

The availability of feed additives 3b301, 3b302, 3b303 and 3b305 (Cobalt salts)

IGFA Briefing

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Introduction

3b301, 3b302, 3b303 and 3b305 (Cobalt salts) are used in a range of ruminant and equine mineral supplements in Ireland and exported across Europe. Ruminants and horses require cobalt in their diet for the synthesis of vitamin B12. Vitamin B12 is essential for energy metabolism and the production of red blood cells. Cobalt deficiency in soils can cause vitamin B12 deficiency in livestock. The common symptoms due to acute cobalt deficiency are paleness, weakness, fatigue, loss of appetite, weight loss, and subsequent poor growth among other welfare issues. Most forages and feedstuffs fed to ruminants do not contain adequate quantities of cobalt to support the rumen and animal requirements. The diet therefore needs to be supplemented with cobalt.

3b305 is particularly critical as it is the only water-soluble cobalt suitable for the manufacture of liquid mineral feedingstuff. It is also worth noting that these additives are used in products listed on Health Products Regulatory Authority (HPRA) website under the class Therapeutic Vitamins and Minerals.

The feed industry is very concerned they could lose these additives as the deadline for submission of a dossier for renewal has been missed. This has been brought to our attention by some IGFA members and through colleagues on the FEFAC premix and mineral feed committee. There is also concern that if they lose these additives, they will not be given the opportunity after 15 July 2023 to use up stocks of cobalt salts or place on the market stocks of premixtures and compound feed containing these feed additives.

Background

Regulation (EC) No 1831/2003 of 22 September 2003 on additives for use in animal nutrition outlines two different stages of feed additive authorisations

- article 10 deals with **re-authorisation** of feed additives
- article 14 deals with **renewal of authorisation** of feed additives

Article 10, paragraph 5 specifies that, for those additives not re-authorised, a withdrawal regulation shall be issued, possibly with transition measures to use up stocks. What happens in practice is the additives are transferred to the feed additive register annex II and continue to be used until a withdrawal regulation is published which provides transitional periods to use up existing stock and reformulate feed replacing the additives with alternative ones.

For example, Cobalt salts were re-authorised (article 10) on 15 July 2013. At that time, not all cobalt salts were re-authorised as there was no application for some of them, e.g., cobalt chloride or cobalt nitrate. These were transferred to annex II. In parallel, the cobalt salts having been re-authorised remained in Annex I with a date of expiration of authorisation on 15 July 2023. In February 2014, a withdrawal regulation was issued for cobalt nitrate, chloride, etc. with transition periods (R107/2014).

Likewise, molybdenum salts underwent re-authorisation (article 10) but only in 2019 (R2019/1965). There was only one application for authorization of sodium molybdate dehydrate for use in sheep feed, which remained in annex I with an expiration of authorization on 18/12/2019. Sodium molybdate dehydrate for use in species other than sheep was transferred under annex II and is awaiting a withdrawal regulation (expected within the next few months).

IGFA concerns on cobalt salts

Cobalt salts have now reached the stage of **renewal of authorization** (article 14) and the applicant for 3b301, 3b302, 3b303 and 3b305 (Cobalt salts) has missed the deadline for submission of a dossier for renewal. Instead, the applicant had to submit a dossier for a completely new authorization (article 4). The consequence of this in the likely event that the process of authorization of these cobalt salts is not completed within the next 4 months, is a risk that cobalt salts (except for coated cobalt carbonate) are no longer authorized as of 15 July 2023. The legislator has also not foreseen the possibility to grant transition period in case of non-renewal of authorization.

IGFA are therefore concerned that we will lose 3b301, 3b302, 3b303 and 3b305 (Cobalt salts) and members using these additives, will not be given the opportunity after 15 July 2023 to use up stocks of these feed additives or place on the market stocks of premixtures and compound feed containing these feed additives. This situation is new and we expect it might set a precedent for the management of feed additives whose authorisation will not be renewed.

Hence, we are asking DAFM to review this situation and provide us views in relation to stocks of these additives and premixtures and compound feed containing them post 15 July 2023. We are also asking for action to be taken to minimise the risk of losing these critical feed additives.

[Reference European Union Register of Feed Additives \(released 6 December 2022\)](#)

Category	Functional Group	Subclassification	Code	Additive	Reference(s) of Community legal act	Reference in OJ	Date of authorisation	Expiry date of authorisation(s)	Date of first entry in the Register
3	b	Compounds of trace elements	3b301	Cobalt(II) acetate tetrahydrate [Ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals]	Commission Implementing Regulation (EU) No 601/2013 of 24 June 2013 / Compendium DE OJ L 179 DE, 29.06.2013, p. 105 / Amended by Commission Implementing Regulation (EU) No 131/2014 of 11 February 2014	OJ L 172, 29.06.2013, p. 147 / Compendium DE OJ L 179 DE, 29.06.2013, p. 105 / Amended by OJ L 41, 12.02.2014, p. 3	15.07.2013	15.07.2023 / Transitional measures in article 2 of Commission Implementing Regulation (EU) No 131/2014 of 11 February 2014	25.06.13
3	b	Compounds of trace elements	3b302	Cobalt(II) carbonate [Ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals]	Commission Implementing Regulation (EU) No 601/2013 of 24 June 2013 / Compendium DE OJ L 179 DE, 29.06.2013, p. 105 / Amended by Commission Implementing Regulation (EU) No 131/2014 of 11 February 2014	OJ L 172, 29.06.2013, p. 147 / Compendium DE OJ L 179 DE, 29.06.2013, p. 105 / Amended by OJ L 41, 12.02.2014, p. 3	15.07.2013	15.07.2023 / Transitional measures in article 2 of Commission Implementing Regulation (EU) No 131/2014 of 11 February 2014	25.06.13
3	b	Compounds of trace elements	3b303	Cobalt(II) carbonate hydroxide (2:3) monohydrate [Ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals]	Commission Implementing Regulation (EU) No 601/2013 of 24 June 2013 / Compendium DE OJ L 179 DE, 29.06.2013, p. 105 / Amended by Commission Implementing Regulation (EU) No 131/2014 of 11 February 2014	OJ L 172, 29.06.2013, p. 147 / Compendium DE OJ L 179 DE, 29.06.2013, p. 105 / Amended by OJ L 41, 12.02.2014, p. 3	15.07.2013	15.07.2023 / Transitional measures in article 2 of Commission Implementing Regulation (EU) No 131/2014 of 11 February 2014	25.06.13
3	b	Compounds of trace elements	3b304	Coated granulated cobalt(II) carbonate [Ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals]	Commission Implementing Regulation (EU) No 601/2013 of 24 June 2013 / Compendium DE OJ L 179 DE, 29.06.2013, p. 105 / Amended by Commission Implementing Regulation (EU) No 131/2014 of 11 February 2014	OJ L 172, 29.06.2013, p. 147 / Compendium DE OJ L 179 DE, 29.06.2013, p. 105 / Amended by OJ L 41, 12.02.2014, p. 3	15.07.2013	Following the provisions of Art. 14 of Reg. (EC) No 1831/2003, an application in accordance with Article 7, has been submitted.	12.02.14
3	b	Compounds of trace elements	3b305	Cobalt(II) sulphate, heptahydrate [Ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals]	Commission Implementing Regulation (EU) No 601/2013 of 24 June 2013 / Amended by Commission Implementing Regulation (EU) No 131/2014 of 11 February 2014	OJ L 172, 29.06.2013, p. 147 / Compendium DE OJ L 179 DE, 29.06.2013, p. 105 / Amended by OJ L 41, 12.02.2014, p. 3	15.07.2013	15.07.2023 / Transitional measures in article 2 of Commission Implementing Regulation (EU) No 131/2014 of 11 February 2014	25.06.13