ADVISORY COMMITTEE ON ANIMAL FEEDINGSTUFFS

ACAF Meeting 15 December 2010

Copper in Animal Feed

DISCUSSION PAPER

Action required:

The Committee is invited to:

a. note the information provided in the attached paper on the regulatory controls for use of copper and estimated consumer intakes of copper; and

b. make any comments on the proposed Code of Practice which has been drafted by the Veterinary Laboratories Agency and members of the feed and feed additives sector.

ACAF Secretariat
December 2010

Controls on Copper in Animal Feed

Purpose

1. The aim of this paper is to inform the Committee of regulatory controls on the use of copper in animal feeds and estimated consumer intakes of copper from foods. The aim is also to provide comments on a proposed code of practice (attached at Appendix I) prepared for the feed industry that gives advice on the best practice for copper supplementation of feeds. This advice will be subsequently developed for veterinarians and farmers.

Background

2. At the September 2010 meeting, Members received a presentation from the Veterinary Laboratories Agency on concerns on likely excessive supplementation of copper to dairy cows.

3. Following the presentation Members agreed that before they could provide advice on this issue, the Committee required more evidence including:

- more information on how much copper is being fed;
- evidence on the optimum intake level;
- evidence on the size of the problem; and
- more information on the potential exposure from milk, including the potential of transfer of copper from milk into human diet.

Regulatory Controls on copper

4. Under EU legislation on animal nutrition, certain copper compounds are authorised as nutritional feed additives. The use of copper in animal feeds is mainly controlled by three EU measures: Regulation 1831/2003 on Feed Additives; Regulation 767/2009 on the Marketing and Use of Feed; and Regulation 183/2005 on Feed Hygiene.

EU Regulation 1831/2003

5. Regulation 1831/2003 requires that additives may be put on the market and used only for the specific purposes provided for in their authorisation. The scope of the legislation includes the use of additives at primary production level. The maximum permitted levels specified for copper in complete feeds (added together with naturally occurring amounts) are as follows:

Animal type		Maximum content of copper in complete feeds (mg/kg)
Porcine		
	Piglets up to 12 weeks	170
	Other pigs	25
Bovine		
	Before the start of rumination:	

	Milk replacers	15
	Other Complete Feeds	15
	Other bovine	35
Ovine		15
Fish		25
Crustaceans		50
Other species		25

6. Additionally, EU feed additive legislation sets out some statements that must be included on the labels of compound feed that contains copper. These are as follows:

    - for sheep: where the level of copper in feedingstuffs exceeds 10 mg/kg the label must state: 'the level of copper in this feedingstuff may cause poisoning in certain breeds of sheep'.

    - for bovines after the start of rumination: where the level of copper in feedingstuffs is less that 20 mg/kg, the label must state: 'the level of copper in this feedingstuff may cause copper deficiencies in cattle grazing pastures with high contents of molybdenum or suphur'.

Other requirements of compound feed labelling are set out in paragraph 10 on EU Regulation 767/2009 below.

7. Many existing feed additives, including several copper compounds, are to undergo a re-evaluation by the European Food Safety Authority (EFSA). For this purpose, applicants must have submitted a dossier of supporting evidence on safety, quality and efficacy to EFSA by November 2010.

8. Additionally, Regulation 1831/2003 sets out provisions on the labelling of feed additives or premixtures of additives. These include the name of the additive according to its authorisation, the net weight, batch number and directions for use, including any safety recommendations and the animal species for which the additive or premixtures are intended.

EU Regulation 767/2009

9. Article 8 of Regulation 767/2009 requires that complementary feeds should not contain additives at levels of more than 100 times the maximum permitted level in complete feeds. In many cases products, (such as pastes, drenches and boluses) have levels of additives, including copper, in excess of the 100 factor. These products are subject to the authorisation procedure for dietetic feeds. This required dossiers for authorisation for such products to be submitted to the Commission by 31 August 2010.

10. Regulation 767/2009 also contains requirements for the declaration of additives in animal feeds. For copper (and other trace elements) this includes the name of the additive (as set out in its authorisation in Regulation 1831/2003) and the amount added to the feed. The total amount of copper (added together with naturally occurring amounts) may also be declared. Labels for compound feeds

(both complete feeds and complementary feeds) must include instructions for use. In particular, for complementary feeds and feed materials that contain levels of additives in excess of the maximum permitted for complete feed, the label must include instructions to ensure that the maximum levels in the daily ration are complied with.

EU Regulation 183/2005

11. This Regulation requires that feed businesses that manufacture or market copper for feed additive use must be approved by enforcement authorities. Other feed businesses that incorporate copper in compound feeds (e.g. compound feed manufacturers), or market feeds containing feeds containing copper, must be registered.

12. Approval requires a prior inspection visit by an enforcement authority before a feed business is allowed to operate. Registration involves the placing of premises on a list with follow-up checks by the authorities.

13. Both approved and registered establishments have to comply with standards relating to facilities, equipment, quality control, storage, transport and record-keeping. Establishments (except most farms) must also apply the principles of HACCP.

14. Farms must ensure that operations are managed to control hazards. However, farms that buy in certain additive products, including copper, to mix into feeds must apply more stringent standards, including HACCP.

Evidence of the problem

15. It is estimated that that the mean level of copper supplementation in dairy cattle is approximately 20 mg/kg dry matter in most regions. However, in regions where there are copper antagonists, the mean level can rise to between 35-40 mg/kg dry matter.

16. Appendix 1 to ACAF Paper/10/13 suggested that an optimum copper level in normal situations should be based on 18 mg/kg DM in a total mixed ration. This figure is adequate where no antagonists are present and was created to help encourage advisors and farmers to consider all sources of copper intake. It is also well within the maximum statutory limit of 35 mg/kg of complete feed (on a 12% moisture basis). However, there may also be dietary inputs from boluses, drenches and supplemented water, which must be considered too.

17. There appears to be no data on the extent of the problem to indicate how many cattle may be receiving excess copper in their diets. A paper by *Livesey et al (2002)* demonstrated that hepatopathy from copper accumulation could occur in herds without signs of clinical disease. Additionally, the Veterinary Laboratories Agency (VLA) found that in 23 herds surveyed, apparent supplementation in 1 of the herds was over 8000 mg/Cu/day, with 9 of the herds receiving between 1001-2200 mg Cu/day. As animals often receive copper from multiple sources, there appears to be a need for a simple and clear code of practice to stress the importance of the need to consider copper contributions from all sources.

18. KITE, a consultancy company that provides advice to farming and allied industries, has recently produced a technical update sheet on copper poisoning in calves having recognised a significant increase in cases occurring. The advice states not to feed any dairy concentrate to calves of less than 16 weeks of age, and for larger cattle, to restrict the dairy concentrate to a maximum of 2 kg/head/day, or switch to a rearer or beef nut.

Consumer intakes of copper from food.

UK perspective

19. At its September 2010 meeting the Committee requested information on consumer exposure to copper via milk consumption. However, given the very low levels of copper likely to be present in milk (see paragraph 32), information has been provided relating to consumer exposures from other animal-derived produce, especially from those where significant accumulation of copper is possible.

20. The Food Standards Agency (FSA) reported on a 'Survey of Metals in a Variety of Foods' in January 2007 (revised March 2007):

    http://www.food.gov.uk/multimedia/pdfs/fsismetals0107.pdf

21. A total of 310 food samples were analysed for their aluminium, arsenic, cadmium, copper, iron, lead, manganese and zinc contents.

22. While the survey concentrated on food from non-animal sources, the Agency advised that on the basis of the levels of copper (and the other elements) found, that current levels of copper in the diet do not pose a significant risk to consumer safety and that it is still recommended that consumers eat five portions of fruit and vegetables per day. The data from this survey suggest that food of non-animal origin is unlikely to be of concern with regard to copper intakes.

23. In 2003 the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) produced a statement on a survey of metals in infant foods:

    http://cot.food.gov.uk/cotstatements/cotstatementsyrs/cotstatements2003/statementmetals

24. The COT's view was that 'the intake of copper from infant foods and formulae is unlikely to be of concern.'

25. In 2006 the FSA reported the results of a survey on the contents of metals and other elements in 165 samples of offal and offal products:

    http://www.food.gov.uk/science/surveillance/fsisbranch2006/fsis1406

26. This included levels of copper in 71 samples of liver. Elevated levels of copper were found in some samples of liver, with a mean content of 52.75 mg/kg. Using this figure in combination with the consumption of liver for high level consumers of liver (97.5%ile), the intakes of copper from this source can be estimated. This intake expressed as a percentage of the Safe Upper Level (SUL)

of 0.16 mg Cu/kg b.w./day (set by the Expert Group on Vitamins and Minerals, FSA 2003) is as follows:

Age group	**Intake (mg Cu/kg b.w./day)**	**Intake as a percentage of the SUL for high level consumers of liver**
Infants	0.285	178
Toddlers	0.129	80.5
Adults	0.0267	16.7

27. It appears that there is a significant risk that infants that consume a high level of liver will be exposed to levels of dietary copper that exceed the SUL.

28. Unpublished results from the Veterinary Laboratories Agency (VLA) for the copper levels of 544 dairy cattle give a mean content of 127.6 mg/kg; in comparison, the mean copper level in livers from 100 beef cattle was 22.06 mg/kg. This level provides the following estimates of copper intake:

Age Group	**Intake (mg/kg Cu b.w./day)**	**Intake as a percentage of the SUL for high level consumers of liver**
Infants	0.688	430
Toddlers	0.312	195
Adults	0.0645	40.3

29. It should be noted that the cattle used are not representative of the UK herd as a whole, and that the assumption is made here that all liver consumed would be from dairy cattle. Liver copper concentrations are measured by the VLA for three reasons: if toxicity is suspected, if deficiency is suspected, or as monitoring (this will be less frequent). As such the data may not be entirely representative. Nevertheless, these data suggest that high level consumers of liver from dairy cattle would be at significant risk of exceeding the SUL. However, more reliance should be placed on the data from the 2006 FSA survey.

30. In January 2009 the Agency reported concentrations of metals and other elements from the 2006 UK Total Diet Study (TDS). Composite samples for the 20 TDS food groups were collected from 24 UK locations and analysed for levels of 24 chemical elements, including copper:

    http://www.food.gov.uk/science/surveillance/fsisbranch2009/survey0109

    The mean concentration of copper found in the offal food group was 52.5 mg/kg, this is in very good agreement with the level reported in the offal survey of 2006 (see paragraph 26). The COT concluded that the estimated mean- and high-level dietary intakes of copper were unlikely to be of toxicological concern:

    http://cot.food.gov.uk/pdfs/cotstatementtds200808.pdf

<u>European Union perspective</u>

31. There has not yet been a general assessment of copper feed additives by EFSA – this will be undertaken during the assessment under Article 10.2 of Regulation 1831/2003. However, in 2009 EFSA provided a Scientific Opinion on the safety

of a copper chelate of hydroxy analogue of methionine (Mintrex®Cu) as feed additive for all species:

http://www.efsa.europa.eu/en/scdocs/doc/1382.pdf

32. This particular form of copper is more bioavailable to the target species, and hence is likely to be incorporated at lower levels in feed. Using a realistic model calculation, EFSA's view is that the use of this particular feed additive would lead to an additional consumer exposure not higher than 0.5 mg/day, and that this additional intake would not lead to consumers exceeding the upper intake level (UL) set in 2003 by the Scientific Committee on Food (SCF) of 5 mg/day:

    http://ec.europa.eu/food/fs/sc/scf/out176_en.pdf

33. It should be noted that EFSA was of the view that liver would be the main contributor of the extra copper to the diet resulting from the incorporation of the additive in feed. This contrasts with very low levels of copper normally being found in milk. Data used in the assessment of Mintrex®Cu showed levels of about 0.05 mg copper/kg milk.

Summary of copper intakes

34. There are no current concerns with the dietary copper intakes of adult UK consumers or those in other European Union Member States. However, there are some concerns for infants and toddlers that consume a high level of liver.

Action required:

35. The Committee is invited to:

    a) note the information provided in the attached paper on the regulatory controls for use of copper and estimated consumer intakes of copper; and

    b) make any comments on the proposed Code of Practice which has been drafted by the Veterinary Laboratories Agency and members of the feed and feed additives sector (see Appendix).

ACAF Secretariat
December 2010

Proposed Code of Practice for Supplementing Copper to Bovines

FOREWARD

This leaflet aims to outline some practical advice for the use of copper in feed, particularly in the dairy industry, on GB farms. It is supported by the following stakeholders: (example only at this stage)

Food Standards Agency (FSA), British Veterinary Association (BVA), British Cattle Veterinary association (BCVA), National Farmers Union (NFU), Agricultural Industries Confederation (AIC), Department for Environment, Food and Rural Affairs (DEFRA), Veterinary Medicines Directorate (VMD), Veterinary Laboratories Agency (VLA), British Association of Feed Supplement Manufacturers (BAFSAM), Royal Association of British Dairy Farmers (RABDF), Dairy Science Forum (DSF)

INTRODUCTION

Background

Copper is an essential trace element and copper deficiency is the most common trace element deficiency diagnosed in the UK. Copper toxicity has been common in sheep for sometime but has become a more common condition in cattle, especially dairy cows. This has prompted an industry-led working group to investigate the causes.

In the overwhelming majority of copper toxicity cases investigated there has been excessive supplementation of copper. The over-supply of copper is usually associated with the provision of multiple copper sources, none in themselves in excess of maximum levels, but sufficient, when added together, to cause copper poisoning.

It is likely that the sensitivity of black and white cattle to copper has increased over the past 20-30 years. In America, the National Research Council has reduced recommended limits for copper in cattle diets from 100 ppm in 1980 to 40 ppm in 2005. Decreased tolerance to copper exacerbates the effects of over-supplementation and explains why supplementation practices followed 30 years ago might not be appropriate today.

Regulatory MPL

The maximum level of elemental copper permitted under domestic and EU legislation without veterinary prescription is 35 mg/kg (88% dry matter) which equates to 40 mg/kg of total diet dry matter (DM).

COPPER REQUIREMENT

Nutritional requirements

To satisfy nutritional requirements the formulation level in normal situations should be based on 18 mg/kg DM

Copper antagonists
The "availability" of copper ingested by adult ruminants is variable, but under optimum conditions it is in the region of 5%.

It is well known that soil ingestion and especially antagonists such as sulphur, iron and molybdenum reduce copper availability to varying degrees.

Estimating copper availability
Estimating the variation in copper availability in the presence of antagonists has largely relied on mathematical equations derived from sheep experiments and extrapolated to predict copper availability to the dairy cow. It is proposed that this prediction be removed from all feedstuff mineral analysis reports to avoid confusion and to reduce the inadvertent risk of over-supply.

Copper deficiency and suspected deficiency has to be dealt with on a case by case basis, assessing copper status, increasing supplementation and monitoring the effects of increased supplementation.

Calves and dry Cows
Young calves are more susceptible to copper poisoning than adult cows. Pregnant females preferentially divert copper to the foetus. This means that we need to be careful with copper supplies to the late pregnancy cow if we are to avoid the calf being born with unnecessarily high copper loading.

[Recommendations overleaf]

RECOMMENDATIONS

The Code of Practice on Farm for Supplementing Copper

- It is incumbent on all contributing agencies to fully consider the need for copper supplementation before advising a level of input.

- It is incumbent on all contributing agencies to fully investigate and calculate total copper inputs from all applicable sources e.g. grass, forages, compounds, straights, mineral powders, mineral blocks, mineral buckets, boluses, injections and water supply and ensure that in combination they are not excessive.

- If significant doubt exists as to the dietary copper contribution, feedingstuffs (including pasture / forage) should be analysed for copper content.

- Feedingstuff analysis reports should not report estimated copper "availability" levels.

- Records of copper supply changes and protocols should be kept and included into herd health plans.

- Copper concentration in total diet dry matter should "normally" be formulated to achieve 18 mg/kg DM.

- When it is deemed necessary to exceed the 18 mg/kg DM level, but not exceed the statutory limit, the situation should be fully reviewed by all participating parties and the course of action agreed for a specified period of time. Outcome monitoring, including copper status, should also be part of the process.

- An assessment of the residual copper status of the livestock should be undertaken prior to and following copper supplementation (to confirm efficacy even when not necessary for avoiding toxicity).

- In situations where the total copper supply is deemed to require a level exceeding 40 mg/kg DM, a full risk assessment should be employed before a prescription is written. Outcome monitoring, including copper status, should also be part of the process.