

II

(Non-legislative acts)

REGULATIONS

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)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 183/2005 of the European Parliament and the Council of 12 January 2005 laying down requirements for feed hygiene ⁽¹⁾, and in particular Article 27(b) and (f) thereof,

Whereas:

- (1) Regulation (EC) No 183/2005 lays down general rules on feed hygiene, conditions and arrangements to ensure that processing conditions to minimise and control potential hazards are respected. Feed business establishments are to be registered with or approved by the competent authority. Additionally, feed business operators lower down the feed chain have the obligation to source feed only from establishments which are registered or approved.
- (2) 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 ⁽²⁾ requires feed placed on the market to be safe and explicitly labelled with the respective type of feed. Additionally, Commission Regulation (EU) No 575/2011 of 16 June 2011 on the Catalogue of feed materials ⁽³⁾ lists detailed descriptions for specific feed materials to be used for labelling purposes.
- (3) The interplay of these requirements should ensure traceability and a high level of consumer protection throughout the feed and food chain.

- (4) Official controls and controls carried out by feed business operators have shown that certain oils and fats and products derived thereof not intended for feed use have been used as feed materials resulting in feed exceeding the maximum dioxin levels laid down in Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed ⁽⁴⁾. As a consequence, food derived from animals fed with contaminated feed may pose a public health risk. In addition, financial losses may result from the withdrawal of contaminated feed and food from the market.

- (5) To enhance feed hygiene and without prejudice to the competence of the Member States as laid down in Article 10(2) of Regulation (EC) No 183/2005, establishments further processing crude vegetable oils, manufacturing products derived from oils of vegetable origin and blending fats should be subject to approval in accordance with that Regulation if these products are intended for use in feed.

- (6) Specific requirements for the production, labelling, storage and transport of those feed materials should be provided for to take into account the experience gained from the application of hazard analysis and critical control points (HACCP)-based systems.

- (7) A reinforced dioxin monitoring would facilitate the detection of non-compliances and the enforcement of feed law. It is necessary to provide for an obligation for feed business operators to test fats, oils and products derived thereof for dioxin and dioxin-like PCBs in order to reduce the risk that contaminated products enter the food chain and, therefore, support the strategy to reduce the exposure to dioxin of EU citizens. The risk of dioxin contamination should be the basis for the establishment of the monitoring plan.

⁽¹⁾ OJ L 35, 8.2.2005, p. 1.

⁽²⁾ OJ L 229, 1.9.2009, p. 1.

⁽³⁾ OJ L 159, 17.6.2011, p. 25.

⁽⁴⁾ OJ L 140, 30.5.2002, p. 10.

The responsibility to place safe feed on the market is with the feed business operators. Thus the costs for the analysis should be fully borne by them. Detailed provisions on sampling and analysis not contained in this Regulation should remain within the competence of the Member States. Furthermore, Member States are encouraged to focus on the controls of feed business operators that are not under the scope of the dioxin monitoring but that obtain the products mentioned above.

- (8) The mandatory risk-based monitoring system must not affect the feed business operator's duty to comply with the requirements of Union legislation on feed hygiene. It should be integrated into good hygiene practices and the HACCP-based system. This should be verified by the competent authority in the context of the approval of the feed business operator. The operator's regular review of his own risk assessment should consider the findings of the dioxin monitoring.
- (9) Laboratories performing dioxin analyses should be obliged to report results exceeding the maximum permitted limits provided for in Directive 2002/32/EC not only to the feed business operator but also to the competent authority in order to improve transparency; this obligation does not exempt the feed business operator from his obligation to inform the competent authority.
- (10) In order to verify the effectiveness of the provisions concerning the mandatory dioxin monitoring and its

integration in the feed business operators HACCP system, a review after two years should be provided for.

- (11) Sufficient time should be allowed to give competent authorities and feed business operators the possibility to adapt to the provisions of this Regulation.
- (12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 183/2005 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 16 September 2012.

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

Done at Brussels, 15 March 2012.

For the Commission
The President
José Manuel BARROSO

ANNEX

Annex II to Regulation (EC) No 183/2005 is amended as follows:

(1) the following section is inserted after the title of Annex II:

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) "products derived from vegetable oils" means any product derived from crude or recovered vegetable oils by oleochemical or biodiesel processing or distillation, chemical or physical refining, other than the refined oil;
- (c) "fat blending" means the mixing of crude oils, refined oils, animal fats, oils recovered from the food industry and/or products derived thereof to produce a blended oil or fat, with the exception of solely the storage of consecutive batches.;

(2) the following point is added in the section headed 'FACILITIES AND EQUIPMENT':

10. Establishments carrying out one or more of the following activities to place on the market products for use in feed shall be subject to approval in accordance with Article 10(3):

- (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.;

(3) the following points are added in the section headed 'PRODUCTION':

7. Fat 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 (*).

8. The labelling of the products shall clearly indicate whether they are intended for feed or other purposes. If the producer declares that a certain batch of a product is not intended for feed or food use, this declaration shall not be subsequently altered by an operator at a later stage of the chain.

(*) OJ L 140, 30.5.2002, p. 10.;

(4) the following section is added after the section headed 'QUALITY CONTROL':

DIOXIN MONITORING

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 (*).

2. 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:

- (a) processors of crude vegetable oils:
 - (i) 100 % of the batches of crude coconut oils shall be analysed. A batch may comprise at the maximum 1 000 tonnes of these products;
 - (ii) 100 % of the batches of the products derived from vegetable oils except glycerol, lecithin and gums intended for feed shall be analysed. A batch may comprise at the maximum 1 000 tonnes of these products.

- (b) producers of animal fat:
- one representative analysis per 2 000 tonnes of animal fat and products derived thereof belonging to category 3, as laid down in Article 10 of Regulation (EC) No 1069/2009 of the European Parliament and of the Council (**).
- (c) operators of fish oil:
- (i) 100 % of the batches of fish oil shall be analysed if it is produced from:
- products derived from crude fish oil other than refined fish oil,
 - 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 EU approved,
 - blue whiting or menhaden,
- a batch may comprise at the maximum 1 000 tonnes of fish oil;
- (ii) 100 % of the outgoing batches of products derived from crude fish oil other than refined fish oil shall be analysed. A batch may comprise at the maximum 1 000 tonnes of these products;
- (iii) one representative analysis per 2 000 tonnes shall be carried out, as regards fish oil not referred to in (i);
- (iv) fish oil decontaminated by an officially approved treatment shall be analysed according to the HACCP principles in compliance with Article 6.
- (d) oleochemical and biodiesel industry:
- (i) 100 % of the incoming batches of crude coconut oils and products derived from vegetable oils except glycerol, lecithin and gums, animal fats not covered by (b), fish oil not covered by (c), oils recovered from the food industry and blended fats intended for feed shall be analysed. A batch may comprise at the maximum 1 000 tonnes of these products;
- (ii) 100 % of the batches of products derived from the processing of the products mentioned in (i) except glycerol, lecithin and gums shall be analysed.
- (e) fat blending establishments:
- (i) 100 % of the incoming batches of crude coconut oils and products derived from vegetable oils except glycerol, lecithin and gums, animal fats not covered by (b), fish oil not covered by (c), oils recovered from the food industry and blended fats intended for feed shall be analysed. A batch may comprise at the maximum 1 000 tonnes of these products;
- or
- (ii) 100 % of the batches of blended fats intended for feed shall be analysed. A batch may comprise at the maximum 1 000 tonnes of these products.
- The feed business operator shall declare to the competent authority in the context of his risk assessment which alternative he chooses.
- (f) producers of compound feed for food producing animals other than those mentioned in (e):
- (i) 100 % of the incoming batches of crude coconut oils and products derived from vegetable oils except glycerol, lecithin and gums, animal fats not covered by (b), fish oil not covered by (c), oils recovered from the food industry and blended fats intended for feed shall be analysed. A batch may comprise at the maximum 1 000 tonnes of these products;
- (ii) a sampling frequency of 1 % of the batches shall be carried out as regards manufactured compound feed containing products referred to in (i).
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. Where a feed business operator proves that a batch of a product or all components of a batch as referred to under point 2 entering his operation has already been analysed at an earlier stage of production, processing or distribution, or are in compliance with the requirements of points 2(b) or (c)(iii) the feed business operator shall be released from the obligation to analyse this batch and shall analyse it according to the general HACCP principles in compliance with Article 6.
5. Any delivery of products as referred to under points 2(d)(i), (e)(i) and (f)(i) shall be accompanied by a proof that these products or all components thereof have been analysed or are in compliance with the requirements of points 2(b) or (c)(iii).
6. If all incoming batches of products mentioned in points 2(d)(i), (e)(i) and (f)(i) entering a production process have been analysed in line 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 final product and shall analyse it according to the general HACCP principles in compliance with Article 6.
7. Where a feed business operator mandates a laboratory to perform an analysis, as referred to in point 1 he shall 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 V of Annex I to Directive 2002/32/EC are exceeded.

Where a feed business operator mandates a laboratory which is located in a Member State other than the feed business operator ordering the analysis he shall instruct the laboratory to report to its competent authority, which shall inform the competent authority of the Member State where the feed business operator is located.

Feed business operators shall inform the competent authority of the Member State where they are located 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.

(*) OJ L 54, 26.2.2009, p. 1.

(**) OJ L 300, 14.11.2009, p. 1.;

- (5) the following point is added in the section headed 'STORAGE AND TRANSPORT':

7. 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.