

ANNEX II

REQUIREMENTS FOR FEED BUSINESSES OTHER THAN AT THE LEVEL
OF PRIMARY PRODUCTION OF FEED REFERRED TO IN ARTICLE 5(1)[^{F1}DEFINITIONS

For the purposes of this Annex, the following definitions shall apply:

- (a) ‘ batch ’ means an identifiable quantity of feed determined to have common characteristics, such as origin, variety, type of packaging, packer, consignor or labelling, and, in the case of a production process, a unit of production from a single plant using uniform production parameters or a number of such units, when produced in continuous order and stored together;
- (b) [^{F2}‘ products derived from oils and fats ’ means any product derived directly or indirectly from crude or recovered oils and fats by oleochemical or biodiesel processing or distillation, chemical or physical refining, other than:
- the refined oil,
 - products derived from refined oil, and
 - feed additives;
- (c) ‘ fat blending ’ means manufacturing of compound feed or, in case of all components belonging to the same entry in PART C of the Annex to Commission Regulation (EU) No 68/2013 ⁽¹⁾ which are derived from the same plant or animal species, of feed materials by mixing crude oils, refined oils, animal fats, oils recovered from food business operators falling within the scope of Regulation (EC) No 852/2004 or products derived thereof to produce a blended oil or fat, with the exception of the:
- sole storage of consecutive batches, and
 - exclusive mixing of refined oils;
- (d) ‘ refined oil or fat ’ means oil or fat that has undergone the process of refining as referred to in No 53 of the glossary of processes listed in Part B of the Annex to Regulation (EU) No 68/2013.]]

Textual Amendments

- F2** Substituted by [Commission Regulation \(EU\) 2015/1905 of 22 October 2015 amending Annex II to Regulation \(EC\) No 183/2005 of the European Parliament and of the Council as regards the dioxin testing of oils, fats and products derived thereof \(Text with EEA relevance\)](#).

FACILITIES AND EQUIPMENT

1. Feed processing and storage facilities, equipment, containers, crates, vehicles and their immediate surroundings shall be kept clean, and effective pest control programmes shall be implemented.
2. The lay-out, design, construction and size of the facilities and equipment shall:
 - (a) permit adequate cleaning and/or disinfection;
 - (b) be such as to minimise the risk of error and to avoid contamination, cross-contamination and any adverse effects generally on the safety and quality of the products. Machinery coming into contact with feed shall be dried following any wet cleaning process.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 183/2005 of the European Parliament and of the Council, ANNEX II. (See end of Document for details)

3. Facilities and equipment to be used for mixing and/or manufacturing operations shall undergo appropriate and regular checks, in accordance with written procedures pre-established by the manufacturer for the products.
 - (a) All scales and metering devices used in the manufacture of feeds shall be appropriate for the range of weights or volumes to be measured and shall be tested for accuracy regularly.
 - (b) All mixers used in the manufacture of feeds shall be appropriate for the range of weights or volumes being mixed, and shall be capable of manufacturing suitable homogeneous mixtures and homogeneous dilutions. Operators shall demonstrate the effectiveness of mixers with regard to homogeneity.
4. Facilities must have adequate natural and/or artificial lighting.
5. Drainage facilities must be adequate for the purpose intended; they must be designed and constructed to avoid the risk of contamination of feedingstuffs.
6. Water used in feed manufacture shall be of suitable quality for animals; the conduits for water shall be of an inert nature.
7. Sewage, waste and rainwater shall be disposed of in a manner which ensures that equipment and the safety and quality of feed is not affected. Spoilage and dust shall be controlled to prevent pest invasion.
8. Windows and other openings must, where necessary, be proofed against pests. Doors must be close-fitting and proofed against pests when closed.
9. Where necessary, ceilings and overhead fixtures must be designed, constructed and finished to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable moulds and the shedding of particles that can affect the safety and quality of feed.
10. [^{F3}Establishments carrying out one or more of the following activities to place on the market products for use in feed are subject to approval by the appropriate authority in such a manner as the appropriate authority may prescribe—
 - (a) processing of crude vegetable oil except those under the scope of Regulation (EC) No 852/2004;
 - (b) oleochemical manufacturing of fatty acids;
 - (c) manufacturing of biodiesel;
 - (d) fat blending.]

Textual Amendments

F3 Words in [Annex 2](#) substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **61(a)**; 2020 c. 1, Sch. 5 para. 1(1)

PERSONNEL

Feed businesses must have sufficient staff possessing the skills and qualifications necessary for the manufacture of the products concerned. An organisation chart setting out the qualifications (e.g. diplomas, professional experience) and responsibilities of the supervisory staff must be drawn up and made available to the competent authorities responsible for inspection. All the staff must be informed clearly in writing of their

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 183/2005 of the European Parliament and of the Council, ANNEX II. (See end of Document for details)

duties, responsibilities and powers, especially when any change is made, in such a way as to obtain the desired product quality.

PRODUCTION

1. A qualified person responsible for production must be designated.
2. Feed business operators must ensure that the different stages of production are carried out according to pre-established written procedures and instructions aimed at defining, checking and mastering the critical points in the manufacturing process.
3. Technical or organisational measures must be taken to avoid or minimise, as necessary, any cross-contamination and errors. There must be sufficient and appropriate means of carrying out checks in the course of manufacture.
4. The presence of prohibited feed undesirable substances and other contaminants in relation to human or animal health shall be monitored, and appropriate control strategies to minimise the risk shall be put in place.
5. Waste and materials not suitable as feed should be isolated and identified. Any such materials containing hazardous levels of veterinary drugs, contaminants or other hazards shall be disposed of in an appropriate way and not used as feed.
6. Feed business operators shall take adequate measures to ensure effective tracing of the products.
7. [F¹Fat blending establishments placing products intended for feed on the market shall keep all products intended for feed physically separated from products intended for other purposes unless the latter products comply:
 - with the requirements of this Regulation or of Article 4(2) of Regulation (EC) No 852/2004, and
 - with Annex I to Directive 2002/32/EC of the European Parliament and the Council ⁽²⁾ .]
8. [F² The labelling of the products shall clearly indicate whether they are intended for feed or other purposes. If a certain batch of a product is declared not intended for feed use, this declaration shall not be subsequently altered by an operator at a later stage of the chain.
9. The labelling of feed materials according to Article 16 of Regulation (EC) No 767/2009 of the European Parliament and of the Council ⁽³⁾ should use, where available, the denominations as laid in Regulation (EU) No 68/2013.]

QUALITY CONTROL

1. Where appropriate, a qualified person responsible for quality control must be designated.
2. Feed businesses must, as part of a quality control system, have access to a laboratory with adequate staff and equipment.
3. A quality control plan must be drawn up in writing and implemented, to include, in particular, checks on the critical points in the manufacturing process, sampling procedures and frequencies, methods of analysis and their frequency, compliance with the specifications – and the destination in the event of non-compliance – from processed materials to final products.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 183/2005 of the European Parliament and of the Council, ANNEX II. (See end of Document for details)

4. Documentation relating to the raw materials used in final products must be kept by the manufacturer in order to ensure traceability. Such documentation must be available to the competent authorities for a period appropriate for the use to which the products are placed on the market. In addition, samples of ingredients and of each batch of products manufactured and placed on the market or of each specific portion of production (in the case of continuous production) must be taken in sufficient quantity using a procedure pre-established by the manufacturer and be retained, in order to ensure traceability (on a regular basis in the case of manufacture solely for the manufacturer's own needs). The samples must be sealed and labelled for easy identification; they must be stored under conditions which prevent any abnormal change in the composition of the sample or any adulteration. They must be kept at the disposal of the competent authorities for a period appropriate to the use for which the feed is placed on the market. In the case of feedingstuffs for animals not kept for food production, the manufacturer of the feedingstuff must only keep samples of the finished product.

[^{F1}[^{F2}DIOXIN MONITORING FOR OILS, FATS AND DERIVED PRODUCTS]

1. Feed business operators placing on the market fats, oils or products derived thereof intended for use in feed, including compound feed, shall analyse those products in accredited laboratories for the sum of dioxins and dioxin-like PCBs in accordance with Commission Regulation (EC) No 152/2009 ⁽⁴⁾.
2. [^{F2}To supplement the feed business operator's HACCP system, the analyses referred to in point 1 shall be carried out with at least the following frequencies (if not further specified, a batch of products to be analysed shall not exceed 1 000 tonnes):
 - (a) Feed business operators processing crude vegetable fats and oils:
 - (i) 100 % of the batches of the products derived from oils and fats of vegetable origin, except for the following:
 - glycerine,
 - lecithin,
 - gums,
 - products referred to in (ii);
 - (ii) acid oils from chemical refining, soap stocks, used filter aids, used bleaching earth and incoming batches of crude coconut oil shall be analysed and documented as part of the HACCP system.
 - (b) Feed business operators producing animal fat including animal fat processors:
 - (i) one representative analysis per 5 000 tonnes with a minimum of one representative analysis per year of animal fat and products derived thereof belonging to category 3 material, as referred to in Article 10 of Regulation (EC) No 1069/2009 of the European Parliament and of the Council ⁽⁵⁾ or from an establishment approved in accordance with Article 4 of Regulation (EC) No 853/2004 of the European Parliament and of the Council ⁽⁶⁾.
 - (c) Feed business operators producing fish oil:
 - (i) 100 % of the batches of fish oil if it is produced from:
 - products derived from fish oil other than refined fish oil;

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 183/2005 of the European Parliament and of the Council, ANNEX II. (See end of Document for details)

- fisheries with no monitoring history, of unspecified origin or from the Baltic Sea;
 - fish by-products from establishments manufacturing fish for human consumption that are not [^{F4}approved under retained EU law];
 - blue whiting or menhaden;
- (ii) 100 % of the outgoing batches of products derived from fish oil other than refined fish oil;
- (iii) one representative analysis per 2 000 tonnes as regards fish oil not referred to in (i);
- (iv) fish oil decontaminated by an officially approved treatment as referred to in Annex VIII of Regulation (EC) No 767/2009 and in Commission Regulation (EU) 2015/786 ⁽⁷⁾ shall be analysed and documented as part of the HACCP system.
- (d) Oleochemical industry placing feed on the market:
- (i) 100 % of incoming batches of animal fats not covered by point (b) or (h), fish oil not covered by point (c) or (h), oils and fats recovered from food business operators falling within the scope of Regulation (EC) No 852/2004 and of blended fats and oils;
 - (ii) 100 % of the batches of products derived from oils and fats placed as feed on the market, except for the following:
 - glycerine,
 - pure distilled fatty acids from splitting,
 - products referred to in (iii);
 - (iii) crude fatty acids from splitting, fatty acids esterified with glycerol, mono and diglycerides of fatty acids, salts of fatty acids and incoming batches of crude coconut oil shall be analysed and documented as part of the HACCP system.
- (e) Biodiesel industry placing feed on the market:
- (i) 100 % of incoming batches of animal fats not covered by point (b) or (h), fish oil not covered by point (c) or (h), oils and fats recovered from food business operators falling within the scope of Regulation (EC) No 852/2004 and of blended fats and oils;
 - (ii) 100 % of the batches of products derived from oils and fats placed as feed on the market, except for the following:
 - glycerine,
 - lecithin,
 - gums,
 - products referred to in (iii);
 - (iii) acid oils from chemical refining, soap stocks and crude coconut oil shall be analysed and documented as part of the HACCP system.
- (f) Fat blending establishments:

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 183/2005 of the European Parliament and of the Council, ANNEX II. (See end of Document for details)

- (i) 100 % of incoming batches of crude coconut oil, animal fats not covered by point (b) or (h), fish oil not covered by point (c) or (h), oils and fats recovered from food business operators falling within the scope of Regulation (EC) No 852/2004, blended fats and oils and products derived from oils and fats, except for the following:
 - glycerine,
 - lecithin,
 - gums,
 - products referred to in (ii);
 - (ii) acid oils from chemical refining, crude fatty acids from splitting, pure distilled fatty acids from splitting and soap stocks shall be analysed and documented as part of the HACCP system;
 - or
 - (iii) 100 % of the batches of blended fats and oils intended for feed.
The feed business operator shall declare to the competent authority which alternative he chooses.
- (g) Producers of compound feed for food producing animals other than those covered by point (f):
- (i) 100 % of incoming batches of crude coconut oil, animal fats not covered by point (b) or (h), fish oil not covered by point (c) or (h), oils and fats recovered from food business operators falling within the scope of Regulation (EC) No 852/2004, blended fats and oils and products derived from oils and fats, except for the following:
 - glycerine,
 - lecithin,
 - gums,
 - products referred to in (ii);
 - (ii) acid oils from chemical refining, crude fatty acids from splitting, pure distilled fatty acids from splitting; filter aids, bleaching earth and soap stocks shall be analysed and documented as part of the HACCP system;
 - (iii) 1 % of the batches as regards manufactured compound feed containing products referred to in (i) and (ii).
- (h) ^{F5}Importers placing the following feed on the market:
- (i) 100 % of imported batches of crude coconut oil, animal fats, fish oils, oils and fats recovered from food business operators, blended fats and oils, tocopherols extracted from vegetable oil and tocopheryl acetate made thereof and products derived from oils and fats, except for the following:
 - glycerine,
 - lecithin,
 - gums,
 - products referred to in (ii);

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 183/2005 of the European Parliament and of the Council, ANNEX II. (See end of Document for details)

- (ii) acid oils from chemical refining, crude fatty acids from splitting, pure distilled fatty acids from splitting and soap stocks shall be analysed and documented as part of the HACCP system.]]
3. If it can be demonstrated that a homogenous consignment is bigger than the maximum batch size according to point 2 and that it has been sampled in a representative way, then the results of the analysis of the appropriately drawn and sealed sample will be considered acceptable.
4. [F² Where a feed business operator has documentary proof that a batch of a product or all components of a batch of a product as referred to under point 2 entering his establishment has already been analysed at an earlier stage of production, processing or distribution, the feed business operator shall be released from the obligation to analyse this batch.
5. Any batch of products analysed in accordance with point 2 shall be accompanied by documentary proof that these products, or all of its constituent components, have been analysed or have been submitted for analysis to an accredited laboratory referred to in point 1, except for the batches of products referred to in point 2(a)(ii), (b)(i), (c)(iii), (c)(iv), (d)(iii), (e)(iii), (f)(ii), (g)(ii) and (h)(ii).
The proof of analysis shall unambiguously link the delivery and the batch or batches tested. This link shall be described in the documented traceability system in place at the premises of the supplier. In particular, when the delivery is obtained from more than one batch or component, the documentary proof to be provided shall be a proof for each of the components of the delivery. In the case where the testing is performed on the outgoing product, the proof that the product has been analysed shall be the analytical report.
Any delivery of products as referred to under point 2(b) (i) or c (iii) shall be accompanied by a proof that these products are in compliance with the requirements of point 2(b)(i) or (c)(iii). If required, the proof of analysis that include the batch or batches delivered must be consigned to the consignee when the operator receives the analysis from the authorised laboratories.
6. If all incoming batches of products referred to in point 2(g)(i) entering a production process have been analysed in accordance with the requirements of this Regulation and if it can be assured that the production process, handling and storage does not increase the dioxin contamination, the feed business operator shall be released from the obligation to analyse the outgoing product and instead analyse it according to the HACCP system.]
7. [F⁶Where a feed business operator mandates a laboratory to perform an analysis, as referred to in point 1 the feed business operator must instruct the laboratory to communicate the results of that analysis to the competent authority in case the dioxin limits set out in points 1 and 2 of Section 5 of Annex 1 to Directive 2002/32/EC are exceeded.]
F⁷
Feed business operators shall inform the competent authority F⁸... if they mandate a laboratory located in a third country. Evidence must be provided that the laboratory performs the analysis in accordance with Regulation (EC) No 152/2009.
8. The dioxin testing requirements shall be reviewed by 16 March 2014 .]

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 183/2005 of the European Parliament and of the Council, ANNEX II. (See end of Document for details)

Textual Amendments

- F4** Words in Annex 2 substituted (31.12.2020) by The Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654), regs. 1, **61(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F5** Inserted by Commission Regulation (EU) 2015/1905 of 22 October 2015 amending Annex II to Regulation (EC) No 183/2005 of the European Parliament and of the Council as regards the dioxin testing of oils, fats and products derived thereof (Text with EEA relevance).
- F6** Words in Annex 2 substituted (31.12.2020) by The Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654), regs. 1, **61(b)(ii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)
- F7** Words in Annex 2 omitted (31.12.2020) by The Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654), regs. 1, **61(b)(ii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)
- F8** Words in Annex 2 omitted (31.12.2020) by virtue of The Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654), regs. 1, **61(b)(ii)(cc)**; 2020 c. 1, Sch. 5 para. 1(1)

STORAGE AND TRANSPORT

1. Processed feeds shall be separated from unprocessed feed materials and additives, in order to avoid any cross-contamination of the processed feed; proper packaging materials shall be used.
2. Feeds shall be stored and transported in suitable containers. They shall be stored in places designed, adapted and maintained in order to ensure good storage conditions, to which only persons authorised by the feed business operators have access.
3. Feeds shall be stored and transported in such a way as to be easily identifiable, in order to avoid any confusion or cross-contamination and to prevent deterioration.
4. Containers and equipment used for the transport, storage, conveying, handling and weighing of feed shall be kept clean. Cleaning programmes shall be introduced, and traces of detergents and disinfectants shall be minimised.
5. Any spoilage shall be minimised and kept under control to reduce pest invasion.
6. Where appropriate, temperatures shall be kept as low as possible to avoid condensation and spoilage.
7. ^{[F1}Containers which are to serve for storage or transport of blended fats, oils of vegetable origin or products derived thereof intended for use in feed shall not be used for the transport or storage of products other than these unless the products comply with the requirements of:
 - this Regulation or of Article 4(2) of Regulation (EC) No 852/2004, and
 - Annex I to Directive 2002/32/EC.
 They shall be kept separate from any other cargo where there is a risk of contamination. Where this separate use is not possible, the containers shall be efficiently cleaned so as to remove any trace of product if those containers were previously used for products not meeting the requirements of:
 - this Regulation or of Article 4(2) of Regulation (EC) No 852/2004, and
 - Annex I to Directive 2002/32/EC.
 Animal fats of category 3, as laid down in Article 10 of Regulation (EC) No 1069/2009, intended for use in feed shall be stored and transported in line with that Regulation.]

RECORD-KEEPING

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 183/2005 of the European Parliament and of the Council, ANNEX II. (See end of Document for details)

1. All feed business operators, including those who act solely as traders without ever holding the product in their facilities, shall keep in a register relevant data, comprising details of purchase, production and sales for effective tracing from receipt to delivery, including export to the final destination.
2. Feed business operators, except those who act solely as dealers without ever holding the product in their facilities, shall keep in a register:
 - (a) Documentation relating to the manufacturing process and controls.

Feed businesses must have a system of documentation designed to define and ensure mastery of the critical points in the manufacturing process and to establish and implement a quality control plan. They must keep the results of the relevant controls. This set of documents must be kept so that it is possible to trace the manufacturing history of each batch of products put into circulation and to establish responsibility, if complaints arise.
 - (b) Documentation relating to traceability, in particular:
 - (i) for feed additives:
 - the nature and quantity of the additives produced, the respective dates of manufacture and, where appropriate, the number of the batch or of the specific portion of production, in the case of continuous manufacture,
 - the name and address of the establishment to which the additives were delivered, the nature and quantity of the additives delivered and, where appropriate, the number of the batch or of the specific portion of production, in the case of continuous manufacture;
 - (ii) for products covered by Directive 82/471/EEC:
 - the nature of the products and the quantity produced, the respective dates of manufacture and, where appropriate, the number of the batch or of the specific portion of production, in the case of continuous manufacture,
 - the name and address of the establishments or users (establishments or farmers) to whom these products have been delivered, together with details of the nature and quantity of the products delivered and, where appropriate, the number of the batch or of the specific portion of production, in the case of continuous manufacture;
 - (iii) for premixtures:
 - the name and address of the manufacturers or suppliers of additives, the nature and quantity of the additives used and, where appropriate, the number of the batch or of the specific portion of production, in the case of continuous manufacture,
 - the date of manufacture of the premixture and the batch number where appropriate,
 - the name and address of the establishment to which the premixture is delivered, the delivery date, the nature

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 183/2005 of the European Parliament and of the Council, ANNEX II. (See end of Document for details)

and quantity of the premixture delivered, and the batch number where appropriate.

- (iv) for compound feedingstuffs/feed materials:
- the name and address of additive/premixture manufacturers or suppliers, the nature and quantity of the premixture used, with the batch number where appropriate,
 - the name and address of the suppliers of the feed materials and complementary feeds and the delivery date,
 - the type, quantity and formulation of the compound feed,
 - the nature and quantity of feed materials or compound feedingstuffs manufactured, together with the date of manufacture, and the name and address of the buyer (e.g. farmer, other feed business operators).

COMPLAINTS AND PRODUCT RECALL

1. Feed business operators shall implement a system for registering and processing complaints.
2. They shall put in place, where this proves necessary, a system for the prompt recall of products in the distribution network. They shall define by means of written procedures the destination of any recalled products, and before such products are put back into circulation they must undergo a quality-control reassessment.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 183/2005 of the European Parliament and of the Council, ANNEX II. (See end of Document for details)

- (1) [^{F1} [^{F2} Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials (OJ L 29, 30.1.2013, p. 1).]]
- (2) [^{F1} OJ L 140, 30.5.2002, p. 10.]
- (3) [^{F2} Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed (OJ L 229, 1.9.2009, p. 1).;]
- (4) [^{F1} OJ L 54, 26.2.2009, p. 1.]
- (5) [^{F1} [^{F2} Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).]]
- (6) [^{F1} [^{F2} 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 (OJ L 139, 30.4.2004, p. 55).]]
- (7) [^{F1} [^{F2} Commission Regulation (EU) 2015/786 of 19 May 2015 defining acceptability criteria for detoxification processes applied to products intended for animal feed as provided for in Directive 2002/32/EC of the European Parliament and of the Council (OJ L 125, 21.5.2015, p. 10).]]

Textual Amendments

- F1** Inserted by Commission Regulation (EU) No 225/2012 of 15 March 2012 amending Annex II to Regulation (EC) No 183/2005 of the European Parliament and of the Council as regards the approval of establishments placing on the market, for feed use, products derived from vegetable oils and blended fats and as regards the specific requirements for production, storage, transport and dioxin testing of oils, fats and products derived thereof (Text with EEA relevance).
- F2** Substituted by Commission Regulation (EU) 2015/1905 of 22 October 2015 amending Annex II to Regulation (EC) No 183/2005 of the European Parliament and of the Council as regards the dioxin testing of oils, fats and products derived thereof (Text with EEA relevance).

Changes to legislation:

There are currently no known outstanding effects for the Regulation (EC) No 183/2005 of the European Parliament and of the Council, ANNEX II.