

ADVISORY COMMITTEE ON ANIMAL FEEDINGSTUFFS

50th Meeting of ACAF on 3 June 2010

Information Paper

**MAXIMUM RESIDUE LIMIT DEVELOPMENTS ON
NICARBAZIN PRODUCTS**

**Food Safety; Chemical Contaminants & Novel Foods Division
Food Standards Agency
May 2010**

MAXIMUM RESIDUE LIMIT DEVELOPMENTS ON NICARBAZIN PRODUCTS

Purpose

1. This paper is to inform the Committee of recent Opinions from the European Food Safety Authority (EFSA) on nicarbazin containing products and proposed maximum residue limits (MRLs) in the tissues of chickens reared for meat.

Background

2. The Food Standards Agency set up the Nicarbazin Project Group in 2006, as a joint initiative with the Veterinary Medicines Directorate, the British Poultry Council and the National Farmers Union, to identify ways in which the poultry industry could reduce the incidence and levels of nicarbazin residues in British chicken, and to raise awareness of this issue amongst farmers. The Committee has received various papers on the work done by this Project Group to reduce the incidence and levels of detectable nicarbazin residues in British chicken.

Recent Developments

3. The European Food Safety Authority Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) has recently published two opinions:
 - (a) on the safety and efficacy of Maxiban[®] G160 (narasin and nicarbazin) for chickens for fattening
<http://www.efsa.europa.eu/en/scdocs/scdoc/1574.htm>; and
 - (b) on the safety and efficacy of Koffogran (nicarbazin) as a feed additive for chickens for fattening
<http://www.efsa.europa.eu/en/efsajournal/doc/1551.pdf>.
4. Of the two nicarbazin containing products Maxiban[®] G160, and Koffogran; Maxiban[®] G160 is currently the only product authorised in the EU.
5. EFSA stated that ingested nicarbazin is rapidly split into two components, 2-hydroxy-4,6-dimethylpyrimidine (HDP) and 4,4'-dinitrocarbanilide (DNC). HDP is rapidly excreted and does not leave toxicologically significant amounts of residues in edible tissues. DNC is

used as the marker residue and is the major residue in edible tissues. It is suggested that human consumers would only be exposed to DNC.

6. New studies conducted by FEEDAP concluded that nicarbazin is not genotoxic, and that an Acceptable Daily Intake (ADI) could be set for DNC at 0.77 mg/kg body weight. FEEDAP proposed MRLs for DNC in tissues derived from chickens for fattening: liver (15 mg/kg), kidney (6 mg/kg), muscle (4 mg/kg) and skin/fat (4 mg/kg). FEEDAP concluded that an ADI for DNC would protect human consumers as they are only exposed to DNC. It was calculated that only 24% of the ADI for DNC could be obtained from dietary exposure to chicken meat following the introduction of these MRLs. A 1-day withdrawal of DNC from the feed was considered an adequate time to achieve this MRL in meat. The MRLs proposed in the Koffogran opinion would also be applicable from any other authorised source, including Maxiban[®] G160 product.
7. The Opinion states that as nicarbazin does not display any antimicrobial properties there are no microbiological safety concerns

EU Legislation

8. It is anticipated that the European Commission will propose legislation that will introduce MRLs for DNC as statutory limits in the near future.

Possible future of the Nicarbazin Project Group and input by ACAF

9. The Agency has written to members of the Nicarbazin Project Group informing them of these EFSA opinions and proposed MRLs, and seeking their views on possible disbandment of the Group. Unless objections are raised, it is expected that ACAF in liaison with the Veterinary Residues Committee will provide future advice required on coccidiostat residues in feed and food once MRLs are established.

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