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Trading in Food Safety?

The impact of trade agreements on quarantine in Australia

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Summary

International trade in food is increasing and bringing new challenges to public health. In the past, Australians have been able to take it for granted that the food they consumed was relatively safe as rigorous national food standards were applied both to domestically produced and imported food. Quarantine regulations ensured that imported foods were subject to the highest food safety standards. The capacity to maintain and apply these standards is now being undermined by international trade agreements and procedures for settling trade disputes. The recent free trade agreement (FTA) between Australia and the US highlights the issues concerning trade and food safety.

Rules of trade are governed by a number of World Trade Organisation (WTO) agreements, which are binding for member countries. Although intended to limit non-tariff barriers to trade, these agreements have the potential to affect food safety adversely. Australia is under increasing pressure to harmonise its risk assessment and quarantine regulations with international recommendations, leading to a weakening of Australian standards. Negotiators increasingly treat quarantine as a bargaining chip. In the Australia-US FTA, for example, Australia agreed to make some quarantine concessions in order to increase market access for the US. Forthcoming FTA negotiations with China and Thailand are likely to place even more pressure on Australia's quarantine standards. Even if quarantine is not explicitly included in trade negotiations, it remains vulnerable to challenge under the WTO dispute settlement process. International trade agreements can therefore diminish the capacity of countries to employ domestic legislation to protect public health.

Australia currently applies the precautionary principle in trade matters. Applying the precautionary principle means taking action (for example, to protect health and agriculture) in the absence of full scientific certainty about a particular risk. Australia therefore invokes quarantine when there is *potential* risk rather than only when a risk has been proven to exist. This cautious approach is not recognised by some trading partners as scientific but instead is considered unnecessarily restrictive of trade. The pressure on Australia to harmonise its quarantine regulations ignores the fact that the cautious approach to food safety has been demonstrably effective in protecting public health. It has, for example, protected Australians from bovine spongiform encephalopathy (BSE). Australia took action to ban imports of British cattle well before the devastating human health consequences of BSE were realised.

Such precautionary action today is considered by trading partners as a purely protectionist measure. BSE is a particularly important example as it highlights the potential for unknown risks arising from the complexity of modern food systems and illustrates some of the shortfalls of internationally accepted practice. Furthermore, health risks from BSE can extend beyond food consumption, potentially to contaminated pet food, cosmetics and vaccines.

While the potential risks associated with BSE are now widely known, Australians are also protected from a range of other health risks by our cautious approach to import risk assessment. For example, Listeria is a form of bacteria that can multiply at refrigerator temperatures and cause meningitis or septicaemia in children and the elderly. Exposure to Listeria during pregnancy can cause miscarriage or stillbirth. Despite the severity of these health effects Australia's import standards in relation to soft cheeses and other

potential sources of Listeria infection have already been reduced as a result of pressure from importers.

Avian flu provides another example of the importance of a cautious approach to import risk assessment. The avian flu virus can be fatal to both humans and poultry and is potentially devastating for the Australian poultry industry. Australian quarantine regulations banning the importation of raw poultry are therefore vital to protecting both Australian public health and the Australian poultry industry. These protections are, however, likely to come under pressure in forthcoming free trade agreements.

This paper examines the impact of trade agreements on Australia's capacity to maintain an appropriate level of protection through cautious import risk assessment and deployment of quarantine to protect public health. It establishes some principles for safeguarding Australia's food supply into the future and concludes that in order to protect public health and preserve food safety, Australia needs to play an active role in ensuring that quarantine and food safety standards are improved worldwide. To date international trade has exerted downward pressure on labour standards, human rights and environmental practices. Australia can protect its own national interest and the interests of developing countries by ensuring that quarantine standards do not become a bargaining chip in future world trade negotiations.

1. Introduction

Access to food that is nutritious and safe is a basic human necessity, but ensuring food safety has been made more difficult in recent years as a result of increasing international trade. A greater quantity and variety of food is travelling further, often with multiple origins and destinations. In order to preserve food safety and protect the agricultural industry from disease, Australia applies quarantine regulations that are more stringent than in many other countries, but frequently these precautions are considered a barrier to trade that must be removed to further trade liberalisation. This challenge to Australian food safety has been highlighted by the recent negotiations for an Australia-US Free Trade Agreement (FTA). Furthermore, planned free trade agreements with China, Thailand and Malaysia will place Australia's quarantine standards under even greater threat.

Australians can take for granted that the food they consume is low risk. Historically, geographic isolation has protected the country from many diseases that are found elsewhere, but in a world where travel and transport of goods are becoming ever easier, stringent quarantine regulations have helped preserve Australia's status as relatively free from agricultural pests and food-borne diseases common in other parts of the world. Australia has had few serious, large-scale outbreaks of disease relating to food contamination, and where these have occurred domestic supply has been at fault. National regulators have worked to protect public health by setting standards of production and storage that apply to both locally produced and imported foods (FSANZ 2003a, FSANZ 2003b).

International trade agreements can threaten food safety regulations in two ways. Firstly, during trade negotiations, changes to quarantine requirements may be sought in exchange for other market concessions. Secondly, even if not officially on the negotiating table or part of a resulting agreement, under the WTO rules quarantine can be challenged by trading partners as unnecessarily restrictive if regulations exceed minimal international guidelines. Consequently, the trade dispute settlement process can erode domestic regulations intended to ensure the safety of imported foods.

Trade agreements, such as the recently negotiated Australia-US FTA, therefore have considerable potential to undermine food safety in Australia and elsewhere. Even before the year-long trade talks concluded, the US explicitly sought changes to several key aspects of Australia's domestic food safety legislation perceived by it as limiting US export capacity (USTR 2000). Subject to particular challenge was the use of quarantine to exclude imports that Australian authorities considered unsafe (Zoellick 2002).

It is widely understood that import risk assessment and quarantine protect Australia's agricultural industry from exotic pests and diseases such as foot and mouth disease, but they also protect against direct and immediate threats to public health from unsafe foods. These direct risks to public health are demonstrable, but WTO rules require proof of an actual and novel hazard, and not just a potential threat. Excluding something that *might* constitute a risk may no longer be sufficient, especially in the case of agricultural pests and diseases where risk must also be quantified. Australia is under increasing pressure to 'harmonise' quarantine regulations with international standards (WTO 2002, 2003b) but if Australia had subscribed to similar standards as other countries in the past, it would not be free of mad cow disease or avian influenza today.

The potential impact of international trade agreements on public health in general – and on food safety in particular – has received very little attention in Australian trade policy debates. Early in the Australia-US negotiations, for example, the Australian Government commissioned impact assessments of an FTA, but these dealt only with potential economic and diplomatic consequences (APEC Study Centre 2001; Berkelmans *et al.* 2003). Neither did the government seek social or environmental impact studies.[1] Their rationale for omitting these concerns arises from the neo-liberal position that free markets increase trade thus extending economic growth which in turn is assumed automatically to raise living standards, including improvements in public health. Improving public health, however, requires specific investment in public goods (Szreter 1997). Such improvements in public health do not automatically result from a bigger economy. On the contrary, better health results from the implementation of specific policies designed to deliver it.

In recognition of the potential for a significant impact, the Australian Government initiated public consultation before the final agreement with respect to the Australia-US FTA was reached. The interests of industry, trade unions, non-government organisations and others proved to be substantial, as nearly 200 submissions were made to a Senate inquiry held in July 2003 (DFAT 2004a). Negotiations had already been underway for some months by this stage. However, as trade negotiations are not open forums, the flow of information remained one way and very little concerning the position held by the Australian Government or the progress of negotiations was made public. Thus independent assessments of the potential costs and benefits of items for inclusion or exclusion as the agreement evolved were rendered difficult. Although state and territory governments were briefed regularly throughout the negotiations (DFAT 2004a), meaningful progress reports to the Australian public and industry representatives were not forthcoming. DFAT did not release the text of the agreement until nearly a month after negotiations concluded, as it was still subject to 'legal scrubbing' (DFAT 2004c). The absence of information in the public realm before and during negotiations and for a considerable time after they were concluded made analysis of the potential impact very difficult.

When details of the agreement were finally released, public submissions were again sought, this time for a further inquiry by a Senate Select Committee and for the Joint Standing Committee on Treaties charged with examining the text of the agreement. It is not clear, however, how much of an impact recommendations from these inquiries had.

This paper examines Australia's capacity to continue to ensure a relatively safe and nutritious food supply. In particular it considers the effect of international trade agreements on Australia's sovereignty to assess the risk of imported goods and apply import restrictions based on the potential risk to public health. Section 2 provides an overview of international trade agreements and procedures that have an impact on food safety. Section 3 examines Australia's position on import risk assessment and quarantine in relation to international standards. In Section 4 several case studies are presented illustrating the effectiveness of Australian policy in ensuring food safety, with a particular focus on bovine spongiform encephalopathy (BSE) given its near global distribution and the recent first confirmed case in the US. The reliance on industry self-

[1] Unlike the US, Australia has no requirement to assess the environmental impacts of an FTA (Cebon 2003).

regulation is questioned. Finally, strategies to ensure the continuing safety of Australia's food supply in the context of greater trade liberalisation are considered.

2. Free trade and the role of the WTO

2.1 International trade agreements

Trade liberalisation has been considered for some years to be the primary pathway to economic growth, which is increasingly highlighted as the single measure of national success. In order to oversee the development and application of trade agreements between countries, the World Trade Organisation (WTO) was established in 1995 as a result of negotiations stemming from the General Agreement on Tariffs and Trade (GATT), an international treaty signed in 1948. The GATT was developed to facilitate international trade in goods by establishing a system of rules designed to liberalise trade and balance regulatory autonomy with discipline for protectionist measures (Marceau and Trachtman 2002).

Several rounds of negotiations continued over the years, with the Uruguay round of 1986-1994 culminating in the formation of the WTO together with a number of agreements aimed at reducing non-tariff barriers to trade (WTO 2003a). The WTO was intended as a non-political 'rule based multilateral regime' that would increase the predictability, security and transparency of international trade (Arup 2003, p. 897). It comprises approximately 150 member nations, including Australia, acts as a forum for international trade negotiations and administers trade agreements (WTO 2003d).

Several agreements and principles now govern international trade between WTO signatories. The agreements on Sanitary and Phytosanitary (SPS) Measures and Technical Barriers to Trade (TBT), and principles of Equivalence (Box 1) are intended to facilitate trade by removing non-tariff barriers and have considerable potential to affect food safety as they govern import risk assessment and the application of quarantine. Failure to comply with these agreements entitles an aggrieved trading partner to initiate dispute settlement proceedings (see Section 2.3).

2.2 Bilateral, regional and global agreements

In general, members of the WTO may not discriminate either between trading partners or between locally made and imported products that are similar (Lawrence 2003). Furthermore, the 'most favoured nation' rule means that whenever a WTO member country upgrades the benefits it provides to a trading partner, it must grant all other WTO members the same privileges so that they remain equal. Bilateral or regional trade agreements (such as APEC, NAFTA, and the Australia-US FTA), on the other hand, seemingly contradict the WTO's principle of non-discrimination between trading partners by setting up a system of preferential trade. However, since the 1948 GATT treaty, establishing preferential trading relations between member countries has been encouraged as part of the wider process to further liberalise global trade. Despite the most favoured nation principle of non-discrimination, smaller regional and bilateral negotiations are becoming increasingly common.

Box 1 WTO agreements that directly affect food safety

Sanitary and Phytosanitary (SPS) Measures

Negotiations during the Uruguay Round in 1994 agreed to reduce agricultural tariffs in order to bring rules for agricultural goods in line with those for manufactured goods (Beierlie 2002). This led to a concern that some countries might invoke quarantine regulations not to protect public health and keep industry free from exotic pests and diseases but rather to protect the economic interests of their agricultural industries (Nairn 1996). The SPS Agreement was therefore developed to limit the restrictions that countries could place on foods in the name of health and safety. Although in theory countries can set levels of protection that they deem appropriate, these must be 'scientifically justifiable' and not merely a means to restrict international trade. SPS measures are subjectively defined, but their purpose is to prevent food-borne risks or pests and diseases affecting the life and health of humans, animals and plants in a manner that impacts on international trade (Pauwelyn 1999). Before the SPS agreement, agricultural and health regulations had to be justified only after a violation of GATT was discovered (Pauwelyn 1999). Agriculture remains highly protected despite SPS rules and efforts to reduce tariffs (Beierlie 2002).

Technical Barriers to Trade (TBT) Agreement

The technical aspects of goods such as size, labelling, shape, performance and packaging are covered by the TBT Agreement (OECD 2003) which lists circumstances where countries may restrict trade although again these restrictions must be considered necessary and not more restrictive than required to meet objectives. Human, animal and plant health, environmental protection, national security and prevention of deception are considered legitimate reasons to restrict trade under TBT (WTO 2003c). The Agreement appears to provide for some freedom for countries to take steps to protect public health, but such measures are subject to international approval, ensuring that health objectives and restrictions are limited to those deemed by trading partners to be appropriate.

Equivalence

Article 4 of the SPS Agreement recognises that member countries may have evolved equivalent measures of protection even though their procedures may be different. Hence an importing country is obliged to accept the protective measures taken by an exporting country as equivalent to its own providing the exporting country is able to prove that its measures afford a similar level of protection to those of the importing country (OECD 2003; WTO 2003c). The exporting country is obliged to prove that its measures are effective and must allow the importing country access for inspection and testing and any other relevant procedures. Equivalence policies are intended to reduce replication of procedures between countries; but in practice, they limit a country's sovereignty over national public health decision-making because the failure to accept another country's procedures as equivalent may be perceived as an unnecessarily restrictive trade practice.

Agreements may be binding or take the form of a memorandum of understanding, and may cover single products or all food commodities (Codex Alimentarius Commission 1997, 1999).

The breakdown in trade negotiations in Cancún, Mexico, in September 2003 was the result of disagreement between poorer and richer nations that was sustained throughout the meeting. It demonstrated the potential efficacy of the combined vote of developing countries and illustrated that sometimes global and large-scale multilateral talks fail to deliver on the desires of wealthy countries.[2] One response by wealthier nations has been a strategic shift away from multilateral talks towards a targeting of individual countries one by one, creating preferential trade relationships with each of them. The US, for example, currently has regional agreements with Canada and Mexico (NAFTA), Costa Rica, El Salvador, Guatemala, Honduras and Nicaragua (CAFTA), and bilateral relationships with Jordan, Chile and Singapore. It is currently negotiating with the Southern African Customs Union (includes Botswana, Lesotho, Namibia, South Africa and Swaziland), with Bahrain and with Morocco. Further negotiations are planned with Thailand, Panama, Colombia, Peru, Bolivia and Ecuador (USTR 2004). Australia has also been pursuing bilateral and regional trade, establishing the Cairns Group with the purpose of fostering the interests of agricultural producing nations. Recently Australia reached a free trade agreement with the US and Singapore and is currently negotiating with China and Thailand.

This preferential approach has been justified as a means of moving towards more open markets globally:

> … Australia and the United States have been working arm and arm in terms of trying to cut subsidies and tariffs in the WTO talks. And frankly, I just think it would be madness to let a few countries in Europe or elsewhere decide that they want to stop trade negotiations; because they won't cut their subsidies, we're all supposed to pack up our bags and go home. The best way to move them is to keep moving forward (Zoellick 2003b).

These bilateral agreements give greater economic advantage to the larger trading partner than to the smaller partner and can effectively close out other small countries, limiting their future market access.

2.3 The trade dispute settlement process

Because the WTO is rule based, disputes sometimes arise when parties disagree over the interpretation of the rules (Brinza 2003). Dispute settlement is administered by the Dispute Settlement Body, which consists of the WTO's General Council, and has the authority to establish Panels to hear disputes. These Panels are able to seek advice from scientific and technical experts. If a Panel's conclusions are not acceptable to the disputing parties, a three-person Appellate Body, chosen from a standing pool of seven persons, will assess the report from a legal and procedural point of view. The Appellate Body's report is adopted unconditionally unless a consensual vote not to accept its findings is reached by the Dispute Settlement Body. Prior to a complaint being brought before the Panel, attempts to resolve the dispute are made through formal consultation between members. More than 300 complaints were received by WTO Panels over the first eight years to 2002, and most of these were reviewed by the Appellate Body (Arup 2003). Neither the Panel nor the Appellate Body makes binding decisions (Pauwelyn 1999), but produces recommendations for the Dispute Settlement Body which then

[2] For an Australian Government perspective on the Cancún negotiations, see DFAT 2004c.

makes the ruling based on these recommendations (McRae 2004). Dispute proceedings are most often initiated by high-income countries, especially the US and the European Community(EC), but recently upper middle income countries have increasingly been involved in such proceedings (Leitner and Lester 2004).

The initial burden of proof in dispute settlement lies with the complaining party, in that it must establish a *prima facie* case of inconsistency. If this succeeds, the burden of proof shifts to the defending party which must either refute or counter the claim (Pauwelyn 1999). Any party asserting a fact must provide proof, but the evidence does not have to be 'watertight' to be accepted (Pauwelyn 1999).

Unlike court proceedings, dispute proceedings are not open, and members who wish to observe the process must become third parties, thus conflating interest in the process and interest in influencing the process (McRae 2004). The lack of public access to the dispute proceedings is a major criticism of the system. McRae (2004) argues that there is no rational basis for this public exclusion from Panel and Appellate proceedings. Although the dispute proceedings are private, the outcomes of the process are made public.

The dispute settlement process has been criticised as being more about making policy than applying rules. It has increasingly become a 'surrogate for negotiations', ruling on and clarifying existing agreements and expanding the scope of these agreements (McRae 2004, p. 3). The Panel and Appellate Body do not merely apply WTO law but legislate it, as they limit members' ability to restrict trade beyond specified limits in the agreements, and are therefore not neutral but are biased towards the complainant (Greenswald 2003). Despite the initial intentions of the WTO, economics and politics continue to play a significant role in the decisions (Arup 2003).

The losers in a dispute must comply immediately with the recommendations and ruling (Pauwelyn 1999). Countries which fail to comply with WTO rules cannot be forced to do so, but retaliatory measures (such as increasing tariffs on imports from that country) may be sanctioned (Arup 2003; Greenswald 2003). Compliance with WTO rulings is high (McRae 2004).

Being a party to WTO agreements is equivalent to accepting jurisdiction of the dispute process (McRae 2004). As a signatory to the WTO, Australia is already compelled to comply with international SPS procedures (Nairn 1996). In any instance where Australia's quarantine and other regulations are considered more stringent than those accepted internationally, trading partners have the right to initiate proceedings against Australia through the WTO dispute settlement processes. Australia's procedures for import risk assessment and quarantine regulations are viewed internationally as restrictive trade barriers (USTR 2000). Australia's quarantine regulations are open to further censure because of discrepancies between states or between states and the Commonwealth. Individual states in Australia have, for example, banned the import of certain products that could be harmful to a major industry (for example, salmon in Tasmania, see Section 3.3), or legislated to remain free of genetically modified (GM) produce.[3] This leaves Australia vulnerable to greater criticism from trading partners, as it is even harder to justify why one state may have one set of rules while another operates under different ones.

[3] New South Wales recently approved cultivation of GM canola (Peatling 2004).

In April 2003, the EC brought a complaint against Australia to the WTP, arguing that unless individual exemptions are granted, Australia's quarantine requirements prohibiting the import of live and dead animals, fresh meat, plants, fruit and vegetables are unduly restrictive to trade. The EC also objected to Australia's refusal to accept the equivalence measures of other countries as unfair (WTO 2003b). Any WTO member country may elect to be involved in a given dispute brought about by another member; for the current EC dispute, India and the Philippines have declared themselves to be interested parties.

Despite the emphasis on international harmonisation, there appears significant room for interpretation of the WTO Agreements, but there remains the matter of determining 'legitimate' reasons to restrict imports. This is of increasing interest to some countries attempting to protect public health from any undesirable consequences of trade liberalisation (Lawrence 2003). Each trade agreement brings increased potential to affect the ability of individual member countries to make and enforce any domestic legislation that limits trade, including quarantine standards that may be more restrictive than those of other countries. The dispute process acts to facilitate trade as decisions are generally made against trade restraints (Greenswald 2003). While this may be good for trade, it may not necessarily be good for public health.

3. The role of quarantine in trade agreements

3.1 Science-based risk assessment

'Science' is invoked in trade law to distinguish legitimate concerns from actions that are taken for protectionist reasons (Harlow 2004). The SPS Agreement enables a country to maintain its standards providing they are scientifically based and consistently implemented (Nairn 1996). WTO members are allowed, in principle, to set their own acceptable level of risk, and can choose SPS measures to reduce risk to a degree considered acceptable in import risk assessment. The SPS measures invoked are not permitted to be more trade restrictive than is necessary to meet the required level of risk. However, there is little recognition that potential risk is assessed within a particular context and is subject to constraints (Harlow 2004). 'Science' therefore remains full of uncertainty. The WTO requires that uncertainty be dealt with consistently by member countries (Crawford-Brown *et al.* 2004). Differences of opinion as to the meaning of 'science-based' should be restricted to the approaches used for risk assessment. There is some disagreement concerning whether or not risk assessment should be 'consistent with internationally accepted approaches' (Codex Alimentarius Commission 1995b, p. 2).

It is widely accepted that quarantine should be science-based, but what this means in practice is in dispute. For example, both sides of the Australia-US FTA negotiations were in public agreement that quarantine regulations must be based on science (Deady and Ives 2003). During the negotiations Australia continued to reiterate its support for the SPS Agreement. With the signing of the Australia-US FTA that included changes to quarantine, DFAT was quick to recommit to science-based risk assessment.

> Both countries have reaffirmed that decisions on matters affecting quarantine and food safety will be based on science. The agreement preserves the rights of both countries to protect animal, plant and human health and life in their respective territories. Australia's regulatory systems, risk assessment and policy development processes are not affected, and the AUSFTA does not compromise Australia's quarantine regime (DFAT 2004b).[4]

The term 'scientifically based' is therefore problematic – even 'science' is not immune to influence from particular economic and political agendas, and the level of what is considered 'acceptable risk' may vary between countries and over time. Given the scope for interpretation in the international recommendations it might be assumed that Australia's stringent regulations would be acceptable. Science is by nature intended to be objective, but making risk assessments and deciding what constitutes an acceptable level of risk to public health requires some level of value-judgement. The stakes are perhaps higher for Australia as an island continent that is relatively disease-free. Howse (2004) suggests that the WTO overestimates the ability of existing science to resolve health-related trade disputes. In order to continue to be relatively disease free, Australia requires that a cautious approach be maintained.

[4] In the draft text of the agreement, released 4 March 2004, human health was not mentioned.

3.2 Australia's cautious approach to risk assessment: a barrier to trade?

An appropriate level of protection is the one that provides confidence that public health and agriculture are safe. Australia seeks a level of very low risk rather than zero risk.

Two agencies run by the Department of Agriculture, Fisheries and Forestry (DAFF) are responsible for Australian policy and application. Since 2000, Biosecurity Australia has been the agency responsible for conducting import risk assessments and setting the policies to achieve the appropriate level of protection. Import risk assessment can take years, and there is growing pressure to reduce the time to gain import clearance to a maximum of six months (Brenchley 2003). New import risk assessments are subject to a review by an expert panel after input from stakeholders (DAFF 2004a) and are then enforced by the Australian Quarantine Inspection Service (AQIS). The regulatory body for food quality and safety in Australia is Food Standards Australia New Zealand (FSANZ).

The 1996 Nairn report *Australian Quarantine* urged government and industry to work together to develop good quarantine practices. Australia's subsequent 'strong and active' participation in the Uruguay negotiations for an SPS agreement was commended by the WTO at the time (WTO 1998) but, because Australia maintains more stringent quarantine standards than other countries, its position has since been perceived by trading partners as hypocritical (European Commission's Delegation 2003), and protectionist. No matter how effective this cautious approach has been in the past, it is not considered appropriate in the current international trade arena. There is a perceived conflict between a country's right to set an appropriate level of protection (which may be conservative as in the case of Australia) and the belief in free trade.

Member countries are, however, allowed under Article 3 of the SPS Agreement to set higher standards of protection than those internationally recognised, as long as they are scientifically justified or considered to provide an appropriate level of risk for the importing country (Biosecurity Australia 2003). Taking a cautious approach is not, however, considered to be scientifically justifiable. Although international food safety standards are not intended as a 'ceiling' on national standards, any national standards deemed to exceed them must justify their more rigorous criteria on 'scientific' grounds (Nairn 1996). The standards set by the Codex Alimentarius Commission have already been invoked as the benchmark in international trade disputes and are expected to be used increasingly as such (FAO and WHO 1999). While international standards are not supposed to prevent governments from protecting public health, welfare and environment (Marceau and Trachtman 2002), nevertheless countries with more stringent requirements, such as Australia, are expected to lower their food and agricultural standards to match those of other countries, or leave themselves vulnerable to retaliatory measures from the dispute settlement process.

3.3 Theoretical, potential and quantifiable risk

Australian food regulators have for some time been committed to a precautionary approach to food safety (FSANZ 2002c). It has also been the standard practice of quarantine regulators in Australia to apply the precautionary principle; that is, in the absence of absolute certainty about potential threats it is better to act on the side of caution (Cebon 2003). The precautionary principle is sound, well established and accepted across scientific disciplines, and has to date served Australia well in protecting

it from disease. Initially developed out of environmental concerns, the precautionary principle has been broadened to include matters that may affect human health, but it is frequently perceived as merely a means to bar trade (Goldstein and Carruth 2004) rather than a valid approach to an uncertain risk. For example, the precautionary approach was invoked by the EC in its defence of banned imports of meat from hormone treated cattle but the WTO found against the EC, thus rejecting the validity of the principle. Under SPS regulations, provisional SPS measures may be enacted on the basis of the precautionary principle where insufficient scientific information is available (Pauwelyn 1999) but there is a strictly limited time frame during which these measures may be in place before a risk assessment must be finalised.

Conducting a risk assessment for food-borne disease is somewhat easier than for agricultural pests and diseases. Only the *potential* for adverse health effects needs to be established in the case of the former rather than the *likelihood* of entry as in the case of the latter (Pauwelyn 1999). In addition, risk assessment for food-borne disease can be qualitative and the importing country can decide that zero risk is the only acceptable level (Pauwelyn 1999). The decision cannot, however, be based on a *theoretical* risk, and the risk assessment needs to be specific, addressing each particular risk (Pauwelyn 1999). Likelihood, in the case of agricultural pests and diseases, is more difficult to establish – merely the possibility of pest or disease entry is not sufficient – as the economic and biological consequences must be quantified.

Despite the relative ease of establishing 'potential' over 'likelihood', which makes food-borne risk assessment somewhat easier than agricultural pests and disease risk assessment, the adverse effects still have to be specifically identified. Food-borne risks that are currently unknown and therefore 'merely theoretical' cannot be justified under the SPS agreement. This has substantial influence over whether countries can, for example, choose to ban imports of genetically modified (GM) foods, as potential threats to human health of consuming GM foods have yet to be established. Furthermore, the reliance on rigid criteria for risk assessment as a means of justifying SPS measures discriminates against countries that may not be able to conduct such assessments.

Australia's cautious approach to the risk assessment of imported goods is considered by some other countries to be inappropriate. With the expansion of international trade, pressures on strict quarantine regulations are increased. A US report on barriers to trade (that is, impediments to US exports) accuses Australia of applying quarantine regulations unscientifically to protect national markets by restricting trade.

> The Government of Australia limits agricultural imports through quarantine and health restrictions, in some cases without the necessary risk assessment to provide the WTO-required scientific basis for such restrictions…The [Australian] process provides for extensive stakeholder consultations and appeals, with 18 months stated as the length of time required to carry out a non-routine risk analysis (USTR 2000, p. 9).

In a dispute over the importation of uncooked salmon because of fears that it carries sea-lice, Australia had requested more time to conduct a risk assessment than was considered by the WTO Panel to be reasonable (Pauwelyn 1999). Although not a threat to human health, sea-lice can kill salmon and entry into the country poses a direct and serious threat to the lice-free status of the Australian industry (Green 2003). In 1999

Australia was ordered to open its market and accept imports of fresh, chilled and frozen salmon (USTR 2000). In response, Tasmania enacted its own quarantine legislation to defend its lice-free salmon industry. Tasmania's action was challenged by Canada, and again the WTO ruled that the ban was unjustified, as Tasmania had failed to evaluate the likelihood of entry, establishment and spread of sea-lice (Pauwelyn 1999). The import restrictions were deemed not to have been based on science in the absence of a quantitative risk assessment (Pauwelyn 1999), and measures were not considered to be consistently applied as other types of fish were being imported (Atik 2004).[5]

The hazard inherent in the WTO ruling became apparent in September 2003 when sea lice were found under the skin of salmon imported into Australia from Norway (Green 2003). This example illustrates that pressure from trading partners and the system of dispute settlement under the WTO forced Australia to compromise its quarantine regulations, and the result was a real threat to an Australian industry. Despite the subsequent discovery of sea-lice in imported salmon and apparent justification of industry concerns and the precautionary principle, the Canadian salmon ruling has set a precedent for further challenges to Australian quarantine regulations. Non-scientific factors (such as cultural and moral preferences or consumer concerns) can in theory be considered in setting the level of acceptable risk and choosing the type of SPS measures to apply, but are not considered suitable to use in a risk assessment (Pauwelyn 1999). Furthermore, the SPS Agreement does 'not speak to such matters as the magnitude of risk needed to justify trade restrictions, standards of proof for assessments of risk, and methodology for weighing health dangers against the consequences of limits on trade' (Bloche 2002, pp. 821-822).

The Australian quarantine system was clearly on the agenda in the Australia-US negotiations (Zoellick 2003b). Australian regulation of fruit imports has been a particular area of concern for the US, which has for some years pursued market access for citrus and grapes (USTR 2000). In the recent agreement, Australia made concessions with respect to US fruit imports, with potential consequences for quarantine that extend beyond this particular agreement. The Philippines, too, recently applied to bring Australia before the WTO's Dispute Settlement Body in a case involving tropical fruit. Import restrictions apply to some fruits from the Philippines (such as paw paws and bananas) because they pose a disease threat (freckle and moko) (*The Canberra Times* 2003). The Philippines claimed that Australia was breaching international regulations, that Australia's system of quarantine is not 'scientifically based' and not in line with international standards (WTO 2002).

Australia has recently removed import bans on bananas from the Philippines, on apples from New Zealand, and on pork from several trading partners, including the US and Europe. The bananas must be certified to come from farms with low levels of disease (Associated Press 2004), and the apples are required to be treated with chlorine and refrigerated for six weeks (ABC 2004a; Karvelas *et al.* 2004). The Australian Banana Growers Council accused the government of watering down quarantine standards, risking the introduction of exotic pests and diseases (Reuters 2004). Recently, Australia's banana import risk assessment was called into question as independent re-analysis found several errors in the initial assessment which caused the risk to be underestimated three-fold. These included underestimating the period of time between

[5] One unexpected outcome of the WTO ruling was that Australia reduced its imports of other fish products (Atik 2004).

infection by the bacterium that causes moko and the appearance of the infection. The initial analysis was based on estimates of latency of 12 weeks, whereas it may take 24 weeks for disease to appear. Other errors included underestimation of ease of bacterial transmission between plants via mechanical equipment, its persistence in soil making it difficult to eradicate once it has become established, and the difficulty of restricting imports to regions that do not grow bananas (Fegan 2004).

Australian apple growers remain concerned about the risk of fire blight to the industry (Young 2004). Even when quantitative risk assessment is available, it can still be ignored. Modelling commissioned by the Australian pork industry and conducted by the CSIRO put the likelihood of an exotic disease outbreak at between 94 and 99 per cent under the new quarantine protocols that allow the importation of uncooked pork (ABC 2004b). The removal of these fruit and pork import bans so close to the signing of the Australia-US FTA appear to be due more to a political decision than the result of scientific risk assessment:

> Prime Minister John Howard said the government has no option but to follow the recommendation of the regulator [the WTO], otherwise it would be seen as protectionist (AFX News 2004).

Australian bans on importing uncooked chicken meat have also been targeted by both the US, which regarded Australia's processing requirements as extreme (USTR 2000), and the EC, which considers them to be more trade-restrictive than necessary as they render the products inedible (WTO 2003b). The EC has already brought Australia before the Dispute Settlement Body over this issue. The dispute has arisen because of claims that Australia already has infectious bursal disease (IBD), and therefore cannot justify banning raw imports on the basis that they come with a risk of bringing in a novel disease (WTO 2003b). In other words, according to the SPS Agreement, the diseases are comparable, despite evidence that the strain of IBD in Australia is much milder than elsewhere (CSIRO 2002). The importation of raw poultry, therefore, continues to pose a real risk to the industry, concerning chicken farmers in Australia about the importation of very virulent IBD (ABC 2003). A number of other countries have asked to join these proceedings including Chile, the Philippines, Canada and India. This dispute explicitly calls into question Australia's quarantine standards, with a result that the potential for watering down quarantine is substantial. Similarly, animal feed grain has been targeted by the US as an area where current Australian regulations restrict imports because they require processing that is 'commercially unviable' (USTR 2000, p. 9).

The US and others are increasing pressure on Australia to abandon the precautionary principle in favour of assessment that only invokes quarantine once a threat has been proven to exist; foreseeable theoretical threats are not considered sufficient for quarantine. It is clear that much of this pressure is coming from the US agricultural industry as it seeks access to Australian markets that are currently protected under strong quarantine laws:

> …several U.S. agriculture interests have raised serious concerns about Australia's use of sanitary and phytosanitary (SPS) measures as a means of restricting trade…We have made progress on specific issues, including the opening of the Australian market to U.S. table grapes (Zoellick 2003a).

Despite this admission from the US negotiator, Australian Minister for Trade Mark Vaile stated throughout the Australia-US FTA negotiations that certain items, including quarantine, were not subject to negotiation, for example:

> Australia will ensure that outcomes from the FTA negotiations do not impair its ability to meet fundamental policy objectives in health care, education, consumer protection, cultural policy, quarantine and environmental policy (DFAT 2003).

Clearly, the dispute settlement process undermines government assurances that quarantine regulations will not be weakened. In the recent FTA negotiations, the US gained some concessions with respect to Australian quarantine regulations, stating in their media release on the signing of the FTA:

> Food inspection procedures that have posed barriers in the past will be addressed (USTR 2004).

The US seeks greater international market access because it produces 40 per cent more food than it needs to supply its domestic market, and it must sell the excess to maintain its economy (Nestle 2002). Consumers are encouraged to eat more (feeding the US obesity epidemic), and overseas markets are aggressively pursued (Nestle 2002). In order to increase exports, it is necessary to remove all barriers, be they actual trade barriers or legitimate health and safety regulations. For this reason Australia's quarantine regulations will remain under pressure from the US for the foreseeable future, and, if more bilateral FTAs are negotiated, then the pressure is likely to be increased.

With regard to food safety and public health, there are four obvious problems that emerge from the required criteria for risk assessment and the application of SPS measures.

1. Theoretical risks cannot be taken into account. In the 1960s when Australia banned animal feed from Britain that contained material from ruminants, any human health risk was purely theoretical (see Section 4.1). Under the SPS agreement, such a decision today would be challenged, and Australia would no doubt be required to accept such material.

2. 'Science' does not define what level of risk is acceptable; it can only inform the assessment process (Crawford-Brown *et al.* 2004), leaving much to be decided in dispute settlement, a process biased towards facilitating trade. There is also no acknowledgement by the WTO that science itself is a process and that current knowledge about risks may be incomplete. Considerable uncertainties are therefore a legitimate part of 'science'.

3. Despite the professed latitude enabling countries to choose an acceptable level of risk that may be zero, in practice zero or low acceptable risk is unlikely to be deemed appropriate, and perceived rather as a purely protectionist measure.

4. The WTO's principle of non-discrimination dictates that where situations are different but display a similar risk, there must be consistency in the risk considered acceptable. There only needs to be a common element to render

> different products comparable. An exotic disease, for example, has only to be similar to an endemic disease to be considered comparable, as is the case for infectious bursal disease in chickens. This is a much broader definition than in the past under GATT where products had to be directly competitive or substitutable (Pauwelyn 1999). Expanded fruit imports from different countries are therefore much more likely now that some imports of fruit from New Zealand and the Philippines have been approved.

The SPS measures invoked by member countries must either conform to international standards, or be justified through risk assessment. This second option is viewed as an exception – SPS measures are expected to be based on international standards (Pauwelyn 1999). Importing countries should be allowed to invoke SPS measures to protect health against theoretical as well as established risks. Despite its sound scientific basis, the precautionary principle is not recognised under the SPS Agreement, except as a temporary measure.

Australia is under increasing pressure to be less cautious, to put assessments and procedures of other countries above its own and to harmonise downwards its quarantine regulations. The Australia-US FTA explicitly includes some quarantine concessions. Although these may initially be minimal, the FTA will increase the pressure Australia is already under in the international marketplace to soften regulations to bring them in line with those of other countries. The concessions granted to the US during the recent FTA negotiations are likely to form the starting point for subsequent negotiations with the Chinese, Thai and Malaysian negotiators. Accepting certain types of goods from some countries means accepting 'comparable' goods, no matter how broadly defined, from the same or other countries, leading to a further erosion of Australia's quarantine practices.

Each FTA opens new doors for dispute over quarantine where countries invoke standards higher than those accepted by other countries. Past experience demonstrates, however, that international standards and a reliance on risk assessment based only on established, rather than theoretical risks, may not provide adequate protection for public health. The WTO ignores the fact that these 'international standards', including the failure to recognise theoretical risks as legitimate, are the same ones that allowed BSE and its human form, variant Creutzfeldt-Jakob disease (vCJD), to emerge in a number of countries including the US, while Australia remains BSE-free (see Section 0). Finally, a rejection of the precautionary principle moves the burden of proof on food safety from the manufacturer to the regulatory body. In the US, for example, manufacturers of diet supplements once had to prove that their product was not harmful, but more recently, the Food and Drug Administration must prove when the product is marketed that it is 'unsafe' before it can take action to restrict its use or remove it from the marketplace (Goldstein and Carruth 2004).

In an effort to make Biosecurity Australia appear more impartial (and perhaps in response to criticism over the banana debacle), DAFF has recently established Biosecurity Australia as a 'business unit' reporting directly to its own deputy secretary and separate from the Market Access area (DAFF 2004c). DAFF also created an 'Eminent Scientists Group' to review all draft import risk assessments. The focus is agricultural; none of the initial appointees (Malcolm Nairn, Jim Peacock and John Radcliffe) provide a public health perspective.

3.4 Safe and wholesome food

International standards to ensure that food is 'safe and wholesome' are defined by the Codex Alimentarius Commission, which was created 40 years ago by the World Health Organization (WHO) and the Food and Agricultural Organization of the United Nations (FAO). While its purpose is to develop food standards and codes of practice, the Commission was created with the explicit aim of facilitating free trade between countries by harmonising food standards. Its objective was to promote a more liberalised system of trade that would be of benefit to the world's poor (FAO and WHO 1999). Signatories to trade agreements are expected to uphold these international food standards (see Box 2).

The Codex 'standards' were not intended to represent a ceiling on the standards imposed by national bodies, but arose as minimum safety recommendations (Silverglade and Heller 1997). In practice, however, these minimum standards are commonly invoked during trade disputes by trading partners as the maximum allowable to ensure trade is not restricted. As the SPS agreement was designed to facilitate trade rather than protect public health, 'there is an implicit pressure for downward harmonization built into [it]' (Silverglade 1999).

Box 2 Defining safe and wholesome food

A food is considered 'safe and wholesome' if it:

- does not cause food-borne infection when properly handled;
- is free from obvious contamination;
- contains residues within Codex limits;
- is free of objectionable defects;
- is hygienically produced; and
- is not treated with illegal substances (this is determined by national legislation).

Source: Codex Alimentarius Commission (1993a, p.10).

Food safety can be compromised in several ways.

1. Inadequate hygiene can lead to microbiological organisms at levels that cause spoilage or are considered unsafe.

2. Food may be subject to unintended contamination, such as with heavy metals.

3. The deliberate introduction of potentially harmful substances during the production process, including pesticides, veterinary medicines, growth promoters and food additives, can make foods unsafe. Gene technology is another, highly controversial, example.

4. Pathogens, such as viruses and bacteria, can be transmitted to humans through exposure to infected animals (for example, avian flu), by handling contaminated

material during production (for example, Q fever[6]), or directly through consumption of infected animals (BSE / vCJD[7] and possibly SARS).

The transmission of pathogens from animals to humans constitutes perhaps the most serious threat to public health. Newly acquired animal viruses often prove especially harmful to humans, and part of the danger can lie in their invisibility and the potential delay between infection and the onset of symptoms. While outbreaks of avian flu tend to be sudden and therefore alarming, they also tend to be obvious and relatively readily contained. The impact of some other pathogens may not be immediately obvious. BSE, for example, is particularly insidious, taking several years for infection to become apparent in both cattle and, as vCJD in people. Young cattle not exhibiting any signs of disease can still transmit the disease. Containing such a disease, with possibly decades-long lead time, is especially difficult. The precise source of a human case can be impossible to trace.

Article 4 of the *Code of Ethics for International Trade in Food* clearly states the conditions under which food may be traded: no food in trade should have 'in or upon it any substance in an amount which renders it poisonous, harmful or otherwise injurious to health' (Codex Alimentarius Commission 1985, p. 2). Determining what constitutes a dangerous amount of a particular substance is a matter of controversy. Furthermore, food must not be 'sold, prepared, packaged, stored or transported for sale under unsanitary conditions' (Codex Alimentarius Commission 1985, p. 2). Although these principles appear explicit, their application is open to interpretation and has been the subject of sometimes fierce debate between trading partners. Different panels of experts have frequently reached different conclusions as to the perceived level of risk. This occurred in June 2003, for example, with the halving of international recommendations for maximum exposure to methylmercury (a common contaminant of some fish and seafood) (JECFA 2003), with Australia taking a further nine months to change its own recommendations (FSANZ 2001e). Furthermore, some people may have a lower threshold of tolerance to some substances and may be more susceptible to the effects. One 'national diet' may also vary substantially from another, creating vastly different patterns of exposure. Some substances may cause long-term damage even at very low levels of exposure, and the delay between exposure and the onset of symptoms may render determining the cause difficult. For example, some chemicals used as pesticides may mimic hormones (Sohoni and Sumpter 1998), and the same chemical may produce extremely diverse outcomes from carcinogenic effects to reduced fertility (Rhind 2002; Binelli and Provini 2003).

The WTO does not require the setting or use of international standards (Harlow 2004), but this is increasingly becoming the practice. The Codex recommendations should be treated as a minimum rather than a maximum standard in food safety.

[6] Caused by a bacterium, Q fever is vaccine-preventable. People who work closely with cattle and sheep (for example abattoir workers) are at greatest risk from infection (Department of Health and Ageing 2003).

[7] Bovine spongiform encephalopathy and its human form, variant Creutzfeldt-Jakob disease.

4. 'Fit for human consumption': the tangled food web

Modern food production is complex. While most Australians are no doubt aware of the recycling of cans and bottles, few would know that animal products deemed not 'fit for human consumption' are readily (and literally) fed back into the food production process. The term 'food web', used by ecologists, acknowledges a degree of feedback. But even this implies some level of order and organisation, a discernible pattern, rather than the random complexity created by modern food production systems. The web has been tangled, creating complex linkages between various organisms, making it difficult to establish the pathways between them. Reality is at odds with regulations, which consider the process to be a linear and unidirectional food 'chain'. The term 'chain' is used throughout the Codex recommendations, but it fails to reflect the redistribution and recycling that actually takes place, giving cause for some serious safety concerns. In some countries herbivores are still fed herd mates and the remains of other animal species; parts 'unfit for human consumption' become food for humans via processing by another species. In many cases this may not create a public health problem, but the potential danger of such use of animal material was demonstrated with the arrival of BSE in Britain in the 1980s followed by vCJD in the 1990s.

4.1 BSE

Animal protein used in feed is an excellent growth promoter, but feeding meat to herbivores can be a dangerous practice. The BSE epidemic in Britain commenced in the 1980s with the feeding to cattle of ruminant meat and bone meal containing material from sheep infected with scrapie, a disease which is similar to BSE and that renders the sheep unfit for human consumption. Although initially centred in Britain, a lack of caution in international trade ensured that BSE risk has become geographically widespread. The feeding of ruminant meat and bone meal to cattle is now banned in the UK and in most – but not all – of Europe (FSANZ 2002c). The degenerative disease vCJD occurred in people as a result of BSE-infected beef products entering the food chain. Human-to-human transmission can also take place, for example, through donated blood products and surgical instruments.

Australia remains BSE-free due to its high standard of agricultural practice and use of the precautionary principle in import risk assessment and strict quarantine regulations. Since 1966 it has not imported any stock feed originating from animals except from New Zealand (Animal Health Australia 2000). However, until the appearance of vCJD in Britain and elsewhere, this ban would have been vulnerable to being ruled a restrictive trade practice had it been challenged under the WTO, because the risk to health was theoretical rather than specifiable at the outset. Similar bans on imports from some countries are still vulnerable under the WTO system of dispute settlement, wherever Australia's regulations are more stringent than those of other countries. The BSE/vCJD case serves as a warning; a practice that is internationally accepted can still be dangerous.

The guidelines recommended by Codex (Codex Alimentarius Commission 1993a) covering the inspection of animals for slaughter appear rigorous and straightforward when referring to material that is to be directly consumed by humans or ruling on material that should be declared unfit for human consumption. The concern for what then happens to the condemned parts of animals or whole animals, however, extends

only as far as considering the next link in the so-called 'chain', the immediate health of the animals (pets or livestock) that are ultimately fed the redirected products. For example, products that transmit disease to other livestock should be destroyed, and pet food manufactured from rejected human food should not transmit infection to companion animals and, from them, to the humans they live with (Codex Alimentarius Commission 1993a). There are therefore several categories of judgement with respect to animals for slaughter (see Box 3).

Box 3 Categorisation of animals for slaughter

- Inspected and passed (unconditionally 'fit for human consumption'). Even animals that undergo emergency slaughter before a condition worsens can be declared fit for human consumption.
- Conditionally passed for human consumption, but distribution limited to restricted areas for the sake of animal health (quarantineable diseases).
- Fit for human consumption despite some acceptable defects (sexual odours, odours from veterinary drugs, unusual odours from being fed fish meal).
- Entire animal/carcass considered unfit for human consumption (systemic disease).
- Partial condemnation, only those body parts affected by the disease or defect are declared unfit for human consumption. The rest of the carcass and offal is considered fit (localised disease or defect).
- Conditionally safe, with treatment such as heating or freezing (applied to some parasitic diseases where heat or cold destroys pathogen).

Source: Codex Alimentarius Commission 1993a.

Animals or materials declared unfit for human consumption may be used in animal feed 'provided there are adequate precautions to prevent misuse and to avoid dangers to human health and animal health' (Codex Alimentarius Commission 1993a, p. 21). Such products can also be used in sterilised pet food and for industrial non-food purposes. Thus, under international regulations, animals that are not deemed fit for human consumption can still end up indirectly as part of the human food system (see Box 4). Incineration is a final option only if the material is not considered salvageable.

Codex also recommends that inspection should be cost-effective and based on risk allocation according to the production history and disease status of a region (Codex Alimentarius Commission 1993a). If the risk for a particular disease or defect is low, then testing for it may not be cost-effective. The importance of safeguarding industry is thus highlighted by Codex; judgements should not impose unnecessary costs on industry (Codex Alimentarius Commission 1993a).

Despite international recommendations, much is left to the decision of national authorities. The Codex guidelines enable a negative judgement (such as condemning an animal as unfit for consumption) to be overturned by the controlling national authority depending on economic conditions and 'wholesomeness needs' in order to maintain food supply (Codex Alimentarius Commission 1993a). The Codex guidelines on animal

inspection are intended to be flexible in order to suit local situations and legal contexts. For example, Codex recommends that abattoir inspection procedures should be appropriate to the expected types and prevalence of diseases present (Codex Alimentarius Commission 1993a). Best practice might make 'efficiency' sufficient were animals either in or out of the human food system, but little consideration is given to food pathways. The Codex guidelines enable animals that have been declared unfit for human consumption to be fed back into the system via processing by other animals.

Cattle 'suspected on clinical grounds of BSE infection should be dealt with in strict accordance with the requirements determined by the local authority [with] laboratory examination where appropriate to confirm diagnosis' (Codex Alimentarius Commission 1993a, p.63). These guidelines leave substantial room for interpretation and application by national governments. Even management and containment of the source of BSE, scrapie, is not dealt with comprehensively. Animals with clinical disease are not considered fit for human consumption, but in the absence of contrary evidence, contacts, offspring and ancestors are (Codex Alimentarius Commission 1993a). Despite the known risks, some countries continue to feed ruminant material to other ruminants.

Specified risk material (skull, brain, eyes, tonsils and spinal cord of cattle more than 12 months old and the intestines of all animals) has a high risk of transmitting BSE (FSANZ 2001c). So too does mechanically recovered meat, given the potential for contamination during the process.[8] Such products, especially from older animals at higher risk of BSE, are often used in smallgoods and canned meat products that are imported to Australia (FSANZ 2002b). The rejection of goods manufactured under risky conditions that do not meet Australia's standards is essential to protect public health in Australia. This capacity is undermined by pressures to bring Australian risk assessment procedures in line with those of other countries through the dispute settlement process. Australia's stringent, precautionary systems of quarantine combined with high domestic standards of production have made it one of the safest countries in terms of BSE. Even so, Australia's assessment of the BSE status of each country could be strengthened as at present it relies on self-reporting and certification by the exporting country (FSANZ 2001d).

The recent case of BSE in the US prompted Australia to ban imports of beef and beef products from the US immediately, but not all beef products were subject to the ban. Products deemed to pose minimal risk (such as collagen, gelatine and dairy, and also fat and tallow if they are present as a 'minor ingredient'[9]) were exempted from this import ban (AQIS 2003). Fat and tallow both pose some small risk of BSE transmission, depending on whether they are produced from fatty tissue (negligible risk) or from rendering (some risk) (FSANZ 2002b). The same is true for gelatine; sourced from skins it may have negligible risk (providing there is no contamination with specified risk material during slaughter), while sourced from bones it may pose some risk (FSANZ 2002b). Given that there is no proven safe level of exposure to BSE, allowing these products in food in any amount carries some unknown level of risk. Furthermore, this single case of BSE confirmed in the US may not be isolated. Cattle carrying BSE, especially young cattle, may not show any signs of disease when they are presented for

[8] The meat remaining on a carcass after most of it has been removed is washed off by machine.
[9] A minor ingredient is defined as one that comprises no more than 300g/kg (that is, 30 per cent) of the food (FSANZ 2003a, Standard 2.2.1).

slaughter. Under the inspection regimes of most countries, only samples of those animals that appear ill (called 'downers': staggering, disoriented or unable to walk) may be sent for laboratory testing. Japan is the exception to this practice. Since its own BSE scare in 2001, Japan now tests every cow intended for human consumption.

Setting an acceptable level of risk is one of the challenges for national regulating authorities, as is deciding how to respond to that risk. If Australia's acceptable level of risk to public health is lower than that accepted by a trading partner, then the risk must be specified, and be proven to be both actual and novel. The risk that BSE posed was not known at the time that Australia invoked import bans on risky material, but its caution has since proved justified. Even now, international regulations may be too weak as BSE is not only a risk through directly consumed contaminated material, but may pose a risk through the manufacture of pet food, cosmetics and some vaccines (see Box 4). Furthermore, much of the certification and regulation is based on industry self-regulation and report.

Although trading partners are expected to abide by Codex standards, these international guidelines are, for the most part, vague. They are 'recommended' rather than obligatory, and they leave a great deal open to national legislators and local regulators to decide. While initially this may seem beneficial in that countries appear to be able to set high standards, it also leaves their interpretation open to dispute. Australia cannot impose regulations on locally produced foods and imported foods that are more stringent than those of other countries if the other countries do not agree to its assessment of risk. The ability to regulate imports also relies on notions of equivalence between countries, so any additional measures by Australia to protect public health are perceived as being restrictive of trade. Trading partners must abide by equivalence agreements or face retribution through the dispute settlement process. What happens if a pesticide has been banned in one country due to safety concerns but is still used in another? Strictly speaking, both countries could be following the Codex principles. The importing country would need to prove that the substance used by the exporting country was harmful. Theoretical harm stemming from use of a substance, such as a pesticide, would not be sufficient reason to ban importation of a food under the 'science-based' approach unless the precautionary principle were to be adopted internationally.

Box 4 Indirect pathways to human infection with BSE

Pet food

Animal material considered unfit for human consumption often makes its way into homes and gardens through pet food and fertilizer (for example, blood and bone fertilizers). Not only are high-risk animals used in this way, but also organ meat and bone meal, the potentially riskier parts of the cow. Sterilisation procedures, such as heat treatment, may not be suitable or sufficient for some pathogens. The modified proteins (prions) that are the agent of BSE, for example, are heat resistant (FSANZ 2002c).

There have been a number of cases of feline spongiform encephalopathy (FSE) in domestic cats in the UK, resulting from ingestion of infective beef products. The pet food industry is not an area that has been high on the public health agenda, but given the presence of pet food in millions of kitchens and the resistance of prions to heat and detergents, pet food remains a potentially hazardous material.

Box 4 continued

Codex has only stated concerns regarding potential diseases that may be transmitted to humans via pets, but does not consider the potential infection pathway through the handling of pet food and through kitchen contamination. This is a significant concern given the origins of many pet foods, which are sourced from countries where BSE occurs. Because pet food products are not intended for human consumption they do not undergo similar levels of surveillance and testing. For most pathogens this may be sufficient, but for some, like BSE, this represents dangerous lack of foresight.

In recognition of the risks inherent in pet food, Japan has banned its importation from the EC (FSANZ 2002c). In Australia, imports of pet food have been subject to 'progressive' bans since 1997 from countries that have reported 'native-born BSE'. Currently Australia imports pet food only from the US, Canada and New Zealand (DAFF 2003a) but these imports should now be revised given the recent US case of BSE, and the likelihood that the affected animal was originally from Canada. There may be other, as yet undetected, risks arising from using sick animals to produce pet food.

The potential for humans to be infected through handling pet food adds another level of complexity to establishing the source of contamination. It would be even more difficult to trace cases of human vCJD transmitted this way than if it occurred only through directly consumed foods. The shorter lifespan of pets means they may themselves never exhibit symptoms after consuming contaminated food, while their owners may be infected through using the same utensils for example, as washing would not destroy the infective protein. At present, the only way for consumers to ensure the safety of their pet food is to buy only those sourced from BSE-free countries, such as Australia.

Cosmetics
Much of the multibillion dollar cosmetic industry relies heavily on products sourced from animals, containing oils and other animal by-products. As these are generally not intended for ingestion, different standards apply from those used for food.

Some cosmetics such as lipstick are ingested, albeit unintentionally, and exposure can also occur through delicate membranes. Given the existence of BSE, regulation regarding the source and safety of these have been dangerously absent, with the DAFF accepting seemingly without question cosmetic industry assurances of product safety (DAFF 2003a).

Vaccines
Calf serum is sometimes used in the manufacture of vaccines. Australia has continued to use vaccines that were cultured in calf serum sourced from the UK in the 1980s, before feed ban measures were put in place. The finished vaccines are considered safe as they contain very little, if any, serum (Department of Health and Aged Care 2000).

Internationally, food safety is considered to be the responsibility of both industry and the controlling authority (Codex Alimentarius Commission 1993a). Officially, co-regulation, where both government and industry are responsible, is becoming more common. In practice, however, co-regulation can often mean industry regulation as governments reduce their monitoring role in order to reduce cost. Rigorous inspection

regimes may be perceived by industry as expensive and frequently unnecessary. Companies are motivated by the desire to make profits, and corners may be cut where self-inspection and certification are carried out internally. In developing countries in particular, trade liberalisation puts increased pressure on producers to streamline the production process. Required inspection regimes may not be implemented fully, and governments may not have the resources to ensure that they are maintained at an appropriate level. Co-regulation of the live sheep export industry between industry and government in Australia was recently condemned, where lack of industry and government accountability was a major criticism of the recent Keniry Report (DAFF 2004b).

In 2001, Australia banned the importation of beef products from 30 European countries after increased surveillance led to the identification of BSE-affected animals (FSANZ 2001d) and the realisation that BSE was much more widespread than previously thought (FSANZ 2001a). That so many countries, previously considered safe, were reclassified as at risk for BSE highlights the importance of rigorous surveillance. The US, with a testing regime that has been described as extremely inadequate (*The New York Times* 2003), recently reported its first case of BSE (DAFF 2003b; AQIS 2003). Samples of animals that are suspected of being diseased are sent for laboratory testing. If testing fails to rule out disease, then the animal is treated as though it is infected. But test results from slaughtered 'at risk' animals are available only after the meat and meat products have left the slaughterhouse. Before the confirmed case of BSE in the US, some 20 000 'downers' were consumed each year (*New Scientist* 2003). The current US testing regime does not prevent infected meat from entering the food chain (*The New York Times* 2003), but only allows products to be recalled. The particular cow in the US found to have BSE was declared fit for human consumption nearly two weeks before the test results were available (Teather 2003).

It is unlikely that this is the only individual animal affected. The US reported that two-thirds of the cattle that had been imported from Canada with the infected cow could not be traced (US Department of Agriculture 2004). Increased sampling and testing would perhaps uncover more cattle at risk.

Japan only detected its first case of BSE in 2001 when it introduced rigorous screening and has since been commended for its thorough response to BSE (FSANZ 2001b). In contrast the US has, at least until now, largely ignored its own BSE risk, with a sampling regime of testing only one in 1000 cattle slaughtered each year (Teather 2003), and most of these were downers (*New Scientist* 2003). The cow confirmed with BSE would not normally have been part of the sample, but was tested only because of an unrelated injury (Teather 2003). The US is now expected to increase its testing almost ten-fold, to between 200 000 and 300 000 cattle annually, or up to one per cent. Canada, too, is increasing its sampling from 8000 to 30 000 cattle per year nationally, but theirs is a target of 100 per cent of cattle slaughtered (Government of Alberta 2004).[10] More intensive surveillance brings with it increased probability of finding a positive case. Such a finding could seriously damage the beef industry through both a domestic backlash and import bans imposed by other countries. The president of the US Meat Export Federation, Philip Seng, recently stated that Japan's call for the US to test all of its cattle was 'unscientific' (US Office of the Scientific Liaison 2004).

[10] Canada reported its first case of BSE in May 2003 (Government of Alberta 2004).

The combination of international trade and complex, non-traceable systems of food production is dangerous. While the US has labelled Canada as the source of the infected cow, Canada has suggested that the cow was infected by feed originally imported from the US (*New Scientist* 2003). While BSE provides a telling example of the need to adopt the precautionary principle in relation to the regulation of food safety, there are a number of other areas where caution is justified in food safety assessment, including the presence of pesticides and veterinary drugs and bacterial contamination. These are discussed in the following sections.

4.2 Pesticides and other residues

A number of contaminants occur in foods as a result of the production process. Chlorinated organic pesticides, also known as persistent organic pollutants (POPs), accumulate in the environment, cause neurological damage, are carcinogens and hormone mimics that can disrupt normal function and reduce fertility (Colborn *et al.* 1996). They are stored in fat and accumulate during a lifetime; the easiest way for a woman to reduce her personal load of organochlorines is to breastfeed (Harris *et al.* 2002), thereby passing them on to her child. A number of these types of pesticides are no longer registered for use in Australia because they are recognised to cause environmental damage and are known to have adverse health effects even at low levels.[11] Overall, dietary exposure to organochlorines is declining in Australia (FSANZ 2002a), but these safety standards have not necessarily been applied internationally. Australia and New Zealand, for example, have separate guidelines for the pesticides permissible in foods, but accept trade from each other (FSANZ 2002a).

International guidelines specify the maximum residue limits (MRLs) permissible. An MRL is the 'type and amount of residue considered without toxicological hazard for human health' (Codex Alimentarius Commission 1993b, p. 1).[12] It is extremely difficult to determine safe levels of consumption as effects from ongoing low levels of exposure are both difficult to measure and attribute to a particular chemical. In addition, exposure to one pesticide at low levels is not a real life scenario. The effect of exposure to multiple pesticides over a number of years and decades remains unknown, but it is possible, in addition to overall cumulative exposure, that the interaction between several different chemicals could produce adverse health outcomes where exposure to one may be harmless.

Residues from veterinary drugs may also impose adverse health impacts. The use of veterinary drugs is virtually universal in animal husbandry. Not only sick animals are treated; antibiotics and hormones are used as growth promoters in healthy animals. Overuse of antibiotics can render them ineffective as bacteria develop resistance so that an increased amount of the drug needs to be used, or the use of multiple drugs becomes necessary in order to treat the infections that do arise. The problems resulting from overuse are not restricted to the farm. Vancomycin-resistant enterococci (VRE), which cause severe intestinal infection, came to public attention in Europe in the 1980s and Australia in the 1990s. Vancomycin is a particularly potent antibiotic that is often used in people as a last line of defence against infections that do not respond to other classes

[11] Such as DDT, chlordane, aldrin, dieldrin and heptachlor (FSANZ 2002a). Several of these have only recently been deregistered.

[12] Australia uses acceptable daily intakes (ADIs) for pesticides and tolerable limits (TLs) for other contaminants (FSANZ 2002a).

of antibiotic. The use of avoparcin (a veterinary drug similar to vancomycin) as a growth promoter in chicken feed was implicated in the development of VRE in people (Collignon 1999; JETACAR 1999). Fortunately, to date this has been the only known drug resistant 'superbug' resulting directly from the use of antibiotics in farming.

The principles set down by Codex for the use of pesticides and veterinary drugs include criteria of maximum effectiveness and minimum risk (Codex Alimentarius Commission 1993b). As with pesticides, veterinary drugs are also frequently used in combination and multiple residues may persist in foods consumed. The responsibility of appropriate use, however, lies with national regulators and individual industry veterinary practitioners to ensure that use falls within guidelines. Codex notes, for example, that resistance to some drugs may develop, but that it is the 'responsibility of veterinarians or other authorised persons' to ensure that the regime applied is safe (Codex Alimentarius Commission 1993b, p. 2).

The maximum residue levels considered safe are open for debate. Any country wishing to protect its public from theoretical harm by setting lower acceptable levels, or even by banning the use of certain chemicals out of concerns for safety, may be subject to retaliation by trading partners. Such national standards may be considered a non-tariff barrier to trade, and therefore subject to the WTO's dispute settlement process. National regulations are developed according to the best available knowledge, and take into account likely exposure due to consumption patterns. Some countries, such as Australia, rely heavily on meat and meat products. Acceptable maximum levels of a veterinary antibiotic in meat, for example, may therefore be higher for a country that does not consume as much meat as Australia does. Acceptable daily intake or a similar measure is one determinant of the type and amount of food additive allowed (Codex Alimentarius Commission 1972).

Estimates of dietary exposure to pesticides and other contaminants are made through the biennial Australian Total Diet Survey (FSANZ 2002a) which aims to test foods that are representative of the Australian diet, and uses geographical and temporal sampling. Estimates of exposure are made for four different age groups, infants, toddlers, young adolescents and young adults. The most recent survey did not find any of the tested antibiotic residues in meat, eggs or dairy products (FSANZ 2002a), an absence in final food products that is encouraging. This absence does not, however, indicate that antibiotics were not administered to the animals during rearing, nor does it indicate the potential role such antibiotic administration had in promoting the development of harmful drug resistance. It does indicate that the withdrawal periods used were sufficient to eliminate residues from food. Importantly, all of the foods tested in the survey were sourced in Australia.

Imported foods are also inspected to ensure they meet Australian standards. The sampling regime depends on the type of food and its risk classification (see Box 5). Australia's import surveillance is only as good as the international standards allow as pressure to harmonise safety standards may reduce its capacity to reject foods that fail to meet its standards. Furthermore, increasing reliance on, and acceptance of, equivalence measures means Australia may be discouraged from continuing to apply such a rigorous inspection regime.

Box 5 Surveillance and sampling of imported foods

Imported foods are subject to different sampling regimes depending on their risk classification. There are three levels of risk:

1. Risk category
As foods in this category are considered to pose high or medium risk to public health, they are all referred to AQIS for inspection. Sampling is performance-based (imported food from producers with a consistent history of meeting Australian standards are inspected less frequently than those from new suppliers or those with a history of not meeting standards). Inspection levels are as follows:

- The first five shipments; after five consecutively cleared shipments, inspection intensity drops to the next level;
- One in four shipments (the other three are automatically released); after 20 cleared inspections and, if importation follows a steady pattern, inspection intensity drops to the next level;
- One in 20 shipments (the other 19 are automatically released).

2. Active surveillance category
Ten per cent of shipments designated 'active surveillance foods' are referred to AQIS for inspection. These are then sampled.

3. Random surveillance category
Five per cent of foods not considered in the risk or active categories are referred to AQIS for inspection. These products are released upon sampling.

Source: FSANZ 2003b

4.3 Bacterial contamination

Australia has had relatively few major outbreaks of food poisoning caused by bacterial contamination. Three well-known bacterial contaminants that can cause severe food poisoning are *Listeria*, *Escherichia coli* and *Salmonella*. The most severe effects tend to occur among the very young and the very old, and those with suppressed immunity. Quarantine regulations enable Australia to limit the importation of food that is at high risk of bacterial contamination.

The risk of *Listeria* contamination has featured prominently in debates over Australian quarantine regulations (see Box 6). Milk and milk products imported to Australia have typically been heat treated, with few exceptions. Products that have not undergone heat treatment are more likely to contain significant levels of *Listeria monocytogenes* bacteria (CSIRO & AFISC 1999).

Box 6 Listeria in import risk assessment

Listeria can multiply at refrigerator temperatures and is thus most likely to occur in products with a relatively long refrigerator shelf life. It can cause flu-like symptoms in people who are otherwise healthy, but much more serious adverse effects, such as meningitis and septicaemia, in small children, the elderly and people with suppressed immunity. Exposure during pregnancy can cause miscarriage and stillbirth. Pregnant women are therefore advised to avoid certain foods that are known to be common media for *Listeria*, including soft cheeses and cheeses made from raw milk. In most outbreaks of Listeriosis, between 20-30 per cent of people with the infection die (WHO 2004a).The very long latency between infection and the development of listeriosis (two months) makes tracing an outbreak particularly difficult.

At present, only some very hard cheeses made from raw milk are imported into Australia, as the maturation process can adequately reduce the bacterial content of the cheese (FSANZ 2002d). France manufactures soft cheeses from raw milk and has suffered a number of serious outbreaks of Listeriosis which have been linked to such cheese (CSIRO & AFISC 1999). A number of other European countries have also been affected in these outbreaks. Australia's quarantine regulations may not be in harmony with those of other countries, but they remain effective in reducing serious risk from Listeriosis.

Despite the severity of the adverse health effects resulting from *Listeria* contamination of food, Australian standards have already been reduced as a result of pressure from importers and industry. The previous standard, which specified a zero limit in cooked crustacea, was considered by some interested parties to have no scientific basis. Although three per cent of crustacea sampled carried *Listeria*, risk to health was considered minimal. There is now no microbiological limit set for the acceptable concentration of *Listeria* in cooked crustacea sold in Australia (FSANZ 2003c).

Australia has had its own food poisoning outbreaks due to bacterial contamination, with two significant epidemics in recent years, both of which primarily affected children. The first involved *Escherichia coli* (*E. coli*) contamination of fermented meat products, and the second was *Salmonella* in peanut butter.

E. coli is a normally harmless bacterium present in the human gut, but some strains, including the notorious O157, produce a toxin that causes severe illness, with symptoms of stomach cramps, vomiting and diarrhoea, and sometimes haemolytic uraemic syndrome. The 1995 *E. coli* outbreak in South Australia was caused by contamination of fermented meat products from the Garibaldi company (ABC 1995). The surface of meat is easily contaminated with *E. coli* from the bovine gut under some slaughtering situations. This occurs especially where there is pressure to increase productivity and reduce costs (Schlosser 2001), as is the case with growing market competition arising from trade liberalisation. Fermented meat products are often the source of outbreaks, as the fermentation process can encourage the multiplication of such bacteria.

Salmonella usually causes gastrointestinal symptoms of cramps, vomiting and diarrhoea, but more serious illness can involve septicaemia. A nationwide *Salmonella* outbreak from contaminated peanut butter occurred in 1996 (Oliver 1996), and was

attributed to contamination by rodent faeces at the peanut storage facilities. Fifteen hundred people affected by the peanut butter contamination successfully filed class action proceedings (Slater & Gordon 2001). Most cases, however, occur on a much smaller scale from improperly handled and stored food at the household or catering business level.

The severity of illness caused by bacterial contamination emphasises the importance of good manufacturing practice, imported food surveillance, and the ability to invoke import bans. Once again it is not just the direct consumption of contaminated foods that poses a risk to human health. Blood and bone fertilisers and cow and chicken manure are used widely, commercially and on home vegetable gardens. Handling the product inappropriately and surface contamination of the crop are potential hazards that need to be addressed.

4.4 Heavy metals

Heavy metals are another food contaminant that can have serious health consequences. Environmental mercury occurs naturally, and some geographic regions such as New Zealand, can have much higher concentrations than others. Pollution from industry also contributes significantly to local mercury concentrations, and one of the major sources of mercury in the environment comes from burning coal. Many popular fish, especially long-lived larger predator species such as shark, snapper and blue-fin tuna, can contain very high levels of methylmercury (organic mercury). The main concern with mercury contamination is reduced cognitive and motor skills in the children of women who consume such fish while pregnant (FSANZ 2001e; JECFA 2003).

Until recently in Australia, there has been little attention paid to the potential dangers of consuming fish. Following the release of the new JECFA[13] recommendations in July last year, Food Standards Australia New Zealand (FSANZ) released their revised guidelines for fish consumption during pregnancy. Since 2001, pregnant women have been advised to restrict their intake of high mercury fish to four portions a week, but this has now been reduced to one serving per fortnight. Given the possibly very different patterns of fish consumption in the two countries, and the very high naturally occurring levels of mercury in fish caught off New Zealand, it may be difficult to reach a recommendation that is appropriate for both countries. Indeed, the new FSANZ guidelines are intended only for Australia. Due to geologic variation, shark caught in New Zealand may have much higher levels of mercury than shark caught off the Australian coast. Shark from New Zealand can be bought in Australian supermarkets.

Both the source of the fish and patterns of consumption therefore need to be considered in import risk assessment. Shark is cheap to buy as it is usually an unintended by-catch. It is frequently used as takeaway fish with chips. Within Australia, patterns of takeaway consumption vary with socioeconomic status, so that even if only a small proportion of shark consumed in Australia is from a high mercury area, some groups may be more likely to be exposed than others.

Even if it is not directly consumed by humans, contaminated fish may pose a threat to public health. As meat and bone meal are used as stock feed in other countries, fish meal is used in chicken and other livestock feed, both here and elsewhere. Unintended

[13] Joint FAO/WHO Expert Committee on Food Additives.

by-catch and other seafood that is not considered fit for human consumption, for example because it contains a high level of methylmercury, may be turned into feed for other animals. The products (milk, eggs) from these animals and the animals themselves are subsequently deemed fit for human consumption. Fish meal may also be converted into fertiliser and used in organic and other farming. Humans can ingest high levels of mercury from consuming fish, but the potential contamination of land animals through consuming high-risk fish meal does not appear to have been considered by food safety authorities.

Further heavy metal contamination of crops can also occur with the application of industrial waste as cheap fertiliser. Currently, there is no requirement for the heavy metal content of imported fertilisers to be labelled (Ryle 2002). Increasing international trade could potentially increase the quantity of such fertiliser on Australian farms.

4.5 Avian influenza

The recent outbreak of avian influenza in Asia further highlights the need for Australia to maintain stringent quarantine regulations, even if they are unpopular with trading partners. Affecting Vietnam, Thailand, Cambodia, China, Indonesia, Japan, Laos and the Republic of Korea, the most recent outbreak has been unprecedented in geographic scale, and countries with no history of avian influenza have been affected (WHO 2004b). Canada experienced an outbreak of another strain of avian flu (H7) earlier this year (WHO 2004c), demonstrating that it is not a problem that is restricted to Asia.

Avian influenza can be fatal to both poultry and humans, potentially devastating the poultry industry and creating a serious public health situation. Influenza viruses are highly transmissible and mutate with ease. Outbreaks of avian influenza tend to spill over into the human population most easily where people and poultry live in close proximity. While transmission from infected poultry to humans is cause enough for concern, at present cases are limited to those in direct contact with birds and control of the spread of disease can be relatively simple. If, however, the avian strain recombines with a human influenza strain, the threat to public health becomes far more serious. Pigs have been found to be infected with the H5N1 strain of avian influenza in China (WHO 2004d) and pigs are thought to play a role in the creation of new human flu viruses if they become infected both with a bird strain and a human strain. The potential for such reassortment has been recognised by Hong Kong which randomly tests the pigs that it imports from mainland China for the H5 strain. So far, none has been found to be infected, and there have been no reported infections from the current outbreak in Vietnam (WHO 2004d). If avian influenza becomes transmissible human to human, it could become a major public health crisis. Human-to-human transmission is suspected to have happened on at least one occasion to date in a recent outbreak (WHO 2004e).

The WHO states that at present, surveillance and reporting for avian influenza are inadequate, and there is currently no system that ensures poultry are free of disease (WHO 2004b). Australian quarantine regulations banning the importation of raw poultry are therefore extremely important both to the industry and to public health.

4.6 Tracing outbreaks in a globalised food market

As the scale and complexity of the food market increase, food-borne disease outbreaks can potentially become more difficult to trace. Exporters are expected to notify

importing countries when a food control emergency[14] arises, and importers are to notify exporters if their inspection procedures uncover an emergency. The problem with this is that determining the final destination of a food product is not always straightforward. Firstly, an exporting country may not know the exact products that contain their ingredients. Secondly, importers may not be aware of the source of each ingredient in a product. Thirdly, under principles of equivalence, importers are unlikely to pick up a problem that may have been missed during export inspection procedures.

In the absence of meaningful trace-back systems, local food production makes the source of an outbreak easier to trace, and hence easier to respond to quickly and appropriately. Source-to-table tracing of food ingredients becomes especially important as the distance and time involved in transport of food products increases with greater trade. At the time of the initial awareness of the connection between BSE and vCJD in Britain, it was not possible to trace all the ingredients of foods sold in Australia – almost any food product could have contained offal or beef product sourced from Britain. A more open international market with fewer import checks not only leaves Australia vulnerable to a greater potential number of outbreaks, but also delays and complicates an appropriate response when an outbreak occurs.

Larger and more complex markets arising from the increase in international trade necessitates a system that can trace all food ingredients to their source. This would enable a more rapid and more targeted response in the event of a food control emergency. Australia currently has in place only two systems for tracing food ingredients, one for food that is to be certified organic and one for halal food. Given that the vast majority of food consumed in Australia is neither organic nor halal, a more generalised system of tracing ingredients needs to be developed in order to protect public health.

[14] A food control emergency is defined as a situation where risk of a serious health effect has been clearly identified and associated with consumption of a food (Codex Alimentarius Commission 1995a).

5. Conclusions

While increased trade has the potential to deliver economic and social benefits, such potential should not be confused with the certainty that it will. Public health is rarely considered in international trade negotiations, yet these processes can place populations at a very real risk of new diseases. Assessments of the costs and benefits of trade agreements are typically limited to potential economic outcomes, focusing primarily on the potential for economic growth. In addition, trade agreements are now marketed as a symbol of the political relationships between countries. Politicians in Australia and the US stated explicitly that their 2004 bilateral agreement was intended to strengthen security ties that have been forged between the two governments in recent years (Downer 2002). The public health consequences need to be considered, as do the environmental and social consequences, if we are to be certain that changed trade arrangements will result in a higher standard of living for Australians.

Stringent quarantine and adequate surveillance are essential prerequisites for ensuring food safety and promoting public health in Australia. Australia's capacity to make and enforce legislation protecting public health is at risk from international trade agreements, in particular from dispute settlement procedures. Theoretical risks to public health should be permissible in import risk assessment and the use of the precautionary principle given legitimacy.

Australia has exceptional standards of food safety that need not be compromised by trade agreements; its use of the precautionary principle for quarantine in food safety is an appropriate mechanism for protecting public health in the absence of absolute certainty. The outbreak of BSE in the UK demonstrates that international standards do not always produce the safest practice. Harmonising standards of quarantine could compromise food safety, in Australia and elsewhere. The dispute settlement process has already been mobilised to force countries to weaken their quarantine regulations and the Australia-US FTA puts pressure on Australia to limit its domestic laws that protect public health. The likelihood of even more trade agreements in the near future will increase this pressure even further. In order to ensure the ongoing high level of food safety in Australia, the following principles need to be considered when dealing with other countries and trade regulatory bodies.

1. **Theoretical risks should be considered in food and agricultural trade, and the precautionary principle should be recognised internationally as best practice in import risk assessment.**

   The absence of certainty should not be a reason for failing to act to protect public health. The Australian government should encourage the WTO to recognise the scientific validity of the precautionary principle and its effectiveness in protecting human health. Australia should not be required to lower its standards to those of other countries. International Sanitary and Phytosanitary (SPS) measures should not be 'harmonised downwards' as directed by current pressures. Australia's use of the precautionary principle should instead be recognised globally as best practice. Codex guidelines should not be used as a ceiling on safety regulations with pressure for universality in regulations, but as a minimum as initially intended. If harmonised standards continue to be sought, then the WTO should work to improve safety standards and adopt the precautionary principle.

2. **Australia's quarantine regulations should be excluded from trade negotiations.**

   Quarantine regulations should be explicitly excluded from trade negotiations in which Australia is a party. The Australian Government's use of quarantine as a bargaining chip undermines the claim that it is based on science.

3. **Quarantine standards should not be compromised in the settlement process for trade disputes.**

   Currently, outcomes of the dispute settlement process can weaken quarantine as member countries are sometimes required to remove import bans and reduce processing requirements for imported products. Quarantine restrictions informed by caution should not be subject to rulings by the WTO's Dispute Settlement Body.

4. **Surveillance and enforcement of regulations should be improved to restore and build consumer faith in food safety.**

   Both government and industry need to take greater responsibility to ensure food safety, especially in the areas of slaughterhouse inspection and the use of pesticides and veterinary medicines. Industry and national governments must be accountable to an international body, providing increased assurance to trading partners that inspection procedures are of the highest possible standard. Assistance should be provided to developing countries to establish these systems to ensure they are not excluded.

5. **Food tracing systems should not be limited to organic and halal food. A general system should be established to facilitate a rapid and appropriate response to food-borne disease outbreaks.**

   In Australia, a system of identity preservation is in place to track GM material from its source to the final food product, and a certification and trace-back system is in place for organic and halal foods. As modern food production is characterised by complex, multidirectional flows of products, these limited systems of traceability are not enough. All foods should be subject to the same rigorous system, documenting the pathways that food products take. Such a system would enhance capacity to trace outbreaks of food-borne disease and facilitate rapid and appropriate response.

Australia is lucky to be relatively free from many agricultural and food-borne diseases. Although initially arising because of Australia's island status, this freedom has been maintained because of tough quarantine protocols that are based on a cautious approach in assessing import risks. Current pressure from the WTO to harmonise international SPS standards is threatening Australia's ability to limit the importation of potentially dangerous foods and agricultural products. Quarantine in international trade does need reconstructing.

In order to protect public health and preserve its food safety, Australia must play an active role in ensuring that quarantine and food safety standards are improved worldwide. To date, international trade has placed downward pressure on labour standards, human rights and environmental practices. Australia can protect its own national interest and the interests of developing countries by ensuring that quarantine standards do not become a bargaining chip in future world trade negotiations.

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