WAS FOOD SAFETY DECLINING? ASSESSING THE JUSTIFICATION FOR THE US FOOD SAFETY MODERNISATION ACT

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Abstract

Food safety regulations limit trade in bioproducts. Every country, however, has a duty to protect its citizens from food safety hazards. If risks are increasing under an existing food safety system then a strengthening of the regulatory regime can be justified, with the inevitable negative impacts on international trade. Alternatively, raising food safety standards may simply be undertaken for reasons of economic protection The US has recently enacted new food safety regulations under the Food Safety Modernisation Act (FSMA) on the basis that foodborne diseases associated with domestic and imported food were on the rise. An assessment of the official justification of the FSMA is undertaken through an examination of trends in foodborne disease incidence. The results show that while the incidence of disease have increased over recent years, suggesting legitimate reasons for concern, some of the FSMA's provisions may violate WTO commitments designed to constrain economic protectionism.

Keywords: food borne illness, food safety, international trade, protectionism, regulation

1.0 Introduction

In January 2011 a new regulatory regime for food safety was passed into law in the United States – the Food Safety Modernization Act (FSMA). It has been described as the most extensive revision of food safety regulations since the 1930s. The new food safety system has aspects that may adversely affect exporters in ways that contradict US commitments under the WTO (Nakuja *et al*, 2011). The primary reason that governments establish standards and protocols to regulate the safety of food is to protect their citizens from harm. It is also true that unilaterally imposed food safety standards act as a barrier to trade – firms that wish to export to a market must comply with the requirements of the food safety standards established for that market. In the absence of international harmonization of food safety standards, protocols and procedures, costs will be imposed on exporters if for no other reason than they must do things differently than in their domestic market. Further, it has long been recognized that food safety regulations can be used nefariously to provide economic protection (Kerr, 2004; Isaac, 2007).[1] Thus, any change in food safety standards will be viewed with suspicion by prudent trading partners. As the true motivations for tightening a regulatory regime for food safety cannot be known, examining evidence regarding any stated motivations is important for assuring trade partners that the changes are justified or to indicate that consultations should be initiated with the imposing country; or even that formal trade actions should be considered.

Increased food safety standards can be imposed for a number of reasons. First, there may be a new threat to food safety (e.g. a new strain of a virus) or an increasing threat from an existing food safety hazard that raises the probability of an incident occurring. Second, there may be an improvement in technology that, if implemented, could reduce the risk of a food safety incident. Third, given other constraints on the ability of governments to respond to those requesting economic protection from foreign competition, imposing more stringent standards can reduce the competitiveness of imports. Fourth, increasing food safety standards may be a way for politicians to respond to calls from (some) consumers to limit imports from a country (or countries) that they perceive as producing products that have unacceptably low levels of food safety – whether or not the perception is justified (e.g. as no food safety regime is fool proof incidents will occur; these normal incidents may be *blown up* by the media raising consumer anxiety even if the frequency of incidents has not changed). Policy makers may wish to respond for reasons of *political precaution*.[2] Dealing with rising civil society requests for protection in recent years has been particularly vexing for international trade policy making (Kerr, 2010). The

[1] For example, according to the official web site of the Office International des Epizootics (OIE), the international organisation that establishes the standards for trade in animals and animal products: "The ratification of the 1924 Agreement creating the OIE reflects a desire clearly expressed by the Secretary General of the League of Nations that year. He invited various governments to designate veterinary experts "to examine the health guarantees that could be provided by cattle-exporting countries, the facilities that importing countries could accord on the basis of these guarantees and, in general, to determine the most effective means of enabling statutory veterinary measures to be applied, taking into account the economic interests of exporting countries and without prejudicing the interests of countries wishing to protect themselves against animal diseases". "…"the Economic Committee of the League of Nations thus proposed to facilitate international trade in animals and animal products to try and reverse the *often highly overt tendency of numerous countries to use sanitary arguments purely for the purpose of economic protection*" (emphasis added) (OIE, 2000)".

[2] (Kerr (2004, pp. 35-36) suggests that "political precaution arises when politicians are being pressured to 'do something, or to be seen to be doing something' in the face of strongly expressed concerns by members of civil society even when risks are very low or largely speculative."

underlying economic model upon which the World Trade Organization (WTO) is based suggests that only producers will ask their governments for protection. As protection increases domestic prices, consumers are not expected to ask for it as they are made worse off. As a result, no provisions for consumer groups (or other groups in civil society) asking their governments for protection (Perdikis *et al*, 2001) have been included in multilateral trade agreements. Issues ranging from trade in genetically modified products, to a ban on imports of beef produced using growth hormones, to barriers on pork imports in the face of the H1N1 flu outbreak, among others, have been challenging for trade policy institution to deal with (Kerr, 2009).

The WTO disciplines on food safety conform to general WTO principles and are dealt with in a sub-agreement of the General Agreement on Tariffs and Trade (GATT) – the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS). The general WTO principles that apply come under the broad umbrella of Non-discrimination. The first principle is National Treatment whereby foreign suppliers should not be treated differently than domestic firms. Second, all foreign suppliers should be treated the equally. In the SPS, however, exceptions to these principles can be made if there is a scientific justification (e.g. if a disease is only found is some exporting countries) (Isaac, 2007). While scientific justifications for the imposition of trade barriers can be examined on a product-by-product basis, this approach is not tractable for a general assessment of a broad-based and wide ranging regulatory regime. There appear to be some aspects of the FSMA that violate National Treatment (Nakuja *et al*, 2011). Hence, examining the rational for putting the FSMA in place is justified, if for no other reason than to put aside the suspicions of trading partners that protectionist forces were at work.

The SPS commitments require a scientific justification and a risk assessment for the imposition of a trade barrier for SPS reasons. While those that negotiated the SPS probably hoped that a scientific consensus regarding the legitimacy of scientific justifications would emerge and that members of civil society would be willing to passively defer to scientific experts (and not pressure politicians), this has not come to pass (Smyth *et al*, 2011). There are a number of contentious issues that have arisen regarding the use of science as a basis of trade policy making (Smyth *et al*, 2009). Countries may also choose not to comply with disputes panels when their view of science is not accepted – most notably in the EU's refusal to open its market to beef produced using growth hormones (Kerr and Hobbs, 2002). The bottom line is that it is difficult to determine if changes to food safety regulations are scientifically justifiable without a formal dispute being launched at the WTO, making it onerous for exporting countries to assess whether increasing food safety standards are legitimate. Other indicators of legitimacy are required.

Finally, the SPS specifies that any measures put in place should be the least trade distorting mechanism that will allow a country to achieve its goals. Such evaluations are difficult to do and are seldom, if ever, undertaken. As a result, governments motivated by the desire to provide protection to domestic vested interests may purposefully design regulatory regimes that have a legitimate scientific basis in such a way that they are more trade distortionary than they need be. In the absence of a means to do an evaluation of the basis of the relative degree of distortion, evidence related to motivation becomes a key indicator of the legitimacy of changes to food safety regulations.

Concern with motivation is particularly acute when the world economy is suffering from a major economic downturn in the wake of the 2008 financial crisis. Protectionist pressure is expected to increase during depressions and severe recessions and, as a result, trading partners need to be particularly diligent in examining regulatory changes that impact trade (Viju and Kerr, 2011).

2.0 Why the US Food Safety Modernisation Act?

Under the SPS member countries are allowed to employ trade distorting food safety measures in order to protect lives and the environment provided those measures are based on sound science (SPS Agreement, Article 1) and an assessment of risk. If risks to food safety are rising, new or stricter science-based non-discriminatory regulatory standards can be justified. The recently enacted Food Safety Modernisation Act was justified on the basis of it being a response to high-profile foodborne disease incidents which are claimed to have undermined public confidence in the safety of food in the US (Carte Pate and Leavitt Partners 2010). A number of these incidents arose in cases involving imported products. Reports of *E. coli* and *Salmonella* outbreaks have been attributed to domestic and imported foods (Carte Pate and Leavitt Partners 2010). In 2011, for instance, *Salmonellosis* attributed to imported pawpaw from Mexico caused 97 hospitalization cases in Texas (FDA 2011a) while *E. coli* associated with strawberry farms in Oregon State reportedly led to a death (Kitzhaber 2011). At the national level, the Center for Disease Control and Prevention (CDC) estimates that about 48 million Americans suffer from foodborne illnesses in a year (Scharff 2012). Unlike other foodborne incidents that have measurably declined, *Salmonella* incidents appear to have continued to increase with an estimated annual infection rate of approximately 1.2 million people, at an annual cost of US$365million. Hence, *Salmonella* remains a significant food safety risk in the US (CDC 2010a). Buzby and Roberts (2011) argue that the globalisation of produce markets could partly explain the persistent incidence[3] associated with food products because new biologically-based risks could be introduced. Further, previously controlled risks could be re-introduced into an importing country. Similarly, Arnade *et al* (2009) argue that globalization and highly publicised food contamination incidents have increased the interest of both the public and policy makers in instituting improved measures to monitor the safety of foods from domestic and international origins.

Recognizing these effects of globalizing food markets, the FSMA has a primary focus on fruit and vegetables because they are increasingly traded in fresh form. Hence, they represent an important source of microbial contamination and one of the major foodborne disease challenges faced by the US food safety system (Ackerman 2002). Meat, poultry and dairy products are regulated independently by the US Department of Agriculture (USDA) and do not fall within the mandate of the FSMA (FDA 2011b; Nakuja *et al*, 2011). Notwithstanding these claims, no study verified whether there was a rise in food borne disease incidents in the US that justified the need for more stringent measures.

Further, the FSMA exempts small-scale producers and processors in the US from its key provisions – traceability and HACCP – but does not allow the same exemptions for similar sized foreign firms (US Food Safety Modernization Act 2011, Section 419(f)). The exemption appears

[3] Incidence is the number of cases per surveillance population (usually 100,000 people).

to violate the Non-discrimination principle of the WTO, and the scientific basis of the food safety regulations imposed; raising questions about the motives underlying the regulatory change. Further, the FSMA mandates increased inspections of firms at all stages of the supply chain, with more frequent inspections of foreign facilities than domestic facilities (Nakuja *et al*, 2011). In addition, the FSMA requires the US Food and Drug Administration to develop a large number of specific regulations covering everything from foreign agronomic practices, to certification of inspectors to standards for testing laboratories.[4] If the motivation for the FSMA lies in protectionism then trade partners need to be particularly vigilant as the new regulations are developed and rolled out over time. These aspects of the FSMA are particularly contentious given that the new regulatory regime comes at the time when the US fruit and vegetable industry is facing increasing foreign competition (Johnson 2012) and when unemployment remained consistently high across almost all sectors of the US economy due to the post-2008 financial crisis recession. Hence, politicians may be faced with considerable pressure to institute an overly strict regulatory framework intended to protect domestic industries.

In what follows, the official justification of the FSMA is assessed on two counts: the *Salmonella* foodborne disease incidence as *prima facie* justification of the regulation and; the conformity of the regulation to US commitments under international trade agreements. It is hypothesised that FSMA is legitimate if foodborne disease incidence show a significant rising trend and conforms to US commitments under the multilateral WTO agreements.

3.0 Salmonella Foodborne Disease Incidence in US

To examine the claim that the FSMA could be justified on the basis of increasing food safety risks, Salmonella incidents are examined. Notable foodborne disease incidence are caused by *Salmonella*, *Campylobacter*, *E. coli*, *Listeria*, *Vibrio*, *Yersinia*, *Clostridium perfringens* and *Staphylococcus aureus*. The CDC reports that Salmonella infections, unlike other major causes of foodborne illness, have not declined for the last fifteen years (CDC 2010b). Buzby and Roberts (2011) indicate that *Salmonella* cases alone accounted for about 85 percent of the foods refused entry into the US for direct food safety reasons and accounted for two-thirds of all pathogenic contaminations.

The monthly foodborne disease incidence for *Salmonella* in the US over the period of 1995 to December 2010 is shown in Figure 1. Monthly data shows frequent fluctuations in *Salmonella* incidence across years. The data on foodborne disease incidence was sourced from the Center for Disease Control and Prevention in the US. It is limited to 2010 because the FSMA's new regulatory regime came into being in January 2011. Hence, it is expected that the reasons for the institution of the new regulations would be observable prior to 2011. Table A.1[5] provides the descriptive statistics of the data.

[4] Acceptable agronomic practices also have to be developed for domestic production. Given that agronomic practices will vary depending upon the specific farming environment, foreign practices will often have to vary from those acceptable for domestic farming systems. Hence, there is the potential for requiring agronomic practices that are not the least trade distorting to achieve the desired food safety result.

[5] Table number preceded with an ' A' indicates it is in an appendix.

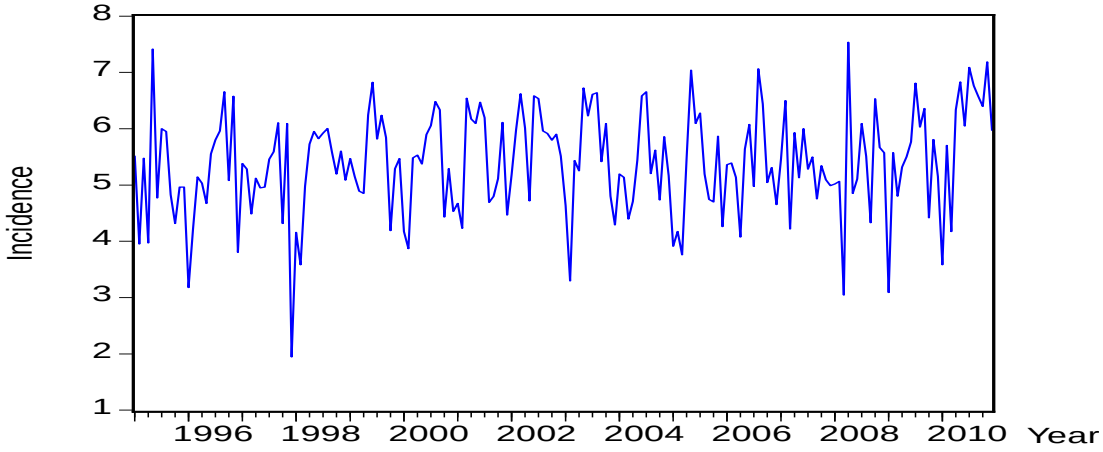

Fig 1 Trend in *Salmonella* incidence in US: 1995 – 2010

3.1 Modeling Salmonella foodborne disease incidence

Salmonella foodborne disease incidence is modelled using an augmented microbial growth model. Todar (2008 -2012) explained that microbial organisms exhibit three stages of growth: the exponential growth stage; the stationary stage; and the death stage. During the exponential stage the population of microbes expand exponentially and then remains fairly constant in the stationary stage. The microbial population rapidly declines during the 'death stage'. Hence, a model of microbial growth under cultured environment would include all these stages.

In modifying the model for our research, while acknowledge the importance of this model, we assert that a microbial population at a particular point in time may not necessarily match the incidence associated with it. First, as the entirety of a given microbial population may be difficult, if not impossible, to measure, our study focuses on modelling the activities of Salmonella microbial organism manifested in the form of foodborne diseases. We drop the 'three stages population growth model' assumption. Instead, we assert that food safety institutions are generally concerned about the trend in foodborne incidence which would follow a linear pattern. Exponential trends are beyond the scope of this paper. Trend in foodborne incidence is important in informing food safety institutions regarding the efficacy of current systems. In particular, a rising trend can indicate that the existing food safety measures have become less effective and might need strengthening or a policy intervention is required to enhance its effectiveness. If that is the case for Salmonella, it provides a justification for the FSMA. *Trend* is a time variable and measured as number of months.

Secondly, we hypothesize that incidence at a given point in time ($Salmonella_t$) is dependent on previous occurrences ($Salmonella_{t-i}$). The reason is that, microbial organisms by virtue of their different population stages, can affect incidence over their life cycle. When the underlying but unobservable previous Salmonella population is rising, constant or declining, we expect incidences to follow those trends. Hence, the sign of previous incidence ($Salmonella_t$) on

current Salmonella foodborne incidences can either be positive or negative. *Salmonella* incidence is therefore modelled from a simple growth model given as:

$$Salmonella_t = e^{(Salmonella_0 + \beta_1 Time)} \quad \text{Eq 1}$$

Taking natural log of Equation 1

$$LnSalmonella_t = Salmonella_0 + \beta_1 Time \quad \text{Eq 2}$$

Adjusting for Salmonella at *t-i*

$$LnSalmonella_t = Salmonella_0 + \beta_1 Time + \beta_2 Salmonella_{t-1} + \varepsilon_t \quad \text{Eq 3}$$

By assuming that incidence at t=0 ($Salmonella_0$) is defined by a constant β_0 the incidence equation becomes

$$LnSalmonella_t = \beta_0 + \beta_1 Time + \beta_2 Salmonella_{t-i} + \varepsilon_t \quad \text{Eq 4}$$

Where: i = number of lags); ε measures the error term; and $\beta_1 > 0$ and $\beta_2 <> 0$ (greater than or less than 0).

3.2 Estimated Salmonella disease incidence model

The results of the econometric estimations are presented in Table 1. The significance of the F-statistic (0.013692, at 5% significance level) suggests that independent variables jointly explain variations in Salmonella foodborne incidence. The coefficient of determination (R-square) is 0.044622 indicating that about 4.5 percent of the variation in incidence is explained by the model. This is expected due to the limited number of variables being included.

Further, Time (0.770412) has a positive effect on disease incidence and is significant at 5 percent. The positive relationship between incidence and Time shows that disease incidence has been growing significantly over time. This suggests that US food regulations were becoming obsolete in preventing *Salmonella* outbreaks and provides a reasonable justification for the US decision to strengthen food safety regulations. Previous incidence lagged by 1 mouth has a significant positive effect on present salmonella incidence thereby suggesting that past incidents increases future occurrences. A percentage increase in previous incidence increases present occurrence by 0.13 percent.

Table 1. Estimated *Salmonella* disease incidence model

Dependent Variable: LNSAMONELLA
Included observations: 191 after adjustments

Variable	Coefficient	Std. Error	t-Statistic	Prob.
C	203.4420	45.29555	4.491434	0.0000
SAMONELLA(-1)	0.130412	0.072310	1.803516	0.0729
TIME	0.770412	0.382212	2.015667	0.0453

R-squared	0.044622	Mean dependent var	319.7801
Adjusted R-squared	0.034459	S.D. dependent var	292.2035
S.E. of regression	287.1248	Akaike info criterion	14.17329
Sum squared resid	15498846	Schwarz criterion	14.22438
Log likelihood	-1350.550	F-statistic	4.390413
Durbin-Watson stat	2.028822	Prob(F-statistic)	0.013692

We also tested for structural change in trend using the Quandts Supremum (Max Chow) Test[6] (See Figure A1). The Quandts Supremum Test builds on the Chow Test in cases where the breakpoints are unknown. The estimated Max Chow Statistic (4.35) is not significant under critical values provided by Andrews (1993). This suggests that Salmonella incidence has not exhibited any significant shift in trend over the study period – incidents were not increasing at an increasing rate.

4.0 Conformity of FSMA to International Trade Commitments

This section discusses the conformity of FSMA provisions to WTO's non-discrimination principle, the SPS agreement and NAFTA commitments.

4.1 Conformity with Non-discrimination

As suggested above, the WTO employs two major principles to ensure that the actions of countries are not applied in a discriminatory fashion to inhibit trade. These are the *Most-Favoured-Nation principle* and the *National Treatment principle.*

The Most-favoured-nation (MFN) principle implies that when a country offers special trade measures such as lowered tariffs or other preferences in connection with importation from a single trading partner, other WTO members automatically become entitled to such offers (GATT 1947, Article I). The original trading partner offered import concessions is considered the

[6] For more information on Quandts Supremum (Max Chow) Test, see Allaro et al (2010, p. 394), Quandt (1958, 1960) and Andrews (1993).

importing country's "most favoured nation". Member countries cannot put in place discriminatory trade measures such that, for example, some countries face higher tariffs than others. These principles are also generally applied in the SPS. The FSMA suggests that countries that are perceived to have lax food safety laws will be targeted and those that demonstrate that their food safety standards provide the same level of protection may be recognised as equivalent to FSMA. This is legitimate under Article 4 of the SPS agreement which allows countries to discriminate, or require stricter measures, against products from countries whose food safety regulations are considered not to be equivalent to the importer's domestic regulations. In these cases, the non-discrimination requirement is waived. In view of this, we conclude that FSMA is in compliance with Most-Favoured-Nation Principle.

The National treatment principle bans discrimination against imported products that wish to enter or have entered the importer's domestic market. For now, the FSMA does not specify any preferential treatments for domestic goods when it takes effect. Imported fruit and vegetables, once they clear border inspections, are expected to be treated in the same way as domestic products. We therefore conclude that FSMA does not have any intent that seems to violate the National Treatment principle and, hence, conforms to broad WTO principles.

4.2 Conformity with the SPS

In accordance with the SPS, member countries can take food safety measures to protect lives and the environment provided those measures are based on sound science (SPS Agreement, Article 1). Further, the SPS agreement requires that in order for food safety measures to not arbitrarily inhibit trade, the food safety measures that a country employs must be proportionate to the level of risk. With respect to the FSMA, the level of risk that is posed by foodborne diseases and illness is not precisely defined. As such, it cannot be ascertained whether the standards set out by the FSMA are proportionate to the level of risk. If this proves contentious, resolution will have to await the outcome of a challenge at a WTO disputes panel.

The SPS also require member countries to execute food safety measures in a non-discriminatory manner. However, the FSMA exemption for US small scale farmers from some of its measures (i.e. traceability and HACCP), despite there being no scientific justification absolving them, may constitute an arbitrary and discriminatory application of food safety measures. The US would need to demonstrate to trading partners that US small scale domestic farmers do not pose a danger to food safety while similar sized foreign farmers do pose a risk. Without a scientific justification, the exemption for small US farmers would qualify as an arbitrary application of SPS measures to restrict trade.

There are precedents for such actions being considered discriminatory. For example, Australia banned the importation of apples from New Zealand because fire blight was found in New Zealand. Fire blight is a fungal disease which damages the leaves of apple trees and young shoots thereby greatly inhibiting the ability of apple trees to photosynthesis and produce fruit. New Zealand established that the fire blight was only associated with leaves and could not be transmitted by mature apples through trade but Australia maintained that the ban was precautionary due to insufficient scientific knowledge. New Zealand subsequently filed a case against Australia at the WTO in 2007. In 2010 the WTO Dispute Settlement Body ruled that

there was sufficient scientific information to do a risk assessment and the risk assessment showed that imports of mature fruit could not lead to spread of fire blight. The Panel therefore ruled that Australia's ban was inconsistent with its obligation under the application of SPS measures (WTO 2011b).

The New Zealand-Australia conflict provides some insights about the likely challenges that the FSMA might be facing from WTO trading partners. The US might be challenged to prove that the risk of foodborne disease in the US is comparable to the standards put against foreign firms. In particular, the exemption of domestic small scale operations in the US, and the relatively more frequent inspection of foreign firms compared to domestic ones, both of which appear to lack scientific justification, appear open to challenge. Hence, the FSMA could be viewed as inconsistent to US obligations under SPS agreement and imposes a higher compliance cost on foreign firms. This is because the FDA determines how frequently foreign firms must be inspected and the fees they pay for inspection. When the implicit and explicit costs are considerable, foreign firms could be rendered less competitive and the FSMA could constitute discriminatory application under the SPS (WTO 2011b).

5.0 Conclusions

The empirical results indicate that Salmonella-based foodborne diseases have risen significantly over time and thereby support the US decision to enact more stringent regulations. While it may be pre-mature to judge the conformity of the regulations to WTO commitments, some elements of the FSMA appear to be cause for concern. It is concluded that the regulations generally follow National Treatment and Most-Favoured Nation principles under the WTO. The exemption of small scale producers in US, without extending the same level of exemption to foreign firms, would appear to be an arbitrary application of food safety measures and does not have a scientific basis. More frequent inspections of foreign firms and the potential costs those impose in the absence compelling evidence of imports representing a higher risk could suggest protectionist intent. Hence, it would be prudent for trade partners to be vigilant in assessing the international commercial implications of new US regulations as the FDA rolls out its new regulatory regime over the next few years as mandated in the FSMA.

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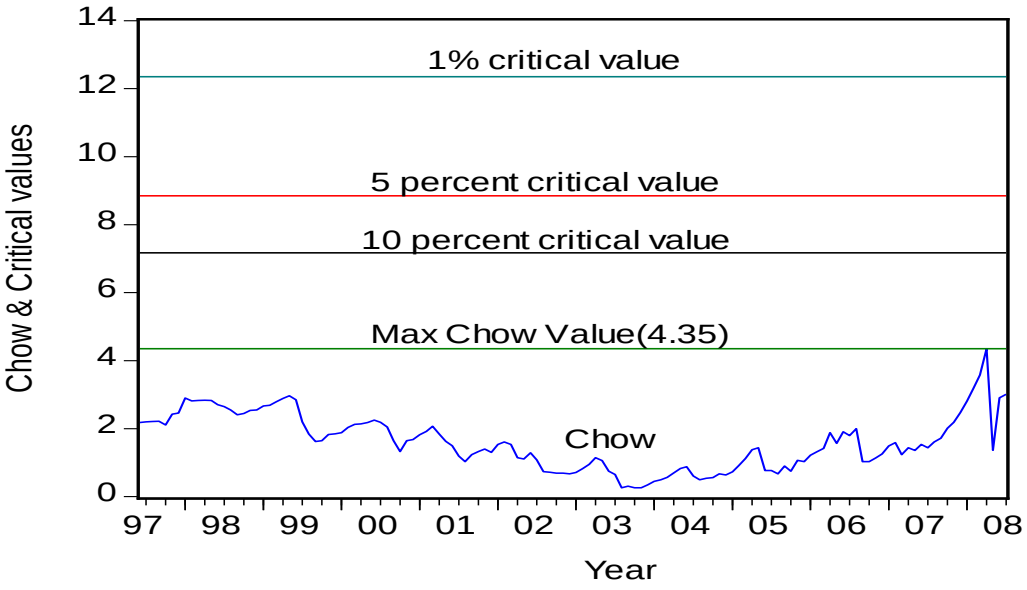
Appendix

Table A.1 Descriptive statistics of *Salmonella* incidence

Statistic	SAMONELLA
Mean	319.4167
Median	233.0000
Maximum	1873.000
Minimum	7.000000
Std. Dev.	291.4810
Skewness	2.153130
Kurtosis	9.331644
Jarque-Bera	469.0687
Probability	0.000000
Sum	61328.00
Sum Sq. Dev.	16227587
Observations	192

Figure A.1 Quandts Supremum (Max Chow) Test



Max Chow Value less than Andrews (1993) *critical values.*