

# **Food Safety Issues, Protection and Trade (with respect to meat products)**

by

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## Contents

### Introduction

### International Trade and the GATT

### Measures for Food Safety and Food Inspection:

#### i. The Traditional View

#### ii. The Move to Management of Risk in Food Safety

### Threats to the International Arrangements for Animal Products

### Institutional and Public Choice Developments

### The Analysis of Risk

### The Future of Food Production Systems

## INTRODUCTION

Food safety is concerned with preventing animal products, not fit for human consumption, reaching consumers. It is also an important component of food market development (Unnevehr and Hirschhorn, 2000). Animal and plant health and food safety issues arise because of incomplete information for food safety or for animal and plant health. Problems may be exacerbated by the failure of market forces to properly signal consumer demand to producers. Imperfect information arises when consumers are only partially aware of the hazards associated with the production and consumption of a good particularly where it involves protecting consumers from unseen or hidden threats like mad cow disease.

Government intervention can be seen as a way to reduce the social costs engendered by poor quality food (Hirschhorn, Unnevehr and Narrod, 1999). Food safety programmes monitor and manage the production, feeding, slaughter, and inspection of farm animals and animal products from farm to consumption (Blaha, 1999; CEC, 2000; WHO, 2000; Thurnham and Roberts, 2000). In the past, Governments have put in place appropriate public health and animal health measures that have monitored animal disease status, zoonotic pathogens, feed contaminants, and problems of food hygiene and proper storage (Leighton and Douglas, 1910; Schonherr, 1991; Hughes, 1991). Generally, departmental perspectives on disease control and safe food production drove such systems. More recently, mixed public/private sector efforts are taking responsibility for different aspects of the safe food chain and consumer and environmental advocacy groups have commenced playing an increasing and quite vocal role in articulating the public expectation for safe food (Hirschhorn *et al, op cit*; Umali, Feder and de Haan, 1992).

This comes at a time when, well-publicised food-safety issues seem to occur on a disturbingly regular basis. Examples of such issues are the 1999 Dioxin and PCB contamination of Belgian meat and poultry products, the world-wide outbreaks of the *verotoxin* producing *E coli 0157:H7* food poisoning, and the BSE or mad cow disease outbreaks in the UK and other member states of the European Union. And, while arguably, whether of food safety importance or not, the use of GMOs in the human food chain.

Governments have mandated 'good agricultural practices' and 'good manufacturing practices' that focus on the shared management of hazards through the food production chain (MOH/MAF, 2000; Watson, 2000). They have banned or placed moratoria on the agricultural application of certain technologies, e.g. hormonal growth promotants and GM foods, and established dedicated Food Safety Agencies to provide a comprehensive overview of food safety, 'from farm to plate' (Ellard, 1999; Birchard, 2000; Watson, *op. cit.*).

In terms of the GATT (1947), human health issues were seen as necessary exceptions to proposed rules for the reduction of quantitative restrictions and tariffs on trade (Article XX). Contracting parties may adopt or enforce any measures necessary to protect human, animal or plant life, among others. This approach has now been supplemented by much broader national and international programs driven by consumer and environmental concerns, as well as by new developments in agricultural technology. For example, WHO in a situation analysis of its Food Safety Programme, talks of emerging problems such as *Bovine Spongiform Encephalopathy* (BSE), *verotoxigenic Escherichia coli*, multidrug resistant strains of bacteria, and genetically modified (GM) organisms as creating additional concerns among both the public and decision makers (<http://www.who.it/programmes/foodsafety>). The WHO has recently announced an enhanced program on food safety concerns involving the provision of sound scientific advice to member states and the *Codex Alimentarius Commission* (WHO, 2000).

The United Nations Convention on Biological Biodiversity has set in motion the development of a multi-lateral agreement regulating biotechnology, trade and transfer of living modified organisms. In January 2000, 130 countries agreed on language for a Protocol on Biosafety, regulating biotechnology transfer and trade in GM products. The protocol raises questions about how it will relate to the WTO and how its approach to risk assessment differs from the SPS agreement. While applying largely to the trade in GMOs related to plant species, the protocol applies to animal products as well.

These new policy trends raise important issues of trade discrimination. Just when the Uruguay Round established a defined role for science-based health and safety measures, perceptions of acceptable safety limits have shifted towards a zero-based approach to risk. In the wider scheme of things, trade in agricultural products will be more difficult and more costly in compliance terms for all players. There will be a continuation of the trend to discriminate against imports in the name of consumerism. It may be that the measures proposed are not consistent with the SPS Agreement. Standards are a movable barrier that can be moved up and down by the relevant authorities to control the flow of imported goods. Supplying countries will have to invest large sums of money in order to meet the standards laid down. Protectionism has a new ally in the consumer and environmental lobbies.

### **INTERNATIONAL TRADE AND THE GATT**

In devising rules for the General Agreement on Tariffs and Trade (GATT) in 1947, explicit recognition was made of the need for countries to maintain sanitary and phytosanitary standards. While the general aim was to encourage trade by the reduction of quantitative restrictions and tariffs, it was recognised that domestic policy

measures that maintain human and animal health should be seen as *exceptions* to the new rules. Article XX provides:

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:.....

(b) necessary to protect human, animal or plant life or health;....(g) relating to the conservation of exhaustible natural resources, if such measures are made effective in conjunction with restrictions on domestic production or consumption; ... (GATT 1986, pp.37-38).

Thus the GATT Articles recognise that animal and human health measures are legitimate domestic policy objectives, and also state the same standards must apply to imports from other countries as apply domestically.

In the Uruguay Round of the GATT a common set of rules and disciplines was adopted to guide the application of sanitary and phytosanitary measures (The Agreement on Sanitary and Phytosanitary Measures)<sup>1</sup>. In the language of international diplomacy, greater 'transparency' in these measures was sought in the sense that countries could achieve a greater understanding of other countries' problems and acceptance of a set of common standards. Greater international 'harmonisation' of standards, rules and procedures using the international scientific organisations would produce trade benefits and reduce disputes (see Appendix 1). Better frameworks for consultation and dispute settlement would also assist. Acceptance of 'equivalence' whereby countries would be able to adopt different measures providing they achieve the same objectives was sought and agreed.

It was thus agreed that trading opportunities between countries could be improved if individual countries could agree on a common set of rules for the conduct of trade. Rules provide common reference points and assist arbitration between countries in cases of conflict. At the same time, Article XX made clear that justifiable domestic measures associated with *human and animal health* constituted a general exception to the original rules of the 1947 GATT. Policy makers should be alert, however, to any measures that are introduced that are simply a disguised form of protection (Runge, 1990).

Research of these issues is quite difficult and very little on meat products has been reported in the international literature. Petrey and Johnson (1993) report a survey of Pacific Basin Countries with regard to meat inspection procedures and state:

...these meat measures are historically the result of bilateral negotiation between countries. To that extent, they are fully transparent to the parties involved. The wider question, however, is whether such measures are transparent in relation to the problem they seek to contain? Is the underlying problem a true health risk or a form of non-tariff protection? Detailed rules for assessment of health risk along the lines proposed in the Uruguay Round would represent a significant advance in this direction.

From the data collected....the following justifications for sanitary regulations in the meat trade area can be identified: threats to animal health; threats to public health; need for truth-in-labelling; meeting consumer aesthetics; maintenance of

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<sup>1</sup> Details can be found at <http://www.wto.org/goods/sps.htm>.

product quality; maintaining security from tampering; meeting customary practice; protection of domestic production; need for market discipline; and prevention of entry into the edible food chain. Within such a broad framework, case-by-case studies would be required to identify the original motives for each domestic policy measure and whether it was 'justified' in WTO terms (*op. cit.*, p.437).

### **MEASURES FOR FOOD SAFETY AND FOOD INSPECTION: THE TRADITIONAL VIEW**

Countries taking part in trade in animals and animal products are signatories to a series of unilateral hygiene agreements, which enable multilateral trade to take place. These agreements were protected by Article XX of the GATT (1947). In the Uruguay Round of the GATT, now WTO, these agreements were harmonised to a large extent by agreement on a set of protocols for the management of non-tariff barriers to trade that were justified by human and animal health concerns.

These unilateral agreements incorporated the time-honoured measures of quarantine, port inspection, animal health inspection and product inspection that had evolved from the middle of the 19th century (Schonherr, *op. cit.*). Trade could only take place if the importing country could be satisfied that the shipped products met its domestic regulations.

Inspection requirements are generally specified in domestic regulations enforced under some covering legislation. These not only serve to guide slaughterhouse/abattoir inspectors but also form the standard for imports of meat products across international borders (Petrey, 1989). Most countries provide *certificates* that accompany every shipment of a given meat product. Some countries require that such certificates include specific clauses relating to their own legislative requirements (Petrey and Johnson, 1993). International manuals might specify conditions for import of fresh and frozen meat and meat by-products, including prohibitions and import restrictions, labelling requirements and certification requirements (Petrey and Johnson, *op. cit.*). As will be discussed below, these requirements are a definite impediment to trade but are considered justified from the point of view of human health protection.

Traditional meat inspection focused on organoleptic inspection and the removal of visual pathological defects from the food chain (Leighton and Douglas, *op. cit.*; Schonherr, *op. cit.*). However, even within this traditional system of inspection, the success of major animal disease control programmes could not be ignored and traditional inspection gave way to modified inspection protocols that reflected the change in disease prevalence within identifiable herds and flocks (Hathaway *et. al.*, 1988). The need, also, for greater efficiencies due to departmental budgetary restraints, while, at the same time, the recognition of the greater importance of microbial contamination of carcass meat, led to the wider introduction of systems of food inspection in many countries based on risk assessment methodologies rather than solely visual and physical methods (Peel and Simmons, 1978; Baird-Parker, 1994; Calder and Tyler, 1999, p.367).

### **THE MOVE TO MANAGEMENT OF RISK IN FOOD SAFETY**

One such system is the application of hazard analysis at critical control points or HACCP to food safety. Derived from engineering process control methods and

deployed in the 1960s by NASA to ensure safe foods for astronauts in America's space program, it is now found almost universally in the food safety programs of developed nations (ILSI,1997; FSIS, 1998; Lee, 2000).

HACCP is a risk management tool that provides a more structured approach to the control of processing or manufacturing products than that achievable by traditional inspection and quality control:

Rather than by testing the end product for failure it functions to prevent failure by systematically controlling the process. It requires systematic analysis for potential risks and then identification of appropriate control and monitoring systems, particularly those deemed critical to the safety of the product. This reduces the risk of food contamination two ways. First, it anticipates potential problems or failures and does not depend only on final inspection. Secondly, because it identifies problems during the process rather than at the end or once the product moves into the supply or marketing chain, there is a greater likelihood of resolving the problem at hand as opposed to pursuing a product recall. HACCP can also yield potential cost savings in product wastage, re-processing, or recall should problems occur .

(Giovannucci and Satin, 2000).

Within North America, the European Community and Australasia, mandated process controls, based on HACCP and quality assurance have become the norm. Animal producers and food manufacturers are now required to design safe food programs and process foodstuffs in accordance with these relatively sophisticated protocols<sup>2</sup>. Costs are passed on to the producer and consumers pay higher prices because of the higher level of assurance required.

The *Codex Alimentarius Commission* (FAO, 1998) has promulgated the concept of HACCP. Recognising the importance of HACCP to food control, the 20th session of the Commission adopted *Guidelines for the application of the Hazard Analysis Critical Control Point system*. FAO notes that the application of HACCP is compatible with the implementation of quality management systems, such as the ISO 9000 series, and HACCP is the system of choice for the management of food safety within such systems. FAO has published a full-scale training manual for HACCP (FAO, *op. cit.*).

### **THREATS TO THE INTERNATIONAL ARRANGEMENTS FOR ANIMAL PRODUCTS<sup>3</sup>**

The major trade dispute in the last decade has been the disagreement over access to Europe for hormone treated beef from the US and Canada. This has not been resolved completely despite appeal to the scientific authorities. An even wider issue in food safety terms has been the reappearance of mad cow disease in several European

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<sup>2</sup> These measures are not without their costs. Here is what the retiring Chairman of the New Zealand Meat Industry Association had to say recently: "The aspect of market access that has taken up most of your Council's time in the past year or so, has been to do with the sanitary and phytosanitary regime. What I prefer to call more bluntly, the technical barriers to trade. Companies have had to cope with exponential growth in the range and complexity of new technical requirements devised by *importing* countries, and either agreed with or imposed by our own regulatory agencies" (our italics).

<sup>3</sup> There has been an outbreak of foot and mouth disease in the UK since this paper was first presented. This contagious disease of cloven animals involves very strict restrictions on the movement of live animals and animal products. We believe that one outcome will be an early implementation of labelling of meat products by point of origin with consequent implications for suppliers unable to fulfil much stricter prescriptive requirements.

countries. This has trade implications in terms of both final product and animal feeds. Most recently, apprehension about food safety in genetically modified foods has caused widespread debate. Underlying these concerns is the issue of informed choice: should consumers be informed about the conditions under which a particular product is produced?

In the following discussion, we use the word "hazard" for an intrinsic property of a system, operation, material or situation that could in certain circumstances lead to an adverse consequence. We use "risk" as the probability that a particular adverse consequence results from a hazard within a stated time under stated conditions (Institute of Food Science and Technology (UK), 2000).

### **The hormonal growth promotants case**

The EU ban on beef from the US treated with growth promotants dates from 1989. The EU maintained that such beef was unsafe for human consumption and stated their action was based on economic, environment and consumer concerns as well as scientific evidence. The US maintained that [the three natural hormones and three synthetic products concerned] had been thoroughly tested and had been shown to have no adverse effects on human or animal health (<http://www.useu.be/agri/ban.html>).

Both the US and Canada launched separate WTO dispute settlement panel cases against the EU regime in 1996. In August 1997, the panel ruled that the EU ban was inconsistent with the principles of the SPS agreement. The EU appealed this finding. In January 1998 the Appellate body released its report and upheld the panel findings. In March 1998, the EU announced that it would implement the Appellate body finding in as short a time as possible.

In 1999, the EU released a report on potential human health risks associated with consumption of beef from animals treated with US approved growth-promoting hormones. The opinion focuses on one growth promotant, estradiol and in particular its genotoxicity, and its cancer causing effects<sup>4</sup>. *The US says this opinion is not consistent with numerous scientific reviews conducted by reputable scientific organisations and continues to maintain that the beef in question poses no cancer risk to consumers.* In May of 2000, the European Commission made a proposal to ban definitively the use of estradiol in farm animals and to maintain the current prohibition on the five other hormones on a provisional basis while it seeks more complete scientific information<sup>5</sup>. This action is said to be WTO compliant. The US finds the action *unacceptable* (Our italics).

This discussion shows that the use of scientific opinion, as required by the SPS, can be quoted by either side to a dispute, and that resolution through the disputes system is

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<sup>4</sup> Additional information on the relevant scientific studies up to May 2000 can be found at <http://europa.eu.int/comm/dgs/health>

<sup>5</sup> The ban obviously has effects on third parties. On 18 October 2000, the NZ Ministry of Agriculture announced a tightening up identification markers of animals treated with hormonal growth promotants (HPGs) (<http://www.maf.govt.nz/meatdoc/techdir/>). This replaced an earlier directive dated 18 November 1998, which required eartag identification of all animals treated. The new directive followed a recent EC audit of the NZ HPG control program, which highlighted deficiencies; NZMAF has given assurances to the EU that the current program will be revised under the Animal Products Act 1999. See also footnote 6.

long-winded and rather tenuous. The EU is also unwilling to offer consumers a choice through labelling. In the meantime the ban remains - sovereignty prevails. In July 1999, WTO arbitrators determined that the EU beef ban resulted in a significant loss to US beef exporters and that the US is entitled to suspend tariff concessions covering EU trade to the amount of \$US116.8m per year (\$US202m was requested). The US, however, remains willing to pursue the issue of compensation, as an interim step until the EU lifts its import ban (<http://www.useu.be/agri/ban>). (The tariff suspension list includes a wide range of pork products, Roquefort cheese, foie gras, prepared mustard and truffles (<http://www.useu.be/issues>)).

#### *Summary*

- i. The dispute involves disagreement on a production process,
- ii. The hazard (in one party's view) remains as long as the process remains,
- iii. There is disagreement on the scientific evidence for the harmful effects of the process,
- iv. The participants remain in disagreement over the level of risk that is acceptable.
- v. The costs of compliance in Europe are passed on to all consumers rather than allow choice through labelling.

#### **The BSE case**

*Bovine Spongiform Encephalopathy* (BSE) in cattle was first identified in 1988, though the link to Creutzfeldt-Jacob disease (CJD) in humans was not established until 1996. The UK government reacted with controls on feeding animal waste back to animals in the late 1980s though an official report documents failures in the execution of those measures (Phillips, 2000). There were delays in taking the necessary decisions and a lack of rigour in implementing them, specifically the monitoring and regulation of slaughterhouses and rendering firms was too lax. There was also an unwillingness to promptly give the public the full facts - "a sedation strategy". The report condemned the culture of secrecy in Whitehall (Klein, 2000).

The trade component in this debate is rather small but the implications for risk analysis are large. (1) If countries can maintain their sanitary measures appropriately, the disease can be contained and attempts made to destroy it and prevent passing it on through the food chain<sup>6</sup>. Problems arise when trade in live animals takes place (which is fairly common) and the animals are unknown carriers of the disease material. In 1952, NZ destroyed imported breeding sheep because scrapie was thought to have been imported unknowingly (S.MacDiarmid, *pers.com.*). This NZ did willingly to protect its scrapie-free status. (2) More importantly, the problem raises a number of issues about how governments should handle risk and deal with potential, unquantifiable hazards in the absence of hard evidence. Should everything possible be done to avert a possible risk, however remote it may appear to be and however great the cost of guarding against it might be? How far should governments rely exclusively on advice from its chosen experts, ignoring dissident scientists challenging the prevailing orthodoxy, in low-probability high-profile cases? (Klein, *op. cit.*).

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<sup>6</sup> The European Commission announced new measures on 29 November 2000 including a temporary ban on the feeding of meat and bone meal to all farm animals (See <http://europa.eu.int/comm/dgs/health>).



New Zealand has a vested interest in BSE, as there is some suspicion that sheep may be an alternative carrier of the disease. NZ has a large sheepmeat trade with Europe and North America. There is also a suspicion that the sheep disease scrapie is related to BSE. Any controls of the sheep industry in the UK would probably be to the benefit of the NZ industry. On the other hand, consumers may lose confidence in all sheepmeat regardless of source.

The unsolved scientific debate is whether BSE, transferable in various forms to humans, originated in cattle, which were fed animal meal and bone, or in sheep fed scrapie infected sheep by-products. The problem is found in several European countries, though national administrations are not very forthcoming in admitting its presence. Most is known about the spread of BSE in the UK.

*Summary:*

- i. BSE is a low-probability, high profile disease of animals transferable to man,
- ii. The link to human disease took nearly 10 years to discover,
- iii. Measures to reduce the hazard were introduced but not fully implemented,
- iv. Domestic and trade restrictions were imposed to protect animals in the first place; humans later,
- v. Evidence that officials advised Ministers that risk was very low; but some cases of human infection emerged after quite a delay,
- vi. Should decision-makers (Ministers) follow a zero risk strategy in this and other cases?

### **The GMO Case**

Since the 1980s there has been a transformation in agricultural R&D as the benefits of genetically modified organisms (GMOs) have been recognised. GMOs are organisms genetically "engineered" by the insertion of a foreign gene. Both crop and animal performance can be enhanced by such manipulation of the living genes in a cell. According to one author:

"adoption rates for transgenic crops are unprecedented and are the highest of any new technologies by agricultural industry standards" (James 1998).

The non-medical commercial applications of GM technologies have largely been in the growing of commodity crops but the principles are applicable to commercial animal production as well. In 1992, only one country grew GM crops; in 1998, there were nine countries (USA, Canada, Argentina, Australia, Mexico, China, Spain, France and South Africa). Principal crops grown were soybean, maize, cotton, canola and potato (James, *op. cit.*). There are a number of animal modifications, in existence. These include modified sheep producing antitrypsin (which can be used to treat congenital emphysema) (Johnson, 1997); sheep that produce muscle relaxants; the transfer of an inactive gene in Belgian Blue cattle for muscle size to other breeds; and the insertion of human genes in cows as part of a project to develop a therapy for multiple sclerosis<sup>7</sup>. Indirectly, animals are likely to be fed GM crops with

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<sup>7</sup> We found a good discussion of these matters in FAO (1998), Committee on Commodity Problems, Intergovernmental Group on Meat, *Biotechnology Developments and their Potential Impacts on the Livestock and Meat Sectors*, CCP:ME 98/7 (<http://www.agriculture.de/discus/messages/37/ccpme987-7.pdf>).

unpredictable results without adequate testing (Wright, 2000). Researchers in New Zealand are working on ways of using GM technology to control breeding in the Australian possum, a widespread pest in New Zealand forests (Wright, *op. cit.*).

There are two kinds of objections to these developments: (a) that manipulating the basic genes in nature will produce unforeseen and potentially harmful effects that should be avoided, and, (b) that agricultural seed technology [and animal technology?] is dominated by multinational companies that will use technology to achieve best outcomes for them, but "poor" outcomes for people in developing countries who may be dependent on their seed products. One is a scientific argument about the precautionary principle<sup>8</sup>, the other is intensely political and little to do with GM technology *per se*. An interesting aspect of seed technology is that plants are self- or open-pollinated: this opens up the externality idea that GM seed might be mixed with non GM seed or pure lines of non GM seed could be unknowingly adulterated by GM derived pollen (Wright, *op. cit.*). The ultimate user would then be unaware of what was being eaten.

The sheer speed with which GM crops are moving from the laboratory, to field trials, to the market accounts for much of the controversy and concern surrounding GMO use and trade:

Agricultural biotechnology raises a number of legitimate concerns about potential agronomic, ecological and health risks. The pace of development has outstripped the capacity of many countries to assess these risks and to develop policies and institutions to manage them. This is particularly true among developing and transitional countries. Countries worldwide are considering both unilateral and multilateral regulation and restriction of trade in GM products (Frisvold and Hillman, 2000).

These developments are likely to place added strain on the international arrangements hammered out in the SPS and TBT Agreements in the Uruguay Round:

The age old question here is whether quarantines are being used to protect domestic producers from agronomic risks such as pests, diseases or invasive species or are they protecting them from economic competition? Are product standards or labelling requirements being used to protect consumers or import -competing industries? (Frisvold and Hillman, *op. cit.*).

In New Zealand, the government has held over any decisions on policy and institutions to manage the problem by appointing a Royal Commission in 2000 to review the issues and recommend appropriate action. In Westminster parliamentary systems a Royal Commission is the highest level of public inquiry into any matter concerning administration or law and is protected by statute. [A commission of inquiry is 'Royal' because it reports to the Governor-General (the representative of the Queen of England in New Zealand) who in turn refers it to Ministers]. The Commission's report is expected in August 2001.

Use of GM technology raises questions about risk management and trade, risk evaluation and consumer perception of risk. It also raises questions about the international institutional arrangements for intellectual property rights and technology

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<sup>8</sup> Article 10 of the Biodiversity Protocol states: "Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism...taking also into account risks to human health, shall not prevent that party from taking a decision, as appropriate, with regard to the import of the living modified organism..."

transfer. There are a number of economic issues centering around externalities, trade-offs and management of risk that would bear further input from economists.

#### *Summary*

- i. There is a possible hazard for food safety in gene manipulation,
- ii. Not all the relevant science work is completed,
- iii. The risks to human health have not been identified,
- iv. There is a case for going ahead with appropriate safeguards (such as HACCP).

## **INSTITUTIONAL AND PUBLIC CHOICE DEVELOPMENTS**

As a result of the Uruguay Round and the ongoing changes in technology and environmental concerns, the international institutions are now more involved in food safety and trade. Not only the standard setting agencies but the health and environmental agencies have declared their interest. A re-alignment of responsibilities is under way. Some readers might like to see these developments in a power and territorial framework<sup>9</sup>. We discuss the Convention on Biological Diversity and recent initiatives at WHO in these terms.

### **Convention on Biological Diversity**

There has been considerable debate over ownership, control and distribution of the benefits of plant genetic resources. These debates focus on plant genetic resources in international research centres, intellectual property rights (IPRs) for commercially developed crop varieties, the growing role of the private sector in plant breeding and seed distribution, and the impacts of biotechnology and modern agriculture on crop genetic diversity (Frisvold and Hillman, *op. cit.*). The main forums for these debates have been in a series of Undertakings of the United Nations Food and Agriculture Organisation (FAO).

At the same time, GATT/WTO were discussing trade-related intellectual property issues, the so-called TRIPs agreement. The Agreement creates minimum standards for the protection of IPRs for commercially developed seed varieties. Article 27, 3(b) states:

Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.....

The debate over IPRs for plant varieties and GMOs ultimately found its way into the **UN Convention on Biological Diversity** (CBD) that opened for signature in 1992 at the UN Conference on Environment and Development in Rio de Janeiro (the Earth Summit). In particular, Article 19 of the CBD called for exploration of the need for a biosafety protocol regulating the trade and transfer of any "living modified organisms resulting biotechnology" that may adversely affect biodiversity. Consequently, on January 29, 2000, 130 countries adopted the **Cartegena Protocol on Biosafety**, regulating biotechnology transfer and trade in GM products. Adoption of the protocol implies that protection of property rights in original plant materials, for example, could be used to prevent beneficial trade between countries.

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<sup>9</sup> The World Bank has recently started developing a Bank strategy on food safety through its Agribusiness and Markets Thematic Group. An issue paper by Hirschhorn, Unnevehr and Narrod, (1999) closely parallels our approach. For further detail see (<http://www.worldbank.org/foodsafety>)

Frisvold and Hillman (*op. cit.*) point out that countries must now work through two competing institutional structures dealing with environmental and trade-related aspects of GMOs. The WTO framework has more history and legal precedent behind, yet it remains to be seen how well it can resolve thorny SPS disputes such as the EU/US dispute over hormone beef. The SPS and TBT agreements do not specifically address GMOs but many issues surrounding GMO trade restrictions are applicable.

The WTO framework, however, is not aimed at achieving environmental objectives. Rather its purpose is to limit trade distortions arising from environmental policies being used as a Trojan horse to further economic protectionism. In contrast, the Biosafety Protocol deals narrowly and specifically with GMOs. *Yet, its language is often ambiguous and seemingly at odds with WTO agreements.* Also, the most controversial aspects of implementation have been put off to a future date. The protocol is aimed more directly at environmental objectives. Negotiators have also attempted to introduce distributional issues as well. Here, trade policies are not of interest, *per se*, but rather as a means of furthering these other objectives (Frisvold and Hillman, *op. cit.*).

### **Developments at WHO**

The WHO is a joint sponsor of the *Codex Alimentarius Commission* with FAO. With the establishment of the WTO SPS Agreements the character of the *Commission* shifted from a voluntary standards setting agency to one that establishes health and safety requirements for food which have implications for national food safety legislation. In May 2000, the World Health Assembly took the view that food safety was an essential public health function and priority area and adopted a resolution calling on WHO to increase its involvement and technical support in the work of the *Commission* and its Committees (WHO, 2000).

The argument appears to be that the UN has declared the eradication of poverty as a major goal and that people's wellbeing depends on their enjoyment of good health. There will be no social and economic development where health is not given priority. Globalisation of the world's food supply also means globalisation of public health concerns. WHO therefore sees itself as expanding its commitment to food safety by way of giving sound scientific advice to member states as well as the *Codex Commission*. Two areas of importance were identified for a leading role: microbiological risk assessment and biotechnology in foods.

There is a view (Laurent Aventin for *Médecins Sans Frontières*) (*MSF*) that the WTO agreements favour the implementation of commercial regulations over those concerning public health (*The Lancet* 2000, 355:580). Health is regarded by WTO as an object for negotiation in the same way as any of the other 160 services listed in the WTO's general agreement on trade in services. *MSF*, in line with WHO, maintains that people's well being should be ranked ahead of other services. *MSF* is therefore against liberalisation of distribution in the health sector. It argues that populations of the poorest countries will continue to suffer discrimination particularly over access to medicines.

WHO Director-General appeared to share this concern when she said that WHO was invited to Seattle:

not as a participant, but as an active and vocal observer (Brundtland, 1999).

An invitation has been issued to governments, industry, NGOs and other partners to establish with WHO an appropriate mechanism for monitoring the actual effect of the new trade agreements.

This is interpreted by *MSF* as a need for WHO to challenge the meaning of Article XX of the GATT:

- The right to take necessary measures to protect the health of their people , but only on condition that these are not applied for the purposes of protectionism and do not present an unnecessary barrier to trade.

WHO requires that any epidemic outbreak is reported to its parent body under the provisions of its international regulations, and it is concerned there is a risk of potential conflict between respecting this requirement and the WTO's SPS requirements. In relation to the standard setting activity of *Codex Alimentarius*, Brundtland (2000) accepts its dual mission of protecting health and promoting fair trade, but says that the protection of consumers' health around the world must always be given the first priority.

This sounds to the present authors as a good example of "turf wars". *MSF* points out that the member countries of WHO are practically the same as those that make up the WTO:

However, the contradiction between the interests of each body does not seem to perturb them. With the risk that public health will be dominated by purely commercial considerations, will WHO have the political and financial means to defend the position of vulnerable countries? (*The Lancet, op. cit.*).

The same observation could apply to the Convention on Biological Diversity and the Rio Declaration. These remarks suggest to us turf wars in the foreign ministries around the world and the competing demands of the respective departmental Ministers.

## **THE ANALYSIS OF RISK**

The adverse effects of unintended imports of disease or pests in traded goods drives the food safety protection system in trade. The SPS agreement has codified procedures for the assessment of such hazards so that a degree of uniformity prevails across countries. The TBT agreement also codifies risk analysis for standards and other products. The protectionist principle adopted is the same in both agreements; i.e. that measures adopted should be no more trade-restrictive than required to achieve the appropriate level of protection for human and animal health reasons.

The WTO recognises three steps in risk management in the SPS and TBT context (GATT 1992, p.9). They are:

- Evaluating the likelihood of a disease or pest entering a country, or determining the potential adverse effects on health of additives or contaminants;
- Determining the acceptable levels of risk; and selection, and

- Application of measures that would limit risk to acceptable levels and which were compatible with trade requirements.

The first is a question of scientific assessment or evaluation; the second is a question of choice; and the third is a matter of design. Evaluation is a matter for science and statistics; choice is a matter of political (and ultimately consumer) preferences; while design is what policy advisors and legal experts do (Johnson, 1997).

In the light of the Seattle imbroglio, it is the question of acceptable risk, which inflames the heart of a protester. There is a lay view that zero risk can be imposed by regulatory means which stands in contrast to a scientific approach to risk based on probability. The aim of managing risk, on the other hand, is to set up protocols and procedures that allow importation on a restricted basis so that the risk is below some desired level. The latter could be tolerances or a maximum residue level (MRL) determined by the standard-setting agencies or international agreements. In the recent case of apple imports into Australia from New Zealand, the Australian authorities simply set the pre-harvest inspection conditions so high that the trade was not worth pursuing.

The assessment of risk, while it may be based on past performance involves in actual fact an assessment of future performance if it is to apply to some world event yet to occur. The occurrence of any event in the future is uncertain (as economists well know) and in many cases in the present context the requisite knowledge may not have been accumulated or explored. The environmentalists and the NGOs have developed a fail-safe philosophy out of this uncertainty embodied in the precautionary principle<sup>10</sup> - the potential threat of adverse outcomes is sufficient to take preventative action in the here and now!

Frisvold and Hillman (*op.cit.*) point out that under the Biodiversity Protocol the importer can require the exporter to carry out or bear the costs of risk assessment. The burden of proof regarding safety appears to fall on the exporter to demonstrate a product or GMO is safe. Under the SPS agreement, an importing country may also impose a more restrictive standard than relevant internationally recognised standards. In this case, the burden of proof falls on the importing country. If the importer is challenged, it must defend its standard by presenting a risk analysis that defines the nature of risk that necessitates the need for a stricter standard.

These authors believe that the rapid adoption of agricultural biotechnology has outpaced the capacity of agricultural, environmental and public health institutions to assess and manage their potential risks. Concerns have been heightened by increased concentration of agricultural input supply industries and the bundling of seed and pest control strategies. Plant technology and not animal technology drive a large proportion of these concerns. Yet we need to remind ourselves that animals eat plant materials and that while use of gene technology in animals may be slower in development than in crops, the potential is still there for some big changes in productive efficiencies and adverse outcomes as well.

### **The precautionary principle**

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<sup>10</sup> See footnote 12.

There are different interpretations of the precautionary principle (PP) in use in national governments and in the international agencies:

The principle states that potential environmental risks should be dealt with even in the absence of scientific certainty. It has long been advocated by environmentalists, who see it as a more effective way of managing hazards than traditional scientific risk assessments, which call for numbers and hard proof as prerequisites for action" (Nature 2000,407:551).

Richard North (2000) points out that Green campaigners use a stricter version of the precautionary principle that has subsequently crept into policy formation. The principle was conceived in Germany and supposed that where there was evidence that harm was likely, even if it could not finally be proved scientifically, a precautionary presumptive approach should be adopted. In official and legislative language and operation, the principle was one of three principles which, when held in tension together, could usefully guide policy. Decisions about regulating processes and products should be made, even in advance of final proof of harm, which erred on the side of caution. But such decisions were also to be proportionate, and should also be pragmatic, decisions should be alert to economic and practical consequences; they should not impose unnecessary costs.

[North says] the Greens have used the PP as a means of putting technology and its proponents on trial, and of assuming their guilt until they are proved innocent. This has led legislators to put the burden of proof on industry and the official regulators; that is to say, the language legislators have been persuaded to use often seems to allow that it is the possibility of harm which should trigger precaution, rather than the tougher standard of probability. [He says] the legislators have tried to meet the Greens half way. They need the restrictive language because they are hoping to satisfy the calls by campaigners for caution. Thus a strict and unfettered version of the PP will always and everywhere allow a crushing objection to be made to any technology, and especially a new one such as GMOs.

Thus the Green position only looks at one side of the distribution of probable outcomes of an event like a new technology, and is biased toward a zero risk assessment to be acceptable. As North points out, no scientist would ever make a statement that a product is absolutely safe. The Greens would say that this is an endorsement of caution. But no scientist would say anything is safe, since to do so is (a) to fly in the face of empirical experience, and (b) betray the empirical understanding that until an experiment has run its course, its results cannot be known. In addition, there is the philosophical principle that hardly any statements are definitively verifiable and those more common ones that are falsifiable often are not of practical use. Essentially, to follow Popper, finding falsifiable statements is a lot easier than finding verifiable ones. From this point of view, there is no such thing as zero risk, which is what the Greens demand.

We find this argument is pretty conclusive as far as the probity of science is concerned, but not a lot of help to decision-makers who have to decide on a course of action in the face of the uncertainties involved. Ministers/Committees are composed of so-called practical (wo)men who are swayed by absolute certainties and are not equipped to interpret the idea of a probability view of risk. How can they be better guided?

## THE FUTURE OF FOOD PRODUCTION SYSTEMS

The future development of food production systems and trade will see increased demands being put on both the product and the production process according to Thomas Urban (1998). He predicts a significant shift in consumer attitudes, buttressed by research discoveries that will move the traditional commodity-based food production system into a *Prescription Food System*. Consumer expectations for food will include standards, which reflect safety, health and the environment. The future structure of the world's food system will primarily be patterned after pharmaceutical standards for research, production, distribution and pricing. Operating and structural consequences of this shift will be extraordinary for each step in the development, production, distribution, and purchase of food.

The key elements in this prescription system are transparency and traceability. The consumer will expect to be able to trace each food item back to its earliest production stage. The system will be driven by heightened sensitivity to food-borne diseases, an increasing concern for animal welfare and the environment, and the potential for closer matching of genetic profiles of individuals in relation to nutritional needs.

Marked changes will be required right down the production and processing chain. Urban expects these changes will be global in nature. As food is produced worldwide, the new standards will also quickly be required in the developing world which aspires to be part of the world food system. Developing countries may well need preferential access to developed country markets for some time unless processes and procedures are updated very quickly.

There is thus every possibility that enhanced food safety standards will continue to be major impediments to greater trade for some countries for many years. The present science-based rules approach and attention to risk management is but the first step in a more encompassing prescriptive system for meat products.

Future development in the area of food safety in meat products raises the following issues:

- Greater emphasis on consumer requirements: what are the informational needs to ensure consumer requirements are being met?;
- Greater costs of compliance: how are these informational requirements to be filled, what are the costs, and who will pay for them?;
- Greater control of production systems: stricter demands on food safety will require much greater monitoring and the implementation and use of more high-technology tools in livestock farming. This will conflict with the wishes of the public in various countries to move towards more natural and animal welfare-friendly production systems;
- Greater restraints on countries with natural advantages: what do such developments mean for the geographic spread and location of farming and agri-business activities?;
- Greater pressures on the marketing chain: what do such developments mean for future organisational patterns of production, processing, and ancillary services?;
- Negative impacts on international food distribution systems: greater conformity with standards in major importing countries required: will more



prescriptive systems for food safety delay the development of more efficient food-producing and exporting countries?

- Disguised protectionism will continue to be a problem: what will be the trade discrimination effects as these changes take place? Will the WTO system of appeals continue to be the appropriate forum?

(after Dijkhuizen and Windhorst, 1999).

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## APPENDIX 1

### International Co-ordination of Public Health and Food Safety in Animal Products: The International Agencies<sup>11</sup>

Animal health is the responsibility of the *Office International des Epizooties (OIE)*, based in Paris, which is an inter-governmental organisation created by international agreement in 1924 and outside the United Nations (UN) ambit but which co-operates with it. One of the objectives of the OIE is safeguarding animal and human health in world trade in animal products. The Sanitary and Phytosanitary (SPS) Agreement of the World Trade Organisation (WTO) explicitly recommends to national authorities the use of standards, guidelines and recommendations developed under the auspices of the OIE.

The **Food and Agriculture Organisation (FAO)** of the UN, founded in 1945, has the mandate of raising the levels of nutrition and standard of living, improving agricultural productivity, and bettering the condition, of rural populations. It has responsibility for all matters of food and agricultural production from farm to marketing and hence all animal production and animal food products. A veterinary public health management project has been established within FAO. Its mission is to determine the major risk factors in the transmission of zoonotic pathogens, drugs and chemical residues in meat, milk and other animal products, and the contamination of food during processing and transport of animals and their products as well as developing strategies for the protection of human health.

The *Codex Alimentarius Commission*, established in 1962, co-ordinates international matters concerning food standards including both animal and plant products. Along with the OIE the *Commission* is accepted by the WTO as the standard-setting institution for sanitary requirements in the trade of animals and animal products. The Food and Agriculture organisation and the World Health Organisation (WHO) jointly established the *Codex Alimentarius Commission (Codex 1993, 1998)*.

The **World Health Organisation (WHO)**, established in 1947, and headquartered in Geneva, is the UN organisation with responsibility for international co-ordination of health matters. With the establishment of the WTO's SPS Agreement and the role now played by the *Codex Alimentarius Commission* (along with OIE and the Plant Protection Convention), WHO has been called upon to expand its commitment to food safety. In May 2000, WHO adopted a resolution that emphasised that food safety was an essential public health function. As a result, the current working relationship between WHO and FAO is being reviewed and WHO is increasing its technical support to the *Commission*. WHO is also providing assistance to national authorities in developing and strengthening national food safety programs, especially in microbiological risk assessment and in safety of genetically modified foods.

The **SPS Agreement** provides for the resolution of disputes between member countries using internationally agreed standards. Resolution will depend on the generation and communication of scientific and regulatory information between countries, including risk assessment procedures. This greatly increased role for the standard-setting agencies will need to be tested in actual dispute situations to ascertain if progress in agreement on technical barriers to trade can be achieved. Thus any success in dispute resolution in the future will depend on the performance of the standard-setting agencies. Capacities will need to be developed and procedures worked out. Even so, sovereignty issues may cloud the scientific evidence. As Hillman (1997) states "despite these misgivings about the capacity of the international scientific organisations to resolve NTB-technical barrier questions and disputes, other alternatives do not readily present themselves".

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<sup>11</sup> Information derived from <http://www.fao.org/docrep/w9114e/w9114e03.htm>.