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Working Party on Agricultural Policies and Markets

ADDRESSING SOCIO-ECONOMIC CONCERNS RELATED TO FOOD SAFETY:
A REVIEW OF INNOVATIVE COUNTRY APPROACHES

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Contact person: Wayne Jones (E-mail: Wayne.Jones@oecd.org)
Tel: (33-1) 45.24.78.74
Fax: (33-1) 44.30.61.19

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NOTE BY THE SECRETARIAT

This document is one of a series of reports prepared under the 2001-2002 Programme of Work on Food Safety. It was first discussed at the 3-4 October 2002 meeting of the Working Party on Agricultural Policies and Markets. A revised version was submitted to the APM for declassification under the written procedure. A second round of revisions were incorporated in response to minor editing comments received from some Member countries.

The document is now declassified under the responsibility of the Secretary-General.
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ADDRESSING SOCIO-ECONOMIC CONCERNS RELATED TO FOOD SAFETY:
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I. Introduction

1. The horizontal programme of work on food safety includes an activity to examine socio-economic concerns and public consultation, as described in the scoping paper Socio-economic Concerns and Public Consultations: A scoping Paper [AGR/CA/APM(2001)34]. The objective of this activity is to increase the transparency as to how Member countries address these issues within the context of a science-based, rules-based approach to food safety as required under the SPS Agreement and as established under Codex procedures.

2. The OECD Compendium on National Food Safety Systems and Activities (OECD, 2000) reported that a number of Member countries were addressing socio-economic concerns and/or improving public consultation and communications within the context of their food safety systems. The scoping paper proposed to follow-up the Compendium by examining different government approaches with the objective of identifying innovative approaches and their impacts on domestic food safety regulatory systems (i.e. what changed?).

3. The Secretariat invited a small number of Member countries to participate in this review by asking them to expand on their particular approach to addressing socio-economic concerns related to food safety and quality. Participating countries were not expected to undertake new work for this activity but were asked to provide a brief note based on existing material or, alternatively provide background material for the Secretariat to summarise.

4. The following countries agreed to participate in this review:

   Australia -- which reported in the Compendium that regulatory impact assessments consider wider issues such as the impact of regulation on food availability, cost and quality, consumer choice and other social costs.

   Canada -- which at the July 2001 OECD Meeting of Food Safety Regulators in Bangkok described a new, multi-faceted decision making process that distinguishes between the role of scientists to assess risk and that of policy advisors to consider the science within the broad range of international and socio-economic factors.

   France -- which in a report for the January 2002 FAO/WHO Global Forum of Food Safety Regulators suggested that other legitimate factors should be taken into account in risk management notably social and economic factors, traditional and ethical factors and environmental factors.

   New Zealand -- which reported in the Compendium that non-scientific or quality concerns are addressed through development of alternative mechanisms that in no way impinge on food safety.

   Norway -- which reported in the Compendium that authorities evaluate the consequences for society in terms of economic impacts on all stakeholders, social and cultural conditions, and conditions related to regional policy, employment, environment, etc.
Section II attempts to identify some of the main highlights of these selected Member country approaches to addressing socio-economic concerns and public consultations related to food safety. This is followed by notes on individual country approaches. The reports received from France and Norway are reproduced as received whereas the Secretariat prepared summaries for Australia, Canada and New Zealand, based on existing documentation and written comments provided by these Member countries.

II. Summary Observations

6. Food safety risk management is becoming more formalised. The Member countries reviewed in this study are formalising and standardising their procedures for regulatory impact assessment to ensure good decision-making processes and regulatory policy. Australia has established guidelines for standard setting that apply over a broad range of responsibilities that include, but are not confined to, food safety. Health Canada has developed a decision-making framework to improve risk management decision-making across its health protection programs. The Ministries of Health and Agriculture in New Zealand have also developed a risk management framework for food safety as part of their “optimal regulatory model”. In Norway, a new scientific committee will be established to further improve risk assessment.

7. Addressing socio-economic concerns need not compromise food safety. All participating Member countries support a science rules based approach to food safety and agree that consideration of socio-economic concerns should not undermine the scientific integrity of the risk assessment process. The report describes how certain countries address socio-economic concerns in the risk management decision making framework. New Zealand suggests that even before risk assessment, in the risk evaluation phase, it may be useful to include information on societal values and perceptions associated with food safety because such risk profiling can influence future risk management activities.

8. Addressing socio-economic concerns is a legitimate part of risk management. Human health remains the highest priority of food safety regulators but some regulatory authorities such as Food Standards Australia New Zealand (FSANZ) suggest that managing risk is not just about protecting public health and safety. The risk management procedures of Food Standards Australia New Zealand (FSANZ) integrate risk assessment with social and economic goals to identify measures that address diverse community interests. Socio-economic analysis (SEA) is imbedded in Health Canada’s decision-making process, encompassing social, cultural and equity considerations. France has identified a long list of “other legitimate factors” and has endeavoured to take at least some of these into account through improved access to information and comprehensive public consultation.

9. Regulators distinguish between food safety and food quality. Food safety regulators make a clear distinction between food safety and food quality attributes, even though consumers may not always agree on the same separation. At the international level, there is continuing debate on the extent to which governments should intervene in regulating quality aspects. One concern is in forcing national preferences on others through trade barriers (extra-territoriality in WTO terminology). Where such standards are having an adverse impact on trade, there may be a case for the development of international standards, guidelines and advisory texts by relevant international standards setting bodies.

10. Implications of socio-economic concerns are increasingly quantified for proper assessment. National guidelines that require regulators to consider socio-economic factors also require them to quantify the potential costs and benefits (as well as distributional aspects). This quantification helps establish the most efficient regulatory option. Cost-benefit analysis is generally considered the most effective approach to measure economic and social impacts through estimation of “net social benefits” (what is best for the community as a whole). Australia’s guidelines for national standard setting indicate such analysis should also take account of impacts which cannot be valued quantitatively.
11. Public consultation on socio-economic concerns is contentious and complex but necessary. Given that food safety concerns all consumers and that consumer expectations about food safety and public health are diverse and complex, regulation of food is often contentious. Yet, all Member countries in this review stressed the public’s strong desire to be consulted on risk management decisions. Public consultation and risk communications have become an integral part of the decision-making process. As risk perceptions vary with age, region, social, cultural and ethical factors, etc., such consultation should be as wide as possible. Regulatory impact assessments can provide a useful starting point for discussion as they give stakeholders a firm proposal to consider.

12. Approaches to public consultation are more effective when designed to meet the circumstance. There is no one “best practice” for engaging stakeholders and the public in the food safety regulatory process. All the countries in this review have implemented multi-faceted systems for consulting civil society on socio-economic concerns related to food safety, including ad hoc forums, special advisory bodies, stakeholder partnerships, and joint decision-making bodies. Common practices for successful consultation involve early stakeholder involvement, clear objectives, flexible and open dialogue and a decision-oriented process.

13. Approaches to addressing socio-economic concerns must be consistent with WTO disciplines. WTO Members are bound to uphold the requirements of the SPS, TBT and TRIPS Agreements. In particular, the SPS Agreement requires Members to base their sanitary and phytosanitary measures on international standards (Codex in the case of food standards), unless there is scientific justification for a departure. There is explicit provision in the SPS Agreement for considering specific, economic factors in assessing risks to animal or plant life or health (but not human life or health) and for determining what measures to apply. However, non-health/non-safety concerns such as consumer preference and animal welfare are not mentioned and are outside the scope of the SPS Agreement.

14. An international consensus has emerged on consideration of “other legitimate factors”. Through Codex, the criteria and processes for addressing “other legitimate factors” in the context of international standards development has progressed. The Codex Statements of Principle Concerning the Role of Science in the Codex Decision Making Process and the Extent to Which Other Factors are Taken into Account limits legitimate factors to those relevant for the protection of consumer health and promotion of fair trade practices. The extent to which socio-economic concerns relevant to a national government would also be relevant for inclusion in a global standard being elaborated by Codex would be considered on a case by case basis. This would be accomplished by applying the Codex criteria noted above and now contained in the latest Codex Procedural Manual (12th Edition).

15. A country can address societal concerns in determining its appropriate level of protection. The appropriate level of sanitary (or phytosanitary) protection (ALOP) is a decision for each country that can take into account all manner of societal factors. However, the WTO SPS Agreement requires that national measures put in place to protect human, plant and animal life and health that result in a higher level of protection than would be achieved through applying relevant international standards must be justified according to a scientific risk assessment must be applied in a manner that avoids arbitrary or unjustifiable discrimination, and must be no more trade restrictive than necessary. For example, France points out that the relative importance of “other legitimate factors” vary across countries and that determining which factors to take into account in a decision regarding food safety is the responsibility of national governments.

16. Socio-economic concerns influence the approach to regulating novel foods. Much of the debate about whether or how to address socio-economic concerns related to food safety can be traced to concerns
about novel foods (a generic term used by the OECD Task Force on Novel Foods and Feeds referring to foods derived from genetic engineering and those produced by other novel processes that cause major changes in composition, structure, nutritional quality, microbiological or chemical safety). All the countries in this review have undertaken extensive consultations on novel foods which have encompassed consideration of socio-economic concerns related to food safety. These consultations have resulted in an explicitly cautionary approach to the regulation of novel foods. The FSANZ philosophy, for example, is that due to potential health concerns, novel foods should be prohibited unless expressly permitted on the basis of appropriate scientific data with provision made to ensure consumer informed choice (many consumer socio-economic concerns can be addressed through labelling).

17. Shared experience can provide valuable lessons for OECD Member countries. Finally, this review has emphasised that Member country approaches to addressing socio-economic concerns and public consultation related to food safety is a constantly evolving process. Institutional structures, regulatory frameworks, consultation mechanisms and the food safety regulations themselves are all undergoing change. With such change comes the development of, and experiences with, new approaches. Countries should continue to discuss these experiences in order to better understand other national approaches, to improve their own systems and to develop international standards and guidelines.

III. Australia

18. Australia is strongly of the view that a science and rules-based approach to food safety remains fundamental to any national food safety system. Communication of the food standards process and consultation are important elements of Australia’s food safety regime and are both important in ensuring that the latest science and information is made available to decision-makers. Nevertheless, it is critical that national policy approaches to food safety are consistent with the requirements of the World Trade Organisation Agreement on the Application of Sanitary and Phytosanitary Measures which place international standard setting organisations, in this instance Codex Alimentarius, and science-based decision-making at the centre of any international food safety regime.

19. The procedures followed for regulatory impact assessment are set out in the document, Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standards-Setting Bodies, which was endorsed by the Council of Australian Governments in 1997 (COAG, 1997). It is important to note that, as outlined in the guidelines, regulation impact assessments are not confined to the area of food safety alone and apply across the broad range of Commonwealth and State/Territory bodies responsible for standard setting. As such, regulatory impact assessments are more accurately defined as tools for ensuring good policy practice rather than having any specific or exclusive role in food safety.

Principles and Guidelines for National Standard Setting

20. The Guidelines emphasise the importance of ensuring that new standards do not impose excessive requirements on business. The aim of any national standard setting process should be to achieve

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1. The OECD’s Task Force for the Safety of Novel Foods and Feeds promotes international harmonisation in the safety assessment and regulation of novel foods and feeds, including the products of modern biotechnology. This definition of ‘novel foods’, used to define the scope of the work of the OECD Task Force on Novel Foods and Feeds, does not imply all novel foods are compositionally/nutritionally different. It is not intended to define what is safe or unsafe. The U.S. Food and Drug Administration (FDA) does not use this term, nor does Canada’s biotech legislation.
Of particular relevance to this exercise is the principle adopted by COAG in February 1994 that:

“Proposals for new regulation that have the potential to restrict competition should include evidence that the competitive effects of the regulation have been considered; that the benefits outweigh the likely costs; and that the restriction is no more restrictive than necessary in the public interest.”

21. Where a possible need for regulation is identified, quantitative analysis is needed to support this position and to establish the most efficient form which this regulation might take. The basic feature of economic appraisal is its systematic examination of all the advantages and disadvantages of each practicable alternative way of achieving an objective. Impact assessment should attempt to assess all costs and benefits to the greatest extent possible, that is, not just economic ones. For example, social and environmental, public health and consumer safety effects should be considered where relevant. The level of assessment will depend upon an estimation of the likely impact. Regulations with significant net costs or benefits require detailed quantitative assessment.

22. The Guidelines require regulators to identify the need for regulation and to quantify the potential costs and benefits. A number of different approaches to quantitative analysis may be employed depending on the circumstances -- risk analysis, cost-benefit analysis and/or cost-effectiveness analysis. Cost-benefit analysis can address the socio-economic concerns related to food safety but requires that all the major costs and benefits of a proposal be quantified in money terms. In this way, the outcomes of a range of options are translated into comparable terms in order to facilitate evaluation and decision-making. Cost-benefit analysis is most effective in instances where there is sound information on which to base the analysis, and it should involve consideration of the distribution of benefits and costs, as well as taking account of impacts which cannot be valued quantitatively.

23. Cost-benefit analysis can measure the economic and social impact of government action by reference to the 'net social benefits' that action might produce. The term 'net social benefits' refers to the difference between social benefits and social costs. Decisions about the overall effectiveness of regulatory action should not be made on the basis only of its effect on particular groups in society. Public policy makers are expected to make judgements based on what is best for the community as a whole. By measuring 'social', as opposed to only private, market-based costs and benefits, CBA is a valuable tool when developing good policy responses to economic and social problems.

24. Public consultation is an important part of the regulatory development process. Consultation occurs when the course of regulatory action is being considered and a draft impact assessment statement is being produced. This gives interested parties a firm proposal to consider. Minimum assessment requirements include documentation of which groups benefit and which groups pay the direct and indirect costs of implementation, as well as a list of persons/groups who made submissions or were consulted and a summary of their views. Evidence is also required that the Ministerial Council or other intergovernmental standard-setting body has considered the views expressed during the consultation process.

25. Consultation should be as wide as possible but at the least, should include those most likely to be affected by regulatory action (e.g. consumer and business organisations) which might provide valuable feedback on the costs and benefits of regulation and on the impact assessment analysis generally. It also provides feedback on the level of support for the proposed regulation. Since public consultation usually only involves interested parties, new regulatory measures are advertised to bring them to the attention of the wider community.

26. If, at the conclusion of the impact assessment process, there is some dissatisfaction with the process or adequacy of the analysis by which its conclusions were reached, two or more jurisdictions may
request a review of the proposed national standard. The Ministerial Council or other intergovernmental standard-setting body must then defer its consideration of the standard and commission a review by a regulatory agency, specialist body or consultant. The process of independent review would be triggered if two Heads of Government write to the Chair of the Ministerial Council or standard-setting body requesting an independent review of the assessment process. The review body may also comment on any aspect of the proposed regulation and will have access to public submissions made in the course of the assessment process. The report of the independent review body is a public document to be considered by the Ministerial Council or standard-setting body in its discussion of the adoption of the proposed regulatory measures.

**Food Standards Australia New Zealand (FSANZ)**

27. The Australia New Zealand Food Authority (ANZFA) was replaced by Food Standards Australia New Zealand (FSANZ) on 1 July 2002. This is part of a broader package of reforms to the food regulatory system in Australia brought about by the signing of a new intergovernmental Food Regulation Agreement, proposed changes to the Australia New Zealand Joint Food Standards Treaty and amendments to the *Australia New Zealand Food Authority Act 1991*. Detailed information is available on the FSANZ website: [www.foodstandards.gov.au](http://www.foodstandards.gov.au), which also includes a selection of current draft reports made available for consultation, and the Food Regulation Secretariat website: [www.foodsecretariat.health.gov.au](http://www.foodsecretariat.health.gov.au).

28. One of the principal changes to the food regulatory system is the implementation of new arrangements for the development of policy guidelines to apply to food standards. Previously all food standards policies were developed by the ANZFA Board, having regard to the broader policies and objectives of government. Under the new system, the new Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) will decide on policy guidelines based on advice from a new Food Regulation Standing Committee comprising senior government officials from the Commonwealth, New Zealand, the States and the Territories. Unlike ANZFA, Food Standards Australia New Zealand will have responsibility for approving standards, and variations to standards, then notifying the Ministerial Council of any approval. The Ministerial Council may then reject, amend or seek a review of any standard notified to it by Food Standards Australia New Zealand.

29. The new arrangements are also intended to bring together, for the first time, standards for the food manufacturing industry and standards for primary producers. Arrangements are being developed to move responsibility for developing mandatory safety standards that apply to primary products to the new organisation and the new Ministerial Council. There is an increasing interest in a number of primary industry sectors in developing new outcomes-based food safety standards, similar to those applying to the food manufacturing sectors. It is envisaged that such standards will be developed using the same consultative and scientifically robust processes that FSANZ currently employs to develop its other standards.

30. Members of the Food Standards Board will be drawn from an expanded list of specialist areas - public health, food science, human nutrition, consumer affairs, food allergy, medical science, microbiology, food safety, biotechnology, veterinary science, primary food production, the food industry, food processing or retailing, small business, international trade, food regulation, consumer rights and consumer affairs policy, the National Health and Medical Research Council and government. The new arrangements for the Board include calling for nominations from prescribed organisations. The organisation will remain dedicated to improving its stakeholder interfaces and community involvement processes and will continue to work with its stakeholder groups to develop food standards for Australia and New Zealand.
World Trade Organization and Codex

31. FSANZ is bound, on behalf of Australia and New Zealand, to uphold the requirements of the World Trade Organization's SPS, TBT and TRIPS Agreements. The Sanitary and Phytosanitary (SPS) Agreement requires that members ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence. In the assessment of risks, members must take into account available scientific evidence, relevant economic factors and attempt to minimise negative trade effects.

32. In order to harmonise sanitary and phytosanitary measures, WTO Members shall base their measures on international standards (Article 3.1), and in the case of food standards, international standards are determined through the mechanisms of the Codex Alimentarius Commission (Codex). Members may introduce or maintain measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate (Article 3.3); and still must adopt the least trade restrictive measure.

33. The Codex procedure for developing and reviewing standards is a slow process, and many are in need of review in light of contemporary scientific knowledge and/or community expectations. Codex proceeds by consensus among its 160 members. Therefore many countries, including Australia and New Zealand, have many standards that depart from Codex standards, but this only occurs where there is sound scientific evidence supporting the need to do so.

34. The Technical Barriers to Trade (TBT) Agreement requires members to ensure that technical regulations are not prepared, adopted or applied with a view to, or with the effect of, creating unnecessary obstacles to international trade. This Agreement also requires application of international standards where these exist except where they would be inappropriate.

35. The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) requires members to respect the intellectual property rights of other members. It has been of particular relevance to the work of ANZFA in relation to the development of standards regulating geographical indications.

36. Because both Australia and New Zealand are significant exporters of food and food products, both are vulnerable to retaliatory action should we not meet these obligations. FSANZ gives full consideration to these issues in considering the various regulatory options and also provides an opportunity for comments from other countries on proposed standards through the WTO notification process, when appropriate. These matters are discussed in its Full Assessment and Inquiry reports.

FSANZ's Risk Management Framework

37. In progressing from application (external parties) or proposal (FSANZ initiative) to gazetted standard, FSANZ is bound to comply with a number of practices and policies - some legislated, others imposed by government decision. It has developed a rigorous risk management system to deliver against these obligations (ANZFA, 1996; ANZFA, 2001).

38. Managing risk is not just about protecting public health and safety, although for FSANZ this must always be the highest priority. Risk management is also about achieving FSANZ's other statutory objectives (the provision of information to consumers and preventing misleading or deceptive conduct) and balancing achievement of these objectives against business and community costs.
39. FSANZ is committed to employing a structured approach to risk. Its integrated approach to risk is based on the Australian/ New Zealand Risk Management Standard 1999 (AS/NZS, 1999) and also incorporates the risk analysis process endorsed by the Codex Alimentarius Commission. Amongst other things, FSANZ's integrated approach to risk is to ensure that risks are systematically identified and considered in regulatory decision-making.

40. The analysis of risk can be divided into two distinct processes, namely risk assessment (using available information to identify, characterise and quantify the adverse health effects of exposure to a biological, chemical or physical agent) and risk management (integrating risk assessment results with social and economic goals, and after considering policy options, identifying a strategy to control the risk). Within FSANZ's role, risk assessment can be further broken down into scientific risk assessment (to protect public health and safety) and assessment of the risks relevant to the other consumer protection objectives (providing information and preventing misleading and deceptive conduct).

41. The task for FSANZ as a regulator is to identify the most appropriate level of all types of risk (measured by likelihood and consequence of occurrence) against the cost of reducing that risk. This is done by ascertaining and evaluating the most appropriate options for addressing these risks and identifying the risk management measure that most optimally protects and addresses the diverse interests of the communities of Australia and New Zealand.

42. In the area of managing public health and safety and consumer expectations about health and safety, this algorithm is necessarily complex. Given that food issues concern every consumer, the regulation of food is often very contentious. This means that FSANZ must be very rigorous in its methodologies. It reinforces the need for FSANZ to maintain its role as the independent expert receptive to evidence and arguments advanced by all stakeholder groups.

**FSANZ's Scientific Risk Assessment Processes**

43. FSANZ's primary task is the protection of public health and safety through the development of food standards for Australia and New Zealand. The current food regulatory system in Australia and New Zealand is based upon a community standard in relation to the safety of food that reflects a long history of safe consumption. There are risks and benefits associated with the consumption of all foods, however, the community has the knowledge necessary to manage or negate the hazards of conventional foods while accessing their benefits. For these reasons, conventional foods are generally considered to be safe so long as manufacturers and consumers exercise due care in their preparation and handling.

44. An explicitly cautionary approach is applied to foods and food ingredients that do not have an established history of safe human use and to environmental contaminants (ANZFA, 1999). These include:

- substances added to food for technological purposes (*i.e.* food additives and processing aids);
- foods with no prior history of safe human consumption (novel foods);
- foods produced using novel processes (*e.g.* foods produced using gene technology and irradiated foods);
- metal and non-metal contaminants which may occur in food through adventitious contamination;
- residues of agricultural and veterinary applications of various chemical compounds.
45. The philosophy applied to these foods within the food regulatory system is that, due to potential health concerns about their use, they should be prohibited unless expressly permitted. The basis for permitting substances with no prior history of safe use is that:

- the relevant and appropriate scientific data indicate that the foods are as safe as their conventional counterparts when present in food;
- the consumer is either empowered through labelling to make informed choices about their presence or is protected from misleading and deceptive conduct by controls placed on their use.

46. In the case of environmental contaminants, a substance that raises health concerns is only permitted in food to the extent that:

- the relevant and appropriate scientific data show that the contaminant does not pose an unacceptable risk to public health and safety even over a lifetime of consumption;
- it is at the lowest level that is reasonably achievable through Good Agricultural and Manufacturing Practices.

47. The concepts and procedures described are broadly consistent with those of other national food regulatory agencies and with principles established both by the Codex Alimentarius Commission (Codex) under the Joint FAO/WHO Food Standards Programme, and the International Programme on Chemical Safety in co-operation with the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

IV. Canada

48. In 1993, Health Canada published a formal framework, which defined and described the risk assessment and risk management process in a structured way (Health Canada, 1993). While the 1993 approach served its purpose well, in recent years there have been a number of changes in society, science and technology, that have prompted the Department and other public health agencies to re-examine the way that they deal with health risks. These changes have had an enormous impact on public health and the work of health protection. Health Canada has recognised the need to modernise its approach to risk assessment and risk management, to deal effectively with these new challenges.

49. In the summer of 1997, Health Canada launched a fundamental review of its health protection operations. This effort, known as “Health Protection Branch (HPB) Transition,” was aimed at helping Health Canada and its partners to better manage risks to the health of Canadians into the next century (Health Canada, 1998). Through HPB Transition, Health Canada developed a decision-making framework and a number of documents that provide guidance in dealing with related considerations. Implementation of the framework, its underlying principles, and the associated guidance documents, will help the Department to deal with the challenges of the current environment, in a consistent, comprehensive and co-ordinated fashion, and consequently will improve the effectiveness of the risk management decision-making process across its health protection programs (Health Canada, 2000).

50. Recommendations for improved decision-making based on the national public health consultations held by HPB Transition and from various Health Canada working groups focused on several major themes including, among others, the examination of health risks from a broad perspective, effective risk communication and public engagement/stakeholder participation.
Examining Health Risks within A Broad Perspective

51. Risk assessment involves determining the likelihood that a specific adverse health effect will occur in an individual or population, following exposure to a hazardous agent. The value of using a broad approach to risk assessment stems from the recognition that a variety of different factors or determinants may influence our health, in addition to the “physical” environment. It also involves considering the outcomes for specific populations in addition to risks to whole populations, including maximally exposed individuals. It further involves considering the perspectives and knowledge of a range of interested and affected parties to the extent possible and appropriate for a given risk situation.

52. Thus risk assessment involves examining and integrating information on risk factors (such as gender, age, ethnic origin, social situation, economic conditions, education, culture or personal convictions), when following critical examination, there is a demonstrated influence on the level and/or likelihood of risk for specific populations. Such an approach may be used for example, when determining different levels of exposure to food contaminants, which may result from different consumption patterns that occur due to social/cultural practices or economic status.

Effective Risk Communication

53. The growing complexity of risk assessment and risk management, the increasing interest and demand of the public for more information, and the number of recent controversies related to the handling of specific risk issues [e.g. whether to permit use of recombinant bovine somatotrophin (rBST) in Canada], all contribute to the need for Health Canada to provide interested and affected parties with timely, relevant information, in a format that is useful to them. The public is no longer satisfied with merely being presented with the results of risk management decisions after the fact.

54. Risk communication is an integral part of the decision-making process, because risk management decisions must be acceptable to a broad range of interested and affected parties. A key factor in communicating risk-related information to the public is to incorporate the target audience perceptions. In order to adequately examine risk perceptions, it is necessary to ensure that the views of a range of interested and affected parties are considered. Risk perception information may be collected in a number of ways, including through surveys, analysis of news media reports, and by inferring perceptions based on other factors, such as past responses to similar risk situations.

55. Risk perception refers to the way that individuals intuitively see and judge risks. Risk perception is influenced by many factors including age, gender, level of education, region of residence, values, social, cultural, and ethical factors, and previous exposure to information on the hazard. Key influences include the degree to which people understand or experience the hazard through their senses; the degree to which the hazard elicits feelings of dread, including fatalities; and the size and type of the population at risk, especially if children are affected. Also important is whether people voluntarily assume a risk or whether it is imposed upon them. Perceptions can change over time, as new information becomes available or as social norms change.

Public Engagement and Stakeholder Participation

56. In recent years, members of the public have become more interested in being involved in decisions that affect them, especially when it comes to their health. The reluctance of many individuals to rely on government to singularly make risk management decisions, requires that mechanisms be put into place to provide greater opportunities, not only for the exchange of information, but where possible, for participation in the risk management decision-making process.
57. Health Canada interacts with a wide range of parties during the decision-making process, including: other federal government departments, provincial and territorial governments, municipal governments, provincial health systems, non-governmental organisations, health professionals, public health agencies, health associations, environmental associations, industry, the academic community, consumer groups, community groups, international governments, international agencies, other agencies, regional representatives, representatives of different cultural, economic, or ethnic groups, and the general public.

58. A (draft) Guidance Document on Public Involvement (Health Canada, 1999a) describes general underlying concepts and values related to public involvement, provides general guidance on involving the public in the risk management decision-making process, and provides an example illustrating the types of public involvement activities that might be undertaken. Some considerations include:

- Involve interested and affected parties early in the decision-making process.
- The nature, extent, and complexity of involvement should be appropriate to the scope and impact of the decision, the potential of the decision to generate controversy, and how quickly action must be taken.
- Attempt to engage representatives of all potentially interested and affected parties to solicit a diversity of perspectives.
- Be clear about the extent that parties can be involved and the goals of involvement; identify considerations and limitations that exist so that the scope and nature of involvement are clear.
- All participants, including those from Health Canada, must be willing to negotiate and be flexible (unless there are legislative or other limitations that preclude this). They must be prepared to listen to and learn from diverse viewpoints.
- Give participants credit for their roles in decisions, and explain how their input was used. If suggestions were not used, explain why.
- Allow for formal inclusion of minority views or dissenting opinions, where appropriate.
- Recognise that broad participation is a learning process.

An Example of Public Consultation on Food Safety

59. Rapid advances in food science and biotechnology have resulted in the development of a variety of foods that were not previously available in the Canadian marketplace, or that have been modified from their traditional composition. In view of these developments, it was agreed that there was a need for a formal mechanism whereby these “novel” foods are notified to the Department of Health and assessed for safety prior to their sale to consumers. Public satisfaction with the thoroughness of the approaches implemented for evaluating the safety of novel foods is important to their acceptance by consumers. A new Division (i.e. chapter) of the Food and Drug Regulations, Division 28, was established that defines the concept of a “novel food” and details the requirements for notification prior to the sale or advertising for sale of such products (Health Canada, 1999b).

60. On August 5, 1992, an Information Letter (IL No. 806) released by Health Canada represented the first public step in the development of regulations in Canada to ensure the safety of novel foods.
Additional consultations were undertaken, including publication of the "Guidelines for the Safety Assessment of Novel Foods", and the co-sponsoring, with the Food Production and Inspection Branch of Agriculture and Agri-Food Canada (predecessor to the Canada Food Inspection Agency (CFIA) and Environment Canada, of a public workshop concerning the regulation of agricultural products of biotechnology. Numerous meetings, as well as written and verbal communications, were conducted with companies, industry associations, consumers groups and individuals. Following the pre-publication in Canada Gazette, on August 26, 1995, a total of 35 responses commenting on the proposed amendments were received. While not numerous, the responses to the proposed amendments of August 26, 1995, were substantial and complex. A number of consultations were subsequently held with specific stakeholder groups in order to clearly determine their concerns and discuss ways to resolve them.

61. The result was a substantial change to the definition of novel food to make the definition clearer and narrow its scope. This approach intended to restrict novel food notifications only to those processes that are truly new and cause substantial changes in the food. However, several industry associations were concerned that the scope of the new definition of novel food remained too broad. Suggestions were made to restrict the definition of novel food to foods derived from biotechnology. Health Canada maintained that novel foods derived from genetic engineering and those produced by other novel processes that cause the food to undergo a major change with regard to composition, structure, nutritional quality, microbiological or chemical safety require an assessment of their characteristics in order to ensure their safety when consumed. Therefore, the amendment covers the two types of novel foods and both require notification.

**Consideration of Socio-Economic Factors in Managing Food Safety Issues**

62. The assessment of health risks and the selection and implementation of effective risk management strategies forms the basis of Health Canada’s food safety activities. The inclusion of socio-economic factors in health risk decision-making is rooted in Health Canada’s structured decision making process based on a Decision-Making Framework (DMF).

63. For the purposes of health risk decision making, a socio-economic analysis (SEA) is defined in broad terms as a methodology used to assist in allocating available resources among alternative risk management options, by examining the positive and negative consequences (respectively, the effects or benefits and costs) of each risk management option; and recognising the broad societal context (i.e. social, cultural, ethical and/or equity considerations) of resource allocation decisions. SEA is intended to provide decision-makers with a comprehensive set of relevant information that will help them take a decision.

64. A good SEA goes far beyond any financial assessment or accounting exercise; and is carried out within a broad, well-defined social context. It considers the impact of risk management decisions on distributions of health, economic and other societal endpoints. SEA can be limited to examining consequences resulting from a single situation or action, or a full-scale SEA which takes a comparative approach to measuring the consequences of alternative actions; and thus allows evaluation of the relative efficiency of the alternatives. In either case, it is important that the broad societal perspective be taken to frame the context of the overall analysis.

65. While SEA is a tool which can lead to more informed decision-making, it should not be viewed as the singular determinant of decisions. These analyses do not replace judgement or consideration of other factors, such as competing policy priorities, the availability of resources for implementation of an intervention, or overriding moral imperatives.

66. The development and use of SEA is intrinsically linked to the six steps of decision-making defined by the DMF - (1) Identify the issue and its context; (2) assess the health risks and benefits;
(3) identify and analyse options; (4) select a strategy; (5) implement the strategy; and (6) monitor and evaluate the results. The interplay between SEA and the DMF is outlined below.

67. **Step 1: Identify the Issue and Its Context.** This step involves determining the nature and context of a risk management issue, using a broad perspective. Step 1 frames the decision making problem and therefore acts as the first step in framing the SEA. Conversely, existing SEAs can help identify important elements of the risk issue and its context.

68. **Step 2: Assess Risks and Benefits.** The assessment of risks and benefits associated with a specific issue provide basic and essential input into any SEA. Note that when the information obtained through risk assessment is not specific enough to use for a full SEA, a simpler analysis such as a cost-consequence analysis, simply listing expected health and economic outcomes may suffice.

69. **Step 3: Identify and Analyse Options.** This step of the framework involves examining alternative courses of action (e.g. regulation, education, changes in technology) to prevent, eliminate, minimise or reduce the risk of concern. Step 3 provides the most direct application of SEA to risk decision making. Socio-economic analysis at this stage of the framework helps to put into context each of the options being put forward as solutions to the issue identified in Step 1; and, via that context, the SEA facilitates the later stages of the Framework.

70. **Step 4: Select a Strategy.** One of the most obvious impacts of SEA is in facilitating the decision-making process with respect to selecting the risk management strategy to be implemented. Decision-makers need access to the SEAs conducted in Steps 2 and/or 3 (as part of the background data and/or risk option analysis) to facilitate the selection process.

71. **Step 5: Implement the Strategy.** This step involves developing and carrying out an action plan to put the risk management strategy into place. It also involves developing criteria or key indicators (health-related, economic and social) to monitor and evaluate the strategy. The function of a SEA at this juncture can vary. For instance, if there are multiple options for implementing the risk management strategy, a SEA could facilitate the decision as to which option to pursue. SEA can also be used to assist in the development of appropriate criteria.

72. **Step 6: Monitor and Evaluate Results.** The last step of the framework sets the stage for the iterative function of the Framework, as well as the development of a corporate database of achievements flowing from the activities of the Framework. The information gathered during the evaluation phase may lead to recommendations to revisit a previous step in the process; or the information may feed into Step 1 the next time a related problem is identified. In this step, SEA contributes to determining the cost-effectiveness of the chosen risk management strategy. In addition, the SEA could help identify unexpected socio-economic consequences of the strategy. Program evaluations are the most common examples for this step in the DMF.

V. **France**

73. France attaches great importance to food policy in the sense in which this term is used by the OECD, that is to say a balanced strategy pursued by government which takes account of the linkages both within the food chain and between the food sector and the rest of the economy.

74. The management of public health risks, particularly those relating to food, is central to this food policy and provides a material basis for action by government. Working in a complex environment, public health managers responsible for implementing government policy must ensure a high level of consumer health protection and are also charged with the task of designing and implementing systems for the
surveillance and control of food production and manufacturing. These managers use risk analysis as part of a comprehensive approach to risk control since it provides a means of identifying and assessing risks so that they can then be reduced to a socially acceptable level. All national risk management measures in France are based on scientific advice provided by the French Food Safety Agency (AFSSA). However, France considers that, in addition to such scientific criteria, account must also be taken of other criteria, namely social, ethical or cultural considerations which reflect the aspirations of society and which help to determine choices and food behaviour.

75. It is therefore necessary to recognise the limits to the role that scientific expertise can play in assessing the risks that actually exist, and to take account of "other legitimate factors". This generic term emphasises the aspect of legitimacy that is common to all these factors in the sense that they reflect shared concepts or values which ought to be taken into account by policy makers.

The Concept of "Other Legitimate Factors"

76. The protection of public health is a prime duty of governments and is central to the decision-making process regarding food safety. It is the responsibility of governments to determine the appropriate level of health protection for their citizens in relation to an acceptable level of risk; this choice is at the discretion of governments. Any public health measure, particularly with regard to food-related risks, should therefore aim to achieve the requisite level of health protection, that is to say to reduce health risks to a level deemed to be acceptable.

77. However, consumer health protection must not be treated as a separate issue to be dealt with in isolation from other areas of government concern, in that any measure taken to protect the health of consumers will inevitably have impacts in other sectors. Concerns other that the protection of public health, where they are worthy of being taken into account by governments, are known as "other legitimate factors". These factors are legitimate in the sense that they fall within the competence of governments and that the actions of the latter are taken in response to a "mandate" given by society as a whole.

78. "Other legitimate factors" taken into account by governments include the following:

- **Prevention of misleading practices** -- This concern may be viewed in terms of one of the two basic goals of the Codex Alimentarius (the promotion of fair trading practices). Account must be taken of aspects relating to the fair trading of products when making a decision relating to food safety. An example of this may be seen in the introduction of special labelling requirements for irradiated food products.

- **Animal health** -- The health of animals must be protected *per se* not only for economic reasons relating to herd or flock management, but also to guarantee the quality of products of animal origin supplied to consumers. Animal health is therefore a legitimate factor.

- **Economic cost to operators** -- Decisions taken with regard to food safety must take account of the economic capacity of operators. For example, a decision to impose a new technique or technology can only be justified if operators have sufficient capacity to implement it.

- **Cultural, religious or moral considerations** -- The objective expectations, based on cultural, religious or moral grounds, expressed by representative segments of the population may be taken into account in decisions relating to food safety. For example, the health measures applicable to abattoirs supplying "halal" products take account of certain religious imperatives (no stunning of animals, orientation of booths where animals are bled out).
• **Protection of workers** -- Employees of farms and enterprises working in the agro-food sector (farmers, workers, etc.) must be protected and the safety of their working conditions is a factor which cannot be ignored. The ban on the use of pithing in abattoirs has led to the introduction of enhanced protection for employees working in close proximity to animals about to be slaughtered.

• **Protection of the environment** -- The environment must obviously be taken into account in all cases where it might pose a risk to the food chain. That said, conservation of the environment must remain an objective in its own right and all impacts of food chain activities on the environment must be examined.

• **Ethical considerations** -- In many cases ethical considerations are addressed through labelling requirements which allow consumers to make a fully informed choice.

• **Animal welfare** -- This concern may be linked to the account taken of cultural or moral demands and is a growing issue in many countries.

• **Maintenance of public order** -- This is one of the fundamental duties of governments. Any decision regarding food safety which might give rise to serious conflict leading to public disorder (violent riots, assaults on the public) must be reconsidered.

• **Government's inspection capacity** -- The capacity of government inspection agencies can occasionally prove to be a limiting factor in decisions regarding food safety. For the same given level of health protection, governments may prefer options that require a lesser degree of inspection. Governments' inspection capacity is a legitimate factor in that it is directly linked to the fiscal burden on taxpayers.

**Consequences**

79. Firstly, the concept of "other legitimate factors" varies both over time and from one country to another. In some countries, for example, considerable efforts are devoted to protection of the environment, whereas in others such protection is still an emerging issue. Determining which factors to take into account in a decision regarding food safety is therefore the responsibility of governments.

80. Secondly, "other legitimate factors" often have a scientific component in that science is not used solely to identify the risks to human health and is therefore not confined to the medical sciences. For example, scientific methods and principles are applied in the assessment of environmental risks; the prevention of misleading practices is based on knowledge provided by the social sciences; and the assessment of the economic impacts of a public health measure on a given agricultural sector falls within the domain of economics.

81. "Science" should therefore not be systematically opposed to "other legitimate factors". On the contrary, it should be understood in a broader sense and applied to all areas taken into account in a public health decision so that each factor can be based on objective and verifiable facts, thereby precluding any risk of arbitrariness.
"Other legitimate factors" must be taken into account in the food safety decision-making process:
In practice, there is no such thing as zero risk for food safety. Accordingly, the job of decision-makers is to manage this risk rather than to seek to eliminate it. The aim of food safety measures is therefore to reduce the element of risk to an "acceptable" level.

In order not to compromise other areas worthy of concern any more than is needed to achieve the requisite level of health protection, the risk manager must not focus solely on the impact that management measures are expected to have on the level of risk for the population in that it might well be possible to use a combination of several measures to achieve an acceptable level of health protection. These options will have differing impacts on each area of legitimate concern. The choice of which option to use therefore depends on the relative degree of importance accorded to the "other legitimate factors".

"Other legitimate factors" must be taken into account in the risk management process: The question we need to answer is whether "other legitimate factors" should be examined during the risk assessment or the risk management stage. France's opinion is that these other factors must not be allowed to interfere with the assessment of risks to human health. The responsibility for taking account of these factors must be vested in those who manage the risks, since they alone can legitimately decide upon the relative degree of importance to assign to each factor. Were these factors to be taken into account, in any way whatsoever, during the risk assessment stage, the outcome of the assessment would be flawed and it would not be possible to reach an informed decision.

The account taken of "other legitimate factors" by risk managers must reflect the aspirations of civil society: Risk managers take account of "other legitimate factors" by attaching a given degree of importance to each factor. The weighting given to each factor must reflect the aspirations of civil society as closely as possible in that the decision concerns the community and the risk manager is fulfilling a mandate given to him by society as a whole. It is therefore important that the process remain clearly defined and transparent and that it draw upon all the information available. France also considers that legitimate factors must be taken into account objectively and proportionately. Experience has shown that a diversified and pluralist assessment based on consultations that are as wide-ranging and as comprehensive as possible is a prerequisite for ensuring that the decisions taken are both acceptable and judicious. Procedures must therefore be put in place to allow the risk manager to ascertain the aspirations of civil society.

Systems Allowing "Other Legitimate Factors" to be Taken into Account

Taking legitimate factors properly into account requires an organisational structure targeted on two prime objectives that France has endeavoured to meet over the past few years, namely to ensure that the parties concerned, including consumers, have the widest and most comprehensive access to information as possible, and to ascertain the opinions and aspirations of different communities within the population as accurately as possible.

With regard to the dissemination of information, France has for many years focused its efforts on the institutional channels available for informing the public. However, it became clear a few years ago that this system needed to be improved. Consequently, when the French Food Safety Agency (AFSSA) was first established in 1998, it was decided that its opinions would be published and made available to as wide an audience as possible through a dedicated website. The Ministry of Agriculture, Food, Fishing and Rural Affairs also opted for transparency by deciding to provide on-line access to a wide range of information relating to food safety issues, and all topical subjects concerning the Ministry in general, on its own dedicated website (www.agriculture.gouv.fr). The opinions issued by the National Food Council (see
As for seeking the opinion of interested parties, France traditionally relies on a number of agencies and bodies whose aim is to promote exchanges or gather opinions. However, France has also put in place a number of specific systems for consulting civil society and other representative organisations in the food chain which offer the latter the possibility of playing an active and effective part in the framing of decisions. The main principles on which the consultative process has been based are as follows:

- dialogue must help to forestall or resolve problems by making it possible to identify major trends and, where possible, solutions that respect the different aspirations of the population;
- the process must be defined beforehand and must develop into a genuine means of taking decisions;
- it must be flexible enough to allow greater involvement of the general public according to the nature and importance of the decision to be taken, as well as the time available;
- it must ensure that no interests or specific considerations are disregarded and must be organised or supervised by a body with a properly diversified or balanced membership base.

The following examples are those of bodies of this type which are currently involved, at different levels and times according to the nature and importance of the topics addressed, in the decision-making process at the level of government.

**National Food Council (CNA):** The CNA is a consultative body created in 1985 and administered by the Ministers responsible for Agriculture and Food, Health and Consumer Affairs. It is composed of representatives of primary production, processing, distribution, consumers, scientists and government departments. It provides government with opinions regarding the framing of food policy and issues relating more specifically to:

- the matching of consumption to nutritional needs;
- consumer food safety;
- food product quality;
- product information for consumers.

The opinions issued by the CNA are made available to the public on the Internet: [http://www.agriculture.gouv.fr/alim/part/cna.html](http://www.agriculture.gouv.fr/alim/part/cna.html). To date, the National Food Council has issued over thirty opinions, two of which address the subject of legitimate factors:

- opinion No. 22, entitled "The role played by science and by other considerations in national and international decisions regarding food policy";
- opinion No. 29, entitled "Public consultation and debate on food policy: Issues at stake and methodological considerations".

**National Consumer Council (CNC):** This is a joint consultative body administered by the Minister responsible for consumer affairs; it has jurisdiction over all matters relating to consumer issues. It
consists of two colleges, one made up of representatives of consumer and user associations and the other of representatives drawn from industry (primary production, processing sector, self-employed sector, service sector).

93. It has two functions. The first is to serve as a forum for discussions with consumers, users and industry; the second is to provide a forum for discussions regarding the future directions for government policy on food consumption. Requests can be submitted to the Council for an opinion on draft legislation or regulations that may have an impact on consumption, and also on the conditions for the implementation of such legislation. It is also mandatory that the CNC be consulted before the publication of any government order regarding prices or the publication of prices. Further details may be found at the following website: http://www.finances.gouv.fr/pole_ecofin/consommation/conseil_consommation/.

94. **Food General Assembly**: The Food General Assembly consisted in a series of studies, analyses and meetings organised between October and December 2000 with the aim of gaining a better understanding of public expectations with regard to food safety and quality. The three Ministers responsible for agriculture and food, consumption and health were all involved in this Assembly, primarily through local government departments within the Prefectures. Five forums were held over a period of 10 days in November 2000 in Lyon, Lille, Nantes, Marseille and Toulouse. Prior to the meetings, a major programme had been undertaken to gather information and canvas opinion through a survey and pre-forum meetings, and a symposium closing the Assembly was held in Paris in December 2001. The methodology adopted was as follows:

- An initial preliminary stage consisting in quantitative surveys conducted by a survey institute with the aim of measuring emerging trends, and qualitative studies based on individual interviews and "adversarial" interviews in which consumers, government risk managers and actors from civil society (drawn from the industrial sector, the distribution sector, doctors, veterinary surgeons, etc.) are confronted with each other in groups of ten.

- Pre-forums were held in each of the towns chosen to host the regional forums. Each event was attended by around a hundred delegates, half of whom were people involved in the industrial food chain, but chosen on an individual basis and not as the institutional representatives of their corporation, and the other half of whom were members of the public. These pre-forums were used to gather a body of opinion and information which provided the main topic for debate at the regional forums.

- The forums, attended by approximately 500 people at each venue, provided an opportunity to open a debate on the topics which emerged in the pre-forums and opinion polls, as well as a dialogue between the public and industry.

- Lastly, the national symposium was attended by over 600 people, some of whom had already participated in the regional forums, as well as various actors from the agro-food sector, health professionals, consumer associations, representatives of the government departments concerned, bodies in charge of monitoring health and scientific assessment, politicians, the press, scientific experts and sociologists.

95. Besides the subjects of these debates, a major part of the assessment of this Food General Assembly focused on the analysis of this "engineered public debate". A more detailed account is available at the following website: http://www.agriculture.gouv.fr/EGA/presentation/presentation_3.htm.

96. **Public debates**: A public debate on "GMOs and field testing" was organised on 4 and 5 February 2002 at the Economic and Social Council in Paris. The format was that of a two-sided debate on several
topics initially identified and formulated as a question "What are the socio-economic implications of research into GMOs and their development? Why progress from tests in a contained environment to field testing? What decision-making procedures and controls apply to field testing?"

97. The debate opposed "those involved" (researchers, government employees, civil society, enterprises, farmers, local government, etc.) to "laymen" (a citizens' panel, groups of young students, unemployed young people, etc.). The public was given an opportunity to ask questions via the Internet, and details of the event, the topics addressed and conclusions reached are available on the MAF website: http://www.agriculture.gouv.fr/OGM/debatpublic/debatpublic_meo.htm.

98. Once again, besides the contents of these discussions, a number of interesting lessons were learnt from this novel form of debate. It was clearly apparent that there are no longer any compelling a priori arguments and that the public not only wishes to have an opportunity to give its opinion, but also to ensure that it plays an effective part in the decision-making process.

An Example of Taking Account of "Other Legitimate Factors": The Selective Slaughter of Herds of Cattle in Which a Case of BSE has been Notified

99. The decisions taken with regard to the slaughter of cattle herds notified as being infected with bovine spongiform encephalitis (BSE); i.e. the herds in which sick animals were originally produced, illustrates the manner in which the French authorities take account of "other legitimate factors". When the first case of BSE was reported in France in 1991, the health policy initially adopted aimed to eradicate the disease through the wholesale slaughter of infected herds. This measure included the payment of full compensation to the farmers concerned and was implemented without encountering any major problems until 2000.

100. From that year onwards, however, the introduction of more stringent screening systems resulted in a substantial increase in the number of cases identified and consequently the number of animals that had to be slaughtered and destroyed. The outcome was that over 35 000 cattle were slaughtered in 2001 and the social acceptability of such measures sharply declined. The outbreak of foot and mouth disease in 2001 in the United Kingdom and subsequently France, which was stamped out by a policy of drastic culling and which was accompanied by widespread media coverage of mass animal graves, also helped increase the reluctance of society as a whole to accept the slaughter of apparently healthy animals.

101. In response to this reaction, France decided to review its policy of wholesale slaughter of herds in which cases of BSE were reported, and the Ministers responsible for agriculture and food, health and consumption jointly informed the authority charged with the assessment of health risks (AFSSA) to that effect. The AFSSA issued an opinion on 25 June 2001 in which it proposed a number of risk management strategies that would allow a gradual shift to be made towards selective slaughter without any change in the level of health protection afforded to consumers.

102. Before taking any decision in this regard, the Minister responsible for agriculture and food felt it necessary to seek the opinion of representatives of civil society and the beef industry and asked the CNA to conduct a survey on its behalf. The CNA sent a written questionnaire to its members before formally debating the issue at its plenary session on 28 June 2001 and issuing an opinion on "terms and conditions for replacing the complete slaughter of herds of cattle in which a case of BSE has been notified with a policy of selective slaughter". The CNA analysed the expected impacts of such a measure and acknowledged that a shift towards selective slaughter was desirable, but nonetheless felt that all the requisite conditions for such a shift had not yet been met and that such an arrangement would need to be carefully and methodically prepared beforehand. In particular, the CNA drew the attention of the
authorities to the major risk that such a measure might fuel public concern or that it might not even be understood by the public which could interpret such a development as an abandonment of the precautionary principle and a threat to health safety.

103. The CNA suggested that the government adopt a strategy towards selective slaughter based on a number of criteria which, in order of priority, might be as follows:

- all efforts should be directed towards achieving a level of safety for consumers equivalent to that afforded by wholesale slaughter;
- measures must be equally comprehensible to both beef farmers and consumers;
- straight-forward procedures for managing the BSE and enforcing controls.

This opinion clearly shows that considerations falling within the scope of "other legitimate factors" should be taken into account by the competent authorities when establishing a strategy towards selective slaughtering.

104. In response to this opinion issued by the CNA, the French authorities postponed introducing the policy of selective slaughter, which eventually entered into force on 21 February 2002 (Order of 20 February 2002) after the AFSSA and CNA had again been consulted and had ruled in favour of the proposed measures which were not to slaughter cattle born after 1 January 2002 in infected herds other than the offspring of cows known to have contracted BSE.

VI. New Zealand

105. While governments around the world recognise and accept their responsibility for food safety assurance, there is a growing trend towards giving industry greater responsibility for ensuring safety of their products. This has resulted in a different approach to food safety regulation - one that is less prescriptive and focused on those elements of regulation that are crucial for food safety and leaving the remainder to industry determination. Concerns have been raised about the impact of “private standards” on international trade. It has to be clearly recognised that such standards are industry driven and are matters for determination between buyer and seller. There is a role for private operators to work with governments in deriving workable standards to attain certain food safety objectives. New Zealand, as in some other countries, enforce these industry agreed standards at government level. They have force of law, and, if complied with, carry government assurances, or attract penalties for non-compliance.

106. Some consumers are concerned about the safety to people and the environment of foods produced by modern agricultural systems. The concerns include the effects of using synthetic pesticides, irradiation and, in particular, biotechnologies (e.g. hormonal growth promotants, genetically modified organisms) to improve the safety of food. These concerns highlight the need for risk communication to explain the basis of decision making and to provide consumers with relevant information to enable them to make informed choices. New Zealand believes that governments have a responsibility to ensure open debate and transparency in the decision-making processes.

107. In New Zealand, as elsewhere, concerns have been expressed about ethical, cultural and social issues related to foods. These concerns are complex, ranging from country to country, and have resulted in differing national approaches to regulation which could adversely affect trade. Where consumer needs are based on issues other than science, it is important that regulators, producers, manufacturers and public
interest groups recognise that each have roles to play in providing information to enable consumers to make informed choices, and prevent deceptive practices in trade.

Ensuring Food Safety

108. It is important that the regulator distinguishes clearly between food safety and those aspects of food that are considered quality. Safety is a basic requirement for food on the market. Consumers want a diversity of quality food produced to high safety standards at affordable prices. The line between safety and quality, from a consumer perspective, can often be exceedingly blurry. Aspects that a regulator may consider to be a quality issue, might be considered a safety issue by some consumers. A classic example is the treatment of food animals with a natural hormone for growth enhancing purposes and consumer rejection of the notion because the final product contains “hormones”.

109. Safety is more generally able to be measured quantitatively, while quality is vitally dependent on the “eye of the beholder”. This in itself is not problem where beholders (consumers) are free to make their own decisions about the quality they wish to purchase, but is important where governments get involved. In Codex, there is continuing debate about the two terms, and more specifically on the extent to which governments should intervene in regulating quality aspects. For example, in a meat quality context, most governments will continue to be involved in “wholesomeness” such as freedom from bruises, icterus, non-zoonotic parasitic cysts, etc. even though there are no food safety connotations, and also “fit for purpose”.

110. Wholesomeness has traditionally been hard to pin down in Codex but the meat hygiene codes define it primarily as being “free of defects generally considered as objectionable to consumers”. Thus in the “fit for purpose” situation, meat trim intended for grinding may be allowed more blood clots/bruising than meat for the retail trade.

111. The term “fit for purpose” is often used to describe what the manufacturer intended when the food was produced and what the consumer expected when they purchased the food. Legally the term “fitness for intended purpose” has a tighter meaning and generally relates to having managed the relevant risk factors and being suitable for the purpose for which the product is intended. Nevertheless, the issues surrounding “informed choice” and truthful labelling need to be worked through with both consumers and processors so that an optimal solution is put into effect.

112. In New Zealand, acceptable levels of protection are established by the Government to protect the health of consumers. Both technical factors such as the feasibility and cost of proposed sanitary measures and social/political or ‘other legitimate factors’, govern the decision on the level of risk that is tolerable or acceptable. In recognising that these levels are often set in terms of criteria other than safety (e.g. grade, quality, method of production), the term “fit for purpose” is applied, rather than “food safety”. The concept of fit for purpose does, however, include a number of aspects associated with food safety such as minimising microbiological, chemical and physical hazards. Performance targets linked to the acceptable levels of protection can then be set for various stages in the continuum from production to consumption, and food producer plans developed to match.

Working within the SPS Agreement

113. New Zealand has actively supported the multilateral trade system, and has played a role in establishing Codex standards and in the negotiations that led to establishing the WTO SPS and TBT Agreements. The SPS Agreement is firmly based on science. A prime objective of the Agreement was to prevent SPS measures from being used for protectionist purposes, which could too easily happen if the focus for justification were allowed to shift from scientific arguments. There is limited room for economic
analysis in the risk assessments upon which SPS measures should be based, relating to entry and establishment of pests and diseases, costs of control or eradication, and cost-effectiveness of alternative approaches of limiting risks.

114. New Zealand maintains that SPS measures must be based on science and risk assessment as provided for within the SPS Agreement. To achieve the objectives of greater international harmonisation, it is important that the science principles are upheld. New Zealand acknowledges that factors other than science such as non-health/non-safety related consumer preference and animal welfare are outside the scope of the SPS agreement (although the SPS agreement does cover measures for protecting the environment, Annex A). Each country determines its own appropriate level of protection (ALOP), which can take into account all manner of societal factors. However, the WTO SPS Agreement requires that national measures put in place to protect human, animal and plant health must be justified according to a scientific risk assessment to demonstrate that they are aimed at achieving the ALOP, and that they are not applied in a discriminatory manner and are no more trade restrictive than necessary (unless based on international standards in which case they are presumed to be consistent with the SPS Agreement). A risk assessment helps countries determine the measures needed to achieve a desired level of protection.

115. A broader consideration of socio-economic concerns related to food safety requires a more sophisticated cost-benefit approach. This issue was debated in New Zealand in the lead up to the Hazardous Substances and New Organisms Act 1996, and the Act provides for cost-benefit considerations to be taken into account in the decision process. However, New Zealand considers the SPS Agreement was well founded in limiting the scope of economic analysis to the costs side of the equation. Improvements of criteria and precision of the analysis would be required before embarking on assessment of the general economic welfare gain of particular measures. In fact, it is difficult to see how the objectives of the SPS Agreement could be protected if it were opened up to wider cost-benefit analysis. However, the objectives of the SPS agreement are to protect human, animal and plant health and life in the least trade-restrictive way possible.

116. This does not mean there can be no rules on the quality side of things, but the danger is “extra-territoriality” (in WTO terms), \emph{i.e.} forcing one’s laws/prejudices on others through trade barriers. There are justifications for challenging rules where they represent only one country’s view of the world or one country’s particular environment. To the extent that there are concerns emerging about various national approaches to setting the appropriate level of protection, a stakeholder review of the impact such concerns are having on setting regulations and impacts on trade may be useful.

\textbf{New Zealand’s Involvement in Codex}

117. Codex has strengthened the criteria and processes for standards development. The Statements of Principle Concerning the Role of Science in the Codex Decision Making Process and the Extent to Which Other Relevant Factors are Taken into Account reflect the strong consensus on the core principles to be applied at the international level (Codex, 2000). Similarly, the current work in clarifying “other legitimate factors” relevant to health protection and fair practices in food trade is important to ensure that these are consistent with Codex’s essential mandate.

\footnote{2. A first part of this Act entered into effect from July 1998.}
118. New Zealand recognises the importance of involving stakeholders in the work of Codex and is committed to incorporating the views of interested and affected parties (NZ Ministry of Health and Ministry of Agriculture, 2001). A sound consultative process is essential for policy development and the advocacy of New Zealand interests. The New Zealand Codex Contact Point, located in the recently established New Zealand Food Safety Authority, operates a consultation process on Codex matters based on the principles of transparency, inclusiveness and open exchange of information. The process involves:

- dissemination of Codex documents to organisations known to be interested in or affected by the work of Codex;
- co-ordination of public pre-meeting consultations and debriefing with interested parties;
- public consultations on matters of significant public interest;
- use of internet to publicise and disseminate information on Codex;
- invite New Zealand industry and non-governmental groups and individuals to attend Codex meetings as observers.

119. A practical illustration of how the consultation process has been used to address broader public concerns is in relation to Codex work on foods derived from biotechnology. Given the significant public interest in GM foods New Zealand initiated wide public consultations to seek the views of stakeholders on the safety evaluation and labelling of GM foods. The consultations were immensely helpful in bringing out the key concerns of New Zealand stakeholders in respect of GM foods. These included the need to have a rigorous safety evaluation framework and the importance of clear accurate and understandable labelling of GM foods to enable consumers to make informed choices.

120. These consultations also brought out some of the broader concerns of stakeholders in respect of these so-called ‘other legitimate factors.’ These included ethical concerns and philosophical objections to the use of GM technology. The issue for the Government was not whether or not these concerns were justified but the extent to which these fell within the framework and mandate of Codex. Many of the broader issues that were raised in public consultations were clearly outside the scope of Codex and more appropriately dealt with at the national level. Public consultation process was more focussed on bringing out those issues and priorities that were relevant at the Codex/international level and how these might be addressed within the framework of Codex.

_Strengthening Stakeholder Input_

121. In September 1997, the Government directed the Ministry of Agriculture (MAF), in co-operation with the Ministry of Health, to undertake a review of the food administration system in New Zealand. Consultations were conducted with a wide range of stakeholders including industry, consumers, health groups and local government representatives. The resulting 1998 report indicated that fragmented responsibilities had resulted in confusion among both industry and consumers as to whom to approach to influence policy or standards, obtain regulatory approvals and seek action because of non-compliance or illness (NZ Ministry of Health and Ministry of Agriculture, 1998). There were general concerns of inadequate consumer representation and/or participation in decision making.

122. A number of organisational reform options were considered -- a new department of state, new ministry of food, an agency within a ministry, an independent regulatory agency and the status quo. The preferred option was the creation of a single agency (located inside MAF) to deal with all food regulation.
A stand-alone agency was considered and rejected owing to the high cost of establishment. The organisation and administrative changes were to provide a single point of contact for consumers and interest groups for information and advice, allow for a co-ordinated approach to consumer education and information needs and allow for consumers to have improved input into policy development and standards-setting.

123. In July 1999, the former MAF Regulatory Authority was split into two agencies—one concentrating on New Zealand’s biosecurity and the other on the primary production, processing and export of food and food-related products—MAF Food Assurance Authority (NZ Ministry of Agriculture, 1999; NZ Ministry of Agriculture, 2000). The change signalled the Government’s wish for a strong, clear focus on each of these areas. The MAF Food Assurance Authority was created, and although the proposal to move the regulation of the domestic food sector from the Ministry of Health to MAF was delayed, the options for a single food administration were under review with further changes anticipated. A Food Advisory Group was set up to help guide the emerging food assurance system, including representatives from MAF, Ministry of Health, industry and consumer stakeholders.

124. The New Zealand Government recognised that the whole issue of consumer and public interest group involvement and participation in government food policy setting was important. A wide array of consumer groups assembled in Wellington in September 2001 to meet with government officials. The Food Safety Consumer Forum explored ways in which consumers can have a more meaningful input into food safety policy and practice. Good consumer education and labelling were key issues. Representatives also felt risks needed to be prioritised, and they wanted to be able to make input on environment and food supply issues such as pesticides, growth promotants and GM foods. Consumers wanted better use of existing networks and to see a national consumer food safety forum established.

125. In 2001, a Consumer’s Forum was created to act as a consultative body on food standards and related issues. Consumer representatives are members of national or regional bodies with an interest in the impact of food and food safety on the health and welfare of New Zealanders. The forum is to meet two to three times a year depending on the issues being considered. Specifically to:

- engage consumers and government agencies in a two-way dialogue about the food safety programme and regulatory processes;
- consumers and government agencies to share their views, opinions and perspectives on the food safety programme;
- serve as a sounding board/reality check for government agencies (the regulator);
- provide a forum for information sharing and discussion in relation to food safety and the food safety programme;
- enable government agencies (the regulator) to make robust decisions;
- nominate consumer group representatives to government decision making bodies as appropriate.

126. In July 2002, the Government established the New Zealand Food Safety Authority (NZFSA); a semi-autonomous body attached to MAF. The NZFSA is responsible for food safety and meeting country requirements for NZ exports. To maintain a whole of government approach to food issues, an Officials Committee on Food Safety involving government agencies with accountability for health and trade, economic development and consumer affairs has been established. At the same time, Food Standards
Australia New Zealand (FSANZ) was established, responsible for developing standards for food labelling and composition for both New Zealand and Australia (see description of FSANZ in section on Australia above).

127. A key objective of the NZFSA will be to engage consumers and encourage participation in the food regulatory process. A 10-member advisory board comprised of representatives from key stakeholder groups will be set up to advise the Minister for Food Safety on the domestic food safety programme. The functions of the board will include:

- assuring the Minister that domestic food policy incorporates the range of consumer/industry/health outcomes sought by the Government and the interests of a wide range of stakeholder groups;
- advising on the efficiency and effectiveness of the food safety programme;
- advising the Minister and the Authority on strategies and policies covering the "farm to plate" food continuum;
- providing a forum for stakeholders to participate in, or initiate debate on, government policies relating to food.

**Accommodating Socio-Economic Concerns in a Risk Management Framework**

128. The New Zealand food safety programme administered by MAF adopted a strategic approach to the regulation of risks in foods, moving from a traditional command and control regime based on prescriptive requirements to a science and risk based approach using the “optimal regulatory model”.

A critical component of this approach is the use of risk based management plans (RMPs). RMPs identify potential hazards before they occur, and put systems into place to prevent them.

129. It is anticipated that, in time, all NZ food producers will be required to operate under risk-based management programmes of some description. A risk management framework for food safety has been developed by the Ministry of Health and MAF (NZ Ministry of Health and Ministry of Agriculture, 2000). Risk management provides the process whereby the results of risk assessment, and evaluation of other factors relevant to health protection of consumers and the promotion of fair trade practices, are used to choose and implement appropriate food safety controls. The four key steps in food safety risk management are risk evaluation, assessment of risk management options, implementation of the risk management decision, and monitoring and review. Effective food safety risk management relies on appropriate risk communication and stakeholder representation at all these steps.

130. Each risk evaluation requires the establishment of a risk profile, which places the issue within a particular food safety context. Setting of risk assessment policy is a key management function that needs to

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3. The optimal regulatory model is a risk based approach to production and processing from the farm/seas to retail sale. It relies on government acting as the regulator setting appropriate sanitary measures (in consultation with stakeholders), industry taking full responsibility for producing food and food related products that are “fit for purpose” using risk based management plans with independent verification that industry have abided by their plans. The model strengthens government accountability by being national and based on quality systems with documentation at all steps. Industry involvement in the safety and wholesomeness of their products is maximised by the use of internationally recognised Hazard Analysis and Critical Control Point (HACCP) risk management techniques to identify and control hazards in the food production process.
be addressed before risk assessment commences. It may involve both risk managers and risk assessors working together in an informal environment, and may include information on societal values and perceptions associated with a food safety issue as well as the likely distribution of risks and benefits. As risk profiling may strongly influence further risk management activities, appropriate communication between all stakeholders (including risk assessors and risk managers) must be maintained at all times.

131. The assessment of risk management options is based on qualitative and quantitative information on risks. Selection of a preferred risk management option will primarily involve a systematic evaluation of the likely impact of different sanitary measures on preventing, reducing or eliminating risks to human health, within the framework of the particular risk management approach that has been chosen. The impact of the chosen sanitary measures on factors other than public health that may be legitimately considered, *e.g.* economic and social factors, will also influence the process. In most cases, the process used to arrive at a decision on an appropriate level of consumer protection (and appropriate sanitary measures) will be broad-based, with relevant “other legitimate factors” ideally having been identified before this part of risk management begins.

132. In most cases, the risk management decision will be enacted by design and implementation of specified sanitary measures. An essential part of a risk management framework is the gathering and analysing of data from appropriate points in the “farm-to-fork” continuum so as to service ongoing risk assessment and risk management activities.

VII. Norway

133. The main goals in Norwegian food policy are to ensure the consumers safe food and food of good quality. It is also a goal that the consumers shall trust the food to be safe. Food safety, in relation to the handling and production of foodstuffs from the farm and fjord to the table, requires enhanced co-operation between health, agricultural, and fishery authorities, as well as with the food producing sector and consumers. The European BSE-crisis and the dioxin affair underline the importance of seeing the food chain as an integrated whole. They also underscore the importance of co-operation across national borders. It has also become evident that the impact of regulations on these areas are substantial to farmers and industry in economic and social terms.

134. Within 2004, Norway will merge the different directorates working with food safety into one Food Safety Directorate. The idea is to establish an efficient, transparent and prevention-oriented food safety and quality system along the entire food chain. In addition to the restructuring of the control authorities, one single Food Act will replace the current laws regarding food safety. A new scientific committee will be established to further improve risk assessment. After the reorganising of the food safety control authorities and application of new food laws, the farm/fjord to table aspect will be even more focused upon.

135. As Norway is part of the European Economic Area (EEA), a major part of the rules and regulations concerning food safety is harmonised with the EU. Through the EEA agreement, Norway has an obligation to produce foodstuffs according to the standards laid down in community legislation, and also revise and develop our national regulations in accordance with the EU. In the work of replacing the current national laws regarding food safety with one new Food Act, the EU regulation concerning Food Law, will be incorporated.
Food Safety Considerations in a Food Security Aspect

136. The Norwegian food policies are based on a broad platform, and the United Nations International Covenant on Economic, Social and Cultural Rights is considered as an important aspect in this context. The Covenant is made part of Norwegian law through the Human Rights Act of 1999. In accordance with the Covenant, the government is responsible for providing all citizens access to sufficient and safe food, which will meet their dietary needs and preferences.

137. The production of safe food of high quality is a main goal of the food production policy. On the other hand, a consumer-oriented policy implies that the consumers’ concerns about food safety must be in focus in the policy making. In the food safety policies it is a goal to respect the right to adequate food by also taking into account the worries of the consumers, in addition to recognising the importance of health concerns.

Consumer Participation

138. Policies for food and agriculture in Norway are mainly based upon a White Paper on food and agriculture from 1999. The White Paper underlines the need for a more consumer oriented agricultural policy. The food chain is regarded as a whole and consumer aspects are to be considered at all stages of the production chain.

139. Transparency concerning food production methods and regulations for the entire food chain is important in order to strengthen consumer confidence in food products. Many consumers have a holistic view on food and food production, and require the food to be produced in an ethical and sustainable way. Considerations about animal welfare, biodiversity, the environment and human rights are aspects that the consumers consider. When developing the Norwegian policies, aspects of consumer relevance are emphasised in addition to efficient and independent risk assessment. Recent studies show that 85% of Norwegian consumers have great confidence in the Norwegian Food Control Authority. It is important to maintain and further strengthen consumer confidence in food products and in the food industry.

140. An action plan for the inclusion of consumer participation in food and agricultural policies has been drawn up. The plan focuses on respect for consumer rights, such as the right to choose a diet based upon one’s dietary preferences, health considerations and other factors such as environmental concerns, animal welfare etc.

141. In accordance with the action plan, work has been started in order to create Consumer Panels in seven counties in Norway. The panels will be funded 100% by the Ministry of Agriculture. Each panel will consist of a group of people with different backgrounds, age, income etc., and the panellists will be trained in order to understand their role as members of a Consumer Panel. The panels will have a consultative function in relation to the development of the official food policies in Norway. The panels will be organised by the Consumer Council of Norway, which will report to a Steering Committee for consumer orientation, consisting of representatives of the Ministry of Agriculture, the Ministry of Health, the Ministry of Fisheries, the Ministry of Children and Family Affairs, relevant Directorates and the Norwegian Consumer Council. Possible topics will be contemporary issues relating to the wider aspects of food safety policies, e.g. GM food and animal welfare. The panels may also address topics on food safety of their own interest.

142. The conclusions and advice given by the panels will be addressed to the Norwegian authorities, through the Steering Committee. The Ministry of Agriculture, as the leader of the Steering Committee will have the responsibility of further processing and taking into account the information gathered. The
conclusions and advice of the panels will also be made available to the public by the media and on the Internet.

143. Through the panels, the authorities will be able to gain new understanding of the consumer opinions in the field of food safety. The Consumer Panels will, according to the plans, start operating by the end of 2002. Through the establishment of these Consumer Panels, the authorities will have to allow for consumer influence more directly in the policy making.

144. In addition to the Consumer Panels, work has also been started to create an Internet gateway to information about food and food safety. The aim is that the consumers will have an easy access to information they require about food. The Internet gateway will start operating in March 2003.

**Consumer Demands**

145. In light of globalisation, it is important for a nation to preserve its identity and distinctiveness. At the same time, the consumers are more conscious, as they demand a wider selection of food, where factors as price, variety and quality play their different roles. Some wish to be able to choose food with a special geographical and cultural identity from local producers, and the requests for ecological products are increasing.

146. In any case, food safety must be an underlying principle. Providing safe food to our citizens is an obligation Norway has according to the food security concept established by the International Covenant on Economic, Social and Cultural Rights. Food safety standards cannot be reduced as a consequence of the consumers’ increased focus on a wide range of quality parameters.

147. The government plays an important role in giving possibilities and adapting the legislation in order to make it possible to preserve cultural and traditional specialities. In the work of creating local added values, it is important to maintain a balance, so that the want for added values does not interfere with the requirements of safe food.

148. Imports to Norway have increased in recent years, following increased trade and globalisation. The extent of the dioxin and BSE affairs has made the consumers more aware of the origin of the food, and more interested in the possibilities of tracing the origin of the food. In 2001, legislation about mandatory labelling of the origin of beef was introduced in Norway. Before the end of 2002, there will also be introduced legislation concerning voluntary labelling, indicating other qualities of the meat. Legislation concerning the origin of fruit and vegetables will also be implemented in 2002.

**Protection of Designations for Agricultural Foodstuffs**

149. In accordance with the consumer orientation of the food policies in Norway, the government seeks to follow up the demands of the consumers. One of the trends that have been seen recently, is a trend towards more consumer focus on quality products and demand for more information about the products. In response to this trend, the Norwegian government has adopted a regulation, which lays down the requirements for governmental protection of designations of origin, geographical indications and designations of specific traditional character for agricultural foodstuffs. The focus of the Norwegian regulation is that through branding of the protected products, consumers will be able to choose products of a specific quality, as well as giving opportunities for farmers and others to develop new products and increase the economic output.
Risk Management

150. The focus of the food policies in Norway is from the fjord and farm to the table, production and distribution included. In this connection, risk management options are legislative measures (such as hygienic provisions, prohibition of sale, maximum limits etc.), control activities, monitoring programmes, labelling, consumer information and dietary recommendations. Norwegian authorities aim at taking safety measures as early as possible in the production chain. Such measures are related to legislation covering primary production, environment etc., and comprise regulation concerning production methods, storage conditions, use of fertilisers, feed and pesticides etc.

151. Choosing suitable measures needs consideration of several factors. Some are associated with the Norwegian governmental food and nutrition policy, e.g. the nutritional value or other risks or beneficial properties of the food in question, food availability and security etc. Norwegian authorities also evaluate the consequences for society in general in terms of economy of all stakeholders, social and cultural conditions for the affected population groups, considerations related to regional policy, effects on the environment etc. Socio-economic concerns, such as consequences for society as a whole or groups in the society, are thus considered in the process of selecting appropriate measures.

152. As the Norwegian food policies have a human rights approach in consistency with the International Covenant on Economic, Social and Cultural Rights, the government is obliged to a certain extent to give access to food that meet the citizens dietary needs and preferences. In line with the human rights approach, it is stated in the Action Plan for human rights that the government in the food policy will emphasise the dietary needs of different groups in the society, food safety, food culture and consumer acceptability, food availability and access and sustainable food production. These aspects must be considered in a risk management process.

153. Taking such a variety of factors into consideration when selecting appropriate measures is not controversial, and to some extent follows from a legal obligation to clarify the case, especially when legislative measures are considered.

Socio-Economic Aspects

154. The Norwegian primary food production exists under difficult conditions that make the products non-competitive at world market prices. The topography and climate of Norway, with its long distances and harsh climate, make it hard to maintain a viable production with economic profits. In that sense, the national producers are very vulnerable, and competition with imported products may be hard. On the other hand, this could be turned into an advantage, while the food is produced in a healthy environment, where contamination rarely occurs. Hereby lies also the opportunity to be competitive in the market, offering products carrying a high level of safety. The products may also be presented as produced under conditions that are preferred by consumers with regard to environmental aspects, animal welfare etc. Thus, Norwegian authorities put emphasis on measures to ensure and increase these competitive factors.

155. In order to keep up the food safety merits of the national production of Norway and maintain the qualities that may differentiate the national products from those of other countries, and to meet the demands of the consumer, a whole set of initiatives have been launched. Examples of this are, surveillance and control programs against salmonella and other zoonoses, and an action plan to fight antibiotic resistance.

156. In addition, achieving a relatively high level of safety and health, the consideration is that this will prove to be beneficial for society as a whole, also from a cost benefit perspective in economical terms. The absence of food born diseases and contagious diseases in plants and animals saves society from large
costs, illness and suffering. Maintaining such a level is not easy, but restoring it after failure may be extremely costly or even devastating.

157. In a long term perspective, the Government believes that society and the individual producers and consumers all will benefit from a high standard of food safety. Accordingly, this perspective is highly important when deciding upon the level of the protection of human, animal and plant health.
REFERENCES

ANZFA (1996), *Framework for the Assessment and Management of Food Related Health Risks*.


