



FEDERATION OF VETERINARIANS OF EUROPE

Position on the treatment of Blackhead in turkeys.

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Background

Black head is an infectious disease of turkeys caused by *Histomonas meleagridis*.

Until recently, March 2003, Nitrofuransol, a nitrofurans, was authorised for use as an additive in feeding stuffs, for the prevention of the disease. The marketing authorisation was given for a period of ten years, without a re-evaluation.

During the years 1990 -1995, both the joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Committee for Veterinary Medicinal Products (CVMP) gave opinions on the use of veterinary medicinal products (VMPs) in food-producing animals of the group of substances known as nitrofurans. They concluded that it was impossible - because of the genotoxicity and carcinogenicity of the substances - to identify acceptable daily intakes. Accordingly it was not possible to set Maximum Residue Levels (MRL) for these substances. All nitrofurans were then inserted into Annex IVⁱ to Council Regulation (EEC) No 2377/90ⁱⁱ with the effect of prohibiting the administration of these substances as VMP to food-producing animals throughout the Community.

The European Commission asked the Scientific Committee on Animal Nutrition (SCAN) to make a new scientific risk assessment for Nifursol. On 11 October 2001, the SCAN adopted its opinion, which concluded that on the basis of the studies on mutagenicity, genotoxicity and carcinogenicity as provided by the holder of the marketing authorisation, and because of the lack of data on developmental toxicity, it was not possible to derive an acceptable daily intake for the consumers. On 18 April 2002, after having examined complementary data provided by the holder of the authorisation, the SCAN confirmed its opinion.

As a consequence of this and in the absence of a favourable opinion of the Standing Committee on the Food Chain and Animal Health, the Commission concluded that the use of nitrofurans for food producing animals should be prohibited. The Council Regulationⁱⁱⁱ that views upon this matter now applies from 31 March 2003.

Actual Problem

Since in the European Community an effective product against blackhead in turkeys is no longer available, many flocks have been or will become infected with *Histomonas meleagridis*, leading to illness and severe suffering of animals and a high mortality, up to 100%. Both, animal health and animal welfare are at stake. For farmers, the outbreak of the disease also means a large economic loss and problems for the continuity of their farms.

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Although the occurrence of this problem was to be foreseen, industry and farmers apparently could not find a way out of that situation. The holder of the authorisation for marketing of nitrofuransol decided to discontinue further product development because of an expected low and uncertain return on investment. And as far as known now, no other pharmaceutical company has planned the introduction of another substance.

If nothing happens and the present situation does not change, more and more flocks will get infected, enormous amounts of animals will suffer and die, and the production of turkeys will gradually disappear out of Europe and go to areas where products are available like the United States of America.

Position FVE

FVE accepts that the use in food producing animals of products that cannot be considered as safe for the consumers has to be avoided.

FVE cannot accept the keeping of animals without the availability of appropriate VMPs, which leads to suffering and the ultimate death of enormous numbers of animals.

FVE recognizes that it is unrealistic to expect pharmaceutical industry to invest money in projects without reasonable expectations about return on investment.

FVE regrets that in toxicological assessments of VMPs *exposure assessment* is not included. The use of acceptable daily intakes assumes the life long intake of the same amount of i.c. turkey every day of the year which obviously is not very realistic.

FVE is aware that in third countries like Canada and in the United States of America products (e.g. 4-nitrophenylarsonic acid / nitarsone) are authorised for the prevention of Histomoniasis.

Because an effective VMP against Blackhead was available, not very much research into the prevention and treatment of the disease has been done in the last decades. FVE therefore thinks that it is urgently needed that representatives from the turkey industry, veterinary experts from the field and research institutes, pharmaceutical industry and also governments work together to explore possibilities to keep turkeys in a sustainable way that does not affect animal health and welfare and that is safe for the consumer. FVE will support such initiatives within the limits of its possibilities.

ⁱ ANNEX IV: Lists of pharmacologically active substances for which no maximum levels can be fixed (List to be established in accordance with the procedure laid down in Article 8)

ⁱⁱ Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin

ⁱⁱⁱ Council Regulation (EC) No 1756/2002 of 23 September 2002 amending Directive 70/524/EEC concerning additives in feedingstuffs as regards withdrawal of the authorisation of an additive and amending Commission Regulation (EC) No 2430/1999