CODEX and the European Union’s food safety policy

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Purpose of lecture

- introduce the Risk Analysis framework
- show its importance for international trade
- make the link with Codex and EU regulations
- introduce some important food safety targets
Role of Governments according to the General Principles of Food Hygiene

- protect consumers adequately from illness or injury caused by food
- provide assurance that food is safe and suitable for normal human consumption
- maintain confidence in internationally traded foods
- provide health education programs which effectively communicate the principles of food hygiene to industry and consumers

Codex Alimentarius
International trade in food regulated by World Trade Organisation (WTO)

- Sanitary and Phytosanitary agreement (SPS)
- Technical Barriers of Trade agreement (TBT)
GATT Sanitary and Phyto-Sanitary (SPS) agreement

SPS measures are measures taken to protect human, animal and plant health.

The agreement should:
- ensure sovereign rights to protect health
- prevent misuse for protectionism purposes
- prevent unnecessary trade barriers

World Trade Organization (WTO) is the governing body.
A sanitary measure is defined as any measure applied to protect human or animal life or health, within the territory of a member, from risks arising from additives, contaminants, toxins or disease causing organisms in food, beverages or foodstuffs

WTO/SPS agreement
Important notions

- Imported food should not endanger a population’s health
- Appropriate Level of Protection (ALOP) is an expression related to a population’s health
- Microbiological Risk Assessment (MRA) is a method to determine whether a pathogen/food combination endangers the health
- International Standards should define the safety of a product.
International Standards

- Basis for national measures
- Presumption of correctness
- Right to deviate based on scientific justification or non-correspondence with the appropriate level of protection (ALOP)
- Codex Alimentarius is the reference

These notions are the basis of the latest EU regulations
The main purposes of this FAO/WHO Programme are

- protecting health of the consumers
- ensuring fair trade practices in the food trade
- promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations
Codex Alimentarius, important documents dealing with microbiology

General Principles of Food Hygiene

HACCP

Establishment of Microbiological Criteria

Principles of Microbiological Risk Assessment

Principles of Microbiological Risk Management

Validation of Food Hygiene Control Measures

Codes dealing with import and export regulation
This expression is used in relation with governmental activities to provide consumers with safe foods that meet national and/or international regulations.

Such activities may be:
- food safety policy establishment
- regulatory activities
- inspection / assessment functions
- advice to industry
- consumer education and information
This is the process adopted and described by the Codex Alimentarius Commission to deal with the organisation of several aspects of Food Control Systems.
Risk Analysis is a management tool for governmental bodies to define an appropriate level of public health protection and establish systems and control measures to ensure the supply of safe foods

(Adapted from Codex 1997)
Safety and Risk

- Safety means “no harm”
- 100% safety does not exist
- There is always a (often very remote) chance that a certain harm is caused by a specific pathogen/food combination
- Risk Assessment estimates this chance
- Risk Analysis provides a framework for managing the risk
Risk reduction

By reducing the probability and severity of harm, the safety of a food is increased. This is the basic principle of Risk Analysis.
Codex Risk Analysis framework

Risk Assessment
- Hazard Identification
- Hazard Characterization
- Exposure Assessment
- Risk Characterization

Risk Management
- Preliminary activities
- Option Evaluation
- Option Implementation
- Monitoring & Review

Risk Communication
Interactive exchange of information and opinions concerning risks, risk management options and control measures

Science based
Policy based
Microbiological Risk Assessment (MRA)

A scientific process which consists of determining the likelihood and severity of an adverse health effect in a population exposed to a certain pathogen / food combination

A task of EU’s EFSA
Purposes of MRA

- estimate the risk of illness from the consumption of a certain pathogen/food combination

- estimate the risk-reduction that may be obtained by certain control measures

- support decision making by risk managers by providing relevant data
EU “food law” regulation No. 178 / 2002

debuts with:

- general principles and requirements of food law
- the European Food Safety Authority
- procedures in matters of food safety
  - risk analysis
  - precautionary principle
  - traceability
  - responsibilities for producers and authorities
Tasks of Risk Management

- Setting Public Health goals and targets such as acceptable level of risk (ALOP) and/or safety (Food Safety Objective, FSO*)

- Deciding on "control" activities such as setting Performance Objectives (POs) execution of education programmes

- Implementing, monitoring and review

* currently under discussion in the EU
“Zero" incidence of foodborne illness is an ideal public health goal.

Realistically, it is not possible to achieve this.

Therefore, there is a need to set targets for food safety considered to be appropriate / acceptable / tolerable.

This can be an FSO, a PO or in EU terminology just a “target”.

Targets for food safety
An expression of the achieved, or to be achieved, health status of a country’s population regarding a pathogen or pathogen / food combination.
The level of risk (ALOP) needs to be converted into a level of safety. Safety is related to the level of a hazard in a food.

This level of a hazard is referred to as a Food Safety Objective (FSO) in the Microbiological Risk Management document of Codex.
Risk Characterization curve

No of illnesses/
100,000 in the USA

(based on current market conditions
and eating habits in the USA)

Based on FAO/WHO report
Examples of a public health goal and a target

- The yearly incidence of food-borne listeriosis should not exceed 2.5 cases per 1,000,000 of population (USA objective for the year 2005)

- Absence of Salmonella in poultry by the year 2010 (EU regulation 2160 / 2003)
Food Safety Objectives

- Provide a link between public health goals and Performance Objectives, performance/process criteria, microbiological criteria etc.
- Provide a basis for discussing food control measures with stakeholders
- Articulate a clear goal in terms pertinent to food control measures
- Provide a more objective means of establishing stringency (and equivalence) of food control systems
Food Safety Assurance

Country level

Risk Management / Food Control
- high level, generic
- policy bases guidance
- specific standards, criteria

Operational level

Food Chain Management / Hazard control
control measures from farm to fork
The maximum frequency and/or concentration of a hazard in a food *at the time of consumption* that provides or contributes to the appropriate level of (health) protection (ALOP)

Example: \(<100 \text{ L.m.} / \text{g at moment of consumption}\)
Performance Objective (PO) definition

The maximum frequency and / or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to an FSO or ALOP, as applicable

Codex Alimentarius
Control measures

Actions and activities that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level

*Codex Alimentarius*
Determination of control measures (HACCP)

Determine *where* measures must be taken (CCPs)

Determine *how and to what extent* they are to be controlled at these CCPs

Establish the critical limits and monitoring procedures
No 2073 / 2005: “Micro criteria”
- End-product criteria for pathogens
- Indicators for “self-control” of industries

No 852 / 2004: “Hygiene” & HACCP *
No 2160 / 2003: “Salmonella” & other zoonotic agents
- Targets as levels to be achieved

* HACCP can be applied with flexibility
The EU regulation allows a certain flexibility in the application of HACCP.

An EU guidance document is based on the Codex text.

The ISO 22000 text on food safety management is clearer and auditable but leaves less room for flexibility.
Process Hygiene Criterion

- A criterion indicating the acceptable functioning of the production process
- Such a criterion is not applicable to products placed on the market
- It sets an indicative contamination value above which corrective actions are required in order to maintain the hygiene of the process in compliance with the food law

EU regulation 2072 / 2005
EU Criteria

- Not many criteria prescribed
- Frequency of sampling and analysis not prescribed in most cases
- Actions in case of deviation:
  - Food safety criterion: lot not on market
  - Process hygiene criterion: improve hygiene, in a few cases: check food safety criterion
Product / Pathogen / Pathway control

- Initial number of pathogens ($H_0$)
- Time / temperature

- Growth
- Reduction
- Recontamination

- GAP
- GHP

Hazard level in product

Hazzards in environment? Which levels?
Codex policy

- Less emphasis on end-product testing
- Outcome orientated, less process prescriptions (PO rather than T/t)
- Investigation and surveillance of line-environment emphasised (Listeria, E. sakazakii)
Target oriented food safety management

Country level
Guidance levels of hazard not to be surpassed

Primary production
manufacturing
transport
retail
preparation
cooking
consumption

Performance Objective
Performance Objective
Performance Objective

Performance criterion
Performance criterion
Performance criterion
Performance criterion

Process parameters
Process parameters

Control Measures
Control Measures

Operational food chain level
Operational actions, changes, outcomes

Public health burden

Food Safety Objective
exposure
To Keep It Simple and Straight

Know what to do

and

Do it!