

## ANNEX IV

### PROCESSING

#### CHAPTER III

##### STANDARD PROCESSING METHODS

###### A. Processing method 1 (pressure sterilisation)

###### Reduction

1. If the particle size of the animal by-products to be processed is more than 50 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is no greater than 50 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 50 millimetres, the process must be stopped and repairs made before the process is resumed.

###### Time, temperature and pressure

2. The animal by-products with the particle size of no greater than 50 millimetres must be heated to a core temperature of more than 133 °C for at least 20 minutes without interruption at a pressure (absolute) of at least 3 bars. The pressure must be produced by the evacuation of all air in the sterilisation chamber and the replacement of the air by steam ('saturated steam'); the heat treatment may be applied as the sole process or as a pre- or post-process sterilisation phase.
3. The processing may be carried out in batch or continuous systems.

###### B. Processing method 2

###### Reduction

1. If the particle size of the animal by-products to be processed is more than 150 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is no greater than 150 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 150 millimetres, the process must be stopped and repairs made before the process is resumed.

###### Time, temperature and pressure

2. After reduction the animal by-products must be heated in a manner which ensures that a core temperature greater than 100 °C is achieved for at least 125 minutes, a core temperature greater than 110 °C is achieved for at least 120 minutes and a core temperature greater than 120 °C is achieved for at least 50 minutes.

The core temperatures may be achieved consecutively or through a coincidental combination of the time periods indicated.

3. The processing must be carried out in a batch system.

###### C. Processing method 3

###### Reduction

1. If the particle size of the animal by-products to be processed is more than 30 millimetres, the animal by-products must be reduced in size using appropriate

equipment, set so that the particle size after reduction is no greater than 30 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 30 millimetres, the process must be stopped and repairs made before the process is resumed.

Time, temperature and pressure

2. After reduction the animal by-products must be heated in a manner which ensures that a core temperature greater than 100 °C is achieved for at least 95 minutes, a core temperature greater than 110 °C is achieved for at least 55 minutes and a core temperature greater than 120 °C is achieved for at least 13 minutes.

The core temperatures may be achieved consecutively or through a coincidental combination of the time periods indicated.

3. The processing may be carried out in batch or continuous systems.

#### D. Processing method 4

##### Reduction

1. If the particle size of the animal by-products to be processed is more than 30 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is no greater than 30 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 30 millimetres, the process must be stopped and repairs made before the process is resumed.

Time, temperature and pressure

2. After reduction the animal by-products must be placed in a vessel with added fat and heated in a manner which ensures that a core temperature greater than 100 °C is achieved for at least 16 minutes, a core temperature greater than 110 °C is achieved for at least 13 minutes, a core temperature greater than 120 °C is achieved for at least eight minutes and a core temperature greater than 130 °C is achieved for at least three minutes.

The core temperatures may be achieved consecutively or through a coincidental combination of the time periods indicated.

3. The processing may be carried out in batch or continuous systems.

#### E. Processing method 5

##### Reduction

1. If the particle size of the animal by-products to be processed is more than 20 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is no greater than 20 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 20 millimetres, the process must be stopped and repairs made before the process is resumed.

Time, temperature and pressure

2. After reduction the animal by-products must be heated until they coagulate and then pressed so that fat and water are removed from the proteinaceous material. The proteinaceous material must then be heated in a manner which ensures that a core temperature greater than 80 °C is achieved for at least 120 minutes and a core temperature greater than 100 °C is achieved for at least 60 minutes.

The core temperatures may be achieved consecutively or through a coincidental combination of the time periods indicated.

3. The processing may be carried out in batch or continuous systems.

F. Processing method 6 (for Category 3 animal by-products originating from aquatic animal or aquatic invertebrates only)

Reduction

1. The animal by-products must be reduced to a particle size which is no greater than:

(a) 50 mm, in case of heat treatment in accordance with point 2(a); or

(b) 30 mm, in case of heat treatment in accordance with point 2(b).

They must then be mixed with formic acid to reduce and maintain the pH to 4,0 or lower. The mixture must be stored for at least 24 hours pending further treatment.

Time, temperature and pressure

2. After reduction, the mixture must be heated to:

(a) a core temperature of at least 90 °C for at least 60 minutes; or

(b) a core temperature of at least 70 °C for at least 60 minutes.

When using a continuous flow system, the progression of the product through the heat converter must be controlled by means of mechanical commands limiting its displacement in such way that at the end of the heat treatment operation the product has undergone a cycle which is sufficient in both time and temperature.

3. The processing may be carried out in batch or continuous systems.

G. Processing method 7

1. Any processing method authorised by the competent authority where the following have been demonstrated by the operator to that authority:

(a) the identification of relevant hazards in the starting material, in view of the origin of the material, and of the potential risks in view of the animal health status of the Member State or the area or zone where the method is to be used;

(b) the capacity of the processing method to reduce those hazards to a level which does not pose any significant risks to public and animal health;

(c) the sampling of the final product on a daily basis over a period of 30 production days in compliance with the following microbiological standards:

(i) Samples of material taken directly after the treatment:

*Clostridium perfringens* absent in 1 g of the products

(ii) Samples of material taken during or upon withdrawal from storage:

Salmonella: absence in 25g: n=5, c=0, m=0, M=0

Enterobacteriaceae: n=5, c=2; m=10; M=300 in 1 g

where:

n = number of samples to be tested;  
m = threshold value for the number of bacteria; the result is considered

		satisfactory if the number of bacteria in all samples does not exceed m;
M	=	maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more samples is M or more; and
c	=	number of samples the bacterial count of which may be between m and M, the samples still being considered acceptable if the bacterial count of the other samples is m or less.

2. Details of the critical control points under which each processing plant satisfactorily complies with the microbiological standards must be recorded and maintained so that the operator and the competent authority can monitor the operation of the processing plant. The information to be recorded and monitored must include the particle size, and, as appropriate, the critical temperature, the absolute time, pressure profile, raw material feed rate and fat recycling rate.
3. By way of derogation from point 1, the competent authority may authorise the use of processing methods which have been approved prior to the date of entry into application of this Regulation, in accordance with Chapter III of Annex V to Regulation (EC) No 1774/2002.
4. The competent authority shall permanently or temporarily suspend the application of processing methods referred to in points 1 and 3, if it obtains evidence that any of the circumstances specified in point 1(a) or (b) have substantially changed.
5. The competent authority shall inform the competent authority of another Member State upon request about the information at its disposal under points 1 and 2 in relation to an authorised processing method.