

Norwegian Scientific Committee for Food Safety
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Your ref:
Our ref: 2014/188511
Date: 19 December 2014
Org. no.: 985 399 077

Statens tilsyn for planter, fisk, dyr og næringsmidler



Request for risk assessment

- **Coccidiostats as a feed additive and the development of antimicrobial resistance**

1. Background

Coccidiostats are authorised for use as an additive in feed for chicken and turkey. Eleven different coccidiostats have been authorised for use in the EU. Norway has been exempted from the EEA Agreement in this field and has approved only five. The reason is that these five were already in use in Norway when the EEA Agreement was entered into in 1994. In the light of the extent of the production of poultry for slaughter at the time and Norway's restrictive approach to feed antibiotics and coccidiostats, exemption was granted from approval of the other coccidiostats that are authorised in the EU.

In 2007 the Norwegian Food Safety Authority made an informal enquiry to the feed industry and relevant organisations, institutions and unions to establish whether it would be appropriate to ask for the exemption for coccidiostats under the EEA Agreement to be repealed. The same enquiry was repeated to the Norwegian Ministry of Agriculture and Food in 2011. This would simplify our regulations and unify all the regulations concerning limit values for coccidiostats contents in feed and limits for permitted residual values in food. The feedback from the industry was largely that there was unlikely to be a professional basis for more/other coccidiostats than those that are currently permitted, but that it would be completely safe to use all those that had been authorised by the EU. Nevertheless, the Ministry of Agriculture and Food did not approve amendment of the EEA Agreement on this matter.

The EU intended to ban coccidiostats as a feed additive with effect from 2012. Trials were conducted in a number of European countries to identify alternative measures to reduce or prevent coccidiosis in poultry. The conclusion of the EU project was that neither vaccination nor other measures tested could replace the use of coccidiostats in feed. Coccidiostats as a preventive measure to manage coccidiosis in commercial poultry farming are necessary for reasons of both animal health and animal welfare. The proposal to ban coccidiostats as a feed additive was

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therefore put on ice. Authorised coccidiostats are currently being evaluated by the EFSA for re-authorisation as and when the current authorisations expire. With regard to the coccidiostats approved in Norway, we will comply with the EU regulations in full.

In recent times there has been widespread concern that the use of coccidiostats in feed could result in the development of bacteria with antimicrobial resistance in both humans and animals. It is therefore necessary to evaluate whether, and potentially how, the use of coccidiostats in feed for poultry can contribute to an increased occurrence of bacteria with antimicrobial resistance. It would also be appropriate to evaluate whether there are differences between the various coccidiostats and the status of the use of those approved in Norway compared with the others that have been authorised for use in the EU with regard to the development of potential antimicrobial resistance.

2. Available data

- Statistics regarding developments in the production of poultry (chicken and turkey) (Statistics Norway)
- Overview of coccidiostats authorised in the EU (The EU Register of Feed Additives).
- Overview of coccidiostats authorised in Norway (The Norwegian Feed Additives Regulations).
- Statistics regarding the use of coccidiostats in poultry feed in Norway (The Norwegian Food Safety Authority's feed statistics).
- Report from trials implemented at the Norwegian Veterinary Institute (Magne Kaldhusdal).
- EFSA reports on the authorisation/re-authorisation of coccidiostats, particularly EFSA Journal (2004) 90, 1-44.
- Regulation no. 814 of 1 July 2013 on limit values for coccidiostats or histomonostats in food as a result of cross-contamination with such substances in feed.
- The NORM VET/ NORM monitoring programme for antimicrobial resistance in the veterinary and food production sectors.
- The Norwegian Food Safety Authority's request for risk assessment, our ref. 2014/224927.

3. Basis for the assignment

The development of antimicrobial resistance is an increasing problem. The use of coccidiostats as a feed additive for poultry might be a contributing factor to this development. There are a number of approved coccidiostats to choose between for broiler and livestock chicken feed and turkey feed. Only five of these are approved in Norway, whereas eleven different preparations have been authorised for use in the EU. It would be desirable to evaluate all the preparations with regard to the development of potential antimicrobial resistance, as the use of coccidiostats appears unavoidable in commercial poultry production.

Narasin is the active ingredient most commonly used in Norway and dominates broiler chicken production. In addition to acting as a coccidiostat, Narasin has also been found to have an antimicrobial effect on gram-positive bacteria including enterococci, staphylococci and *Clostridium perfringens*. The latter may cause necrotic enteritis in chicken, and Narasin in feed has a preventative effect. Gram-negative bacteria such as *E. coli* are resistant to Narasin. For such reasons the use of Narasin should be assessed separately.

4. Assignment

Based on the above issues the Norwegian Food Safety Authority requests that the Norwegian Scientific Committee for Food Safety evaluate the following in respect of poultry:

1. To what extent can the 11 EU-authorised coccidiostats induce antimicrobial resistance and/or cross-resistance?
2. To what extent can the 11 EU-authorised coccidiostats induce impaired sensitivity in *Coccidia*?

3. Are there advantages or disadvantages associated with the development of antimicrobial resistant bacteria under the current practice in Norway with only five coccidiostats available compared to the 11 EU authorised coccidiostats?
4. Are there advantages or disadvantages associated with the development of impaired sensitivity in *Coccidia* under the current practice in Norway with only five coccidiostats available compared to the 11 EU authorised coccidiostats?
5. What are the risks of antimicrobial resistant bacteria being developed in and/or transferred to people (workers) handling coccidiostat preparations, feed, poultry, poultry products or manure? If so, what risk-reducing measures are available?
6. What are the risks of antimicrobial resistant bacteria being developed in and/or transferred to people (consumers) handling and eating poultry products from poultry production using coccidiostat feed additives?
7. What are the risks of an increase in the therapeutic use of antimicrobials in poultry production under current production practices if coccidiostats with antibacterial effects are replaced by coccidiostats without such effects?
8. Do alternative measures exist that can be employed to reduce the risk of coccidiosis in broiler chickens as effectively as coccidiostats?

5. Timeframe

This request should be managed as an ordinary case. However, it should be viewed in context with the Norwegian Food Safety Authority's request "Antimicrobial resistance in the food chain – a public health perspective", our ref. 2014/224827, submitted to the Norwegian Scientific Committee for Food Safety on 3 November 2014. The two risk assessments have a number of similarities and could be published together in 2015.

6. Contacts

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Yours sincerely,

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