

**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)**

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 of the Council of 12 January 2005 laying down requirements for feed hygiene <sup>(1)</sup>, and in particular Article 27 thereof,

Whereas:

- (1) Regulation (EC) No 183/2005 lays down general rules on feed hygiene, as well as conditions and arrangements to ensure that processing conditions to minimise and control potential hazards are respected. It also provides that feed business establishments are to be registered with or approved by the competent authority. In addition, feed business operators lower down the feed chain are required to source feed only from registered or approved establishments.
- (2) Annex II to Regulation (EC) No 183/2005 sets out requirements for feed businesses other than at the level of primary production. In particular, it requires that the dioxin testing requirements set out in that Annex are to be reviewed by 16 March 2014.
- (3) The definition of products derived from vegetable oils set out in Annex II to Regulation (EC) No 183/2005 should be amended in order to clarify that products derived from refined oil and feed additives authorised in accordance with Regulation (EC) No 1831/2003 of the European Parliament and of the Council <sup>(2)</sup> are not covered by that definition.
- (4) The definition of fat blending set out in Annex II to Regulation (EC) No 183/2005 should also be amended in order to clarify the difference between fat blending and the solely storage of consecutive batches of fats and oils without mixing them. Furthermore, it should be clarified when blended fats are considered a compound feed and when they are feed materials.
- (5) As it is prudent to detect products that are clearly contaminated with dioxin at the point of entry in the feed chain, it should be clarified that the requirements concerning dioxin monitoring set out in Annex II to Regulation (EC) No 183/2005 apply to all feed business operators placing feed on the market, including importers.
- (6) In order to ensure traceability of and proper information about the feed, compliance with the labelling requirements established in Regulation (EC) No 767/2009 of the European Parliament and of the Council <sup>(3)</sup> and in particular the denominations, specifications and numbers in Commission Regulation (EU) No 68/2013 <sup>(4)</sup> should be highlighted.

<sup>(1)</sup> OJ L 35, 8.2.2005, p. 1.

<sup>(2)</sup> Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29).

<sup>(3)</sup> 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).

<sup>(4)</sup> Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials (OJ L 29, 30.1.2013, p. 1).

- (7) It is necessary that the requirement of a representative analysis per large quantity is performed on the basis of a representative sample. Therefore it is appropriate that incremental samples to form the aggregate sample are taken at regular intervals, e.g. at least one incremental sample every 50 tonnes, which is in line with the provisions on sampling as provided for in Commission Regulation (EC) No 152/2009 <sup>(1)</sup>.
- (8) The results of the dioxin testing established by Regulation (EC) No 183/2005, the reports <sup>(2)</sup> of the audits of the Commission's Food and Veterinary Office and the fact that no non-compliant sample of products derived from vegetable oils, except fatty acid distillates from physical refining and deodistillates, were notified to the Rapid Alert System for Food and Feed <sup>(3)</sup> show that those products do not have a high risk for dioxin contamination. As a result, it is appropriate to alleviate the requirements as regards the 100 % dioxin testing for these products set out in Annex II to Regulation (EC) No 183/2005.
- (9) In order to clarify the responsibility for the dioxin testing of imported products, a specific provision should be set out in Annex II to Regulation (EC) No 183/2005. This should also assure that imported products have the same safety level of those produced in the Union.
- (10) The system established by Annex II to Regulation (EC) No 183/2005 in order to prove by means of a certificate that the mandatory analysis of a specific batch has been undertaken should be amended by several specifications concerning the tasks for the different feed business operators in order to clarify the responsibilities of the various actors in the feed chain.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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 twentieth day following that of its publication in the *Official Journal of the European Union*.

Point 2(h) in paragraph (3)(b) of the Annex to this Regulation shall apply from 23 April 2016.

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

Done at Brussels, 22 October 2015.

*For the Commission*  
*The President*  
Jean-Claude JUNCKER

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<sup>(1)</sup> Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

<sup>(2)</sup> [http://ec.europa.eu/food/fvo/audit\\_reports/index.cfm](http://ec.europa.eu/food/fvo/audit_reports/index.cfm): Audit numbers 2013-6748, 2013-6749, 2013-6750, 2013-6751, 2013-6752, 2013-6753, 2014-7036, 2014-7037 and 2014-7038

<sup>(3)</sup> [http://ec.europa.eu/food/safety/rasff/portal/index\\_en.htm](http://ec.europa.eu/food/safety/rasff/portal/index_en.htm)

## ANNEX

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

(1) in the Section headed 'DEFINITIONS', points (b) and (c) are replaced by the following points (b) and (c) and the following point (d) is added:

'(b) "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 (\*) 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.

(\*) 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) in Section headed 'PRODUCTION' point 8 is replaced by the following and the following point 9 is added:

'8. 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 (\*\*) should use, where available, the denominations as laid in Regulation (EU) No 68/2013.

(\*\*) 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).;

(3) the Section headed 'DIOXIN MONITORING' is amended as follows:

(a) the heading of that Section is replaced by the following:

'DIOXIN MONITORING FOR OILS, FATS AND DERIVED PRODUCTS';

(b) point 2 is replaced by the following:

'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 (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 (\*) or from an establishment approved in accordance with Article 4 of Regulation (EC) No 853/2004 of the European Parliament and of the Council (\*\*).
- (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;
    - 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;
  - (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 (\*\*\*) 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:
- (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) 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);
  - (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.

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- (\*) 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).
- (\*\*) 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).
- (\*\*\*) 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).;

(c) points 4, 5 and 6 are replaced by the following:

- ‘4. 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.’
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