geneva, March 13–17, 1995, WHO document WHO/FNU/FOS/95.3.

FAO/WHO. (1998). The application of risk communication to food standards and safety matters. *Report of joint FAO/WHO expert consultation*, Rome, February 2–6, 1998, FAO Food and Nutrition Paper, No. 70, 1999.

FAO/WHO. (1997). Risk management and food safety. *Report of a joint FAO/WHO expert consultation*, Rome, Italy, 27–31 January, 1997, FAO Food and Nutrition Paper, No. 65.

FAO/WHO. (1999). Understanding the Codex Alimentarius. Food and Agriculture Organization, Rome, 1999.

ICN. (1991). International Conference on Nutrition. World Declaration on Nutrition. Rome.

van Schothorst, M. (1998). Principles for the establishment of microbiological food safety objectives and related control measures. *Food Control*, *9*(6), 379–384.