

# European Filing Process: Similarities and Differences

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# Presentation Outline

- Evolution of food standards
- Heat treatment regulations, 2004 (EU)
- HACCP, 1997/2006 (WHO/FAO)
- British Retail Consortium, 2005
- UK Department of Health, 1994/2004
- Codex Alimentarius - various documents



# Official Governing Organisations

- European Commission (EC)
- UK Food Standards Agency (FSA)
- Department of Health (DoH)
- British Retail Consortium (BRC)
- Food and Agricultural Organisation of the United Nations (FAO)
- World Health Organisation (WHO)

## Similarities (with USA)

- there are legislative and regulatory bodies.

## Differences

- there are no filing requirements.

# Milestones in the evolution of food standards

(<http://www.fao.org/docrep/w9114e>)

## ANCIENT TIMES

- Attempts are made by early civilizations to codify foods

## EARLY 1800s

- Canning is invented

## MID-1800s

- Bananas are first shipped to Europe from the tropics

## 1800s

- The first general food laws are adopted and enforcement agencies established
- Food chemistry gains credibility and reliable methods are developed to test for food adulteration



## **LATE 1800s**

**- A new era of long-distance food transportation is ushered in by the first international shipments of frozen meat from Australia and New Zealand to the United Kingdom**

## **EARLY 1900s**

**- Food trade associations attempt to facilitate world trade through the use of harmonized standards**

## **1903**

**- The International Dairy Federation (IDF) develops international standards for milk and milk products.**



**1945**

**- FAO is founded, with responsibilities covering nutrition and associated international food standards**



**1948**

**- WHO is founded, with responsibilities covering human health and, in particular, a mandate to establish food standards**



**1949**

**- Argentina proposes a regional Latin American food code, *Código Latino-Americano de Alimentos***

**1950**

- **Joint FAO/WHO expert meetings begin on nutrition, food additives and related areas**

**1953**

- **WHO's highest governing body, the World Health Assembly, states that the widening use of chemicals in the food industry presents a new public health problem that needs attention**

**1954-1958**

- **Austria actively pursues the creation of a regional food code, the *Codex Alimentarius Europaeus*, or European Codex Alimentarius**

**1961**

**- The Council of the *Codex Alimentarius Europaeus* adopts a resolution proposing that its work on food standards be taken over by FAO and WHO**

**1963**

**- Recognizing the importance of WHO's role in all health aspects of food and considering its mandate to establish food standards, the World Health Assembly approves establishment of the Joint FAO/WHO Programme on Food Standards and adopts the statutes of the Codex Alimentarius Commission**

# International ventures:

Thermal Processing training in South Africa, Oct 2006



# International ventures:

Thermal Processing training in Thailand, Oct 2006

Harmonisation of standards within the EU



## **Regulation No. 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs. (Official Journal L226, 25/06/2004)**

- Any heat treatment ..... is to raise every part of the product to a given temperature for a given period of time and to prevent the product from becoming contaminated during the process;
- To ensure that the process achieves the desired objectives, food business operators must check regularly the main relevant parameters (particularly temperature, pressure, sealing and microbiology);
- The process used should conform to an internationally recognised standard (for example, pasteurisation, ultra high temperature or sterilisation).



**Regulation (EC) No. 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (Official Journal L226, 25/06/2004)**

When raw milk or dairy products undergo heat treatment, food business operators must ensure that this satisfies certain requirements in Regulation (EC) No. 852/2004. In particular, it must be ensured that when using the following processes they comply with the specifications mentioned:



**Pasteurisation** is achieved by a treatment involving:

- i. a high temperature for a short time (at least 72°C for 15 seconds);
- ii. a low temperature for a long time (at least 63°C for 30 minutes); or
- iii. any other combination of time-temperature conditions to obtain an equivalent effect, such that the products show, where applicable, a negative reaction to an alkaline phosphatase test immediately after such treatment.

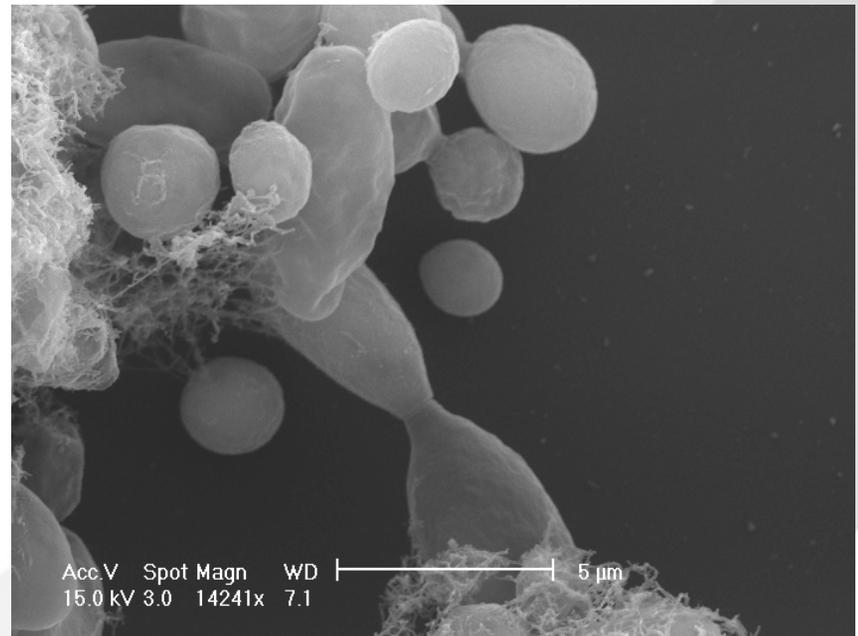
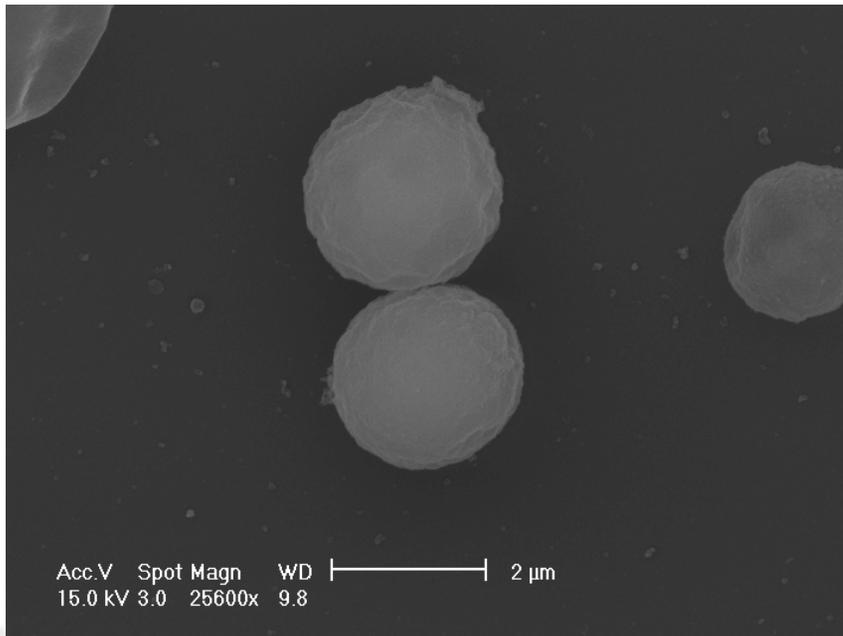


**Ultra High Temperature (UHT)** treatment is achieved by a treatment:

- i. involving a continuous flow of heat at a high temperature for a short time (not less than 135°C in combination with a suitable holding time) such that there are no viable microorganisms or spores capable of growing in the treated product when kept in an aseptic closed container at ambient temperature, and
- ii. sufficient to ensure that the products remain microbiologically stable after incubating for 15 days at 30°C in closed containers or for 7 days at 55°C in closed containers, or after any other method demonstrating that the appropriate heat treatment has been applied.

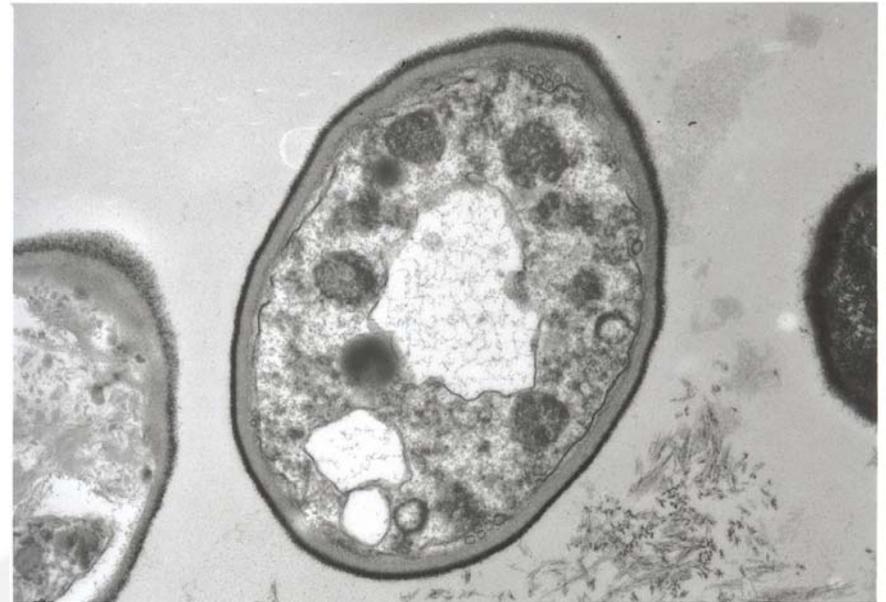
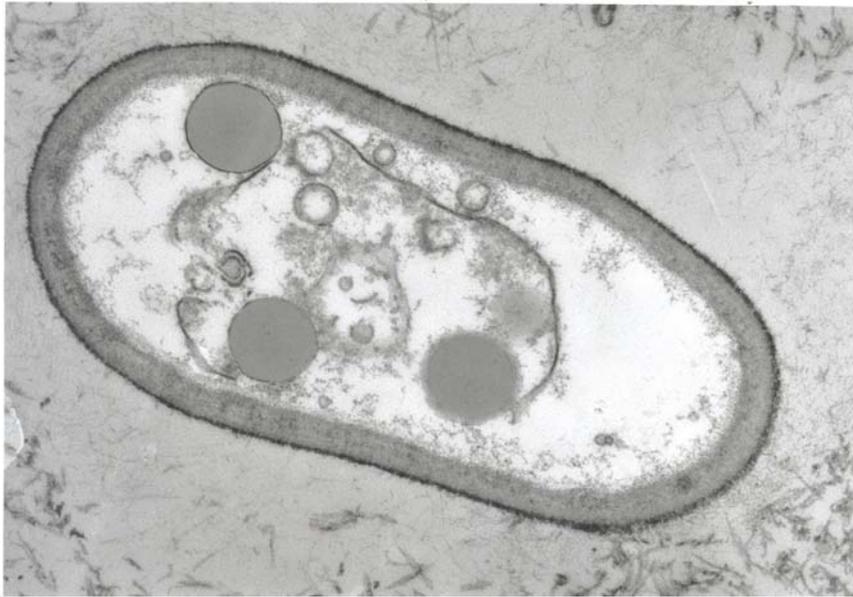


# Sterilisation TTI: *Pyrococcus furiosus* amylase



SEM pictures courtesy of Ian Brown,  
University of Birmingham

# Sterilisation TTI: *Pyrococcus furiosus* amylase



TEM pictures courtesy of Ian Brown,  
University of Birmingham



**HACCP concept endorsed by the WHO/FAO as an effective means to ensure control of food borne illness.**

Codex Alimentarius Commission (CAC) alongside the United States National Advisory Committee on the Microbiological Criteria for Foods (NACMCF) published documents (CAC, 1997b, NACMCF 1997) that are regarded as the reference documents worldwide and have been instrumental in harmonizing the approach.



Up to the 1<sup>st</sup> January 2006 the legal position throughout Europe was to follow Council Directive on the Hygiene of Foodstuffs 93/43/EEC which laid out the general guidance across the food industry. The legal requirement was that food business operators had to identify any step in their activities critical to ensuring food safety and ensure that adequate safety procedures were identified, implemented, maintained and reviewed on the basis of the following principles, used to develop the system of HACCP (Hazard Analysis Critical Control Point)

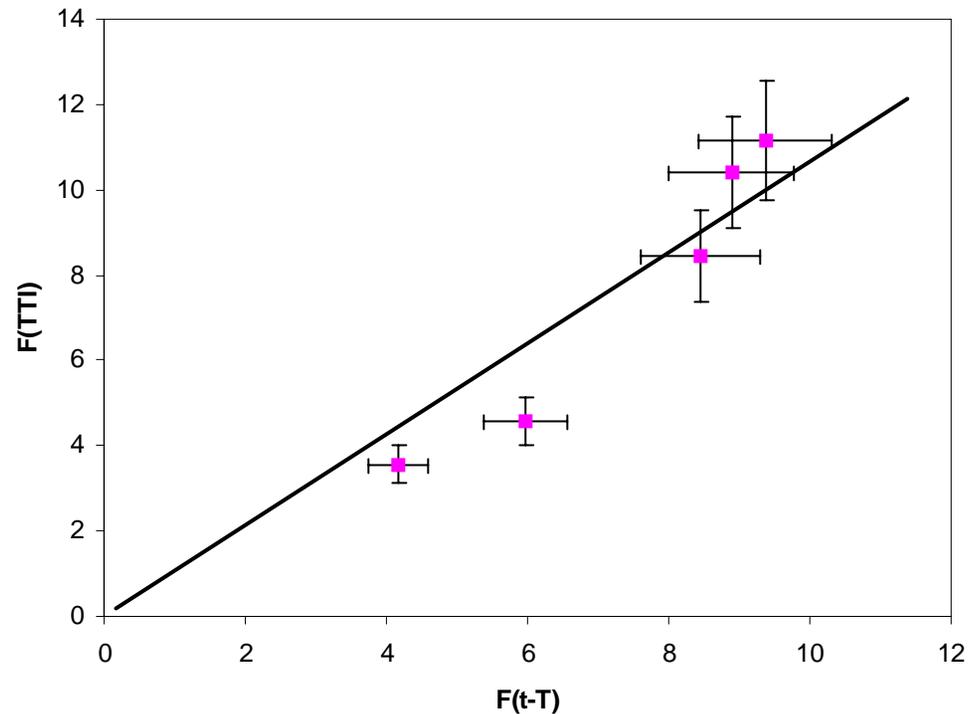
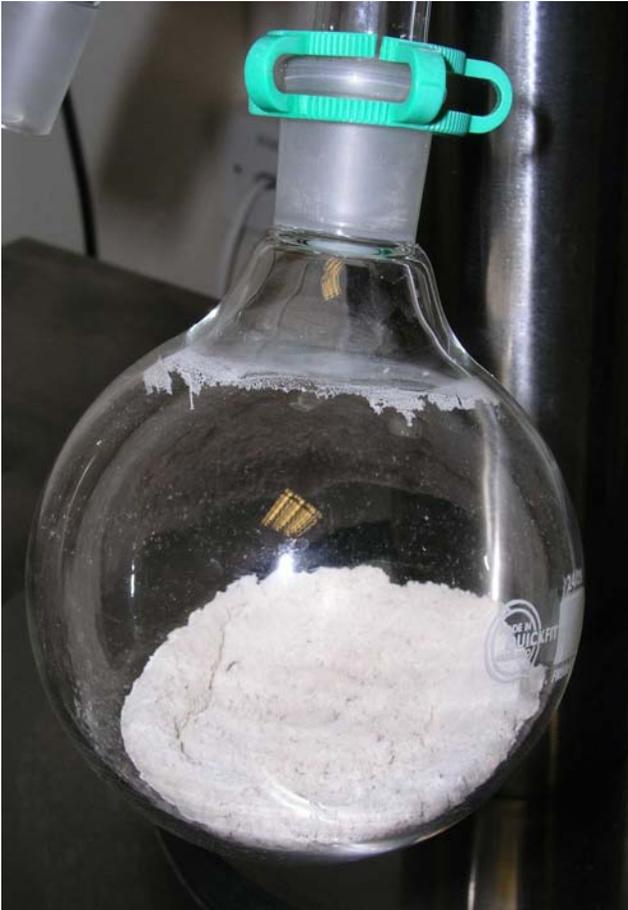


From the 1<sup>st</sup> January 2006 a new suite of hygiene regulations came into force. Regulation 852/2004 covers the general principles for the hygiene of foodstuffs throughout the food chain with the primary principle of ensuring a high level of consumer protection with regard to food safety.

All food manufacturing operations must have a HACCP-based system.

# Sterilisation TTI:

Freeze dried protein from a *Pyrococcus furiosus* fermentation ( $D_{121} \approx 21$  minutes,  $z \approx 10^\circ\text{C}$ )



**BRC Global Standard Guidelines.  
Process validation: low acid canning  
British Retail Consortium, 2005**

The Standard was created to establish a standard for the supply of food products and to act as key piece of evidence for UK retailers and brand owners to demonstrate ‘due diligence’ in the face of potential prosecution by the enforcement authorities.



# **BRC Global Standard Guidelines. Process validation: low acid canning British Retail Consortium, 2005**

The Standard covers such critical topics as:

- HACCP system
- quality management
- factory environment standard
- product and process control



# **BRC Global Standard Guidelines. Process validation: low acid canning British Retail Consortium, 2005**

5.1.3 Where physical and chemical control (including temperature) of the raw materials, intermediate or finished product, processes and/or environment is critical to product safety, legality and quality, this shall be adequately controlled, monitored and recorded.  
(examples given)

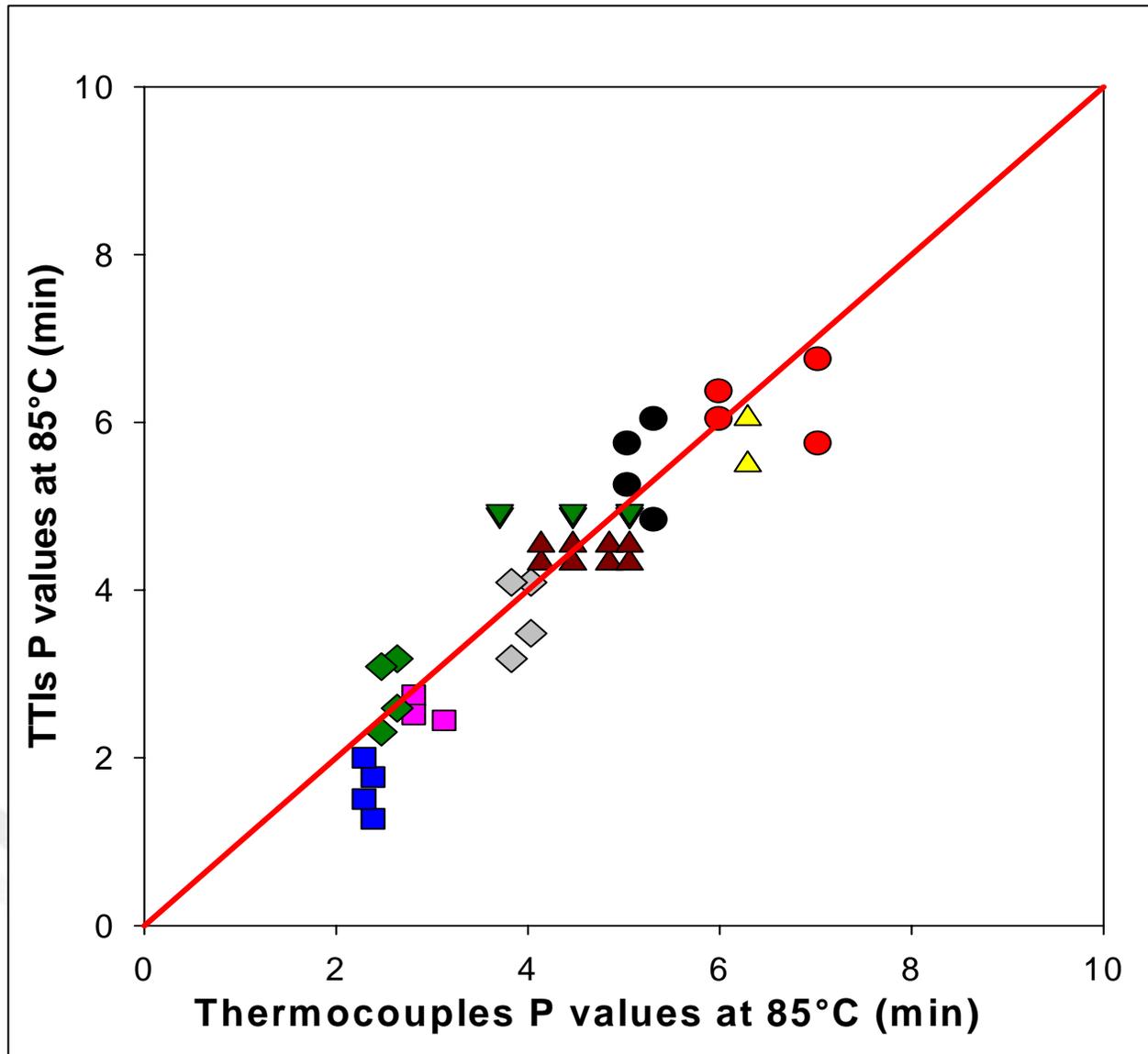
**This is one of the most important documents for food companies.**



# A selection of TTI particles



# Comparison of P-values measured with TTIs and thermocouples



Graph courtesy of  
Karin Mehauden,  
University of  
Birmingham

**Guidelines for the safe production of heat preserved foods.  
Department of Health, 1994, p 43, 46  
(formerly Food Hygiene Code of Practice No. 10: The  
canning of low acid foods)**

8.1.10 Every effort should be made to keep the temperature for fresh meat, fish and poultry below 7°C up to the point where it is cooked or filled into containers....

8.1.11 Where raw meat, fish and poultry are cooked prior to filling, the cooked product should be either filled hot or reduced quickly and without delay to a temperature below 7°C and held at this temperature until required for filling. The scheduled process should specify the temperature of the product at filling.

**Section 10.** The Thermal Process - Low acid products  $\text{pH} > 4.5$   
.....gives equation for minimum thermal process value.  
*Cl. Botulinum*, F value of 3 minutes at  $121.1^{\circ}\text{C}$

**Section 12.** Acidified (normally low acid) foods

**Section 17.** Post-thermal process procedures

17.2.2 After sterilisation, containers, if they are water cooled, must be cooled quickly down to temperatures of about  $40^{\circ}\text{C}$ ...

In UK all (most) companies follow these guidelines

Synthetic gene encoding the *Pyrococcus furiosus* extracellular amylase was cloned in *Saccharomyces cerevisiae* under the control of the galactose inducible GAL7 promotor



Unilever Vlaardingen shake flask experiments to produce thermostable yeast amylase

**Recommended international code of  
hygienic practice for canned fruit and  
vegetable products**

**CAC/RCP 2 (1969)**

**Codex Alimentarius Commission**

**Recommended international code of  
hygienic practice for Low-Acid and  
Acidified Low-Acid Canned Foods**

**CAC/RCP 23 (1979)**

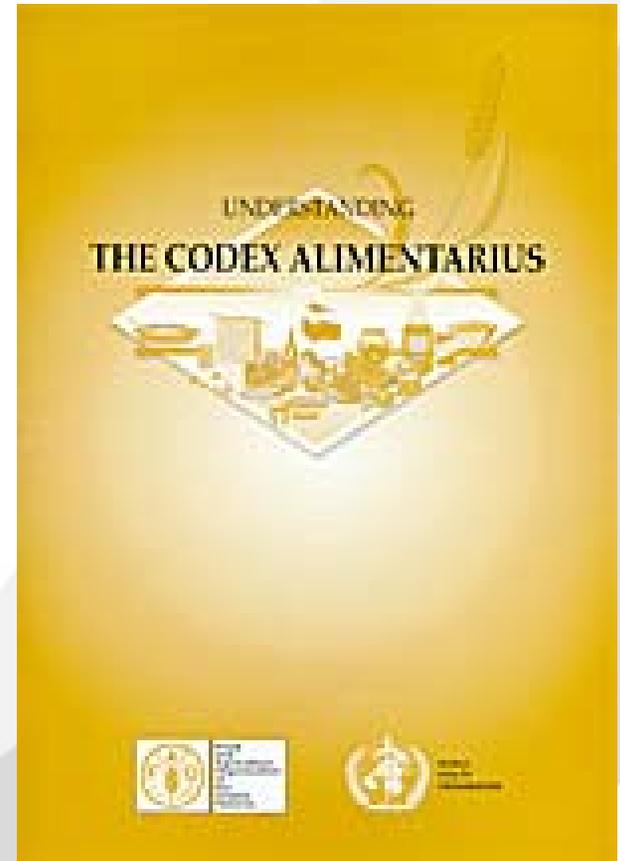
**Codex Alimentarius Commission**

**Code of hygienic practice for aseptically  
processed and packaged low-acid foods.**

**CAC/RCP 40 (1993)**

**Codex Alimentarius Commission**

**<http://www.codexalimentarius.net>**



# Summary: Documentation Required

Validation data must be gathered to prove that the scheduled thermal processing conditions result in at least the minimum process target being achieved.

A report should be written to describe the validation tests and how the scheduled process was calculated.

# Concluding Remarks

There are no requirements for processes to be filed within Europe

Many guidelines exist

EU regulations cover the hygienic production of foods

There is a legal requirement for companies to produce a HACCP-based plan