Commission Regulation (EU) 2015/327 of 2 March 2015 amending Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards requirements for the placing on the market and conditions of use of additives consisting of preparations (Text with EEA relevance)

COMMISSION REGULATION (EU) 2015/327

of 2 March 2015

amending Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards requirements for the placing on the market and conditions of use of additives consisting of preparations

(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 Articles 3(5) and 16(6) thereof,

Whereas:

(1) In some preparations, authorised as additives in accordance with Regulation (EC) No 1831/2003, technological additives and other substances or products are incorporated to exert a function on the active substance contained in the preparation, such as stabilising or standardising it, facilitating its handling or its incorporation into feed. For example, those technological additives or other substances or products may increase flowability or homogeneity or reduce the dusting potential of the active substance. The specific composition of authorised additives consisting of preparations will therefore vary according to the rationale for the use of those preparations. The technological additives or other substances or products added to maintain the integrity of an active substance are however not intended to perform a function in the feed in which the preparation is to be incorporated.

(2) Taking into account that technological progress contributes to the development of new preparations, it is appropriate to better consider the specificities of additives consisting of preparations and to bring more transparency and clarity when placing them on the market, without affecting intellectual property rights relating to the composition of premixtures containing such additives.

(3) In particular, it is appropriate to introduce into Annex III to Regulation (EC) No 1831/2003 additional labelling requirements for this type of additives and for premixtures containing them, so as to allow a verification that technological additives used in a preparation are authorised for the intended purpose and that those additives exert a function only on the active substance contained in the preparation.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2015/327. (See end of Document for details)*

(4) While the most relevant information should be kept on the packaging or container of the additive or the premixture, technological progress also allows providing information about the composition of the preparations in a more flexible and less costly way via other written means. This is in compliance with the definition of labelling provided for in Regulation (EC) No 767/2009 of the European Parliament and of the Council[(2)].

(5) Operators should be able to provide information about the composition of the preparations which are placed on the market since such information enables the end-user or the purchaser to make an informed choice, allows appropriate risk assessment and contributes to fairness of transactions.

(6) Those additional labelling and information requirements should apply only to additives belonging to the categories referred to in Article 6(1)(a), (b) and (c) of Regulation (EC) No 1831/2003. Where such additives are authorised as preparations, only the active substance is indeed the subject of the authorisation, and not the other components of the preparations, which may vary.

(7) In order to prevent any undesirable effects on human health, animal health or the environment, operators should ensure that there is physico-chemical and biological compatibility between the components of the preparation which is placed on the market and used.

(8) Annex III to Regulation (EC) No 1831/2003, on specific labelling requirements for certain additives and for premixtures, and Annex IV thereto, on general conditions of use, should therefore be amended in order to take into account technological progress and scientific development concerning additives consisting of preparations.

(9) A transitional period is needed to avoid disruptions in the placing on the market and use of existing additives consisting of preparations, and of feed containing them, so that they may be used until stocks are exhausted.

(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:

Article 1

Amendment to Annexes III and IV

Annexes III and IV to Regulation (EC) No 1831/2003 are amended in accordance with the Annex to this Regulation.

Article 2

Transitional provision

Additives consisting of preparations and premixtures containing such additives, which are produced and labelled before 23 March 2017 in accordance with Regulation (EC)

No 1831/2003 as it stood before 23 March 2015 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 3

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, 2 March 2015.

For the Commission

The President

Jean-Claude JUNCKER