Public Health and Food Safety Policies and Regulation in the United States

NOTE

2013
Abstract
This briefing note is made of two parts. The first on "Public Health Policy and Regulation in the United States", the second on "Food Safety Policy and Regulation in the United States".
Part 1 provides an overview of public health policy and regulation in the United States. It examines patterns of health care spending, health outcomes, and public health programmes. It describes the system of public and private health insurance, and the recent health care reform legislation. This note also examines the role and function of the Food and Drug Administration.
Part 2 reviews the food and drink industry in the United States, existing food safety policy, structure control systems and key indicators for food safety development in the country. In particular the review considers the basic relevant legislative acts and the organisation of various branches of government. A brief description is also given of current food safety emergencies in the United States.
This document was requested by the European Parliament's Committee on Environment, Public Health and Food Safety.

AUTHORS

Public Health Policy and Regulation in the United States
Prof. Adam Sheingate, Milieu Ltd.
Ms Monica Guarinoni, Milieu Ltd.

Food Safety Policy and Regulation in the United States
Mrs Susan Keenan, Campden BRI
Mr John Hammond, Campden BRI

RESPONSIBLE ADMINISTRATOR

Public Health Policy and Regulation in the United States
Mr Lorenzo VICARIO

Food Safety Policy and Regulation in the United States
Mr Lorenzo VICARIO

Policy Department Economic and Scientific Policy
European Parliament
B-1047 Brussels
E-mail: Poldep-Economy-Science@ep.europa.eu

LINGUISTIC VERSIONS

Original: EN

ABOUT THE EDITOR

To contact the Policy Department or to subscribe to its newsletter please write to:
Poldep-Economy-Science@ep.europa.eu

Manuscript completed in June 2013.

This document is available on the Internet at:
http://www.ep.europa.eu/studies

DISCLAIMER

The opinions expressed in this document are the sole responsibility of the author and do not necessarily represent the official position of the European Parliament.

Reproduction and translation for non-commercial purposes are authorised, provided the source is acknowledged and the publisher is given prior notice and sent a copy.
CONTENTS

PUBLIC HEALTH POLICY AND REGULATION IN THE UNITED STATES 5
LIST OF ABBREVIATIONS 6
LIST OF FIGURES 7
LIST OF TABLES 7
EXECUTIVE SUMMARY 8
GENERAL INFORMATION 9
1. HEALTH STATUS AND HEALTHCARE ORGANISATION 12
   1.1 Health Care Spending 12
   1.2 Health Outcomes and Disparities 15
   1.3 Health Care Delivery and Financing 16
   1.4 Health Care Access 17
2. PUBLIC HEALTH POLICY 19
   2.1 Medicare and Medicaid 19
   2.2 The Patient Protection and Affordable Care Act 21
   2.3 Public health policy in a federal system 21
3. U.S. FOOD AND DRUG ADMINISTRATION (FDA) 23
   3.1 Organisation and scope of FDA authority 23
   3.2 FDA drug approval 25
   3.3 Food safety regulation 27
   3.4 The Future of the FDA 28
REFERENCES 30
APPENDIX 31
1. EXECUTIVE SUMMARY

2. INTRODUCTION
   2.1. Method
      2.1.1. Sources of information:
      2.1.2. Map of USA

3. USA, FOOD PRODUCTION, IMPORTS AND EXPORTS

4. STRUCTURE OF THE FOOD SAFETY AND CONTROL SYSTEM IN THE USA
   4.1. Principal Federal Organisations
      4.1.1. Food and Drug Administration
      4.1.2. US Department of Agriculture (USDA)
      4.1.3. Department of Homeland Security (DHS)
      4.1.4. Centre for Disease Control and Prevention (CDC)
      4.1.5. Environmental Protection Agency (EPA)
      4.1.6. Other Agencies
      4.1.7. State and local agencies
   4.2. Legislation
      4.2.1. Food Drug and Cosmetic Act (FDCA)
      4.2.2. Food Code
      4.2.3. Federal Meat Inspection Act (FMIA)
      4.2.4. Poultry Products Inspection Act (PPIA)
      4.2.5. Egg Products Inspection Act (EPIA)
      4.2.6. Bioterrorism Act
      4.2.7. Food Safety Modernisation Act (FSMA)

5. CURRENT FOOD SAFETY EMERGENCIES IN THE USA
   5.1. Trends in the incidence of foodborne illness
      5.1.1. Recent trend
      5.1.2. Long term trend
      5.1.3. Food recalls
      5.1.4. Trends contributing to food safety challenges
      5.1.5. Approach to preventing foodborne illness

6. POSSIBLE ISSUES FOR DISCUSSION WITH THE US COMPETENT AUTHORITIES

REFERENCES

ANNEX 1
PUBLIC HEALTH POLICY AND REGULATION
IN THE UNITED STATES
LIST OF ABBREVIATIONS

ACA    Affordable Care Act
CDER   Centre for Drug Evaluation and Research
CHIP   Children’s Health Insurance Program
CIIO    Centre for Consumer Information and Insurance Oversight
CMS    Centre for Medicare and Medicaid Services
DHHS   Department of Health and Human Services
ENVI    Environment, Public Health and Food Safety Committee
EU    European Union
FDA    Food and Drug Administration
FFDCA  Federal Food Drug and Cosmetic Act
FPL    Federal Poverty Line
FSMA  Food Safety Modernisation Act
GDP    Gross Domestic Product
GNP    Gross National Product
HMO    Health Maintenance Organisation
IND    Investigational New Drug
MCO    Managed Care Organisation
NDA    New Drug Application
OECD   Organisation for Economic Co-operation and Development
PDUFA  Prescription Drug User Fee Act
PPO    Preferred Provider Organisation
U.S.    United States
USDA  United States Department of Agriculture
LIST OF FIGURES

Figure 1: Map of the United States 9
Figure 2: Median Household Income, 1975-2011 11
Figure 3: Health Care Spending by Source, 2011 13
Figure 4: Health Care Spending by Function, 2011 13
Figure 5: OECD Health Spending as a Share of GDP by Source, 2009-2010 14
Figure 6: Health Insurance Coverage of the U.S. Population 17
Figure 7: The Fragmented U.S. Health Care System 18
Figure 8: Median State Medicaid/CHIP Eligibility Thresholds, 2013 20
Figure 9: Responsibilities for Health Policy and the ACA 22
Figure 10: FDA units with responsibility for food safety and drug approval 23
Figure 11: Composition of the FDA Budget, 2012 (Millions of Dollars and %) 24
Figure 12: Drug Discovery and Development Timeline 25
Figure 13: Median Approval Times for NDAs, 1993-2011 26
Figure 14: Federal Agencies Responsible for Ensuring Safe Pizza 27
Figure 15: Public Perceptions of the FDA 28
Figure 16: The Department of Health and Human Services 31
Figure 17: The Food and Drug Administration 32

LIST OF TABLES

Table 1: Population by age and race, 2012 and 2050 projections 10
Table 2: Governments, employees, receipts, and outlays by level of authority 10
Table 3: Incarceration Rates by Region and Race, 2010 11
Table 4: Ten Year Annual Growth Rates, Adjusted for Inflation 14
Table 5: Health Measures in the United States and OECD 15
Table 6: Infant Mortality and Low Birth Weight, by Race and Education 15
Table 7: The Varying Price of Health Care in the United States 17
Table 8: Budget Outlays and Employees of DHHS, 2013 33
EXECUTIVE SUMMARY

This briefing responds to a request of the Committee on Environment, Public Health and Food Safety (ENVI) of the European Parliament and aims to provide Members of European Parliament with an overview of public health policy and regulation in the United States, in the light of the ENVI delegation to the United States from 15 to 18 July 2013.

It covers the following topics:

- Health status and healthcare organisation;
- Public health policy;
- The Food and Drug Administration.

The United States is a large, diverse country of more than 300 million people. It has a political system that divides authority across multiple levels of federal, state and local government and among legislative, executive and judicial functions within governments. Health care delivery and financing is also highly fragmented among individual health care providers, numerous private insurers and various federal and state programmes.

This fragmentation and decentralisation explains several prominent features of health and health care in the United States. The United States spends 17.9% of GDP on healthcare, almost twice the average of other advanced industrial countries. Yet, health outcomes in the United States are often below average. Moreover, 48 million people, including 7 million children, are uninsured in the United States.

These figures reflect the rising cost of private insurance and the limited reach of public programmes, particularly for the working poor. Most non-elderly Americans receive care through private insurance offered as a benefit of employment. However, many Americans cannot afford private insurance, work in low wage jobs for employers who do not offer insurance, or lose their insurance as a result of unemployment. Health care legislation passed in 2010 will close some of these gaps; however, many individual states have opted out of key provisions of the new legislation and this will limit the reach of reform.

The U.S. health system is highly advanced, but it is also extremely complex. The mixture of public and private programmes coupled with overlapping state and federal jurisdictions make reform efforts difficult. As the United States population becomes older and even more diverse, policymakers will have to address these challenges in order to create a more cost-effective, higher quality healthcare system.

This brief also examines the Food and Drug Administration (FDA), especially its role in the regulation of pharmaceuticals. The FDA is a model of effective consumer protection. However, the need and desire to make new drugs available is sometimes at odds with the role of the FDA as a gatekeeper protecting the public from unsafe or ineffective medicines. The challenges are greater in the area of food safety, where authority is divided between the FDA and several other agencies. The FDA will have to address these and other difficulties if it is to maintain its role and reputation in public health.
GENERAL INFORMATION

KEY FINDINGS

- The United States is the third largest country in the world by size (after Russia and Canada) and third in population (after China and India).
- The population of the United States is racially diverse and will become older and more diverse in the decades ahead.
- The United States has a federal system with political authority divided between national, state and local governments. The national government has a bicameral legislature, a separately elected President and an appointed judicial branch.
- The United States is the largest economy in the world. Although recovery since the Great Recession of mid-2007 is ongoing, unemployment remains above and median household income below pre-recession levels.
- The economic crisis has highlighted the growing problem of income inequality and concentrated wealth.
- The U.S. has the highest incarceration rate in the world.

Geography and Demographics

Covering more than 9.8 million km², the United States consists of fifty states and a federal district. It is the third largest country in the world by size (after Russia and Canada). As of 2013, the population of the United States stands at more than 316 million persons, third after China and India. As illustrated in Figure 1, the 48 contiguous states and the federal district of Washington D.C. stretch across continental North America, bordering Canada in the North and Mexico in the South. The state of Alaska is west of Canada and east of Russia across the Bering Strait, and the state of Hawaii is in the mid-North Pacific.

Figure 1: Map of the United States

Source: Central Intelligence Agency, World Fact book
By 2050, the U.S. population will be older and more racially diverse than it is now (see Table 1). The United States will also have a larger share of foreign-born residents. These developments have implications for health policy as the majority of government health care costs go to programmes for individuals age 65 and above. Moreover, a growing minority population will likely increase the number of Americans who receive health care through public programmes that provide assistance to the less well off.

Table 1: Population by age and race, 2012 and 2050 projections

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2050</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population (millions)</td>
<td>313.9</td>
<td>399.8</td>
</tr>
<tr>
<td>Persons under 18, per cent</td>
<td>23.7</td>
<td>21.5</td>
</tr>
<tr>
<td>Persons over 65, per cent</td>
<td>13.3</td>
<td>21.0</td>
</tr>
<tr>
<td>White, Non-Hispanic, per cent</td>
<td>63.4</td>
<td>46.6</td>
</tr>
<tr>
<td>Hispanic or Latino, per cent</td>
<td>16.7</td>
<td>27.9</td>
</tr>
<tr>
<td>African-American or Black, per cent</td>
<td>13.1</td>
<td>14.4</td>
</tr>
<tr>
<td>Asian, per cent</td>
<td>5.0</td>
<td>7.6</td>
</tr>
<tr>
<td>American Indian/Native Alaskan, per cent</td>
<td>1.2</td>
<td>1.5</td>
</tr>
<tr>
<td>Foreign-born, per cent</td>
<td>12.8</td>
<td>15.9</td>
</tr>
</tbody>
</table>

Source: United States Census Bureau

Government
The United States is a federal system with political authority distributed between federal, state and local government. Political jurisdictions are highly fragmented. There are more than 89,000 local authorities in the United States consisting of county and municipal governments as well as special districts that oversee education, transportation and sanitation for multiple localities.\(^1\) As indicated in Table 2, 87% of the public service is employed at the sub-national level; however, federal receipts and outlays are more than 1.5 times larger than those of state and local government.

Table 2: Governments, employees, receipts, and outlays by level of authority

<table>
<thead>
<tr>
<th></th>
<th>Units, 2007</th>
<th>Employees, 2009 (1000s)</th>
<th>Receipts, billions, 2011(^a)</th>
<th>Outlays, billions, 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federal</td>
<td>1</td>
<td>2,824</td>
<td>$2,519</td>
<td>$3,923</td>
</tr>
<tr>
<td>State</td>
<td>50</td>
<td>5,329</td>
<td>$903</td>
<td>$1,513</td>
</tr>
<tr>
<td>Local</td>
<td>89,476</td>
<td>14,480</td>
<td>$680</td>
<td>$1,185</td>
</tr>
</tbody>
</table>

Sources: U.S. Census Bureau; Bureau of Economic Analysis
\(^a\)State and Local receipts do not include federal, state, or local grants-in-aid

\(^1\) U.S. Census Bureau, Census of Governments
Economy
The United States is the largest economy in the world with Gross Domestic Product (GDP) valued at $16 trillion. Although a wealthy country by international standards, 15% of the U.S. population lives below the government poverty threshold of $23,000 in annual income for a family of four.² Unemployment is down to 7.6% from a high of 10% in 2009.³ Despite hopeful signs of recovery, median household income has yet to rebound from the Great Recession of mid-2007 (see Figure 2).

Figure 2: Median Household Income, 1975-2011

![Graph showing median household income from 1975 to 2011.](image)

The Great Recession has highlighted the widening gap between rich and poor in the United States. Since 1981, the share of income received by the top 1% of earners increased from 8 to 17% of total personal income.⁴ Income inequality has important implications for health policy as the poor generally score lower on most health indicators and have less access to regular sources of care.

Criminal Justice
The United States has an exceptionally high rate of incarceration, particularly for African-American and Hispanic/Latino men who together comprise over 60% of all prisoners in the United States (see Table 4). In terms of public health, the correctional system provides medical care for more than 2.2 million Americans currently in prison or jail.

Table 3: Incarceration Rates by Region and Race, 2010

<table>
<thead>
<tr>
<th>Region</th>
<th>Incarceration Rate per 100,000 persons</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>760</td>
</tr>
<tr>
<td>White Males</td>
<td>678</td>
</tr>
<tr>
<td>Hispanic Males</td>
<td>1,775</td>
</tr>
<tr>
<td>Black Males</td>
<td>4,347</td>
</tr>
</tbody>
</table>

Source: Bureau of Justice Statistics; OECD Fact book 2010

---

² Federal Reserve Bank of St. Louis, Federal Reserve Economic Data
³ U.S. Census Bureau
1. HEALTH STATUS AND HEALTHCARE ORGANISATION

KEY FINDINGS

- The United States spends more on health care per capita and as a share of GDP than any other country in the world.

- Life expectancy is lower and infant mortality is higher in the United States than the OECD average. This discrepancy between health care expenditures and health outcomes reflects disparities in health care access and quality among low income and minority populations.

- Delivery of care in the United States is organised on a fee-for-service model in which payers (insurers) negotiate prices with providers (doctors).

- The United States has a highly fragmented system of private and public health insurance programmes.

- In 2011, there were more than 48 million persons, or 16% of the population, without health insurance; almost 7 million children (under 18) are uninsured.

1.1 Health Care Spending

The United States spends more on health care than any other country in the world in terms of per capita spending ($8,680) and as a share of GDP (17.9%). As illustrated in Figure 3, approximately 45% of all health care spending in the United States is on private insurance and on individual out-of-pocket expenses on health services not covered by insurance. Another 45% comes from public insurance programmes such as Medicare and Medicaid (see Chapter 2 for more information). Public and private investment in research is around 6% of expenditures. Public health activities of federal, state, and local governments is just 3% of total health care spending.

---

One half of every dollar spent on health care goes to hospitals and physician services (see Figure 4). Ten per cent of health care spending goes to prescription drugs. Administrative costs and net profits from associated private health insurance is around 7% of total spending.

Private spending on health care distinguishes the United States from other wealthy countries. Health insurance purchased individually or provided as a benefit of employment plus individual out-of-pocket expenses on premiums, insurance deductibles, and payments for service is around 9% of GDP. Expenditures on public programmes in the U.S. as a share of GDP is comparable to other wealthy nations (see Figure 5).
Over the past decade, health care expenditures have risen faster than the rate of inflation, economic growth, or household income. This spending growth is particularly pronounced in private health insurance. In 2012, the average health insurance premium for family coverage was $15,745 per year. This represents more than a 50% increase over the past decade, after adjusting for price inflation, resulting in an annual growth rate of 4.6%. By contrast, as shown in Table 4, over this same period inflation increased by only 2.5% per year, real GDP grew by only 1.6% per year, and median household income actually declined in real terms.

Table 4: Ten Year Annual Growth Rates, Adjusted for Inflation

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>3.7%</td>
<td>4.6%</td>
<td>1.6%</td>
<td>2.5%</td>
<td>-0.5%</td>
</tr>
</tbody>
</table>

Sources: Centre for Medicare and Medicaid Services, National Health Expenditures; Kaiser Foundation, 2012 Employer Health Benefits Survey; Bureau of Labour Statistics; U.S. Census Bureau

The rising cost of health care has had a devastating effect on the personal finances of many Americans. According to a 2009 study, nearly two-thirds of individual bankruptcy filings in the United States were related to medical debt and the share of bankruptcies attributable to personal medical bills increased by 50% between 2001 and 2007.6

---

1.2 Health Outcomes and Disparities

Many health outcomes in the United States are fair to middling when compared to other countries. As shown in Table 5, the United States has lower life expectancy and higher infant mortality rates than other OECD countries. Mortality rates for cancer and heart disease, the two leading causes of death in the United States, are also higher than the OECD average. In addition, the United States suffers from the highest rate of obesity in the OECD. A lone bright spot is tobacco use: smoking rates in the United States are among the lowest in the OECD.

Table 5: Health Measures in the United States and OECD

<table>
<thead>
<tr>
<th></th>
<th>Life Expectancy</th>
<th>Infant Mortality</th>
<th>Cancer</th>
<th>Heart Disease</th>
<th>Obesity</th>
<th>Tobacco Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>78.7</td>
<td>6.1</td>
<td>227.0</td>
<td>142.6</td>
<td>28.1</td>
<td>15.1</td>
</tr>
<tr>
<td>OECD Average</td>
<td>79.8</td>
<td>4.3</td>
<td>214.9</td>
<td>131.1</td>
<td>15.0</td>
<td>21.1</td>
</tr>
</tbody>
</table>

Source: OECD Health Statistics Database
Notes: aYears; bDeaths per 1,000 live births; cDeaths per 100,000; d% of population; e% of population 15+ who are daily smokers

These overall indicators can mask important differences in health status among subpopulations. For instance, the infant mortality rate among babies born to African-American women is more than twice the rate of mortality among babies born to Non-Hispanic White women. These differences persist even after controlling for factors such as income or education that might influence access to pre-natal care or individual health behaviours. For instance, university-educated African-American women were almost twice as likely to deliver low birth weight babies (less than 2,500g) than similarly educated White women (see Table 6).

Table 6: Infant Mortality and Low Birth Weight, by Race and Education

<table>
<thead>
<tr>
<th>Infant Mortality, 2005</th>
<th>All Races</th>
<th>Black</th>
<th>White</th>
<th>Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>All education levels</td>
<td>6.9</td>
<td>13.6</td>
<td>5.8</td>
<td>2.3</td>
</tr>
<tr>
<td>Less than twelve years of education</td>
<td>7.6</td>
<td>14.8</td>
<td>9.3</td>
<td>1.6</td>
</tr>
<tr>
<td>12 years of education</td>
<td>7.9</td>
<td>14.2</td>
<td>7.1</td>
<td>2.0</td>
</tr>
<tr>
<td>13 or more years of education</td>
<td>5.0</td>
<td>11.4</td>
<td>4.1</td>
<td>2.8</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Low Birth Weight, 2008</th>
<th>All Races</th>
<th>Black</th>
<th>White</th>
<th>Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>All education levels</td>
<td>8.2</td>
<td>13.9</td>
<td>7.2</td>
<td>1.9</td>
</tr>
<tr>
<td>Less than twelve years of education</td>
<td>8.0</td>
<td>15.3</td>
<td>9.5</td>
<td>1.6</td>
</tr>
<tr>
<td>12 years of education</td>
<td>8.4</td>
<td>13.9</td>
<td>7.8</td>
<td>1.8</td>
</tr>
<tr>
<td>13 or more years of education</td>
<td>7.7</td>
<td>12.8</td>
<td>6.7</td>
<td>1.9</td>
</tr>
</tbody>
</table>

Source: National Center for Health Statistics, Health, United States, 2008 and 2011
The persistence of these differences points to racial disparities in health as well as a variety of social, economic and physical determinants that shape individual health outcomes. These health determinants include economic stability, education, social and community context, health care quality and access, and physical characteristics of neighbourhoods and built environments. The U.S. government has taken a very active role in collecting data, sponsoring research, and setting benchmarks and goals for reducing or eliminating health disparities by the year 2020.7

1.3 Health Care Delivery and Financing

The high cost and uneven quality of American health care is a product of the unique system of delivery and financing in the United States. The majority of health care providers (doctors and hospitals) operate on a fee-for-service basis, meaning they charge for individual procedures such as office visits, diagnostic tests and surgical procedures.

The majority of physicians in the United States are self-employed owners of a medical practice. Almost half of all physicians are either solo practitioners or work in a practice with five or fewer doctors. For doctors in private practice, compensation is typically a share of overall revenue based on billing for individual procedures.

Most doctors (87%) have contracts with Managed Care Organisations (MCOs) that negotiate lower prices for medical services in exchange for access to a larger pool of patients.8 Many MCOs are operated by for-profit insurance companies and in many states the health insurance market is dominated by one or two firms.9 The most common form of MCO is a Preferred Provider Organisation (PPO) in which enrollees can access a network of physicians to receive their care. A less popular, more restrictive model is a Health Maintenance Organisation (HMO) in which salaried staff physicians coordinate the provision of care.

MCOs play an important role in the operation of public insurance programmes. Nearly two-thirds of all Medicaid beneficiaries receive at least some of their care through MCOs. In addition, one quarter of Medicare beneficiaries are enrolled in managed care plans and 59% of Medicare enrollees have prescription drug coverage provided as a stand-alone benefit by an MCO or as part of an overall managed care plan.10

There is wide variation across different states, and even within the same state, in the prices doctors and hospitals receive for medical services (see Table 7). For Medicare, which is a public programme, the government sets prices for services based on the type of procedure performed. Many private insurers pay rates higher than Medicare in order to give customers access to specific doctors and hospitals. Providers also charge higher rates to individuals without insurance.

---

10 Henry J. Kaiser Family Foundation, State Health Facts.
Table 7: The Varying Price of Health Care in the United States

<table>
<thead>
<tr>
<th>Simple pneumonia without complications</th>
<th>Average Hospital Charges</th>
<th>Average Medicare Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>High</td>
<td>low</td>
</tr>
<tr>
<td>United States</td>
<td>$4,078</td>
<td>$88,521</td>
</tr>
<tr>
<td>Philadelphia Area</td>
<td>$13,489</td>
<td>$79,365</td>
</tr>
</tbody>
</table>

Source: Centers for Medicare & Medicaid Services, Medicare Provider Charge Data

As shown above, the cost of treatment in hospital for simple pneumonia, without complications, can range from $4,000 in Birmingham, Alabama to $88,000 in Newark, New Jersey. Prices range widely even within a single city; in Philadelphia, Pennsylvania hospitals charge between $13,000 and $79,000 to treat pneumonia.

1.4 Health Care Access

As indicated in Figure 6 on the next page, the majority of non-elderly Americans secure health insurance coverage through their employer, who typically pays a large share of the premium. Around five per cent of Americans purchase coverage individually from insurance companies. Approximately one third of Americans are enrolled in some kind of government insurance plan like Medicare or Medicaid (see Chapter 2 for more information).

Figure 6: Health Insurance Coverage of the U.S. Population

Source: Henry J. Kaiser Family Foundation, State Health Facts

However, the patchwork system of private insurance and public programmes leaves significant gaps. Around 16% of Americans are uninsured; in a majority of these households (60%), at least one family member is in full time employment but working in low wage jobs or for small firms that do not provide an insurance benefit. Medicare and Medicaid partly fill these gaps, yet large holes remain.
Figure 7: The Fragmented U.S. Health Care System

Figure 7 illustrates the patchwork quality of American health care. The bulk of the middle class are in the employer-based insurance system. Individuals over 65 receive health coverage through Medicare. Wealthier retirees may also receive health benefits from their former employers. Poor retirees (dual eligible) may receive Medicare and Medicaid, the latter providing long term care services such as nursing home facilities. Medicaid provides health care for the very poor, but individual states typically limit coverage to families with children at or just above the poverty line. The Children’s Health Insurance Programme (CHIP) provides insurance coverage to children of families that do not otherwise qualify for Medicaid, however many parents remain without insurance. For the working poor, many are underinsured: they might possess catastrophic coverage insurance but cannot afford regular medical care.

In conclusion, the rising cost of private insurance is gradually eroding the system of employer-provided managed care such that many middle class Americans risk losing part or all of their insurance. Only the very rich can afford to purchase health care “on demand” without restriction.

---

2. PUBLIC HEALTH POLICY

**KEY FINDINGS**

- Medicare provides universal health insurance for individuals age 65 or older. It is the largest government health programme in the United States in terms of cost.
- Medicaid is a means-tested health insurance programme for the poor. It is the largest government health programme in terms of coverage.
- Medicare is financed through federal payroll taxes and general revenue; Medicaid is jointly financed by the federal government and the states.
- The Patient Protection and Affordable Care Act (PPACA) built upon the existing health care system by expanding Medicaid and increasing access to the individual insurance market.
- Political battles and debates over the implementation of the Affordable Care Act illustrate the complexity of health care in a federal system.

### 2.1 Medicare and Medicaid

The two largest public health insurance programmes, Medicare and Medicaid, together cover almost 100 million Americans at an annual cost of $975 billion, or 6.4% of GDP. The scope and cost of both programmes is likely to increase in coming years as result of an aging population and health reform legislation that seeks to reduce the number of uninsured Americans.

**Medicare** was created in 1965 by an act of Congress as an amendment to the 1935 Social Security Act. Medicare is federally administered and financed through a combination of payroll taxes, general revenues, and premiums paid by beneficiaries. Initially, there were two components to Medicare, Part A covers hospitalization and Part B covers physician services. All U.S. residents are automatically enrolled in Part A at age 65. Part B is a voluntary programme; individuals may choose to enrol or receive coverage through another source.

In 1973, the Congress expanded Medicare to cover individuals under 65 with permanent disabilities. In 1997, the Congress created Part C, which allows Medicare beneficiaries to enrol in managed care plans (also known as Medicare Advantage). In 2003, the Congress passed the Medicare Modernization Act, which created a prescription drug benefit for enrollees (Part D). Medicare currently covers 52 million people (43 million over 65). This number is expected to increase to 86 million by the year 2035.

**Medicaid** was created by the same act of Congress as Medicare in 1965. Originally conceived as a medical assistance supplement for the poor, Medicaid has grown to address the widening gaps in the private health insurance system. In 1997, Congress created the State Children’s Health Insurance Programme (CHIP), which provides states with additional funding for children of families who did not otherwise qualify for Medicaid. Today, Medicaid covers 62 million Americans. This includes 1 in 3 children, over 40% of births, and 60% of people in nursing homes.

---

12 Non-citizen, permanent residents in the United States at least five years are eligible for Medicare.
13 Centers for Medicare & Medicaid Services; Annual Report of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds.
14 Kaiser Commission on Medicaid and the Uninsured, Medicaid: A Primer.
Medicaid is administered and financed jointly by the federal government and the states. The federal government provides matching funds, with poorer states receiving a higher reimbursement rate up to 73% of Medicaid expenditures. Medicaid eligibility varies widely from state to state. In sixteen states, coverage for working parents is limited to households with income less than 50% of the Federal Poverty Line (FPL), under $12,000 in annual income for a family of four. As illustrated in Figure 8, eligibility is more generous for children; forty-five states (including the District of Columbia) provide insurance to children of families making more than twice the poverty threshold or $46,000 a year. Only a handful of states provide any assistance to childless adults. Benefits vary as well; however, all states must provide a minimum set of mandatory health services.

**Figure 8: Median State Medicaid/CHIP Eligibility Thresholds, 2013**

Other federal government programmes provide health services to specific groups. More than 13 million veterans, active duty military, and their families receive care from the Veterans Administrations Health System or the Department of Defence health programme, Tricare. This number has grown by 40% in the last ten years due to the wars in Iraq and Afghanistan. The Indian Health Service serves 2.1 million Native Americans residing on or near tribal reservations in the United States.

Federal law also governs important features of the private health insurance system in the United States. For example, the federal tax code does not treat employer contributions to individual health benefits as income. It is estimated that this tax benefit costs the federal government $180 billion a year in lost revenue. In effect, the tax code subsidises the purchase of insurance by higher income individuals who receive more generous health benefits from their employers.

---

15 For information on the Military Health Service, including Tricare, see [http://www.health.mil/About_MHS/Health_Care_in_the_MHS.aspx](http://www.health.mil/About_MHS/Health_Care_in_the_MHS.aspx) (accessed May 27, 2013)
16 U.S. Census Bureau, Current Population Survey; Indian Health Service 2013 Profile
17 Office of Management and Budget, Analytical Perspectives for Fiscal Year 2013, 251.
2.2 The Patient Protection and Affordable Care Act

The Patient Protection and Affordable Care Act (ACA) is the most comprehensive health care legislation passed since the creation of Medicare and Medicaid in 1965. The ACA touches upon virtually every aspect of the health care system, public and private.

Key provisions of the ACA (and the year they take effect) include:

- Health insurance reforms that eliminate lifetime caps on benefits and prohibit denial of coverage based on pre-existing medical conditions (2010).
- Health insurance exchanges in states so that individuals can purchase coverage at lower cost (2014).
- A mandate that everyone purchase insurance, with subsidies available for lower income individuals (2014).
- An expansion of Medicaid to parents and childless adults with incomes up to 138% of the federal poverty line (2014).
- Lower Medicare payments to providers (2010), the elimination of subsidies to insurance companies (2011), and a rise in premiums for the wealthy (2013).

Although comprehensive in its goals, the ACA builds on the current system without transforming its underlying structure. Medicaid will become more important as a safety net and more individuals will buy private insurance through health exchanges.

While potentially reducing the number of uninsured by 25 million people in the next four years, the ACA does little to address the high cost of care in the United States. By 2021, health expenditures are projected to be 19.6% of GDP. Most of this increase will come from expenditure growth in public programmes like Medicare and Medicaid.18

2.3 Public health policy in a federal system

The passage and implementation of the Affordable Care Act illustrates the complexity of public health policy in a federal system. Because U.S. health care has many moving parts, comprehensive reform requires the coordination of multiple actors. This is difficult, especially given the differences among actors over what role the government should play in the health care system.

As shown in Figure 9 on the next page, responsibility for overall implementation of the ACA falls to the Executive Branch of the federal government. For the new law to take effect, the government must issue rules and regulations. This can be a lengthy process as federal law requires that agencies issue proposed rules for public comment before they can take effect. Since passage of the act in 2010, the Department of Health and Human Services (DHHS) has taken the lead in this process. Within DHHS, the Centre for Medicare and Medicaid Services (CMS) is preparing rules for the Medicaid expansion and the Centre for Consumer Information and Insurance Oversight (CIIO) is responsible for creating the new health insurance exchanges and other insurance reforms. These agencies will continue to administer the new law once regulations take effect.

---

The **U.S. Congress** was critical to passage of the ACA, especially the key health committees in the House of Representatives (Ways & Means; Energy & Commerce) and Senate (Finance; Health, Education, & Labour). Following passage, Congress will continue to play a role, especially through its oversight function and investigative powers of federal agencies. In addition, annual budgetary decisions by Congress can effect implementation. Budget cuts, for example, may reduce staffing levels in DHHS, which could slow down the rulemaking process and implementation of the ACA.

**Figure 9: Responsibilities for Health Policy and the ACA**

The **Judicial Branch** has played a very influential role in defining the scope of federal authority to implement the ACA. Following passage in 2010, opponents of the new law, including twenty-six states, challenged its constitutionality in court. In July 2012, the U.S. Supreme Court decided in *National Federation of Independent Business v. Sibelius* that the core of the ACA, including the individual mandate that everyone purchase insurance, was constitutional. However, the Court also decided that the federal government could not require states to expand Medicaid coverage, essentially leaving each state to decide how to proceed on this critical piece of the new law.

As a result of the Supreme Court decision, there will continue to be wide variation in the scope of state coverage under Medicaid. As of May 2013, twenty state Governors have issued official statements opposing the Medicaid expansion under the ACA. In addition, twenty-seven states have opted not to set up health insurance exchanges. Under the ACA, the federal government can administer a health exchange in a state unwilling or unable to establish one of their own.\(^{19}\) Finally, states can continue to experiment with Medicaid coverage by seeking a waiver from aspects of federal law. The approval of state waivers is at the discretion of the Secretary of Health and Human Services.

Lastly, the **insurance industry** has a large role to play in the implementation of health care reform. In exchange for tighter regulations on industry practices, insurance companies will see a sizable expansion in the number of insured—almost 27 million in the next few years. For many of the newly insured, the federal government will subsidize a large portion of their insurance premium.\(^{20}\)

---


3. U.S. FOOD AND DRUG ADMINISTRATION (FDA)

**KEY FINDINGS**

- The Food and Drug Administration is an agency within the Department of Health and Human Services headed by a commissioner appointed by the President and confirmed by the Senate.
- The FDA is responsible for regulating human and veterinary drugs, biological products, medical devices, cosmetics and food.
- The FDA is the single gatekeeper for new drugs to enter the U.S. market; FDA authority for food safety is divided among several agencies.
- The source of regulatory power for the FDA is its reputation for consumer protection, especially judging the efficacy and safety of pharmaceuticals.

3.1 Organisation and scope of FDA authority

The Food and Drug Administration is an agency within the Department of Health and Human Services (DHHS, see Figure and Table in the Appendix). The FDA carries a broad portfolio that includes the regulation of human and veterinary drugs, vaccines and other biological products, medical devices, food safety, cosmetics, and radiation-emitting products. The FDA also has responsibility for regulating the manufacture and marketing of tobacco products.

Figure 10 illustrates the overall structure of the FDA and the units with primary responsibility for food safety and pharmaceutical regulation (a complete organisational chart is included in the Appendix). As indicated, the FDA is organised into four directorates. The **Office of Foods and Veterinary Medicine** oversees the safety of food, animal feed, and veterinary drugs. The **Office of Medical Products and Tobacco** is responsible for the approval and regulation of pharmaceuticals and tobacco policy. The **Office of Global Regulatory Operations** is responsible for the coordination of domestic and global regulatory procedures, including the harmonisation of standards, product quality, and enforcement activities. The **Office of Operations** provides agency-wide services and support for technology, procurement, and financial management. Overall direction and management of the agency falls under the **Office of the Commissioner**.21

**Figure 10: FDA units with responsibility for food safety and drug approval**

![Diagram of FDA units]

**Source:** Food and Drug Administration

21 Food and Drug Administration, available at: [http://www.fda.gov/AboutFDA/CentersOffices/default.htm](http://www.fda.gov/AboutFDA/CentersOffices/default.htm).
Within the Office of Medical Products and Tobacco, responsibility for drug approval is divided between the **Centre for Drug Evaluation and Research** and the **Centre for Biologics Evaluation and Research**, the latter has responsibility for vaccines and other biological products. Within the Office of Foods and Veterinary Medicine, the **Centre for Food Safety and Applied Nutrition** has responsibility for food safety, whereas regulation of animal drugs is the responsibility of the **Centre for Veterinary Medicine**.

As indicated in Figure 11, one third of the FDA budget is allocated to the approval of medicines, around $1.3 billion in 2012. Food safety responsibilities compose around one quarter of the agency budget, or $875 million annually. However, since 1992 the FDA has collected user fees from pharmaceutical companies and other private actors that offset the cost of regulatory review and approval. In 2012, the FDA collected more than $1.3 billion in user fees.\(^\text{22}\)

**Figure 11: Composition of the FDA Budget, 2012 (Millions of Dollars and %)**

![Pie Chart](image)

**Source:** DHHS, Fiscal Year 2014 Budget in Brief

The source of statutory authority for the FDA is the Federal Food, Drug, and Cosmetic Act of 1938 (FFDCA); however, the origins of the FDA go back to the Food and Drugs Act of 1906. In 1962, following the Thalidomide tragedy in Europe, Congress passed the Kefauver-Harris Amendments to the FFDCA. This strengthened the rules for drug safety and established clear procedures for the regulatory approval of pharmaceuticals. Today, the FDA regulates $1 trillion worth of products each year, ranging from bottled water and infant formula to vaccines, drugs, and medical devices. According to some scholars, the FDA is the most powerful regulatory agency in the world.\(^\text{23}\)

---

\(^{22}\) Department of Health and Human Services, Fiscal Year 2014 Budget in Brief, 13.

3.2 FDA drug approval

Although its responsibilities range widely, the core competence of the FDA is the approval and regulation of pharmaceuticals. In fact, the drug approval process developed by the FDA has been widely replicated around the world.

As shown in Figure 12 on the next page, the drug approval process is a long and complex one. Once researchers identify a promising new compound, they must submit an **Investigational New Drug (IND) application** with the Centre for Drug Evaluation and Research (CDER). Drug sponsors then begin clinical trials. During **Phase 1 trials**, researchers examine the safety of the new drug, usually on a small number of healthy volunteers. If the drug poses minimal risk, **Phase 2 trials** begin to obtain preliminary data on its effectiveness. If the drug is both safe and effective (when compared to a placebo), **Phase 3 trials** begin. These large scale trials examine the safety and effectiveness of the drug in several thousand patients, including different populations and in different dosages.\(^{24}\)

![Figure 12: Drug Discovery and Development Timeline](source.png)


If the results of Phase 3 trials are positive, the drug sponsor files a **New Drug Application (NDA)** with the FDA. The NDA is a formal request for FDA approval to market the drug. Although communication between drug companies and the FDA takes place during clinical trials, submission of the NDA is considered the beginning of the official review process. After the NDA is filed, an FDA team evaluates existing studies and other data to establish whether the new drug is safe and effective for use.

The CDER receives approximately 100 NDAs each year. Around half of these applications will be approved on the first review and almost 80% of applications submitted in any given year will be approved eventually. The median review time for new drugs is 10 months. In addition to the standard review process, the FDA offers priority review procedures for drugs that offer major advances in treatment or provide treatment where no adequate therapy exists. Approximately 20% of NDAs receive priority status. The median approval time for priority applications is around 8 months.\textsuperscript{25}

During the 1980s, the FDA came under criticism from Congress, patient advocacy groups, and the pharmaceutical industry, each calling on the agency to streamline and speed up its drug approval process. These concerns led to passage of the Prescription Drug User Fee Act (PDUFA) in 1992 (reauthorized in 1997, 2002, 2007, and 2012). The law provides the FDA with additional resources from drug company user fees, and it establishes performance targets the agency must meet if this additional funding is to continue. As indicated in Figure 13, the FDA responded: median approval times for standard and priority applications dropped significantly since 1993 when PDUFA came into effect.\textsuperscript{26}

**Figure 13: Median Approval Times for NDAs, 1993-2011**

![Figure 13: Median Approval Times for NDAs, 1993-2011](image)

\textbf{Source:} FDA, CDER New Drug Review: 2012 Update

The authority of the FDA derives in large part from its reputation as a protector of consumer safety, a reputation that dates back to the early 1960s when the agency prevented the sale of Thalidomide in the United States. However, the emphasis on faster approval times puts pressure on the gatekeeping role of the FDA. The removal of Vioxx and other drugs from the market due to adverse effects demonstrates the challenges and importance of post-marketing surveillance, a function for which the FDA has limited capacities.


\textsuperscript{26} Figure 13 uses a LOWESS smoothing procedure to fit lines for median approval times. Data is for New Molecular Entities only.
3.3 Food safety regulation

Unlike pharmaceuticals, for which the FDA has sole jurisdiction, responsibility for food safety is split between the FDA, the U.S. Department of Agriculture (USDA), and several other federal agencies. This results in a complex regulatory system that suffers from unnecessary duplication as well as critical gaps in oversight. For instance, as shown in Figure 14, several agencies regulate the production of frozen pizza, with ultimate jurisdiction over product safety determined by whether it has cheese or meat topping.

Figure 14: Federal Agencies Responsible for Ensuring Safe Pizza

In addition to overlapping authority, the FDA lacks the capacity it needs to address the risks of food borne illness. There are over 50,000 food processing facilities in the United States that are subject to FDA inspection and regulation. Yet, as of 2013, the FDA employs only 2,664 staff in the field and 882 at headquarters to handle food safety responsibilities. According to a 2010 report by the DHHS Inspector General, the FDA inspects less than a quarter of food facilities each year and more than half of food processing facilities have gone five or more years without a single inspection. 27 Although direct comparisons are difficult, the UK Food Standards Agency reported inspection rates upwards of 60% for all food-related establishments, with rates approaching 100% for food entities that pose the greatest risk to public health. 28


28 Food Standards Agency, "Local Authority Enforcement Monitoring System (LAEMS) Report," 12/11/06, available at: http://food.gov.uk/multimedia/pdfs/board/fsa121106.pdf (accessed June 14, 2013). Inspections are conducted by local authorities and include all food establishments including manufacturers, retailers, and restaurants. Inspections of high risk establishments must be carried out every 6-12 months.
Mindful of the risks to public health, and following several widely publicised outbreaks or foodborne illness, Congress passed the Food Safety Modernization Act (FSMA) in 2011. The act aims to strengthen FDA food safety capacity by granting the agency authority to issue mandatory recalls of tainted food (previously recalls were voluntary), conduct more frequent inspections, and strengthen FDA surveillance of imported food. As of this writing, the FSMA has not been fully implemented due in part to the complexity of the proposed rules and the continued impasse over the federal budget.  

3.4 The Future of the FDA

The FDA remains a global model of pharmaceutical regulation. The United States was the first country to establish a unified regulatory agency for pharmaceuticals, a standardised application procedure for new drugs, a regulated process for research and development, and standards for best laboratory and manufacturing practice. These innovations created a reputation for scientific expertise and consumer protection. Americans trust the FDA. However, this trust may be eroding. Public opinion polls record a decrease in support for the FDA. As indicated in Figure 15, positive views of the agency declined and negative views increased between 2004 and 2009. Although such evidence should be interpreted with caution, it points to several challenges the FDA must address in the future.

Figure 15: Public Perceptions of the FDA

![Figure 15: Public Perceptions of the FDA](image)

Source: Harris Poll, November 2004 and February 2009

First, over the past fifty years, U.S. presidents (Democrat and Republican) have sought greater control of the bureaucracy by adding a layer of political appointments on top of the civil service and by centralising administrative authority in the Executive Branch. However, efforts to enhance political control from the top puts the reputation of the FDA for objective scientific decision-making at risk. Second, the dependence on drug user fees and the focus on faster review times can create an impression that the FDA is more responsive to industry demands than consumer protection. Third, periodic outbreaks of foodborne illness or the revelation that drugs thought to be safe pose a danger to public health will steadily erode trust in the FDA.

30 Carpenter, Reputation and Power, 724-725.
As a result, the FDA faces an uncertain future and possibly a further decline in its reputation if these challenges are not addressed. Reforms may be needed that insulate the agency from political interference, for example appointing the FDA commissioner to a six year term like the head of the U.S. Federal Reserve. Other possible reforms include a change to the agency’s financing, replacing the system of user fees with a tax on pharmaceutical sales for example.\(^{31}\) In the area of food safety, the FDA may face a reorganisation of its responsibilities. For example, leaving the task of food inspection and enforcement to other agencies would allow the FDA to focus more on risk assessment of foodborne pathogens rather than risk management in a highly decentralised and global food industry.\(^{32}\)


REFERENCES

- Center for Studying Health System Change, Data Bulletin 35, September 2009
- Centers for Medicare & Medicaid Services; Annual Report of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds
- Centers for Medicare and Medicaid Services, National Health Expenditures
- Department of Health and Human Services, Fiscal Year 2014 Budget in Brief
- Department of Health and Human Services, Office of Inspector General, FDA Inspections of Domestic Food Facilities, April 2010
- Federal Reserve Bank of St. Louis, Federal Reserve Economic Data
- Henry J. Kaiser Family Foundation, State Health Facts
- Kaiser Family Foundation, Summary of the Affordable Care Act. April 23, 2013
- Office of Management and Budget, Analytical Perspectives for Fiscal Year 2013, 251
- Secretary’s Advisory Committee on Health Promotion and Disease Prevention Objectives for 2020. Healthy People 2020: An Opportunity to Address the Societal Determinants of Health in the United States. July 26, 2010
- U.S. Census Bureau, Census of Governments
APPENDIX

Figure 16: The Department of Health and Human Services

Source: Department of Health and Human Services
Figure 17: The Food and Drug Administration

Source: Food and Drug Administration
<table>
<thead>
<tr>
<th>Description</th>
<th>Outlays (millions)</th>
<th>Employees (FTE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administration for Children and Families</td>
<td>50,604</td>
<td>1,379</td>
</tr>
<tr>
<td>Administration for Community Living</td>
<td>1,470</td>
<td>119</td>
</tr>
<tr>
<td>Agency for Healthcare Research and Quality</td>
<td>205</td>
<td>320</td>
</tr>
<tr>
<td>Centers for Disease Control and Prevention</td>
<td>6,696</td>
<td>10,823</td>
</tr>
<tr>
<td>Centers for Medicare and Medicaid Services</td>
<td>1,132,239</td>
<td>6,160</td>
</tr>
<tr>
<td>Food and Drug Administration</td>
<td>2,546</td>
<td>14,572</td>
</tr>
<tr>
<td>Health Resources and Services Administration</td>
<td>9,168</td>
<td>1,894</td>
</tr>
<tr>
<td>Indian Health Service</td>
<td>4,655</td>
<td>15,587</td>
</tr>
<tr>
<td>National Institutes of Health</td>
<td>31,792</td>
<td>18,497</td>
</tr>
<tr>
<td>Office of the Inspector General</td>
<td>54</td>
<td>1,883</td>
</tr>
<tr>
<td>Substance Abuse and Mental Health Services</td>
<td>3,594</td>
<td>631</td>
</tr>
<tr>
<td>Office of the Secretary</td>
<td>4,358</td>
<td>4,344</td>
</tr>
<tr>
<td>Offsetting Receipts</td>
<td>-339,584</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>907,797</strong></td>
<td><strong>76,209</strong></td>
</tr>
</tbody>
</table>

*Source: DHHS, Fiscal Year 2014 Budget in Brief*
FOOD SAFETY POLICY AND REGULATION
IN THE UNITED STATES
LIST OF MAPS

Map 1: Map of USA

LIST OF TABLES

Table 1: Roles of state and local agencies in food safety
Table 2: Food Safety Modernisation Act – Summary
Table 3: Changes in the incidence of laboratory-confirmed bacterial infections

LIST OF FIGURES

Figure 1: FDA – Organisation Chart
Figure 2: Organisation chart - United States Department of Agriculture (USDA)
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
USDA  United States Department of Agriculture
1. EXECUTIVE SUMMARY

Background

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 15 to 18th July 2013.

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 (eg 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.

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. The FDA have 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)
2. INTRODUCTION

This briefing has been prepared for the Environment, Public Health and Food Safety Committee (ENVI) Delegation to the USA in July 2013. 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.

2.1. Method

2.1.1. Sources of information:

The websites and official publications of the relevant regulatory and other authorities in USA were examined. The USA has been subject to Foreign Veterinary Office (FVO) inspections which have been considered.

Relevant scientific literature was also methodically searched.

2.1.2. Map of USA

Map 1: Map of USA

3. 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 $106 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 $145 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 1.2% 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 (eg 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 (FATUS) the main source of imports by value (2011) are Canada ($18 billion), European Union ($16 billion) and Mexico ($15 billion). US imports of food and agricultural products totalled approximately $106 billion of which the majority ($69 billion) were plant foods (ERS, Food Imports 2012).

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 Canada, China, Mexico, Japan and the European Union (ERS). In 2012 US food and agricultural exports were over $145 billion, an increase of 11% over 2011. 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.
4. STRUCTURE OF THE FOOD SAFETY AND CONTROL SYSTEM IN THE USA

**KEY POINTS**

- 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.
4.1. 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)

4.1.1. Food and Drug Administration

The Food and Drug Administration (FDA) is a federal agency within the US Department of Health and Human Services (HHS). (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). 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 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.

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.
**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 18: Food and Drug Administration (FDA) – Organisation Chart (Food safety competencies only)**

![Organisation Chart](chart.png)

**Office of Foods and Veterinary Medicine (FVM)**

The Office of Foods and Veterinary Medicine was created in August 2009. It's 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.

**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.

**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.
4.1.2. 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)**


**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 interstate 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.

**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.

**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.

**4.1.3. 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.

**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.
4.1.4. 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.

4.1.5. 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.

4.1.6. Other Agencies

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.

4.1.7. 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.
### Table 1: Roles of state and local agencies in food safety

<table>
<thead>
<tr>
<th>Activity</th>
<th>State</th>
<th>Local</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surveillance</td>
<td>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.</td>
<td>Frontline responsibility for reporting foodborne diseases and on-going foodborne illness surveillance Collect and respond to consumer complaints</td>
</tr>
<tr>
<td>Outbreak response and recalls</td>
<td>Typically lead responsibility large-scale outbreak investigations Oversee industry recalls in collaboration federal and local regulatory authorities</td>
<td>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</td>
</tr>
<tr>
<td>Laboratory testing</td>
<td>Conduct majority of all government food-safety-related testing</td>
<td>Some jurisdictions conduct food safety laboratory functions</td>
</tr>
<tr>
<td>Retail and foodservice</td>
<td>In some states – Retail food safety standard setting Inspection of retail and food service establishments</td>
<td>Set retail food safety standards License retail establishments Extensive role in inspection of grocery stores and restaurants</td>
</tr>
<tr>
<td>Food manufacturing inspections</td>
<td>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</td>
<td></td>
</tr>
<tr>
<td>Farm inspections</td>
<td>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 <em>S. enteritidis</em>)</td>
<td></td>
</tr>
<tr>
<td>Technical and training</td>
<td>Extensive technical training and assistance to: State agency employees Health department staff Grocery, restaurant and other retail food service workers</td>
<td>Technical and training assistance to: Local agency staff Grocery, restaurant and other retail service workers</td>
</tr>
<tr>
<td>assistance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td>Food safety education provided for: Local health department staff Food workers Other commercial participants in food safety system Consumers Medical community</td>
<td>Frontline source of food safety information and education for consumers and retailers 75% have food safety education programs</td>
</tr>
</tbody>
</table>

**Source:** Taylor, RT and David, SD 2009
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 1).

**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.

**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
- 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.

**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.
4.2. 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.
4.2.1. **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).

4.2.2. **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 (due in 2013).

4.2.3. **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.

4.2.4. 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.

4.2.5. 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.

4.2.6. 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.
4.2.7. 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. 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. Five proposed rules have been established:

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.

A summary of their requirements is given in Table 2. To date only proposals for the first have been published. The others remain under review.
### Table 2: Food Safety Modernisation Act – Summary

<table>
<thead>
<tr>
<th>Rule:</th>
<th>Produce Safety Standards</th>
<th>Preventive Controls for Human Food</th>
<th>Foreign Supplier Verification Programme</th>
<th>Preventive Controls for Animal Feed</th>
<th>Accredited Third Party Certification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Brief Description</strong></td>
<td>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</td>
<td>Focus – preventing problems that cause human foodborne illness Requirements: Hazard analysis – written plan Risk based preventive controls to encompass: Process, food allergen; sanitation controls and a recall plan Monitoring procedures Corrective actions Exceptions: Certain low risk activities</td>
<td>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</td>
<td>Equivalent to those for human food</td>
<td>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</td>
</tr>
<tr>
<td><strong>Applies to</strong></td>
<td>All unprocessed fruits and vegetables intended for human consumption</td>
<td>Facilities that manufacture, process, pack or hold human food. Domestic and foreign companies</td>
<td>Imported food (certain exemptions apply)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Additional requirements</strong></td>
<td>Training</td>
<td>Revision of current GMP controls re cross contamination and allergens</td>
<td>Third party accreditation Voluntary qualified importer program</td>
<td></td>
<td>May deny entry to an import if foreign facility refuses FDA inspection</td>
</tr>
<tr>
<td>Revised date:</td>
<td>16 September 2013</td>
<td>Not yet given</td>
<td>Enactment + 1 year; FDA recognition accreditation bodies Enactment+ 2 years Voluntary qualified importer program – Enactment + 18mths</td>
<td></td>
<td></td>
</tr>
<tr>
<td>--------------</td>
<td>------------------</td>
<td>---------------</td>
<td>--------------------------------------------------------------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Publication final rule (P)</td>
<td>Not yet given</td>
<td>P + 60 days</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Effective date (E)</td>
<td>E + 2 years</td>
<td>E + 1 year</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General compliance</td>
<td>E + 3 years</td>
<td>E + 2 years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small business compliance</td>
<td>E + 4 years</td>
<td>E + 3 years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very small business compliance</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Source:** [FDA, Background on the FDA Food Safety Modernization Act (FSMA)](https://www.fda.gov/food/food-safety-modernization-act-fsma/)

<table>
<thead>
<tr>
<th>Revised date:</th>
<th>16 September 2013</th>
<th>Not yet given</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Publication final rule (P)</td>
<td>Not yet given</td>
<td>P + 60 days</td>
<td></td>
</tr>
<tr>
<td>Effective date (E)</td>
<td>E + 2 years</td>
<td>E + 1 year</td>
<td></td>
</tr>
<tr>
<td>General compliance</td>
<td>E + 3 years</td>
<td>E + 2 years</td>
<td></td>
</tr>
<tr>
<td>Small business compliance</td>
<td>E + 4 years</td>
<td>E + 3 years</td>
<td></td>
</tr>
<tr>
<td>Very small business compliance</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Source:** [FDA, Background on the FDA Food Safety Modernization Act (FSMA)](https://www.fda.gov/food/food-safety-modernization-act-fsma/)
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 preventing it
- 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 – for example it does not address USDA’s responsibilities which continue to remain distinct from those of the FDA.
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
- The level of incidence of six major food pathogens has not shown a significant improvement during the period 2006 – 2012.
- 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) 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 2013) reported that in the European Union more than 5,000 food-borne outbreaks were reported in 2011 related to nine foodborne pathogens, resulting in 70,000 cases of food poisoning, more than 7000 hospitalisations and just under 100 deaths. Overall however in 2011 there were over 300,000 confirmed human case of infection with nine zoonoses, 15,000 hospitalisations and 300 deaths.

5.1. Trends in the incidence of foodborne illness

5.1.1. Recent trend

Trend information (CDC,2012) showed no improvement, and in some increases, in the recent incidence of foodborne illness. Changes in the incidence of laboratory-confirmed bacterial infections 2012 compared with 2006–2008 are given in Table 4 below:

<table>
<thead>
<tr>
<th>Food Pathogen</th>
<th>Percentage change</th>
<th>Statistically significant</th>
<th>2012 incidence per 100,000 population</th>
<th>2020 Target per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Campylobacter</td>
<td>+14%</td>
<td>Yes</td>
<td>14.3</td>
<td>8.5</td>
</tr>
<tr>
<td><em>Escherichia coli</em> O157</td>
<td>-10%</td>
<td>No</td>
<td>1.12</td>
<td>0.6</td>
</tr>
<tr>
<td>Listeria</td>
<td>-6%</td>
<td>No</td>
<td>0.25</td>
<td>0.2</td>
</tr>
<tr>
<td>Salmonella</td>
<td>+3%</td>
<td>No</td>
<td>16.42</td>
<td>11.4</td>
</tr>
<tr>
<td>Vibrio</td>
<td>+43%</td>
<td>Yes</td>
<td>0.41</td>
<td>0.2</td>
</tr>
<tr>
<td><em>Yersinia</em></td>
<td>-6%</td>
<td>No</td>
<td>0.33</td>
<td>0.3</td>
</tr>
</tbody>
</table>

*Source:* CDC Food safety progress report for 2012
Similarly the overall incidence of infection with the six key pathogens transmitted commonly through food (Campylobacter, Listeria, Salmonella, E. coli O157, Vibrio, and Yersinia) was not significantly different in 2012 compared to that in 2006–2008.

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.

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

  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 \textit{Salmonella enteriditis}.

Tainted turkey burgers 2011
50,000lbs of ground turkey were recalled following illness in 10 states. Cause \textit{Salmonella hadar}

Contaminated vegetables—such as lettuce in 2010, peppers in 2008, and spinach in 2006

Food incidents and Europe
The number of notifications in the Rapid Alert System for Food and Feed (RASFF) of foods entering the European Union from America has reduced from a high of 238 in 2009 to 112 in 2011 (RASFF Annual Report 2012). (The United States was the eighth highest listed country).

5.1.4. 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.

5.1.5. 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 February 2011, the Government Accountability Office reported in its High-Risk Series Update that food safety agencies have not developed a Government-wide performance plan that includes results-oriented performance measures which could measure progress in preventing foodborne illness from meat, poultry, and processed egg products.

However in September 2011, the Food Safety and Inspection Service (FSIS) published its strategic plan, 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.
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. Are there any plans, or is there seen a need, to implement the approach adopted under FSMA to those products which fall under the remit of FSIS?

**Foodborne illness and incidents**

- The recent trend shows no improvement in the incidence of foodborne illness due to food pathogens and some increases. 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?
REFERENCES

- David, S et al The essential role of state and local agencies in food safety and food safety refor: [http://www.thefsric.org/State_Local/StateLocal_June17_background.pdf](http://www.thefsric.org/State_Local/StateLocal_June17_background.pdf)
- Food Code: [http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/default.htm](http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/default.htm)
- FDA, 2013 Report to Congress on building domestic capacity to implement the FDA Food Safety and Modernisation Act (FSMA) - Ensuring a safe food supply April 2013: [http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm351868.htm](http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm351868.htm)
• Food Safety Modernisation Act: http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm267460.htm
  http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm237758.htm
  http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm319053.htm


• Government Accountability Office (GAO), (July 2012) FDA’s Food advisory and recall process needs strengthening GAO-12-589: http://www.gao.gov/products/GAO-12-589

• Government Accountability Office (GAO) (September 2012) Food Safety – FDA can better oversee food imports by assessing and leveraging other countries’ oversight resources GAO-12-933: http://www.gao.gov/products/GAO-12-933


• ISO 17025 General requirements for the competence of testing and calibration laboratories: http://www.iso.org/iso/catalogue_detail.htm?csnumber=39883

• President’s Food Safety Working Group: http://www.foodsafetyworkinggroup.gov/


• Stevens, S Five key areas that will shape the food industry in 2012 Food Quality February / March, 2012


• Toops, D (2012) The new American majority Food Processing 73(9), 28-33, 2012


Note: All websites accessed during May 2013.
## ANNEX 1

### Federal and State collaboration

<table>
<thead>
<tr>
<th>Foodborne Illness Surveillance</th>
<th>Foodborne Diseases Active Surveillance Network</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FoodNet</strong></td>
<td><strong>Agencies:</strong> CDC, FDA, USDA and ten participating states</td>
</tr>
<tr>
<td><strong>Aim:</strong></td>
<td>To provide more accurate estimates of foodborne illness associated with food-borne pathogens</td>
</tr>
<tr>
<td><strong>Activity:</strong></td>
<td>Conducts active, population-based surveillance in 10 states for laboratory-based confirmed cases caused by nine specified pathogens</td>
</tr>
<tr>
<td><strong>Outcome:</strong></td>
<td>Contributed to standardisation of laboratory methods</td>
</tr>
</tbody>
</table>

| **FoodNet**                  | **Activity:** Performs targeted case-control studies to identify risk factors for pathogen specific illnesses |
| **Outcome:**                 | Contributed to standardisation of laboratory methods |

| **FoodNet**                  | **Activity:** Performs targeted case-control studies to identify risk factors for pathogen specific illnesses |
| **Outcome:**                 | Contributed to standardisation of laboratory methods |

| **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 |

| **PulseNet**                 | **Activity:** |
| **Outcome**                  | Identification of related strains so enabling the connection of cases to a common source |

| **PulseNet**                 | **Outcome:** |
| **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 |

| **FERN**                     | **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 |

| **FERN**                     | **Outcome:** |
| **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 |

| **eLEXNET**                  | **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 |

| **Epi-X**                    | **Aim:** To provided CDC officials, state and local health departments, poison centre and other public health professionals ability to access and share preliminary |

| **Epi-X**                    | **Outcome:** |
### Outbreak response

<table>
<thead>
<tr>
<th><strong>OutbreakNet/NORS</strong></th>
<th><strong>National Outbreak Reporting System</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Agency</strong></td>
<td>CDC coordinated network of public health officials in local and state health departments and federal agencies</td>
</tr>
<tr>
<td><strong>Aim</strong></td>
<td>Collaboration and information exchange relating to foodborne outbreaks</td>
</tr>
<tr>
<td><strong>Activity</strong></td>
<td>Investigation of foodborne outbreaks Reporting mechanism for state members report findings to CDC</td>
</tr>
<tr>
<td><strong>Outcome</strong></td>
<td>National web-based system that tracks foodborne, person-to-person, animal contact, waterborne and Norovirus outbreaks</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>CIFOR</strong></th>
<th><strong>Council to Improve Foodborne Outbreak Response</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Agency</strong></td>
<td>CDC, FDA, USDA, AFDO, APHI, ASTHO, CSTE, NACCHO, NEHA, NASDA Industry workgroup – 16 members for food production, restaurant and retail companies.</td>
</tr>
<tr>
<td><strong>Aim</strong></td>
<td>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</td>
</tr>
<tr>
<td><strong>Activity</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Outcome</strong></td>
<td></td>
</tr>
</tbody>
</table>

| **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** | |

<p>| <strong>FoodSHIELD</strong> | |
| <strong>Agency</strong> | Laboratories and regulatory agencies at all levels of the food safety system |
| <strong>Aim</strong> | To support federal, state and local governmental regulatory agencies and laboratories through web-based tools To create community and share information about |</p>
<table>
<thead>
<tr>
<th><strong>Prevention, Inspection and Regulatory Activities</strong></th>
<th><strong>EHS-Net</strong></th>
<th><strong>Environmental Health Specialist Network</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Agency</strong></td>
<td>CDC-co-ordinated forum of environmental health specialist for CDC, FDA and nine states</td>
<td></td>
</tr>
<tr>
<td><strong>Aim</strong></td>
<td>Translating investigatory findings into improved food safety prevention efforts</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Strengthening relations among epidemiology, laboratory and environmental health programs</td>
<td></td>
</tr>
<tr>
<td><strong>Activity</strong></td>
<td>Collaborative forum of environmental health specialists, epidemiologists and laboratorians</td>
<td></td>
</tr>
<tr>
<td><strong>Outcome</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**FDA’s Food Code**

<table>
<thead>
<tr>
<th><strong>Agency</strong></th>
<th>FDA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aim</strong></td>
<td>To provide a sound legal and technical basis for regulating the retail and food service</td>
</tr>
<tr>
<td><strong>Activity</strong></td>
<td>Publish the Food Code, a model ordinance for the retail and food service sector</td>
</tr>
<tr>
<td><strong>Outcome</strong></td>
<td>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.</td>
</tr>
</tbody>
</table>

**FDA Voluntary National Retail Food Regulatory Program**

<table>
<thead>
<tr>
<th><strong>Agency</strong></th>
<th>FDA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aim</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Activity</strong></td>
<td>Provision of recommended standards and assessment procedures for the regulatory programs through which state, local, territorial and tribal regulatory agencies implement the Food Code.</td>
</tr>
<tr>
<td><strong>Outcome</strong></td>
<td>Provides the framework for future federal-state-local collaboration to improve food safety practices at the retail level.</td>
</tr>
</tbody>
</table>

**FDA-State Contract Inspection Agreements**

<table>
<thead>
<tr>
<th><strong>Agency</strong></th>
<th>FDA and state</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aim</strong></td>
<td>Inspection of domestic food processing plants</td>
</tr>
<tr>
<td><strong>Activity</strong></td>
<td>State employees carry out FDA inspections at domestic</td>
</tr>
</tbody>
</table>
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**

<table>
<thead>
<tr>
<th>Agency</th>
<th>FDA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aim</td>
<td>As that of the Voluntary National Retail Regulatory Program but focusing on state programs for the regulation of food processing plants</td>
</tr>
<tr>
<td>Activity</td>
<td>Compliance will become a pre-requisite for states conducting inspections under contract to FDA</td>
</tr>
<tr>
<td>Outcome</td>
<td>Ensure state-conducted FDA inspections are performed to a uniformly high level of quality nationwide</td>
</tr>
</tbody>
</table>

**Grade A Pasteurised Milk Ordinance (PMO) and the National Conference of Interstate Milk Shipments (NCIMS)**

<table>
<thead>
<tr>
<th>Agency</th>
<th>FDA, USDA, state authorities, milk industry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aim</td>
<td>To ensure safety of milk shipped in interstate commerce</td>
</tr>
<tr>
<td>Activity</td>
<td>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.</td>
</tr>
<tr>
<td>Outcome</td>
<td>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</td>
</tr>
</tbody>
</table>

**National Shellfish Sanitation Program**

<table>
<thead>
<tr>
<th>Agency</th>
<th>FDA and Interstate Shellfish Sanitation Programme Federal-State cooperative program</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aim</td>
<td>To ensure the sanitary control of shellfish</td>
</tr>
<tr>
<td>Activity</td>
<td>FDA sets uniform, science-based standards which are implemented and enforced by state authorities</td>
</tr>
</tbody>
</table>

**Talmadge-Akin Federal-State cooperative inspection of Meat and Poultry Plants**

<table>
<thead>
<tr>
<th>Agency</th>
<th>USDA and state agencies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aim</td>
<td>Inspection of meat and poultry plants</td>
</tr>
<tr>
<td>Activity</td>
<td>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.</td>
</tr>
</tbody>
</table>

**Source:** Taylor, RT and David, SD 2009
ROLE

Policy departments are research units that provide specialised advice to committees, inter-parliamentary delegations and other parliamentary bodies.

POLICY AREAS

- Economic and Monetary Affairs
- Employment and Social Affairs
- Environment, Public Health and Food Safety
- Industry, Research and Energy
- Internal Market and Consumer Protection

DOCUMENTS