ANNEX V

TRANSFORMATION OF ANIMAL BY-PRODUCTS AND DERIVED PRODUCTS INTO BIOGAS, COMPOSTING

CHAPTER III

TRANSFORMATION PARAMETERS

Section 1

Standard transformation parameters

1. Category 3 material which is used as raw material in a biogas plant equipped with a pasteurisation/hygienisation unit must be submitted to the following minimum requirements:

(a) maximum particle size before entering the unit: 12 mm;

(b) minimum temperature in all material in the unit: 70 °C; and

(c) minimum time in the unit without interruption: 60 minutes.

However, Category 3 milk, milk-based products, milk-derived products, colostrum and colostrum products may be used without pasteurisation/hygienisation as raw material in a biogas plant, if the competent authority does not consider them to present a risk of spreading any serious transmissible disease to humans or animals.

The minimum requirements set out in points (b) and (c) of this point shall also apply to Category 2 material which is introduced into a biogas plant without prior processing in accordance with Article 13(e)(ii) of Regulation (EC) No 1069/2009.

2. Category 3 material which is used as raw material in a composting plant must be submitted to the following minimum requirements:

(a) maximum particle size before entering the composting reactor: 12 mm;

(b) minimum temperature in all material in the reactor: 70 °C; and

(c) minimum time without interruption: 60 minutes.

The minimum requirements set out in points (b) and (c) of this point shall also apply to Category 2 material which is composted without prior processing in accordance with Article 13(e)(ii) of Regulation (EC) No 1069/2009.

Section 2

Alternative transformation parameters for biogas and composting plant

1. The competent authority may authorise the use of parameters other than the parameters set out in point 1 of Section 1 of Chapter I and other than the standard transformation parameters, provided that the applicant for such use demonstrates that such parameters ensure adequate reduction of biological risks. That demonstration shall include a validation, which shall be carried out in accordance with the following requirements:

(a) Identification and analysis of possible hazards, including the impact of input material, based on a full description of the transformation conditions and parameters;

(b) A risk assessment, which evaluates how the specific transformation conditions referred to in point (a) are achieved in practice under normal and atypical situations;

(c) Validation of the intended process by measuring the reduction of viability/infectivity of:

(i) endogenous indicator organisms during the process, where the indicator is:
— consistently present in the raw material in high numbers,
— not less heat resistant to the lethal aspects of the transformation process, but also not significantly more resistant than the pathogens for which it is being used to monitor,
— relatively easy to quantify and to identify and to confirm; or

(ii) a well-characterised test organism or virus, during exposure, introduced in a suitable test body into the starting material.

(d) The validation of the intended process referred to in point (c) must demonstrate that the process achieves the following overall risk reduction:

(i) for thermal and chemical processes by:
— a reduction of 5 log10 of *Enterococcus faecalis* or *Salmonella Senftenberg* (775W, H2S negative),
— reduction of infectivity titre of thermoresistant viruses such as parvovirus by at least 3 log10, whenever they are identified as a relevant hazard; and

(ii) as regards chemical processes also by:
— a reduction of resistant parasites such as eggs of *Ascaris* sp. by at least 99,9 % (3 log10) of viable stages;

(e) Designing a complete control programme including procedures for monitoring the functioning of the process referred to in point (c);

(f) Measures ensuring continuous monitoring and supervision of the relevant process parameters fixed in the control programme when operating the plant.

Details on the relevant process parameters used in a biogas or composting plant as well as other critical control points must be recorded and maintained so that the owner, operator or their representative and the competent authority can monitor the operation of the plant.

Records must be made available by the operator to the competent authority on request. Information relating to a process authorised under this point must be made available to the Commission on request.

2. By way of derogation from point 1, pending the adoption of rules as referred to in Article 15(2)(a)(ii) of Regulation (EC) No 1069/2009, the competent authority may authorise the use of specific requirements other than those laid down in this Chapter, provided that they guarantee an equivalent effect regarding the reduction of pathogens, for:

(a) catering waste used as the only animal by-product in a biogas or composting plant; and

(b) mixtures of catering waste with the following materials:

(i) manure;

(ii) digestive tract content separated from the digestive tract;

(iii) milk;

(iv) milk-based products;

(v) milk-derived products;

(vi) colostrum;

(vii) colostrum products;

(viii) eggs;

(ix) egg products;

(x) animal by-products referred to in Article 10(f) of Regulation (EC) No 1069/2009, which have undergone processing as defined in Article 2(1)(m) of Regulation (EC) No 852/2004.

3. Where the materials referred to in point 2(b) or derived products referred to in Article 10(g) of Regulation (EC) No 1069/2009 are the only starting material of animal origin being treated in a biogas or composting plant, the competent authority may authorise the use of specific requirements other than those specified in this Chapter provided that it:

(a) does not consider that those materials present a risk of spreading any serious transmissible disease to humans or animals;

(b) considers that the digestion residues or compost are unprocessed material and obliges operators to handle them in accordance with Regulation (EC) No 1069/2009 and with this Regulation.

4. Operators may place on the market digestion residues and compost, which have been produced according to parameters which have been authorised by the competent authority:

(a) in accordance with point 1;

(b) in accordance with points 2 and 3, only within the Member State where those parameters have been authorised.

Section 3

Standards for digestion residues and compost

1.

(a) Representative samples of the digestion residues or compost taken during or immediately after transformation at the biogas plant or composting at the composting plant in order to monitor the process must comply with the following standards:

Escherichia coli: n = 5, c = 1, m = 1 000, M = 5 000 in 1 g;

or

Enterococcaceae: n = 5, c = 1, m = 1 000, M = 5 000 in 1 g;

and

(b) Representative samples of the digestion residues or compost taken during or on withdrawal from storage must comply with the following standards:

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

Where in the case of point (a) or (b):

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 sample still being considered acceptable if the bacterial count of the other samples is m or less.

2. Digestion residues or compost, which do not comply with the requirements set out in this Section, shall be resubmitted to transformation or composting, and in the case of Salmonella handled or disposed of in accordance with the instructions of the competent authority.