

The Bioterrorism Act of the USA and international food trade: Evaluating WTO conformity and effects on bilateral imports

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Abstract

The September 11th event focused the world's attention on the threat of bioterrorism to the food chain. As a consequence, the U.S. implemented the Bioterrorism Act (BTA).

These new administrative import rules will be evaluated regarding WTO conformity and trade impact. This analysis is based on an inventory approach systematizing the BTA, and a trade flow analysis.

The BTA do not significantly deviate from WTO rules, however, the findings are driven by existing flexibility in international administrative import guidelines. The trade analysis highlights that products and countries with prior expedited or less regulated procedures and small import quantities are affected.

Keywords: food terrorism, non-tariff barriers, trade facilitation, Bioterrorism Act, food trade, SPS Agreement

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1 Introduction

1.1 Background

Increasing global trade and decreasing tariffs brought sanitary and phytosanitary (SPS) trade issues to the forefront of the discussion. Several countries overhauled and streamlined their food safety legislation in order to ensure a safe supply of food products and to prevent the introduction of invasive alien species potentially harming domestic livestock or crop production (e.g. New Zealand¹, European Union²). In general, these legislative steps focused on the prevention of unintentional pests' introduction or food adulteration; however, since the events of September, 11th, the threat of *intentional* food, crop or livestock manipulation is at the centre of interest.

These intentional manipulations are captured under the term *bioterrorism* and are defined as “the threat or use of biological agents [to cause harm] by individuals or groups motivated by political, religious, ecological, or other ideological objectives” (Meyerson and Reaser 2002, p.593 following Carus 2001, p.3). The World Health Organisation (WHO), defining *food terrorism* as “an act or threat of deliberate contamination of food for human consumption with chemical, biological or radionuclear agents for the purpose of causing injury or death to civilian populations and/or disrupting social, economic or political stability”, (WHO 2002, p.8) focus on the specific problem of food terrorism and even expand the definition of terrorism by including chemical and radionuclear agents into the picture. However, both definitions have in common that the wilful harm of humans or assets is the distinction between (bio-) terrorism and accidental outbreak of crop or livestock diseases or foodborne illnesses. Some authors also are talking about

¹ Biosecurity Strategy adopted in 2003. See <http://www.biosecurity.govt.nz/bio-strategy/index.htm>

² General Food Law adopted in 2002. See http://europa.eu.int/comm/food/food/foodlaw/index_en.htm

agroterrorism and relate to the specific risks, agricultural production and the food chain are exposed to. A definition for agroterrorism is provided by the National Defense Research Institute as “deliberate introduction of a disease agent, either against livestock or into the food chain, for purposes of undermining socioeconomic stability and/ or generating fear” (Chalk 2004, p. xi). Others differentiate terrorism by the underlying motivation for the attack. For example Carus distinguishes terrorist, criminal and state activities by motivation and objective. Terrorist activities are defined as activities of certain groups/individuals having an ideological objective, where criminal activities are undertaken without ideological objectives but may be based on pathology or individual motivation like revenge, and states’ activities characterise the use of biological agents as weapons e.g. within wars (Carus 2001, footnote 7). Given the framework that is provided by the Bioterrorism Act (BTA), we use a slightly modified WHO definition, i.e. focussing on food terrorism resulting from biological agents only.

According to Meyerson and Reaser, bioterrorism differs from other form of terrorism in three different way (Meyerson and Reaser 2002): First, the *mass destruction of life* (humans, animals, or plants) is a major goal besides the intimidation of governments or societies; depending on the incubation period and visibility of symptoms, second, the *attack may not be readily apparent* until the biological agent has spread significantly among populations or species; and third, it may be impossible to establish whether the *release of the organisms was intentional*. In recent years, bioterrorism has received much more emphasis relative to chemical and nuclear weapons of mass destruction since nuclear weapons require extensive infrastructure to produce and chemical weapons require greater quantities of material to produce mass casualties. Furthermore, they are not self-replicating after an attack. Biological weapons, however, are relatively easy to manufacture and bioterrorism infrastructure can be hidden within legitimate health infrastructure. They are much more difficult to detect and an attack may not be immediately apparent. (Kuliasha 2003)

Given this, the food chain must be evaluated as an especially vulnerable part of the American industry since many different actors are involved in production, processing, storage, distribution, and retail and a biological attack might not be readily apparent and easily vertically spread over all participant actors. Agriculture and related sectors

contribute with up to 13% to domestic GDP (GAO 2003), and a threat might cause significant economic disruption in addition to the general effects for social and political stability (Schaub 2002). Further economic impacts of bioterrorism attacks relate to (based on Schaub 2002, Monke 2005, Chalk 2004):

- Direct losses of crops, livestock, and other assets
- Secondary losses in upstream and downstream markets
- Indirect effects address the international level as well, e.g. a loss of export markets, price effects, reduction of economic growth caused from a reallocation of resources.

Given that nearly 20% of all imports into the U.S. are food and food product imports (FDA 2003) governments are challenged to find the right balance between border security and trade openness. As a response to September 11th, the U.S. is implementing several security measures to ensure the safety of U.S. ports and the food chain. In 2002, the Homeland Security Bill created the Department for Homeland Security (DHS), which among other responsibilities unified all agencies and personnel responsible for border protection and import inspection under one administrative body. Besides the development of a National Strategy for Homeland Security³, several new legislative acts shall help to reduce the vulnerability of the U.S. to terrorism. One of these measures is the *Public Health Security and Bioterrorism Preparedness and Response Act* (“The Bioterrorism Act”, BTA) of 2002, entering into force December 12, 2003.⁴

After the notification of this act as a sanitary and phytosanitary measures to the World Trade Organization (WTO), the European Union (EU) and several other countries have raised concerns about the widespread trade impacts and costs of this regulation for imports (WTO 2003). The trading partners wanted to ensure that the requirements applied to imports from foreign countries are based on a risk assessment and not more burdensome than similar domestic requirements. Even though there was no follow up on

³ This strategy defines three key priorities for the U.S. and six critical mission areas for action (e.g. border and transportation security, protection of critical infrastructure, or the emergency preparedness and response). The food and agricultural sector is part of the critical infrastructure therefore deserving special attention in the prevention of terrorist attacks. See <http://www.whitehouse.gov/homeland/book/>

⁴ Further legislation responding to this are the Container Security Initiative and the 24-hour Advanced Vessel Manifest Rule.

the trade concerns in the WTO framework, smoothness of trade does not seem to be satisfying, as the BTA is still a point on the agenda of meetings and organization (e.g. EU Commission 2005).

1.2 Methodological context

Administrative import regulations like those covered by the U.S. Bioterrorism Act belong to the group of non-tariff barriers (NTBs) covering all measures that are not tariffs such as quantitative restrictions, technical regulations regarding product and process standards, labeling and packing requirements, and administrative imports requirements which may include different instruments (e.g. licensing, certification, border inspections). Such administrative import requirements may hinder trade because of the following reasons (National Board of Trade 2002): Data and documentation requirements, lack of transparency on requirements, lack of audit-based controls and risk-assessment techniques to justify certain barriers, high degree of unpredictability and lack of automatization of procedures or lack of co-operation between agencies.

At the political level, the group of administrative import rules has been increasingly discussed by aiming at positive benefits from a reduction or harmonization of such barriers. The objective of *trade facilitation* was added to the WTO agenda as one of the Singapore Issues in 1996 and specific negotiations were commenced in 2004 by integrating it in the Doha Work Programme declared at the General Council of 1 August 2004 (WTO 2004). The WTO defines trade facilitation as “simplification and harmonization of international trade procedures” (WTO website), where trade procedures are the “activities, practices and formalities involved in collecting, presenting, communicating and processing data required for the movement of goods in international trade” (OECD 2002, p.6).

Studies on the methodological analysis of NTBs or the effects of trade facilitation have increased in the recent past, however, empirical quantitative measurement of NTBs’ is still facing difficulties. Due to the heterogeneity of such measures comprehensive studies on general methods are limited (OECD 2003a), and most often they are focusing on certain sectors or selected types of NTB groups (OECD 2003a).

In particular, when it relates to quantifying the impact of import regimes studies are very rare or use data that is rather old. However, there are some recent examples such as Doran (1999) assessing the costs due to import administration for the service sector, and Wilson et al. (2003) who first defined trade facilitation by differentiating indicators like port efficiency and second, quantified the impact of indicators on trade flows regarding the Asian Pacific region. A comprehensive OECD study of 2002 (OECD 2002) summarizes the results of existing studies on quantifying the costs of trade regimes. A range of assessed costs of 2% to 15% of the trade transaction value is identified depending on different covered cost components and different methodological approaches (OECD 2002, p. 12).

Among the approaches used for quantification of NTBs (OECD 2003a, p. 43ff.) is the price-wedge method to provide a tariff-equivalent calculated by determining the difference between the domestic price (when a NTB is in place) compared to a reference price without NTB. As the latter is unobservable, this calculation most often compares the domestic and the foreign price (e.g. on world market or F.O.B. price at the port of entry) of a comparable good. Other methods for identification and quantification use econometric frameworks as e.g. the class of gravity models where bilateral trade flows are regressed on a set of internal and foreign prices and explanatory variables that are associated with the trade barrier (Anderson and Wincoop 2004). Supplementary work uses expert surveys or inventory methods to identify relevant NTBs and evaluate their level of protection.

1.3 Objective of the paper

This paper is focussing on a certain type of NTBs: Import regulations in the area of food safety. As an example for this type of NTB, we use the newly introduced Bioterrorism Act of the U.S. to show how food safety concerns and administrative import requirements interplay and therefore impact bilateral trade. Given this, this paper has the following objectives:

1. The analysis is based on a *qualitative inventory approach* identifying the provisions addressed by the BTA and comparing them with existing international measures. Some studies exist that use a comparative inventory evaluation (Henson et al. 2000)

or that add further econometric evaluation (Moenius 1999, Otsuki et al. 2001). An accurate systematization of these measures will be undertaken according to the relevant WTO-framework since the inventory approach will be used subsequently to *evaluate* the measures regarding *conformity with the WTO principles* of the SPS-Agreement.

2. Finally, bilateral trade data for food imports will be reviewed in order to analyse if empirical evidence for the trade impact of the legislation can be found. The approach is based on *a trade flow analysis* as performed in OECD (2003a).

The remainder of the paper is organized as follows: First, an overview on the existing provisions of the BTA is given. Afterwards, the BTA provisions will be evaluated according to the WTO principles of the SPS Agreement. Subsequently, the trade flow analysis will be used to provide some empirical evidence on trade impact for selected products and countries beforehand identified as most strongly affected by the BTA provisions. Finally, further issues for research are identified and conclusions are drawn.

2 Import rules under the Bioterrorism Act

Objective of the Act

The objective of the Bioterrorism Act is “to improve the ability of the United States to *prevent, prepare for, and respond* to bioterrorism and other public health emergencies” by providing additional information and action tools to the administration.⁵

Relevant provisions

The BTA is divided into five titles of which Title III explicitly relates to food safety under the heading “Protecting Safety and Security of Food and Drug Supply”. The other relevant title referred to in this analysis is Title II “Enhancing Controls on Dangerous Biological Agents and Toxins” aiming at the control of domestic laboratories using certain agents and toxins.

⁵ The act in full can be found on the following web page: <http://www.fda.gov/opacom/laws/>. Additionally, the FDA maintains a separate web side with all relevant information on the BTA legislation and implementation (<http://www.fda.gov/oc/bioterrorism/bioact.html>).

Title III of the BTA is applied to all food products determined for the U.S. market regardless of if the product is processed within or outside U.S. territory. It contains four important provisions⁶:

1. *Administrative detention of food*⁷ when “credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals” (Section 303) is given. Furthermore, Section 304 allows the authorities to debar persons or firms from imports into the U.S. when they repeatedly violate the import regulations set out in this act.

2. *Registration of food facilities and determination of an agent* (Section 305): This provision requires domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the U.S. to register with the FDA. Domestic facilities must register whether or not their food enters interstate commerce and foreign facilities and must additionally designate a U.S. agent who must live or maintain a business place in the U.S. and is physically present in the U.S. Excluded from registration are private residences of individuals with food manufacturing or storage capacities, farms, restaurants, retail food establishments, non profit food establishments, and fishing vessels. Additionally all facilities regulated exclusively by the United States Departments of Agriculture (USDA) are excluded.

3. *Establishment and maintenance of records* (Section 306). All domestic firms that manufacture, process, pack, distribute, receive, hold, or import food must establish and maintain a record keeping system. This measure applies to all foreign persons that transport food into the U.S. or place food directly in contact with its finished container. Exclusions apply again to the group of facilities as listed above. Source and recipient of all food items must be recorded including address, type of food, brand, variety, type of

⁶ Final or interim rules of these measures are published in the Federal Register (FR). These publications contain additional information on background of the proposed legislation, summary of comments received on earlier version of the rules, economic impact analysis, and some administrative issues. For the measures discussed in this paper, the following version of the legislation are used: *Administrative Detention*: Final Rule published June 4, 2004, FR 69; *Registration of Food Facilities*: Interim Final Rule published October 10, 2003, FR 68; *Prior Notice of Imported Food*: Interim Final Rule: Interim Final Rule published October 10, 2003, FR 68; *Establishment and Maintenance of Records*: Final Rule December 9, 2004, FR 69.

⁷ The term *food* in this regulation generally refers to the definition as provided by Section 201(f) of the Federal Food, Drug, and Cosmetics Act. It includes all food and beverages for human and animal consumption including chewing gum and all items used for components of any such article.

packaging, and receive and delivery date. Records must be kept for 6 month to two years, depending on the nature of the food item, and must be accessible within 24 hours.

4. *Prior notice of food shipments* (Section 307). All food items that are imported into the U.S. must be notified within a time frame, depending on the mode of transportation, of maximum 5 days and minimum 2-8 hours prior to arrival with information containing article specification, the manufacturer and shipper, the grower (if known within the specified time in which notice is required), the country of origin, the country from which the article is shipped, and the anticipated port of entry. An inadequate notice leads to import refusal or detention. Excluded from this requirement are items for personal use and gifts, products under USDA jurisdiction, and food that was made by an individual in the personal residence and enters the U.S. for non-business reasons.

Responsible agencies

The food safety and inspection system for agricultural commodities in the U.S. is complex and based on the interaction of several agencies (GAO 2005). The BTA provides the Food and Drug Administration (FDA) with the responsibility for carrying out the provisions related to the security of the food and drug supply (Title III). However, cooperation with other agencies is necessary: The USDA has the oversight over agents and toxins deemed to be a threat to animal or plant health as laid out in Title II as well as authority⁸ for the safety of the products meat, poultry, and processed eggs. The DHS has the responsibility for inspection of all animal and food imported into the U.S. conducted by the Customs and Border Protection (CBP) personnel. For the imports of live animals and not edible plant and plant products, the Animal and Plant Health Inspection Service (APHIS), another branch agency of the USDA, has oversight. Furthermore, APHIS is responsible for the issuing of Import Permits for animal, fruit and vegetable food products.

Changes in the import regulations

In order to provide an overview on changes in the import regimes introduced by the BTA, Table 1 summarizes the most important import requirements that were in place prior to

⁸ Conducted mainly by the Food Safety Inspection Service (FSIS), a branch agency of the USDA.

the BTA. The basic reference for product and admissibility standards is the Food, Drug, and Cosmetic Act (FD&C Act) that is enforced by the FDA.⁹

Prior to the BTA, the *general import procedure* for food consisted of the following steps: Filing of entry information with the U.S. Customs authorities by the importer, entry notification from the Customs authorities to the FDA, a decision process within FDA if an examination of the entry is necessary, and if this should take place, then the owner or consignee should hold the shipment and no further distribution was allowed until a final decision was made (FDA 1999). Hence, a major difference compared to the BTA relates to the notification time frame for entry of food shipments. According to the former system, the FDA received the information up to several days after arrival, implying that the food may have already been delivered to the ultimate consignee (FR 68, Vol. 197, p. 58976).

However, there are a number of product categories where more detailed import requirements were specified and further administrative steps for food imports were prior to the BTA being enforced. Depending on the category, these requirements consist of a registration of the food facility and specific product information with arrival at the port (low-acid canned products), obtaining of import permits prior to shipment (alcoholic beverages, fruit and vegetables, dairy products), or having a food safety control system in the production facility in place (seafood, live fish). The import permits were issued for the complete firm and kept valid for up to five years (e.g. fruits and vegetables).

Therefore, for some products the provisions of the BTA do not alter very much from already existing procedures (e.g. canned products), whereas for most other products (e.g. alcoholic beverages, fruit and vegetables, seafood, other food items), larger changes were required and relate to the above described information requirements with respect to products and facility as well as the timeliness within the import process.¹⁰

⁹ The FD&C Act can be found under http://www.access.gpo.gov/uscode/title21/chapter9_.html.

Note that there exist numerous other laws regulating issues related to production and marketing of food products (e.g. Public Health Service Act, Fair Packaging and Label Act, Nutrition Labeling and Education Act, Food Quality Protection Act). Further information can be found in FAS (1999).

¹⁰ Note that the requirements related to obtain import permits or inspection certificates are still in place.

Table 1 Summary on important import requirements for specific food categories prior to the BTA

Product group	Basic legislation	Provisions in addition to the “general import procedure” prior to BTA
Meat, poultry and eggs	Federal Meat Inspection Act Poultry Products Inspection Act Egg Products Inspection Act	Equivalence of food safety system Inspection and approval of foreign facility Firm-related import permit Inspection at port-of-entry
Food categories covered by BTA		
Low-acid canned products	FD&C Act Low-Acid Canned Food program	Registration of food facility Providing of processing information
Alcoholic beverages	FD&C Act Federal Alcohol Administration Act	Firm-related import permit
Fresh fruit and vegetable	FD&C Act	Inspection certificate Firm-related import permit
Dairy products	FD&C Act Federal Import Milk Act	Firm-related import permit Quota system
Seafood and live fish	FD&C Act Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products	HACCP system must be in place and verified by foreign government inspection authority or Equivalence or compliance agreement with the U.S.
All other food items	FD&C Act	-

Note: For alcoholic beverages, the Bureau of Alcoholic, Tobacco and Firearms (ATF) is responsible for administering the Federal Alcohol Administration Act. Herein, further import requirements (e.g. with respect to the label) are laid down.

Source: Own compilation based on information from FDA, APHIS, Foreign Agricultural Service (FAS), Center for Food Safety and Applied Nutrition (CFSAN), Government Accountability Office (GAO).

The group of other products face the most drastic changes due to the BTA implementation as formerly no special requirements in addition to the general import procedures were in force. Depending on the ability of firms to adapt these new components in the import protocols, this may lead to product and country specific trade impacts as they will be analyzed in chapter 4.

3 WTO conformity assessment

In this chapter it will be analyzed whether the BTA provisions are in line with relevant WTO rules. WTO disputes on NTBs gain increasing relevance¹¹ and a regime evaluation in light of WTO compliance may not only avoid extensive dispute activities but may also contribute to improve the design of such measures.

However, rules for trade facilitation are covered by different WTO agreements rendering a conformity assessment difficult. Only a few explicit WTO agreements on import procedures exist, such as the “Agreement on Preshipment Inspection” or the “Agreement on Import Licensing Procedures”. Other explicitly security motivated rules are addressed by the GATT Article XXI implying “that no country shall be prevent from taking action to its essential security interests”.

Since the BTA has been notified to the WTO under the SPS Agreement¹², our analysis focuses on the food safety-specific trade provisions as covered by this agreement.

3.1 The food-specific framework for the conformity assessment: The SPS Agreement

The objective of the SPS agreement is twofold and combines both, granting a national protection level to be defined sovereign by the members and minimizing resulting trade effects (Josling et al 2004, p. 4). Since the adopting of the SPS Agreement in 1994, the articles of this agreement provide the relevant framework for trade-related food safety rules in the context of international trade.

The SPS rules selected for the following conformity assessment can be interpreted as core provisions since most of the food safety related disputes referred to them (Rudloff 2005). The first set of rules described under (1) is targeting at the national protection

¹¹ Out of 328 cases initiated after 1995 more than 60 refer to the Agreement on Technical Barriers to Trade (TBT) and the SPS Agreement which are the relevant agreements for NTBs in the food sector (Rudloff 2005).

¹² See G/SPS/N/USA/690 (Prior notice), G/SPS/N/USA/691 (Registration of food facilities), G/SPS/N/USA/703 (Establishment and Maintenance of Records), and G/SPS/N/USA/704 (Administrative Detention). Note, that the measure “Registration of food facilities” is also notified under the TBT agreement (G/TBT/N/USA/32). Available at http://docsonline.wto.org/gen_home.asp?language=1&_=1.

level that is chosen by a country whereas the second set (2) is linked to the specific measure used to enforce the protection level at the border:

(1) Appropriate level of protection. Under the SPS agreement each member has the right to implement measures seen as appropriate to achieve human and animal and plant safety by ensuring that measures are only applied to the extent necessary (Art. 2, par. 2). The appropriate level of protection should be based on risk assessment considering the levels of probability and damage in terms of loss of production or sales (Art. 5).

- Standards of international organisations are recommended as they are deemed to be scientific necessary (Article 3). The relevant international organisations are the Codex Alimentarius Commission (CAC) for food safety standards, the International Office for Animal Health in the context of animal health standards (OIE) and the International Plant Protection Convention for plant health standards (IPPC) (Annex A).
- If higher safety levels compared to international standards should be achieved a scientific justification has to be provided (Art. 3, par. 3).

(2) Once a level of protection is accepted according to the above mentioned rules this protection level is allowed to be enforced at the border to avert imports potentially undermining the protection level. However, the SPS Agreement also provides guidance on the choice and design of an implemented trade measure:

- Enforcing measures should be *non-discriminating* and *national treatment* should be ensured (Art. 2, par. 3). These are core rules that hold not only for food trade and are covered by the GATT (GATT Art. I and III). They target at both equal treatment of imports coming from different members and of imported and domestically produced goods.
- Additionally *equivalence* (Art. 4) is recommended. Hereby, SPS measures of the exporting countries should be accepted as being equivalent if achieving the same protection level. The exporting country has to proof that its varying measure is able to achieve the protection level of the importing country. Members shall establish bilateral agreements to recognize the equivalence.

- *Regionalization* is an important rule for animal and plant diseases as part of food safety (Annex A, par. 6). According to this concept pest and disease free regions (areas) are defined for specific diseases and out of such regions exports should be accepted. An area is defined not on a country basis but can either be a region within one country or can gather regions across several countries. This offers the possibility to export from one region even if another region in the same country may not be risk-free. Like for equivalence the burden of proof to demonstrate the risk free status lies with the exporting country.
- The most often used argument related to the chosen measure in WTO food disputes (Rudloff 2005) is that the measure at stake should be the *least- trade distorting* one. A measure is seen as not more trade-restrictive as required unless there is another measure that is less trade-restrictive but achieves the same level of protection (Article 5, par. 6 and footnote 3). Additionally the *technical and economic feasibility* is considered when evaluating a trade measures (Article 5, par. 6).

3.2 Evaluation of BTA provisions

3.2.1 The appropriate level of protection – The problem of assessing bioterrorist risks

The scientific necessity for accepting a domestic protection level that can be required from importers is the starting point of the SPS-Agreement. In all concluded WTO disputes on food safety, this argument was the major basis for the final findings of the dispute bodies (Rudloff 2005).

Risk assessment describes the process of defining the probability of adverse effects (Hood et al. 2001, p. 3). On the international level and with respect to food safety risks, the CAC defines a four step procedure for assessing food risks : (1) identifying hazards, (2) characterizing hazards with regard to adverse effect e.g. by dose-response assessments, (3) analyzing exposure assessment by describing likely intake of identified hazards and agents, and (4) risk characterization by a qualitative or quantitative

assessment of the probability of occurrence and the severity of the known or possible adverse effect (CAC 2003c, p 183).

Probability assessment

Bioterrorist risk may be characterised as “new” risks where the probabilities are unknown and therefore they face the situation of uncertainty. Probabilities can hardly be based on frequencies as empirical information on past events is weak.¹³ Besides this general problem of few reported events the existing literature lacks comprehension and accuracy regarding the type of attacks (deliberate or incidental; terrorist, criminal or state motivated; bio- or food terrorism) (Tucker 1999 p. 1, Carus 2001 p. 3).¹⁴

Covering all types of activities (terrorist, criminal, state), Carus (2001) derives an increasing trend of biological attacks. In particular in the last decade, the number of reported cases increased¹⁵ though the minority of them was caused by terrorist motivation.

Table 2 Empirical frequency – conflicting coverage in different studies

Period	Terrorist	Criminal	Other	Total
1990-99	19	40	94	153
1980-89	3	6	0	9
1970-79	3	2	3	8
1930-69	2	4	0	6
1900-29	0	4	0	4
total	27	56	97	180

Source: Carus 2001, p. 11.

To identify food terrorist cases that are according to our definition, i.e. caused by deliberating biological agents in the food chain, a review of existing studies was necessary (Chalk 2004, Carus 2001, Manning et al. 2005, Parker 2002, Tucker 1999,

¹³ Moffitt et al. 2005 provides an analysis of modelling concepts for bioterrorism in the context of uncertainty.

¹⁴ Carus is probably the most comprehensive and accurate source in terms of both number of analyzed cases and strict use of proper definitions (Carus 2001).

¹⁵ A relevant influencing parameter could be the improved reporting over the time.

WHO 2002, Wilson et al. 2000). As a result only three food terrorist attacks could be identified since 1900:

1. Rajneeshee case: In 1984 a fanatic religiously motivated group contaminated food in salad bars and restaurants in Oregon, U.S.A. in order to incapacitate voters to win local elections. About 10 restaurants had to be closed for a longer period and 751 cases of illnesses are reported.
2. Anthrax case: In 1972 Anthrax was brought out in Rhodesia to cattle (Manning et al. 2005).¹⁶
3. Mau Mau case: In 1952 a plant toxin from the African Milk Bush was used to kill livestock by a rebellion group (Mau Mau) that was fighting against the British colonization (Manning et al. 2005).

Neither for the Mau Mau nor the Anthrax case human health effects are reported. In addition to the accomplished cases, Carus (2001) lists all potential but never finally clarified cases as well all known threats. But out of this group no explicit case linked to food terrorism can be added.

Damage assessment

The evaluation of adverse effects is covered by the CAC guidelines for risk assessment as part of the final step to characterize risks. In general such adverse effects consist of direct economic effects on supply and demand, secondary losses for up- and downstream markets, indirect effects including trade losses, and all socio-psychological long-term effects reducing political and social stability: Just a minority of the few studies on bioterrorist attacks lists or evaluate the caused damage (see Table 3) and only for the Rajneeshee case as food terrorist case, information on illnesses in the population is available.

A possible proxy for assessing the damages of food terrorist attacks can be the costs of food accidents¹⁷, since in this area of *incidental* contamination more studies (see Table 3, last column). The case of the Enteriditis infection from contaminated ice cream

¹⁶ No further background on motivation and target of the attack could be found. This case is only referred to in Wilson et al. (2000).

¹⁷ See for an overview on existing studies OECD (2003b).

in 1994 in the U.S. causing 224000 cases of illness indicates the potential for huge damages on public health. However, only very few data on the monetary evaluation of damages is available. Nevertheless, these values can be rather significant, as for example the damage of the Listeria accident of 1998 in the U.S. was assessed with 50-70 Mio \$, and the Escherichia coli accident of 1996 in the U.S. with 14 Mio \$ (see Table 3). A very comprehensive study of Buzby et al. (1996) calculated costs per single pathogen for the U.S. per year and estimates 6.5 - 30 Mio \$ and 9000 deaths each year.

Table 3 Damage assessment of terrorist and incidental food contamination

Food- terrorist contamination	Listed cases of illness	Incidental contamination	Listed cases of illness
(1) Rajneeshee case	751	Chemically contaminated cooking oil, 1981, Spain	200 cases of illness and 800 deaths
(2) Anthrax case	no information	Chemically contaminated watermelon, 1985 USA	1 272 cases of illness
(3) Mau Mau case	no information	Typhimurium infection by pasteurized milk, 1985 USA	170 000 cases of illness
		Enteriditis infection from ice cream, 1994 USA	224 000 cases of illness
		Escherichia coli infection from radish sprouts, 1996 in Japan	8000 cases of illness including deaths
		Escherichia coli infection of apple juice, 1996 USA	70 cases, 1 death 14 Mio \$
		Listeria infected meat, 1998 USA	35 cases of illness 50-70 Mio \$
		All microbiological pathogens in food per year, U.S. (Buzby et al. 1996)	9 000 deaths 6,5 – 30 Mio \$

Source: Incidental cases in WHO 2005 and Manning et al 2005. Other cases from Carus 2001.

Conclusion

Because of the mentioned difficulties, the basis for assessing the bioterrorist risk of an individual country is limited. Therefore conclusions for the U.S. specific food terrorist risks cannot be drawn easily. However, in the area of agroterrorism risk Parker (2005) and Chalk (2004) identified a potentially high risk level for the U.S. They base their result on U.S. specific production patterns that tend to increase damages and

probabilities: Large size or complexity of agribusiness networks, high degree of monocultures, huge (spatial) production concentration, high degree of vertical integration, large scope of unregistered illicit employment especially in the service area (restaurants and bars), and intensive husbandry systems¹⁸. As institutional factors that increase the U.S. vulnerability, Parker (2005) and Chalk (2004) identified an ineffective surveillance and reporting system and a lack of knowledge about foreign animal diseases.

Food terrorism may depend on different parameters than agroterrorism since other actors are involved (e.g. processing and retail systems). However, it is to assume that a similar risk could be identified for the U.S. food chain.¹⁹ Given the above highlighted limited data availability, the protection level achieved by the implementation of the BTA cannot be evaluated. Here, further research is necessary.

3.2.2 Harmonization and scientific risk assessment

In this section it will be evaluated whether the BTA provisions are following the SPS criteria for harmonization by recommending international standards or justifying stricter standards by a scientific risk assessment. Given that different types of international standards exist for dangerous substances and for import regimes, the analysis will be separate for these areas: First, the covered hazardous agents of the BTA are compared with international standards, and second the outlay of the measures that are used to achieve the U.S. protection level will be analyzed with respect to international provisions.

3.2.2.1 Harmonization as regards addressed hazards

The identification of hazards is the starting point for the CAC risk assessment process. However, the bioterrorist relevant hazards are not specifically addressed in Title III of the

¹⁸ The modern husbandry system can increase the vulnerability of livestock to diseases due to the high densities.

¹⁹ The risk assessment undertaken from official site came to a similar finding for food terrorism. They conclude “that there is a high likelihood, over the course of a year that a significant number of people will be affected by an act of food terrorism” (FDA 2003b, p. 8). Note that the official risk assessment related to the BTA legislation is not publicly available. Only a brief qualitative summary is accessible.

BTA and only the very general statement on relevant hazards in the form of “bioterrorist threats to the food supply” is provided (Section 301a).²⁰

BTA provisions

The application area of the BTA is not restricted to certain potentially hazardous substances as the BTA addresses without any substance-related differentiation all FDA products similarly (table 1). Nevertheless, the BTA regulates the possessing and transfer of listed agents and toxins under another title: Title II on “Enhancing Controls on Dangerous Biological Agents and Toxins” rules the authorization of laboratories dealing with these substances. The listed agents serve as indicators for what the U.S. in general defines as crucial hazards even though not explicitly related to food.

The agents referred to by the BTA are defined by different U.S. agencies: APHIS lists 52 agents as potentially bioterrorist dangerous.²¹ The USDA identifies 43 livestock pathogens and toxins dangerous for animals and plants and the Centers for Disease Control and Prevention (CDC) identify 37 bioterrorism agents especially with impact for human health.²² Comparing all domestic lists overlaps can be identified (Monke 2005), but the relevant focus in this analysis lies on a comparison of the domestic lists with existing international standards.

The analysis will focus on agents and toxins with impact on public health. Therefore all addressed animal diseases are zoonotics²³ and the list of the USDA that is restricted to animal and plant health is excluded.

²⁰ Additionally, a further challenge for this analysis lies in the fact that - at least to our knowledge - the BTA is the first *trade related* legislation written with explicit reference to the prevention of bioterrorism attacks. Furthermore, no WTO dispute case ever has been brought up in the international dispute settlement framework that could provide guidance on the definition and evaluation of protection measures against these sorts of incidents.

²¹ Title 7 CFR, Part 331, Title 9 CFR, Part 121 and Title 42, Parts 72 and 73, March 18, 2005. Available at http://www.aphis.usda.gov/programs/ag_selectagent/ag_bioterr_toxinlist.html at 17 July 2005.

²² CDC standards are available at <http://www.bt.cdc.gov/agent/agentlist.asp>, at 17 July 2005.

²³ Diseases that may spread from animals to humans.

International standards

With respect to the international standards, it is important to distinguish that the type of coverage can be different for the CAC and for OIE, the two relevant standard setting bodies:

- One traditional area of Codex' standards are product standards that are for instance addressed by maximum residua levels for substances. These standards though are not expressed for any of the bioterrorist agents. More relevant are processing standards for which the Codex developed a several ones. Examples are “General principles of meat hygiene (CAC 2003a) relating to influence on staphylococcus, or “Guidelines for canned products” (CAC 1985) influencing the contamination with Botulinum neurotoxin.
- The OIE standards of the Terrestrial Animal Health Code (“The Code”) defines health measures to be used by the veterinary authorities of importing and exporting countries (OIE 2004a).²⁴ Relevant for the following analysis are the standards of the “Code” with regard to the requirement of notifying certain diseases (OIE 2004, part 2).²⁵

Evaluation

The following table summarizes the comparison of agents relevant for public health addressed in the BTA and by international organizations. The comparison only refers to the general coverage i.e. whether hazards are tackled in any manner by not looking at different instruments to address them.

With respect to the BTA references, for six agents the APHIS list is more comprehensive than the CDC list (marked in grey). On the other hand four agents are not covered by APHIS although listed by the CDC, among which the Salmonellosis can be mentioned.

²⁴ The other catalogue of standards is the “Manual of Diagnostic Tests and Vaccines for Terrestrial Animals” (“The Manual”). This is covering detailed diagnostic procedures for the help of any veterinary (or parasitologic) diagnostic laboratory (OIE 2004b). Both categories of standards exist specifically for “aquatic” animals.

²⁵ Diseases to be notified fulfill criteria of international relevance – i.e. they should have the potential for international spread and for human infections or causing other relevant diseases.

Table 4 Comparative coverage of food terrorist agents with public health impact

BTA reference		International Organizations	
APHIS	CDC	OIE	CAC
Antrax	X	X	
Botulinum neurotoxins	X		X
Botulinum n. producing species of Clostridium	X		X
Brucella abortus	X	X	X
Brucella melitensis	X	X	X
Brucella suis	X	X	X
Burkholderia malle	X	X	
Burkholderia pseudomallei	X	X	
Clostridium perfringens epsilon toxin	X		X
Coccidioides immitis	-	X	
Coxiella burnetii	X	X	
Eastern equine encephalitis virus	X	X	
Francisella tularensis	X	X	
Hendra virus	-	X	
Nipah virus	-	X	
Rift Valley fever virus	-	X	
Shigatoxin	X		X
Staphylococcal enterotoxins	-		X
T-2 toxin	-		X
Venezuelan equine encephalitis virus	X	X	

Source: Own compilation based on information from APHIS, CDC, CAC, OIE and Monke 2005.

The comparison of the BTA agents with internationally covered agents shows that all zoonotics are tackled by both frameworks and therefore the BTA cannot be seen as stricter (Monke 2005). According to Article 3 of the SPS Agreement no risk assessment would be necessary to justify a stricter or more comprehensive coverage of identified hazards with impact on public health.²⁶

²⁶ When extending the analysis to agents that are only dangerous to animal and plant health, the BTA is stricter than the OIE in three cases: Akabane, Camel pox, and Menangle (Monke 2005). The likelihood of a possible human infection with Menangle is currently discussed in the scientific community (OIE 2004c). If that would be proved the BTA would be stricter as well for agents dangerous for human health.

3.2.2.2 Harmonization as regards enforcing measures at the border

Manifold instruments can be used to achieve a domestic protection level. The instruments of the BTA can be classified as process standards and as administrative import rules (Josling et al. 2004, p.18). Respective international standards are covered by different agreements but we still focus on food specific measures as ruled under the SPS-Agreement and the recommended organisations.

BTA provisions

The BTA measures can be summarized according to their general objectives as (1) informative requirements targeted by registration and agent definition, prior notice and record keeping and as (2) controlling measures implemented by the provisions on detention. As regards the information objective the BTA requires highly individualized information, i.e. at the single companies' level. As regards the control imports may be detent due to a failure in fulfilling the BTA provisions.

International standards

For these categories international counterparts exist. These counterparts are not necessarily reflecting precise standards for import controls (e.g. frequency of controls) but rather more often just broad frameworks and principles to be considered are developed on the international level (CAC 2003b). This flexible character of the import rules makes it difficult to evaluate whether international standards are fulfilled.

Evaluation

The major difference between the BTA and international standards concern the first category, the information addressee and the required *information criteria*: Whereas the international organisations demand regionalized information the BTA's addressee is the individual company. International guidelines require risk-specific and regional information as specified for example for anthrax in the OIE "Code", Article 2.2.1.2 (OIE 2004a) or on certification schemes (CAC 2000). Here, specific requirements to be covered by a certificate are defined in detail for each single disease. The type of information required by the BTA differs in this respect as no disease-specific but traceability-related information is requested. This identified difference between

information requirements of the BTA and existing international guidelines does not allow drawing the conclusion that the BTA is stricter than the SPS Agreement requires.

Information about process standards is more individualized and flexible than product standards: With regard to the risk status, the burden of proof lies with the exporter to demonstrate the risk free status (Brückner 2004, p. 10). Therefore, the option for additional measures to control the validity of the process standards is granted. Often import permits are based on additional evaluation of on the spot conditions, on a comprehensive assessment of regulatory programmes and quarantine procedures leading in the end to individualized information similar to those of the BTA.

Related to *controlling measures* the BTA defines only the provision of detention if there is credible evidence whereas the OIE defines risk-oriented minimal duration periods for quarantine (OIE Code, Appendix 3.51) or rules for the diagnostic procedures to be undertaken at the border (OIE Code, Appendix 2.10.1.4.). It is important to state that neither the Codex provides specific standards for import control systems in terms of frequency (CAC 2003b, CAC 1995) nor does the BTA specify its sampling procedure and frequency. In this regard no deviation of the BTA from international standard can be seen.

The identified distinctions between the BTA and international guidelines are by nature linked to the different purpose: The BTA addresses explicitly bioterrorism incidents whereas the international organisations aim at food safety and least-hindered trade. Given the flexibility of the respective international standards, the BTA cannot be evaluated as being stricter.

3.2.3 Specific design of the enforcement measures

3.2.3.1 Non-discrimination and national treatment

Formally all BTA provisions are applicable to all importers leading to *non-discrimination*. However, there may be some factual different effects because of individual trade patterns: If some trade partners had certain bilateral arrangements facilitating trade prior to the adoption of the BTA, their situation has become comparatively worse in relation to other countries (see on empirical evidence chapter 4).

Similar findings might hold with respect to product categories and size of import quantities leading to different individual country effects. However, as these effects are usual adjustments of trade patterns due to changed legislation, the provisions of the BTA cannot be interpreted as discriminatory.

Formally, *national treatment* is ensured as well as the BTA provisions are applicable to both, domestic and foreign producers. But because some provisions are not relevant for domestic producer their economic burden may be lower:

- Designation of a U.S. agent is not relevant for U.S. firms. Since there is already established a professional market offering the agent's services to foreign companies²⁷, this provision must be seen as problematic in the international framework as it certainly leads to a compliance cost difference between domestic and foreign producers. The specific burden for foreign companies is depending on the transactions costs and fees for finding and maintaining such agents.
- Prior notice of imports is not relevant for domestic producers. Hence, they are not facing delays in border processing as importers do. An evaluation of related costs identify significant relative burden for foreign companies (see "Analysis of Economic Impacts" as provided in FR 68, Vol. 197, p. 59023f).
- Differences may also refer to the frequency of controls either at the border or critical points in the domestic supply chain. Further empirical research would be necessary to elaborate on this issue.

3.2.3.2 Equivalence

While international standard setting aims at harmonizing the individual food safety levels, equivalence targets at the harmonization of specific measures to achieve the protection level. The SPS Agreement encourages explicitly bilateral consultations on equivalence and refers to international guidelines for conformity assessment. In principal, this provision recognizes that regulatory flexibility allows countries to allocate resources efficiently rather than identical (Josling et al. 2004, p. 48).The burden of proof for

²⁷ One examples for such services is the company U.S. Food Agents, requiring around 600 \$ for providing an agent for a facility per year. See <http://www.usafoodagents.com/pricing.html#BPP>, July 2005.

demonstrating equivalence lies with the exporter. Hereby, the scope for unhindered trade based on equivalence is restricted since the failure of proof may allow for additional import requirements. The most relevant provisions in existing equivalence agreements refer to process standards rather than to product standards. Compliance with existing international product standards is more easily to be determined at the border as they can be checked directly by means of product characteristics. Therefore, Equivalence Agreements on product standards would not add any value. Process standards as search or trust characteristics (Caswell 1991) are more difficult to be controlled at the border and rely on the overall food safety system in the partner's countries (OECD 1994). In this category most OIE and IPPC standards are located, and hence offering potential for trade facilitation by equivalence acceptance. However, only very few equivalence agreements exist as administrative transaction costs for negotiating and accepting equivalent measures are seen to be very high.²⁸

The resulting difficulties with actually adopting equivalence agreements was a topic of a WTO SPS committee meeting and addressed steps that are necessary for fulfilling the equivalence process (WTO 2003, p. 12 and Brückner 2004, p. 98ff.). Some guidelines to support the process of negotiation and design of an Equivalence Agreement exist (CAC 1999) Besides the Veterinary Agreement with the EU, additional equivalence acceptance exists only for selected meat or dairy products with selected partner countries (APHIS 2004): In 2002, the U.S. granted altogether for 1080 establishments for meat and poultry imports equivalence. Most of the covered countries, except Japan, belonged either to NAFTA (92.5% of all granted equivalence) or European countries (7%) (George 2003). With other trading partners, as for example Chile, free trade agreements might exist that address SPS measures and target at an enhancement of cooperation and implementation of SPS related issues (see Chile-US Free Trade Agreement, par.6)²⁹.

The provisions of the BTA clearly overrule existing provisions within the bilateral agreements as far as FDA products are concerned. Meat and poultry products of the U.S.-EU Veterinarian Agreement are not addressed by the BTA and therefore, agreed import

²⁸ The Veterinarian Agreement between the U.S. and the EU, signed in 1999, took six years of negotiations (Josling et al. 2004, p. 49). This agreement defines equivalence for selected animal products.

²⁹ See http://www.ustr.gov/Trade_Agreements/Bilateral/Chile_FTA/Final_Texts/Section_Index.html

protocols should be still valid.³⁰ For other products, as for example live fish and seafood, the BTA provisions are applicable. For such countries, beforehand benefiting from easier import procedures, a relative disadvantage under the new regime can be expected and will be analyzed subsequently empirically.

3.2.3.3 Least-trade distortion

The measurement of least-trade distortion according to Art.5.6. of the SPS Agreement requires a comparative analysis of alternative import regimes that achieve the appropriate level protection. Because of the described constraints in evaluating the appropriate level of protection, the following evaluation will not cover such a comparative analysis of alternative trade measures. Hence, a first simplification in the analysis is that only the BTA provisions will be analyzed and no other alternative measures. A second simplification relates to the fact that trade distortion will be assessed by the trade impact as proxy. This is possible since we assume that less trade impact goes along with measures that tend more towards being less trade distorting. Hence, for provisions that are found to be without prejudice to trade, we assume that they are less (or not more) trade distorting than any other potential alternative. However, the question if they are the least-trade distorting way of implementation is not possible to another with this procedure. A third simplification is related to the other requirement of Art. 5.6: The technical and economic feasibility of the measure. In some cases this might lead to a result where an import ban is the only answer to a health, sanitary, or phytosanitary risk since all other measures of protection would be either too costly to implement or not provide the same level of protection.³¹ As we are not comparing different alternatives for the U.S. to enforce their protection level comparative conclusions on economic and technical feasibility cannot be drawn.

³⁰ However, further information for a final evaluation is necessary. Due to the short time since the BTA inception and the shared objective to improve the security of the food supply, further bilateral communication between partner countries is necessary in order to clarify the new scope of existing agreements. For example the EU, as well as Canada, are engaged in bilateral discussion with the U.S. about trade and security issues. See for Canada <http://www.inspection.gc.ca/english/liaison/secure/20030325fse.shtml>; for the EU: http://europa.eu.int/comm/external_relations/us/intro/summit.htm.

³¹ For example, this was the case in the appellate body decisions in the two hormone cases (WTO 1998).

Cost impact and trade effect of BTA provisions

In Table 5, an overview of the cost and trade impact of the food-related BTA provisions can be found.

Table 5 Cost and trade impact of BTA provisions

Measure	Cost impact on firms	Probable trade impact of measure
Registration (US Agent)	Increases costs Increase of administrative burden	FDA estimate: 16% of foreign firms will cease imports, esp. firms with only few shipments Contribution of U.S. agent questionable: no legal liability, only communication point, emergency contact can be a non U.S. phone number Development of "Agent industry"
Record keeping	Might be covered in firms by existing record keeping systems Increase of administrative burden	Might increase quality assurance and logistics Quick response in cases of emergencies might help to keep/restore consumer confidence
Prior notice	Mostly within normal import procedure (ABI/ACS) Importers working formerly under expedited arrival procedure have disadvantages (BRASS) Problem for firms without internet access/computer equipment	Slow down of food entry into the U.S. (perishable products) Processing of data and inspection capacities questionable However: Inspections might be better targeted
Detention	Firms have to bear costs of detention (disposal reduced sales prices)	Increases uncertainty of trade (no definition of "credible evidence")

Source: Own compilation based on FDA information available in the Federal Register.

Evaluation

There are two measures from which potential trade impact can be expected. The requirement to send a *prior notice* for all food shipments has different impact depending on the import procedure prior to the implementation of the BTA. In particular Mexico and Canada, countries with formerly expedited import procedures (see FR 68, Vol. 197, p. 59028) have disadvantages with the new system since planning of shipments and entry

into the U.S. makes a longer time horizon necessary³². Furthermore, the prior notice can only be electronically submitted to the FDA, implying that firms without computer equipment and internet access either have to acquire this equipment or cease trade with the U.S. For some firms in development countries this might be a burdensome or impossible requirement, not only because of the occurring costs but also because information technology in those countries often suffers from unreliability and related problems.

With respect to administrative feasibility of the measure, however, one must add that the FDA considered comments from trading partners suggesting to streamline their import information system and made the option available to give the prior notification within the Automated Broker Interface of the Automated Commercial System (ABI/ACS) that process all other import information. In the year 2004, about 77% of all prior notice were handled over the ABI/ACS (FDA 2005).

A second potential and probably significant trade impact result from the requirements that all foreign firms must designate a *U.S. agent* that represents their company in the U.S. and is 24 hours a day available 7 days per week. Since this person only serves as a communication link between the FDA and the foreign company and no legal liability is related to the function, in theory this agent might be a private individual. In practice, the requirement to be available 24 hours a day all year long not easy to fulfil for private persons and most foreign firms are seeking some type of business partner, foreign chamber of commerce representative, or legal entity to execute that function. This results in costs that can differ considerably.^{33 34} Furthermore, it is very much questionable if this is the least-trade distorting way of implementing a “communication link” between the FDA and food producing/transporting firms, since these firms are allowed to give as an emergency contact a phone number which might be located outside the U.S. (FDA

³² However, some of these disadvantages are going to be offset by e.g. the introduction of the FAST initiative of U.S. customs that allows participating entities with a “low-risk” profile to benefit again from an expedited procedure.

³³ The company U.S. Food Agents requires e.g. around 600 \$ p.a. whereas the German American Chamber of Commerce is providing this service for 140 Euro per year for member firms (see <http://www.gaccny.com/index.php?id=71&L=1>).

³⁴ Similar critics were raised by Kerr (2004).

2004, No. 14.10). Given that the FDA estimated in its economic impact analysis of the proposed rules that up to 16% of the firms or an equivalent of up to 2% of all line entries might be affected by this regulation and cease trade with the U.S. (FR 68, Vol. 197, p. 58943) it is difficult to see that this requirement is addressed in the least-trade distorting way. The FDA expected in particular the small firms with less than 10 yearly line entries (shipments) into the U.S. to be affected by this provision.

The other two proposed measures, *administrative detention* and *record keeping*, however, should not impose too many new requirements on exporting firms, since record keeping of suppliers and recipients of products is a well established fact in many food branches³⁵. Here again however, countries with less developed food safety and traceability systems will have problems to comply. It is to assume that mainly developing countries will be affected by this provision.

In the case of the provision of *administrative detention*, procedure and trade impact is not as clear as no further specification of the “credible evidence” is given and it is difficult for firms to evaluate if their shipment might be detained due to terrorism information about their firm or products that is not available to them. A further clarification of this procedure would certainly contribute to an easier assessment.

4 Empirical evidence from trade flow data

This chapter analyzes if empirical evidence in import data can be found that the implementation of the BTA had an impact on the trade flows directed towards the U.S.

Methodological considerations

Even though the BTA provisions apply to domestic producers as well, we only focus on import data in this chapter, since two out of the four provisions, prior notice and registration with the designation of a U.S. agent, target specifically at importers and have a potential deterrent effect on trade. The focus of the analysis will lie on commodities and

³⁵ And also condition in food safety systems of other countries, as for example laid down in the food law of the EU.

countries for that we associated in the previous conformity analysis with countries being potentially adversely affected by the BTA legislation.

Following theoretical considerations as provided by Roberts et al. (1999) and Buzby (2003), and based on the evaluation of the provisions as done in section 3.2.3.3, we assume that the implementation of the BTA will lead to a cost increase in the supply of imported goods. Depending on the burden sharing of these costs, these are losses that either importers or exporters have to carry, thereby reducing their profits. Additionally, these costs could also be rolled over to consumer prices and lead to a decrease in demand of foreign products and a probable substitution of imported with domestically produced goods. These developments– if they take place – should be seen in the trade flow development over time.

Our analysis follows an approach provided by OECD (2003a) where trade flows were analyzed to deduct if average import quantities change as a result of a policy change. In performing this analysis we work with the underlying hypothesis that all deviations from past import patterns can be attributed to this policy change. This assumptions neglect other exogenous factors such as exchange rate movements, or changes in the macroeconomic or regulatory environment, that might affect trade flows and could be captured when defining a more formal model for an import flow – policy relationship. However, since our approach is rather easy to perform, this analysis provides a good starting point for a more thoroughly analysis of trade impact and might hint on sectors that are of particular interest for a more scrutinized BTA analysis.

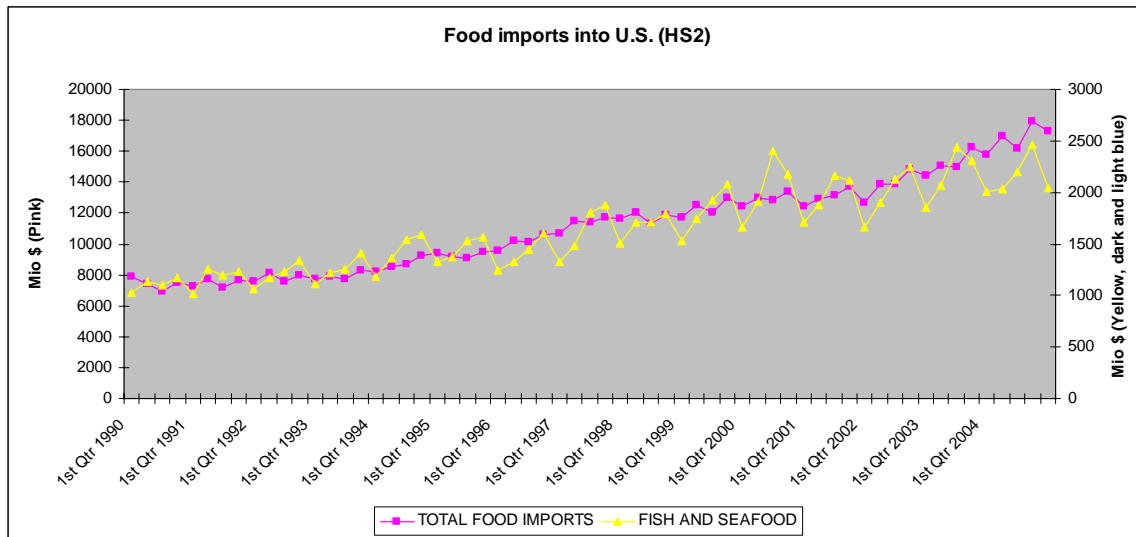
Furthermore, it is important to note that we cannot distinguish in the following analysis among the trade impacts of single BTA provisions, but rather look on the regulatory impact as a whole. Though it was possible to associate with each of the single provision a possible cost and trade impact, in the analysis of the trade data this is no longer feasible, since all measures entered into force at the same time and no further cost differentiation for the exporters is available.

Insights from trade flow data

As an introduction, in Figure 1, the development of total food imports in Mio \$ in quarterly data over the time period 1990-2004 is presented. The food imports show a

clear positive trend that prevail the development also in the last year. For illustrative purpose, we introduced as well the imports of seafood and fish. Here as well, we observe a positive trend, however, with a much seasonal variation.

Figure 1 Total food imports into U.S. (HS2)



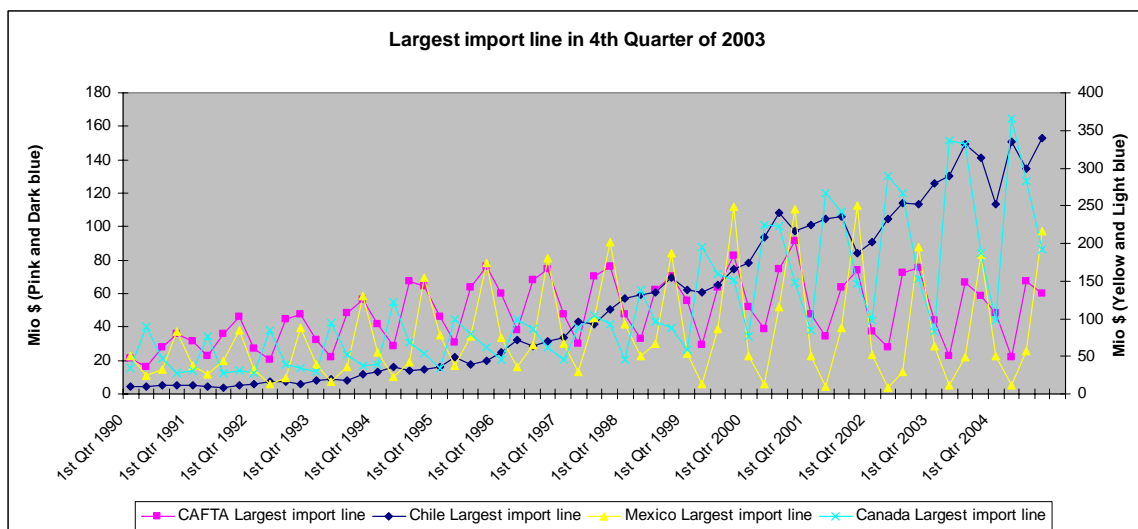
Note: Import lines are sorted according to import values in the 4th quarter of 2003.
 Source: World Trade Atlas 2005

However, this data is presented on HS2 level, a very broad food category classification which does not allow showing any substitution processes within categories and may overshadow all developments that take place in small important lines within these categories. Therefore, in the following we will present data for only one food category, seafood, and on a much more disaggregated classification. We opted for the seafood category, as seafood is the second biggest single food import category and is provided by many different countries which allow us to analyse several of the hypotheses on compliance related trade issues we identified in section 3.2.3 **Error! Reference source not found.** Furthermore, seafood is one of the products where the provisions of the BTA with respect to prior notice and registration with U.S. agent take effect.

The largest import lines within the seafood category for four important U.S. importing countries are presented in Figure 2. We opted for these four countries since they can offer a broad perspective on several issues: Canada and Mexico, neighbor countries and most important food importers into the U.S. formerly had easier market access, and Chile and CAFTA countries have close trade relations with the U.S. and both

agreed on free trade agreements in the recent time. The importing lines in this category are chosen from all import lines on HS4 level and are sorted according to the import value in the 4th quarter of 2003. For the Canada, Mexico, and the CAFTA country aggregate, these imports consists of products related to the category “crustaceans”, whereas for Chile these are all products in the category “fillet and other fish meat”. According to the previous figure on total food imports, here again, it is not visually possible to find any alteration of the import developments over time. For Chile we observe a small decrease in the 1st quarter of 2004, however, imports in the following three quarters seem to pick up again with the trend.

Figure 2 Imports of seafood: Country comparison for large import lines

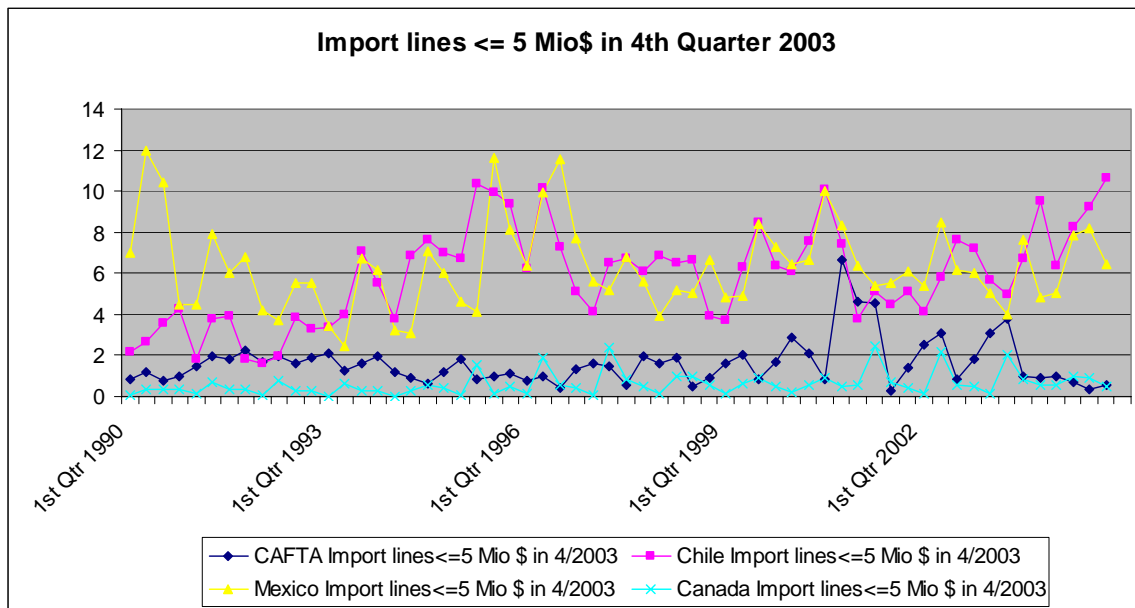


Note: Import lines are sorted according to import values in the 4th quarter of 2003.
 Source: World Trade Atlas 2005

Next, we are focusing on the smallest import lines of these countries in the seafood category (Figure 3) since we argued in the last chapter that smaller import lines may be affected by the additional cost burden introduced by the legislation. The smallest import line is the sum of all import lines that show an import value of less than 5 Mio \$ in the 4th quarter of 2004. For the CAFTA countries, this aggregate consists of 4 import lines (dried/salted fish, frozen fish not fillets, other seafood, live fish), for Chile this sum contains also four items (dried/salted fish, crustaceans, other seafood, live fish), Mexico’s aggregate is built on five import lines (dried/salted fish, frozen fish not fillets, other seafood, live fish, fillet and other fish meat), whereas for Canada this import aggregate

consists only of one import line (live fish). Contrary to the previous figures, these import lines provide a different picture. Here, a clear decrease of imports is observable for the countries Canada and CAFTA after the BTA entered into force. This figure seems to indicate that there might actually be costs related to compliance with the implementation of the BTA that makes it prohibitive for some firms to keep up their trade relations with the U.S.

Figure 3 Import of seafood: Country comparison for small import lines

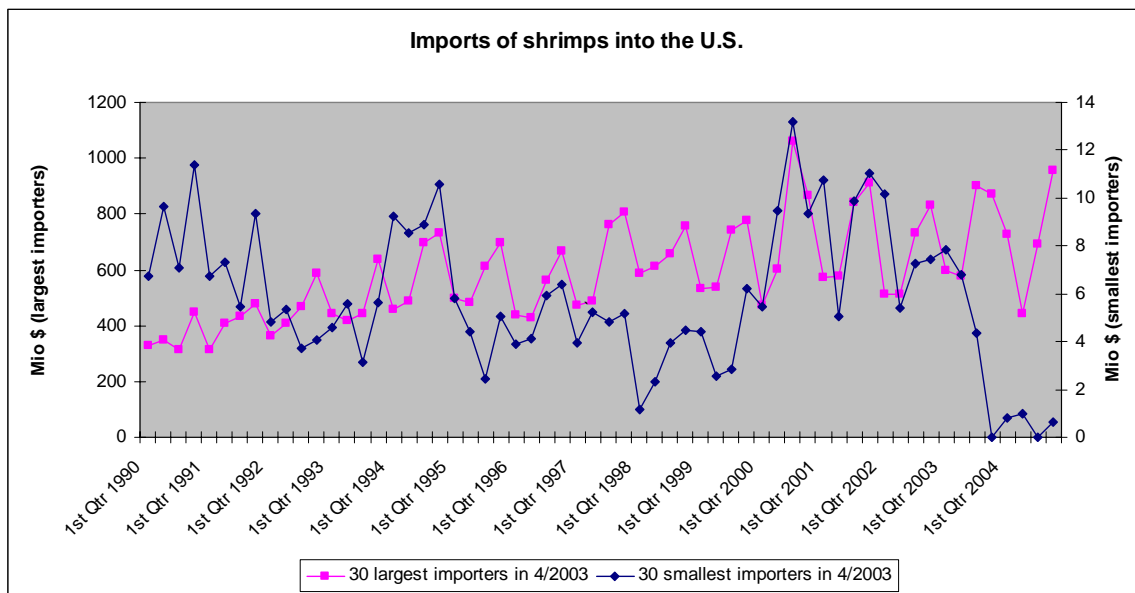


Note: Import lines are sorted according to import values in the 4th quarter of 2003.
 Source: World Trade Atlas 2005

In order to further scrutinize on the finding that the smaller import quantities might be adversely affected by the BTA, we chose one product from the HS4 food category “crustaceans” and did a similar aggregation, however, across all countries importing into the U.S. The chosen product is “shrimp and frozen prawn”, since it shows the largest import values within this category. The total number of importers over the depicted time period is 117. Hence, we aggregated the import values of the 30 largest and smallest importers to one import line, respectively. Again, the ranking of small and large importers were done according to import values in the 4th quarter of 2003. The result can be seen in Figure 4. Here, the effect, indicated in the last figure is even more pronounced: In the first quarter of 2004, we observe a strong reduction of import levels and even

though imports go slightly up in the following period they do not again reach historical levels. We take this as a further indication that the BTA legislation has some or even significant impact on trade. Depending on the country perspective and the amount of imports affected it that might be the case that the impact is even stronger than to be called only least-trade distorting. It is worthwhile to note that under these countries that seize or strongly reduce trade with the U.S. are a number of developing countries (e.g. Senegal, Somalia, Gambia), but also some developed (e.g. New Zealand, Portugal).

Figure 4 Shrimp imports: Comparison of countries with large and small imports



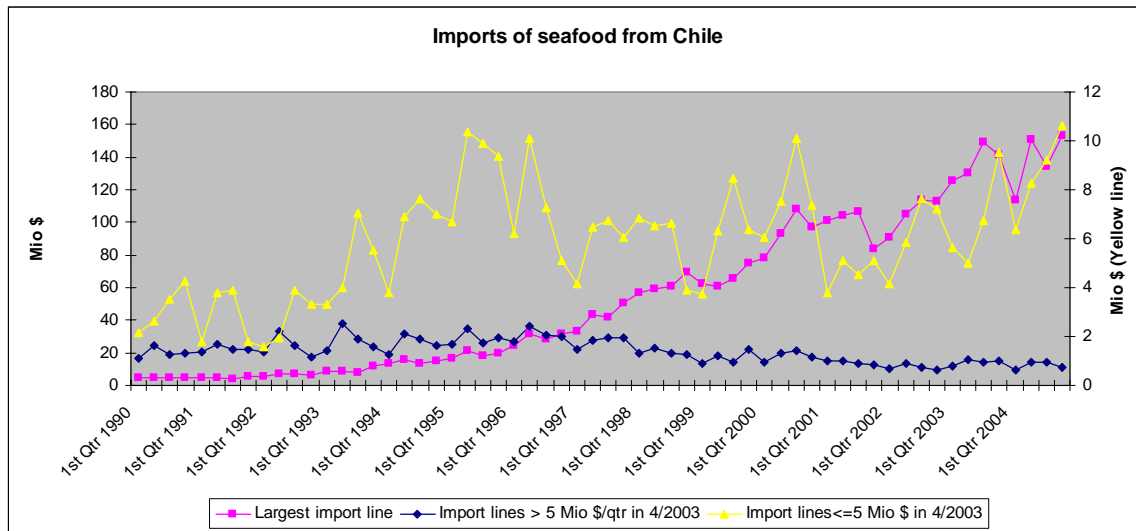
Note: Import lines are sorted according to import values in the 4th quarter of 2003.
Source: World Trade Atlas 2005

As a last point on the agenda, we wanted to focus on the import development of a country that is partner in a free trade agreement with the U.S. covering some food relevant provisions and hence benefited from some import facilitation.³⁶ Accordingly, in Figure 5, seafood imports for Chile are presented and the same import line aggregation as before is used. The overall picture from this figure is that at least on the first sight no clear changes in import patterns are observable. However, for all three import lines, a slight depression in the first quarter of 2004 is recognizable which might hint at an adjustment process that

³⁶ See Chapter V of the US-Chile Free Trade Agreement (See http://www.ustr.gov/Trade_Agreements/Bilateral/Chile_FTA/Final_Texts/Section_Index.html).

took place in that time in order to comply with the new rules. This is further underpinned by the fact that this sort of depression is not evident for other years, but of course, a better analysis of the seasonal pattern would be necessary, to put this finding on safe ground.

Figure 5 Imports of seafood from Chile



Note: Import lines are sorted according to import values in the 4th quarter of 2003.

Source: World Trade Atlas 2005

Similar examples as shown for seafood could be found on a disaggregated product level for selected alcoholic beverages, coffee and spices, as well as for selected countries. However, on the other side there are also food categories, as e.g. vegetables, where no effects could be found.

Conclusion

This preliminary trade flow analysis shows that potential trade impacts from the BTA implementation can be expected. However, it should be again underlines that in order to come to meaningful and more robust results, a statistical verification of these effects is necessary. A further drawback in the analysis is, that since the inception of the BTA only one year has passed and available observations are scarce. It is to assume that over times firms are able to adapt to the new standards and that imports will move back towards old import levels.

5 Putting the BTA in a broader perspective: Further issues for research

Given that there is only very limited experience with food terrorism attacks and design of regulatory protection frameworks against these effects, this work provides an introduction for a framework of analysis. However, in the course of the work there were several areas where only preliminary assessment could be offered as either information was scarce or the methodological framework is not yet well elaborated. Hence, in the following we want to address these issues briefly and show potential for further work.

In regard to the *WTO conformity assessment* it would be necessary to expand our food-related framework to all relevant WTO provisions. In particular, the specific rules on trade facilitation like the Agreement on Preshipment Inspection and the overall provision to protect national security under GATT-Article XXI could supplement the analysis. Additionally, the evaluation of *national treatment* would need further information on different impacts for domestic and foreign producers due to diverging requirements of the BTA (e.g. the requirement of determining a U.S. agent or potentially different testing frequencies). Here, empirical data of related costs like transaction costs caused by the search for an agent or the level of fees may be considered.

The discussions on *risk assessment* showed that the identification and evaluation of the appropriate level of protection is difficult due to limitations in determining probabilities and damage. In order to use information from past food contamination events, a clear indication and separation of the analyzed cases in terms of the underlying terrorist definition and more specific information on the damages are necessary. The evaluation of existing approaches as applied in other areas such as nuclear power or the use of genetically modified organisms may contribute to this issue.

Subsequently, a risk assessment analysis based on a *cost-benefit analysis* could be possible where the *benefits* correspond to the reduction of food terrorist damages. Related to the *costs*, implementation related compliance costs are a first component. Here, only a few empirical studies on the assessment of these costs on firm level exist, though they indicate the high importance of these costs. More analysis could provide interesting insights for the future design of legislations and might contribute to a better

understanding of why certain product categories are affected differently than others. A second component on the cost side would be foregone trade gains due to less imports and herewith related effects on price or consumer choice. Such a comprehensive cost-benefit analysis would require a clear identification of single relevant parameters influencing costs and benefits and could serve to evaluate the welfare effects of different measures. Related to this, the provisions of the BTA could be furthermore analyzed in the more general context of efficient risk management strategies, i.e. a comparative cost analysis of different measures that are applied to achieve certain risk reduction levels. Again, this strongly depends on an appropriate risk assessment that allows specifying certain risk levels.³⁷

Regarding the *empirical analysis of trade flows*, an extension of the analysis toward firm samples or more disaggregated product categories promises to be fruitful and could provide more insight on adaptation processes in the affected industries. Similarly, a more detailed analysis for country groups, for example related to their developing status, could hint on specific implementation problems faced by these groups. Additionally, the time span of imports under the new legislation is rather short. In this situation, it would be interesting to see, if the indicated trade effects persist over time and what adaptations take place. Lastly, all sectoral *interdependencies* leading to price and productions effects in up-and downstream markets both domestically and internationally have been neglected, but certainly provide an interesting field for analysis.

6 Conclusion

The analysis showed the general difficulties in evaluating trade effects both, qualitatively and quantitatively, for the increasingly relevant NTB group of administrative import measures. In particular, the link of the U.S. BTA administrative rules to the issue of bioterrorism makes the analysis difficult: Whereas the analyzed WTO rules are targeted

³⁷ Related to this context is the question whether the provisions in existing food safety laws in most countries and for which the SPS Agreement provides the international rules, are sufficient with respect to terror prevention or whether some additional explicit terrorism provisions as implemented by regulations like the BTA are superior. The EU referred to these arguments in its submitted comments on the BTA stating that existing food rules like rapid alerts systems would be sufficient (EU Commission 2002 and 2003).

at food safety, the BTA is explicitly aimed at biosecurity in terms of reducing bioterrorism risks. This emerging new area of bioterrorism risk is by nature linked to food trade without having a direct counterpart in the frame of the SPS Agreement. The analysis of the question regarding whether the BTA is stricter than existing SPS rules highlights the underlying issue of flexibility in the area of process standards which are the relevant standards in the area of administrative import provisions. This was shown for the example of information requirements where international guidelines grant scope for individual adjustments. This flexibility facilitates disease and risk appropriate reactions by the importing country, relevant in preventing the spread of diseases, but constrains the evaluation whether international standards are overruled.

This general finding may be relevant for the future debate on trade facilitation. It is expected that the question will not only be raised with respect to the design of least-trade distorting measures but also on how binding existing international standards should be defined. This is relevant a relevant point when trade facilitation should be realized by harmonization of existing legislation since this requires to set a standards “corridor” around given international benchmarks.

The results of the empirical trade flow analysis illustrate comparative burden differentiation between countries. These differences can be caused by adjustment and learning costs that may differ among countries³⁸: For countries facing an more open import environment prior to the legal amendment due to expedited import procedures, free trade agreements, or equivalence agreements, adjustments may be relatively higher than for countries used to strict rules. The same is true in relation to products for which stricter rules are in place under the BTA. Other results indicate the “fixed cost” character of administrative import rules as small import quantities are affected most. A special problem may appear for developing countries that are lacking technical or human resource capacities to comply with these administrative rules. Additionally, they often import only small lots which imply an over-proportional cost increase. Furthermore, they are often importers of those products for which major regulatory changes could be identified (e.g. selected seafood).

³⁸ One may take these trade losses also to approximate learning costs.

If part of the questions outlined in the last chapter could be answered in the future, contributions to a better understanding of the actual trade effects in the area of trade facilitation could be made. By identifying more efficient and administrative trade measures, transaction costs could be reduced and overall welfare increased.

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