# 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 (Text with EEA relevance)

## 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

## (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[(1)], and in particular Article 10(3) thereof,

Having regard to Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed[(2)], and in particular the second indent of Article 8(2) thereof,

Whereas:

(1) Directive 2002/32/EC provides that the use of products intended for animal feed which contain levels of undesirable substances exceeding the maximum levels laid down in Annex I of that Directive is prohibited.

(2) Directive 2002/32/EC provides also that Member States are to ensure that measures are taken to guarantee the correct application of any acceptable detoxification process on products intended for animal feed and the conformity of those detoxified products with the provisions of Annex I of that Directive. In order to ensure a uniform assessment across the European Union of the acceptability of detoxification processes, it is appropriate that acceptability criteria for detoxification processes are established at Union level as a complement to the criteria provided for products intended for animal feed which have undergone such processes.

(3) The acceptability criteria for detoxification processes should ensure that the detoxified feed does not endanger animal and public health and the environment and that the characteristics of the feed are not adversely altered by the detoxification process. The compliance of a detoxification process with those criteria shall be scientifically assessed by the European Food Safety Authority (EFSA) on a request from the Commission.

**Changes to legislation:** *There are outstanding changes not yet made to Commission Regulation (EU) 2015/786. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(4) Detoxification of contaminated materials, according to the definition in Article 3(2)(p) of Regulation (EC) No 767/2009 of the European Parliament and of the Council[(3)], can be performed by a physical, chemical or (micro) biological detoxification process.

(5) It is necessary to exclude from the scope of this Regulation the simple detoxification processes through which the contamination by an undesirable substance is reduced or eliminated solely by the usual refining process, cleaning, sorting or mechanical removal of contaminants or certain parts of the contaminated feed as such processes are part of the usual production process.

(6) A functional group of additives which suppress or reduce the absorption of mycotoxins, promote their excretion or modify their mode of action and thereby mitigate possible adverse effects of mycotoxins on animal and public health has been added in the category of technological additives in the Annex I to Regulation (EC) No 1831/2003 of the European Parliament and of the Council[(4)]. As these additives do not change the level of the undesirable substance in the feed, the feed is not detoxified by the use of these additives and consequently, the use of these additives does not fall in the scope of this Regulation. Furthermore, as such products are not intended to be used for non-compliant feed, they do not fall in the scope of this Regulation.

(7) In accordance with Article 10(3) of Regulation (EC) No 183/2005, the detoxification process should be performed in an establishment approved for that purpose. To ensure a correct and effective application of the detoxification process, the detoxification process should be accepted by the competent authority to be performed in the relevant establishment.

(8) It may occur that a very large quantity of feed is contaminated with a contaminant for which a decontamination process exists but which has not yet been assessed by EFSA. In order to avoid that such a large quantity of feed needs to be unnecessarily destroyed, it may be appropriate in such exceptional situations to request EFSA to provide an assessment of the detoxification process on short notice, e.g. 10 working days. In case of a favourable outcome of such an assessment, the competent authority may allow the detoxification of the identified contaminated feed within a defined period of time. A full risk assessment with favourable outcome of the detoxification process is needed to apply the detoxification process without a time limit.

(9) Currently detoxification of feed is applied. As after the date when this Regulation starts to apply only detoxification processes can be used which have undergone a scientific assessment by EFSA with favourable outcome and have been accepted by the competent authority, it is appropriate to provide for sufficient time before this Regulation starts to apply.

(10) 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:

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*Article 1*

**Scope**

1 This Regulation shall apply to a detoxification process through which an undesirable substance listed in Annex I of Directive 2002/32/EC is on purpose removed from non-compliant contaminated feed, hereinafter 'physical detoxification process', broken down or destroyed by a chemical substance into harmless compounds, hereinafter 'chemical detoxification process', or metabolised or destroyed or deactivated by a (micro)biological process into harmless compounds, hereinafter '(micro)biological detoxification process'.

2 This Regulation shall not apply to a simple detoxification process through which the contamination by an undesirable substance is reduced or eliminated by a usual refining process, cleaning, sorting or mechanical removal of contaminants or certain parts of the contaminated feed.

*Article 2*

**Application of a detoxification process**

A detoxification process shall only be applied if:

— the process is exclusively intended for the detoxification of feed in which the non-compliance as regards Directive 2002/32/EC does not result from an on purpose non-compliance to the requirements set out in articles 4 and 5 of Regulation (EC) No 183/2005,

— the European Food Safety Authority (EFSA) has performed, on request of the Commission, a scientific assessment of the detoxification process, and concluded that the detoxification process complies with the acceptability criteria, as set out in Articles 3, 4 and 5.

*Article 3*

**Acceptability criteria for a physical detoxification process**

1 A scientific assessment shall be performed by EFSA on a physical detoxification process assessing if the following criteria are met:

a the process is effective;

b the process does not adversely affect the characteristics and the nature of the feed; and

c a safe disposal of the removed part of the feed is guaranteed.

2 The information which the feed business operator shall provide to the Commission for the purpose of the assessment of such a process is listed in point 1 of the Annex.

*Article 4*

**Acceptability criteria for a chemical detoxification process**

1 A scientific assessment shall be performed by EFSA on a chemical detoxification process assessing if the following criteria are met:

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a the process is performed with a fully characterised and acceptable chemical substance;
b the process is effective and irreversible;
c the process does not result in harmful residues of the chemical substance used in the detoxification process in the detoxified feed;
d the process does not result in reaction products of the contaminant that endanger animal and public health and the environment; and
e the process does not adversely affect the characteristics and the nature of the feed.

2 The information which the feed business operator shall provide to the Commission for the purpose of assessment of such a process is listed in point 2 of the Annex.

*Article 5*

**Acceptability criteria for a (micro)biological detoxification process**

1 A scientific assessment shall be performed by EFSA on a (micro)biological detoxification process assessing if the following criteria are met:
a the process is performed with a fully characterised and acceptable (micro)biological agent;
b the process is effective and irreversible;
c the process does not result in harmful residues of the (micro)biological agent used in the detoxification process in the detoxified feed;
d the process does not result in metabolites of the contaminant that endanger animal and public health and the environment; and
e the process does not adversely affect the characteristics and the nature of the feed.

2 The information which the feed business operator shall provide to the Commission for the purpose of assessment of such a process is listed in point 3 of the Annex.

*Article 6*

**Establishments where the detoxification process is carried out**

1 Feed business operators shall ensure that establishments under their control and covered by Regulation (EC) No 183/2005 are approved by a competent authority, as defined in Article 3(e) of Regulation (EC) No 183/2005, where such establishments carry out a detoxification process referred to in Article 1. The approval shall be carried out in accordance with Article 10(3) of Regulation (EC) No 183/2005.

2 The competent authority, referred to in point 1, may require that the feed business operator provides independent expert advice in order to decide on the acceptability of the application of the detoxification process in the relevant establishment, ensuring a correct and effective application of the detoxification process in the establishment.

3 The national list of approved establishments, as defined in Article 19(2) of Regulation (EC) No 183/2005, shall mention for the establishments, approved for carrying out a detoxification process, the accepted detoxification process. The Commission shall display the national links to those lists on the Commission's website, for information purposes.