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# North American Approaches to Regulatory Coordination



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#### INTRODUCTION

Greater integration of the Canadian, Mexican, and United States (US) agricultural and food markets has been one of the key developments in North America since the implementation of the Canada-US Free Trade Agreement (CUSTA) in 1989 and its successor accord, the North American Free Trade Agreement (NAFTA), in 1994. During the period 1991 to 2003, agricultural trade within the region climbed from \$14.0 billion to \$33.8 billion, as agrifood enterprises across North America devoted more attention to an emerging continental market based on similar consumer preferences. In addition, a burst of foreign direct investment (FDI) in the food and beverage industries of each NAFTA country took place during the first several years following NAFTA's implementation as industry took advantage of the opportunity for increased efficiencies and access to expanded expertise and resources. Although this trend appears to have tapered off for the US and Canadian food and beverage sectors, corresponding industries in Mexico continue to attract significant, new inflows of FDI today, some 11 years after NAFTA's inception.<sup>2</sup>

Increased trade, investment, and integration call for greater regulatory coordination among NAFTA governments. As regional trade in fresh produce today includes substantial quantities of commodities that

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<sup>&</sup>lt;sup>2</sup> Doan et al. and Zahniser explore these developments in much greater detail.

were hardly traded (if at all) by the three countries just 15 years ago, appropriate phytosanitary measures need to be crafted to ensure that producers in importing countries are not exposed to undue risks to plant health. For North American animal product industries to become more tightly intertwined in terms of trade in breeding stock, feeder animals, slaughter animals, processing facilities, and cross-border investments, the three countries must have the capacity to respond appropriately to changing conditions related to animal health and food safety without needlessly causing the disintegration of these economic arrangements. And for North American food processors to view all three countries as part of their prospective sales territory, they must assure themselves that they can meet a whole host of regulations concerning the transportation, integrity, labeling, and safety of their product in each of the three countries.

The trend towards the expansion of trade goes beyond NAFTA's borders. The vast majority of World Trade Organization (WTO) members are party to one or more regional trade agreements. As trading blocs form, these countries are taking advantage of efficiencies produced by integration. Narrow interests that result in internal disagreements among the NAFTA partners can create barriers to integration that result in less efficient agrifood industries that could affect North American competitiveness in third markets.

NAFTA's architects were well aware that some form of regulatory coordination among the member countries would be necessary and beneficial to market integration. Through regulatory harmonization, government could play a key role in facilitating the further integration of the North American market. To this end, the Agreement formally specified an extensive set of trilateral committees and working groups, some of which directly address aspects of regulatory coordination in the agricultural and food sectors (Figure 2.1).

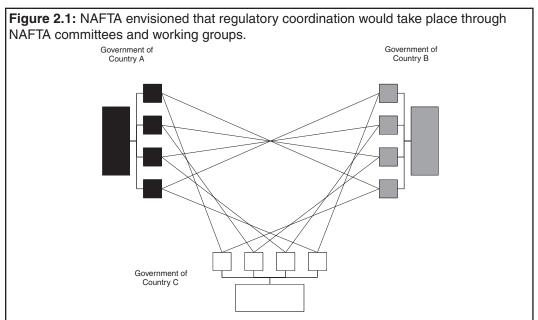
This framework received mixed use during the first decade of NAFTA. Some committees and working groups played an active role in regulatory coordination, while others remained largely dormant. At the same time, the NAFTA partners pursued regulatory coordination in other venues, sometimes as a substitute for activities that could have taken place in the NAFTA committees and working groups.

This chapter takes stock of regulatory coordination among the NAFTA countries during the first 11 years of the Agreement, including the extent to which regulatory coordination has taken place within the context of NAFTA's committees and working groups, and the extent to which it has occurred elsewhere. Through the use of case studies, the chapter illustrates that it is very often the nature of the issue itself that dictates

how it is eventually resolved. While cooperation among government bureaucrats often leads to productive coordination in less volatile situations, other instances require the involvement of higher-level decision makers. The case studies presented in this chapter have been chosen to provide a range of scenarios in which regulatory coordination has affected trade among the NAFTA members. The chapter concludes with suggestions for improving the existing committee structure and identifies opportunities for greater cooperation.

#### NAFTA'S FRAMEWORK FOR REGULATORY COORDINATION

The architects of NAFTA envisioned that the member countries would need to work together on a variety of trade-related issues to ensure that the three countries fully benefited from the integration of their markets. Pursuant to this objective, the text of NAFTA specified the creation of an extensive set of NAFTA committees and working groups, and the member countries have created additional trilateral committees and working groups along similar lines since the Agreement's initial implementation (Appendix 2.1). Several of these entities directly concern the agrifood sector, including the Committee on Sanitary and Phytosanitary Measures (also referred to as the SPS Committee) and its various working groups, the Working Group on Agricultural Grading and Marketing Standards, and the Committee on Agricultural Trade.



**Note:** The smaller boxes represent the staff members tasked to participate in particular trilateral committees and working groups, while the triangles linking the staff represent the activities of those groups.

Outside of specifying the creation of particular committees and working groups and, in some instances, how often (at a minimum) these entities are to meet, NAFTA's text provides few specifics about how these entities are to operate. Through the activities of these committees and working groups over the past decade, one can observe two basic commonalities in structure. First, each member country is to designate a national chair to the committee or working group. Second, the meetings of the committee or working group primarily serve as occasions when a mutual work plan is established and when progress towards previously implemented work plans is reported and reviewed.

Upon the completion of the NAFTA negotiations in 1993, it was anticipated that the participating countries would continue their involvement in a variety of bilateral, trilateral, and multilateral regulatory mechanisms. At that time, the end of the Uruguay Round of international trade negotiations was approaching, so there was the anticipation that many of the principles being established within NAFTA for regulatory coordination would also be secured at the multilateral level. The text of NAFTA also makes numerous references to various regional and multilateral organizations, such as the North American Plant Protection Organization (NAPPO), the Codex Alimentarius Commission of the Food and Agriculture Organization and the World Health Organization, and the International Office of Epizootics (now known as the World Organization for Animal Health), which is indicative of the NAFTA governments' intentions to continue their participation in these entities.

#### **CURRENT SITUATION**

The current situation regarding regulatory coordination among the NAFTA countries differs in important ways from the vision set forth by the Agreement. While the formal structure of committees and working groups has been used to address some regulatory challenges, many activities have taken place outside this structure. Virtually all efforts toward regulatory coordination have required the national bureaucracies of the NAFTA governments to interact on an almost daily basis – a phenomenon that we call "workaday cooperation." To ensure that these efforts achieve the common objectives of the NAFTA governments at a faster pace than might occur otherwise, top-down leadership is sometimes exercised, and new organizational structures have been created to address regulatory issues on a bilateral basis, an approach that we refer to as "strategic bilateralism."

#### NAFTA Committees and Working Groups

Of all the NAFTA committees and working groups, the Committee on Sanitary and Phytosanitary Measures was one of the more active ones during NAFTA's first decade. Since NAFTA's implementation in 1994, the committee has met ten times, with the most recent meeting taking place in March 2005. At these meetings, representatives of the member countries review the status of certain bilateral and trilateral SPS issues, as well as the progress made by the committee's nine technical working groups. Five of these groups have active agendas and continue to hold regular meetings: Animal Health; Labeling, Packaging, and Standards; Meat, Poultry, and Egg Inspection; Pesticides; and Plant Health, Seeds, and Fertilizers. At the committee's 2003 meeting, the member countries suspended the activities of the four remaining groups – Dairy, Fruits, Vegetables, and Processed Foods; Fish and Fishery Product Inspection; Food Additives and Contaminants; and Veterinary Drugs and Feeds - but reserved the option to reinstate these groups and create new ones if the need should arise.<sup>3</sup> Interestingly, the Working Group on Plant Health, Seeds, and Fertilizers sometimes assembles at the meetings of the North American Plant Protection Organization (NAPPO), an organization that predates NAFTA by some two decades. Recently, the US and Mexican Governments agreed to allow NAPPO to address their disagreement regarding the establishment of a systems approach without fumigation for the export of US stone fruit to Mexico.

The Technical Working Group on Labeling, Packaging, and Standards answers to both the SPS Committee and the Committee on Standards-Related Measures, the NAFTA committee that addresses technical barriers to trade. This working group, which started as a bilateral US-Canada working group in 1993, became a trilateral group also involving Mexico in 1998. Efforts of the Labeling, Packing, and Standards Working Group concerning the labeling of foods with trans fatty acids illustrate how Mexico's participation in the NAFTA committees and working groups could enable that country to make rapid advances in its regulatory capabilities. Based on the output of this working group and similar work by the Technical Barriers to Trade Committee at the WTO, the Mexican Government could implement food labeling requirements for trans fats that are comparable in quality and scope to requirements currently existing in any developed country.

In the area of agricultural grading and quality standards, the NAFTA countries merged the two Bilateral Working Groups (Mexico-US and Canada-Mexico) devoted to these subjects to form a single NAFTA Working Group on Agricultural Grading and Marketing Standards.

<sup>&</sup>lt;sup>3</sup> Article 722 of NAFTA states that the SPS Committee "may, as it considers appropriate, establish and determine the scope and mandate of working groups" (NAFTA Secretariat).

However, this working group eventually became inactive as it depleted the available bilateral and trilateral issues on these topics.

Separate from this working group, the Advisory Committee on Private Commercial Disputes Involving Agricultural Goods met several times during the initial years following NAFTA's implementation. Based on a recommendation by this committee to the member governments, produce companies from the three NAFTA countries formed a private, nonprofit organization called the Fruit and Vegetable Dispute Resolution Corporation (DRC) in 1999, with the objective of facilitating the efficient resolution of commercial disputes. A main innovation of the DRC is a multistep dispute resolution system that begins with preventative activities and cooperative problem-solving and then proceeds gradually to more binding measures. The DRC also maintains a public list of companies for which membership was suspended or terminated for not abiding by the organization's rules and standards. Although the DRC has been most active in issues concerning the US and Canada, further development of an independent, third-party inspection system in key destination markets in Mexico might enable the DRC to play a broader role concerning US produce exports to Mexico.

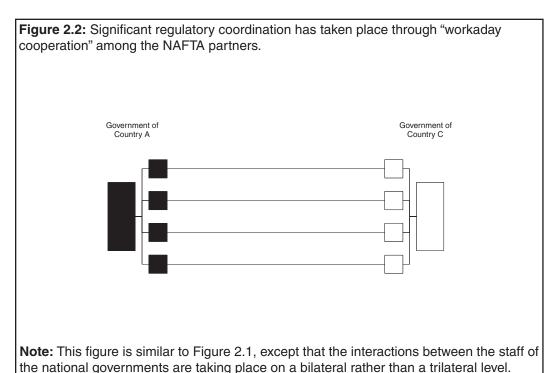
#### **Workaday Cooperation**

The term "workaday cooperation" is meant to describe the day-to-day activities of the NAFTA governments as they address trade-related regulatory issues. Although the word "workaday" can be interpreted as meaning mundane, workaday cooperation is not intended to be a negative term. Instead, it is meant to describe efforts towards regulatory coordination that are part and parcel of the everyday activities of the NAFTA governments and their employees. In addition, workaday cooperation should not be interpreted as meaning casual or relaxed. Efforts toward regulatory coordination can be quite intense, featuring highly complex and technical policy issues and challenging interpersonal work relationships within and among national governments.

Workaday cooperation usually involves the coordinated activities of employees within government regulatory agencies (Figure 2.2). Examples include the evaluation and negotiation of proposals concerning trade-related sanitary and phytosanitary measures, the response of agricultural trade officials to new trade regulations, and the pursuit of binational projects of mutual capacity building. The most significant participants in workaday cooperation are usually the rank-and-file staff and mid-level managers of the government ministries of agriculture, trade, and the environment. High-level leadership is involved in workday cooperation only to the extent that such participation is normally part of the day-to-day activities.

Workaday cooperation thrives upon the application of recent advances in telecommunications, including electronic mail, the Internet, and cellular phones. Staff members who are involved in workday cooperation have relatively easy access to their counterparts in other national governments and have collegial working relationships. Moreover, such interactions between the staff members of different national governments are viewed as part of their normal day-to-day work activities and normally do not require extensive notice and involvement of high-level national leaders.

Although workaday cooperation sometimes takes place at the multilateral and regional levels, most activities of this sort occur at the bilateral level because they directly concern only two countries at a time. For a number of reasons, meetings involving all three NAFTA partners are not always well-suited for addressing bilateral regulatory issues. There is the very real possibility that the representatives of one country will conclude that they are squandering valuable time when discussions turn to issues that do not concern them. Alternatively, there is the possibility that one country might voice support for one side or the other in a bilateral issue involving the other two countries, leaving the country in the minority with the feeling that they are being isolated within a trilateral forum. When the bilateral issue involves the possibility of one country taking an action that would allow the other country to increase its exports to



the first country, simple protocol might suggest that the representatives of the country seeking to increase its exports should travel to the other country to engage in discussions.

Participation in cooperative activities at the multilateral and regional levels is extremely important, however. As was suggested above, all three NAFTA countries have continued their participation in a variety of multilateral and regional organizations devoted to regulatory coordination that predate NAFTA. Each member government is an active participant in the long-standing international organizations that have become the standard setting bodies associated with the WTO's SPS Committee: the Codex Alimentarius Commission, the World Organization for Animal Health, and the FAO's Secretariat of the International Plant Protection Convention. At the Codex Alimentarius, for example, Mexico chairs the committee for fresh fruit and vegetable marketing standards.

#### Strategic Bilateralism

In response to pressure from stakeholders to deliver concrete results on a variety of trade-related regulatory issues, a second approach to regulatory coordination has emerged that can be called "strategic bilateralism." Prominent examples of this approach include:

- two bilateral agreements concerning US-Canada agricultural trade

   the US-Canada Record of Understanding (September 1994) and
   the US-Canada Memorandum of Understanding (December 1999);
- three bilateral Consultative Committees on Agriculture (CCAs) created by the agricultural and trade ministries of the NAFTA countries (Canada-US, April 1999; Mexico-US, April 2002; and Canada-Mexico, February 2003).

There are also a few instances of "strategic trilateralism," the most noticeable of which is perhaps the effort by the NAFTA governments to work together on issues related to bovine spongiform encephalopathy (BSE). But such instances are relatively uncommon, due again to the fact that the vast majority of the regulatory issues addressed by the NAFTA countries directly concern only two countries at a time.

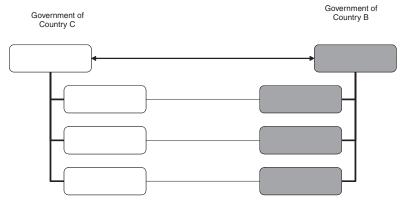
Under strategic bilateralism, leaders from the highest levels of two national governments are directly involved in the negotiation and crafting of objectives and the definition of assignments to a task force, some of which may be specified for the first time by senior leadership (Figure 2.3). Sometimes, leadership may incorporate ongoing, workaday projects within the framework of assignments. For example, the Action

Plan for 2002-2003 that accompanied the creation of the US-Mexico CCA included a number of activities that were already underway in the areas of grain inspection, sanitary and phytosanitary issues, and fruit and vegetable marketing. Some of these efforts, in fact, were taking place in the context of NAFTA committees and working groups.

A formal expression of continued support for an existing initiative through a memorandum of understanding or some other agreement associated with strategic bilateralism can be extremely helpful. First, it provides a marker of what the two parties expect will be accomplished. While the existence of this marker does not assure immediate results, it does provide a standard by which progress, or the lack thereof, can be gauged. In the case of US efforts to establish a systems approach that does not include fumigation for the export of stone fruit to Mexico, the presence of a particular line in the CCA's Action Plan concerning this issue may help to assure its ultimate resolution.

Second, a formal expression of support can help to energize an ongoing activity. Efforts by USDA's Grain Inspection, Packers, and Stockyard Administration (GIPSA) and Supports and Services for Agricultural Marketing (Apoyos y Servicios a la Comercialización Agropecuaria – ASERCA) of the Mexican agricultural secretariat (Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca, y Alimentación

**Figure 2.3:** "Strategic bilateralism" enables high-level leadership to assume a more active role in directing regulatory coordination.



**Note:** Strategic bilateralism features not only bilateral workday interactions among the staff members of national governments, but also interactions between high level officials of national governments (as illustrated by the horizontal arrow between the top box in each government) and more top-down direction from these officials to their respective staffs (as illustrated by bold lines linking the top box in each government to the lower boxes).

– SAGARPA) to advance the development of a standardized grain inspection system in Mexico, for instance, drew additional justification and support from the US-Mexico CCA, even though this highly technical endeavor could have been pursued by the two countries outside the framework of the CCA. Moreover, GIPSA and ASERCA have fostered the creation of a Consultative Grain Industry Group to address private sector concerns involving inspections and the grain trade. This entity, consisting of nine members each from the private sectors of Mexico and the US, is scheduled to meet for the first time in October 2005. Relying on the private sector to help address regulatory issues is an established aspect of strategic bilateralism in particular and of regulatory coordination among the NAFTA countries in general. In their 1994 Record of Understanding, the US and Canada created a similarly constituted Joint Commission on Grains, which examined the use by both countries of end-use certificates for imported wheat.

#### **EVALUATION OF SPECIFIC ISSUES**

As the case studies that follow will show, to date the nature of a particular regulatory challenge has predominantly dictated whether the committees and working groups established by NAFTA are employed, or whether member countries turn to alternative mechanisms. Ongoing issues that have longer term implications are often well-suited to the committees and working groups, which tend to be less well positioned to deal with emerging hot button issues that require the immediate attention of high-level decision makers.

#### **Pesticides**

A prominent example of a working group within the SPS Committee is the Technical Working Group (TWG) on Pesticides. The TWG on Pesticides was established in 1996 to develop a coordinated approach to pesticide registration among NAFTA partners in order to address trade irritants, build national regulatory and scientific capacity, share the review burden, and coordinate scientific and regulatory decisions on pesticides. The goal is to promote harmonization and work sharing as a means to reduce costs through the elimination of duplicative testing and the sharing of reviews, while recognizing the environmental, ecological, and human health objectives of NAFTA. Risk assessment remains the responsibility of individual countries (NAFTA Technical Working Group on Pesticides 2003).

This working group has a workaday element in that the participating staff members from the three national governments have made it a priority to invest significant time and resources to NAFTA TWG activities. The working group addresses issues that require specific

knowledge and technical expertise, and it energetically engages in "work-sharing," in which the results of scientific studies, administrative evaluations, and the like are shared and discussed among the working group's participants and expert scientists from all three national governments. While these efforts are resource-intensive, significant benefits are anticipated over the long-term with respect to conserving regulatory and scientific resources and enhancing the timeliness and quality of science-based decision making.

While the TWG's focus is North America, many of its projects have their roots in bilateral work conducted by Canada and the US prior to NAFTA. Mexico has traditionally accepted the maximum residue limits (MRLs, which are referred to as "tolerances" under the US Federal Food, Drug, and Cosmetic Act) established by its trading partners for pesticides in or on food, and generally, the Mexican government requires the approval of a pesticide in another country as a prerequisite to its approval in Mexico.<sup>4</sup> Within the framework of joint reviews, Mexico has been involved in the evaluation of efficacy data, especially in conjunction with Canada. In addition, the US and Mexico have undertaken joint projects concerning pesticides and worker safety. The TWG is working to identify initiatives that will result in greater Mexican involvement, building on the first trilateral review which is currently underway.

Although Canada and the US have developed common approaches to regulatory reviews, the Canadian regime is perceived by some within industry to be more burdensome or lengthy due to legislated efficacy testing. While the US requires that efficacy data be developed, it generally requires that these data be reviewed only for certain limited categories of pesticides; for example, pesticides used for public health purposes or to control termites. For agricultural pesticides, the US generally relies on the market to deal with efficacy issues. As noted above, some persons in industry believe that systematic government review of efficacy studies may contribute to longer review times. On the other hand, it could generate savings for growers by allowing them to use minimum effective amounts of pest control product per hectare with greater confidence, which in turn may support more sustainable agricultural practices.

Because the Canadian pesticide market is considerably smaller than that of the US (just two percent of world sales, compared with about

<sup>&</sup>lt;sup>4</sup> Since 28 December 2004, pesticide registration in Mexico is the responsibility of the Federal Commission for Protection against Sanitary Risks (Comisión Federal para la Protección contra Riesgos Sanitarios – COFEPRIS), a decentralized part of the Secretariat of Health. This activity is carried out in consultation with SAGARPA and the Secretariat of Environment and Natural Resources (Secretaría de Medio Ambiente y Recursos Naturales – SEMARNAT). The importation of pesticides requires the authorization of both COFEPRIS and SEMARNAT.

one third of world sales for the US), the cost of registration and the regulatory requirements discourage some pesticide manufacturers from seeking approval to sell their products in Canada. Manufacturers who do try and register their products in Canada may face a longer approval process which can date their product and limit the ability of producers to use the newest innovations. As a result, Canadian producers do not always have timely access to the latest pesticide innovations. This may present a modest advantage for US growers compared with their Canadian counterparts, as long as there is an applicable MRL for products that US exporters want to ship to Canada. The TWG is in the process of developing NAFTA import tolerance guidance to deal with this issue.

Regulatory Coordination Infrastructure The TWG's Executive Board meets twice each year, and one of these meetings involves the participation of stakeholders. The input of stakeholders is sought before each meeting, and they are debriefed following meetings through teleconferences. Summaries are published following each meeting of the Executive Board to report on key decisions reached by the TWG. The working group has established technical subcommittees in four key areas: joint review of pesticides, food residues, risk reduction, and regulatory capacity building. These subcommittees provide an opportunity for stakeholder involvement in the development and implementation of specific projects. Project sheets are also updated regularly and then released to the public.

Lead TWG partners include the Canadian Pest Management Regulatory Agency (PMRA), the Office of Pesticide Programs at the US Environmental Protection Agency (EPA), and representatives of their counterpart agencies in the Mexican agricultural and health secretariats. The Pest Management Centre of Agriculture and Agri-Food Canada (AAFC) and the InterRegional Research Project #4 (IR-4) program of the US also participate in the TWG, addressing minor use pesticide issues.

Results One innovative regulatory approach employed by the TWG is the joint review of pesticide registration applications and MRLs. In a joint review, submissions for pesticide registration are received by countries at the same time, and their national regulatory bodies share the work of evaluating the submission. This approach permits coordination of the timing of registration and associated MRL decisions, and ideally, the establishment of the same MRLs and consistent conditions of registration in each participating country. The NAFTA governments strongly encourage registrants to use the joint review process. Joint

<sup>&</sup>lt;sup>5</sup> A study measuring the competitive impact of Canada's regulatory process for pesticides has been initiated by the Harmonization Working Group of the Horticulture Value Chain Roundtable in Canada and is scheduled to be completed in May 2005.

reviews require negotiated timelines to address cross-country differences in approval times. In the past, joint reviews were solely US-Canada affairs, but the first joint review involving all three NAFTA countries is underway and scheduled to be completed in the summer of 2005.

As of 15 May 2005, 21 technical grade active ingredient registrations and 36 associated end use product registrations have been approved under the joint review and work-share programs, plus one minor use label expansion and one import MRL. In sum, 59 registrations have been granted through this successful joint initiative. Over 50 percent of the new active ingredients submitted to the PMRA are evaluated through the joint review process. The TWG has also worked with stakeholders to eliminate a number of trade barriers by establishing common MRLs for many pest/crop combinations. In addition, the group continues to encourage the establishment of NAFTA labels for pesticides where appropriate.

The NAFTA countries seek to promote harmonization at the broader international level through the Working Group on Pesticides of the Organization for Economic Co-operation and Development (OECD). Participants in this group include representatives of the OECD member governments, the European Commission and other international organizations, the pesticide industry, and other stakeholders, depending on the issues under consideration. There is a good deal of crosspollination between NAFTA and non-NAFTA activities, as many of the same staff who participate in the NAFTA TWG also are involved in the OECD work. In February 2005, the US and Canada announced that they were committed to the global approach developed by the OECD for the regulation of agricultural pesticides. The NAFTA countries have had considerable success in harmonizing data submission requirements, templates, approaches to risk assessment, and several other technical areas. The NAFTA templates have been shared with the OECD Working Group on Pesticides for wider consideration as that group continues its template work.

Another important product of the TWG is the extension of the map of residue zones to encompass the entire NAFTA region. This accomplishment should facilitate the development of field studies for the establishment of MRLs and tolerances in agricultural areas with

<sup>&</sup>lt;sup>6</sup> The OECD Vision for the Future of a Global Approach to the Regulation of Agricultural Pesticides calls for countries to work to achieve significant work-sharing and harmonization goals by 2014, including, on a routine basis: 1) acceptance of data and submissions in an agreed OECD format; 2) exchange and use of reviews of data in the OECD format to support independent risk assessments and regulatory decisions; 3) generation of a single review report or "monograph" for each new pesticide that can be used across all OECD countries, where feasible; and 4) wide dissemination of the benefits and experience gained through work-sharing to help developing countries manage their regulatory systems.

similar agri-ecological conditions in order to have representative results across all three countries.

Ongoing Initiatives and Opportunities To date, harmonization of data requirements for pesticide registration has largely been achieved through the efforts of the NAFTA TWG on Pesticides. Ongoing work is expanding to promote the development of compatible data review programs, joint reviews, coordinated decision making, and resolution of trade problems caused by differences in MRLs for pesticide residues in food. Some of the projects that the TWG will be undertaking during 2005 and 2006 are:

- Developing a long-term trade irritant/risk reduction strategy for pulse crops and resolution of specific priority trade issues identified by stakeholders by December 2005;
- Completing collaborative data collection activities for pest control
  products to meet the needs of growers of "minor crops" (most fruits,
  nuts, and vegetables) and simultaneous submission of studies to
  regulatory agencies in 2005, with the goal of dividing the review
  burden between Canada and the US as much as possible rather
  than conducting resource-intensive, duplicative reviews; and
- Releasing final risk assessments based on a thorough re-evaluation of heavy duty wood preservatives in 2006, as a prelude to coordinated decision making and ideally a harmonized North American position on future uses, if possible.

Lessons Learned The competitiveness of the North American food market is dependent on access to affordable and effective pest control tools and the maintenance of high standards of food safety, health, and environmental protection. Grower groups and the crop protection industry (pesticides and herbicides) have played an important role in the process of harmonization by identifying trade barriers, supporting harmonization projects, and contributing scientific expertise (NAFTA Technical Working Group on Pesticides 2001). At the same time, there is general recognition that harmonization improves competitiveness in third markets, from both a cost perspective and a trade disruption perspective. Developing a NAFTA approach to pesticide regulation and working to harmonize at an international level is crucial to competing effectively and maintaining the protection of food safety, health, and the environment within and outside the NAFTA marketplace (NAFTA Technical Working Group on Pesticides 2004).

The NAFTA TWG on Pesticides is a good example of a NAFTA working group that is seeking to remove regulatory differences that can produce trade irritants. The workaday interaction of the NAFTA governments is a product of both the technical nature of the work being undertaken,

and the adoption of a cooperative approach, resulting in limited use of strategic bilateralism. In 2003, the working group identified two goals that they hope to achieve over a five-year period: to make work-sharing the way to do business; and to develop a North American market for pesticides, while maintaining current high levels of protection of public health and the environment and supporting the principles of sustainable pest management.

Work-sharing is an important and innovative practice. Some have suggested moving beyond work-sharing to an approach of mutual acceptance or equivalency, in which regulatory approval by one member country would be accepted automatically by other member countries. For example, the Canadian Council of Chief Executives, a nonprofit, nonpartisan organization comprised of chief executive officers from various sectors of the Canadian economy, has recommended that Canada and the US initially pursue this approach, in combination with "convergence of product and process standards" and "cooperative enforcement" (Canadian Council of Chief Executives). At this time, it seems doubtful that the NAFTA countries are prepared to adopt a wide-sweeping policy of mutual acceptance or equivalence, in light of their responsibilities under their respective national laws.

Working toward an internationally harmonized approach to regulations can facilitate access and help maintain competitiveness in other markets as well. US pesticide authorities have made reviews available in public documents and have encouraged other countries to use them in the spirit of work sharing and avoiding duplicative review work. This can be helpful to countries like Japan, for example, which is in the process of upgrading its pesticide and food safety system, and can prevent unnecessary trade disruptions that could result from more unilateral approaches. At the December 2004 meeting of the TWG, the view was also expressed that a single "NAFTA voice" was necessary to address potential issues in dealing with China and other trading partners (NAFTA Technical Working Group on Pesticides 2004).

#### **Potato Wart**

On 24 October 2000, the Canadian Food Inspection Agency (CFIA) confirmed the presence of potato wart disease in part of a field of potatoes in the province of Prince Edward Island (PEI). Potato wart is a disease of potatoes caused by the presence of the soil-borne fungal pathogen *Synchytrium endobioticum*. Although not a threat to human health, potato wart is categorized as a quarantine pest that renders potatoes unmarketable and reduces yield. The disease attacks the growing points on the potato plant, such as eyes, buds, and stolon tips and can remain dormant in the ground for as long as 40 years or more as resting spores

(CFIA 2004b). Consistent with Canada's obligations, CFIA contacted USDA to inform them of the discovery. On 31 October 2000, USDA implemented an emergency quarantine measure closing the border to all potatoes originating from PEI (Canada Gazette Directorate).

A three-stage approach was proposed by CFIA to enable the resumption of trade in early November 2000. In order to meet the scientific requirements for demonstrating adequate containment of the disease, CFIA undertook extensive inspections, soil, and laboratory analysis survey work. The work determined the extent of the contamination, which was shown to be contained to a small part of one field in PEI. Canada began requesting that the border be reopened to PEI potatoes in November 2000 based on scientific evidence that the outbreak was contained to a single field and that adequate control measures were in place.

Officials from CFIA and USDA's Animal and Plant Health Inspection Service (APHIS), along with scientists from Canada and the US, reached an agreement on 13 December 2000, outlining control measures and certification requirements which would have allowed the border to reopen. This agreement was then repealed, with more restrictive conditions for the proposed resumption of trade being presented to CFIA on 29 December 2000. These conditions were deemed excessive and cost prohibitive by the PEI potato industry, at which point Canada initiated consultations through NAFTA's formal dispute resolution mechanism.

On 17 January 2001, Canada held formal NAFTA consultations with the US, as Canada did not feel continued trade restrictions were warranted based on the science and the regulatory controls that CFIA had implemented. These consultations were inconclusive, with USDA indicating that it would require additional advice from international science experts. However, these consultations did have an impact by communicating the rigor of procedures put in place by the CFIA based on international standards under the International Plant Protection Convention.

Mechanisms Used to Re-establish Trade Over the course of the dispute, CFIA worked on an ongoing basis with APHIS to advance technical discussions. A bilateral technical working group was put in place with a broad range of representatives from various levels of government including regulatory, research, scientific, and risk assessment experts. At the same time, political representatives at the most senior levels in the US and Canada attempted to resolve the issue.

At the time of the outbreak, it was generally acknowledged that there was a surplus of potatoes in North America. This surplus created an atmosphere in which certain sectors of the potato industry could benefit from an interruption in the trade of PEI potatoes, with lobbying groups actively looking to protect their economic interests on both sides of the border. At the same time, the perishable nature of the product demanded a quick resolution to the dispute.

After protracted negotiations, officials were able to resolve the issue outside NAFTA by agreeing on a systems approach to mitigate risk and reopen the border to PEI potatoes. While an agreement was reached to allow restricted access to PEI table stock potatoes in April 2001, most of the restrictions were lifted by August 2001. The key to the eventual removal of restrictions was the development of a three year monitoring work plan by CFIA and APHIS which provided sufficient scientific basis to allow all parties to be satisfied with the control measures that were in place to adequately mitigate risk.

Lessons Learned The potato industry faces several challenges. On the one hand, it has been widely suggested that the industry as a whole is under pressure from over-production. Industry groups like the US-Canada Potato Committee can help to find solutions to surplus inventories. At the same time, both the US and Canada have potato disease issues. As a result, it is necessary to have mechanisms in place that enable parties to quickly identify and contain disease outbreaks using a standard protocol in order to avoid the politicization of an outbreak and mitigate the risk exposure through effective science.

It has been suggested that the NAFTA committees and working groups are best suited to low-level, low-interest disputes. While these groups are quite effective at avoiding disputes, they are less effective at resolving them once a dispute has emerged (Clarkson, Ladly, and Thome). In addition, for an emerging sanitary or phytosanitary issue, science is the key to the resumption of trade. However, science takes time to reach a definitive, acceptable conclusion for all parties involved, which can hamper efforts to minimize the impact on trade.

The key to resolving the initial potato wart outbreak in 2000 was not only to establish a science-based monitoring system, but to rapidly gather surveillance data clearly delimiting the extent of the detection of potato wart and to effectively communicate the steps taken to contain the outbreak in an open and transparent way to relevant stakeholders. As a result of the regulatory measures that were put in place following the first outbreak, subsequent discoveries of potato wart in 2002 and 2004 were not nearly as damaging and had a minimal impact on trade.

Bilateral negotiations at a senior official level and extensive technical consultations were required to resolve the dispute and to mitigate the risk of the spread of the disease at a level that was acceptable to both parties. Workaday cooperation allowed the technical experts to craft a solution to the problem, while the strategic bilateralism that took place between higher-level officials in Canada and the US ensured that the issue maintained a high level of visibility and was satisfactorily resolved. Thus the issue benefited greatly from the solid relationships that exist between Canada and the US at both the technical and political levels.

#### Avocados

For much of the 20th century, the US banned the importation of fresh avocados from Mexico. The original impetus for this ban was the detection in 1914 of certain host-specific avocado pests that were prevalent in Mexico but not in the US (Orden). Attempts to lift the ban were unsuccessful until the NAFTA negotiations provided an opportunity for Mexico to reopen the issue. After four years of extensive bilateral technical negotiations, APHIS published a proposed rule in 1995 that would allow the importation of fresh Mexican avocados under certain conditions.

Despite significant resistance from the US avocado industry, APHIS published a final rule in 1997 to allow the importation of Hass avocados from approved orchards in approved municipalities in the Mexican State of Michoacán, subject to specific geographic and seasonal restrictions (Orden). APHIS concluded that while Mexican avocados are susceptible to eight pests of quarantine significance, the likelihood of pest introduction is extremely low if an appropriate pest control system is in place (USDA-APHIS 1997). Producers are required to follow strict phytosanitary procedures and standards and to submit to a series of APHIS inspections during the growing, packing and exporting process (Bredahl). Should a pest be detected, imports from the affected area are prohibited until corrective actions have been taken. Inspection of more than ten million avocados over a six year period has not revealed a single live pest and only one dead pest.

As a result of a quantitative risk assessment evaluation prepared by APHIS, the geographical and seasonal limitations have been further reduced. In November 2004, APHIS published a final rule that allows fresh Hass avocados from approved orchards and municipalities in Michoacán to enter all 50 US States except California, Florida, and Hawaii on a year-round basis, starting in January 2005. By 2007, imports will be allowed into the remaining three states.

Economic Impact of Regulatory Changes<sup>7</sup> Full opening of the US market to Mexican Hass avocados is expected to have a pronounced economic impact. With the new rule allowing year-round access to all but three states, US avocado consumption is expected to increase by nine percent, from 264,000 to 288,000 tonnes, according to analysis conducted by APHIS. The quantity supplied by California producers will decline by seven percent, while imports from Mexico will increase to about 2.6 times their initial level, from 26,000 to 70,000 tonnes. Accordingly, Mexico's share of total US consumption will climb from 10 to 24 percent. Once distribution to California, Florida, and Hawaii is also allowed, Mexico's market share could rise to 32 percent of an even larger quantity consumed.

Prices for California avocados under the new rule are projected to fall by 12 percent at the wholesale level and by 21 percent at the producer level as California avocados are displaced by Mexican product. Once the entire market is open to Mexican avocados, an even larger decrease in wholesale prices is expected. Declining prices are projected to cause a decrease in avocado production in California. Given the decline in producer prices, California avocado producers would experience a total welfare reduction equivalent to \$71.4 million with the new rule. The net change in US welfare, computed by subtracting losses for California producers from the expected overall gain for consumers, would be a gain of \$50.3 million.

Lessons Learned The process by which Hass avocado producers from Michoacán gained access to the US market has been gradual and lengthy, and the systems approach used to mitigate the risk of pest introduction is elaborate. While there were valid concerns about the risk of pest infestation, other economic considerations motivated some opposition to the opening of the US market. During the comment period on the rule that ultimately will permit year-round access to the entire US, APHIS received multiple comments related to the rule's potential impact on market share rather than its impact on the presence of pests.

Rather than turning to formal WTO/NAFTA dispute resolution channels, regulators in the US and Mexico worked together over time to develop the science-based risk mitigation system in order to successfully negotiate the removal of what was perceived by Mexican producers as a nontariff SPS barrier. Although some efforts to address the issue took place within the framework of the NAFTA SPS Committee, the start of these efforts predated NAFTA's implementation and featured both workaday cooperation and high-level leadership. The technical expertise required to settle the dispute, coupled with the bilateral nature of the issue, made it well suited to an ongoing, collaborative workaday approach. High-level

<sup>&</sup>lt;sup>7</sup> The source of all data in this section comes from the Economic Analysis prepared by USDA APHIS (2004).

leadership ensured that the issue remained a priority for both parties. Based on the evidence to date, the risk of pest infestation from Mexican avocados appears to be controllable when a rigorous inspection system is in place.

#### Cantaloupe

Contaminated cantaloupe has been associated with food-borne illnesses since 1990. In the springs of 2000, 2001, and 2002, outbreaks of Salmonella occurred in the US and Canada as a result of individuals eating contaminated cantaloupe imported from Mexico (CFIA 2004a). Following each outbreak, the US Food and Drug Administration (FDA), in conjunction with Mexican and Canadian food regulatory agencies, conducted traceback investigations of cantaloupes purchased.

The 2000 outbreak was traced to a single farm in Mexico and a particular shipper in the US: Shipley Sales Service, located in Nogales, Arizona. On-farm investigations in Mexico led FDA to conclude that measures were not in place to minimize microbial contamination in the growing, harvesting, packaging, and cooling of cantaloupe. This led to an import alert in 2000 for the shipper and farm, which was lifted once the distributor provided documentation demonstrating corrective action had been taken. However, in the spring of 2001, Mexican cantaloupe contaminated with Salmonella resulted in numerous illnesses in the US and Canada, and strong epidemiological evidence linked the contaminated cantaloupe to two deaths in the US. Once again, the outbreak was traced to the shipper and farm implicated in the 2000 outbreak (Calvin). This led to the re-imposition of an import alert on Shipley Sales Service, along with two associated Mexican companies (US FDA 2001).

A subsequent outbreak in May 2002 led FDA to issue an import alert on all Mexican cantaloupes in October 2002, and the CFIA took similar action in November 2002 (Calvin). FDA justified its countrywide action as a preventive measure to minimize the risk of illnesses associated with Mexican cantaloupes. Although the outbreak itself was traced back to just two states in Mexico (Michoacán and Guerrero), samples collected by FDA in 1999, 2001, and 2002 generated positive findings of Salmonella in cantaloupe from six different states in Mexico (Sonora, Colima, Coahuila, Jalisco, the State of Mexico, and Tamaulipas), covering both the fall/winter and spring/summer growing seasons (US FDA 2004).

The US decision to impose a countrywide import alert for Mexican cantaloupe occurred at an inopportune time for growers in the northern state of Sonora, who were at the start of their harvest season. Growers were largely unable to navigate the requirements associated with the

import alert in time to receive clearance to ship to the US, resulting in crop spoilage. As a result, the import alert effectively halted exports from virtually all cantaloupe producers in Mexico. Mexican growers and US distributors were severely affected, with millions of dollars and many jobs lost related to the picking, packing, and shipping of cantaloupes.

The Mexican Government brought the issue of the countrywide import alert before the WTO's Sanitary and Phytosanitary Committee. In its intervention before the committee, Mexico argued that the actions were inconsistent with the provisions of the Agreement on the Application of Sanitary and Phytosanitary Measures. Specifically, the measures were not based on scientific principles and were being used unfairly as a trade barrier. It was pointed out that while the US had reported similar food safety concerns with producers from the US and other countries, the restrictions were only being assessed against Mexican producers. In addition, the banning of all Mexican cantaloupe failed to account for the regional nature of the outbreak (WTO 2002).

In direct response to the intervention by Mexico, the US informed the committee that deaths and serious illnesses in the US had been linked through strong epidemiological evidence to contaminated cantaloupe from Mexico and that the US had acted completely within its rights under the SPS Agreement to take actions necessary to protect public health. The US further informed the committee that FDA had discussed the serious nature of the outbreaks with the Mexican Government on several occasions prior to implementing the import alert.

Subsequently, in response to requests from Mexican officials to remove the ban, FDA took the position that once effective systems were in place to prevent or significantly mitigate the problem, it could consider revising the countrywide detention status for Mexican cantaloupe. As an interim arrangement, FDA advised Mexican cantaloupe producers and US importers to work closely with Mexican officials in order to develop appropriate information and data submissions that would facilitate the removal of producers from detention on a case-by-case basis (WTO 2003).

Certification Program Prior to the countrywide import alert, the Mexican Government had been working with FDA to improve regulations and inspection procedures for cantaloupes. The agency in charge of food safety, SAGARPA's National Service of Health, Safety, and Agrifood Quality (Servicio Nacional de Sanidad, Inocuidad, y Calidad Agroalimentaria – SENASICA), had been developing a certification program to identify cantaloupe growers who follow good agricultural practices (GAPs) and good manufacturing practices (GMPs). Following the countrywide import alert issued by the US (and Canada's similar

action), the Mexican Government published legislation that gave the government the legal authority to require all cantaloupe growers to comply with the new food safety program.

The certification program includes a ten-page questionnaire that requires cantaloupe growers to provide considerable detail on the food safety measures employed in order to be certified as eligible to export to the US. Each application is reviewed and endorsed by SAGARPA before being passed on to FDA. FDA then reviews the submissions and works with Mexican authorities to identify and address any remaining deficiencies in on-farm practices with the aim of enabling cantaloupes from these producers to enter the US market.

According to the import alert, after reviewing these submissions, FDA, either solely or in conjunction with the relevant Mexican regulatory authority, may conduct a limited number of on-site inspections of the growing/processing areas to audit the validity of the information submitted to FDA. FDA intends to give priority in scheduling these inspections to firms or growers who provide certification from an independent institution or third party that has expertise in agricultural and transportation processes (US FDA 2004). If FDA finds inconsistencies between submissions and actual conditions at farm and packing facilities, it will impose severe restrictions on the import of cantaloupe from the shipper for up to two shipping seasons. Many Mexican producers consider the certification program to be lengthy and cumbersome, and so far only a few growers and packers have been certified. Canadian import requirements acknowledge that the Mexican Cantaloupe Certification Program constitutes an acceptable approach to minimize the risk of contamination (CFIA 2004).

SAGARPA also has released a new Federal Recognition Program (FRP) that states the requirements for the production, harvest, packing, processing, and transportation of cantaloupe. Developed in conjunction with FDA, the FRP is a collaborative effort on the part of SENASICA, COFEPRIS, and SEMARNAT's National Commission of Water (CNA), and it outlines the GAPs and GMPs for cantaloupes. This official program gives growers clearer steps in documenting their food safety programs for cantaloupes. However, until all participating Mexican secretariats and FDA have signed the final Memorandum of Understanding to implement the FRP, growers must still face the comprehensive process to document and verify their food safety steps with Mexican agencies and FDA.

Lessons Learned The NAFTA and WTO Agreements clearly state that countries have the right to take SPS measures in order to protect human, animal, or plant life, or health in their own territories. The numerous illnesses and losses of life connected to the Salmonella contaminations

were clearly a legitimate concern for US and Canadian regulators. Prior to the outbreak in 2002, the US and Mexico were primarily engaged in workaday cooperation to develop regulations and processes that would be acceptable to both countries. With the third outbreak, the death of two US citizens linked to a prior outbreak, and evidence of unsanitary conditions in some parts of the Mexican cantaloupe industry, it was not clear whether these efforts would satisfactorily address the public health risks associated with Mexican cantaloupe in a timely fashion, and the US proceeded with its countrywide import alert for Mexican cantaloupe.

A primary complaint from the Mexican Government was the lack of communication between US and Mexican officials just prior to the imposition of the countrywide import alert. In its intervention to the WTO SPS Committee (WTO 2002), the Mexican Government stated that "Mexican health authorities were notified by telephone [only] a few hours before the measure was applied at the goods' points of entry into the US." Given the ongoing work already taking place between SENASICA and FDA, it was generally felt that the imposition of the countrywide import alert with little advance communication and no consideration to regionalizing the restrictions caused a loss of goodwill and hurt many innocent producers and importers.

There was also a perception, strongly contested by the US, that the same standards were not being applied to US and Mexican growers as a result of the outbreaks. For Mexican growers to be removed from the import alert, they must demonstrate higher levels of food safety than US growers, despite the fact that samples from US growers in 2001 also showed contamination. US cantaloupe growers did lobby FDA to take a more aggressive role as a result of the outbreak (Calvin). This created the perception among some Mexican growers, also strongly contested by the US, that excessive regulatory requirements were being used to protect US growers. Thus while concerns regarding the safety of Mexican cantaloupes are certainly legitimate and extensive collaboration has occurred among NAFTA members to resolve the issue, further coordination might help to streamline the certification process while reducing the likelihood of a similar food safety situation.

The problem was further complicated by the actions of Shipley Sales Service, formerly one of the top US importers of cantaloupe. In November 2002, a federal grand jury in Tucson, Arizona issued a 66-count indictment charging the importer with impeding a government investigation, misrepresenting their supplier, and shipping contaminated cantaloupe. As part of a plea agreement in January 2005, the importer and his son were fined \$250 each, forfeited \$2.7 million from sales of illegally imported cantaloupe, and were sentenced to four years probation

for conspiracy and false reporting to the US Government (McQueen). The importer also has settled two lawsuits filed on behalf of two victims of the 2001 outbreak (Associated Press).

#### Bovine Spongiform Encephalopathy (BSE)8

Since 2003, the North American cattle industry has contended with the detection of several cases of BSE. In May 2003, BSE was confirmed in a cow from northern Alberta, Canada, and in December 2003, USDA announced the detection of the disease in a US cow that was born in Canada. In January 2005, Canadian authorities confirmed the detection of BSE in two additional cows in Alberta. In June 2005, test results indicated the presence of BSE in a second US cow, this one born in the US (USDA Office of Communications). BSE is a degenerative disease that affects the central nervous system of adult cattle which eventually results in death. A variant form of Creutzfeldt-Jacob Disease (vCJD) that affects humans is believed to be caused by consuming infected tissues from BSE-affected cattle.

Upon confirmation of the positive BSE case in May 2003, international reaction was immediate, as over 40 countries, including the US and Mexico, placed import restrictions on Canadian cattle, beef, and other bovine products. The impact on the Canadian cattle and beef sector was economically devastating. Prior to the detection of BSE in May 2003, the US was Canada's largest beef market, representing 80 percent of Canada's exports of beef and nearly all live cattle in 2002, while Mexico was Canada's second largest beef market. According to a report prepared for the Canadian Animal Health Coalition, the direct economic cost to the Canadian livestock industry by early 2004 was nearly C\$3.3 billion. An additional loss in equity to the cow-calf sector was estimated at C\$3.0 billion, for a total economic impact from BSE of C\$6.3 billion (Serecon Management Consulting).

Regulatory Mechanisms Used to Address the Issue Following the detection of BSE in May 2003, it was important to assess the level of risk present in the Canadian herd and to determine the necessary steps required to ensure a safe food supply. In June 2003, an International Team of Experts convened to examine the CFIA's investigation into Canada's case of BSE. The experts acknowledged the thoroughness and transparency of the investigation, and the high level of communication established with the international community and the public. The report, released on 26 June 2003, recommended that four additional

<sup>&</sup>lt;sup>8</sup> Appendix 2.4 contains a detailed chronology of North American beef trade following the initial detection of BSE in Canada in May 2003. Developments concerning the BSE situation are fast moving. This chapter reflects the authors' understanding of the situation through July 2005.

precautionary measures be taken to address the possibility that other animals were exposed to BSE and could be incubating the disease.

In response to one of the recommendations of the International Team of Experts, Canada announced that specified risk materials (SRMs) would be removed from all cattle slaughtered in Canada.<sup>9</sup> This action was consistent with those taken by other countries with respect to food safety and minimizing the risk to the public. In July 2004, proposed changes to feed restrictions were published, requiring the removal of SRMs from the animal feed chain (including pet food) in order to further strengthen existing animal feed controls.

Extensive technical and scientific discussion between Canada and the US resulted in the development of a minimal-risk rule in the US that would allow for trade normalization between the two countries. These requirements, in combination with the animal and public health measures already in place in the US and Canada, are considered by USDA to provide the utmost protection to both US consumers and livestock based on science.

Result On 4 January 2005, USDA published its BSE minimal risk rule in the US Federal Register. This rule was to have taken effect 7 March 2005, but the US District Court of Montana granted an application for a preliminary injunction of this rule from the Ranchers-Cattlemen Action Legal Fund, United Stockgrowers of America (R-CALF USA). On 14 July 2005, the Ninth Circuit Court of Appeals reversed the injunction. Once implemented, the rule would provide access to the US for a range of live animals and beef and ruminant products from minimal risk countries. In particular, the rule would once again allow for the importation into the US of live cattle under 30 months for immediate slaughter or for feeding, provided they are slaughtered before reaching the age of 30 months. It does not, however, provide access for older animals or breeding animals. This rule would help to normalize trade between the US and Canada and to reduce the hardship faced by the Canadian livestock industry since the first detection of BSE in May 2003. US officials are working to develop a plan to allow imports of animals 30 months and older for slaughter as well as beef from over 30 month animals as the next step in resuming full trade.

<sup>&</sup>lt;sup>9</sup> SRMs are tissues that, in BSE-infected cattle, contain the agent that may transmit the disease. In diseased animals, the infective agent is concentrated in certain tissues. SRMs are defined as the skull, brain, trigeminal ganglia (nerves attached to the brain), eyes, tonsils, spinal cord, and dorsal root ganglia (nerves attached to the spinal cord) of cattle aged 30 months or older (scientific research has shown that these tissues, in cattle younger than 30 months, do not contain the infective agent); and the distal ileum (portion of the small intestine) of cattle of all ages.

Possible Future Adaptation On an international level, the World Organization for Animal Health (OIE) has acknowledged that some trade bans that are being employed by member countries in response to the detection of BSE are not consistent with OIE guidelines and standards, leading to major trade disruptions. Furthermore, the failure to conduct a risk analysis or to consider the control mechanisms put in place by a country that has reported the presence of BSE can lead to reluctance to report future cases and the increased likelihood of the disease spreading internationally (World Organization for Animal Health 2004).

Both Canada and the US have undertaken international advocacy activities to support their ruminant industries in recovering international markets. In August 2003, Canada, the US, and Mexico jointly requested that the OIE encourage a more current, practical, risk-based approach to BSE. The revised approach was debated at the OIE annual meeting in May 2004, and in June 2005, the OIE formally released its new set of recommendations for managing the animal and human health risks associated with BSE, shortly after its annual meeting in May 2005 (World Organization for Animal Health 2005). In addition, Canada, Mexico, and the US announced the establishment of a harmonized approach to BSE risk mitigation in April 2005.

Lessons Learned Science is the key to resolving the trade disruption caused by the detection of BSE in Canada. Once the initial detection was made, steps were taken immediately to implement measures to minimize the risk to consumers. Although the actual risk to human health of exposure is extremely low, the human disease associated with consumption of infective tissues from BSE infected cattle (vCJD) is incurable and fatal, and as such, the political impact of such an incident cannot be overlooked. While workaday cooperation is critical to developing the protocols required to fully resume trade, the importance of the issue requires high-level political involvement. In this instance, strategic trilateralism has taken place, given the impact that detection of BSE has had on the entire North American beef market. As a result, it is necessary to have protracted interaction at the technical level, in addition to senior political levels, to resolve the issue.

Prior to the detection of the first BSE case in May 2003, the North American cattle market had become highly integrated. While beef and cattle exports to the US have been historically important to Canada, US processing firms and US producers/packers have also benefited from supplies of Canadian live cattle. Efficiencies had emerged as the sector underwent structural shifts to reflect the regional competitive advantages that exist across the value chain.

The result of the BSE detection is a temporary disintegration of the North American cattle market, as Canada has expanded slaughter and packing capacity for cattle in response to the prolonged border closure to live cattle. In September 2003, Canada announced a repositioning strategy that will increase ruminant slaughter capacity in Canada and expand access to export markets for both livestock and beef products. As Canadian cattle producers become less reliant on US slaughterhouses, certain changes in the industrial organization of the North American cattle and beef sectors threaten to become permanent. The potential downside to this shift is a loss in economic efficiency, as the US and Canada are no longer optimally marketing animals or beef. The shift in processing from the US to Canada has forced Canadian plants to pay large overtime bills while idling some US plants. This reduced efficiency not only weakens the ability of North American beef exporters to reenter third country markets, but it could discourage the creation of cross-border supply chains in other sectors.

#### CONCLUSIONS

Countries clearly have the right and the responsibility to determine the appropriate level of protection for their citizens and animal and plant resources and to design and implement the regulations necessary to achieve that level of protection. There are many legitimate reasons for countries to have different regulations and standards, including different levels and types of risks across countries (e.g., due to environmental factors), different national policy objectives, and different consumer preferences. However, some regulatory differences cause needless frictions to market integration. As regulatory frameworks are developed in response to existing or emerging concerns, it is important that narrow interests do not influence regulatory requirements in order to protect a domestic market from free trade. The creation of more costly regulatory frameworks ultimately results in higher costs to consumers, as well as less efficient industries that are vulnerable in an increasingly global marketplace.

Regulatory coordination among the NAFTA partners is thus an exercise of national sovereignty. In many instances, this coordination occurs through the workaday interactions of the NAFTA governments and their bureaucracies. In addition, it is driven, managed, and organized by high-level leaders within these governments. Sometimes regulatory coordination takes place within the context of NAFTA's committees and working groups. Ultimately, successful regulatory coordination, particularly of politically sensitive issues, requires both the technical expertise featured in workaday activities and the political authority and judgment characterized by strategic bilateralism and other instances of high-level leadership.

Because of the high degree of market integration that exists within North America, how one NAFTA country manages its risk affects the international reputation of the others. Detection of a BSE case in the US, for example, effectively resulted in the closure of foreign markets to US beef. Mexico cannot depart from the US position on Canadian beef, as this could affect its status with the US and other countries. Nor can Mexico depart from the position of major Asian importers on US beef, as this could affect its status with those countries. Japan, along with other countries, has indicated that it will treat the US in a manner comparable with how the US treats Canada. This example illustrates that North America is not only integrated economically, but also at a scientific and regulatory level.

### The Role of NAFTA Working Groups and Committees Moving Forward

NAFTA preserves the autonomy of each member country to apply SPS standards that achieve the level of protection deemed appropriate, as long as the member country bases these standards on science. As long as this autonomy is desired by at least one member country, the creation of an enhanced NAFTA Secretariat or some other supranational entity to facilitate regulatory coordination will be difficult to achieve and nearly impossible to implement. Thus, regulatory coordination among the NAFTA countries during the Agreement's second decade is likely to rely on mechanisms similar to those used during its first decade.

In order to increase the effectiveness of NAFTA committees and working groups, it may be useful to implement a set of best practices for these entities. Given the importance of workaday cooperation and strategic bilateralism to regulatory coordination, best practices could also be useful for work outside these entities. Suggestions include:

- Clearly defining the assignment tasked to the committee or working group;
- Allocating the resources necessary to carry out that assignment;
- involving stakeholders from government and the private sector; and
- Publicizing the activities of the group and widely disseminating its output.

While stakeholders are not necessary for the work of a committee or working group to be successful, they build additional support for the group's activities. With respect to publicity and dissemination, the NAFTA TWG on Pesticides has engaged in these activities in a solid fashion.

Given the proliferation of bilateral and regional trade agreements involving the NAFTA partners, it may be beneficial to include additional countries in regional efforts toward regulatory coordination. For instance, since each NAFTA country has a bilateral free trade agreement with Chile, inviting Chile to participate in these efforts is one possible next step. However, there is the possibility that widening the circle in this fashion could dilute the effectiveness of ongoing North American efforts. This concern is believed to be one of the reasons why the new and prospective FTA partners of the US have sought to have their own SPS committees with the US, rather than asked to be added to an existing SPS committee.

Greater flexibility in the establishment and maintenance of regulatory committees and working groups is another logical approach. While NAFTA specified the creation of numerous groups of this type, it did not provide for the possibility of shutting down the ones that were no longer needed, although the Agreement did give the SPS Committee the flexibility to establish and determine the scope of its working groups. The recent bilateral and regional trade accords negotiated by the US generally provide for just two committees: 1) Sanitary and Phytosanitary Committee; and 2) Technical Barriers to Trade Committee.

In addition, it is revealing to identify the subjects for which NAFTA committees and working groups were not designated. Despite concerns prior to the Agreement that market integration would present significant challenges to rural development, particularly in Mexico, NAFTA does not include a committee or working group devoted to rural development. Although the Agreement specified a formal mechanism for final national determinations of antidumping and countervailing duties to be appealed before an arbitration panel, it did not specify a committee or working group for the NAFTA countries to better align the application of their trade remedy mechanisms. These gaps, while not directly linked to regulations, can nonetheless result in regulatory trade issues emerging in order to protect a domestic industry. For example, establishing excessive regulatory requirements to address a plant or animal health issue can be used to create a nontariff trade barrier.

#### Science-based Risk Mitigation Systems

Developing a North American food market that effectively competes on an international scale will depend in part on the construction and implementation of science-based regulatory systems during periods of relative calm so that established protocols can be easily employed in times of crisis. Systems-based management action plans, similar to the one used to resolve the US-Mexico avocado issue, should enable the use of less restrictive measures and assist in minimizing trade disruptions. By employing a systems approach to certification, a number of independent activities can be taken to minimize

the risk that an agricultural commodity poses to the importing country while meeting import standards. This approach assures the application of a measured and appropriate response should an issue emerge, and the importing country can be confident that containment of the issue will be achieved.

At times, there is the perception that regulatory issues are politically linked to one another, in that progress in one area will be rewarded by other member countries with progress in other areas. If science-based risk assessments are to be the foundation of the regulatory approach, such quid pro quo linkages should not exist, unless there is a scientific reason for why one regulatory issue is related to another. Requiring a science-based risk assessment, however, could be used as a delay tactic, especially when a country has limited resources to pursue such an assessment.

#### Moving from Negotiation to Cooperation

Regulatory coordination is a challenging area in which to advance market integration, primarily because it requires two or more sovereign national governments to realign their regulatory mechanisms in a concordant fashion. Complicating matters is the simple fact that regulatory changes often have important distributional consequences, giving some producers access to new markets, lowering the risks associated with cross-border business activities, and subjecting other producers to heightened competition. Similarly, a lack of progress in the regulatory arena can also have distributional consequences, denying some producers access to new markets, raising the risks associated with cross-border trade and investment, and protecting the existing markets of other producers. For these reasons, many efforts toward regulatory coordination have the potential to take on the features of a negotiation, and in many instances, negotiations among the NAFTA governments form a crucial and indispensable aspect of these activities.

During NAFTA's second decade, the ongoing challenge for the member governments in the regulatory arena is to move beyond negotiations and engage in a series of joint projects and other cooperative activities. Already, many of the efforts undertaken by the member governments in this area, regardless of whether they took place within the framework of a NAFTA committee or working group, have ultimately resembled joint projects, as was illustrated by several of the case studies examined in this chapter. Further efforts of this type are likely to deepen the integration of North America's agricultural and food sectors and may lead to additional instances of regulatory coordination that have not yet been contemplated.

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#### Appendix 2.1: NAFTA Committees and Working Groups<sup>10</sup>

Committee on Trade in Goods (Article 316)

Committee on Trade in Worn Clothing (Annex 300-B, Section 9.1)

Working Group on Rules of Origin (Article 513)

Customs Subgroup (Article 513)

Committee on Agricultural Trade (Article 706)

Working Group on Agricultural Subsidies (Article 705)

Advisory Committee on Private Commercial Disputes regarding Agricultural Goods (Article 707)

Working Group on Agricultural Grading and Marketing Standards (Annex 703.2)<sup>a</sup>

Committee on Sanitary and Phytosanitary Measures (Article 722)

Animal Health Working Group<sup>b</sup>

Dairy, Fruits, Vegetables, and Processed Foods Working Group<sup>b,c</sup>

Fish and Fishery Product Inspection Working Group<sup>b,c</sup>

Food Additives and Contaminants Working Group<sup>b,c</sup>

Labeling, Packaging, and Standards Working Group<sup>b</sup>

Meat, Poultry, and Egg Inspection Working Group<sup>b</sup>

Technical Working Group on Pesticides<sup>b</sup>

Plant Health, Seeds, and Fertilizers Working Group<sup>b</sup>

Veterinary Drugs and Feeds Working Group<sup>b,c</sup>

Committee on Standards-Related Measures (Article 913)

Land Transportation Standards Subcommittee (Article 913)

Telecommunications Standards Subcommittee (Article 913)

Automotive Standards Council (Article 913)

Subcommittee on Labeling of Textile and Apparel Goods (Article 913)

Committee on Small Business (Article 1021)

Financial Services Committee (Article 1412)

Working Group on Trade and Competition (Article 1504)

Temporary Entry Working Group (Article 1605)

#### Notes:

<sup>a</sup> Trilateral working group was formed by merging the US-Mexico and Canada-Mexico bilateral working groups devoted to this subject.

<sup>&</sup>lt;sup>b</sup> Established by the SPS Committee. Article 722 of NAFTA states that the committee "may, as it considers appropriate, establish and determine the scope and mandate of working groups."

<sup>&</sup>lt;sup>c</sup> Activities suspended by the SPS Committee in 2003.

<sup>&</sup>lt;sup>10</sup> This appendix is drawn from the list that appears in the text of NAFTA and is expanded using information obtained from the NAFTA governments. It is possible that the list does not include all of the NAFTA committees and working groups created since the Agreement's implementation in 1994.

#### Appendix 2.2: Chronology of Mexico-US Avocado Trade

1911: US plant health officials prohibit the importation of fresh avocados from Mexico because of avocado seed weevils.

1970's: Mexican officials request approval to export avocados from the State of Michoacán. Request eventually rejected by APHIS.

1975: The Mexican government seeks entry for avocados grown in the State of Sinaloa. Requests eventually rejected by APHIS.

1990-1992: Mexico submits three different work plans under which avocados grown in Michoacán could be imported into the US.

**July 1993:** Under one of those work plans, APHIS allows the entry of Mexican avocados into Alaska under certain conditions.

5 July 1994: The Mexican government formally requests that APHIS further amend its import regulations to allow importations into the northeastern US.

1997: Exports of fresh Mexican Avocados are allowed into 19 states for four months of the year.

**2001:** The number of States is increased to 31 and the number of months to six. Mexican fresh avocado exports to the US approach 13,000 metric tons.

2002: Mexican fresh avocado exports to the US surpass 26,000 tonnes.

**June 2003:** APHIS completes a risk assessment evaluation for the importation of avocados to the entire US the whole year.

**2003:** Mexican avocado exports to the US approach 35,000 tonnes.

**31 January 2005:** A rule becomes effective that allows the importation of fresh Mexican Hass avocados from selected growers in Michoacán year round to all States except California, Florida and Hawaii. On 31 January 2007, the rule will apply to all 50 States.

# Appendix 2.3: Chronology of Salmonella Outbreaks Linked to Contaminated Mexican Cantaloupe

**1990:** Salmonella infections are linked to the consumption of contaminated melons.

2000: Mexico exports more than 136,000 metric tons of fresh cantaloupe to the US.

**2000-2002:** Outbreaks of Salmonella across multiple states and provinces in the US and Canada are associated with the consumption of contaminated cantaloupe imported from Mexico.

25 May 2001: FDA advises consumers of an outbreak of food-borne illness associated with cantaloupe from two Mexican companies, S.P.R. de R.I. Legumbrera San Luis and S.P.R. de R.I. Los Arroyos, and imported by Shipley Sales Service of Nogales, Arizona. This outbreak of Salmonella results in numerous illnesses and is linked by strong epidemiological evidence to two deaths.

2001: Mexico exports more than 104,000 tonnes of fresh cantaloupe to the US.

May 2002: A Texas importer and distributor of Susie brand cantaloupe from Mexico issues a voluntary nationwide recall of the product because it has been associated with outbreaks of illness in the US and Canada.

**2002:** FDA conducts on-farm investigations in Mexico and concludes that measures are not in place to minimize microbial contamination in the growing, harvesting, packaging and cooling of cantaloupe.

**28 October 2002:** FDA issues a countrywide import alert on Mexican cantaloupe and detains all such products for entry at all U.S. ports.

**4 November 2002:** The Canadian Government bans the importation of Mexican cantaloupes because of health concerns and recommends that the fruit not be imported again until Mexico establishes a program of "sound agricultural practices."

**November 2002:** The Mexican Government delivers an intervention before the WTO SPS Committee alleging that the US has acted inconsistently with certain provisions of the agreement by imposing a countrywide import alert on Mexican cantaloupe. The US responds to the intervention by citing deaths of US citizens linked by strong epidemiological evidence to contaminated cantaloupe from Mexica and stressing that US actions were completely in accord with the relevant articles of the WTO SPS Agreement.

13 November 2002: The Mexican Government releases an official norm for the cultivation, harvest storage and transport of cantaloupe.

**December 2002:** Two Mexican growers, both located in the State of Sonora, secure exemption from the countrywide US import alert. Mexican exports of fresh cantaloupe to the US for 2002 total roughly about 59,000 tonnes.

**2003:** An additional grower in Sonora is exempted from the countrywide US import alert. A Mexican processor of cantaloupe also obtains exemption from the alert, as long as the fruit is either imported from the US or purchased from one of the Mexican growers exempt from the alert. Mexican exports of fresh cantaloupe to the US for 2003 total about 6,000 tonnes.

**2004:** FDA reviews the program prepared by Mexico and passes inspection. The program includes a 10 page guidance questionnaire that asks grower to go into considerable detail on food safety measures employed on cantaloupe growing and packing operations that may help growers and packers to be removed from FDA's import ban.

**9 March 2004:** The Canadian Government releases import requirements replacing the ones issued in November 2002 and reissued in December 2002. These requirements acknowledge that the Mexican Certification Program constitutes an acceptable approach to minimize the risk of contamination from cantaloupes.

 $\mathbf{April}-\mathbf{May}$  2004: Two additional growers from Sonora are exempted from the countrywide US import alert.

2004: Mexico exports about 11,000 tonnes of fresh cantaloupe to the US.

# Appendix 2.4: Chronology for North American Beef Trade Following the Detection of BSE

- **20 May 2003:** The World Reference Laboratory confirms that a cow in northern Alberta suspected of having BSE has tested positive to the disease. Within hours, the US announces a ban on all imports of Canadian beef.
- 18 July 2003: Canada announces an additional measure to enhance existing food safety controls requiring the removal of SRM materials from carcasses of cattle older than 30 months. This new SRM policy is developed jointly by the CFIA and Health Canada and is consistent with international standards.
- 11 September 2003: The US and Mexican markets are opened to boneless beef products from Canada for animals under 30 months of age, although the ban on live cattle is unchanged. This is followed by some progress in other markets.
- 4 November 2003: USDA publishes a proposed rule that creates a new minimal risk category and places Canada in this new category. The proposed rule outlines import conditions for live feeder and slaughter cattle under 30 months of age, as well as other products.
- 23 December 2003: The US announces a case of BSE in a Holstein cow in Washington State. The cow is later determined to have been born on an Alberta farm.
- **30 December 2003:** The US announces a number of new BSE control measures, including the removal of specified risk materials at slaughter. Most of these measures are comparable to Canadian measures, except for the removal of downers from the food supply. Consequently, as requested by the US for all of its trading partners, Canada mirrors the US action.
- **9 January 2004:** Canada commits C\$92.1 million over five years to increase current surveillance efforts and enhance the existing Canadian Cattle ID program.
- **16 January 2004:** Canada, the US, and Mexico issue a joint statement underlining their intention to work together to normalize North American trade in beef and live cattle, to effect changes to OIE guidelines, and to harmonize BSE control measures among the three countries.
- **26 January 2004:** The US announces new measures on animal feed, removing poultry litter and plate waste from animal feed on which Canada took action in 1997. However, the US also requires removal of mammalian blood and segregation of processing lines for ruminant and non-ruminant feed for which Canada is assessing the US scientific rationale and determining whether changes are required to the Canadian feed ban.
- 8 March 2004: The US reopens the comment period, and in addition to the former rule, the Federal Register notice requests comments on whether to allow the importation of beef from cattle 30 months of age or older from which the specified risk materials have been removed.
- 19 April 2004: USDA revises the import controls on Canadian beef to include all cattle products from animals under 30 months. The CFIA makes a similar change for US cattle products on April 23. This is a technical amendment to bring the controls in line with the existing science-based policy in both countries. The US changes are put on hold following a court injunction won by the Ranchers Cattlemen Action Legal Fund, United Stockgrowers of America (R-CALF USA), on the grounds that the correct rulemaking process had not been followed.

- **9 July 2004:** Canada announces it will introduce new animal feed restrictions to further strengthen Canada's safeguards against BSE. Canada intends to require the removal of bovine specified risk materials (SRM) from the animal feed chain.
- 12 August 2004: A group of cattle producers called Canadian Cattlemen for Fair Trade files a lawsuit against the US government seeking \$150 million under a provision of NAFTA. The group says its members have suffered because of the US decision to close the border to Canadian beef in May 2003.
- 10 September 2004: Canada announces a strategy to assist Canada's livestock industry in repositioning itself to ensure its long-term viability. The strategy includes continuing efforts to reopen the US border, taking steps to increase ruminant slaughter in Canada, introducing measures to sustain the cattle industry until capacity comes online, and expanding access to export markets for both livestock and beef products.
- 1 December 2004: US President George W. Bush makes his first official visit to Canada. He indicates that the intent is to reopen the US border to Canadian live cattle within a few months.
- 3 January 2005: CFIA officials confirm that a second case of BSE has been found in Alberta
- **4 January 2005:** USDA publishes BSE minimal risk rule in the Federal Register. The rule would allow live cattle under 30 months of age to be exported from Canada to the US. USDA indicated that Canada met the definition of a minimal risk country under the rule as a result of adopting the following measures, among others:
- · Prohibition of specified risk materials in human food.
- Import restrictions sufficient to minimize exposure to BSE: Since 1990, Canada has
  maintained stringent import restrictions, preventing the entry of live ruminants and
  ruminant products, including rendered protein products, from countries that have
  found BSE in native cattle or that are considered to be at significant risk for BSE.
- Surveillance for BSE at levels that meet or exceed international guidelines: Canada
  has conducted active surveillance for BSE since 1992 and exceeded the level
  recommended in international guidelines for at least the past seven years.
- Ruminant-to-ruminant feed ban in place and effectively enforced: Canada has had
  a ban on the feeding of ruminant proteins to ruminants since August 1997, with
  compliance monitored through routine inspections.
- Appropriate epidemiological investigations, risk assessment, and risk mitigation measures imposed as necessary: Canada has conducted extensive investigations in response to any BSE finding and has taken additional risk mitigation measures.
- 10 January 2005: R-CALF USA files a lawsuit to prevent the implementation of the US BSE minimal risk rule, seeking a ban on the importation of all cattle and beef products from Canada.
- 11 January 2005: CFIA announces that a third case of BSE has been found in Alberta. Agency staff indicates that the animal was born after the 1997 ban on feeding cattle remains to cattle but became infected by eating left-over feed produced before the ban came into effect.
- 12 January 2005: US Secretary of Agriculture Ann Veneman announces that the border will reopen March 7 as planned, but that officials are monitoring the latest BSE investigation very closely. A US team of technical experts is sent to assess Canada's compliance with the feed ban.

- **9 February 2005:** US Secretary of Agriculture Mike Johanns announces that implementation of the rule as it relates to meat products from over 30 month cattle will be indefinitely delayed. He also calls for US officials to move forward in consideration and development of a plan to allow imports of animals 30 months and older for slaughter as well as beef from over 30-month animals as the next step in resuming full trade with Canada.
- 25 February 2005: In both the risk assessment conducted by APHIS as part of the BSE minimal-risk rule, as well as the feed ban assessment, the agency finds that compliance by feed mills and rendering facilities in Canada to their feed ban regulations is good and, just like the US, Canada is continually looking for ways to make it even better.
- **2 March 2005:** US District Court in Montana grants a preliminary injunction preventing implementation of the US rule that would allow a resumption of US imports of live cattle, other ruminants and a wider range of products derived from them. This preliminary injunction will be in force either until it is successfully appealed or until the merits of the R-CALF USA lawsuit are decided upon. USDA announces it will appeal the injunction.
- 3 March 2005: The rule is also subject to Congressional review. The Congressional Review Act provides for an accelerated process under which Congress can disallow a rule within 60 "legislative" (i.e., sitting) days of its publication in the Federal Register. The Senate votes to disallow the BSE minimal risk rule. The House has not yet voted on the issue (though the Chair of the House Agriculture Committee has spoken out against disallowing it), and President Bush has indicated his intent to veto any bill disallowing the rule.
- 17 March 2005: USDA announces it will appeal the temporary court-imposed delay on reopening the US border, handed down by the US District Court in Montana. The appeal request seeks to reopen the border until the July hearing begins. The Court has set July 27 as the start date for the trial. R-CALF USA intends to argue in favour of keeping the border closed.
- 1 April 2005: USDA announces that Canada, Mexico and the US have established a harmonized approach to BSE risk mitigation to more effectively address any BSE risk in North America. This science-based framework of risk management measures for BSE has been developed with the objective to help normalize trade in ruminants and ruminant products within North America and to promote an international BSE strategy consistent with OIE guidelines.
- **2 June 2005:** The OIE unveils a new set of recommendations concerning the management of the animal and human health risks associated with the presence of BSE in cattle, following its annual meeting in May 2005.
- 14 July 2005: The US Ninth Court of Appeals reverses the injunction granted by the US District Court of Montana.