

*Changes to legislation: There are currently no known outstanding effects for the
Commission Regulation (EU) No 142/2011, ANNEX XI. (See end of Document for details)*

ANNEX XI

ORGANIC FERTILISERS AND SOIL IMPROVERS

CHAPTER I

REQUIREMENTS FOR UNPROCESSED MANURE, PROCESSED MANURE AND DERIVED PRODUCTS FROM PROCESSED MANURE

Section 1

Unprocessed manure

^{F1}1.

Textual Amendments

F1 Annex 11 Ch. 1 Section 1 points 1-5 omitted (E.W.S.) (31.12.2020) by virtue of [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), regs. 1(2)(c), **13(59)(a)**

^{F1}2.

^{F1}3.

^{F1}4.

^{F1}5.

6. The competent authority may authorise the dispatch of manure transported between two points located on the same farm subject to conditions for the control of possible health risks, such as obligations for the operators concerned to keep appropriate records.

Section 2

Guano from bats, processed manure and derived products from processed manure

[^{F2}The placing on the market of processed manure, derived products from processed manure and guano from bats shall be subject to the following conditions: ^{F3}...]

Textual Amendments

F2 Substituted by [Commission Regulation \(EU\) No 749/2011 of 29 July 2011 amending Regulation \(EU\) No 142/2011 implementing Regulation \(EC\) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive \(Text with EEA relevance\)](#).

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F3 Words in Annex 11 Ch. 1 Section 2 omitted (E.W.S.) (31.12.2020) by virtue of [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), regs. 1(2)(c), **13(59)(b)(i)**

- (a) They must come from a plant for derived products for uses outside the feed chain or from a biogas or a composting plant or from a plant for the manufacturing of organic fertilisers or soil improvers.
- (b) They shall have been subjected to a heat treatment process of at least 70 °C for at least 60 minutes and they shall have been subjected to reduction in spore-forming bacteria and toxin formation, where they are identified as a relevant hazard.
- (c) However, the competent authority may authorise the use of other standardised process parameters than those referred to in point (b), provided an applicant demonstrates that such parameters ensure minimising of biological risks.

That demonstration shall include a validation, which shall be carried out as follows:

- (i) Identification and analysis of possible hazards including the impact of input material, based on a full definition of the processing conditions, and a risk assessment, which evaluates how the specific processing conditions are achieved in practice under normal and atypical situations.
- (ii) Validation of the intended process
 - (ii-1) by measuring the reduction of viability/infectivity of 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 confirm; or
 - (ii-2) by measuring the reduction of viability/infectivity, during exposure, of a well-characterised test organism or virus introduced in a suitable test body into the starting material.
- (iii) The validation referred to in point (ii) must demonstrate that the process achieves the following overall risk reduction:
 - for thermal and chemical processes by reduction of *Enterococcus faecalis* by at least 5 log₁₀ and by reduction of infectivity titre of thermoresistant viruses such as *parvovirus*, where they are identified as a relevant hazard, by at least 3 log₁₀,
 - for chemical processes also by reduction of resistant parasites such as eggs of *Ascaris* sp. by at least 99,9 % (3 log₁₀) of viable stages.
- (iv) Designing a complete control programme including procedures for monitoring the process.
- (v) 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 plant as well as other critical control points shall be recorded and maintained so that the owner, operator or their

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representative and the competent authority can monitor the operation of the plant. Information relating to a process authorised under this point must be made available to the [F4appropriate authority] on request;

- (d) Representative samples of the manure taken during or immediately after processing at the plant in order to monitor the process must comply with the following standards:

Escherichia coli: $n = 5$, $c = 5$, $m = 0$, $M = 1\ 000$ in 1 g;

or

Enterococcaceae: $n = 5$, $c = 5$, $m = 0$, $M = 1\ 000$ in 1 g;

and

Representative samples of the manure taken during or on withdrawal from storage at the plant of production or the biogas or composting plant must comply with the following standards:

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

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

Processed manure or processed manure products not complying with the standards in this point shall be regarded as unprocessed;

- (e) They must be stored in such a way that once processed contamination or secondary infection and dampness is minimised. They must therefore be stored in:
- well-sealed and insulated silos or properly constructed storage sheds; or
 - properly sealed packs, such as plastic bags or 'big bags'.

Textual Amendments

- F4** Words in Annex 11 Ch. 1 Section 2 substituted (E.W.S.) (31.12.2020) by [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), regs. 1(2)(c), **13(59)(b)(ii)**

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CHAPTER II

REQUIREMENTS FOR CERTAIN ORGANIC FERTILISERS AND SOIL IMPROVERS

Section 1

Conditions for the production

1. Organic fertilisers and soil improvers, other than manure, digestive tract content, compost, milk, milk-based products, milk-derived products, colostrum, colostrum products and digestion residues from the transformation of animal by-products or derived products into biogas, shall be produced by:
 - (a) applying processing method 1 (pressure sterilisation), when Category 2 material is used as starting material;
 - (b) [^{F5}using processed animal protein, including processed animal protein produced in accordance with point B.1(b)(ii) of Section 1 of Chapter II of Annex X, which has been produced from Category 3 material in accordance with Section 1 of Chapter II of Annex X, or materials which have been subject to another treatment, where such materials may be used for organic fertilisers and soil improvers in accordance with this Regulation; or]
 - (c) by applying any of the processing methods 1 to 7, as set out in Chapter III of Annex IV, when Category 3 material is used as starting material which is not used for the production of processed animal protein.

Textual Amendments

- F5** Substituted by [Commission Regulation \(EU\) No 294/2013 of 14 March 2013 amending and correcting Regulation \(EU\) No 142/2011 implementing Regulation \(EC\) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive \(Text with EEA relevance\).](#)

2. Organic fertilisers and soil improvers which consist of or which have been produced from meat-and-bone meal derived from Category 2 material or from processed animal protein, shall be mixed, in a registered establishment or plant, with a sufficient minimum proportion of a component which is authorised by the competent authority of the [^{F6}constituent nation] where the product is to be applied to land, in order to exclude the subsequent use of the mixture for feeding purposes.

Textual Amendments

- F6** Words in Annex 11 Ch. 2 Section 1 point 2 substituted (E.W.S.) (31.12.2020) by [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\), regs. 1\(2\)\(c\), 13\(61\)](#)

3. The competent authority shall authorise the component referred to in point 2 according to the following:

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- (a) the component shall consist of lime, manure, urine, compost or digestion residues from the transformation of animal by-products into biogas or other substances, such as mineral fertilisers, which are not used in animal feed and which exclude the subsequent use of the mixture for feeding purposes according to good agricultural practice;
- (b) the component shall be determined based on an assessment of the climatic and soil conditions for the use of the mixture as a fertiliser, on indications that the component renders the mixture unpalatable to animals or it is otherwise effective in preventing misuse of the mixture for feeding purposes and in accordance with the requirements laid down in [F7retained EU law] or, where applicable, national legislation, for the protection of the environment regarding the protection of soil and groundwater.

Textual Amendments

- F7** Words in Regulation substituted (E.W.S.) (31.12.2020) by [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), regs. 1(2)(c), **13(2)(a)**

The competent authority shall make the list of the authorised components available to the [F8appropriate authority,] and to other [F9appropriate authorities] upon request.

Textual Amendments

- F8** Words in Annex 11 Ch. 2 Section 1 point 3 substituted (E.W.S.) (31.12.2020) by [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), regs. 1(2)(c), **13(62)(a)**
- F9** Words in Annex 11 Ch. 2 Section 1 point 3 substituted (E.W.S.) (31.12.2020) by [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), regs. 1(2)(c), **13(62)(b)**

4. However, the requirements referred to in point 2 shall not apply:
- (a) to organic fertilisers and soil improvers which are in ready-to-sell packages of not more than 50 kg in weight for use by the final consumer; or
 - (b) to organic fertilisers and soil improvers in big bags of not more than 1 000 kg in weight, on the packages of which it is indicated that the organic fertilisers are not destined to land to which farmed animals have access, provided that the competent authority of the [F10constituent nation] where the organic fertiliser or soil improver is to be applied to land, has authorised the use of such big bags on the basis of an assessment of the likelihood of a potential diversion of the materials to farms keeping animals or to land to which farmed animals have access.

Textual Amendments

- F10** Words in Annex 11 Ch. 2 Section 1 point 4(b) substituted (E.W.S.) (31.12.2020) by [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), regs. 1(2)(c), **13(63)**

5. Producers of organic fertilisers and soil improvers must ensure that decontamination of pathogens is carried out prior to their placing on the market, in accordance with:

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- Chapter I of Annex X, in the case of processed animal protein or derived products from Category 2 or Category 3 material,
- Section 3 of Chapter III of Annex V in the case of compost and digestion residues from the transformation of animal by-products or derived products into biogas.

Section 2

Storage and transport

After processing or transformation, organic fertilisers and soil improvers shall be properly stored and transported:

- (a) in bulk, under appropriate conditions that prevent contamination;
- (b) packaged or in big bags, in the case of organic fertilisers or soil improvers destined for sale to final users; or
- (c) in the case of storage on farm, in an adequate storage space to which no farmed animals have access.

F11 Section 3

Requirements for approval of establishments or plants

In order to be approved in accordance with Article 24(1)(f) of Regulation (EC) No 1069/2009, operators shall ensure that establishments or plants carrying out the activities referred to in point 1 of Section 1 meet the requirements laid down in Article 8 of this Regulation and:

- (a) have adequate facilities for storage of incoming ingredients to prevent cross-contamination and avoid contamination during storage;
- (b) dispose of unused animal by-products or derived products in accordance with Articles 13 and 14 of Regulation (EC) No 1069/2009.]

Textual Amendments

F11 Inserted by [Commission Regulation \(EU\) 2015/9 of 6 January 2015 amending Regulation \(EU\) No 142/2011 implementing Regulation \(EC\) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive \(Text with EEA relevance\).](#)

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