



DIRECTORATE-GENERAL FOR INTERNAL POLICIES

POLICY DEPARTMENT **A**
ECONOMIC AND SCIENTIFIC POLICY

Economic and Monetary Affairs

Employment and Social Affairs

**Environment, Public Health
and Food Safety**

Industry, Research and Energy

Internal Market and Consumer Protection



Food Safety Policy and Regulation in the United States

Study for the ENVI Committee



**DIRECTORATE GENERAL FOR INTERNAL POLICIES
POLICY DEPARTMENT A: ECONOMIC AND SCIENTIFIC POLICY**

Food Safety Policy and Regulation In the United States

STUDY

Abstract

This study reviews and updates the previous 2013 report on Food safety policies and regulation in the United States. In particular the review considers the basic relevant legislative acts and the organisation of various branches of government, key changes in approach or implementation have also been identified. In addition, a list of the legislative requirements related to food safety in relation to the Transatlantic Trade and Investment Partnership (TTIP) is presented. A brief description is also given of current food safety emergencies in the United States.

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LIST OF ABBREVIATIONS

AFSI	American Food Safety Institute
CBP	Customs and Border Inspection
CDC	Centre for Disease Control and Prevention
CFSAN	Centre for food safety and Applied research
CVM	Centre for Veterinary Medicine
DHS	Department of Homeland Security
ERS	Economic Research Service
FATUS	Foreign Agricultural Trade of the United States
FCDA	Food Cosmetic and Drugs Act
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
FSMA	Food Safety Modernisation Act
FVM	Foods and Veterinary Medicine
FVO	Food and Veterinary Office
GAO	Government Accountability Office
HHS	Department of Health and Human Services
IFT	Institute of Food Technologists
TTB	Tobacco, Tax and Trade Bureau
TTIP	Transatlantic Trade and Investment Partnership
USDA	United States Department of Agriculture

EXECUTIVE SUMMARY

This briefing has been prepared to inform the Environment Public Health and Food Safety (ENVI) Committee's delegation to United States of America planned for 16-19 March 2015.

The USA is the world's largest economy and the third largest country by both land mass and population and has a diverse ethnic population mix. In food purchases recent research indicates that taste remains the most important driver for 87% of consumers, followed by price (79%), healthiness (66%), convenience (66%) and sustainability (52%). General trends in the consumers' purchasing are reported to be an increase in private labels, the use of convenience stores and the amount and variety of imported foods.

Whilst agriculture forms only a relatively small part of the gross domestic product (GDP) the food industry as a whole is very important to the American economy. It forms 20% of GDP and employs about 18 million individuals (including related industries). There are over 377,000 registered food facilities (including approximately 154,000 domestic facilities and 223,000 foreign facilities) that manufacture, process, pack, or hold food consumed by humans or animals in the United States (not including restaurants, institutional food service establishments, or supermarkets, grocery stores, and other food outlets).

Imported food comprises approximately 15% of the US food supply and for some foods (fresh fruits, vegetables and seafood) more is imported than is produced domestically. In addition a number of food ingredients (e.g. wheat gluten, soy and rice protein) are primarily sourced from outside the US and often from developing nations. US imports total approximately \$106 billion and exports \$145 billion hence the US is a net exporter of food and agricultural products. The main trading partners are reported to be Canada, European Union and Mexico for both imports and exports plus China and Japan as destinations for exports.

There is a long established system of food safety control and regulation which occurs at the federal (interstate commerce and import) and regional (intrastate commerce) level. The main agencies involved at the federal level include the Food and Drug Administration (FDA) and the Food Safety Inspection Service (FSIS) of the United States Department of Agriculture (USDA). The Food, Drug and Cosmetic Act 1938 (FDCA) as amended sets out the authority of the FDA whilst the Meat and Poultry Inspection Acts and the Egg Inspection Act set out the authority of FSIS.

Each state however also has its own agencies and regulations which each differ in their organisation and complexity. In addition certain state agencies undertake inspections, under contract, on behalf of the FDA.

The Centre for Disease Control, the Environmental Protection Agency and the Department for Home Security also contribute to the regulation and control of food safety.

Recent results (2013) of foodborne infection report that (compared to 2010 – 2012) there has been progress in reducing the number of Salmonella infections (9% less) although there was an increase (32%) in Vibrio infections. There was no statistically significant difference in the occurrence of other pathogens, although there was concern expressed about the rise in the incidence of E. coli infections which had previously shown past progress. None met the Healthy People 2020 targets. Since 2006 – 2008 the overall incidence of foodborne has not changed significantly.

There have been a number of recent high profile food incidents related to both domestic and imported food which have lead to the introduction of new legislation – the Food Safety Modernisation Act (FSMA) 2011. This is reportedly the most significant item of legislation in over 70 years and introduces a new approach to the regulation of food safety. It moves

away from the previous method of monitoring and reacting to food instances when they occur to one of prevention.

The main requirements include that of a scientific, risk based approach, hazard analysis and implementation applying to all food production establishments; importer verification and third party accreditations. The FDA is also given increased authority to issue a mandatory recall and to detain goods. The FDA is required to increase the frequency of inspection of both domestic and foreign food establishments. The act also calls for increased integration between federal and state agencies. As well as direct integration this includes such aspects as standardisation of laboratory accreditation and test methods, improved communication systems involving IT and requirements and permission for the exchange of such information.

The FSMA includes a timescale for its introduction and implementation. Seven rules have been proposed and are due to be finalised in 2015 and 2016 and implemented in 2016 and 2017. In preparation the FDA has begun the necessary planning and has taken initial steps, to ensure successful implementation, in the following areas: Inspection modernization; Technical staffing, FDA/state staff training, guidance development; Education and technical assistance for industry (including importers), new import food safety systems and Risk analysis and evaluation.

Initially the FDA had commented that the funding available through the annual budget will be a factor in the way that it handles its activities, including the way that the FSMA is implemented. The Congressional Budget Office has concluded that "there is a gap between FDA's current food safety resources and the level of funding that will be needed to implement FSMA". (FDA, 2013). Additional funding has been made available and the budget for 2016 includes an additional \$110 million.

The FSMA affects the controls of imported food, placing requirements on importers and third party audits. At the same time negotiations are also ongoing between the US and EU in relation to the Transatlantic Trade and Investment Partnership (TTIP) in the context of facilitating trade. This involves regulatory cooperation, making regulations in the EU and US more compatible. Concerns have been expressed however about the potential impacts for food safety. Both the US and EU have well developed food safety control structures and associated legislation. Although the US, under FSMA, is adopting a risk based approach similar to that in the EU, there are differences however in a number of areas. In particular the control of the use of growth promoting hormones and antibiotics for animals and antimicrobial rinses; novel foods including genetically modified organisms, cloned animals and nanomaterials are areas of concern. Fewer food allergens need to be declared in the US and there are differences on how food additives are defined and approved. Food labelling differs so that labels from either country are not acceptable in the other.

1. INTRODUCTION

This briefing has been prepared for the Environment, Public Health and Food Safety Committee (ENVI) Delegation to the USA in March 2015. It addresses:

- The structure of the existing food safety policy in the United States;
- The food safety organisation and key indicators for food safety development in the country.
- In particular the review considers:
 - Basic legislative acts
 - Organisation of legislation and regulation in various branches of government with regards to food safety.
- Current food safety emergencies in the USA.

1.1. Method

1.1.1. Sources of information

This briefing is based on the earlier report prepared for the ENVI Delegation to the USA in July 2013. The earlier document has been reviewed, key developments or changes to policy, responsibilities or approach identified, particularly in relation to the Food Safety Modernisation Act, and the report amended accordingly. In addition the Transatlantic Trade and Investment Partnership and food safety issues are listed. Thus the websites and official publications of the relevant regulatory and other authorities in USA were examined.

1.1.2. Map of USA

Map 1 Map of USA



Source: National Atlas of the United States 14 January 2013 –www.nationalatlas.gov

2. USA, FOOD PRODUCTION, IMPORTS AND EXPORTS

KEY FINDINGS

- The US food industry is large and diverse and the food industry contributes 20% of the US Gross National Product
- Imported products (value \$109 billion) have been increasing in amount and variety and account for 15% of the US food supply. For some products more is imported than is produced domestically (50% of fresh fruit, 20% of fresh vegetables and 80% of seafood are imported).
- The US however is a net exporter of food and agricultural products
- (Exports value \$144 billion)
- Main trading partners include Canada, Mexico, European Union, China and Japan
- Taste, price, healthiness, convenience and sustainability are drivers for consumer choice. Recent years have also seen the increase in sales of private label goods.

This chapter provides general information on the food industry in the USA.

The United States of America is the world's largest economy and the third-largest country by both land mass (after Russia and Canada) and by population (after China and India). It consists of 50 states and has a federal republic system of government.

Agriculture represents 1.1% of the US Gross National Product and farming, forestry and fishing employs 0.7% of the workforce (CIA Worldfact Book). The American food industry however contributes about 20 percent of the US Gross National Product, employs about 14 million individuals, and provides an additional 4 million jobs in related industries. There are over 377,000 registered food facilities (including approximately 154,000 domestic facilities and 223,000 foreign facilities) that manufacture, process, pack, or hold food consumed by humans or animals in the United States (not including restaurants, institutional food service establishments, or supermarkets, grocery stores, and other food outlets) (CFSAN – What we do).

The US population has a diverse ethnic mix which affects food preferences, the products offered for sale, outlet type, availability of different cuisines and also contributes to the requirement for the variety of imported foods. Imported food (from approximately 130,000 manufacturers in more than 150 countries) comprises 15% of the US food supply. For some foods more is imported than is produced domestically – 50% of fresh fruits, 20% of fresh vegetables and 80% of seafood consumed in America are produced outside the US. In addition a number of food ingredients (e.g. wheat gluten, soy and rice protein) are sourced from outside the US often from developing nations (FDA, 2013).

In addition, the Economic Research Service (ERS) reports (ERS, US imports) that a growing share of US imports can be attributed to intra-industry trade, whereby agricultural-processing industries based in the United States carry out certain processing steps offshore and import products at different levels of processing from their subsidiaries in foreign markets. Therefore, as well as fresh produce, ready-to-eat products form an increasing proportion of imported food products (FDA, 2013).

Whilst imports come from a large number of countries (Foreign Agricultural Trade of the United States, FATUS) the main source of imports by value (2013) are Canada (\$22

billion), Mexico and European Union (each \$17 billion) US imports of food and agricultural products totalled approximately \$109 billion of which the majority (\$70 billion) were plant foods (ERS, Food Imports 2013).

Americans spend \$600 billion each year on groceries, a figure expected to increase to \$700 billion in 2015 (Stevens, Food Quality, 2012). US food production therefore will continue to increase to meet this demand although this will also be under competition from increased imports.

A recent report indicated that taste remained the most important driver for 87% of consumers, followed by price (79%), healthfulness (66%), convenience (66%) and sustainability (52%) (Sloan, Food Technology 2012). Private labels' share of the US supermarket sales rose to 19.1%.

General trends in the food industry are reported to be an increase in private labels, the use of convenience stores amount and variety of imported foods.

The United States' main export markets for food and agricultural products in 2011 were China, Canada, Mexico, Japan and the European Union (ERS). In 2013 US food and agricultural exports were over \$144 billion. The US has held discussions and come to agreements with a number of countries in reducing sanitary and Phytosanitary barriers that applied to US food and agricultural exports.

Overall the US is a net exporter of food and agricultural products.

3. STRUCTURE OF THE FOOD SAFETY AND CONTROL SYSTEM IN THE USA

KEY FINDINGS

- Regulation exists at the federal, state, and local level
- The main federal agencies are the Food and Drug Administration (FDA) and the Department of Agriculture (USDA)
- Within USDA the main agency is the Food Safety Inspection Service (FSIS)
- The FDA has responsibility for 80% of food whilst FSIS regulates meat, poultry and eggs, although some overlap does occur
- Federal regulations govern interstate trade, imports and exports whilst State and local regulations govern intrastate trade
- The main federal regulations are the Food Drug and Cosmetic Act 1938, The Meat Inspection Act, The Poultry Inspection Act, The Egg Inspection Act
- The recent Food Modernisation Safety Act 2011 aims to improve food safety and mostly impacts on the activities of the FDA

This chapter provides an overview of the structure of the food safety and control system in USA.

The safety and quality of the US food supply is governed by a highly complex system which is collectively administered by fifteen agencies and stems from at least thirty laws (GAO, 2011).

The food supply chain in USA is regulated at the Federal (national), state and local level and by a number of agencies. Federal (National) law regulates interstate and international trade whilst state governments regulate intrastate businesses.

Thus the food safety system consists of federal agencies exercising designated food safety responsibilities in accordance with the main authorising statutes. Individual states may supplement these with their own statutes, regulations and agencies for regulating and inspecting food safety and quality.

Principal Federal Organisations

The principal organisations responsible for food safety are:

The Food and Drug Administration (FDA)

US Department of Agriculture (USDA) – Food Safety and Inspection Service (FSIS)

3.1. Food and Drug Administration

The Food and Drug Administration (FDA) is a federal agency within the US Department of Health and Human Services (HHS)¹. It consists of six product centres, one research centre, and two offices. The FDA's responsibilities extend to the 50 United States, the District of

¹ The FDA also has regulatory authority of many non-food products, including drugs, vaccines, medical devices, cosmetics and tobacco. This report however relates only to the FDA's regulation of foods.

Columbia, Puerto Rico, Guam, the Virgin Islands, American Samoa, and other US territories and possessions.

The current mission of the FDA Foods Program is to protect and promote the health of humans and animals by:

- Ensuring the safety of foods for humans, including dietary supplements;
- Ensuring the safety of animal feed and the safety and effectiveness of animal drugs;
- Setting science-based standards for preventing foodborne illness and ensuring compliance with these standards;
- Protecting the food and feed supply from intentional contamination;
- Ensuring that food labels contain reliable information consumers can use to choose healthy diets.

3.1.1. Responsibilities and activities

The responsibilities and activities of the FDA include:

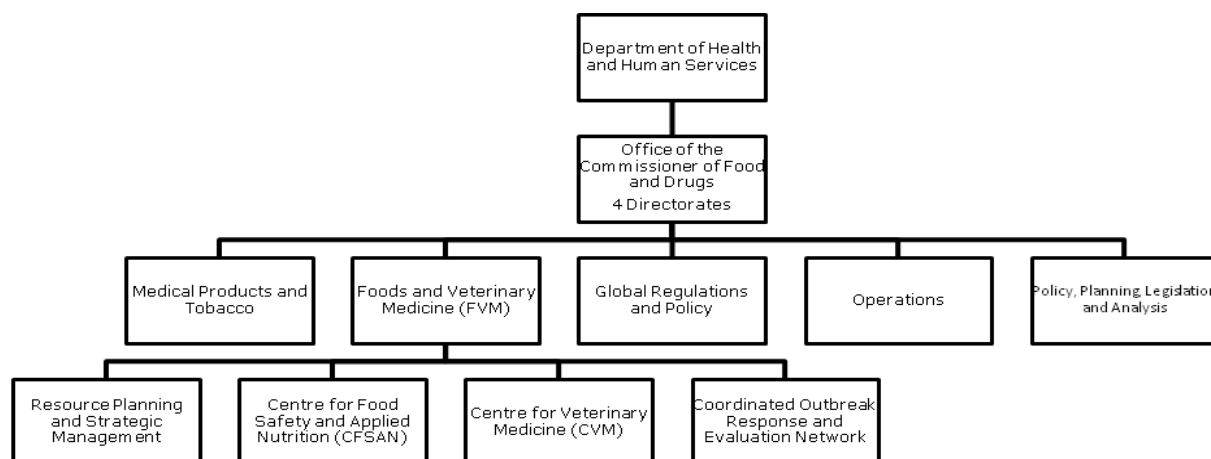
- Overseeing most (80%) of the US food supply (except for most meat and poultry products, which are regulated by the US Department of Agriculture – see below) and for ensuring its safety and security, so protecting the public health;
- Enforcing the regulations within its remit;
- Conducting inspections of manufacturers or processors of FDA-regulated products (including food processing facilities; dairy farms; animal feed processors; foreign manufacturing and processing sites; imported products at the border) to verify that they comply with relevant regulations;
- Working with state, local, tribal and territorial counterparts. The FDA funds contracts, grants and cooperative agreements for states to conduct inspections on its behalf and to build the necessary infrastructure and capacity to carry these out;
- Providing guidance, training, program evaluation, and scientific advice and technical assistance to state and local regulatory agencies, the industries they regulate and to public health partners. These include the Food Code and the Manufactured Food and Retail Regulatory Program Standards (see below) which promote uniform coverage of food establishments.

The FDA's responsibilities and activities and how these are undertaken have been influenced by developments related to the Food Safety Modernisation Act which are discussed further below.

3.1.2. FDA – Organisational structure

The FDA is an agency within the Department of Health and Human Services and consists of four directorates encompassing nine centres and offices. The chart below focuses on those which have food safety competencies.

Figure 1: Food and Drug Administration (FDA) – Organisation Chart
(Food safety competencies only)



Source: FDA website – [FDA Organisation overview](#). 19/02/2015

3.2. Office of Foods and Veterinary Medicine (FVM)

The Office of Foods and Veterinary Medicine was created in August 2009. Its responsibilities include:

- Providing all elements of FDA's Foods Program leadership, guidance, and support to achieve the Agency's public health goals;
- Acting as the focal point for planning the implementation of:
 - the recommendations of the President's Food Safety Working Group (FSWG)
 - the new food safety authorities contained in the 2011 FDA Food Safety Modernization Act.

3.3. Centre for Food Safety and Applied Nutrition (CFSAN)

CFSAN is the primary centre for food safety and is responsible for FDA initiatives to reduce the risk of foodborne illness, including standard setting and compliance strategies for domestically produced and imported products, and the provision of technical guidance to states and localities.

3.4. Centre for Veterinary Medicine (CVM)

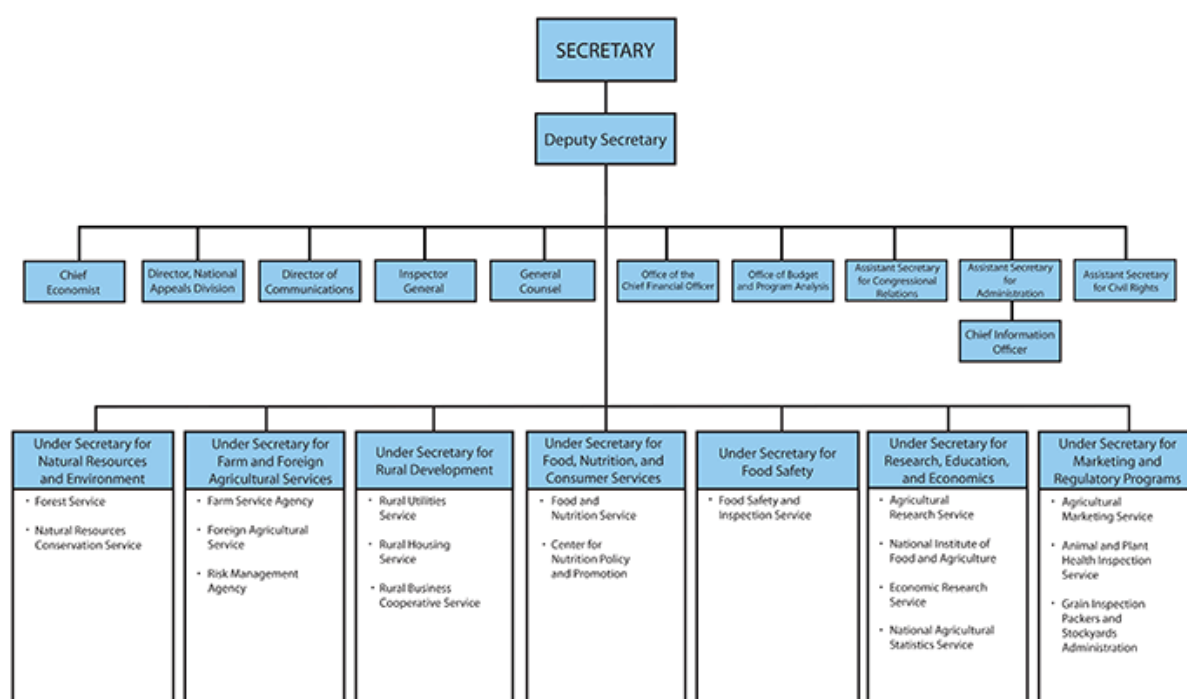
The Centre for Veterinary Medicine (CVM) regulates the manufacture and distribution of food additives and drugs that will be given to animals. These include animals from which human foods are derived, as well as food additives and drugs for pet (or companion) animals.

3.5. US Department of Agriculture (USDA)

The mission statement of USDA is to “provide leadership on food, agriculture, natural resources, rural development, nutrition, and related issues based on sound public policy, the best available science, and efficient management” and further includes that of enhancing food safety by taking steps to reduce the prevalence of foodborne hazards from farm to table.

USDA has seven main areas of responsibility – one of which is food safety and is comprised of a single agency, the Food Safety and Inspection Service:

Figure 2: Organisation chart - United States Department of Agriculture (USDA)



Source: USDA website http://www.usda.gov/wps/portal/usda/usdahome?navid=USDA_ORG_CHART 19/02/2015

3.6. Food Safety and Inspection Service (FSIS)

The Food Safety Inspection Service is responsible for meat and poultry inspection in processing plants that trade across state lines. If a processing plant sells its products in-state only, the inspection can be conducted by state inspectors. Conversely if a processing plant has undergone state inspection it is only able to sell its products within that state. State meat and poultry inspections are however an integral part of the nation’s food safety system. FSIS operates under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act and inspects and monitors all meat, poultry and egg products sold in interstate and foreign commerce, reinspecting imported products, to ensure compliance with mandatory US food safety standards and inspection legislation.

USDA consists of a network of Federal inspectors in more than 6,000 locations nationwide.

FSIS is mandated to visually examine every carcass passing through slaughter plants - including over 8 billion chickens and 125 million head of livestock—and to inspect the several thousand processing plants daily. FSIS collaborates with state inspection agencies that conduct meat and poultry inspection in certain plants.

Unlike FDA, FSIS does not have jurisdiction on farms and generally defers to FDA and the states and localities to oversee food safety at retail.

3.7. Animal and Plant Health Inspection Service (APHIS)

APHIS is a multi-faceted agency with a broad area of responsibility that includes protecting and promoting US agricultural health, regulating genetically engineered organisms, administering the Animal Welfare Act and carrying out wildlife damage limitation activities. In support of USDA's overall aims its role has expanded to incorporate matters relating to the protection of public health and safety that are subject to invasive pests and pathogens.

3.8. Agricultural Marketing Service (AMS)

AMS is an agency within the United States Department of Agriculture (USDA), supports the fair marketing of US agricultural products by providing testing, standardization, grading and market news services, overseeing marketing agreements and orders and administering research and promotion programs. The AMS enforces certain federal laws such as the Perishable Agricultural Commodities Act and the Federal Seed Act and also regulates organic food production.

3.9. Department of Homeland Security (DHS)

DHS is the primary agency responsible for integrating and coordinating efforts among federal, state, and local agencies, as well as the private sector, to protect critical infrastructure and key resources from intentional attack, including in the food and agriculture sectors. DHS works closely with the USDA, FDA, and other federal, state, and local agencies to secure the nation's food supply through programs aimed at education, prevention, surveillance, threat detection, and rapid response. It operates under presidential directives relating to food defence.

In carrying out these directives, DHS, in conjunction with FDA and USDA, created two bodies in March 2004, one for government officials (the Government Coordinating Council) and one for private industry (the Food and Agriculture Sector Coordinating Council), to work together on food security initiatives.

The Government Coordinating Council comprises those federal, state, tribal, and local governmental agencies responsible for a variety of activities including agricultural, food, veterinary, public health, laboratory, and law enforcement programs.

The Food and Agriculture Sector Coordinating Council comprises private companies and associations representing key components of the food system.

3.10. Customs & Border Protection (CBP)

The Customs and Border Protection Agency (CBP) is one of the Department of Homeland Security's largest and most complex agencies. CBP personnel have authority to hold suspect shipments for further examination and sampling under the Bioterrorism Act. Their laboratories and scientific services coordinate technical and scientific support to all CBP trade and border protection activities.

3.11. Centre for Disease Control and Prevention (CDC)

The Centre for Disease Control and Prevention (CDC) is part of the Department of Health and Human Services (DHHS). It is, and has historically been, involved in tracking single cases of food poisoning and outbreaks. CDC leads federal efforts to gather data on foodborne illnesses, investigate foodborne illnesses and outbreaks, and monitor the

effectiveness of prevention and control efforts in reducing foodborne illnesses. CDC also plays a key role in building state and local health department epidemiology, laboratory, and environmental health capacity to support foodborne disease surveillance and outbreak response.

The Food Safety Modernisation Act (FSMA) (see below) requires CDC to strengthen the capacity of state and local health departments to respond to foodborne outbreaks and improve the coordination and integration of surveillance systems and laboratory networks. In addition to developing a national strategy for food safety, CDC will also provide support to the Food and Drug Administration in implementing new hazard analysis, prevention, performance, and training activities required by the law.

3.12. Environmental Protection Agency (EPA)

The EPA sets limits for pesticides, establishing their permitted uses and use conditions including those used in food production which USDA and the FDA enforce. EPA is also responsible for setting the tolerances that define the limit on the amount of an agricultural pesticide that can legally remain in food. Pesticide use restrictions are enforced by state agencies under contract to EPA, while FDA enforces pesticide tolerances. As EPA makes far more regulatory decisions about the safety of chemicals in food than FDA or any other agency, it plays an important scientific role in establishing practices for chemical risk assessment.

3.12.1. Other Agencies

3.12.2. National Marine Fisheries Service (NMRS)

The National Marine Fisheries Service (NMRS) (part of the National Oceanic and Atmospheric Administration) is the federal agency, a division of the Department of Commerce, responsible for the stewardship of the nation's living marine resources and their habitat. NOAA's National Marine Fisheries Service assesses and predicts the status of fish stocks, ensures compliance with fisheries regulations and works to reduce wasteful fishing practices.

3.12.3. Tobacco, Tax and Trade Bureau (TTB)

The regulatory responsibility for alcoholic beverages in the US is shared between two different federal agencies dependent on their composition. They are the FDA and the Alcohol and Tobacco Tax and Trade Bureau. The TTB is responsible for all malt beverages regardless of strength, spirits, and wines (including fruit wines) over 7%. This means that beverages such as ciders that contain under 7% alcohol by volume fall under the jurisdiction of the FDA. A similar situation occurs whereby all beers that are not defined as malt beverages; for example, beer made from sorghum which are also subject to FDA. The TTB requires that labels be approved by them prior to being placed on the market in the US. This process is known as the Certificate of Label Approval (COLA) system.

3.12.4. State and local agencies

The majority of government food safety activities are undertaken by more than 3,000 state and local agencies. The particular agencies involved and division of responsibilities depends upon the particular state's governmental structure although typically this is the state's health and agriculture departments.

There is significant diversity at the local level in terms of size, capacity, capability (food safety expertise) and in how they relate to the agencies at the state level. Nevertheless the federal, state and local agencies have a long history of collaboration and all three are

interrelated and inter-dependent. In particular there are a number of collaborative programs in place which contribute to foodborne illness surveillance and response as well as to prevention, inspection and regulatory activities (see Annex 2).

3.12.5. General role

The roles undertaken by state and local governments include conducting surveillance, investigating and containing illness outbreaks, inspection (of restaurants, retail outlets and food processing plants, providing education to food workers and consumers and taking regulatory action such as removing products from the market. A further indication of the responsibilities of state and local authorities is given in Table 1 in the next page.

3.12.6. Cooperative Programs – FDA

Three cooperative programs are authorised by the US Public Health Service Act to protect consumers from foodborne illness arising from: retail food, milk and shellfish.

Under these state and local governments have the responsibility and authority for regulating retail and food service establishments, milk plants and dairy farms and shellfish plants and growing waters.

The FDA assists by providing model national codes (Food Code), interpretive guidance, training, certification and other technical assistance.

3.12.7. Cooperative Programs - USDA

State Meat and Poultry Inspections (MPI) programs operate under a cooperative agreement with FSIS. Under the agreement, a State's program must enforce requirements "at least equal to" those imposed under the Federal Meat Inspection Act and the Poultry Products Inspection Act. In States with inspection programs, establishments have the option to apply for Federal or State inspection. However, product produced under State inspection is limited to intrastate commerce. 27 states operate their own inspection system. The other states have given up their meat or poultry inspection programs or both to FSIS. FSIS must provide for the inspection in the designated category regardless of whether the product is shipped in interstate commerce. State Meat and Poultry Inspection (MPI) Programs are an integral part of the nation's food safety system. About 1,900 meat and poultry establishments are inspected under State MPI programs.

FSIS conducts comprehensive reviews of the State Meat and Poultry Inspection (MPI) programs and their requirements - including enforcement of those requirements - with respect to slaughter, preparation, processing, storage, handling, and distribution of livestock carcasses and parts, meat and meat food products, and poultry products to ensure they are at least equal to the Federal inspection programme. This consists of an annual review of the state's self-assessment submission and a triennial on-site review.

Table 1: Roles of state and local agencies in food safety

Activity	State	Local
Surveillance	Key responsibility for ongoing foodborne illness surveillance: Working independently and with CDC and local agencies Implementing reportable disease requirements Participating in FoodNet, PulseNet, OutbreakNet and other national foodborne surveillance activities.	Frontline responsibility for reporting foodborne diseases and on-going foodborne illness surveillance Collect and respond to consumer complaints
Outbreak response and recalls	Typically lead responsibility large-scale outbreak investigations Oversee industry recalls in collaboration federal and local regulatory authorities	First responders and lead investigators for local outbreaks Collaborate with state and federal agencies on larger, multi-jurisdictional outbreaks Implements recalls Communicate with the public and food establishments
Laboratory testing	Conduct majority of all government food-safety-related testing	Some jurisdictions conduct food safety laboratory functions
Retail and foodservice inspection	In some states – Retail food safety standard setting Inspection of retail and food service establishments	Set retail food safety standards License retail establishments Extensive role in inspection of grocery stores and restaurants
Food manufacturing inspections	Conduct 80% all non-retail food establishment inspections (not including USDA-inspected meat and poultry establishments) Conduct majority of FDA inspections in food manufacturing and processing facilities under contract with FDA	
Farm inspections	On-farm inspections for animal health and other conditions related to food safety Enforce federal pesticide use restrictions Good Agricultural Practice assessments of produce growers Partnership programs with shell egg producers (reduction of <i>S enteritidis</i>)	
Technical and training assistance	Extensive technical training and assistance to: State agency employees Health department staff Grocery, restaurant and other retail food service workers	Technical and training assistance to: Local agency staff Grocery, restaurant and other retail service workers
Education	Food safety education provided for: Local health department staff Food workers Other commercial participants in food safety system Consumers Medical community	Frontline source of food safety information and education for consumers and retailers 75% have food safety education programs

Source: Taylor, RT and David, SD 2009

3.13. Legislation

Food safety agencies at all levels of government work within the legal framework that is created by their respective legislative bodies, interpreted by the courts, and underpinned by the federal and state constitutions. Under the federal system of government, food safety agencies work within a legal framework that is generally conducive to federal-state-local collaboration. The US constitution underpins the current legal framework which provides the basis for such collaboration (Whitehouse website – State agencies).

Food safety falls under the requirement to protect public health which, according to the US constitution, comes under the powers of the states. State governments are therefore empowered and expected to protect the safety of the food supply within their boundaries. They have the power to set and enforce their own food safety standards even if that standard is different from and more stringent than that of an applicable federal standard.

The federal government has the broad power, under the US constitution, to protect the general welfare of the population and to regulate interstate commerce and activities that affect commerce, including food safety. As such Congress has introduced a large number of enactments establishing the food safety programs of FDA, USDA, CDC, EPA and the other agencies discussed above.

Divergences, for example under the Supremacy clause where Congress expressly or by clear implication pre-empts a state enactment, or under the Commerce clause – if a state law or regulation unduly burdens or discriminates against interstate commerce, are determined by the courts on a case-by-case basis. Generally however courts recognise and respect the food safety and regulatory roles of state and local governments.

Most states have adopted statutes that are modelled on, and are consistent with, the federal food safety laws. In the case of the Food Code for example this can result in the adoption of science-based retail food safety standards that are consistent not only between federal and state governments but also among the states (Taylor and David, 2009; David).

This section therefore considers the federal rules concerning food safety, rather than those of individual states.

The general and permanent rules published in the Federal Register by the departments and agencies of the Federal Government are codified in the Code of Federal Regulations (CFR). This is divided into 50 titles of which:

- Title 21 – parts 1-199 addresses food issues (encompassing FDA regulations)
- Title 9 – addresses animals and animal products (encompassing USDA regulations).

As indicated above the control of food safety is primarily governed by two agencies (FDA and USDA) and in turn they are directed by different items of legislation:

- FDA - The Food Drug and Cosmetic Act 1938 (FDCA)
- USDA - Federal Meat Inspection Act (FMIA)
 Poultry Products Inspection Act (PPIA)
 Egg Products Inspection Act (EPIA).

Legislation concerning the food safety system has developed in response to particular policy needs and it can be fragmented whereby more than one agency has responsibility for different aspects of a product.

3.13.1. Food Drug and Cosmetic Act (FDCA)

The Food, Drug and Cosmetic Act (FDCA), a federal law enacted by Congress in 1938, is the primary food law in the United States and gives authority to the Food and Drug Administration to:

- Oversee the safety of food (as well as drugs and cosmetics);
- Set standards for foods;
- Conduct factory inspections.

It is found in the United States Code which contains all general and permanent US laws beginning at Title 21, USC 301. The FDCA consists of ten chapters of which Chapter 4 relates to food. This chapter details a range of criteria establishing the quality and safety of foods; inspection priorities; laboratory requirements and the registration of facilities. It protects the safety and quality of the food supply by prohibiting two acts: adulteration and misbranding.

FDA develops detailed regulations based on the laws set out in the FDCA or other laws under which it operates. Typically this involves a process known as "notice and comment rulemaking" that allows for public input on a proposed regulation before FDA issues a final regulation.

The FDA ensures that food companies are complying with the FDCA through inspections of factories, warehouses or other establishments where food is manufactured, processed, packed or held and the vehicles used to transport it. The act has been amended a number of times, most recently in relation to the Bioterrorism Act and also the Food Safety and Modernisation Act (see below).

3.13.2. Food Code

The US Food and Drug Administration (FDA) also publishes guidance in the form of the Food Code, the purpose of which is to "safeguard public health and provide to consumers food that is safe, unadulterated, and honestly presented". The Code establishes definitions and sets standards for management and personnel, food operations, and equipment and facilities. It is a model that assists food control jurisdictions at all levels of government by providing them with a scientifically sound technical and legal basis for regulating the retail and food service segment of the industry (restaurants and grocery stores and institutions such as nursing homes). Local, state, tribal, and federal regulators use the FDA Food Code as a model to develop or update their own food safety rules and to be consistent with national food regulatory policy.

The FDA works with CDC and FSIS on a biennial update: a fully revised edition is published every four years and was last issued in 2013.

3.13.3. Federal Meat Inspection Act (FMIA)

The Federal Meat Inspection Act of 1906 (FMIA) is a United States Congress Act to prevent adulterated or misbranded meat and meat products from being sold as food and to ensure that meat and meat products are slaughtered and processed under sanitary conditions. The four primary requirements of the FMIA are:

- Mandatory inspection of livestock before slaughter (cattle, sheep, goats, equines, and swine);
- Mandatory post-mortem inspection of every carcass;

- Establishment of sanitary standards for slaughterhouses and meat processing plants;
- Ongoing monitoring and inspection of slaughter and processing operations by USDA.

These requirements also apply to imported meat products. However, the Food, Drug, and Cosmetic Act authorises the Food and Drug Administration (FDA) to provide inspection services for all livestock and poultry species not listed in the FMIA or PPIA, including venison and buffalo.

3.13.4. Poultry Products Inspection Act (PPIA)

The Poultry Products Inspection Act requires the United States Department of Agriculture's Food Safety and Inspection Service (FSIS) to inspect all domesticated birds when slaughtered and processed into products for human consumption. By regulation, FSIS has defined domesticated birds as chickens, turkeys, ducks, geese, and guinea fowl. **Ratites were added in 2001. FSIS provides for the inspection of all poultry products sold in** interstate commerce, and the re-inspection of imported products to ensure that they meet US food safety standards.

3.13.5. Egg Products Inspection Act (EPIA)

The Egg Products Inspection Act (EPIA) imposes specific inspection requirements for two categories of eggs - egg products and shell eggs. Federal agriculture officials, or state officials acting on behalf of USDA, visit egg packers and hatcheries at least every three months to ensure that they are in compliance with the law. Firms which transport, ship or receive shell eggs and egg products may also be checked periodically. Plants that break, dry and process shell eggs into liquid, frozen or dried egg products must operate under the continuous inspection program of the USDA. An official inspector must be present at all times when eggs are being processed.

Under the Egg Products Inspection Act (EPIA), FSIS inspects egg products sold in interstate commerce, and reinspects imported products to ensure that they meet US food safety standards. In egg processing plants, inspection involves examining, before and after breaking, eggs intended for further processing and use as food.

3.13.6. Bioterrorism Act

The events of September 11, 2001 highlighted the need to enhance the overall security of the US food supply and resulted in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act/BTA).

The Act required domestic and foreign facilities that manufacture, process, pack or hold food intended for human consumption to register with the FDA. The Act includes a number of provisions designed to improve the food safety efforts of the Food and Drug Administration (FDA) in cooperation with US Customs and Border Protection (CBP), including new authority to protect the food supply against terrorist acts and other threats.

Under a special agreement, CBP personnel at many ports of entry around the country have been formally commissioned and specially trained to conduct cargo and other examinations under the BTA. CBP personnel have authority to hold suspect shipments for further examination and sampling.

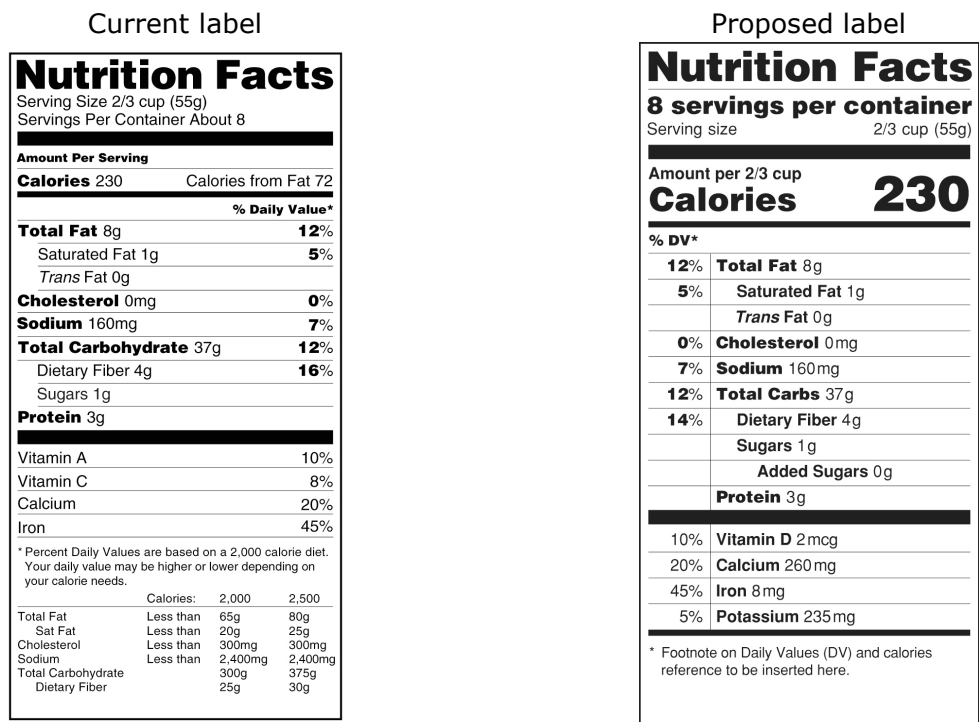
3.13.7. Food Labelling

Food labelling is required for most prepared foods, such as breads, cereals, canned and frozen foods, snacks, desserts, drinks. Nutrition labelling for raw produce (fruits and

vegetables) and fish is voluntary. Food labelling is under the jurisdiction of the FDA and the relevant Federal laws are the Food, Drug, and Cosmetic Act (FDCA) and the Fair Packaging and Labelling Act. In addition, the Nutrition Labelling and Education Act (NLEA), which amended the FDCA, requires most foods to carry nutrition labelling and requires food labels that carry nutrient content claims and certain health messages to comply with specific requirements.

This area of legislation is currently undergoing change to reflect the greater understanding in nutrition science and concerns about diet, health, obesity and cardiovascular disease. The nutrition fact panel was introduced in the US 20 years ago to help consumers make informed food choices. In 2014 the FDA (Federal Register, 3rd March 2014) introduced two proposed changes to the nutrition fact panel relating to modifications to the required nutrients, updated serving size requirements to reflect current eating habits, new labelling requirements for certain pack sizes and a revised design to highlight key elements such as calories. The proposed changes would affect all packaged foods except certain meat, poultry and processed egg products, which are regulated by the U.S. Department of Agriculture’s Food Safety and Inspection Service.

Figure 3: Examples of current and amended nutrition fact labels



Source: FDA [Proposed changes to nutrition facts label](#)

The legislative requirements apply to foods produced domestically, as well as those from foreign countries. The labelling requirements however differ between the US and the EU in a number of areas including: where information needs to be placed on the label; mandatory information; name of the food; allergen statement (including the allergens requiring declaration); quantitative ingredient declaration (QUID); net quantity of food; date of minimum durability, any special storage conditions or conditions of use; name and address of the food business; alcoholic strength declaration; nutrition declaration; language requirements, text size requirements. Key areas of difference with respect to nutrition labelling relate to the basis of the declaration (per portion (US) / per 100g/100ml EU); presentation and placement of the information; text size requirements.

As such it is not currently possible to have one label for a foodstuff that is legally compliant in both markets. An example of a US label and an EU label for a 37g bar of chocolate is given below and a further detailed comparison of the labelling requirements in Annex 1.

Figure 4: Example of US and EU nutrition labelling (37g chocolate bar)

US nutrition facts

Nutrition Facts			
Serving Size 1 bar (37g)			
Amount Per Serving			
Calories 180		Calories from Fat 80	
			% Daily Values*
Total Fat 9g		14%	
Saturated Fat 5g		25%	
Trans Fat 0g			
Cholesterol 0mg		0%	
Sodium 55mg		2%	
Total Carbohydrate 23g		8%	
Dietary Fiber 0g		0%	
Sugars 18g			
Protein 2g		4%	
*Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs.			
	Calories	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2400mg	2400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Source: FDA Nutrition facts label

NUTRITION INFORMATION			
	Per 100g	Per Bar (37g)	Reference Intakes*
Energy	2025 kJ 485 kcal	749 kJ 179 kcal	8400 kJ/ 2000 kcal
Fat	24.0g	8.9g	70g
of which Saturates	14.0g	5.3g	20g
Carbohydrate	61.0g	22.5g	260g
of which Sugars	48.5g	18.0g	90g
Fibre	0.4g	0.2g	-
Protein	5.1g	1.9g	50g
Salt	0.38g	0.14g	6g

*Reference intake of an average adult (8400 kJ/2000 kcal)

Source: Campden BRI

3.13.8. Food Safety Modernisation Act (FSMA)

The FDA Food Safety Modernization Act (FSMA) was signed into law on January 4, 2011 and represents the first major overhaul of food safety legislation in more than 70 years. It aims to ensure that the US food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing it. This new law affects the activities of the FDA, rather than USDA, and provides it with new enforcement and inspection authorities.

Whilst the FDA is charged with regulating most food products, the legislation also recognizes that food safety is a responsibility shared among US state, local, territorial, tribal, and foreign food safety agencies and therefore requires additional integration of the food control system and participation by all stakeholders. The FSMA strategy recognizes that the food industry has the primary responsibility and capacity to produce safe food, but it calls for a new definition of public and private roles on food safety and a modern new framework for regulatory oversight, integration of government food safety efforts, and public-private collaboration.

It was recognised that to build and implement a new food safety system would take time so specific implementation dates were established in the legislation with deadlines to issue key final FSMA rules in the second half of 2015, and in the first quarter of 2016. Initially an implementation management structure was put into place to ensure clearly defined roles and accountability for each FSMA deliverable. Implementation is focused on six major areas each headed by an Implementation Leadership Team. Task-specific working groups report

to these teams and are responsible for developing the regulations, reports, guidance and processes required by the legislation. The six implementation teams are: Prevention standards; Inspection and compliance; Imports; Federal / State Integration; Fees; Reports and Studies.

The FSMA's planned implementation process involves "notice and comment rulemaking" allowing for public input on a proposed regulation. During the development of the Food Safety Modernisation there has been considerable effort to inform the food industry and other stakeholders about the rules.

3.13.9. Key developments 2013-2015 – Rules

Seven proposed rules have been established: four key rules in 2013 and a further three during 2013 – 2014 i.e.:

1. Produce Safety Standards
2. Preventive Controls for Human Food
3. Foreign Supplier Verification Programme
4. Preventive Controls for Animal Feed
5. Accredited Third Party Certification
6. Mitigation strategies to protect food from intentional adulteration
7. Sanitary transportation of human and animal food.

A summary of the requirements is given in Table 2.

Proposals have been published for all of the initial five rules. Except in the case of the rule for Accredited third party accreditation, all have been made available for public comment, subsequently amended and revised proposed rules published in 2014. Some rules underwent significant revision. Typically the revised proposals address the scope of the rule, identifying areas for inclusion or exclusion and providing additional definitions (e.g. small business). The comment period for the latter two rules closed in May and June 2014.

Table 2: Food Safety Modernisation Act – Summary

Rule:	Produce Safety Standards	Preventive Controls for Human Food	Foreign Supplier Verification Programme	Preventive Controls for Animal Feed	Accredited Third Party Certification	Mitigation against intentional adulteration	Transportation
Brief Description	Sets enforceable standards: For the growing, harvesting, packing and holding of fruits and vegetables on farms; Considerations for how produce will be used and consumed once it leaves the farm Exceptions for those: Rarely consumed raw; For personal consumption; Destined for commercial processing from exempted farms	Focus – preventing problems that cause human foodborne illness Requirements: Hazard analysis – written plan, to include economic adulteration Risk based preventive controls to encompass: Process, food allergen; sanitation controls and a recall plan Monitoring procedures Corrective actions Exceptions: Certain low risk activities – Process qualified On farm packing and holding	Importer accountable Requires importers to: Conduct risk-based foreign supplier verification activities To determine imported food is not adulterated and is produced according to FDA’s preventive control requirements and produce safety standards as applicable. Certification for high risk foods Authority to deny entry Renewal of food facility registrations	Previously referred to human food requirements. Revised rules include the implementation of current good manufacturing practices (CGMP) rules that are more applicable to animal food producers. Takes into account feed mills associated with farms; Other changes are in line with preventative controls for human food	Qualified third parties can certify that foreign food facilities comply with US food safety standards. Audit report available to FDA Auditor must immediately notify any serious risk to public health FDA to consider existing international standards and accreditation bodies when developing standard Prior notice to advise if food refused entry elsewhere	To address intentional adulteration where the intention is to cause large-scale public health harm. Targets processes within a facility that are most likely to be vulnerable, rather than specific foods or hazards.	To prevent practices in transport that create food safety risks such as not maintaining the integrity of the cold chain by proper refrigeration; inadequate cleaning and not properly protecting the food
Applies to	All unprocessed fruits and vegetables intended for human consumption, including on farm	Facilities that manufacture, process, pack or hold human food. Domestic and foreign companies	Imported food (certain exemptions apply)		Imported food: Requirement based on risk of the food and any legal requirements	Domestic and foreign food facilities that manufacture, process, pack or hold food	Shippers, receivers, and carriers of food by road or rail and to exporters shipping food to US

Rule:	Produce Safety Standards	Preventive Controls for Human Food	Foreign Supplier Verification Programme	Preventive Controls for Animal Feed	Accredited Third Party Certification	Mitigation against intentional adulteration	Transportation
	packing and holding						
Additional requirements	Training; Review of: manure standards, flexible water standard; wild animals	Revision of current GMP controls re cross contamination and allergens	Third party accreditation Voluntary qualified importer program		May deny entry to an import if foreign facility refuses FDA inspection	Preparation of food defence plan, Training	Vehicle and transport equipment and operation requirements, Information exchange, training, records
Status: Proposed rule Comments: Revised date: Publication final rule (P) Effective date (E) General compliance Small business compliance Very small business compliance	Revised 4 th Jan 2013 15 th Dec 2014 29 th Sept 2014 31 st Oct 2015 P + 60 days E + 2 years E + 3 years E + 4 years	Revised 4 Jan 2013 15 th Dec 2014 29 th Sep 2014 30 th Aug 2015 P + 60 days E + 1 year E + 2 years E + 3 years	Revised 29 th July 2013 29 th Sept 2014 31 st Oct 2015 Enactment + 1 year; FDA recognition accreditation bodies Enactment+ 2 years Voluntary qualified importer program – Enactment + 18mths	Revised rule 29 th Oct 2013 29 th Sept 2014 30 th Aug 2015	Proposed 29 th July 2013 31 st Oct 2015	Proposed 24 Dec 2013 31 May 2016 P + 60 days Tiered compliance based on business size	Proposed 31 May 2014 31 Mar 2016 P + 60 days Tiered compliance based on business size

Source: [FDA, Background on the FDA Food Safety Modernization Act \(FSMA\)](#)

3.13.10. Key developments 2013-2015 – FDA actions

Preparation is required so that the rules can be implemented when they come into force in late 2016 and 2017. The FDA has begun necessary planning and has taken initial steps, to ensure successful implementation, in such areas as:

- Inspection modernization,
- Technical staffing, FDA/state staff training, guidance development,
- Education and technical assistance for industry (including importers),
- New import food safety systems,
- Risk analysis and evaluation.

Initially the FDA had commented that the funding available through the annual budget will be a factor in the way that it handles its activities, including the way that the FSMA is implemented. The Congressional Budget Office has concluded that “there is a gap between FDA’s current food safety resources and the level of funding that will be needed to implement FSMA” (FDA, 2013).

In order to meet the requirements of the FSMA additional resource has been provided to the FDA. The Agency received an additional \$27.5 million in the current fiscal year. Further additional resource is proposed including an increase of £109.5 million of new budget authority in 2016.

3.13.11. Changes in approach

FSMA is reported to be the first major overhaul of food safety legislation in the US for 70 years. A summary of the changes in the key areas is given below:

• Standards and Guidance documents

Before FSMA

The emphasis was on verifying and monitoring the end result. Commodity specific standards existed for certain products such as eggs following the association with Salmonella; HACCP was required for juice and seafood and Good Manufacturing Practice (GMP) regulations described requirements for processed foods.

Following FSMA

Product standards remain however the emphasis is on the use of risk-based systems to prevent problems:

- Preventive control - Food production facilities (human and animal) to undertake hazard analysis and have preventive controls in place including monitoring to verify the controls and preventive actions
- Farms to comply with science based minimum standards for the safe production and harvesting of fruit and vegetables
- Foreign Supplier Verification Programme - Importers have the responsibility to undertake risk-based verification to ensure that their foreign suppliers supply food that is produced to the same standards to those required by FSMA
- Performance standards – FDA to set appropriate performance standards for

contaminants as needed.

- **Inspection and Compliance**

Before FSMA

FDA was responsible for conducting inspections of food facilities both domestic and foreign. Concerns had been expressed however concerning the low frequency of such inspections with many firms remaining uninspected.

After FSMA

Rather than detecting legal violations and constructing judicial enforcement cases, the FDA is empowered to ensure that firms are consistently implementing the modern preventive measures mandated by FSMA.

New enforcement authorities allow for food to be detained, the suspension of food facility registration and the ability to issue a mandatory product recall.

Facility registration – Facilities are required to renew their registration every other year.

Reportable food registry – An electronic system through which industry must and public health officials may submit reports concerning a reportable food has been established to enhance the exchange and provision of information.

- **Federal State Integration**

Before FSMA

The FDA has been working with its state and local partners for a number of years to develop an Integrated National Food Safety Network (IFSS). There have also been programmes such as the Presidents Food Party Working Group looking at integration.

After FSMA

Historically the challenge to integration has been the differing approaches to food safety adopted in federal and state agencies; and the potential lack of uniformity and consistency between laboratories and methods of analysis and sampling. FSMA mandates the federal and state authorities to greater integration and to adopt national food and feed regulatory programs to ensure a consistent approach to inspection. Laboratories undertaking regulatory controls are to be accredited to ISO 17025 relating to the general requirements for the competence of testing and calibration laboratories and to adopt consistent methods of analysis. It would therefore be easier to exchange information and as such to identify trends and improve reactions to foodborne incidents.

In summary the new approach to food safety adopted by the FSMA:

- Shifts the focus of FDA regulators from responding to contamination to one of prevention
- Requires food facilities to evaluate hazards in their operations, implement and monitor effective measures to prevent contamination and to have a corrective action plan to implement as necessary
- Expands FDA's oversight authority by:
 - Directing FDA to increase the frequency of its inspections

- Allocating resources to inspect facilities according to the facilities' known risks, with high risk facilities being inspected more frequently
- Requires interagency collaboration in various areas such as inspections, seafood safety and food import.

However FSMA does not apply to the federal food safety system as a whole –e.g. it does not address USDA's responsibilities which remain distinct from those of the FDA.

3.13.12. Food safety administration – recent developments

Subsequently (28th January 2015), a Bill (The Safe Food Act) has been introduced to Congress which would establish a single independent federal Food Safety Agency. The purpose of this new single agency would be to:

- Regulate food safety and related labelling
- Ensure food facilities fulfil their responsibility to produce food in a manner that protects US public health
- Lead an integrated approach to food safety and food safety research.

As such the Bill proposes the consolidation, into one body, the food safety, labelling, inspection and enforcement functions currently dispersed among fifteen discrete agencies. This is not a new concept however, it having been proposed several times previously, the most recent being in 2007. It is not clear how this would affect the FDA, and Congress has not yet weighed in on the proposal. It is unlikely that a proposal to merge the fifteen separate agencies with food safety responsibilities into a single government body will come to fruition.²

² Ron Nixon, "Obama Proposes Single Overseer for Food Safety," New York Times (February 20, 2015).

4. TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP (TTIP) AND FOOD SAFETY

KEY FINDINGS

- Negotiations in connection with TTIP aim to reduce barriers to trade
- Concerns have been expressed about the regulatory protection with regard to food safety
- The US and EU both have well developed food control structures and legislation, but these do differ in approach and specific requirements
- Such differences in the areas of regulatory approach as well as specific differences in permitted animal treatments (use of hormones, antibiotics, antibiotics washes); novel foods, genetically modified organisms, cloned animals, nanomaterials and food labelling requirements have caused concern
- The TTIP negotiations would appear to conflict with the requirements of FSMA which place extra requirements on imports to the US.

The EU and USA account for almost half of the world GDP and one third of global trade flows with £1.6 billion of goods and services being traded every day (UK Government, 2015). The overall aim of the TTIP is to reduce trade barriers in a wide range of economic sectors in order to facilitate trade. It includes three main sections:

- Market access (including tariffs);
- Regulatory issues and Non-Tariff Barriers;
- Rules (e.g. intellectual property rights).

Concerns have been expressed however (BEUC 2014; Friends of the Earth 2014, Center for Food Safety, 2015) about the implications of the TTIP on the regulatory protection for people and for food safety.

Whilst both the US and the EU have well established food control systems, legislation and standards in place do differ. The main areas of difference in approach and / or specific requirements are indicated and compared in the following table, and summarised below, within the following broad categories where concern has been expressed in relation to food safety and information to consumers:

- **Approach to food safety:** With the implementation of FSMA the approach taken to food safety reflects that of the EU. The Food Supply Verification Proposal of the FSMA does however place additional requirements on imports and European Food Business operators
- **Animal health, production and treatments:** The control of their use and specific substances permitted (e.g. hormones, antibiotics) do not agree
- **Novel foods (including GMOs, cloned animals, nanomaterials):** There is an apparently opposite attitude and method of approach to regulation
- **Information to consumers (Labelling):** Due to the differences in labelling requirements (particularly nutrition, health claims and allergens) the two cannot currently co-exist.

Table 3: Comparison of US and EU controls with respect to areas of food safety concern

ASPECT	USA	EU
Approach to food safety		
Overall approach	<p>Historically the US control system was based on the 'reasonable certainty of no harm'. Risk assessment mostly based on companies' private risk assessments. Controls verify the safety of the end product.</p> <p>The introduction of FSMA has introduced the requirement for a risk based, HACCP approach and use of accredited third party auditing bodies and auditors.</p>	Control is based on the 'precautionary principle', is risk based with risk evaluation conducted by officially organised bodies. Controls apply all along the food supply chain.
Food standards	<p>US law addresses food regulation from the perspectives of adulteration and misbranding.</p> <p>The FDA is directed by law to establish definitions and standards for food to avoid such contamination and economic fraud. A food is considered to be misbranded if such a standard of identity exists but the food does not conform to it. There are 300 identity standards in 20 categories of food.</p> <p>FSIS (USDA) also establishes standards of identity for the food products it regulates.</p> <p>According to the FDA: "the hallmark of most of these regulations has been their attention to detail that includes not only each product's name and mandatory and optional ingredients, but in many cases also the minimum levels of valuable constituents and the manufacturing process."</p>	Early attempts to establish an internal market for food products in the EU included harmonised product compositions. This approach is no longer being followed, however, a number of these compositional standards were published and are still in existence. The list however is far less comprehensive than that of the US and the requirements of the standards are not necessarily the same.
Animal health		
Hormone treated beef	<p>Growth promoting hormones are widely used in beef production in the US and have been approved there since the 1950s. (The use of such hormones allows animals to grow faster requiring fewer other inputs and produce a leaner carcass).</p> <p>All animal drug products are</p>	<p>Substances having a hormonal action may not be given to farm animals. This restriction is to protect consumer health and safety as they are alleged carcinogens.</p> <p>The EU ban on hormone treated meat has been the cause of a long-standing dispute between</p>

	approved for safety, currently there are about 30 growth promoting products available in the US.	the US and EU, and a significant source of friction between the two parties.
Livestock antibiotics	Allows non-therapeutic antibiotic use. It is estimated that 80% of the antibiotics used in the US are on farm animals. They are used to help animals avoid illnesses but the drugs also boost the animal's weight.	Prohibits antibiotic use as growth promoters but allows their use for disease prevention. There are concerns that large scale use will lead to microbes developing resistance causing threats to humans as well as animals.
Ractopamine	Ractopamine as a feed additive accelerates the rate of weight gain in pigs by improving feed efficiency and it increases leanness in finishing pigs. It is permitted in the US and is fed to an estimated 60 to 80 percent of pigs there.	Ractopamine use is banned in the EU. This ban is based on an EFSA safety evaluation of the drug. They concluded that there was insufficient evidence to derive a safe residue level for human consumption.
Poultry treated with antimicrobial rinses	The practice of washing chicken in chlorine baths is commonplace in the US. This is in the belief that doing so prevents salmonella and other pathogens which cause food poisoning.	Not permitted in the EU. There is a preference for an approach based on good hygienic practices, particularly during handling, and a non-chemical approach. There is debate as to whether or not chlorine is an effective approach to control pathogens.
Novel Foods		
Novel foods	The USA has relatively minimal regulations concerning novel foods. Producers of new foods have a legal obligation to ensure the foods they offer consumers are safe and in compliance with applicable legal requirements. It is recommended that firms informally consult with the FDA prior to marketing to ensure that the safety and regulatory status of a new food is properly resolved. The position of the FDA is that novel foods are extensions of conventional foods.	In contrast, in the EU under the Novel Foods Regulations, firms must achieve pre-market registration before a novel food may enter the market. The EU is viewed as having one of the most challenging markets worldwide for novel foods.
Genetically modified foods	The FDA makes no distinction between novel foods and GM foods. Its view is that foods developed using 'new' techniques do not differ from other foods in any meaningful	Specific EU legislation takes GM foods outside the scope of the Novel Foods Regulation. There is a general regulatory prohibition on GMOs placed on the market for food use unless

	<p>way or present different or greater safety concerns than foods developed by traditional plant breeding. They state that GM foods would not normally be required to be disclosed in the labelling of the food. This was set out in "the 1992 policy". The FDA subsequently issued industry guidance in 2001 regarding voluntary labelling of GM foods but these recommendations constitute guidance only and there is no legal requirement to label. It is estimated that over 70% of all processed foods on US supermarket shelves contain GMOs.</p>	<p>the particular GMO is covered by an authorisation. Food that is GM, contains GM organisms, or food produced by GM organisms therefore must receive pre-market approval. The European Food Safety Authority gives an opinion against three criteria that the GMO must not:</p> <ul style="list-style-type: none"> • have adverse effects on human health, animal health or the environment; • mislead the consumer; or • differ from the food it is intended to replace to such an extent its normal consumption would be nutritionally disadvantageous for the consumer. <p>These criteria are largely the same as those used for novel foods. The EU Commission makes a draft decision based upon EFSA's opinion. There are far fewer 'approvals' in the EU and relatively few GM crops are grown commercially. There are mandatory labelling requirements for pre-packaged foodstuffs which contain or consist of GMOs. Foods that have come into incidental contact with GM foods are permitted in the EU but only as small traces of no more than 0.9% and then only if they are adventitious and unavoidable. Early in 2015 the EP voted by a large majority to endorse a significant change to EU legislation allowing EU member states to restrict, or ban, the cultivation of GM crops on their own territory even if it is allowed at EU level.</p>
Cloned animals	<p>In the US, there are no binding regulations for animal cloning or for marketing or labelling of cloned animal products. In 2008, FDA completed a comprehensive multi-year assessment of cloning risks and determined that meat and milk from cow, pig, and goat</p>	<p>In the EU, food from cloned animals falls under the Novel Food Regulation (NFR), requiring food products from cloned animals to undergo pre-market approval, based on a safety risk assessment, and be subject to specific labelling requirements. To date, no</p>

Nanomaterials	<p>clones and the offspring of any animal clones are as safe as food from conventionally-bred animals and that no further regulation or labelling requirements are needed. However, industry has been requested to continue to follow a voluntary moratorium against putting cloned animal products on the market.</p> <p>There are no labelling requirements.</p>	<p>requests for approval under the NFR for food products derived from cloned animals have been submitted. These provisions do not extend to food from the offspring of cloned animals (EP, 2014).</p> <p>There is no tracking mechanism of the offspring of cloned animals but the EU is considering restrictions on meat and dairy products from the offspring of cloned animals.</p> <p>All ingredients present in the form of engineered nanomaterials require labelling in the list of ingredients by following the name of the ingredient with the word 'nano' in brackets.</p>
Information to consumers		
Food labelling: Allergens	<p>There are eight major food allergens which may be declared in the ingredient list in brackets surrounding the usual name of the allergen or immediately below the ingredient list following the word 'contains'.</p>	<p>There are 14 allergens on prepacked foods that need to be emphasised in the ingredients list (or indicated using 'contains' in the absence of one). Allergens may not be declared after the ingredient list. The six additional allergens that require labelling in the EU but not on foods in the US are:</p> <ul style="list-style-type: none"> • Celery; • Mustard; • Sesame seeds; • Sulphites (>10ppm); • Lupin; • Molluscs.
Nutrition	<p>As highlighted elsewhere in this report there are significant differences in how nutrition information is declared. The two styles of nutrition labelling may not co-exist on one label.</p>	
Food additives	<p>There are differences between the regions in how additives are defined and approved. Consequently there are additives approved in the US that are not allowed in the EU.</p> <p>Additionally there are label warning statements required in the EU for some colours. They identify a possible adverse effect on activity and attention in children. Such warnings are not found on US products.</p>	
Regulating health foods	<p>Nutrient content claims - A nutrient content claim describes what a food is. Both regions have established specific requirements for nutrient content claims. There are however differences in the lists of permitted claims. For instance:</p> <ul style="list-style-type: none"> • <i>The US system of nutrition claims includes particular provisions in relation to 'main dish products' and 'meal products' which is not reflected in the EU system.</i> <p>Health claims - A health claim states what a food does. In establishing regulatory frameworks with regard to health foods</p>	

		<p>there is a necessary balance to be struck between consumer protection from false or misleading claims and facilitating innovation. The EU has one of the world's most specialised and stringent health claim systems, only relatively few claims have been approved (256 at the time of writing from an initial submission in excess of 40,000). The US regulatory environment is less restrictive towards the approval of new health claims. Some US authorised health claims:</p> <ul style="list-style-type: none"> • <i>Dietary lipids (fat) and cancer;</i> • <i>Fruit and vegetables and cancer.</i> <p>Qualified health claims – Only found on US products, they are not found in the EU. The US allows qualified health claims to be placed on food packages even if the significant scientific agreement standard cannot be met, as long as there is "credible" science to support the claim and a qualifying statement is added. The EU does not appear to have any comparable type of packaging labelling, which could be confusing and potentially misleading for consumers. Before a qualified health claim may be used the FSA must issue a letter of enforcement discretion. Many of the qualified health claims the FDA has approved carry with them conditions that make them not very useful to manufacturers. For instance, regarding the possible connection between tomatoes and prostate cancer, the FDA authorised the following claim:</p> <p><i>"Very limited and preliminary scientific research suggests that eating one-half to one cup of tomatoes and/or tomato sauce a week may reduce the risk of prostate cancer. FDA concludes that there is little scientific evidence supporting this claim."</i></p> <p>Structure/function claims – Describe the impact a particular nutrient or substance within a food has on the normal growth, development or functioning of the human body. For instance: <i>Helps maintain a healthy cholesterol level.</i> In the US these are not subject to FDA premarket approval or review. In the EU they are most akin to general health claims which do require premarket approval.</p>
Protected designations of origin	of	<p>There is no voluntary scheme in the US that functions in the same way as the EU. There are many examples of names protected in the EU being used on products manufactured in the US.</p> <p>Voluntary indications of origin relating to quality characteristics may be legally protected once registered. These are protected designations of origin, protected geographical indications and traditional specialities guaranteed. Examples include: Parma ham; feta cheese and Cornish pasties.</p>

5. CURRENT FOOD SAFETY EMERGENCIES IN THE USA

KEY FINDINGS

- Foodborne illness is considered to present a significant burden
- The level of US imports is considered to be a source of foodborne illness
- A number of major food incidents continue to occur
- In 2013 (compared to 2010 – 2012) there has been progress in reducing the number of *Salmonella* infections (9% less); an increase (32%) in *Vibrio* infections and, although there was no statistically significant difference for the other pathogens, concern has also been expressed about the rise in the incidence of *E. coli* infections which had shown past progress. None met the Healthy People 2020 targets.
- Since the period 2006 – 2008 the overall incidence has not changed significantly
- The longer term (1997 to 2012) incidence shows a 22% reduction overall.

The US, like all countries, experiences food safety emergencies. Whilst individual high profile cases affect consumer confidence and inflict reputational damage, there is also understandable concern at the overall current burden of foodborne illness.

The Centre for Disease Control and Prevention (CDC, 2011) estimates that each year in the US roughly 48 million people get sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases. This is due to pathogens and unspecified agents transmitted through food, of which it is estimated that 31 of the most important known agents of foodborne disease found in foods consumed in the United States each year cause 9.4 million illnesses, 55,961 hospitalizations, and 1,351 deaths. Whilst it is difficult to make direct comparisons, due for example to the specific information reported and for which foodborne diseases, a recent study (EFSA/ECDC 2015) reported that a total of 5,196 food-borne outbreaks, including water-borne outbreaks, were reported in the European Union. Overall, 43,183 human cases, 5,946 hospitalisations and 11 deaths were reported. The evidence supporting the link between human cases and food vehicles was strong in 839 outbreaks.

5.1. Trends in the incidence of foodborne illness

5.1.1. Recent trend

Trend information (CDC, 2013) of changes in the incidence of laboratory-confirmed bacterial infections 2013 compared with 2010 - 2012 are given in Table 4 below:

Table 4: Changes in the incidence of laboratory-confirmed bacterial infections 2013 compared with 2010 - 2012

Food Pathogen	Percentage change	Statistically significant	2013 incidence per 100,000 population	2020 Target per 100,000 population
<i>Campylobacter</i>	+2%	No	13.82	8.5
<i>Escherichia coli</i> O157	+8%	No	1.15	0.6

<i>Listeria</i>	-3%	No	0.26	0.2
<i>Salmonella</i>	-9%	Yes	15.19	11.4
<i>Vibrio</i>	+32%	Yes	0.51	0.2
<i>Yersinia</i>	+7%	No	0.36	0.3

Source: CDC Food safety progress report for 2013

The incidence of laboratory-confirmed *Salmonella* infections was lower in 2013 than during 2010 – 2012, whereas the incidence of *Vibrio* infections increased. There was no significant change for infection with the other pathogens listed. None met the Healthy People 2020 target levels.

Comparison of the 2013 data with 2006 – 2008 data shows that the incidence of infection increased for *Campylobacter* (increase of 13%) and *Vibrio* (increase of 75%). Rates of the other pathogens did not change significantly nor did the overall incidence of infection with six key foodborne pathogens (*Campylobacter*, *Listeria*, *Salmonella*, *STEC O157*, *Vibrio*, and *Yersinia*).

These results indicate a continued requirement for more food safety interventions.

Recent examples of efforts to reduce the contamination of food and prevent these illnesses are given below:

- Since *Campylobacter* is often associated with infected chicken, performance standards for *Campylobacter* contamination of whole broiler chickens in processing plants were established by USDA in 2011;
- *Vibrio* infection is associated with eating raw or undercooked seafood / shellfish. Thus more stringent time and temperature controls for oysters after harvest were approved to prevent *Vibrio vulnificus* infections.

5.1.2. Long term trend

The long term trend showed, by comparison with the first three years of surveillance (1996–1998), that the overall incidence of infection with the six key foodborne pathogens (*Campylobacter*, *Listeria*, *Salmonella*, *STEC O157*, *Vibrio*, and *Yersinia*) was 22% lower although there continued to be differences between the incidence of the individual pathogens – which in some cases can be attributed to the tightening of particular procedures and processing standards:

- The incidence of infections caused by *Campylobacter*, *Listeria*, *STEC O157*, *Shigella*, and *Yersinia* declined, mostly in the first years;
- The overall incidence of *Salmonella* was unchanged, but the incidence of some species of *Salmonella* have increased while others have decreased;
- The incidence of *Vibrio* infection is 116% higher.

5.1.3. Food recalls

Information on food recalls is made available via various government websites. Although contamination with food pathogens is one of the reasons for a food recall others include undeclared ingredients (typically allergens), chemical contamination, presence of foreign bodies, production in unlicensed premises and release of product prior to inspection.

In the case of a food borne outbreak which agency is involved depends upon its scale:

- **Local agencies:** Most foodborne outbreaks are local events and public health officials in just one city or county health department investigate these outbreaks
- **State agencies:** Outbreaks that spread across several cities or counties are typically investigated by the state health department. This department often works with the state department of agriculture and with federal food safety agencies (see following)
- **Federal agencies:** For outbreaks that involve large numbers of people or severe or unusual illness, a state may ask for help from the Centers for Disease Control and Prevention (CDC). CDC usually leads investigations of widespread outbreaks—those that affect several states at once. States communicate regularly with one another and with CDC about outbreaks and ongoing investigations. FSMA mandates greater co-operation between agencies.

America has been the subject of a number of high profile food incidents in recent years including:

- **Multistate outbreak of Listeriosis associated with commercially produced pre-packed caramelised apples 2014:** Contamination with *Listeria monocytogenes* at the apple-packing facility resulted in 35 reported infections in 12 states. 34 were hospitalised Listeriosis contributed to at least three of the seven reported deaths. Cause: *Listeria monocytogenes*
- **Multistate Outbreak of Salmonella Infections Associated with Peanut Butter and Peanut Butter--Containing Products 2008–2009:** A processing plant contamination (*Salmonella typhimurium*) resulted in many foods causing sickness in 46 states.
- **Egg recall 2010:** In 2010, just one foodborne outbreak sickened thousands of people throughout the country and led to the recall of approximately a half-billion eggs. The cause was identified as chicken and feed contamination with *Salmonella enteritidis*.
- **Tainted turkey burgers 2011:** 50,000lbs of ground turkey were recalled following illness in 10 states. Cause *Salmonella hadar*.
- **Contaminated vegetables**—such as cucumbers in 2014, 2013; beans sprouts and sprouts in 2014; lettuce in 2010, peppers in 2008, and spinach in 2006.

5.1.4. Food incidents and Europe

The number of notifications in the Rapid Alert System for Food and Feed (RASFF) of foods entering the European Union originating from America has reduced from a high of 238 in 2009 to 101 in 2013 (RASFF Annual Report 2013). The United States was the tenth highest listed country.

5.1.5. Trends contributing to food safety challenges

Three trends are considered to present food safety challenges:

- The increase in the amount and variety of imported foods: An estimated 15% of the US food supply is imported, including 60% of fresh fruits and vegetables and 80% of seafood
- The increased consumption of raw or minimally processed foods
- Increased susceptibility of the population to food-borne hazards resulting from a changing demographic, increasing elderly population and those with immunosuppressed conditions.

5.1.6. Approach to preventing foodborne illness

The pursuit of a comprehensive prevention strategy that involves all participants in the food chain in an integrated system resulted in the development of the Food Safety Modernisation Act as discussed in Chapter 4. The outcome of which is intended to be “sweeping improvements to the safety of the food supply”.

Previous reports have identified areas of improvement of the food supply chain to include:

- Improving produce safety
- Reducing salmonella contamination
- Improving integration
- Developing food safety performance measures.

Measures to address produce safety and improve stakeholder integration in food safety will address salmonella contamination.

In 2011, the Food Safety and Inspection Service (FSIS) published its Strategic Plan for 2011-2016 (updated August 2012), which includes results-oriented performance measures. FSIS has made attribution estimates of the total number of illnesses from meat, poultry, and processed egg products, and developed a key performance measure of its progress toward preventing these illnesses. Each year an annual performance plan is published which outlines the activities and expected results for that year. In 2015 the Salmonella Action Plan has been identified as one of the areas of high priority with the aim to reduce the number of foodborne associated illnesses.

Whilst the individual agencies with responsibilities for food safety publish individual strategy and performance plans, the Government Accountability Office reported, in its 2014 High-Risk Series report, that their recommendation of 2011 for a government-wide performance plan for food safety had not been acted upon. They recommend that such a centralised broad based collaboration is required to ensure leadership and coordination across all agencies with responsibilities for food safety. In addition it is recommended that this should be implemented by statute.

6. POSSIBLE ISSUES FOR DISCUSSION WITH THE US COMPETENT AUTHORITIES

Food Safety Modernisation Act

- What procedures are in place to ensure that the funding and capacity required for the implementation of the requirements of the Food Safety Modernisation Act are in place?
- The Food Safety Modernisation Act requires the exchange of information potentially about individuals subject to foodborne illness, or companies, and laboratory results between the different federal and state agencies. Are there any barriers to the exchange of such information which may affect the overall effectiveness of the system?
- What support is in place to support smaller businesses comply with the requirements of the FSMA?
- What support is in place to assist the smaller local and state agencies?
- FSMA covers foods that fall under the remit of the FDA. Other products fall under the remit of FSIS. Although FSMA requires greater inter-agency cooperation the need for an over-arching body has been recommended by the Government Accountability Office and a single independent federal Food Safety Agency proposed by the Safe Food Act bill. What implication, if any, does this have for the implementation of FSMA and the preparations being undertaken by the FDA?

Foodborne illness and incidents

- The recent trend shows no overall improvement in the incidence of foodborne illness due to food pathogens and some increases. There has also been an increase in multi-state outbreaks. The incidence rates also do not meet the 2020 Healthy People targets. What steps have been taken to investigate these further? What further actions have been taken?

Trade impacts

- Is the requirement for importer verification and the inspection of foreign facilities considered to present a barrier to trade in terms of the World Trade Organisation treaty?
- Is state legislation ever employed as a disguised restriction on trade in order to protect local producers?

Transatlantic Trade and Investment Partnership (TTIP)

- Differences do exist between US and EU legislative requirements relating to food. What steps can be taken to resolve and reconcile these?
- Do the TTIP negotiations contradict the increased requirements for importer verification under FSMA and is this a potential source of conflict?

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Note: All websites accessed during May 2013 and additional websites accessed as part of this review 23 February – 5 March 2015.

ANNEX 1 Comparison of US and EU food labelling requirements

Table 5: Overview of the differences in general food labelling US and EU

Labelling Element	United States	European Union
Principal legislation	Federal Food, Drug & Cosmetic Act	Food Information to Consumers Regulation 1169/2011
Mandatory information	Five specific elements required:- <ul style="list-style-type: none"> • Statement of identity; • Net quantity of ingredients; • Nutrition facts; • Ingredient statement; • Manufacturer's statement. 	Twelve mandatory elements as appropriate to the food concerned:- <ul style="list-style-type: none"> • Name of the food; • List of ingredients; • Allergens; • QUID; • Net quantity; • Date of minimum durability; • Special storage conditions; • Business name & address; • Country of origin; • Instructions for use; • Alcohol content (>1.2%); • Nutrition.
Name of Food	Also referred to as "Statement of Identity" and tied in with the extensive list of food standards. It must: Be the legal name or customary name if one exists. If there is no such legal or customary name a descriptive one may be used Appear in the Principle Display Panel (PDP) where it must be the most prominent information. Be located parallel to the base of the package.	Must: Be a legal, or customary name (a descriptive name may be used if no such names exists); Appear in the same field of vision as the net quantity of the food: State the alcoholic strength, if it contains greater than 1.2% alcohol by volume.
Allergen Statement (Key area of difference)	There are eight major food allergens listed that must be declared if present. Gluten containing cereals other than wheat are also not present in the American allergen list. The allergen may be named either in the ingredient list, in brackets following the allergen containing ingredient, or in a statement starting "contains" and naming the allergens immediately below the ingredient declaration.	Fourteen allergens must be declared. Those listed by the EU but not present in the American legislation are celery, mustard, sesame seeds, sulphur dioxide, lupin and molluscs. A statement on the presence of allergens that are present as an ingredient or a processing aid is mandatory and must be indicated in the list of ingredients, with the allergen named and clearly distinguished from the rest of the ingredients in the list.

Labelling Element	United States	European Union
		Where an ingredient declaration is not given an indication of the allergens is made with a statement comprising the word "contains", followed by the named allergen.
Quantitative Ingredient Declaration (QUID)	No such mandatory provision. When, however, an ingredient quantity is indicated, it must be in percentage terms to the nearest whole percent following the name of the ingredient, in parentheses, and as a percentage by weight.	A mandatory particular, a percentage must be given when: emphasis of an ingredient appears in the name; is emphasised on the label in words or pictures; or is essential to characterise a food.
Net Quantity of the Food	Must appear in the bottom 30% of the PDP, parallel to the base of the container. The declaration must appear in both US Customary Units (ounce, pound, fluid ounce, pint, gallon) AND metric (gram, kilogram, millilitre, litre). Words that exaggerate the size of the net quantity must not be used. NOTE: beers (subject to regulation by the TTB rather than the FDA) must only state the net quantity in US Customary Units, namely gallons, quarts, pints or fluid ounces, including combinations and fractions thereof depending on the total volume.	The net quantity of the food must appear in the same field of vision as the name of the food and the alcoholic strength declaration (for beverages containing greater than 1.2% alcohol by volume). Must be presented in litres, centilitres or millilitres for liquid food, and kilograms or grams for solid food. Certain foods may be sold by count according to established practice.
Date of Minimum Durability (Use by Date)	With the exception of infant formula product dating is not expressly required although all food on the market in the United States must be "wholesome and fit for consumption". If addition of a "best before" or "use by" date ensures that the food is fit for consumption and not hazardous to health, then its application would be advised.	A mandatory particular. If a food is highly perishable and will therefore cause immediate danger to human health after a short period, a "use by" date must be used.
Any Special Storage Conditions or Conditions of Use	No provision explicitly laid out, though it would be advisable that the food is "fit for consumption", including instructions on storage and usage where otherwise difficult. Warning statements must appear on certain pressurised containers to ensure appropriate	Such a statement is mandatory when foods require special storage to reach their stated shelf life or to enable appropriate use after opening.

Labelling Element	United States	European Union
	use and storage.	
Name and Address of Food Business	Name and address of the packer, manufacturer or distributor should appear on the information panel. The firm's relation to the product must be made clear (packer, distributor for instance).	The name and business address of the food business operator or importer within the EU responsible for the food that is able to receive postal communication. This does not prohibit an address outside the EU also appearing on the label.
Alcoholic Strength Declaration	Not required on a Federal level, although it may be required on a state level. Any alcoholic beverage over 0.5% alcohol by volume must bear the following warning: GOVERNMENT WARNING: (1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects. (2) Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems.	Must appear on beverages containing more than 1.2% alcohol by volume. It must appear in the same field of vision as the name of the food and the net contents declaration. Unit and health information, including advice on drinking and pregnancy, may be included on a voluntary basis.
Nutrition Declaration – (Key area of difference)	Is required for foods under the jurisdiction of the FDA, with few small exceptions, and must appear on the information panel. This must be in a box, with the title "Nutrition Facts". At the very minimum, the required nutrients to be declared are: calories, fat, cholesterol, sodium, total carbohydrate and protein. Other nutrients may be required to be declared based on claims made on the food.	With some exceptions declaring nutrition becomes mandatory for all foods containing less than 1.2% alcohol by volume on 13 th December 2016, however if it is volunteered before that date it must be done in a prescribed fashion. It must list energy (in kilojoules and kilocalories), fat, saturates, carbohydrates, sugars, protein and salt.
Language Requirements	If a foreign language is used on the label, all required label statements must also appear in English. Where the food is specifically aimed at non-English speaking communities, the required labelling must also be present in the foreign language.	Any mandatory information must appear in a language that will be easily understood by the consumers of the Member States in which the food is being marketed.
Text Size Requirements	1/16 th of an inch of a lower case "o" for the following: ingredients, allergens, address. Net quantity can also be 1/16 in. when the PDP	Mandatory particulars must be clearly legible using a font size with a lower-case x-height that is equal to or greater than 1.2mm

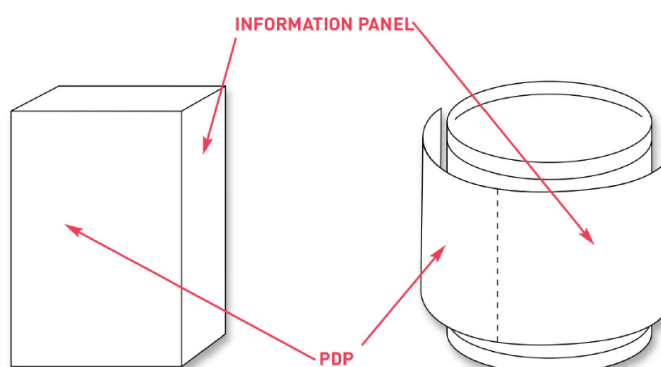
Labelling Element	United States	European Union								
	<p>is less than 5 sq in.</p> <p>Text size requirements for net contents based on PDP size:</p> <ul style="list-style-type: none">• 1/8in – between 5 and 25 sq. In.• 3/16in – between 25 and 100 sq. In.• 1/4in – between 100 and 400 sq. In.• 1/2in – over 400 sq. In. <p>The statement of identity should be in bold and the most prominent text on the PDP.</p> <p>Nutrition Facts panel has its own text size requirements that will be described in more detail following this table.</p>	<p>for packaging surface area >80cm² and 0.9mm beneath that threshold.</p> <p>Text size requirements for net contents:</p> <table><tr><td>Exceeding 1kg/l</td><td>6mm</td></tr><tr><td>200g/ml – not exceeding 1kg/l</td><td>4mm</td></tr><tr><td>50g/ml – not exceeding 200g/ml</td><td>3mm</td></tr><tr><td>Not exceeding 50g/ml</td><td>2mm</td></tr></table>	Exceeding 1kg/l	6mm	200g/ml – not exceeding 1kg/l	4mm	50g/ml – not exceeding 200g/ml	3mm	Not exceeding 50g/ml	2mm
Exceeding 1kg/l	6mm									
200g/ml – not exceeding 1kg/l	4mm									
50g/ml – not exceeding 200g/ml	3mm									
Not exceeding 50g/ml	2mm									

Key differences are:

- US labelling must be provided on a per portion basis, EU labelling is provided on a per 100g/100ml basis, with a portion declaration being an additional option.
- The manner of presentation of the US Nutrition Facts panels is very different the EU being more conspicuous. It must appear in the information panel of a packet. There is no such location requirement for labelling in the European Union for mandatory nutrition.
- Text requirements – like all EU mandatory particulars, there is a minimum font size for text. In the US the text size and style is more complicated being decided, as shown below.

In addition food labelling in the US is far more prescriptive than the EU concerning where certain pieces of information need to appear on a label. For instance, in US legislation there are definitions of a “Principal Display Panel” and an “Information Panel”. The Principal Display Panel, also known as the PDP, is the portion of the package label that is most likely to be seen by the consumer at point of purchase. There is a similar concept in EU food labelling law of a ‘principal field of vision’ but it only finds application in locating voluntary repetition of nutrition information (‘front of pack’ nutrition). To the immediate right of the PDP, when viewed by the consumer lies the information panel. An example of how this works is shown in the figure:

Figure 5: Principle field of vision



Source: [FDA – Guidance for industry – A food labelling guide](#)

Figure 6: Nutrition facts label – Text requirements and graphic enhancements

Example of Graphic Enhancements used by FDA

Nutrition Facts

Serving Size 1 cup (228g)
Servings Per Container 2

Amount Per Serving

Calories 260 **Calories from Fat** 120

% Daily Value*

Total Fat 13g
Saturated Fat 5g
Trans Fat 2g

Cholesterol 30mg
Sodium 660mg
Total Carbohydrate 31mg
Dietary Fiber 0g
Sugars 5g

Protein 5g

Vitamin A 4% • Vitamin C 2%
Calcium 15% • Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs:

		Calories:	2,000	2,500
Total Fat	Less than	65g	80g	
Sat Fat	Less than	20g	25g	
Cholesterol	Less than	300mg	300mg	
Sodium	Less than	2,400mg	2,400mg	
Total Carbohydrate		300g	375g	
Dietary Fiber		25g	30g	

Source: [FDA – Nutrition labelling](#)

ANNEX 2 FEDERAL AND STATE COLLABORATION

Foodborne Illness Surveillance		
FoodNet	Foodborne Diseases Active Surveillance Network	
	Agencies:	CDC, FDA, USDA and ten participating states
	Aim:	To provide more accurate estimates of foodborne illness associated with food-borne pathogens
	Activity:	Conducts active, population-based surveillance in 10 states for laboratory-based confirmed cases caused by nine specified pathogens
	Outcome:	Contributed to standardisation of laboratory methods Performs targeted case-control studies to identify risk factors for pathogen specific illnesses
PulseNet	National Molecular Sub-typing Network	
	Agencies	CDC and state public health laboratories
	Aim:	Early warning system for outbreaks of foodborne disease
	Activity	National network of public health laboratories Perform DNA fingerprinting on bacteria that may be foodborne
	Outcome	Identification of related strains so enabling the connection of cases to a common source
FERN	Food Emergency Response Network	
	Agencies	FDA, USDA, CDC, EPA and state agencies
	Aim	Integration of the nation's food-testing laboratories at the local, state and federal level.
	Activity	Provision of national surveillance program
	Outcome	Provide early warning of threat agents in the food supply Respond to emergencies involving biological, chemical or radiological contamination of food Provide surge capacity for responding to widespread complex food contamination emergencies
eLEXNET	Electronic Laboratory Exchange Network	
	Agencies	Coordinated by FDA
	Aim	Provision of a web-based information network allowing federal, state and local food safety officials to compare, share and co-ordinate laboratory findings Data capture and communication system for FERN
	Activity	Electronic data access and exchange of laboratory findings
	Outcome	Early warning system to potentially identify hazardous foods Risk assessment and trend analysis tool
Epi-X	Epidemic Information Exchange	
	Agencies	CDC
	Aim	To provided CDC officials, state and local health departments, poison centre and other public

		health professionals ability to access and share preliminary health surveillance information
	Activity	Web-base communication tool for public health professionals
	Outcome	Notification of breaking health events, rapid outbreak reporting, multi-jurisdictional peer-to-peer consultation
Outbreak response		
OutbreakNet/NORS	National Outbreak Reporting System	
	Agency	CDC coordinated network of public health officials in local and state health departments and federal agencies
	Aim	Collaboration and information exchange relating to foodborne outbreaks
	Activity	Investigation of foodborne outbreaks Reporting mechanism for state members report findings to CDC
	Outcome	National web-based system that tracks foodborne, person-to-person, animal contact, waterborne and Norovirus outbreaks
CIFOR	Council to Improve Foodborne Outbreak Response	
	Agency	CDC, FDA, USDA, AFDO, APhi, ASTHO, CSTE, NACCHO, NEHA, NASDA Industry workgroup – 16 members for food production, restaurant and retail companies.
	Aim	To improve performance and coordination among federal, state and local agencies with respect to routine surveillance of foodborne outbreak detection and response, laboratory methods for foodborne pathogens and food borne disease prevention, communication and education at the state and local levels
	Activity	
	Outcome	
Epi-Ready		
	Agency	CDC, NEHA
	Aim	Nationwide team-training
	Activity	Provision of up-to-date foodborne disease outbreak investigation and surveillance training to public and private sector environmental health professionals and others involved in conducting foodborne disease outbreak investigations
	Outcome	
FoodSHIELD		
	Agency	Laboratories and regulatory agencies at all levels of the food safety system
	Aim	To support federal, state and local governmental regulatory agencies and laboratories through web-based tools To create community and share information about capacity, training and other matters Focus on bioterrorism and other intentional contamination
	Activity	Provision of web based tools

	Outcome	Enhancement of threat prevention and response, risk management, communication and asset coordination as well as public education
Prevention, Inspection and Regulatory Activities		
EHS-Net	Environmental Health Specialist Network	
	Agency	CDC-co-ordinated forum of environmental health specialist for CDC, FDA and nine states
	Aim	Translating investigatory findings into improved food safety prevention efforts Strengthening relations among epidemiology, laboratory and environmental health programs
	Activity	Collaborative forum of environmental health specialists, epidemiologists and laboratorians
	Outcome	
FDA's Food Code		
	Agency	FDA
	Aim	To provide a sound legal and technical basis for regulating the retail and food service
	Activity	Publish the Food Code, a model ordinance for the retail and food service sector
	Outcome	Local, state, territorial, tribal and federal regulators use the FDA food Code as a model to develop or update their own food safety rules and to be consistent with the national food regulatory policy and emphasise prevention. The majority of states and territories have adopted food codes based on one of the five versions of the Food Code, beginning with the 1993 edition.
FDA Voluntary National Retail Food Regulatory Program		
	Agency	FDA
	Aim	To ensure agencies have the capacities and procedures in place to achieve widespread compliance with the Food Code's food safety provisions and thereby effectively prevent foodborne illness.
	Activity	Provision of recommended standards and assessment procedures for the regulatory programs through which state, local, territorial and tribal regulatory agencies implement the Food Code.
	Outcome	Provides the framework for future federal-state-local collaboration to improve food safety practices at the retail level.
FDA-State Contract Inspection Agreements		
	Agency	FDA and state
	Aim	Inspection of domestic food processing plants
	Activity	State employees carry out FDA inspections at domestic food processing plants under contract to the FDA Inspections are conducted under the States' laws and authorities, the US Food, Drug and Cosmetic Act (FDCA) or both.
FDA Manufactured Food Regulatory Program Standards		
	Agency	FDA

	Aim	As that of the Voluntary National Retail Regulatory Program but focusing on state programs for the regulation of food processing plants
	Activity	Compliance will become a pre-requisite for states conducting inspections under contract to FDA
	Outcome	Ensure state-conducted FDA inspections are performed to a uniformly high level of quality nationwide
Grade A Pasteurised Milk Ordinance (PMO) and the National Conference of Interstate Milk Shipments (NCIMS)		
	Agency	FDA, USDA, state authorities, milk industry
	Aim	To ensure safety of milk shipped in interstate commerce
	Activity	PMO is a model ordinance, generally recognised as a national standard for milk sanitation and safety. The states carry out much of the monitoring and enforcement.
	Outcome	PMO has been adopted by all 50 states. It is used as a basis for certification of interstate milk shippers through a federal-state cooperative program
National Shellfish Sanitation Program		
	Agency	FDA and Interstate Shellfish Sanitation Programme Federal-State cooperative program
	Aim	To ensure the sanitary control of shellfish
	Activity	FDA sets uniform, science-based standards which are implemented and enforced by state authorities
Talmadge-Akin Federal-State cooperative inspection of Meat and Poultry Plants		
	Agency	USDA and state agencies
	Aim	Inspection of meat and poultry plants
	Activity	The Federal State Cooperative Act authorises FSIS to enter into co-operative agreements with state agencies to inspect meat and poultry plants on behalf of the federal government and in accordance with federal requirements. The meat and poultry inspection laws also authorise state agencies to inspect plants under state inspection laws providing the state requirements are 'at least equal to' the federal inspection requirements, but products from plants inspected in this way may only be sold within the state where they were processed and inspected.

Source: Taylor, RT and David, SD 2009

DIRECTORATE-GENERAL FOR INTERNAL POLICIES

POLICY DEPARTMENT ECONOMIC AND SCIENTIFIC POLICY **A**

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