

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

## Das Bioterrorismus-Gesetz der USA und der internationale Lebensmittelhandel: Bewertung der WTO-Konformität und Auswirkungen auf bilaterale Importströme

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### Abstract

The September 11<sup>th</sup> event focused the world's attention on the threat of bioterrorism on the food chain. As a consequence, the USA implemented the Bioterrorism Act (BTA) containing new import requirements that can be classified as non-tariff barriers (NTBs). This paper analyses these NTBs by performing an assessment of WTO conformity and trade impact: hereby general problems in the analysis of bioterrorist risks are explored as for this new and unknown threat explicit WTO rules are still missing. Additionally, in exploring the BTA relevant process standard rules laid out by the WTO, the analysis indicates the extensive flexibility provided in this framework. This leads to larger scope for national policies on process standards compared to product standards (e.g. residual levels). The empirical trade flow analysis illustrates differences in the compliance costs between countries. This differentiation can be caused by learning costs that may differ among countries. The analysis highlights that perishable products and countries with small import quantities are mostly affected.

### Key words

food terrorism; non-tariff barriers; trade facilitation; Bioterrorism Act; international food trade; SPS Agreement

### Zusammenfassung

Durch den Terroranschlag vom 11. September 2001 wurde dem Risiko bioterroristischer Attacken auf die Lebensmittelkette neue Aufmerksamkeit zuteil. Die USA verabschiedeten als Reaktion den "Bioterrorism Act" (BTA), der neue Importregelungen formuliert, die als nicht-tarifäre Maßnahmen (NTBs) bezeichnet werden können. Der vorliegende Artikel analysiert diese NTBs hinsichtlich ihrer Konformität mit WTO-Regeln und ihrer Handelseffekte: Hierbei zeigen sich grundsätzliche Probleme für die Beurteilung bioterroristischer Risiken als neue und bislang unbekannte Bedrohung für die explizite WTO-Regeln fehlen. Weiterhin wird die große Flexibilität deutlich, die die WTO im Bereich von Prozessstandards, zu denen die BTA-Regelungen zählen, gewährt. Hieraus resultiert ein größerer nationaler Spielraum der Politikgestaltung bei Prozessstandards im Vergleich zu Produktstandards (z.B. Grenzwerte für Rückstände). Die empirische Analyse der Handelsströme verdeutlicht unterschiedliche Kosten der Anpassung an die neuen BTA-Regeln in einzelnen Ländern. Diese Unterschiede können begründet sein durch national unterschiedliche Lernkosten. Die Analyse zeigt auf, dass leicht verderbliche Produkte und Länder mit geringen Importmengen am stärksten betroffen sind.

### Schlüsselwörter

Bioterrorismus; nicht-tarifäre Handelshemmnisse; Handelserleichterung; Bioterrorismus-Gesetz; Lebensmittelhandel; SPS-Abkommen

### 1. Introduction

As a response to September 11<sup>th</sup>, the U.S. implemented several security measures to ensure the safety of U.S. infrastructure and the food chain. To address this new threat, current food safety and security systems have been bolstered and new regulatory authorities created. Furthermore, 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* of 2002 ("THE BIOTERRORISM ACT", BTA, CONGRESS OF THE U.S., 2002), entering into force December 12, 2003.

After the notification of the BTA as a sanitary and phytosanitary measure to the World Trade Organization (WTO), the European Union (EU) as well as several other countries raised concerns about the widespread trade impacts and costs of this regulation for imports (WTO, 2003): the main objections referred to the scientific justification of the import requirements and the potential discrimination of foreign companies over U.S. companies. Even though no dispute settlement procedure was initiated, smoothness of trade seems not to be satisfying as the BTA is still a point on the agenda of meetings of several organizations (e.g. EUROPEAN COMMISSION, 2004).

National food law focuses on the prevention of unintentional pest introduction or food adulteration<sup>1</sup>; however, since the events of September 11<sup>th</sup>, 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: 593; following CARUS, 2001: 3). *Food terrorism* specifically is defined by the World Health Organisation (WHO) 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

<sup>1</sup> For instance, New Zealand adopted its general Biosecurity Strategy in 2003 and the EU's new General Food Law was amended in 2003.

populations and/or disrupting social, economic or political stability” (WHO, 2002: 8). 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.<sup>2</sup> This analysis is based on a slightly modified WHO definition since we only focus on food terrorism resulting from biological agents.

Administrative, information related import regulations as those addressed by the BTA are examples of non-tariff barriers (NTBs). NTBs can be defined as “any device or practice other than a tariff which directly impedes the entry of imports into a country” (HILLMAN, 1991: 8) as for example quantitative restrictions, technical regulations regarding product and process standards, and labeling or packing requirements. Administrative import requirements may hinder trade because of data and documentation demands, a lack of transparency on requirements and audit-based controls, a high degree of unpredictability, and a lack of automatization of procedures or co-operation between agencies (NATIONAL BOARD OF TRADE, 2002).

Studies on methodology and analysis of NTBs and the effects of trade facilitation have increased in the recent past, however, empirical and 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, studies that quantify the impact of import regimes are very rare or use data that is rather old. However, a comprehensive OECD study (OECD, 2002) summarizes the results of existing studies on the quantification of the costs of trade regimes, and identified the potential relevance of those measures: a cost range of 2% to 15% of the trade transaction value is assessed depending on covered cost components and methodological approaches (OECD, 2002: 12).

The objective of this paper is to provide an introduction on scope and impact of the very recently implemented administrative NTBs in the BTA. First, we systemize the BTA provisions within the relevant WTO framework based on a qualitative *inventory approach* (MOENIUS, 1999; HENSON et al., 2000; OTSUKI et al., 2001a) and subsequently, an *evaluation* of the measures regarding *conformity with the WTO principles* of the Sanitary and Phytosanitary (SPS) Agreement takes place. Finally, to show potential trade impacts of the legislation we provide *evidence on the development of the import pattern* of food imports before and after the BTA implementation. Our analysis has an explorative character given that in the area of probability and damage assessment of food terrorism acts, and information-related, administrative NTBs only limited research has been done and the framework for conformity analysis and measurement is not clearly defined yet.

<sup>2</sup> Some authors also use the term *agrorterrorism* when referring to the specific risks agricultural production and the food chain are exposed to.

## 2. Import rules under the Bioterrorism 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” (preamble of the BTA) by providing additional information and action tools to the administration.<sup>3</sup> The relevant rules for food products<sup>4</sup> cover the following four provisions:

1. *Administrative detention* of food is possible<sup>5</sup> 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, authorities are allowed to debar persons or firms from imports into the U.S. when they repeatedly violate the import regulations set out in this act (Section 304).
2. *Registration of food facilities and determination of an agent is required* (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 Food and Drug Administration (FDA). Domestic facilities must register whether or not their food enters interstate commerce, foreign facilities must additionally designate a U.S. agent that can be any entity or individual person who lives or maintains a business place in the U.S. and is physically present in the U.S.<sup>6</sup>
3. *Establishment and maintenance of records is required* (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.<sup>7</sup> Source and recipient of all food items must be recorded including address, type of food, brand, variety, type of packaging, and receive and delivery date. Records must be kept for six month to two years, depending on the nature of the food item, and must be accessible within 24 hours.

<sup>3</sup> 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>).

<sup>4</sup> “Protecting Safety and Security of Food and Drug Supply” is Title III of the BTA. Another relevant title in the following analysis is Title II “Enhancing Controls on Dangerous Biological Agents and Toxins” aiming at the control of domestic laboratories using certain agents and toxins.

<sup>5</sup> 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 (FD&C 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.

<sup>6</sup> All facilities regulated exclusively by the United States Departments of Agriculture (USDA) and private residences of individuals with food manufacturing or storage capacities, farms, restaurants, retail food establishments, non-profit food establishments, and fishing vessels are excluded.

<sup>7</sup> Exclusions apply again to the group of facilities listed in the registration provision.

**Table 1. Changes in the import requirements for specific food categories due to the BTA**

Product group	Basic legislation	Provisions in place prior to BTA supplementing the general import rules	Stronger provisions in BTA
<b>Food categories not covered by the BTA (USDA authority)</b>			
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	not applicable
<b>Food categories covered by the BTA (FDA authority)</b>			
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.	(+)
Other food items (e.g. pasta)	FD&C Act	No specific requirements	(++)

Note: For alcoholic beverages, the Bureau of Alcoholic, Tobacco and Firearms is administering the Federal Alcohol Administration Act.

() indicates no or only minor changes due to the BTA provisions.

(+) indicates stronger provisions in the BTA in terms of prior notice, record keeping, and detention.

(++) indicates stronger provisions in the BTA with respect to all four provisions.

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

4. *Mandatory prior notice of food shipments* (Section 307) implies that 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 five 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.<sup>8</sup>

Whether these rules are applicable to a specific product depends on the respective institutional competence (FDA or USDA) and only products under the responsibility of the FDA are affected by the new rules. Table 1 provides a summary of the most important import requirements that were in place prior to the BTA.<sup>9</sup> The previously enforced so-called "general import procedure" was easier especially in terms of the notification time frame for entry of food

shipments, the registration of food facilities, and the record keeping obligations. According to this 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: 58976).

However, some product categories faced more detailed import requirements already prior to the BTA enforcement and therefore the BTA does not lead to a stronger import protocol for these products. Depending on the category, these requirements consist of a registration of the food facility and specific product information that had to be filed 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 (e.g. HACCP) 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 initiated and relate to the above described information requirements and the timeliness of the import process.<sup>10</sup>

<sup>8</sup> 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.

<sup>9</sup> The basic reference for product and admissibility standards is the FD&C Act, but there exist numerous other laws that regulate the production and marketing of food products (e.g. Fair Packaging and Label Act). Further information can be found in FAS (2001).

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

The group of "other food items" faces the most drastic changes due to the BTA implementation as formerly no special requirements in addition to the general import procedures was in force. Depending on the ability of firms to adjust to these new components in the import protocols, this may lead to product and country specific trade impacts.

### 3. WTO conformity assessment

WTO disputes on NTBs and in particular trade facilitation measures gain increasing relevance.<sup>11</sup> A WTO compliance evaluation of an import regime may not only avoid extensive dispute activities but also improve the design of such measures. Since the BTA has been notified to the WTO under the SPS Agreement<sup>12</sup>, our analysis focuses on the food safety related trade provisions as covered by this agreement, but it is important to note that there are several other WTO Agreements that may be relevant for trade regimes and bioterrorism.<sup>13</sup>

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

The overall objective of the SPS Agreement is to minimize the trade effects of SPS measures without prejudice to the sovereign right of members to define a national protection level (JOSLING et al., 2004: 37). The specific 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 targets at the appropriate protection level chosen by a country whereas the second set is linked to the specific measure used to enforce the protection level at the border (WTO, 1994):

1. The *appropriate level of protection* should be based on risk assessment considering an evaluation of probability and damage (Art. 5). *Harmonization* of these protection levels is targeted by the WTO recommendation to *apply international standards* that deemed to be scientifically necessary (Art. 3). The relevant international organisation developing food standards is the Codex Alimentarius Commission (CAC). If a WTO member pursues stricter standards<sup>14</sup>, this deviation from harmonization has to be justified by a *risk assessment* (Art. 3, par. 3).
2. Border measures to enforce the protection level should ensure *non-discrimination* and *national treatment* (Art. 2, par. 3) which refer to both equal treatment of imports from different members and equal treatment of imported and domestically produced goods. Additionally, the

*equivalence* principle (Art. 4) is recommended, i.e. accept measures of the exporting countries if they achieve 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 equivalence. *Least-trade distortion* of measures is the dominating argument in WTO food disputes (RUDLOFF, 2005). A measure is seen as not more trade-restrictive than necessary unless there is another measure that is less trade-restrictive but achieves the same level of protection (Art. 5, par. 6 and footnote 3). No defined classification of least-trade distorting measures exists and evaluation proceeds on a case-by-case basis. Additionally, *technical and economic feasibility* should be considered when evaluating the trade effect of a measure (Art. 5, par. 6).

#### 3.2 Evaluation of BTA provisions

The following chapters apply the SPS frame to the BTA provisions in order to indicate potential scope for conflicts.

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

The scientific justification of a measure by providing results of a risk assessment is the starting point of the SPS Agreement. Risk assessment is defined as the process of determining the probability and the extent of the adverse effects, i.e. damage assessment (HOOD et al., 2001: 3) for which the CAC developed some guidelines (CAC, 2003c: 83). However, the assessment of bioterrorist risk is facing problems regarding both elements, the assessment of probabilities and of the adverse effects:

1. *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.<sup>15</sup> 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: 1; CARUS, 2001: 3).

In particular for the last decade, CARUS (2001) derives an increasing trend of all biological attacks (table 2).<sup>16</sup> The minority of all attacks was caused by terrorist motivation.

Table 2 does not differentiate among types of terrorist attack and therefore a review of existing studies was necessary to identify specific *food terrorist cases* caused by deliberating biological agents in the food chain (CHALK, 2004; CARUS, 2001; MANNING et al., 2005; PARKER, 2002; TUCKER, 1999; WHO, 2002). As a result only *three food terrorist attacks* could be identified out of the sum of 27 cases since 1900 of which the contamination of salad bars by a religious fanatic

<sup>11</sup> Out of 328 cases initiated after 1995 more than 60 refer to the Agreement on Technical Barriers to Trade (TBT) and the SPS Agreement, the two relevant agreements for NTBs (RUDLOFF, 2005).

<sup>12</sup> See e.g. G/SPS/N/USA/690 (prior notice).

<sup>13</sup> For instance the "Agreement on Preshipment Inspections" or the "Agreement on Import Licensing Procedures". Other explicitly security motivated rules are addressed in the GATT Article XXI saying "that no country shall be prevent from taking action to its essential security interests".

<sup>14</sup> So far no case on lower standards has been opened, therefore we always refer to a deviation from international standards in terms of stricter standards (RUDLOFF, 2005).

<sup>15</sup> MOFFITT et al. (2005) provides an analysis of modelling concepts for bioterrorism in the context of uncertainty.

<sup>16</sup> Note, that the improved reporting over time can be a relevant parameter influencing this result.

**Table 2. Motivation of terrorism cases: frequency over time**

Period	Terrorist motivation	Criminal motivation	Other motivation	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: 11

group in Oregon, U.S., in 1984, is the most known one (Rajneeshee case).<sup>17</sup>

2. *Damage assessment.* Potential damages 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. The damages depend on the relevance of the agricultural sector for an economy: the economic impacts of bioterrorism attacks relate to direct losses of crops, livestock, and other assets, losses in the agribusiness network, and indirect effects resulting from loss of export markets, price, and growth effects (SCHAUB, 2002; MONKE, 2005; CHALK, 2004). Just a minority of the few studies on bioterrorist attacks list or evaluate the caused damage and only for the Rajneeshee case, information on illnesses in the population is available (see table 3).

A possible proxy for assessing the damages of intentional food terrorist attacks can be the costs of food incidents<sup>18</sup>, since in this area of *unintentional* contamination more evidence exists (see table 3, last column). However, only very few data on the monetary evaluation of damages is available. Nevertheless, these studies indicate that the values can be rather significant, as for example the damage of the Listeria incidence of 1998 in the U.S. was assessed with 50-70 Mio \$, and the Escherichia coli incidence 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 per year and estimated 6.5-30 Mio \$ and 9 000 deaths each year for the U.S.

3. *Conclusions on WTO conformity.* Because of the mentioned difficulties, the basis for assessing the bioterrorist risk of an individual country is limited. Therefore conclusions for food terrorist risks cannot be drawn easily. PARKER (2002) and HALK (2004) identified a potentially high risk level for agroterrorism attacks for the U.S. They base their result on U.S. specific production patterns that tend to increase probabilities and damages: large size or complexity of agribusiness networks, high degree of monocultures, large spatial production concentration, high degree of vertical integration, large scope of unregistered illicit employment especially in

**Table 3. Damage assessment of terrorist and incidental food contamination**

Case	Listed cases of illness
<b>Food terrorist attacks</b>	
Rajneeshee (CARUS, 2001)	751
<b>Food incidences</b>	
Enteriditis infection from ice cream, 1994 USA (WHO, 2002)	224 000 cases of illness
Escherichia coli infection from radish sprouts, 1996 in Japan (WHO, 2002)	8 000 cases of illness including deaths
<b>Monetary damage assessment</b>	
Escherichia coli infection of apple juice, 1996 USA (WHO, 2002)	70 cases, 1 death 14 Mio \$
Listeria infected meat, 1998 USA (WHO, 2002)	35 cases of illness 50-70 Mio \$
All microbiological pathogens in food per year, USA (BUZBY et al., 1996)	9 000 deaths 6,5-30 Mio \$

Source: own compilation

the service area (restaurants and bars), and intensive husbandry systems that increase the vulnerability of infections.

Food terrorism may depend on different parameters than agroterrorism since other actors are involved (e.g. processing and retail systems). Nevertheless, it is to assume that a similar risk will be identified for the U.S. food chain.<sup>19</sup> However, given the limited knowledge about food terrorism probabilities and damage, it is difficult to evaluate whether the U.S. protection level achieved by the implementation of the BTA is justified and thereby WTO conform.

### 3.2.2 Use of recommended international standards: harmonization

In this section it will be evaluated whether the BTA provisions follow the harmonization rules of the SPS Agreement using recommended international standards or whether the BTA implements stricter standards that must be justified by a scientific risk assessment. For dangerous substances and the design of import regimes, the two regulatory areas covered by the BTA, different international standards exist. Therefore, the analysis will be carried out separately for these two parts.

#### Harmonization related to addressed hazards

As indicated in chapter 3.2.1 the identification of hazards is the basis for a risk assessment process. However, the relevant hazards are not specifically addressed in Title III of the BTA and only the very general statement in the form of "bioterrorist threats to the food supply" is provided (Section 301a).

<sup>17</sup> The other two happened in Africa but were not linked directly to human consumption as cattle were attacked.

<sup>18</sup> See OECD (2003b) for an overview on existing studies.

<sup>19</sup> The risk assessment undertaken by 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, 2003a: 8).



1. *BTA provisions for bioterrorism hazards.* The application area of the BTA is not referring to selected hazardous substances, but addresses the transmitter of risky agents, i.e. products. Nevertheless, under Title II on “Enhancing Controls on Dangerous Biological Agents and Toxins” the BTA regulates the possessing and transfer of listed agents and toxins. These listed agents can serve as indicators for the U.S. definition on relevant hazards and are defined by different U.S. agencies: APHIS lists 52 agents as potentially bioterrorist dangerous<sup>20</sup> and the Centers for Disease Control and Prevention (CDC) identifies 37 bioterrorism agents with special impact for human health. As we concentrate on human health the following analysis focuses only on those agents and toxins with impact on public health<sup>21</sup> (i.e. zoonotic diseases<sup>22</sup>).

2. *International standards.* It is important to distinguish between different types of standards for which international standards are provided by either the CAC regarding food or the World Organization for Animal Health (OIE) regarding animal health:

- CAC standards for food focus mainly on product standards (e.g. maximum residual levels for pesticides). For bioterrorist agents processing standards are more relevant, however these standards are not covered by the existing list. For such standards usually only very rough CAC provisions exist like the “General principles of meat hygiene” (CAC, 2003a) or the “Guidelines for canned products” (CAC, 1985).

- The OIE standards of the Terrestrial Animal Health Code (“The Code”) define health measures to be used by the veterinary authorities of importing and exporting countries (OIE, 2004a). Relevant here are the standards with regard to the requirement of notification of certain diseases (OIE, 2004a: part 2).<sup>23</sup>

3. *Conclusions on WTO conformity.* Table 4 summarizes the comparison of agents relevant for public health addressed in the BTA and in international guidelines: divergence of standards can be identified already among the U.S. standards’ lists as APHIS covers six more agents than CDC (marked in grey). Comparing the BTA list with the standards addressed by international organizations, no difference can be recognized: all BTA zoonotics are also covered at international level. Therefore the BTA is not more stringent than SPS standards and not in conflict with WTO rules (MONKE, 2005).<sup>24</sup>

<sup>20</sup> Title 7 CFR, Part 331, Title 9 CFR, Part 121 and Title 42, Parts 72 and 73.

<sup>21</sup> Therefore, all agents determined by USDA are excluded as they are referring to livestock pathogens and toxins which are only dangerous for animals and plants.

<sup>22</sup> Zoonoses are diseases that may spread from animals to humans. The list of the USDA that is restricted only to animal and plant health is excluded.

<sup>23</sup> Diseases to be notified fulfill criteria of international relevance, i.e. they should have the potential of international spread and human infections or causing other dangerous diseases.

<sup>24</sup> But if extending this analysis to agents that are only dangerous to animal and plant health, the BTA covers more standards than OIE: Akabane, Camel pox, and Menangle (MONKE, 2005).

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

BTA reference	International organizations			
	APHIS	CDC	OIE	CAC
Anthrax		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)

#### Harmonization of rules related to the enforcement measures at the border

Manifold instruments can be used to achieve a chosen domestic protection level. The administrative instruments of the BTA can be classified as process standards that are not physically observable in the product (JOSLING et al., 2004: 18). Respective international standards for import administration are covered by different WTO Agreements (see footnote 13) but we still focus on food specific measures as regulated by the SPS Agreement and relevant international organisations.

1. *BTA provisions.* The BTA measures can be summarized according to their general objectives as (1) informative requirements targeted by registration, U.S. agent definition, prior notice, and record keeping and as (2) control measures implemented through the provision on detention. With respect to the information objective, the BTA requires highly individualized information at the single company level, and imports may be detained at the border when failing to fulfill this requirement.
2. *International standards.* Regarding information requirements, standards relate to risk specific and regional in-

Whether Menangle can cause human infections and thereby would be relevant for public health is currently discussed in the scientific community (OIE, 2004b). If this possibility would be confirmed, the BTA could be evaluated as diverging from SPS provisions for the case of those agents which are dangerous to human health.

formation (e.g. OIE Code, Article 2.2.1.2, OIE, 2004a) or on certification schemes (CAC, 2000). Regarding import controls, no precise standards (e.g. frequency of controls) but rather broad frameworks and principles exist (CAC, 2003b): For example, the OIE defines rules for the diagnostic procedures to be undertaken at the border (OIE Code, Appendix 2.10.1.4).

3. *Conclusions on WTO conformity.* The major difference between the BTA and international standards concerns the first category, the information addressee and the required information: whereas the international organisations only demand broad regionalized information, the BTA call for individual company information. Furthermore, the BTA does not request any disease specific information but only traceability related information. However, this identified difference does not allow drawing the conclusion that the BTA is stricter than requirements of the SPS Agreement: at the WTO level, information requirements of process standards are anyhow more individualized and flexibly adjustable to country and disease specific conditions than those of product standards. For instance, whereas the burden of proof to demonstrate the process standards having the "risk free status" in a region or country (process standard) lies with the exporter, the importer has the option to control the validity of the declared risk status by additional measures: import permits granted by the importer are often based on either the additional evaluation of "on the spot conditions", a comprehensive assessment of regulatory programmes, or on quarantine procedures leading in the end to a degree of information's individualization similar to that of the BTA (BRÜCKNER, 2004: 10).

Related to the second category, control measures, the BTA only regulates procedures for detention in cases of "credible evidence" whereas the OIE defines risk specific requirements like diagnostic procedures (OIE Code, Appendix 2.10.1.4.). It is important to state that neither the CAC provides specific standards for import control systems in terms of frequencies or samples (CAC, 2003b; CAC, 1995) nor does the BTA. Hence, since no guidelines are specified, no deviation of the BTA from international standard can be identified.

Given the flexibility of the existing international standards, the BTA cannot be evaluated as being stricter. The identified distinctions between the BTA and international guidelines result from the different regulatory purposes: the BTA explicitly addresses national security whereas the standards of international organisations aim at food safety and least-hindered trade.

### 3.2.3 Specific design of the enforcement measures

#### 3.2.3.1 Non-discrimination and national treatment

Formally, the BTA provisions are applicable to all importers and thereby they are *non-discriminatory*. However, there may be some factual differences because of individual trade patterns: if some trade partners had certain bilateral arrangements facilitating trade prior to the adoption of the BTA, their situation became relatively worse compared to other countries. Similar findings might hold with respect to product categories affected differently (table 1) and size of import quantities if we expect smaller lots to be affected

relatively stronger. However, as these effects result from usual economic adjustments of trade patterns due to changed legislation, the provisions of the BTA as such cannot be interpreted as discriminatory.

*National treatment* is ensured since, in principal, the BTA provisions are applicable to both, domestic and foreign producers. Nevertheless, some provisions are either not relevant for domestic producers or their economic burden may be lower:

- The 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 companies<sup>25</sup>, 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 representatives.
- Prior notice of imports is not relevant for domestic producers. Hence, they are not facing transportation delays as importers do. An evaluation of related costs identifies significant additional burden for foreign companies (see table 5).
- Differences may also refer to the frequency of controls either at the border or critical points in the domestic supply chain. No cost assessments on different control types exist so far.

#### 3.2.3.2 Equivalence

While international standard setting aims at the harmonization of the protection level, equivalence grants flexibility in the implementation process, i.e. with respect to the choice of specific measures to achieve the protection level. The SPS Agreement explicitly encourages bilateral consultations on the acceptance of different implementation measures 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: 48). The burden of proof for demonstrating equivalence lies with the exporter. Trade can be hindered if the importer is not accepting the proof and additional import requirements or a trade ban are imposed.

Equivalence agreements are potentially more beneficial for process than product standards since for product standards, compliance with existing standards can be checked directly by means of product characteristics. On the contrary, process standards are more difficult to verify at the border and need to be inspected through expensive on-spot controls in the exporting country itself (OECD, 1994). Therefore, in particular for this group of BTA agents equivalence agreements offer potential gains since they replace the proof of similarity which involves expensive on-spot measures for each standard. BTA provisions that define information and control aspects belong to this group of process standards. Here, equivalence agreements may facilitate trade. How-

<sup>25</sup> One example 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.

<b>Measure</b>	<b>Potential business impact</b>	<b>Potential trade impact</b>	<b>Cost of compliance estimates<sup>1)</sup></b>
<b>Registration (US Agent)</b>	(-) Increase of administrative burden (-) Maintenance of US Agents involves cost for firms	(-) FDA estimate: 16% of foreign firms will cease imports, especially firms with only few shipments	One time costs: 176 \$ Agent fee: 10 00 \$
<b>Record keeping</b>	(0/-)Unclear. – Records might be covered by existing record keeping systems – If not: increase of administrative burden	(+) Might increase quality assurance and logistics (+) Quick response in cases of emergencies might help to keep/restore consumer confidence	One time costs: 1 517 \$ Maintenance: 270 \$
<b>Prior notice</b>	(0) Notice can be done mostly within normal import procedure (-) Importers working formerly under expedited arrival procedure have disadvantages (-) Problem of notification for firms without internet access/computer equipment	(-) Slow down of food entry into the U.S. due to processing or inspection problems (especially relevant for perishable products) (+) Inspections might be better targeted	One time costs: 3 698 \$ Costs per entry: 75 \$
<b>Detention</b>	(-) Firms have to bear costs of detention: cost of disposal or sale at reduced prices	(-) Increases uncertainty of trade	Costs per detention: 100-90 000 \$ depending on product and procedures (handling, storage, appeal, re-labeling)

Note: (-)/(+)/(0) refers to a potentially negative/positive/unclear trade impact, respectively.  
1) Estimates result from the FDA "Analysis of Economic Impact" of the Proposed (administrative detention, record keeping) and Interim Final Rule (registration, prior notice) published in FR 68, Vol. 90 and Vol. 197, respectively. Where a distinction in the FR was made, the assumed costs for foreign firms and sufficient English knowledge were chosen.  
Source: own compilation based on FDA

ever, only very few equivalence agreements exist as administrative transaction costs for negotiating and accepting equivalent measures seem to be very high.<sup>26</sup>

Besides the comprehensive U.S. Veterinary Agreement with the EU, other equivalence acceptance only exists for certain meat and dairy products with selected partner countries (APHIS, 2004), or are addressed within free trade agreements (e.g. Chile). However, in free trade agreements, SPS measures are usually only covered in a very general manner via general cooperation obligations and the promise to implement WTO standards (see Chile-U.S. Free Trade Agreement, par. 6). The provisions of the BTA clearly overrule existing provisions within the bilateral agreements as far as FDA products are concerned.

### 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 achieving the same protection level. Since no comparative analysis of alternative trade measures is possible and given the described constraints in evaluating the appropriate level of protection (see chapter 3.2.1), several adjustments in the analysis were necessary. Furthermore, trade distortion will be assessed taking the trade impact as proxy. This is admissible since we assume that a lower trade effect is associated with less trade distortion. A third adjustment relates to the second requirement of Art. 5.6, i.e. the technical and economic feasibility of

measures. In some WTO disputes, this has led to findings where an import ban was the accepted answer to a sanitary or phytosanitary risk since all other measures of protection would be either too costly to implement or would not provide the same level of protection.<sup>27</sup> 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.

Table 5 presents an overview of the cost and trade impact of the food related BTA provisions. 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.<sup>28</sup> Furthermore, the prior notice can be only 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 developing countries this might be a difficult or impossible requirement, not only because of the occurring costs but also due to ineffective information technology.<sup>29</sup>

<sup>26</sup> The Veterinarian Agreement between the U.S. and the EU, signed in 1999, took six years of negotiations (JOSLING et al., 2004: 49).

<sup>27</sup> For instance, in the *Hormone Cases* the Appellate Bodies stated that the import ban on U.S. and Canadian beef was accepted as the only feasible measure but was condemned because of the missing risk assessment (RUDLOFF, 2005).

<sup>28</sup> In particular Mexico and Canada, countries with formerly expedited import procedures (see FR 68, Vol. 197: 59028) have disadvantages with the new system since planning of shipments and entry into the U.S. makes a longer time horizon necessary.

<sup>29</sup> Note that some of these administrative concerns were addressed by the FDA in the regulatory process. Upon suggesti-



A second potential and probably more significant trade impact results 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. In theory, this agent might be a private individual 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 practice however, the requirement to be available 24 hours a day all year long is not easy to fulfil for private persons and most foreign firms are seeking some business partner, foreign chamber of commerce representative, or legal entity to execute that function. This results in costs that can differ considerably.<sup>30</sup> 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 shipments might be affected by this regulation and cease trade with the U.S. (FR 68, Vol. 197: 58943) it is difficult to see that this requirement is addressed in the least-trade distorting way.<sup>31</sup> The FDA expected in particular that small firms with less than 10 yearly line entries into the U.S. will be affected by this provision.

The other two proposed measures, *administrative detention* and *record keeping*, should not impose too many new requirements on exporting firms, since record keeping of suppliers and recipients is well established in many countries.<sup>32</sup> Here again, 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.<sup>33</sup> The provision of *administrative detention* is probably the least trade distorting element of the BTA. In addition, a "Dear Colleague" Letter from May 27, 2004 further clarifies this rule and points out that they "do not [...] foresee frequently using administrative detention under" this rule (FDA, 2004). A review of FDA detention statistics for the year 2005 reveals that no product detention related to Section 304 of the BTA has occurred.

#### 4. Evidence from bilateral trade data

In this chapter we focus on the trade impact of the BTA provisions. As we have seen in the previous section, some of the provisions apply specifically to imports and involve compliance costs for the importing firms. Depending on the burden sharing of the costs, these are losses that either importers or exporters have to carry, thereby reducing their profits. If these compliance costs of foreign firms cannot be

carried over to the market price of the importing country, these cost asymmetry between domestic and foreign firms may lead to a substitution of imported with domestically produced goods (see ROBERTS et al., 1999; BALDWIN, 2001, and BUZBY, 2003). These developments – if they take place – are assumed to be identified in the import pattern over time. Hence, we work under the hypothesis that potential trade effects of the BTA may be seen in reduced import volumes for food categories that are most affected by the compliance costs of the provisions.<sup>34</sup> This implies that we expect to see no changes in the trade pattern if the BTA provisions have only a minor or no trade impact. In this case, food imports after the implementation of the BTA will develop according to the trade pattern of the last decade, i.e. follow the positive trend that could be observed for a number of food categories (see appendix).

Our approach follows an analysis provided by OECD (2003a) where trade flow patterns were used to analyze if import quantities changed as a result of a policy reform. This approach implies 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 may affect trade flows.<sup>35</sup> In addition, this method cannot distinguish among the individual impacts of single BTA provisions, but look on the regulatory impact as a whole. However, since our approach is rather easy to perform, this analysis provides a good starting point for a more thorough analysis of the trade impact and may hint on sectors that are of particular interest for such an analysis.

Given the findings of the analysis of the least-trade distorting effect of the BTA in the last section, our analysis of bilateral import data for the U.S. is driven by the following questions:

1. Does the import pattern change after the time of the implementation of the BTA?
2. What is the impact on small and large import volumes?
3. How are different types of importing countries affected?

We use bilateral import data for the U.S. as recorded in the WORLD TRADE ATLAS which is based on the UN COM-TRADE data base. The trade flow analysis is done for all relevant food categories (see table 1). In the following analysis we compare the import pattern of the year 2003 ("before the BTA entered into force") with the year 2004 ("after the BTA entered into force").<sup>36</sup> We chose to only rely on a direct comparison of import developments of the two years adjacent to the BTA implementation, given that this comparative analysis of trade flow developments cannot account for any other exogenous variables that may

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ons of trading partners, the FDA streamlined their import information system and made prior notification within the usual import information processing system available (FDA, 2003b).

<sup>30</sup> 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 p.a. for member firms (see <http://www.gaccny.com/index.php?id=71&L=1>). See also KERR (2004).

<sup>31</sup> This is even more questionable given that an emergency contact for foreign firms is allowed to be located outside of the U.S.

<sup>32</sup> See also the traceability provisions in the EU (EUROPEAN COMMISSION, 2002).

<sup>33</sup> See OTSUKI et al. (2001b) for an impact estimation and JAFFEE and HENSON (2004) for a discussion of standards on the competitive situation of developing countries.

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<sup>34</sup> Note that this hypothesis implicitly assumes that no positive demand effect is created through the BTA. NTB theory suggests that demand stimulation may occur when newly implemented standards achieve a higher safety level in the food chain and these new standards are comprehensible to consumers (THILMANY and BARRETT, 1997).

<sup>35</sup> These effects can be captured when estimating a gravity model or import demand system.

<sup>36</sup> Given that the BTA entered into force December, 8 of 2003, we have a small bias in the reference situation covering the trade volume of three weeks.

**Table 6. Import pattern before and after the BTA implementation (number of HS4 commodity lines)**

Food category	Prior to BTA	After BTA (Import lines 2004)							
	Import lines (2003)	stop		decrease		decrease > 2 std.	increase		increase > 2 std.
	abs.	abs.	%	abs.	%	abs.	abs.	%	abs.
Fish, seafood	531	75	14	195	37	15	261	49	73
Vegetables	441	88	20	153	35	21	199	45	52
Edible fruits, nuts	439	85	19	139	32	20	215	49	84
Spices, coffee, tea	431	81	19	152	35	13	198	46	61
Cereals	102	31	30	23	23	2	48	47	20
Milling, malt, starch	285	68	24	88	31	16	129	45	52
Miscellaneous grain	251	49	20	80	32	10	122	49	49
Fats, oils	311	52	17	106	34	13	153	49	66
Prepared fish	123	14	11	38	31	2	71	58	20
Sugars	86	8	9	35	41	1	43	50	8
Cocoa	182	23	13	72	40	7	87	48	22
Baking related	309	22	7	105	34	6	182	59	41
Preserved food	542	61	11	210	39	14	271	50	68
Miscellaneous food	350	38	11	122	35	10	190	54	50
Beverages	442	41	9	159	36	13	242	55	56
<b>Sum</b>	<b>4825</b>	<b>736</b>	<b>15</b>	<b>1677</b>	<b>35</b>	<b>163</b>	<b>2411</b>	<b>50</b>	<b>722</b>

Note: The analysis is done at HS4 classification. This table presents the aggregated results on HS2 level.

“Decrease (increase) > 2 std.” represents the import lines where the decrease (increase) in the period after the implementation of the BTA where larger than the mean of the reference period minus (plus) two times the standard deviation of the respective import line in the reference period.

Source: own calculations based on WORLD TRADE ATLAS, 2006

change (e.g. exchange rates, GDP) and impact on the trade pattern. Hence, a short-term comparison horizon is advisable. All calculations are done for quarterly values at HS4 level of the international commodity classification of the World Customs Organisation, however, for the ease of presentation, they are subsequently aggregated to yearly HS2 level.

#### 4.1 Import pattern before and after the implementation of the BTA

Table 6 presents an overview on the import pattern before and after the implementation of the BTA. In average, 4 825 import lines<sup>37</sup> were recorded at the U.S. border during the reference period. After the implementation of the BTA, 15% of these import lines no longer show any trade with the U.S., 35% of the import lines show a decrease in the average trade volume, and 50% of the import lines recorded in the reference period show an increase in the trade volume after the implementation of the BTA. The observation of the increase in trade volume for half of the import lines is in accordance with the observation that the *aggregate trade volume* of food imports increased also after the introduction of the BTA (see appendix). This is an indication that not all importers were similarly affected by the BTA implementation. A further differentiation of the impacts will be provided in the following sections.

Out of the 35% import lines that show a decrease in trade volume, only 3% show a significant decrease, i.e. the volume reduction of the import line lays outside a confidence

interval that was constructed around the mean of the import line in the reference period. If we add up the countries that stopped imports to the U.S. and those that showed a significant decrease, we may conclude that at least 18% of almost all U.S. food import *lines* of the year 2003 were negatively affected after the BTA implementation. Nevertheless, table 6 shows that not all food categories are similarly affected. We observe a mostly negative impact for perishable products, spices, coffee, tea, and for various grain and processed grain products. On the other side, for most of the processed categories less impact can be found given that the number of countries that cease imports decrease considerably for those commodities.

In general, the findings are in line with the identified potential impacts of the FDA who estimated that around 16% of foreign firms will cease trade with the U.S. (see previous section). Similarly, the FDA expected a more severe effect for perishable products due to the time sensitivity of these products. An aspect that needs further consideration is the development of the trade pattern of the processed/value-added product groups such as sugars, preserved food, or miscellaneous foods. According to Table 1, these are the groups with the most significant changes in the import protocol, however, this is not reflected in the development of the import pattern.

#### 4.2 Differences among small and large import volumes

Table 7 shows the development of the import pattern before and after the BTA implementation differentiated by small and large import volumes in the various HS categories. The volume differentiation of the import lines is done according to the total import volume in the year 2003. Subsequently,

<sup>37</sup> Each import line represents the average imports at HS4 level of a country in the indicated time period. The terms “import line”, “importer”, and “importing country” are used interchangeable for these quantities.

the lowest ("small") and highest ("large") quartile of the distribution is chosen for the analysis.

The comparison across all food categories shows a considerable impact difference for small and large import volumes: whereas only 1% of the large importers quit trade with the U.S., around 40% of the small importers ceased imports after the implementation of the BTA. For the group of importers that decrease imports since the implementation, we observe the opposite effect: only 20% of the small importers decrease the trade volume compared to 40% of the large importers. However, the quartile with the small import lines contain a much higher number of cases where the trade reduction is considerably more pronounced

(98 cases compared to only 1 for the large import volumes). The statistics on increase in trade volume after the adoption of the BTA follows again the trend observed already in the category of ceased imports: only 39% of the small import lines show an increase in imports compared to circa 60% of the import lines with the largest trade volumes. However, the significance of the increase is much more pronounced for the small volumes. For the different HS categories the picture differs somewhat depending on the product, but the findings are in line with the developments observed in table 6 where we concluded that perishable products and cereals based commodities seem to be more affected than processed food.

**Table 7. Import pattern of small and large import volumes before and after the BTA implementation (number of HS4 commodity lines)**

	Import volume	Prior to BTA	After BTA (Import lines 2004)							
		Import lines (2003)	stop		decrease		decrease > 2 std.	increase		increase > 2 std.
		abs.	abs.	%	abs.	%	abs.	abs.	%	abs.
Fish, seafood	small	134	58	43	24	18	12	52	39	44
	large	134	1	1	68	51		65	49	1
Vegetables	small	112	65	58	15	13	7	31	28	25
	large	112	2	2	35	31		75	67	
Edible fruits, nuts	small	112	58	52	12	11	7	42	38	38
	large	112		0	39	35		73	65	4
Spices, coffee, tea	small	109	53	49	17	16	9	39	36	32
	large	109	1	1	45	41		63	58	
Cereals	small	27	14	52	2	7		11	41	9
	large	27	3	11	11	41	1	13	48	3
Milling, malt, starch	small	72	32	44	16	22	10	24	33	20
	large	72	3	4	32	44		37	51	5
Miscellaneous grain	small	63	30	48	11	17	8	22	35	18
	large	63	2	3	20	32		41	65	7
Fats, oils	small	79	26	33	15	19	4	38	48	33
	large	79	3	4	28	35		48	61	6
Prepared fish	small	31	10	32	7	23	2	14	45	12
	large	31		0	10	32		21	68	
Sugars	small	22	8	36	5	23	1	9	41	5
	large	22		0	10	45		12	55	
Cocoa	small	45	16	36	15	33	6	14	31	11
	large	45		0	20	44		25	56	
Baking related	small	78	18	23	20	26	6	40	51	25
	large	78		0	32	41		46	59	
Preserved food	small	136	42	31	39	29	10	55	40	42
	large	136	1	1	55	40		80	59	3
Miscellaneous food	small	88	30	34	17	19	3	41	47	34
	large	88		0	33	38		55	63	1
Beverages	small	112	32	29	32	29	13	48	43	35
	large	112		0	48	43		64	57	
<b>Sum</b>	<b>small</b>	<b>1220</b>	<b>492</b>	<b>40</b>	<b>247</b>	<b>20</b>	<b>98</b>	<b>480</b>	<b>39</b>	<b>383</b>
	<b>large</b>	<b>1220</b>	<b>16</b>	<b>1</b>	<b>486</b>	<b>40</b>	<b>1</b>	<b>718</b>	<b>59</b>	<b>30</b>

Note: The analysis is done at HS4 classification. This table presents the aggregated results on HS2 level.

"Decrease (increase) > 2 std." represents the import lines where the decrease (increase) in the period after the implementation of the BTA where larger than the mean of the reference period minus (plus) two times the standard deviation of the respective import line in the reference period.

Source: own calculations based on WORLD TRADE ATLAS, 2006

### 4.3 Regional differentiation of the import pattern

Finally, we analyze the regional impact of the BTA implementation. We ordered the importing countries according to typical country classifications (NAFTA, CAFTA, LCD etc.) and analyzed their import pattern (table 8). Out of the 4 825 import lines that were recorded in total for these country groups in the year 2003, 208 import lines came from NAFTA countries (i.e. Canada and Mexico). After the BTA implementation, we observe a stop of imports for 5% of the lines, a slight decrease for around 31% of the volumes, and an increase for the rest of the import lines.

If we compare this development with the one of the other country groups we can find a somewhat different picture. In particular for the LCD and African countries, a significant share of their trade seems to be affected by the BTA. However, as before, at the same time, we also can observe that some of their import quantities show slight to strong increases in the trade volume. The EU is the importer that shows by far the highest number of import lines into the U.S. before the implementation of the BTA. 15% of these imports are set out after the BTA implementation, and around 37% decrease with 10% (65) showing a significant reduction. On the other hand, 48% of the EU imports show light to strong increases.

This exploratory analysis of the development of the import pattern of the U.S. before and after the implementation of the BTA shows that the BTA potentially did have an effect on the import pattern and trade of certain commodities (perishable products, grains) and countries (with small import volumes, LDC, Africa). The above presented indicators disclosed broad short-term changes in the import pattern after the BTA implementation that may result from the ongoing compliance process. However, the results should be cautiously interpreted and a further a statistical verification of these effects is necessary (and underway) to obtain more robust results. In addition, the analyzed time span of imports under the new legislation is rather short. It is to assume that over times, firms are able to adapt to the new standards and reduce costs of compliance and that imports will move back towards old import levels.

### 5. Conclusion

The analysis explored challenges in evaluating trade effects for the increasingly relevant NTB group of administrative, information-related import measures in the context of the Bioterrorism Act of the U.S. An additional difficulty arises from the fact that the administrative rules of the BTA target at the reduction of bioterrorism risk whereas existing WTO rules as set out in the SPS Agreement focus on food safety. This newly emerging area of biosecurity issues in food trade is still without an explicit counterpart in the WTO framework. The analysis of conformity of the BTA with existing SPS rules highlights the available flexibility in the area of process standards, which is the relevant group of standards for administrative import provisions. This flexibility allows appropriate scope for the prevention of disease spread by considering disease specific characteristics, but constrains the evaluation whether international standards are overruled.

The results of the empirical trade flow analysis illustrate differences in the compliance costs between countries. This differentiation can be caused by adjustment and learning costs that may differ among countries: countries working prior to the legal amendment in a more open import environment characterized by expedited import procedures, free trade agreements, or equivalence agreements, face adjustments that may be relatively more difficult than for countries always used to strict rules. The same is true in relation to products for which stricter rules are in place under the BTA compared to other products. Additional analyses indicate the "fixed cost" character of administrative import rules as small import quantities are affected most. A special problem seems to appear for developing countries that are lacking technical or human resource capacities to comply with these new administrative rules. Developing countries often import only small lots which imply an over-proportional cost increase and they are often importers of those products for which major regulatory changes could be identified.

Given that there is only very limited experience with food terrorism attacks and the design of regulatory protection

**Table 8. Regional differentiation of import pattern before and after the BTA implementation (number of HS4 commodity lines)**

	Prior to BTA	After BTA (Import lines 2004)							
	Import lines (2003)	stop		decrease		decrease > 2 std.	increase		increase > 2 std.
		abs.	abs.	%	abs.	%	abs.	abs.	%
NAFTA	207	11	5	65	31	1	131	63	17
CAFTA	306	36	12	105	34	11	165	54	40
LDC	202	62	31	58	29	11	82	41	49
EU	1124	164	15	415	37	43	545	48	160
Pacific Asia	741	67	9	253	34	9	421	57	99
South America	584	66	11	190	33	17	328	56	95
Africa	305	73	24	113	37	21	118	39	37

Note: The analysis is done at HS4 classification. This table presents the aggregated results on HS2 level.

The group of African countries does not include African LDCs.

"Decrease (increase) > 2 std." represents the import lines where the decrease (increase) in the period after the implementation of the BTA where larger than the mean of the reference period minus (plus) two times the standard deviation of the respective import line in the reference period.

Source: own calculations based on WORLD TRADE ATLAS, 2006

instruments, this work highlights areas that should be considered in further analyses. However, the discussion made clear that with respect to identification and evaluation of the appropriate level of protection, determination of probabilities and damage, and related cost-benefit analysis of proposed protection measures existing studies are so far limited.

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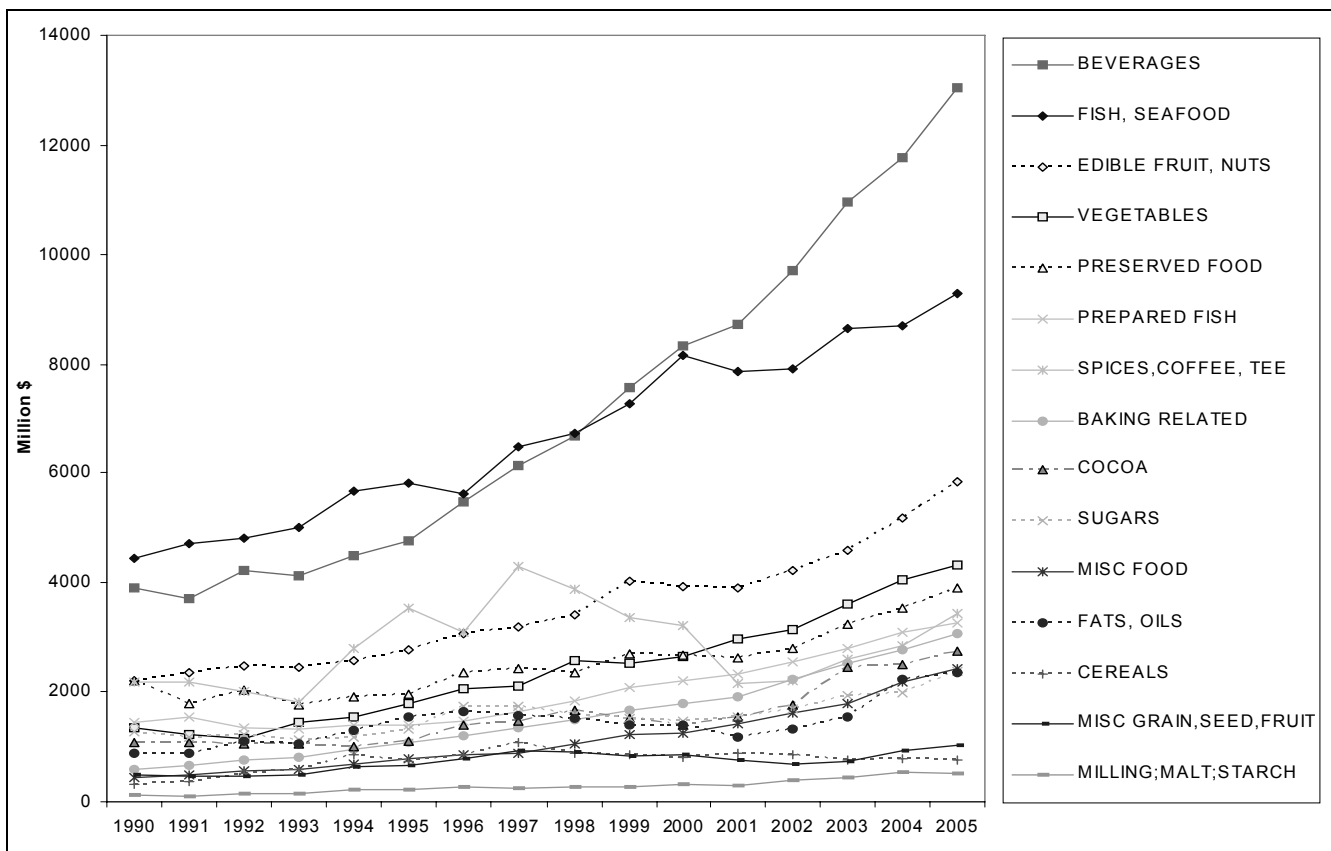
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## Appendix

Figure 1. Development of aggregated U.S. import volumes (HS2 classification)



Source: WORLD TRADE ATLAS, 2006