EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

suspending the authorisation of ethoxyquin as a feed additive for all animal species and categories

(Text with EEA relevance)

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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 13(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, denying or suspending 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 additive ethoxyquin was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for use for all animal species and categories. The additive was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted on 21 September 2010 for the authorisation of ethoxyquin as a feed additive for all animal species, requesting the additive to be classified in the category "technological additives". That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ("the Authority") stated in its opinion of 21 October 2015[3] that the assessment of the particulars and documents submitted by the applicant makes it impossible to conclude on the safety of the additive ethoxyquin for any target animals, for consumers and for the environment. This is due to an overall lack of data submitted to assess the exposure and the safety of ethoxyquin for animals, consumers and the environment. In particular, no conclusion is possible on the absence of genotoxicity of one of the metabolites of the additive ethoxyquin, ethoxyquin quinone imine. In addition, p-phenetidine, an impurity of the additive ethoxyquin, is recognised as a possible mutagen. The Authority considered the additive ethoxyquin as a potent antioxidant in feed but efficacy at the proposed use level, which has been reduced as compared with the currently authorised maximum content in feed, could not be confirmed by the submitted data. The Authority also

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1 OJ L 268, 18.10.2003, p. 29.
2 OJ L 270, 14.12.1970, p. 1.
3 *EFSA Journal* 2015; 13(11):4272.

verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) Consequently, it has not been established that the additive does not have an adverse effect on animal health, human health or the environment when used under the proposed conditions.

(6) The existing authorisation of the additive ethoxyquin therefore no longer meets the conditions set out by Article 5 of Regulation (EC) No 1831/2003.

(7) It is possible that supplementary data concerning the safety of use and the efficacy of the additive ethoxyquin bring new elements that would allow a re-consideration of the assessment carried out for that additive. In this respect, the applicant for the authorisation of the additive ethoxyquin argues that additional studies may be performed in order to demonstrate the safety and efficacy of the additive. To this end, the applicant committed itself to produce supplementary data according to a time schedule listing in order of priority the studies to be carried out successively and planning that the outcome of the last of them would be available by July 2018. The prioritisation in the process of the planned data generation is based on the level of importance of the issues identified in the Authority's opinion. Those studies would consist essentially of an update of the additive's characterisation, in particular as regards relevant impurities and degradation products, of toxicological studies, in particular related to the genotoxicity of ethoxyquin quinone imine, of metabolism and residue studies in target animal species (including levels of residues in tissues and animal products), of target animals' safety studies and of an environmental risk assessment.

(8) In addition, as the presence in the additive ethoxyquin of the impurity *p*-phenetidine results from the manufacturing process of the additive, the applicant committed itself to take steps in order to reduce progressively the content of that impurity in the additive to the level of 2,5 ppm *p*-phenetidine in ethoxyquin by June 2017. For that purpose, an appropriate method of analysis for the detection of *p*-phenetidine in the additive ethoxyquin and in feed containing the additive should be submitted by the applicant and accepted by the Authority on the basis of a report of the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(9) In accordance with Article 13(2) of Regulation (EC) No 1831/2003, the authorisation of the additive ethoxyquin should therefore be suspended, pending the submission and assessment of the supplementary data. The suspension measure should be reviewed after due assessment of those data by the Authority. In any event, a review of the suspension measure should be adopted where, during the process of the submission and assessment of the supplementary data, the Authority adopts a non-favourable opinion on the safety or efficacy of the additive ethoxyquin.

(10) Since further use of the additive ethoxyquin might cause a risk to human, animal health and the environment, the additive and feed containing it should be withdrawn from the market as soon as possible. For practical reasons, however, a limited transitional period should be allowed for the withdrawal from the market of the products concerned in order to enable operators to comply properly with the withdrawal obligation.

(11) Feed materials from marine origin, which contain high levels of fatty acids, are very sensitive to oxidation and high temperature and need to be stabilised by an antioxidant, in particular where the feed materials are subject to a long shipping or storage period.

Due to that high risk of oxidation, ethoxyquin is widely used to protect the feed materials concerned in an effective manner. Those feed materials, in particular fish meal and fish oil, are of high nutritional value and contain an important concentration of easily digestible proteins, which are required in aquaculture and in young animals' diet, but are also used for other animal species, especially for pigs and poultry. In addition, the high content in those feed materials of poly-unsaturated fatty acids, which are transferred to animal products, is recognised to provide health benefits to livestock and to the consumers of animal products. Therefore, an immediate withdrawal from the market of ethoxyquin could lead to negative consequences for animal health and welfare and to an inability to meet the animals' specific nutritional requirements until suitable alternatives are in place.

(12) Ethoxyquin is also widely used as constituent of certain feed additives preparations containing an active substance which is particularly sensitive to oxidation and heat treatment and needs to be stabilised by an antioxidant in order to maintain its properties. Those feed additives consist in preparations of certain essential vitamins, carotenoids and colourants which are lipo-soluble and need to be protected during the manufacturing process, storage and transport of the preparations and of feed containing them, until the delivery to animals. Due to the wide use of ethoxyquin in those feed additives preparations, an immediate withdrawal from the market of ethoxyquin would negatively impact animal health and welfare, as a result of a lack of essential micronutrients in the feed for several species of both food-producing and non-food producing animals. In addition, a shortage in the Union of the feed additives preparations concerned could lead to lower feed efficiency and lower livestock performance, but also to the inability to meet market specifications for certain animal products.

(13) It appears that a substitution of ethoxyquin by suitable alternative antioxidants could not be undertaken immediately, as the currently authorised alternative antioxidants – several of them being still under re-evaluation process in accordance with Regulation (EC) No 1831/2003 – do not possess the same characteristics as ethoxyquin, in particular as regards effectiveness and the concentration of active substance needed, duration of action, process behaviour but also in terms of production costs. Consequently, a certain time is needed in order to allow operators to evaluate and test the functionality of alternative antioxidants through new formulations and to adapt the production process to the inclusion of those potential alternative substances. A specific definite transition period should therefore be provided for the withdrawal from the market of the products referred to in recitals 11 and 12, in order to enable operators to adapt themselves to the new situation and thereby to comply properly with the withdrawal obligation. Due to the specific method of production and storage of the feed additives preparations mentioned under recital 12, alternative antioxidant substances for those preparations may be made available in a shorter period than for the feed materials referred to in recital 11, allowing the provision of a shorter transitional period.

(14) 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
Suspension of the authorisation

The authorisation provided by Directive 70/524/EEC and extended by Regulation (EC) No 1831/2003, concerning the additive ethoxyquin specified in entry E 324 of the Register of feed additives referred to in Article 17 of that Regulation ("the additive ethoxyquin"), is suspended.

Article 2
Transitional measures

1. Existing stocks of the additive ethoxyquin and of premixtures containing it may continue to be placed on the market until *[**3 months** from the date of entry into force of this Regulation - To be completed by the Service responsible for the publication]* and may be used until *[**6 months** from the date of entry into force of this Regulation – To be completed by the Service responsible for the publication]*.

2. Feed materials and compound feed produced with the additive ethoxyquin or with premixtures containing it may continue to be placed on the market until *[**6 months** from the date of entry into force of this Regulation - To be completed by the Service responsible for the publication]* and may be used until *[**9 months** from the date of entry into force of this Regulation – To be completed by the Service responsible for the publication]*.

Article 3
Specific transitional measures for certain feed materials and related products

1. By way of derogation from Article 2:

   (a) the additive ethoxyquin and premixtures containing it, intended to be incorporated in the feed materials listed under entry 7.1.2 and under Chapter 10 of the Catalogue of feed materials established by Commission Regulation (EU) No 68/2013[4], may continue to be placed on the market until 30 September 2019, provided that the labelling of the additive ethoxyquin or of premixtures containing it mentions the intended incorporation in those feed materials;

   (b) feed materials referred to in point (a) produced with the additive ethoxyquin or with premixtures containing it may continue to be placed on the market until 31 December 2019;

   (c) compound feed produced with the feed materials referred to in point (b) may continue to be placed on the market until 31 March 2020.

2. The products referred to in points (a), (b) and (c) of paragraph 1 may be used until 3 months after the dates specified respectively in those points.

Article 4
Specific transitional measures for certain additives preparations and related products

1. By way of derogation from Article 2:

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

(a) the additive ethoxyquin intended to be incorporated in the following additives preparations which have been authorised in accordance with Regulation (EC) No 1831/2003, may continue to be placed on the market until 31 March 2018, provided that the labelling of the additive ethoxyquin mentions the intended incorporation in those additives preparations:

- preparations of vitamin A;
- preparations of vitamin D;
- preparations of vitamin E;
- preparations of vitamin K;
- preparations of lutein;
- preparations of zeaxanthin;
- preparations of ethyl ester of beta-apo-8'-carotenoic acid;
- preparations of citranaxanthin;
- preparations of capsanthin;
- preparations of astaxanthin;
- preparations of astaxanthin dimethyldisuccinate;
- preparations of canthaxanthin;
- preparations of beta-carotene;

(b) the additives preparations referred to in point (a) which contain the additive ethoxyquin and premixtures containing those additives preparations may continue to be placed on the market until 30 June 2018;

(c) feed materials and compound feed containing the products referred to in point (b) may continue to be placed on the market until 30 September 2018.

2. The products referred to in points (a), (b) and (c) of paragraph 1 may be used until 3 months after the dates specified respectively in those points.

Article 5
Review

This Regulation shall be reviewed by 31 December 2020 at the latest and in any event after the adoption by the Authority of a non-favourable opinion on the safety or efficacy of the additive ethoxyquin.

Article 6
Entry into force

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

Done at Brussels,

For the Commission
The President
Jean- Claude JUNCKER