Food safety

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Introduction

In this chapter, we examine food safety in greater detail, focusing on the factors influencing food safety regulations. Standards, an essential part of food safety regulations, are treated separately in Modules 4 and 5.

Although the WHO considers the availability of safe food to be a basic human right, for a long time *common wisdom* dictated that while both developed and developing countries battle with food safety outbreaks (occasional but more publicized in case of developed countries), developing countries focus on ensuring food security before attending to food safety considerations. While it is true that urgent food needs do take precedence over food safety consideration, food safety is of interest to both developed and developing countries. In reality, people in developing countries are more prone to food safety outbreaks.

Centers for Disease Control and Prevention (**CDC**) estimates that in the US each year:

- 76 million cases of foodborne illness occur.
- More than 300,000 persons are hospitalized.
- 5,000 die from foodborne illness.

The World Health Organization states that food and waterborne diarrheal diseases are leading causes of illness and death in less developed countries, killing approximately 2.2 million people annually, 1.9 million of whom are children. The WHO goal is to reduce the health and social burden of foodborne disease by:

- supporting the development of risk-based, sustainable, integrated food safety systems;
- devising science-based measures along the entire food chain; and
- assessing and managing foodborne illness.

Approaches chosen to achieve the goal include:

- surveillance of foodborne diseases
- better risk assessment
- safe new technologies
- risk communication
- international cooperation
- capacity building

Food safety is an evolving problem. New pathogens are discovered with advancements in science and technology. Although a systematic food-chain approach is being advocated, food safety regulations in many countries still represent a patchwork of regulations. In the United States, 12 different federal agencies derive their authority over food products from 35 different federal statutes. In the EU, despite the common market, the **European Food Safety Authority** (**EFSA**) was not established until after the series of food crisis in the 1990s.

1. What is food safety?

Food safety and **food quality** are interrelated but yet distinctive concepts.

- **Safety** is an essential component of quality, and contributes to determining purchase intentions and food choice.
  Safety is also a freedom from danger, risk or injury. Food safety is the guarantee that food has no harmful consequences for the health of the end user when it is prepared and consumed as it was intended to.

- **Quality** is a more multi-dimensional concept and we will cover it later in this course, although many aspects that influence food safety also influence food quality.

Bibliographical reference

Grunert, K. G. (2005). "Food quality and safety: consumer perception and demand". *European Review of Agricultural Economics* (Vol. 3, no. 32, pp. 369-391).

Food safety deals with:

- **Microbiological** hazards, which include bacteria, viruses, yeasts, parasites, etc.
- **Biological** contaminants, among which we find bones, hair, insects, and alike.
- **Chemical** contaminants in food may include:
  - Natural toxicants, such as mycotoxins and marine toxins.
  - Environmental contaminants, such as mercury and lead, pesticides and veterinary drug residues.
  - Naturally occurring substances in plants.

- **Physical** hazards, like dirt, glass, metals, etc.

We already discussed that some aspects of food safety have characteristics of an experience good which are known only after the product was consumed (such as microbiological contamination) and some have characteristics of a credence good which might not be known until later (such as presence of heavy metals). In these situations, individuals cannot adequately assess product safety, even after experiencing the good, and are facing uncertainty and having to trust the information provided. In addition, producers (or sellers) of the good know more about the product attributes (such as safety, healthiness, origin, nutritional value) than buyers do, leading to situation of an information asymmetry. Once the information is revealed and regulations imposed, food safety has the characteristics of a public good and other consumers cannot be excluded from its *consumption*. As such, governments are often heavily involved in ensuring food safety and only safe and wholesome foods may be marketed.

Caswell and Joseph argue that in most countries, a major force for demand for food quality, particularly food safety, is the government.

Bibliographical reference

Caswell J. and S. Joseph (2006). "Consumers' Food Safety, Environmental, and Animal Welfare Concerns: Major Determinant for Agricultural and Food Trade in the Future?". Paper prepared for the IATRC Summer Symposium "Food Regulation and Trade: Institutional Framework, Concepts of Analysis and Empirical Evidence". Bonn, Germany.

This is true of higher income countries where already high standards continue to be ratcheted up and for lower income countries where standards are beginning to be established and enforced. Governments are interested for at least two reasons interest in improving public health, and assurance for consumers that they are being protected from substandard products.

The government protection argument is particularly valid in case of food safety.

From the agriculture and food producer perspective, food quality and food safety are quite distinct.

- Food quality serves as a possible means for product differentiation which is frequently signalled through branding or labelling programmes.

- Food safety is a non-negotiable attribute, an absolute prerequisite for market access, and as such not a voluntary choice for those involved in the agro-food chain. However, a decision to exceed minimal food safety requirements could be a tool for differentiation.

Different hazards require different sampling and testing methods, and establishing of different safety limits.

Micro-organisms, for example, might not be evenly distributed.

Thus, although ex-post methods of product recalls are still used, food safety increasingly relies on prevention, such application of **Good Hygiene Practices** (**GHP**) and **Good Manufacturing Practices** (**GMP**) and the **Hazard Analysis Critical Control Point** (**HACCP**) principles in combination with microbiological risk assessment as defined by the Codex Alimentarius which will be covered later in the chapter.

In the area of food safety, new technology developments are also considered, such as genetic engineering, irradiation of food, or modified atmosphere packaging.

2. Factors influencing food safety regulations

Factors influencing increased interest in food regulation and food policies also influence food safety regulations. Although governments across countries share the goal of ensuring safe food to its citizens and avoiding public health scares, their domestic environment differs. Consumers can value different attributes differently, have different degrees of risk averseness or choose a different regulatory framework. Domestic regulations of any sort can be also used to protect domestic producers from competition but they are also introduced at a request of consumer demands based on their preferences.

2.1. Differing conditions and perceptions across countries and consumers

Informed consumers would never knowingly consume unsafe food. However, different consumers –and different countries– are willing to take different risks.

Let us start by examining countries. Countries in different economic and climatic conditions find themselves in different risks of foodborne disease:

- Food safety pathogens might find more suitable conditions for their development in warmer climates.

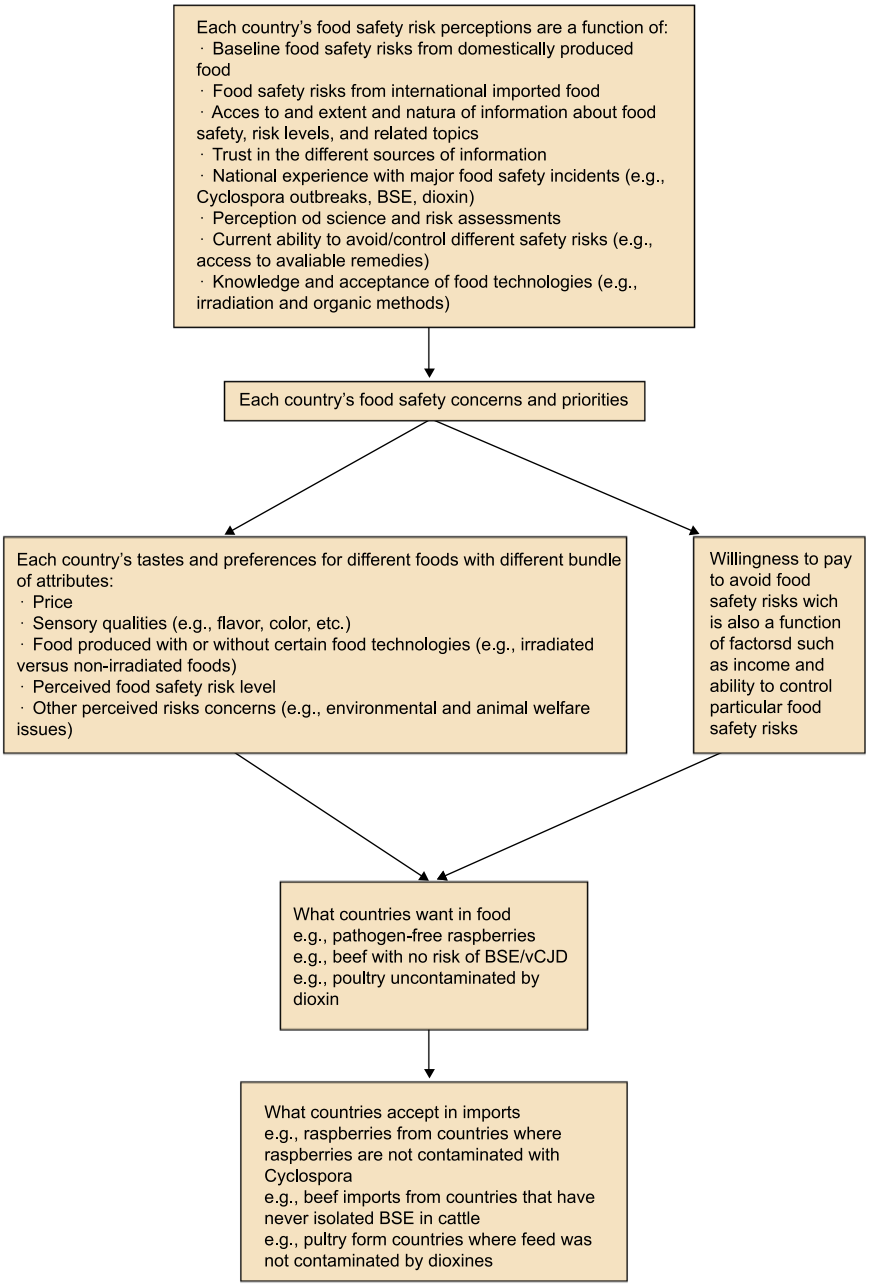
- Different food production practices, captured by access and use of pesticides and veterinary drugs, impact the levels of residuals.

- Sizes of herds and animal husbandry practices influence transmission of animal diseases.

- Developing countries with inadequate supplies of safe water, poor waste disposal or a lack of refrigeration partially due to shortages in electric supply are particularly susceptible.

- Cultural differences exposing themselves to the consumption of meats prepared rare, raw meat, cheeses made of unpasteurized milk, consumption of raw seafood or raw eggs play a role.

For example, some consumers in France prefer cheese made from unpasteurized milk and are willing to accept the associated higher health risks from Listeria contamination. Other countries, such as the United States, ban the sale of most unpasteurized cheese, even though it constrains consumer choice.



Bibliographical reference

Buzby J. C. "International Trade and Food Safety: Economic Theory and Case Studies". *Agricultural Economic Report* (No. AER 828). Economic Research Service, USDA.

Bibliographical reference

http://www.ers.usda.gov/publications/wrs011/wrs011i.pdf

Bibliographical reference

Patterson, 1990

Given the factors described above, each country attends to its own unique set of health concerns and priorities and different perceptions of food safety.

There are many examples: for example, the United States has a zero tolerance policy for Listeria monocytogenes in foods that are not intended for further heat treatment (i.e., ready-to-eat foods such as luncheon meats). While, from the point of public health protection, it has a right to do so, many countries have questioned this policy claiming it acts as a barrier to trade to keep safe products from the US market. Similarly, Denmark's tolerance for Salmonella contamination in pork prevents it from trading with countries whose pork poses higher levels of risk from Salmonella.

Although the objectives of food safety are the same in the EU and US, there are differences in the EU and the US in the objective of implementation of food safety systems (such as HACCP). For example, the traceability, transparency, and assurance system (TTA) in the EU has been implemented because it is a requirement to gain access to markets whereas in the US it has focused more on consumers' willingness to pay –meaning the systems are more often mandatory in the EU than in the US.

Bibliographical reference

Caswell J.; S. Joseph (2006). "Consumers' Food Safety, Environmental, and Animal Welfare Concerns: Major Determinant for Agricultural and Food Trade in the Future?" Paper prepared for the IATRC Summer Symposium "Food Regulation and Trade: Institutional Framework, Concepts of Analysis and Empirical Evidence". Bonn, Germany.

Consumer acceptance of innovative technologies, as such food radiation, genetic modification and alike, differs across and within countries. The acceptance is particularly challenged when consumers are not fully aware of risk association with new technologies or when risks are not yet known, including the long-term impact of biotech foods on the environment.

While so far for the sake of simplicity we discussed only differences across countries, consumers differ within countries as well. For example, only about half of US adults are willing to buy irradiated meat and poultry, according to 1998-99 FoodNet survey data.

Bibliographical reference

Frenzen et al., 2000

Preferences for food related regulations depend on the consumer preferences for safe food which, in turn, depend on their perception of risk and risk assessment.

Government's and consumers' levels of risk taking might not be the same. In their decision making individual consumers might not take into account the total cost of foodborne illness which the government does. Different perceptions of food safety are tied to different levels of risk. Risk-averse consumers require high levels of food safety assurance, especially following an outbreak of a foodborne disease.

Consumers are willing to pay for food safety and request more stringent regulations on both domestic and imported products. Following an outbreak, studies have shown consumers are willing to pay more for products that were certified and tested. That is, they are willing to pay for information about the product. Following the BSE infection in United States and Canada in 2003, Schroeder examined whether consumers altered their beef consumption behaviour because of their risk aversion and risk perceptions stemming from information about beef food safety in recent years. Results reveal differences in risk perceptions and risk aversion regarding beef food safety across consumers in the four countries. Relative to consumers in the United States, Canada, and Mexico, consumers in Japan are more risk averse with respect to beef food

safety. Relative to US and Canadian consumers, Japanese and Mexican consumers perceive beef to be less safe and consider eating beef to involve greater food safety risk.

Bibliographical reference

Schroeder, Ted C.; Tonsor, Glynn T.; Pennings, Joost M. E.; Mintert, James (2007). "Consumer Food Safety Risk Perceptions and Attitudes: Impacts on Beef Consumption across Countries". *The B.E. Journal of Economic Analysis & Policy* (Vol. 7, no. 1, contributions, article 65).

Consumers in the US and Canada are found to be more willing to pay for information on animal treatment and food safety assurance than on traceability alone. Consumers who are more concerned are willing to pay more.

2.2. Science based regulations

But what does *science-based* mean? Attorney–general report on meat inspection in Canada provides a fine description:

> "The term *science-based* is used to describe a number of *science* features.... food hazards arise from biological, chemical and physical hazards. Many of these hazards cannot be seen by the naked eye. Therefore, understanding the *science of biology*, the conditions that promote the growth of microorganisms, and the spread of animal disease helps us to predict where problems may arise and what measures can be taken to prevent them or reduce their impact. Understanding the *science of chemistry*, particularly how chemicals such as drugs and feed are processed and metabolized in an animal's body, helps us to predict the point in time at which there should be no unsafe residues. Even with respect to physical hazards, science has a role in their avoidance, detection and elimination from our food.
>
> There are a number of benefits to a science-based approach. Science is not just about what we know about a problem; it is also a way of approaching problems. It involves making observations and making and testing predictions. It tries to make a causal link. A science-based regulatory system contains rules that have been chosen because there is evidence that by following them, safer food will result. Because science-based approaches can be measured, they can be used to develop universally accepted food safety standards".
>
> http://www.attorneygeneral.jus.gov.on.ca/english/about/pubs/meatinspectionreport/chapter_3.pdf

The role of science is two-fold:

- It helps to identify risks covering the spectrum from commodity production and processing to final consumption.
- It provides options to mitigate them.

International accords encourage the use of science based standards and regulations. However, although scientific results are often shared among countries, the policy decisions based on them are not. Policy decisions take into account:

- social values,
- consumer preferences and perceptions,
- economic and political considerations, and alike.

In the EU science based regulations are endorsed in its Amsterdam Treaty by "taking into account in particular of any new development based on scientific facts". The Amsterdam Treaty reinforced existing objectives "to contribute to a high level of human health protection" into "a high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities".

Bibliographical reference

Amsterdam Treaty

2.3. Precautionary principle

A misleading interpretation of precautionary principle puts it opposite scientific evidence. A more fitting description of precautionary principle would be that it complements science.

> "Where scientific information is insufficient, inconclusive, or uncertain and where there are indications that the possible effects of the environment, or human, animal or plant health may be potentially dangerous and inconsistent with the chosen level of protection," action may be taken in order to prevent such negative effects".
>
> ???

In the EU precautionary principle is widely used. The EU General Food Law or Regulation (EC)178/2002 is based on the precautionary principle where "a risk to life or health exists but scientific uncertainty persists".

A Communication from the **Commission on the Precautionary Principle** from February 2000 outlined the Commission's approach on using the precautionary principle and established the Commission's guidelines for applying it to avoid unwarranted recourse to the precautionary principle as a disguised form of protectionism. Precautionary principle shares similarities with a *foresight* principle. Among its basic concepts are preventive anticipation, safeguarding ecological spaces, proportionality of response, duty of care, etc.

Nevertheless, application of precautionary principle often balances domestic socio-economic and political considerations.

2.4. Example of GMOs: science and precaution

Although scientific evidence and precautionary principle are not mutually excludable, the discussion on genetically modified products often puts the discussion in such a light. Three principal positions are backed by different countries:

- The first position is that free trade allows in the presence of science-based evidence that genetically modified products do not result in any damage to humans and the environment is backed up by USA, Canada, and Brazil, major exporting countries.

- The second position is that some NGOs discard science-based criteria as biased.

- The third position is that of the EU taking a middle ground balancing science-based criteria with (domestic) socio-economic and political considerations. However, bringing socio-economic and political considerations into question raises questions of protectionist motives.

However, proving the complete safety of GMOs or other products or production methods is impossible, raising a question of the willingness to take risks and at what level. A potential answer is the introduction of labelling schemes that inform consumers. However, labelling might be expensive on its own as it requires traceability to be put in place, might be trade restricting, and finally might lead to information overload for consumers.

2.5. System based risk analysis in food safety regulations

Comprehensive risk analysis is relatively new to the area of food safety. Traditional regulatory systems for food safety were based on:

- Legal definitions of unsafe food.
- Enforcement programmes for the removal of unsafe food from the market.
- Sanctions for the responsible parties after the fact.

During the past decade there was a transition to risk analysis based on better scientific knowledge of foodborne illness providing a preventive basis for regulatory measures.

Risk analysis is an integrated process that includes:

- **Risk assessment.** A risk assessment may be defined as the use of scientific data to identify, characterize and measure hazards, assess exposure, and characterize the risk involved with a particular food product.
  Risk assessment should take into account susceptible populations, such as children, pregnant women and the elderly to ensure that products are in principle safe for everyone. It should also address concern about cumulative, low level exposure to multiple chemicals. Testing procedures and other methods of assessment for adequate evaluation of these potential risks are being developed and validated. However, estimates of the exposure of specific subpopulations are often hampered by inadequate data on dietary intake and on levels of contamination of food. This lack of information is particularly pressing in developing countries, where little reliable information is available on the exposure of their populations to chemicals in food.

- **Risk management.** It is defined in the Codex as the process of weighing policy alternatives in light of the results of risk assessment and, as required,

Bibliographical reference

http://www.attorneygeneral.jus.gov.on.ca/english/about/pubs/meatinspectionreport/chapter_3.pdf

selecting and implementing appropriate control options including regulatory measures.

- **Risk communication.** It is the part of risk analysis that involves the exchange of information and opinions, concerns, risk and risk-related factors with stakeholders designed to lead to a better decision-making process. Without proper risk communication, the most carefully drafted policies are likely to fail.

Powers of risk assessment lie with public authorities. There is an agreement among countries on how to conduct risk assessment in theory. With respect to foodborne illness, risk is a measure of the probability that a certain adverse health effect will occur as a result of a food hazard and the severity of that effect.

- What is an acceptable level of food safety?

The answer is usually based on risk assessment and adjusted to realities in a society taking into account political, economical, cultural, ethical and other considerations. For some substances and circumstances the appropriate tolerance limit is zero. In other situations, zero tolerance limits would be unrealistic, unachievable and unaffordable. In some cases risks are justified and consumers are willing to take them. No food or produce can be made completely risk free.

Application of zero risk tolerance is especially pressing when the long-term effects are not known. Let us consider an example of carcinogens. Studies on animals can show that a substance is carcinogenous. The so-called Delaney Clause in 1958 amended the US **Food, Drugs, and Cosmetic Act of 1938** prohibiting the use in food "any chemical additive found to induce cancer in man, or after tests, found to induce cancer in animals". The amendment was an example of zero tolerance –zero risk. In 1959, Aminotriazole (pesticide) residues were detected in cranberry products leading to a recall of cranberry products just before the Thanksgiving holidays. Aminotriazole had been tested on rats and had caused thyroid cancer. Analytical detection of chemicals improved significantly while the scientific evidence and data on the interpretation are missing. The **Food Quality Protection Act of 1996** abolished the Delaney Clause for pesticides where there is a negligible risk (1 in a million) for carcinogens and there is no residue in edible portion. Higher safety factors apply for children.

Consumers might not be very open to food treated by technologies when there is lack of information regarding the risks attached to them.

2.6. Food safety as a public health problem: cost of foodborne illness

According to one USDA **Economic Research Service** (**ERS**) report, foodborne illnesses account for about 1 of every 100 US hospitalizations and 1 of every 500 US deaths. Food safety in many countries is considered to be a public health problem in a sense that workers lose working time, suffer personal discomfort, and are (often) cured at the public expense. Foodborne illness affects millions of people a year, resulting in several billions in costs and thousands of death.

According to the CDC, foodborne disease is caused by consuming contaminated foods or beverages. Contamination can be caused by pathogens, poisonous chemicals, or other harmful substances.

Bibliographical reference

http://www.cdc.gov/ncidod/dbmd/diseaseinfo/foodborneinfections_g.htm

More than 250 different foodborne diseases have been described, most of which are infections caused by a variety of bacteria, viruses, and parasites that can be foodborne. Other diseases are poisonings, caused by harmful toxins or chemicals that have contaminated the food, for example, poisonous mushrooms. Chemicals are a significant source of foodborne illness, although the effects are often difficult to link with a particular food.

Many microbes can spread in more than one way, so we cannot always know that a disease is foodborne.

> For example, *Escherichia coli O157:H7* infections, first identified in 1979, can spread through contaminated food (such as ground beef, unpasteurized apple cider, milk, lettuce, alfalfa and other sprouts), contaminated drinking water, contaminated swimming water, and from toddler to toddler at a day care centre.

Depending on which means of spread caused a case, the measures to stop other cases from occurring are different. In addition, many chemical substances occur in the environment in more than one form or way and, thus, are difficult to tie to a particular food.

Some harmful substances, such as bacteria, result in an immediate illness or an illness in a short run which might or might not carry a danger of complications and long term health effects. The other group includes illnesses and conditions resulting from a long term exposure to substances where the health consequences might not be known. Public awareness of chemicals in food is relatively high, and consumers continue to express concern about the risks to health due to the deliberate addition of chemicals to food. Increasing concern is also being expressed about the introduction of contaminants into the food chain from industrial pollution of the environment. Further challenges are presented by bacteria developing resistance to antibiotics, as was the case of

Bibliographical reference

WHO (2002). "WHO global strategy for food safety: safer food for better health".

Salmonella typhimurium DT104 developing resistance to five commonly prescribed antibiotics and is a major concern in many countries because of its rapid spread during the 1990s.

Some layers of population are more susceptible to foodborne illnesses than others. Foodborne diseases most seriously affect children, pregnant women, the elderly and those already weakened by other diseases. According to the **Center for Foodborne Illness** the most frequent pathogens in the United States are:

- *Camplyobacter*. It causes approximately 2.5 million illnesses and 1,000 deaths each year. Almost 20% of all reported cases occur in children under the age of 10 and the incidence in children under the age of one is twice that of the general population.

- *E. coli O157:H7* and other shiga-toxin producing pathogens cause an estimated 73,000 illnesses and 61 deaths each year. Nearly half of all reported cases occur in children under the age of 15. Approximately 2% to 7% of all illnesses will result in Hemolytic Uremic Syndrome which is the leading cause of acute kidney failure in children in the United States.

- *Listeria monocytogenes*, a bacterium found in ready-to-eat products, causes an estimated 2,500 illnesses and 500 deaths each year. Pregnant women are 20 times more likely to develop listeriosis than healthy people and about 1/3 of reported cases occur in pregnant women. Furthermore, listeriosis kills more than 1/3 of perinatal victims.

- *Salmonella* causes approximately 1.5 million illness and 600 deaths each year. More than one third of all cases occur in children under the age of 10 and the incidence for children under the age of 1 is 10 times higher than that of the general population.

Not surprisingly, the most comprehensive data on occurrence of foodborne illness are recorded in developed countries. The ERS estimates that, each year in the United States, just five foodborne illnesses –*Camploybacter*, *Salmonella*, *E. coli O157:H7*, *Listeria monocytogenes* and *Toxoplasma gondii*- cause $6.9 billion in medical costs, lost productivity and premature deaths. The **Food and Drug Administration** (**FDA**) estimates 2 to 3 percent of foodborne illness victims develop secondary long-term medical complications resulting in over 1.5 million lingering health problems per year.

The cost estimate includes:

- **Medical costs.** Medical costs cover medications, office visits, emergency room visits, hospitalization, and outpatient clinic visit costs.

- **Productivity costs.** Loss of productivity is based on average daily productivity of the US workers and average wage depending on age.

- **Disutility costs**, such as the cost of pain and suffering, inconvenience, lost leisure time, etc. Disutility costs are usually estimated using the Quality Adjusted Life Years.

- **Premature death costs.** The most controversial calculation is usually the cost of human life based on labour market studies.

Based on the CDC estimates of a number of cases, the ERS maintains a foodborne illness cost calculator.

Bibliographical reference

http://www.ers.usda.gov/Data/FoodborneIllness

Cases of foodborne illness are classified into categories based on severity, from those who were not hospitalized, did not visit a physician or survived to those who had complications and died. While data on hospitalized patients are available, the number of cases of those who did not visit a physician is based on estimates and is likely to be underreported.

The economic costs also do not reflect the hidden cost incurred by the sick and their families: the cost of travelling to receive medical care and time lost from work caring for sick family members.

Other studies estimating the costs of a foodborne illness exist as well. However, by using different methodologies and assumptions, the results are not directly comparable.

2.7. Costs and benefits of food safety regulations

The goal of mandatory food safety regulation is to mandate firms to produce safer products for consumers. Cost-benefit analysis is the principal analytical tool of **Regulatory Impact Assessment** (**RIA**) in public decision making. Impact assessment is required by many countries before a regulation is passed to demonstrate its effectiveness in achieving desired objectives, such as to ensure the supply of safe food.

The conventional form of cost benefit analysis computes the present discounted value of benefits and costs associated with the regulatory intervention. In the case of food safety, benefits are derived from the reduction in foodborne illness and death associated with the regulation, the costs are based on the changes in the cost of production in the industry as well as the costs associated with regulatory oversight (and usually paid by taxpayers).

Antle lists the benefits of food safety regulations as:

- reductions in risks of morbidity, and

- mortality associated with consuming foods that could be contaminated with microbial pathogens and other hazards.

Bibliographical reference

Antle, John (1998). "Benefits and Costs of Food Safety Regulation". *Research Discussion Paper* (18, also in Food Policy, december 1998).

To attach figures to concepts, economic approaches to model and value reductions in health risk are used. Models are also used to derive **willingness to pay** (**WTP**) for reduced morbidity and mortality. WTP for reduced morbidity risk can be decomposed into four basic components:

- the cost of treating the illness,
- forgone income from lost work time,
- cost of averting illness, and
- the disutility of illness.

We discussed the cost of a foodborne illness. It should be mentioned that medical costs are not always borne by individuals and should be added to the societal cost. Risk of death is usually measured by using the value of a statistical life. Methods used include discounting forgone income and using wage differences between occupations with different skills. Different methods produce a wide range of values of a statistical life, from less than 1 million to tens of millions dollars.

Various economic models to estimate the cost of compliance exist and take into account the structure of production. Some costs, such as purchasing new equipment, are one time fixed costs. Others, such as the cleaning of equipment, the removal costs of a contaminated product, record keeping, or testing enter as variable costs. Plant level regulatory costs can be estimated using an accounting approach, an economic-engineering approach based on a quantitative model of the production process or an econometric approach which econometrically estimates cost functions.

Antle shows an example of the benefit cost analysis of a HACCP and pathogen reduction in the United States over a 20 year time period.

Bibliographical reference

Antle, John (1998). "Benefits and Costs of Food Safety Regulation". *Research Discussion Paper* (No. 18, also in Food Policy, december 1998).

The benefits of implementing a HACCP would range from 0.99 billion USD to 3.69 billion USD annually (in 1995 dollars) if the regulations were completely effective in eliminating the risk of illness and death from four major pathogens. Discounted over a 20 year time horizon at 7%, these benefits would range from 7.13 to 26.59 billion. The costs of sanitation procedures, pathogen sampling, and a HACCP plan development and operation were estimated to be in the order of 100USD million annually, and in the range of 1 – 1.2 billion over a 20 year period. By assuming that benefits of the regulations would be proportional to their effectiveness in reducing pathogens, while assuming costs of implementation would be independent of effectiveness, the FSIS analysis concluded that the net benefits of the regulations were likely to be positive for all levels of regulatory effectiveness in excess of about 16 percent.

Since RIA is usually concerned about domestic constituents only, it does not consider trade effects of regulations. If trade effects and complete cost-benefit analysis were considered, we could also include:

- value of health benefits abroad incurred by foreign consumers if the good is traded,
- benefits for producers if the new regulation allows them to access new export markets,
- costs of targeting products to different markets if new domestic regulation is different from international regulation,
- administrative cost of regulation, etc.

3. Regulatory trends in food safety in developed and developing countries

Regulatory programmes intend to protect and improve public health by controlling the safety of products on the domestic market regardless of whether they come from domestic supply or are imported. Countries regulate food safety through the use of the process.

3.1. The case of developed countries

Roberts and Unnevehr recognize the following trends in food safety regulations in industrial countries in the 1990s:

Bibliographical references

Roberts and Unnevehr (2004)
http://www.ers.usda.gov/publications/AIB789/AIB789-3/aib789-3.pdf

- The growing use of risk analysis.
- Having public health as the primary goal of food safety regulation.
- Recognizing that a farm-to-table approach is often desirable for addressing food safety hazards.
- Adopting the Hazard Analysis and Critical Control Point (HACCP) system as a basis for new regulation often of microbial pathogens in food.
- Increasing the stringency of standards for many food safety hazards.
- Adding new and more extensive regulation to handle newly identified hazards.
- Improving market performance in food safety through the provision of food safety information such as the use of voluntary guidelines or standards, the provision of third-party certification, the provision of information through labelling, establishing the legal liability for food safety, and establishing voluntary or mandatory systems for traceability.

One of the factors responsible to increasing the occurrence of food safety regulations is the preference for fresh foods in developed countries. Fresh foods harbour bacteria lead to microbiological foodborne illnesses. The demand for higher levels of food safety has lead to the implementation of regulatory programmes that:

- Address more types of safety related attributes (such as BSE, microbial pathogens, environmental contaminants, animal drugs and pesticide residues).

- Impose stricter standards for those attributes complemented by liability laws.

- Prescribe how food safety is to be assured and communicated.

Bibliographical reference

www.mtnforum.org/rs/ol/counter_docdown.cfm

Major regulatory trends in developed countries include:

- Stronger public health and consumer welfare emphasis in decisions by regulatory agencies with focus on the supply chain.
- Adoption of more stringent safety standards with a boarder scope of the standard.
- Adoption of the HACCP approach and hybrid regulatory systems (e.g., HACCP with performance standards).
- Increased reliance on certification, including traceability.
- Greater transparency for national regulations.
- Export of some regulatory responsibility and burden.

We have already described the costs of foodborne illness and how vulnerable populations are more susceptible. Policies in developed countries should account for changing demographic profiles and an increasing share of vulnerable populations susceptible to foodborne illness as the population is aging in many developed countries.

New problems are emerging. More and more countries are designing and implementing policies directed at obesity, a health problem which complications with likely more far reaching consequences than foodborne illness.

In an effort to streamline administration, governments might opt for a third party certification.

3.2. The case of developing countries

The problem of a foodborne illness is likely to be even more widespread in developing countries as the poor are the most susceptible to ill-health. While in many developed countries with national health insurance cost of healthcare falls on the state, health costs in many developing countries are born by individuals. Inability to work and related loss of income extends the poverty cycle.

Developing countries are developing regulations and participate in the workings of international bodies. The WHO recognises that many developing countries lack the technical expertise and financial resources to implement food policies. Capacity building would not only protect health, improve domestic markets but also contribute to trade. However, there is a danger that a two-tier market develops:

- One tier produces goods for exports.

- The other produces lower tier goods for the domestic market.

Food safety regulations in developing countries serve two purposes:

- **Food safety as an instrument of public health**. In the area of public health, investment in food safety often competes with other serious public health issues, such as AIDS or malaria, and often also with infrastructure investment, such as water and sewage systems.

- **Food safety as a tool for economic development**. In this case, food safety expenditures would be judged in terms of the benefits they generate (in terms of keeping markets open or generating new markets) per unit of cost, in relation to other economic projects receiving public support (export promotion, industrial development, certain types of infrastructure, etc.).

Bibliographical references

Hanak, E.; Boutrif, E.; Fabre, P.; Pineiro, M. (2000). "Food Safety Management in Developing Countries". *Proceedings of the International Workshop* (CIRAD-FAO, 11 – 13 december, 2000). Montpelier, France.

http://wwww.cirad.fr/colloque/fao/pdf/intro.pdf

http://wwww.cirad.fr/colloque/fao/an/papers.html

Nevertheless, the need for capacity development persists.

As developing countries grow richer and develop a taste for meats and dairy, the potential for foodborne illness also increases.

Animal husbandry methods can lead to a faster spread of animal disease.

4. Approaches

Food safety is assured by:

- **Traceability**
- **Good Manufacturing** and **Good Hygienic Practices**
- **HACCP**

4.1. Traceability

Traceability is crucial in tracking product back to its origins and recalling products which have been identified as unsafe. Traceability means the ability to track any food, feed, food producing animal or substance that will be used for consumption, through all the stages of production, processing and distribution. Traceability carries a cost of record keeping for producers and processors. Traceability is mandatory in the EU and is under discussion in the US.

4.2. Good Manufacturing Practices

One way to address food safety is via Good Manufacturing Practices. Good Manufacturing Practices, also part of Codex Alimentarius, are procedures developed to ensure the production of safe foods and provide a safe working environment. Unlike process standards, GMP are not process specific but relate to the entire operation by controlling:

- production,
- storage,
- equipment,
- personnel training, etc.

When the good practices are unable to lead to an acceptable level of safety, the government usually turns to mandatory tools such as minimum safety standards, labelling (including certification) and liability.

4.3. HACCP

Hazard Analysis and Critical Control Point (**HACCP**) is a science based management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from:

- raw material production,
- procurement,
- handling,
- manufacturing,

- distribution, and
- consumption

of the finished product to ensure safe food. GMPs and Good Hygienic practices cannot guarantee safety but they are a prerequisite for a HACCP.

The HACCP was initiated by the US in the early 1960s to produce zero defect food for astronauts by NASA. NASA asked Pillsbury (US manufacture of frozen and refrigerated baked products) to design products without defects and safe to use by astronauts in the space program. Checking final products lacks practicality in open space. An alternative method developed by Pillsbury was to test at critical points.

The HACCP prevents: it detects potential hazards before they occur and implements control measures to reduce or eliminate the likelihood of their occurrence.

Consumers benefit from reduced risk of foodborne disease. Producers might enjoy greater market access in the cases where the HACCP is not a prerequisite to supply the domestic market.

The HACCP is an example of a previously voluntary process-oriented management tool. In 1993 it was endorsed by Codex Alimentarius as an international guideline. The HACCP is mandatory in the EU. The United States mandated the HACCP for seafood in 1997 and for meats in 1996.

Bibliographical reference

Anders, S. M.; J. A. Caswell (2009). "Standards as Barriers versus Standards as Catalysts: Assessing the Impact of HACCP Implementation on US Seafood Imports." *American Journal of Agricultural Economic* (Vol. 2, no. 91, pp. 310-321).

The HACCP was based on seven elements:

- **Accessing potential hazards**. *Hazards* is a more specific term than adulterant because an adulterated product is not necessarily hazardous. Hazards are microbiological, chemical, or physical poisonous or deleterious substances. Hazards can originate from material inputs into production but also from a breakdown in some parts of processing.

- **Identifying critical control points**. C*ritical control point* (**CCP**) is a point at which a hazard might develop. If a quality is affected at a particular point, that point is called a *quality control point* (**QCP**).

- Establishing **control limits** or requirements for each CCP.

- Establishing a **procedure to monitor** each CCP. Continuous monitoring is preferred to random sampling.

- Establishing a **corrective action** for deviations. It could involve several actions:
  - rejecting a batch of inputs,
  - adjusting the process, etc.

  In some cases a corrective action could involve shutting down an operation.
- Establishing **record keeping** procedures.

- **Verifying** the programme.

Other management systems exist, such as ISO-9000 developed by the **International Standardisation Organisation**. ISO-9000 does not prescribe quality standards but mandates that a company defines appropriate quality standards, documents its processes and proves it adheres to both.

5. The producers' role in food safety

The responsibility to fulfil consumer expectations of safe food is shared by:

- **Food producers**
- **Processors**
- **Distributors**
- **Regulatory agencies**

Producers are crucial stakeholders in food safety regulations as they bear full responsibility for their products. Producers are also active lobbyists when regulation is considered.

Compliance with the safety and quality regulation increases producer costs, both fixed and variable. Fixed cost investments are usually sunk: they are unrecoverable once undertaken, and they could become an entry barrier to new entrants to the industry and influence industry structure. An increase of variable costs is usually passed on to consumers via higher prices. Some studies show that strict food safety standards help explain the concentration in the US meatpacking industry.

Bibliographical reference

(Babcock and Clemens, 2005)

Some firms invest to meet the existing standard while others, especially bigger ones exceed it. Compared to small plants, large plants invest more in higher levels of food safety. Results from the national survey of the types and amounts of food safety investments made by meat and poultry slaughter and processing plants since the late 1990s show that market forces have worked in conjunction with regulation to promote the use of more sophisticated food safety technologies. From 1996 through to 2000, US plants as a group spent about $380 million annually and made $570 million in long-term investments to comply with USDA's 1996 Pathogen Reduction/Hazard Analysis Critical Control Point (PR/HACCP) regulation, according to a survey initiated by the Economic Research Service. The US meat and poultry industry as a whole during the same period spent an additional $360 million on food safety investments that were not required by the PR/HACCP rule.

Bibliographical reference

http://www.ers.usda.gov/Publications/TB1911/

This additional investment by large firms could act as a disadvantage to small and medium enterprises with limited financial and personnel resources.

With food safety being a prerequisite to being on the market, the fear of losing the reputation as a safe food provider plays a significant role.

As such, investment in food safety does not yield an immediate pay off. Complying producers, however, are likely to enjoy lower transaction costs and improved reputation. In some countries, such as the US, fears of lawsuits arising from the sale of contaminated products also serve as a weighty incentive.

Summary

Résumé

The threat of the loss of producers' or retailers' reputations caused by high-profile cases of foodborne illness has led to market driven efforts to provide safe food. Major buyers of food products, such as retailers or restaurant chains impose stringent food safety process control standards on their suppliers.