

COMMISSION REGULATION (EU) No 5/2014

of 6 January 2014

amending Directive 2008/38/EC establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes

(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 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC ⁽¹⁾, and in particular Article 10(5) thereof,

Whereas:

- (1) In accordance with Article 32(2) of Regulation (EC) No 767/2009, several applications for authorisation were submitted to the Commission before 1 September 2010 for updating the list of intended uses as referred to in Article 10 of that Regulation.
- (2) Some of those applications concern changes of the conditions associated with the particular nutritional purposes 'Nutritional restoration, convalescence' as regards dogs and 'Stabilisation of physiological digestion' in respect of feed that may contain additives in concentrations higher than 100 times the relevant fixed maximum content in complete feed as referred to in Article 8(2) of Regulation (EC) No 767/2009. The other applications concern new particular nutritional purposes with respect to the requirement established in Article 8(2) of Regulation (EC) No 767/2009.
- (3) In addition, in accordance with Article 10 of Regulation (EC) No 767/2009, the Commission received an application to add the particular nutritional purpose 'Reduction of iodine levels in feed in case of hyperthyroidism' as regards cats.

- (4) A specific way of feeding is the administration of a bolus. In order to guarantee an appropriate and safe use of a bolus as feed for particular nutritional purposes, general requirements should be established for the conditions associated with certain intended uses.
- (5) The Commission made all applications, including the dossiers, available to the Member States.
- (6) The dossiers included in the applications demonstrate that the specific composition of the respective feeds fulfil the particular intended nutritional purposes 'Nutritional restoration, convalescence' as regards dogs, 'Stabilisation of physiological digestion' 'Reduction of iodine levels in feed in case of hyperthyroidism' as regards cats, 'Support the preparation for and recovery from sport effort' as regards equidae, 'Compensation for insufficient iron availability after birth' as regards suckling piglets and calves, 'Support the regeneration of hooves, trotters and skin' as regards horses, ruminants and pigs, 'Support the preparation for oestrus and reproduction' as regards mammals and birds and 'Long-term supply of grazing animals with trace elements and/or vitamins' as regards ruminants with a functional rumen.
- (7) Furthermore, the evaluation showed that the feeds concerned have no adverse effects on animal health, human health, the environment or animal welfare. The evaluation of the dossiers included verification that the characterisation 'high level of a certain feed additive' implies an important level of the respective additive which is close to the relevant fixed maximum content in complete feed but not exceeding this content.
- (8) The applications are therefore valid and the particular nutritional purposes should be added to the list of intended uses and the conditions associated with the particular nutritional purposes 'Nutritional restoration, convalescence' and 'Stabilisation of physiological digestion' should be changed.
- (9) Directive 2008/38/EC should therefore be amended accordingly.

⁽¹⁾ OJ L 229, 1.9.2009, p. 1.

- (10) Since safety reasons do not require the immediate application of the modifications for the feed currently legally placed on the market, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Directive 2008/38/EC is amended in accordance with the Annex to this Regulation.

Article 2

Feed included in the Annex to this Regulation and referred to in Article 8(2) of Regulation (EC) No 767/2009 that have already been legally placed on the market before 1 September 2010 which are produced and labelled before 27 July 2014 may continue to be placed on the market and used until the existing stocks are exhausted. In case this feed is intended for pets, the date mentioned in the last sentence is 27 January 2016.

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

Done at Brussels, 6 January 2014.

For the Commission
The President
José Manuel BARROSO

ANNEX

Annex I to Directive 2008/38/EC is amended as follows:

(1) In Part A, the following point is added:

10. When a feed intended for particular nutritional purposes is placed on the market in the form of a bolus, being a feed material or complementary feed intended for individual oral administration by forced feeding, the label of the feed shall, if applicable, mention the maximum period of continuously release of the bolus and the daily release rate for each additive for which a maximum content in complete feed is fixed. At the request of the competent authority the feed business operator which is placing a bolus on the market shall provide proof that the daily available additive level in the digestive tract will not exceed, if applicable, the maximum content of the additive established per kg complete feed during the whole feeding period (slow release effect). It is recommended that feed in form of bolus is administered by a veterinarian or any other competent person.'

(2) Part B is amended as follows:

Particular nutritional purpose	Essential nutritional characteristics	Species or category of animal	Labelling declarations	Recommended length of time	Other provisions
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(a) The following row is inserted between the row of the particular nutritional purpose 'Regulation of lipid metabolism in the case of hyperlipidaemia' and the row of the particular nutritional purpose 'Reduction of copper in the liver':

'Reduction of iodine levels in feed in case of hyperthyroidism	Restricted level of iodine: maximum 0,26 mg/kg complete pet food with a moisture content of 12 %	Cats	Total iodine	Initially up to 3 months	Indicate on the labelling: "It is recommended that advice from a veterinarian be sought before use and before extending the period of use"
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(b) The row of the particular nutritional purpose 'Nutritional restoration, convalescence', species or category of animals: 'dogs and cats', is replaced by the following:

'Nutritional restoration, convalescence (*)	High energy density, high concentrations of essential nutrients and highly digestible ingredients	Dogs and cats	<ul style="list-style-type: none"> — Highly digestible ingredients, including their treatment if appropriate — Energy value — Content of n-3 and n-6 fatty acids (if added) 	Until restoration is achieved	In the case of feed specially presented to be given via tubing, indicate on the labelling: "Administration under veterinary supervision."
	Enterococcus faecium DSM 10663 / NCIMB 10415 (E1707) The complementary feed may contain feed additives of the functional group of "gut flora stabilisers" in a concentration higher than 100 times the relevant fixed maximum content in complete feed.	Dogs	Name and added amount of the gut flora stabiliser	10 to 15 days	<ul style="list-style-type: none"> — The instructions for use of the feed shall ensure that the legal maximum content of the gut flora stabiliser for complete feed is respected. — Indicate on the labelling: "It is recommended that advice from a veterinarian be sought before use and before extending the period of use."

(*) The manufacturer may complete the particular nutritional purpose with a reference to "Feline hepatic lipidosis".

(c) The row of the particular nutritional purpose 'Stabilisation of physiological digestion' is replaced by the following:

'Stabilisation of physiological digestion	Low buffering capacity, and highly digestible ingredients	Piglets	<ul style="list-style-type: none"> — Highly digestible ingredients including their treatment if appropriate — Buffering capacity — Source(s) of astringent substances (if added) — Source(s) of mucilaginous substances (if added) 	2 to 4 weeks	Indicate on the labelling: "In case of risk of, during periods of, or recovery from, digestive disturbance."
	Highly digestible ingredients	Pigs	<ul style="list-style-type: none"> — Highly digestible ingredients including their treatment if appropriate — Source(s) of astringent substances (if added) — Source(s) of mucilaginous substances (if added) 		
	<p>Feed additives of the functional group "Gut flora stabiliser" of the category "zootechnical additives" as referred to in Annex I to Regulation (EC) No 1831/2003.</p> <p>The complementary feed may contain feed additives of the functional group of "gut flora stabilisers" in a concentration higher than 100 times the relevant fixed maximum content in complete feed.</p>	Animal species for which the gut flora stabiliser is authorised	Name and added amount of the gut flora stabiliser	Up to 4 weeks	<p>Indicate on the labelling of the feed:</p> <p>(1) "In case of risk of, during periods of, or recovery from digestive disturbance."</p> <p>(2) If applicable: "The feed contains a gut flora stabiliser in a concentration above 100 times the authorised maximum content in complete feed."</p> <p>The instructions for use of the feed shall ensure that the legal maximum content of the gut flora stabiliser for complete feed is respected.'</p>

(d) The following rows are inserted between the row of the particular nutritional purpose 'Reduction of the risk of acidosis' and the row for the particular nutritional purpose 'Stabilisation of water and electrolyte balance':

'Long-term supply of grazing animals with trace elements and/or vitamins	<p>High level of</p> <ul style="list-style-type: none"> — Trace elements <p>and/or</p>	Ruminants with a functional rumen	<ul style="list-style-type: none"> — Names and total amounts of each added trace element, vitamin, provitamin and chemically well-defined substance having similar effects. 	Up to 12 months	<ul style="list-style-type: none"> — Application in the form of bolus is allowed. A bolus may contain up to 20 % iron in an inert, non-bioavailable form, in order to increase its density.
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	<p>— vitamins, provitamins and chemically well-defined substances having similar effects.</p> <p>The complementary feed may contain feed additives in a concentration higher than 100 times the relevant fixed maximum content in complete feed.</p>		<p>— Daily release rate for each trace element and/or vitamin if a bolus is used;</p> <p>— Maximum period of continuously release of the trace element or vitamin if a bolus is used.</p>		<p>— Indicate on the labelling of the feed:</p> <p>“— Simultaneous supplementation of additives with a maximum content from other sources to those incorporated in a bolus, if applicable, shall be avoided.</p> <p>— Before using, it is recommended to have advice from a veterinarian or nutritionist concerning:</p> <p>(1) the balance of trace elements in the daily ration;</p> <p>(2) the trace elements status of the herd</p> <p>— The bolus contains x % inert iron in order to increase its density, if applicable.”</p>
Compensation for insufficient iron availability after birth	<p>High level of iron compounds authorised under the functional group “compounds of trace elements” of the category “nutritional additives” as referred to in Annex I to Regulation (EC) No 1831/2003.</p> <p>The complementary feed may contain iron in a concentration higher than 100 times the relevant fixed maximum content in complete feed.</p>	Suckling piglets and calves	Total iron content	After birth up to 3 weeks	The instructions for use for the feed shall ensure that the legal maximum contents of iron for complete feed are respected.
Support the regeneration of hooves, trotters and skin	<p>High level of zinc.</p> <p>The complementary feed may contain zinc in a concentration higher than 100 times the relevant fixed maximum content in complete feed.</p>	Horses, ruminants and pigs	Total amount of <ul style="list-style-type: none"> — zinc — methionine 	Up to 8 weeks	The instructions of use for the feed shall ensure that the legal maximum contents of zinc for complete feed are respected.

Support the preparation for oestrus and reproduction	<p>— High level of selenium and a minimum content of vitamin E per kg complete feed with a moisture content of 12 % for pigs of 53 mg, rabbits of 35 mg, for dogs, cats, mink of 88 mg;</p> <p>a minimum content of vitamin E per animal and day for ovines of 100 mg, cattle of 300 mg, horses of 1 100 mg</p> <p>or</p> <p>— High level(s) of vitamins A and/or vitamin D and/or a minimum content of beta-carotene of 300 mg per animal and day.</p> <p>The complementary feed may contain selenium, vitamin A and D in a concentration higher than 100 times the relevant fixed maximum content in complete feed.</p>	Mammals	Names and total amounts of each added trace element and vitamin.	<p>— Cows: 2 weeks before the end of gestation until the next gestation is confirmed.</p> <p>— Sows: 7 days before until 3 days after parturition and 7 days before until 3 days mating.</p> <p>— Other female mammals: from the last part of gestation until the next gestation is confirmed.</p> <p>— Males: during periods of reproductive activity.</p>	<p>— The instructions of use for the feed shall ensure that the respective legal maximum contents for complete feed are respected.</p> <p>— Indicate on the labelling of the feed: “Guidance on the situations in which the use of the feed is appropriate.”</p>
	<p>— High level(s) of vitamin A and/or vitamin D</p> <p>or</p> <p>— High level(s) of selenium and/or zinc and/or a minimum content of vitamin E of 44 mg/kg complete feed with a moisture content of 12 %.</p> <p>The complementary feed may contain selenium, zinc, vitamin A and D in a concentration higher than 100 times the relevant fixed maximum content in complete feed.</p>	Birds	Names and total amounts of each added trace element and vitamin.	<p>— For females: during oestrus</p> <p>— For males: during periods of reproductive activity</p>	

(e) The following row is inserted between the row of the particular nutritional purpose 'Compensation of electrolyte loss in the cases of heavy sweating' and the row of the particular nutritional purpose 'Nutritional restoration, convalescence', species or category of animals: 'equidae':

<p>'Support the preparation for and recovery from sport effort</p>	<p>High level of selenium and a minimum content of 50 mg vitamin E per kg complete feed with moisture content of 12 %.</p> <p>The complementary feed may contain compounds of selenium in a concentration higher than 100 times the relevant fixed maximum content in complete feed.</p>	<p>Equidae</p>	<p>Total amount of</p> <ul style="list-style-type: none"> — vitamin E — selenium. 	<p>Up to 8 weeks before sport effort – Up to 4 weeks after sport effort</p>	<p>The instructions for use for the feed shall ensure that the legal maximum contents of selenium for complete feed are respected.'</p>
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