The availability of feed additives 3b301, 3b302, 3b303 and 3b305 after July 15, 2023

IGFA Submission

19 May 2023

Dear Ms. Clodagh Whelan,

Our members have expressed great concerns for animal welfare in Ireland, following the late application for renewal of authorization of feed additives 3b301, 3b302, 3b303, and 3b305 (Cobalt salts) and, as a consequence, the authorization of these salts expiring on 15 July 2023. The lack of access to these additives post-15 July 2023, will dramatically impact the welfare of ruminants, which rely on complementary feed in the form of bolus, drenches, or liquid for their supply of essential nutrients, including cobalt, to avoid critical deficiencies.

Animal Welfare

Cobalt is an essential trace element for ruminants and horses as it is needed in the manufacture of vitamin B12 in the digestive tract by microbial action (NRC, 1980 and 1989) which is, in turn, required for the metabolism of propionate through the gluconeogenesis pathway, an important source of energy for these animals. Vitamin B12 is degraded in the rumen when fed directly by oral route therefore cobalt supplementation is the only solution.

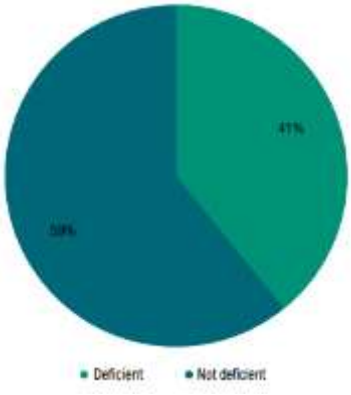
The consequences of deficiencies are well documented. Most are common to cattle and sheep, but some are specific as noted below.

- loss of appetite
- reduced growth rate
- weight loss
- pica a 'depraved appetite'. Affected animals (cattle) may eat bark, leaves, or dirt
- anemia and lethargy
- scaly ears causing discomfort to the animals.
- weepy eyes with damp matted wool below the eyes (sheep)
- disturbances of lipid metabolism
- reduced folate level
- accumulation of iron and nickel in the liver
- resistance to diseases such as gastro-intestinal parasites may also be impaired
- there is also evidence that cobalt deficiency in pregnant ewes reduces the viability of their offspring.
- ovine white liver disease is a specific disease of sheep associated with cobalt deficiency. Histologically, this results in lesions of hepatic lipidosis
- severe deficiencies can result in death

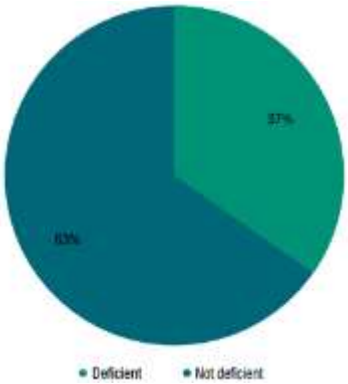
References: González-Montaña et al. 2020; CFIA,2018, NADIS report; EFSA opinions on cobalt from 2009 and 2012; Underwood and Suttle 1999; Vellema **et al**., 1996 ; Fisher and MacPherson, 1991; Paterson and McPherson 1990; Kennedy et al., 1994; Stangl et al. 1989 and 2000). In young sheep and young cattle, cobalt deficiency symptoms are often referred to as PINE (Greig and Dryerre)

All-Ireland Animal Disease Surveillance Report

The All-Ireland Animal Disease Surveillance Report 2105 reported that 41% of sheep were found to be deficient in Cobalt and 37% of cattle were found to be deficient in Cobalt.



The total number of ovine liver samples submitted to by DAFM laboratories during 2015 which were analysed for cobalt status and which were identified as deficient or not deficient (n=231)



The total number of bovine liver samples submitted to DAFM laboratories during 2015 which were analysed for cobalt status and which were identified as deficient or not deficient (n=246).

https://www.afbini.gov.uk/sites/afbini.gov.uk/files/publications/aiadsr2015_30-11-16%20LR_Designer%204.pdf

In the 2016 report the figures were remarkably similar 40.7% of sheep were found to be deficient in Cobalt, 38% of sheep were found to be deficient in Cobalt
https://www.afbini.gov.uk/sites/afbini.gov.uk/files/publications/All%20Island%20Disease%20Surveillance%20Report%202016.pdf

Low cobalt soils

Co deficiency in animals can be simple (low levels in soil and feed) or induced by high soil manganese (Mn), which prevents uptake of Co by herbage (Phil Rogers MRCVS & Tom Gately MAgrSc, MS, PhD). Many soils and pastures across the world are deficient in cobalt, causing a deficiency in sheep and cattle grazing those pastures. Some European countries are more at risk of cobalt deficiency as outlined in this paper Ireland is one such country Maps of heavy metals in the soils of the European Union and proposed priority areas for detailed assessment - ScienceDirect.

This is backed up by Teagasc – Ireland's Agriculture and Food Development Authority who report that many Irish soils are known to be low in cobalt and high manganese https://www.teagasc.ie/crops/soil--soil-fertility/trace-elements/grassland/cobalt/.

When is the use of liquid supplements, drenches, and bolus necessary?

- When a targeted more controlled method of supplementation is required (individual animals get the supplement in a controlled manner).
- When cattle and sheep that are grazing on extensive pastures where it is not possible to provide other supplementary feed, the only known means to compensate for the consequences of cobalt-deficient pastures on the welfare of grazing ruminants is to supplement the grazing diet with cobalt in the form of a bolus or a mineral drench as other supplementary feed is not possible including mineral blocks (licks) which are impacted by competition between animals, climate and handling by the farmers and intake challenges at a time when it is critical for the animal to be provided with cobalt supplementation.

The potential number of animals that could be subjected to animal welfare issues if 3b301, 3b302, 3b303 and 3b305 are removed from the market.

- All beef cattle and beef calves plus dairy calves could be adversely affected (as these are animals that graze and grow on grass diets for most of the year). According to the CSO as of June 2022 (ref CSO) there were approx. 7.4m cattle in Ireland of which 1.6m are dairy cows. Therefore, there is the potential of over 5.7m cattle including calves which may be affected.
- Dairy cows wouldn't be affected as much as supplementation of Cobalt via feed is possible with the use of 3b304.
- Out of a population of just under 6m ovine in Ireland, all these animals would be potentially affected by low cobalt status as our sheep are predominantly grazed on grass all year round.

Therefore, the total number of animals in Ireland that could potentially be affected could exceed 11.7m

Why 3b304 coated granulated Cobalt (II) carbonate is not a suitable substitute.

Differences in the properties of the Co (II) salts are critical to their use in animal nutrition. 3b304 coated granulated Cobalt (II) carbonate is not suitable for the manufacturing boluses, drenches and liquid feeds as outlined below.

It is not suitable for liquid supplements or liquid drenches because.

- It is impossible to deliver a homogeneous mixture using coated granulated Cobalt (II) carbonate (3b304) as insoluble particles crystallize and form a sediment in the liquid.

It is not suitable for bolus manufacture because.

- It is 10 times less concentrated in cobalt than the other forms therefore it would be necessary to provide 10 times more in a bolus for an equivalent cobalt intake. However, a bolus, by its design and its physical and technological constraints, has a very limited formulation space and must be able to cover all the needs of animals in vitamins and trace elements whose pastures are deficient. Increasing the size of the bolus is not an option as it would not be possible for an animal to swallow a large bolus.
- The coating of the granules coated with cobalt carbonate (3b304) has an elasticity effect which makes it not suitable for compressing into bolus format. After compression, it will quickly regain its initial shape, stretch the bolus, or even crack it and go until the bolus breaks. The bolus is then too fragile and unusable.
- Coated forms (3b304) are much coarser than the uncoated forms (3b302 and 3b303). As a general rule, to make a bolus, you have to compress powders of similar particle sizes.

We believe all this provides strong evidence of the need to retain these cobalt forms on the Irish market to avoid severe animal health & welfare problems and contravene the five freedoms contained in the Council of Europe's Convention for the Protection of Animals kept for Farming Purposes https://eur-lex.europa.eu/EN/legal-content/glossary/animal-welfare.html

In summary considering the exceptional nature of the situation and to mitigate the animal welfare consequences of the lack of access to these 4 cobalt compounds for several months on the welfare of animals, we hereby call on you to seek urgent and provisional authorization for these compounds in accordance with Article 15 of Regulation (EC) No 1831/2003.

We remain at your disposal for any additional information you might need in support of our request for such an urgent authorization.