AgEcon SEARCH
RESEARCH IN AGRICULTURAL & APPLIED ECONOMICS

The World's Largest Open Access Agricultural & Applied Economics Digital Library

This document is discoverable and free to researchers across the globe due to the work of AgEcon Search.

Help ensure our sustainability.

Give to AgEcon Search

AgEcon Search
http://ageconsearch.umn.edu
aesearch@umn.edu

*Papers downloaded from **AgEcon Search** may be used for non-commercial purposes and personal study only. No other use, including posting to another Internet site, is permitted without permission from the copyright owner (not AgEcon Search), or as allowed under the provisions of Fair Use, U.S. Copyright Act, Title 17 U.S.C.*

Agricultural Outlook Forum

Emerging Food Safety Issues in U.S. & Foreign Markets

Emerging Strategies for Managing Food Safety

Frank F. Busta

Professor Emeritus, University of Minnesota

20 February 2003

UNIVERSITY OF MINNESOTA

INSTITUTE OF FOOD TECHNOLOGISTS

Risk Analysis Process

- Risk Assessment
- **Risk Management**
- Risk Communication

Risk Assessment

- Hazard Identification & Impact
- Hazard Characterization
- Exposure Assessment

  [qualitative and quantitative]
- Risk Characterization

Risk Management

- Safe handling procedures and practices, food processing quality and safety assurance controls, food quality and safety standards

A risk management framework is needed to:

- **incorporate scientific information into regulatory and company policies**

- **assess the efficacy of measures used to control microbial hazards**

Steps for managing microbial hazards

1. Information indicates a need for improved control
2. Conduct a risk evaluation
3. Assess risk management options (ALOP)
4. Establish a food safety objective (FSO)

5. Confirm that the FSO is achievable through GHP and HACCP

6. Establish performance/process/product criteria

7. Establish acceptance procedures:
   - audits to approve food suppliers
   - product criteria (e.g., pH, a_w, microbiological)

Analytical systematic scientific determinations are preferred.

Emphasis will be placed on
the Food Safety Objective (FSO) approach coupled with HACCP
that offers
a transparent determination in
risk management.

Recently proposed by the International Commission on Microbiological Specifications for Foods and on its way to acceptance by Codex Alimentarius

FSO is a statement of the maximum frequency and/or concentration of a microbial hazard in a food at the time of consumption that provides the appropriate level of protection.

Food Safety Objectives integrate scientific data from risk assessment to designate quantifiable frequencies and concentrations that address specific public health demands.

Processor knows level of hazard considered appropriate in final product and designs process considering initial number of pathogens and any subsequent growth after processing during storage, distribution and preparation.

Food Safety Objectives integrate scientific data from risk assessment to designate quantifiable frequencies and concentrations that address specific public health demands.

FSO defines expected level of control that must be achieved to meet the appropriate level of consumer protection, considering storage, distribution, sale, and preparation.

Steps for managing microbial hazards

1. Information indicates a need for improved control
2. Conduct a risk evaluation
3. Assess risk management options (ALOP)
4. Establish a food safety objective (FSO)
5. Confirm that the FSO is achievable
   through GHP and HACCP
6. Establish performance/process/product criteria
7. Establish acceptance procedures:
   audits to approve food suppliers
   product criteria (e.g., pH, aw, microbiological)

Step 1

Information indicates a need for improved control

FoodNet: 1996-2001

	Cases/100,000/year
Listeriosis	0.3 - 0.6
Yersiniosis	0.4 - 1.0
E. coli O157:H7	1.6 - 2.9
Shigellosis	5.0 - 11.6
Salmonellosis, nontyphoid	12.0 - 15.1
Campylobacteriosis	13.8 - 25.2

Step 2
Conduct risk evaluation

Examples:

Quantitative RA

- **FDA/USDA and WHO/FAO - *Lm* in RTE foods**

Qualitative RA

- **Health Canada - *Salmonella* in cracked eggs**
- **IFT - *C. botulinum* and *Lm* in cold smoked salmon**
- **FSIS expert panel - *E. coli* O157:H7 in fermented meats**

Step 3

Consider risk management options

- Consider the level of risk that would be tolerable for the hazard (ALOP)
- Identify possible options for controlling the hazard
- Select the preferred option(s)

ALOP examples

ALOP = 0.0 cases of botulism/100,000/year from commercially prepared foods, including foodservice

ALOP = 0.25 cases of listeriosis/100,000/year

Food operators cannot effectively respond to an ALOP

Regulatory authorities can not use an ALOP to evaluate a food operation

Step 4

Establish a Food Safety Objective (FSO)

A statement of the maximum

frequency and/or concentration of a microbiological hazard in a food

***at the time of consumption* that provides the appropriate level of protection.**

FSO

- An outcome of risk evaluation and risk management and intended to:
  - limit risk among an exposed population
  - inform industry of the expected level of control for food operations.

- **Serve as a basis for measuring the effectiveness of:**
  - **control systems adopted by industry**
  - **inspection systems adopted by regulatory authorities**
- **Limited to food safety**

FSO example: *Listeria monocytogenes* in Ready-To-Eat Foods

FSO = *L. monocytogenes* shall not exceed 100/g or 3.5 $\log_{10}$ cfu/serving in RTE foods.

Achieving an FSO through a PC

In some cases, the desired level of consumer protection is better achieved through a performance criterion

Performance Criterion (PC)

The expected level of control

at one or more steps

***in the food chain*.**

Performance Criteria

$$H_o - SR + SI \leq FSO$$

FSO = food safety objective

H_o = initial level of the hazard

SI = total increase (growth or recontamination)

SR = total reduction (pathogen inactivation or removal)

FSOs and PC can be used:

- as the basis to validate and/or assess the acceptability of a food operation
- to force change in an industry to improve food safety

Response to FSOs and PC

Industry :

establishes control measures based upon GHP and HACCP

Regulatory authorities :

adjust inspection procedures to verify the FSOs and/or PC are being met

Step 5

Confirm that the FSO is achievable through GMPs and HACCP

Basic Control Measures

Controlling initial levels

- Avoiding high risk foods (e.g., undercooked ground beef)
- Selecting ingredients from approved sources

Controlling increase in a hazard

- Preventing contamination (e.g., GMPs)
- Preventing growth of pathogens (e.g., pH, a_w)

Reducing a hazard

- Destroying pathogens (e.g., pasteurization)

HACCP

The scientific basis for CCPs and critical limits is in:

- **establishing and validating PC, and then**
- **applying appropriate process and/or product criteria**

FSOs and PC can lead to:

- **process criteria,**
- **product criteria and**
- **default criteria**

Step 6

Establish process/product requirements

Process criteria:

Heating at 71.7C for 15 seconds to pasteurize milk

Product criteria:

pH = £ 4.6 for high acid canned foods

Default criteria:

Values stated in regulations or guidelines

Step 7

Establish acceptance procedures

Finished product specifications:

- **chemical**
- **physical**
- **organoleptic**
- **microbiological**

Validation

Collecting evidence to prove that the control measures are effective and the FSO(s) and/or PC will be met.

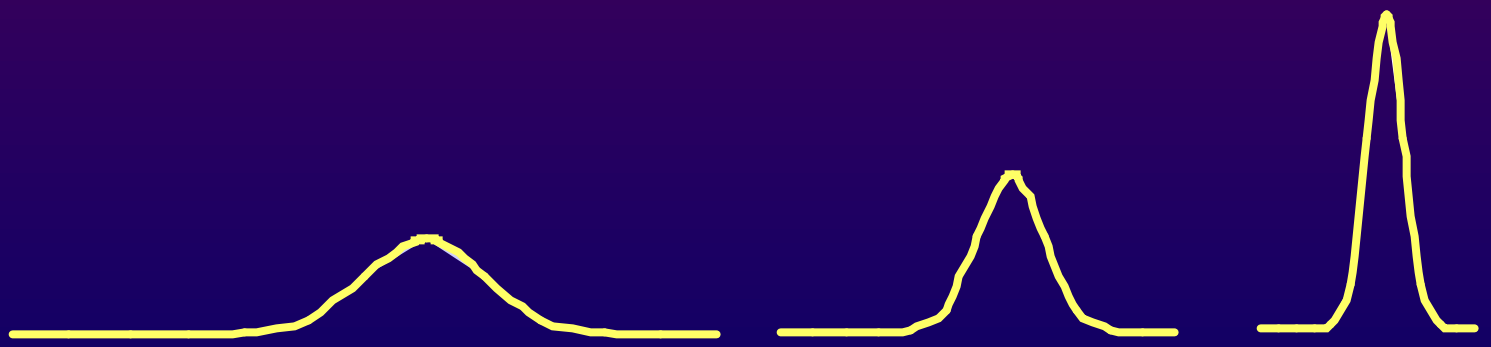
Basis for process validation

- reports from expert panels
- regulations with a scientific basis
- scientific literature
- laboratory research (e.g., challenge studies)
- commercial experience with process and products

Validation

Examples of data collected during production:

- **measurements of time-temperature, pH, a_w**
- **microbiological data:**
  - **initial, in-process, final product**
- **determining process variability and how to minimize**



FSOs and PC are values that must be met; otherwise, they can not be used as a basis for process validation.

FSOs and PC are a line in the sand, not target values.

H_o - SR + SI £ FSO

$H_{o,}$ SR and SI are concentration or frequency distributions, not point values, for the microbial hazard. The distributions are influenced by many factors such as:

- source of the food or ingredients
- pathogen characteristics
- impact of the food on survival/growth
- conditions of processing
- process variability, etc

Confidence in the safety of a food depends on the ability of the food industry to control variability in H_o, SR and SI throughout the food chain.

Variability must be considered during process validation to ensure safety but also to avoid over-processing.

Flowchart of Framework

in

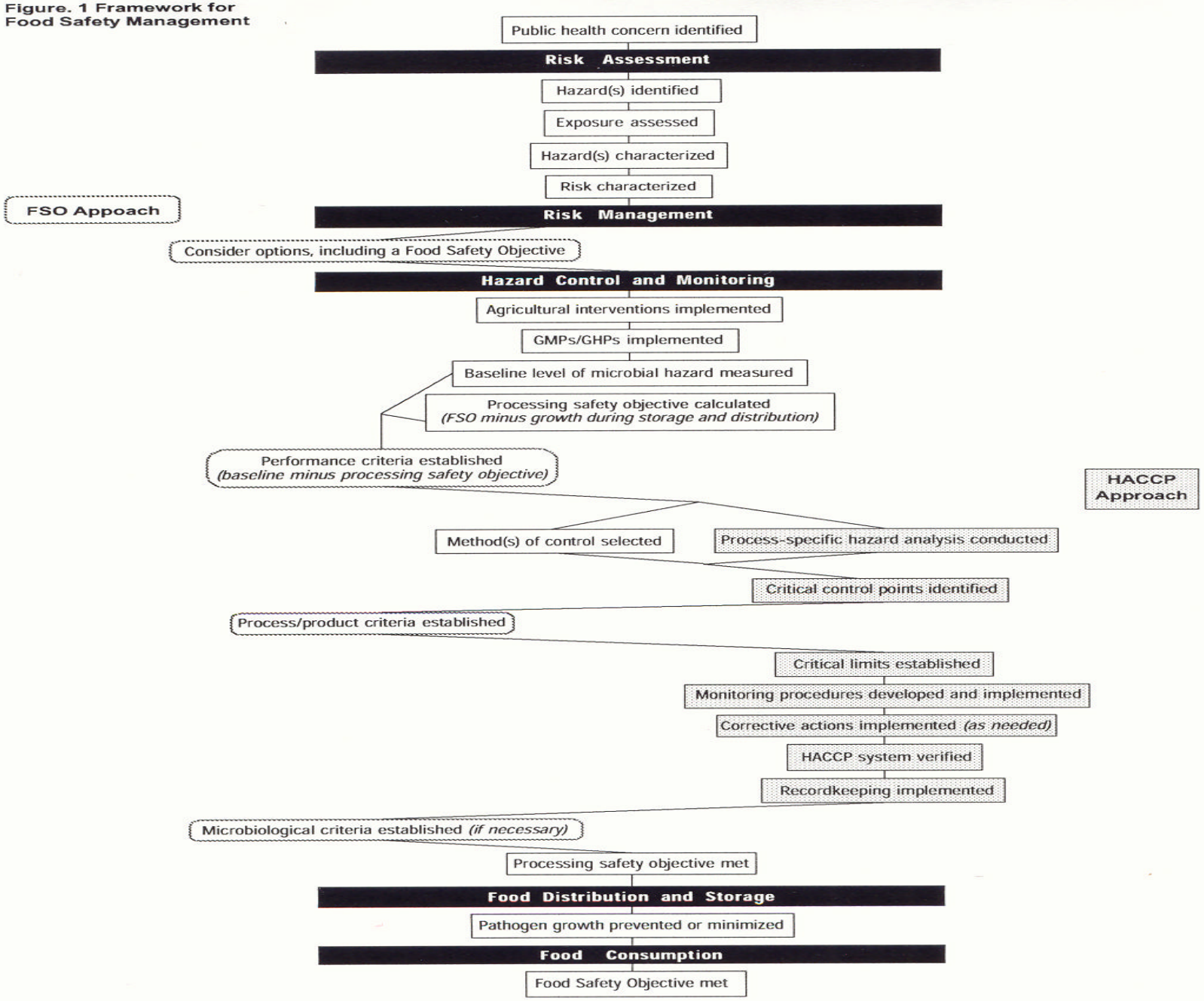
"Emerging Microbiological Food Safety Issues"

published by the

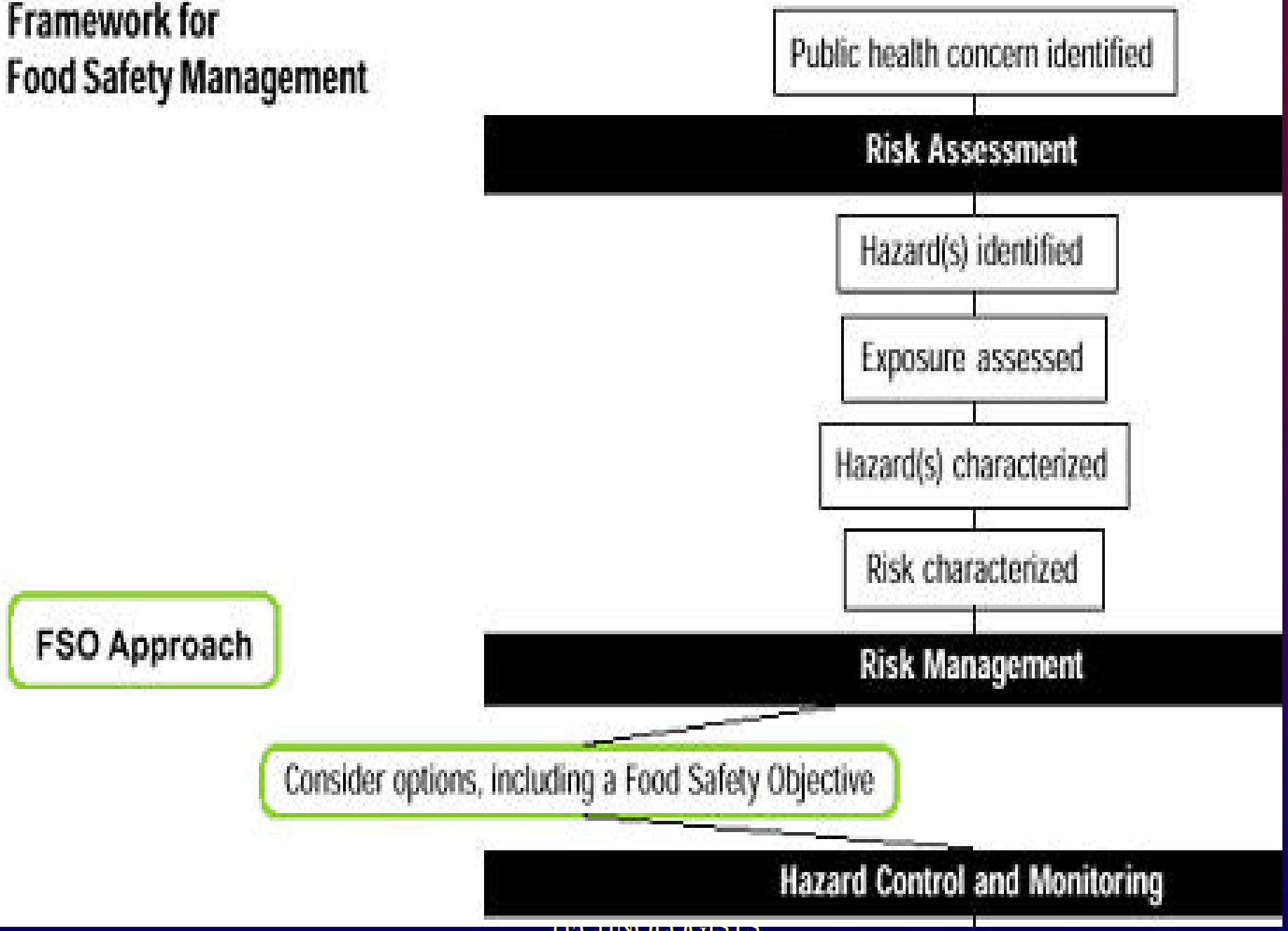
Institute of Food Technologists

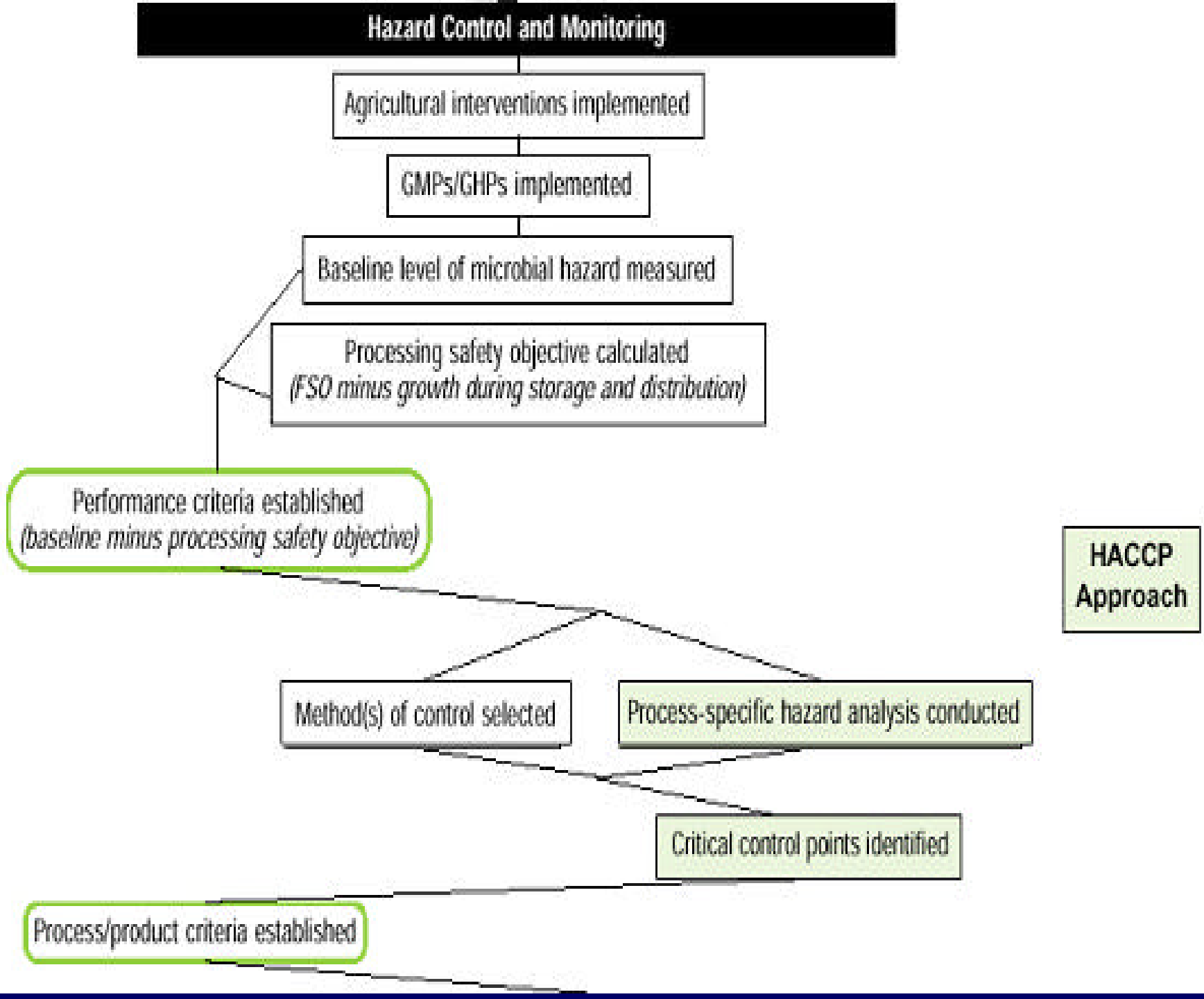
www.ift.org

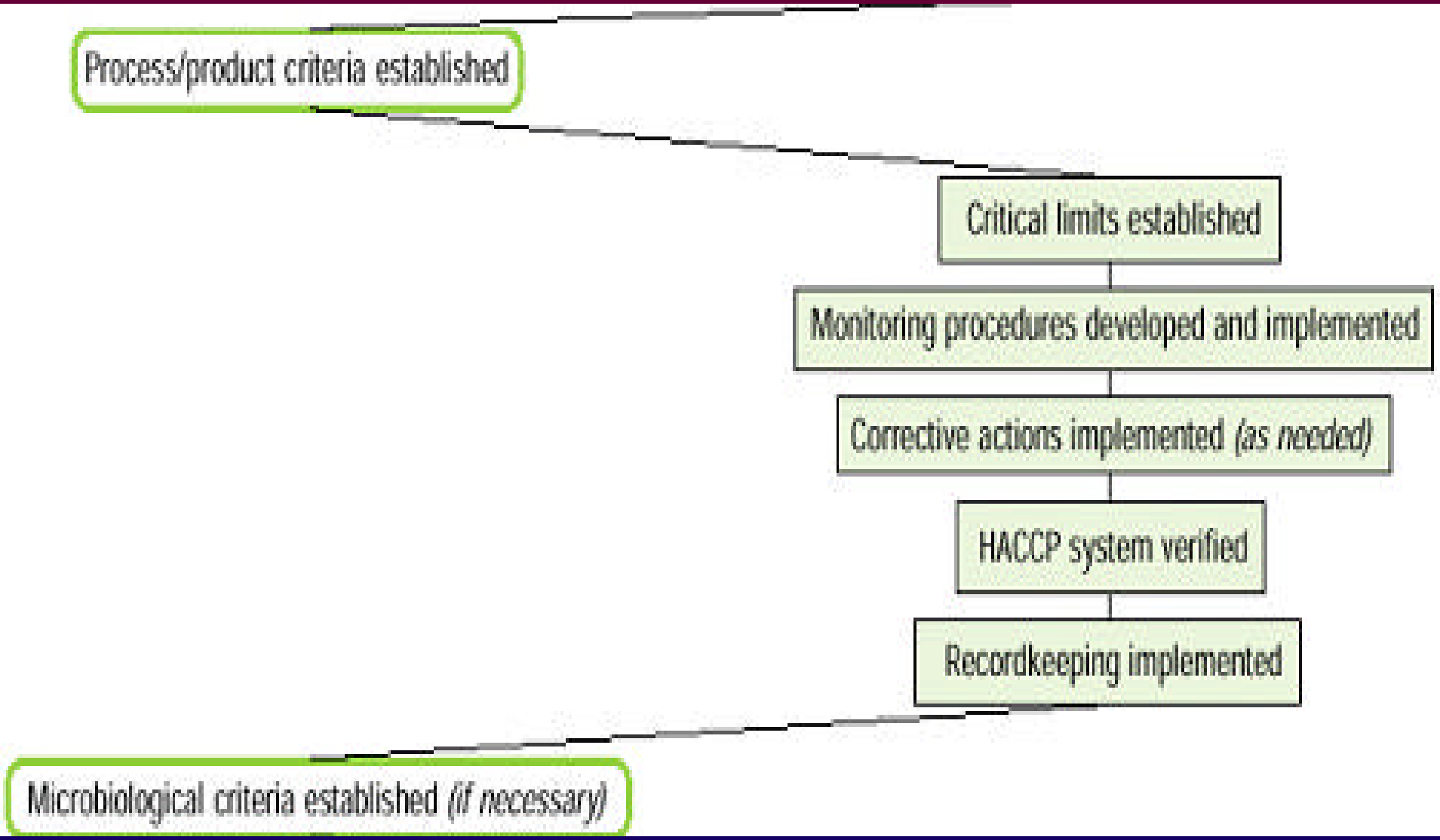
Figure. 1 Framework for Food Safety Management



Framework for Food Safety Management




Hazard Control and Monitoring
Agricultural interventions implemented
GMPs/GHPs implemented
Baseline level of microbial hazard measured
Processing safety objective calculated
(FSO minus growth during storage and distribution)
Performance criteria established
(baseline minus processing safety objective)
HACCP Approach
Method(s) of control selected
Process-specific hazard analysis conducted
Critical control points identified
Process/product criteria established


Process/product criteria established
Critical limits established
Monitoring procedures developed and implemented
Corrective actions implemented (as needed)
HACCP system verified
Recordkeeping implemented
Microbiological criteria established (if necessary)

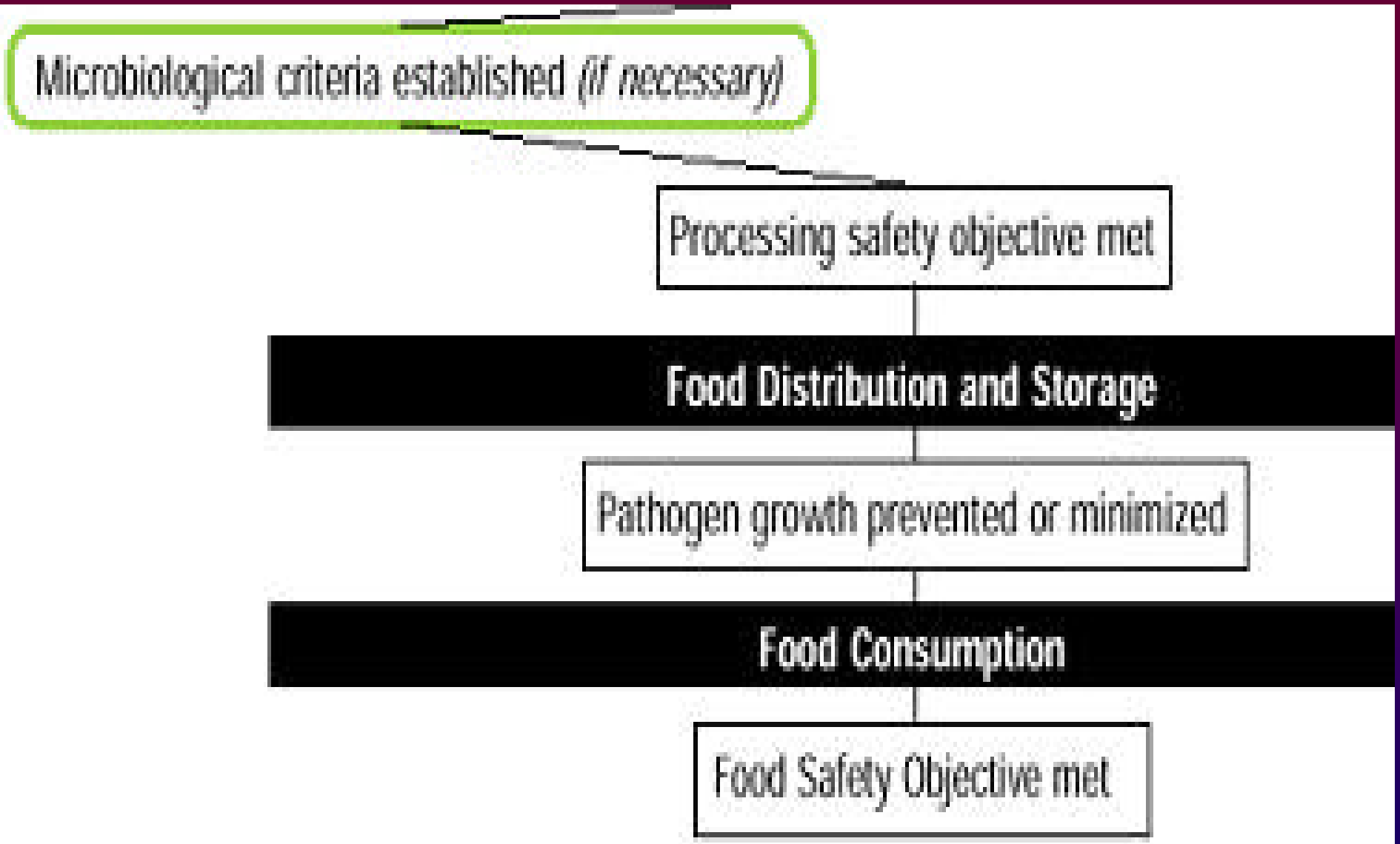
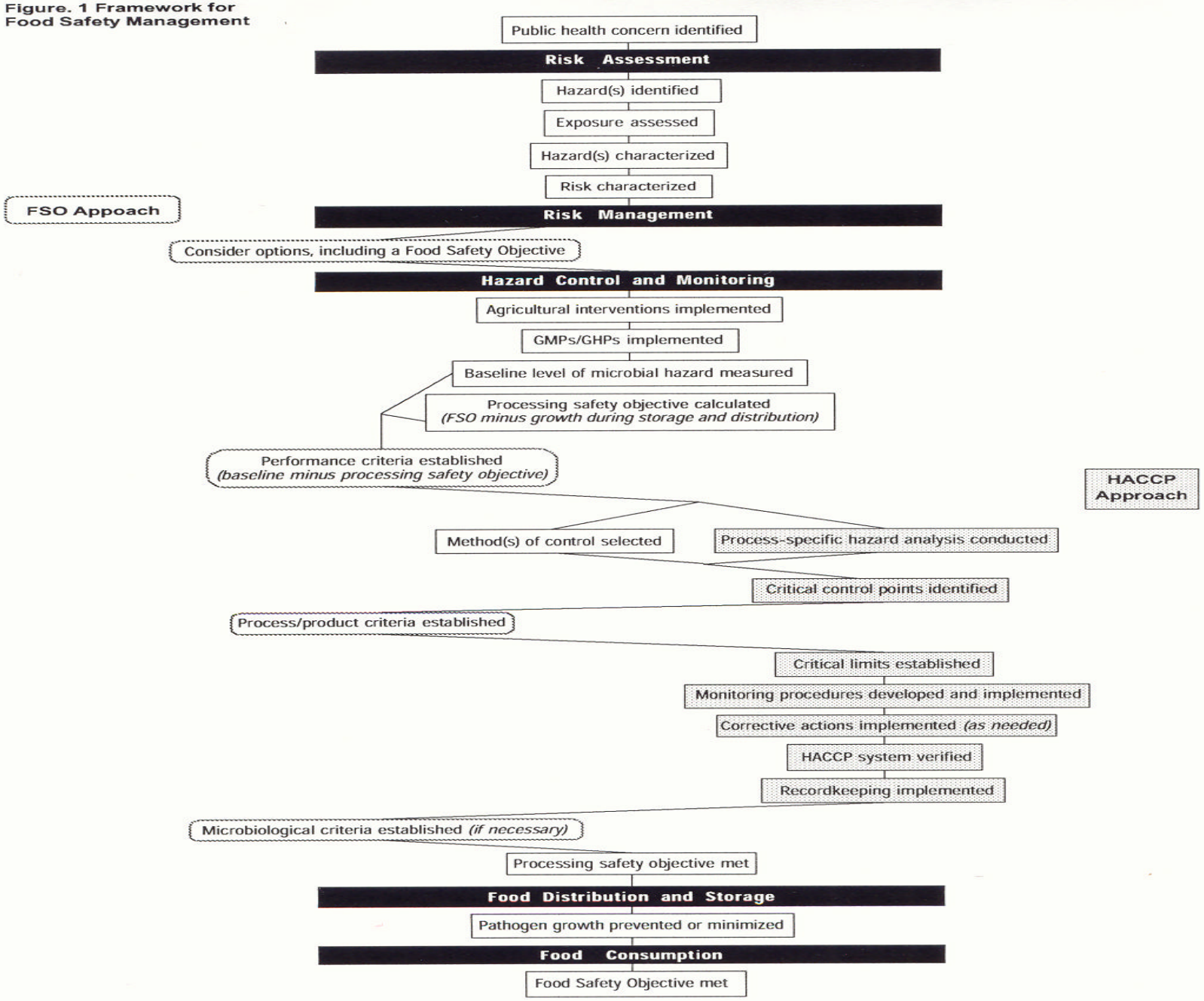

Microbiological criteria established (if necessary)
Processing safety objective met
Food Distribution and Storage
Pathogen growth prevented or minimized
Food Consumption
Food Safety Objective met

Figure. 1 Framework for Food Safety Management



Risk Communication

- **provides public with results of expert scientific review of food hazard identification and assessment of risk to general population or target group**
- **provides private and public sectors with information necessary to prevent, reduce, minimize food risks through systems of quality and safety**

Steps for managing microbial hazards

1. Information indicates a need for improved control
2. Conduct a risk evaluation
3. Assess risk management options (ALOP)
4. Establish a food safety objective (FSO)
5. Confirm that the FSO is achievable
   through GHP and HACCP
6. Establish performance/process/product criteria
7. Establish acceptance procedures:
   audits to approve food suppliers
   product criteria (e.g., pH, aw, microbiological)

This risk management framework

- **incorporates scientific information into regulatory and company policies**
- **assesses the efficacy of measures used to control microbial hazards**