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Safety of a feed additive consisting of halofuginone hydrobromide (STENOROL®) for chickens for fattening and turkeys (Huvepharma N.V.)

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Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the safety for the target species of the coccidiostat halofuginone hydrobromide from STENOROL® when used as a feed additive for chickens for fattening and turkeys. In its previous assessment, the FEEDAP Panel could not conclude on the safety of STENOROL® for the target species at the highest proposed use level of 3 mg halofuginone hydrobromide/kg complete feed. On the basis of the new data provided, the FEEDAP Panel updates its previous conclusions on the safety for the target species as follows: halofuginone hydrobromide from STENOROL® is safe for chickens for fattening and for turkeys up to a maximum of 12 weeks of age at the highest proposed concentration of 3 mg/kg complete feed. For chickens for fattening, a margin of safety of about 1.3 can be established while for turkeys for fattening a margin of safety cannot be established.

Keywords: coccidiostats, halofuginone hydrobromide, chickens for fattening, turkeys, safety

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1831/2003 establishes the rules governing the European authorisation of additives for use in animal nutrition and, in particular, Article 9 thereof defines the terms of the authorisation by the Commission.

The applicant, Huvepharma NV, is seeking the European authorisation of halofuginone hydrobromide as a feed additive to be used as a coccidiostat and histomonostats for chickens for fattening and turkeys (Table 1).

Table 1: Description of the substances

Category of additive	Coccidiostats and histomonostats
Functional group of additive	Coccidiostats and histomonostats
Description	Halofuginone hydrobromide
Target animal category	Chickens for fattening and turkeys
Applicant	Huvepharma NV
Type of request	New opinion

On 17 November 2020, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) of the European Food Safety Authority (EFSA), in its opinion on the safety and efficacy of the product, could not conclude on the safety of Halofuginone hydrobromide.

The Commission gave the possibility to the applicant to submit supplementary information and data in order to complete the assessment and to allow a revision of the EFSA's opinion.

Following the road map, a part of new data have been received on 18 March 2021 and were already transmitted to the Authority by the applicant. A new data on safety for chickens for fattening and turkeys have been received on 18 January 2022 to complete the required information.

In view of the above, the Commission asks EFSA to deliver a new opinion on Halofuginone hydrobromide as a feed additive for chickens for fattening and turkeys based on the supplementary data submitted by the applicant, in accordance with Article 29(1)(a) of Regulation (EC) No 178/2002.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of supplementary information[1] to a previous application on the same product.[2]

In accordance with Article 38 of the Regulation (EC) No 178/2002[3] and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39 e of the same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,[4] a non-confidential version of the supplementary information has been published on Open.EFSA.[5]

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA to deliver the present output.

[1] Dossier reference: EFSA-Q-2022-00182.
[2] Dossier reference: FAD-2010-0293.
[3] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p.1–48.
[4] Decision available at: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements
[5] Available at: https://open.efsa.europa.eu/questions/EFSA-Q-2022-00182

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of halofuginone hydrobromide (STENOROL®) is in line with the principles laid down in Regulation (EC) No 429/2008[6] and the relevant guidance documents: Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017).

3. Assessment

Halofuginone hydrobromide (halofuginone HBr) from STENOROL® is intended for use in feed for the prevention of coccidiosis in chickens for fattening and in turkeys for fattening up to a maximum of 12 weeks of age at the level of 2–3 mg halofuginone HBr/kg complete feed.

The present opinion assesses the safety for the target species of this additive.

3.1. Safety for the target species

In its former opinion (EFSA FEEDAP Panel, 2020), the FEEDAP Panel was not able to conclude on the safety of STENOROL® for chickens and turkeys for fattening at the highest proposed use level of 3 mg halofuginone HBr/kg complete feed based on the available tolerance studies.

In the study previously reported with chickens for fattening, the zootechnical performance of the birds in all groups, including the untreated control group, was substantially below the target values given in the relevant performance objectives of the breed. The FEEDAP Panel considered that such a low performance did not allow to extend any conclusion to fast growing birds under standard European farming conditions.

The safety for turkeys for fattening at the proposed maximum use level could not be established based on the available tolerance study in turkeys due to the lower performance of the birds and the adverse effect seen at the 1.5× and 2.0× overdose levels on final body weight.

The applicant provided three new studies, one in chickens for fattening and two in turkeys for fattening to support the safety for the target animals.

3.1.1. Safety for chickens for fattening

A total of 1,200 day-old male chickens for fattening (Ross 308 broiler strain, 37.6 g body weight at placement) was allocated to four groups with 15 replicate pens (20 birds/replicate) each.[7] Birds were fed mash diets based on maize, wheat and soybean meal, containing 0, 3.0 (1.0× the maximum proposed use level), 4.0 (1.33×) or 5.0 (1.67×) mg halofuginone HBr/kg complete feed, respectively, for 35 days (intended concentrations were analytically confirmed). A starter diet (23.4% crude protein (CP), 12.5 MJ metabolisable energy (ME)/kg) was provided for the first 10 days, followed by a grower diet (21.6% CP, 13.0 MJ ME/kg) from day 11 until day 21, and a finisher diet (18.6% CP, 13.4 MJ ME/kg) for the rest of the study.

General health was monitored daily (including dead and culled birds). Body weight and feed intake were recorded at 1, 10, 21 and 35 days; feed to gain ratio was calculated for the corresponding intervals. On day 35, blood samples were taken from two birds per replicate (30 birds/treatment) for routine haematology[8] and clinical blood chemistry.[9] At the same time, another bird per replicate (15 birds/treatment) was killed and subjected to necropsy; selected organs[10] were grossly examined, and their weight were determined. Histopathology was performed for liver, kidney, heart and the

[6] Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1.

[7] Techncial dossier/Annex-1.

[8] Haematocrit (Hct), haemoglobin (Hb), erythrocyte count (RBC), mean corpuscular haemoglobin (DMCH), mean corpuscular haemoglobin concentration (MCHC), mean corpuscular volume (DMCV), total leucocyte count (WBC), differential leucocyte count, avian platelets (THBC), prothrombin time and fibrinogen.

[9] Alkaline phosphatase (ALP), alanine aminotransferase (ALT), aspartate aminotransferase (AST), lactate dehydrogenase (LDH), creatine kinase (CK), total bilirubin (Bili), Bile acids (BiAc), urea (Ur), uric acid (Ua) creatinine (Creat), glucose (Gluc), total cholesterol (Chol), acute phase proteins (ovotransferrin and C-reactive protein), amylase (Am), sodium (Na), potassium (K), chloride (Cl), calcium (Ca), inorganic phosphorus (P), magnesium (Mg), total protein (Total Prot), albumin (Alb), globulin (Glo).

[10] Liver, kidneys, spleen, adrenal gland, lung, stomach, pancreas, small intestine, colon, caecum, thymus, thyroid gland, heart, intestinal lymph nodes/intestinal tonsils and testes.

gastrointestinal tract (oesophagus, stomach, duodenum, jejunum, ileum, colon, and caeca) in the control and in the 1.67× overdose group.

The data were analysed as a completely randomised design by GLM and group comparisons were made by a Tukey-test. Statistical significance was established at $p \leq 0.05$. In addition, weight gain and feed intake of the two overdose groups (1.33× and 1.67×) were tested for non-inferiority compared to the control and the use level group (1.0×).

Mortality was low and not different among the experimental groups. Zootechnical parameters, blood parameters and organ weight showing modifications are summarised in Table 2.

Table 2: Main results of a five-week tolerance study in chickens for fattening with halofuginone HBr from STENOROL®

Group	Control	1.0× use level	1.33× overdose	1.67× overdose
Intended halofuginone HBr concentration in feed (mg/kg)	0	3.0	4.0	5.0
Mortality (%)	1.0	3.3	2.7	2.3
Final body weight (kg)	2,166^{a}	2,199^{a}	2,149^{a}	2,011^{b}
Weight gain (g/day)	60.7^{a}	61.0^{a}	59.8^{a}	56.0^{b}
Feed intake (g/day)	94.2^{ab}	95.8^{a}	91.9^{ab}	93.5^{b}
Feed to gain ratio	1.55^{a}	1.57^{a}	1.54^{a}	1.67^{b}
RBC ($\times 10^{6}$ cells/μl)	2.27^{a}	2.19^{ab}	2.15^{ab}	2.08^{b}
Glucose (mg/dL)	271^{b}	276^{ab}	299^{a}	294^{ab}
Globulin (g/dL)	1.83^{a}	1.53^{b}	1.65^{ab}	1.64^{ab}
Uric acid (mg/dL)	4.08^{b}	4.82^{ab}	5.45^{a}	5.26^{a}
AST (U/L)	399^{b}	420^{ab}	522^{a}	375^{b}
ALP (U/L)	20,046^{a}	17,189^{ab}	10,169^{b}	13,429^{ab}
LDH (U/L)	4,251^{ab}	3,780^{ab}	5,485^{a}	3,311^{b}
CK (U/L)	34,987^{b}	28,797^{b}	52,894^{a}	26,686^{b}
Mg (mg/dL)	2.66^{c}	2.83^{bc}	3.16^{ab}	3.28^{a}
P (mg/dL)	8.71^{b}	9.13^{ab}	9.19^{ab}	9.57^{a}
K (mmol/L)	7.2^{c}	8.2^{b}	9.4^{a}	9.9^{a}
Cl (mmol/L)	115^{b}	117^{ab}	116^{ab}	118^{a}
Liver weight (% of body weight)	1.84^{b}	2.05^{ab}	2.05^{ab}	2.18^{a}

^{a,b,c}: Different letter superscripts in the same line indicate significant differences ($p < 0.05$).

The chickens reached at the end of the study about 91% of the commercially achievable body weight.[11]

No differences in the zootechnical parameters were observed in the 1× and 1.33× groups compared to the control. The 1.67× group significantly reduced final body weight, average daily gain and increased feed to gain ratio compared to the control and the other two treatment groups. The non-inferiority of the 1.33× group to the control and the 1× group was also demonstrated.

All mean haematology and clinical chemistry values were within reference ranges for healthy control broiler chickens derived from previous trials in the same facility. In both overdose groups, a significant increase for serum Mg and uric acid was seen in comparison to the control group. All supplemented groups showed higher serum K concentration compared to the control group. Serum P and Cl were elevated in the 1.67× overdose group when compared to the control while RBC was reduced. Other significant differences in clinical blood chemistry were considered of small biological relevance and not always dose related.

Birds from the four groups were considered healthy at the end of the trial by necropsy. Necropsy results did not show any difference among the experimental groups, except for liver weight, which was increased for the 1.67× overdose compared to the control. The histological evaluation showed that livers in the control and in the 1.67× overdose group exhibited inflammatory cell aggregates, independently of the dietary treatment. The lesions were mainly classified as of small relevance,

[11] https://en.aviagen.com/assets/Tech_Center/Ross_Broiler/RossxRoss308-BroilerPerformanceObjectives2022-EN.pdf

aggregates classified as moderate were seen in only 1/15 livers of the control group and 2/15 livers from the 1.67× overdose group. A light vacuolar degeneration of the hepatocytes was observed in two livers of the control and in one liver of the 1.67× overdose group.

Conclusions on the safety for chickens for fattening

Halofuginone HBr offered at 5 mg/kg complete feed is not tolerated by chickens for fattening. No adverse effects were observed in the highest recommended level (3 mg/kg feed) group and at 4 mg/kg feed of inclusion level. It can therefore be concluded that halofuginone hydrobromide from STENOROL® is safe for chickens for fattening at the highest proposed concentration of 3 mg/kg complete feed with a margin of safety of about 1.3.

3.1.2. Safety for turkeys

Study 1

A total of 480 day-old male turkeys for fattening (Hybrid Converter; 62.5 g body weight at placement) was allocated to four groups with 15 replicates[12] each (8 birds/floor pen). Birds were fed pelleted diets consisting mainly of maize, wheat and soybean meal supplemented with 0, 3.0 (1.0× the maximum concertation), 4.0 (1.33×) or 5.0 (1.67×) mg halofuginone HBr/kg complete feed, respectively, for 48 days (intended concentrations were analytically confirmed). Feed and water were offered on *ad libitum* basis. A starter diet (calculated 26.8% CP, 0.60% digestible methionine, 11.7 MJ ME/kg) was provided for the first 14 days, followed by a grower diet (calculated 23.7% CP, 12.1 MJ ME/kg) for the rest of the study.

General health observations were made and recorded once a day and mortality (including culling) was recorded. All dead turkeys were subjected to necropsy. Body weight and feed intake were recorded at days 1, 14, 28 and 48, and feed to gain ratio was calculated for the corresponding intervals.

On week 7, blood samples were taken from two birds per replicate (30 turkeys per treatment) for haematology[13] and blood biochemistry.[14] The same birds were killed and subjected to necropsy, organ weights were determined for liver, kidneys, spleen, lung, stomach, pancreas, small intestine, colon, caecum, heart and testes. Organs showing macroscopic lesions during autopsy underwent histological analysis.

Statistical analysis for the zootechnical parameters was done on replicate basis. Feed consumption and weight gain were subjected to a non-inferiority test (+ Sidak's correction). Body weight, weight gain, feed consumption and organs weights were analysed by ANOVA. Initially a Dunnett test was used to compare the group means with the control; upon request of EFSA, the applicant performed pair-wise comparisons among all treatment groups.[15] Wilcoxon rank sum test with Sidak's correction was applied to feed to gain ratio, haematology and blood chemistry parameters. Statistical significance was established at $p \leq 0.05$.

Zootechnical parameters, blood parameters and organ weight showing modifications are summarised in Table 3.

[12] Technical dossier/Annex-2.
[13] Packed cell volume, total white blood cell count, differential white blood cell count (heterophils, lymphocytes, monocytes, eosinophils, basophils), haemoglobin, haematocrit.
[14] Albumin, globulin (calculated as TP – Alb), alkaline phosphatase, glucose, amylase, aspartate aminotransferase (AST), lactate dehydrogenase, bilirubin, magnesium, calcium, phosphorus, chloride, potassium, cholesterol, sodium, total protein, creatine phosphokinase, uric acid.
[15] Technical dossier/Additional data September 2022/Annex_RTQ_03.

Table 3: Main results of a seven-week tolerance study in turkeys for fattening with halofuginone HBr from STENOROL®

Group	Control	1.0× use level	1.33× overdose	1.67× overdose
Intended halofuginone HBr concentration in feed (mg/kg)	0	3	4	5
Mortality (%)	1.7	3.3	3.3	6.7(1)
Final body weight (g)	3,587[a]	3,520[ab]	3,366[b]	3,126[c]
Weight gain (g/day)	73[a]	71[ab]	68[b]	63[c]
Feed intake (g/day)	122	121	113	115
Feed to gain ratio	1.67	1.70	1.66	1.84
Glucose (g/L)	2.83[ab]	2.86[a]	2.71[ab]	2.67[b]
Liver weight (% of body weight)	1.87[b]	1.94[ab]	1.96[ab]	2.03[a]

[a,b,c]: Means with different letters within the same row are significantly different ($p < 0.05$).
(1): When subtracting two culled animals which escaped, mortality was < 5%.

Mortality was generally low during this study and not different among the experimental groups. The turkeys reached at the end of the study about 90% of the commercially achievable body weight.[16] During the whole study period, final body weight and body weight gain of both groups receiving overdoses (1.33× and 1.67×) were significantly depressed compared to the control group. Non-inferiority was observed for feed intake and weight gain of the use level group (1.0×) compared with the control. Non-inferiority was not significant for feed intake in the 1.33× and the 1.67× overdose groups as well as for weight gain in the 1.67× overdose group.

For all haematological endpoints, no significant differences were observed among the groups. Regarding blood glucose a significant reduction was found in the 1.67× overdose group compared to the use level group (1.0×).

Abnormalities were found only in the overdose groups (1.33× and 1.67×), in four turkeys in the 1.33× group (three birds with proventriculus ulceration) in and only two in the 1.67× group (one bird with gizzard ulceration). There was no clear evidence of a dose–response effect.

The only difference in organ weight was seen for a higher relative liver weight of the 1.67× overdose group compared to the control.

Study 2

In a second study[17] with turkeys for fattening, 480-day-old male turkeys (B.U.T.6; initial body weight 63.9–64.9 g) were allocated to four groups with 15 replicates (8 birds/floor pen). Birds were fed pelleted diets consisting mainly of maize, wheat and soybean meal with 0, 2.0 (0.67×), 2.75 (0.92×) and 3.5 (1.17×) mg halofuginone HBr/kg complete feed respectively, for 42 days (intended concentrations were analytically confirmed). It is noted that in this study the currently proposed maximum use level (3 mg/kg) was not tested. Feed and water were offered on *ad libitum* basis. A starter diet (calculated 28.8% CP, 11.9 MJ ME/kg) was provided for the first 14 days, followed by a grower diet (calculated 26.0% CP, 12.4 MJ ME/kg) for the rest of the study.

General health observations were made and recorded once a day and mortality (including culling) was recorded. All dead turkeys were subjected to necropsy. Body weight and feed intake were recorded at days 1, 14, 28 and 42, and feed to gain ratio was calculated for the corresponding intervals. At study end, blood samples were taken from two birds/pen for haematology[18] and blood chemistry,[19] the same birds were necropsied for gross pathology.[20]

A non-inferiority test with the control group was applied for the feed intake and weight gain parameters. All zootechnical parameters, organ weights and blood parameters were also analysed with ANOVA. Multiple comparisons of means were performed.

[16] https://www.hybridturkeys.com/documents/1227/Converter_NA_CS_Performance_Metric_052021.pdf
[17] Technical dossier/Additional data September 2022/Annex_RTQ_04.
[18] Packed cell volume, total white blood cell count, differential white blood count (heterophils, lymphocytes, monocytes, eosinophils, basophils), haemoglobin, haematocrit, leukocyte count, differential leukocytes counts.
[19] Albumin, globulin (calculated as TP – Alb), alkaline phosphatase, glucose, amylase, aspartate aminotransferase (AST), lactate dehydrogenase, bilirubin, magnesium, calcium, phosphorus, chloride, potassium, cholesterol, sodium, total protein, creatine phosphokinase, uric acid.
[20] Liver, kidneys, spleen, lung, stomach, pancreas, small intestine, colon, caecum, heart and testes.

Zootechnical parameters are displayed in Table 4. Total mortality across treatments was reported to be 1% (5 birds out of 480) and not related to treatments. Birds grew considerably below (less than 35%) the expected performance of B.U.T.6 genetic potential[21] for males of 42 days (i.e. 2,820 g). Bird growth performance was impaired in the 3.5 mg halofuginone HBr group as evidenced by the differences in body weight and daily weight gain relative to the control group at the end of the study period. However, 2 and 2.75 mg halofuginone HBr did not influence body weight at 42 days. Feed consumption and feed to gain ratio were not affected by halofuginone HBr.

Table 4: Main results of a six-week tolerance study on turkeys for fattening with halofuginone hydrobromide from STENOROL®

Group	Control	0.67×	0.92×	1.17×
Intended halofuginone HBr concentration in feed (mg/kg)	0	2	2.75	3.5
Mortality (n/120)	1	2	1	1
Final body weight (g)	1,828[a]	1,843[a]	1,812[a]	1,657[b]
Weight gain (g/day)	42[a]	42[a]	42[a]	38[b]
Feed intake (g/day)	67	67	68	64
Feed to gain ratio	1.60	1.59	1.64	1.72

[a,b,c]: Means with different letters within the same row are significantly different ($p < 0.05$).

The haematological and biochemical parameters of the blood only revealed two values that were affected statistically by halofuginone HBr. Thus, uric acid and globulin in the 3.5 mg/kg group led to higher values than the 2 mg/kg group only, however the differences were small and not of biological relevance. No relevant macroscopic observations were identified.

Considering the lower performance of the birds in study 2 and the adverse effect seen at the 1.17× treatment on final body weight, the safety at the proposed maximum use level (not tested) cannot be established from this study.

Conclusions on the safety for turkeys

In study 1, adverse effects were evidenced at 4 and 5 mg/kg feed, while no adverse effects were observed at the maximum recommended level of 3 mg/kg feed.

In study 2, the animals showed a low performance and exposure to the additive, and the maximum recommended level was not tested. However, the results showed an adverse effect at 3.5 mg/kg feed, which indicates that this level is not tolerated by the turkeys for fattening.

It can therefore be concluded that halofuginone HBr from STENOROL® is safe for turkeys for fattening at the highest proposed use level of 3 mg halofuginone HBr/kg complete feed. A margin of safety cannot be established.

4. Conclusions

Halofuginone hydrobromide from STENOROL® is safe for chickens for fattening and for turkeys for fattening up to a maximum of 12 weeks of age at the highest proposed concentration of 3 mg/kg complete feed. For chickens for fattening a margin of safety of about 1.3 can be established while for turkeys for fattening a margin of safety cannot be established.

5. Documentation provided to EFSA/chronology

Date	Event
30/06/2021	Supplementary information received by EFSA. Halofuginone hydrobromide (STENOROL®). Submitted by Huvepharma NV
28/01/2022	Reception mandate from the European Commission
04/03/2022	Acceptance of the mandate of the European Commission by EFSA – Start of the scientific assessment
03/06/2022	Additional data request to the applicant in line with Article 7(3) of Commission Regulation (EC) No 1304/2003 – Scientific assessment suspended. *Issues: Target animal safety*

[21] https://www.aviagenturkeys.com/uploads/2022/03/16/POBRMLB_V5_BUT%20Males_Breeder%20Goals_UK_2022.pdf

Date	Event
12/09/2022	Reception of additional data from the applicant - Scientific assessment re-started
23/11/2022	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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Abbreviations

CP	crude protein
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
ME	metabolisable energy