Commission Implementing Regulation (EU) No 796/2013 of 21 August 2013 concerning the denial of authorisation of the substance 3-acetyl-2,5-dimethylthiophene as a feed additive (Text with EEA relevance)

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concerning the denial of authorisation of the substance 3-acetyl-2,5-dimethylthiophene as a feed additive

(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[(1)], and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting or denying such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC[(2)].

(2) The substance 3-acetyl-2,5-dimethylthiophene was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for use on all animal species as part of the group ‘Flavouring and appetising substances — All natural products and corresponding synthetic products’. That substance was subsequently entered in the European Union Register of Feed Additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003, with CAS number 2530-10-1 and Flavis number 15.024.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of this substance as a feed additive for all animal species, requesting that additive to be classified in the additive category ‘sensory additives’ and in the functional group ‘flavouring compounds’. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The substance 3-acetyl-2,5-dimethylthiophene was also included in the list of flavouring substances in Part A of Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No

110/2008 and Directive 2000/13/EC[(3)], as a flavouring substance under evaluation for which additional scientific data had to be submitted. Such data was submitted.

(5) The European Food Safety Authority ('the Authority') concluded in its opinion of 15 May 2013[(4)] about the use of this substance as a flavouring substance in food that this substance is mutagenic *in vitro* and *in vivo* and that its use as a flavouring substance in food raises a safety concern.

(6) This assessment indicates that 3-acetyl-2,5-dimethylthiophene is very likely to be mutagenic also for animals consuming feed containing this substance as a sensory additive. Consequently, it has not been established that this substance does not have an adverse effect on animal health, when used as a feed additive under the proposed conditions of use.

(7) The conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are therefore not satisfied. Accordingly, the authorisation of 3-acetyl-2,5-dimethylthiophene as a feed additive should be denied.

(8) Since further use of 3-acetyl-2,5-dimethylthiophene as a feed additive may cause a risk to animal health, it should be withdrawn from the market as soon as possible.

(9) Taking into account practical reasons, a transitional period should be laid down to address the situation of existing stocks of feed containing the flavouring substance 3-acetyl-2,5-dimethylthiophene already in the market before the entry into force of this Regulation.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation of 3-acetyl-2,5-dimethylthiophene as an additive in animal nutrition is denied.

Article 2

Existing stocks of 3-acetyl-2,5-dimethylthiophene and premixtures containing it shall be withdrawn from the market as soon as possible and at the latest by 11 October 2013. Compound feed produced containing 3-acetyl-2,5-dimethylthiophene before the date of entry into force of this Regulation may be used up until stocks are exhausted and at the latest by 11 October 2013.

Article 3

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

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