Changes to legislation: *Commission Regulation (EC) No 208/2006 is up to date with all changes known to be in force on or before 03 February 2022. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

Commission Regulation (EC) No 208/2006 of 7 February 2006 amending Annexes VI and VIII to Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards processing standards for biogas and composting plants and requirements for manure (Text with EEA relevance)

COMMISSION REGULATION (EC) No 208/2006

of 7 February 2006

amending Annexes VI and VIII to Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards processing standards for biogas and composting plants and requirements for manure

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption[1], and in particular Article 32(1) thereof,

Whereas:

(1) Regulation (EC) No 1774/2002 provides for measures to ensure that manure and products derived there from are used or disposed of in such a way as not to pose a risk to public or animal health.

(2) Chapter II of Annex VI to Regulation (EC) No 1774/2002 sets out specific requirements for the approval of biogas and composting plants using animal by-products.

(3) Following the opinion of the European Food Safety Authority (EFSA) of 7 September 2005 on the safety *vis-à-vis* biological risks of biogas and composting treatment standards of animal by-products, it is appropriate to amend Chapter II of Annex VI to Regulation (EC) No 1774/2002 by allowing authorisation of other process parameters.

(4) Chapter III of Annex VIII to Regulation (EC) No 1774/2002 sets out requirements for manure, processed manure and processed manure products and lays down the processing and control parameters manure has to undergo to fulfil the requirements for processed manure and processed manure products.

(5) Following the opinion of EFSA of 7 September 2005 on the biological safety of heat treatment of manure, it is appropriate to amend the relevant requirements of Chapter III of Annex VIII to take account of that opinion.

(6) Regulation (EC) No 1774/2002 should therefore be amended accordingly.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

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Article 1

Annexes VI and VIII to Regulation (EC) No 1774/2002 are amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the third day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2006. However, the requirements in Annex VI, chapter II, point C(13a) and in Annex VIII, chapter III, point (II)(A)(5)(c) to Regulation (EC) No 1774/2002 shall apply from 1 January 2007.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 7 February 2006.

For the Commission

Markos KYPRIANOU

Member of the Commission

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ANNEX

Annexes VI and VIII to Regulation (EC) No 1774/2002 are amended as follows:

1. In Annex VI, Chapter II is amended as follows:

(a) Points A(1) and (2) are replaced by the following:

1. A biogas plant must be equipped with:

(a) a pasteurisation/hygienisation unit, which cannot be by-passed, with:

(i) installations for monitoring temperature against time;

(ii) recording devices to record continuously the results of the monitoring measurements referred to in (i); and

(iii) an adequate safety system to prevent insufficient heating;

(b) adequate facilities for the cleaning and disinfecting of vehicles and containers upon leaving the biogas plant.

However, a pasteurisation/hygienisation unit shall not be mandatory for biogas plants that transform only:

(i) animal by-products that have undergone processing Method 1;

(ii) Category 3 material that has undergone pasteurisation/ hygienisation elsewhere; or

(iii) animal by-products which may be used as raw material without processing.

If the biogas plant is located on premises where farmed animals are kept and does not only use manure which accrues from those animals, the plant shall be located at an adequate distance from the area where such animals are kept and there must be, in any case, total physical separation between that plant and those animals and their feed and bedding, with fencing where necessary.

2. A composting plant must be equipped with:

(a) a closed composting reactor, which cannot be by-passed, with:

(i) installations for monitoring temperature against time;

(ii) recording devices to record, where appropriate continuously, the results of the monitoring measurements referred to in (i); and

(iii) an adequate safety system to prevent insufficient heating;

(b) adequate facilities for cleaning and disinfecting of vehicles and containers transporting untreated animal by-products.

However, other types of composting systems may be allowed provided they:

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(i) ensure adequate measures to control vermin;

(ii) are managed in such a way that all the material in the system achieves the required time and temperature parameters, including, where appropriate, continuous monitoring of the parameters;

(iii) comply with all other requirements of this Regulation.

If the composting plant is located on premises where farmed animals are kept and does not only use manure which accrues from those animals, the composting plant shall be located at an adequate distance from the area where animals are kept and there must, in any case, be total physical separation between that composting plant and the animals and their feed and bedding, with fencing where necessary.

(b) Point B(11) is replaced by the following:

11. Digestion residues and compost must be handled and stored at the biogas respective composting plant in such way as to prevent recontamination.

(c) Point C(12) is replaced by the following:

12. Category 3 material 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, colostrums and milk 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.

(d) Point C(13) is replaced by the following:

13. Category 3 material 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 in the reactor at 70 °C (all material): 60 minutes.

(e) The following Point C(13a) is inserted:

13a. However, the competent authority may authorise the use of other standardised process parameters provided an applicant demonstrates that such parameters ensure minimising of biological risks. That demonstration

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shall include a validation, which shall be carried out in accordance with points (a) to (f):

(a) Identification and analysis of possible hazards, including the impact of input material, based on a full definition of the processing conditions.

(b) A risk assessment, which evaluates how the specific processing conditions referred to in (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 treatment process, but also not significantly more resistant than the pathogens for which it is being used to monitor,

— relatively easy to quantify and relatively easy 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 (c) must demonstrate that the process achieves the following overall risk reduction:

(i) for thermal and chemical processes by:

— reduction of 5 log10 of *Enterococcus faecalis or Salmonella Senftenberg (775W, H2S negative),*

— reduction of infectivity titre of thermo resistant 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:

— 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 (c).