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Safety of a feed additive consisting of lignosulphonate for all animal species (Borregaard AS)

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Abstract

Following a request from the European Commission, the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the safety of lignosulphonate, when used as a technological additive (functional group: binders) in feed for all animal species. In two previous assessments, the FEEDAP Panel concluded that the maximum level proposed of 10,000 mg lignosulphonate/kg complete feed is safe for weaned piglets, pigs for fattening, chickens for fattening, laying hens and cattle for fattening, but a margin of safety could not be identified. Consequently, these conclusions could not be extrapolated to other animal species/ categories. In the current application, the applicant proposed to reduce the maximum content of lignosulphonate in feed for all animal species to 8,000 mg/kg complete feed. The results of two newly submitted tolerance studies allowed the Panel to conclude that 8,000 mg lignosulphonate/kg complete feed is also safe for dairy cows and salmonids, with a margin of safety of at least 1.25. Considering the results of the studies previously assessed and those of the two new tolerance studies, the FEEDAP Panel concluded that lignosulphonate is safe for all animal species when used at a maximum content of 8,000 mg/kg complete feed.

Keywords: lignosulphonate, all animal species, technological additive, binders, safety

Requestor: European Commission

Question number: EFSA-Q-2022-00195

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1. Introduction

1.1. Background and terms of reference as provided by the requestor

Regulation (EC) No 1831/2003[1] establishes the rules governing the Community 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, Borregaard AS, is seeking a Community authorisation of lignosulphonate as a feed additive to be used as a binder for all animal species (Table 1).

Table 1: Description of the substances

Category of additive	**Technological additives**
Functional group of additive	Binders
Description	Lignosulphonate
Target animal category	All animal species
Applicant	Borregaard AS
Type of request	New opinion

On 10 January 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 lignosulphonate for salmonids and dairy cows.

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. The new data have been received on 21 February 2022.

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

1.2. Additional information

Lignosulphonate is currently authorised for use as a technological additive (functional groups: binders, anti-caking agents and coagulants) in feedingstuffs for all species and categories of animals, with no maximum feed inclusion limit, and without a time limit,[2] and foreseen for re-evaluation according to the provisions set in Regulation (EC) No 1831/2003. The applicant is seeking the re-evaluation of lignosulphonate as a technological additive, functional group: binders, in feedingstuffs for all animal species.

The European Food Safety Authority (EFSA) Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) has adopted two opinions on this additive (EFSA FEEDAP Panel, 2015, 2020). The FEEDAP Panel could not conclude on the safety of the additive for the target species. In the current submission, the applicant proposes a modification of the conditions of use and provides additional tolerance studies in dairy cows and in salmonids.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of supplementary information[3] to a previous application on the same product.[4]

[1] Regulation (EC) No 1831/2003 of the European Parliament and of the council of 22 September 2003 on the additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.
[2] COMMISSION REGULATION (EC) No 2439/1999 of 17 November 1999 on the conditions for the authorisation of additives belonging to the group 'binders, anti-caking agents and coagulants' in feedingstuffs.
[3] Dossier reference: EFSA-Q-2022-00195.
[4] Dossiers reference: FAD-2010-0209 and FAD-2017-0012.

In accordance with Article 38 of the Regulation (EC) No 178/2002[5] and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,[6] a non-confidential version of the supplementary information has been published on Open.EFSA.[7]

The FEEDAP Panel used the data provided by the applicant to deliver the present output.

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of lignosulphonate is in line with the principles laid down in Regulation (EC) No 429/2008[8] and the Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017).

3. Assessment

The present opinion deals with safety for the target species of lignosulphonate as a technological additive (functional group: binders) in feedingstuffs for all animal species.

In its previous opinions (EFSA FEEDAP Panel, 2015, 2020), the FEEDAP Panel concluded that the additive is safe at the concentration of 10,000 mg/kg complete feed for weaned piglets, pigs for fattening, chickens for fattening, laying hens and cattle for fattening, but with no margin of safety. In the same opinions, the FEEDAP Panel concluded that it was not possible to identify a safe concentration of lignosulphonate for dairy cows and for salmonids.

In the current submission, the applicant provided additional tolerance studies in dairy cows and in rainbow trout. In addition, the applicant is requesting a modification of the conditions of use of the additive. In particular, the applicant is proposing a reduction, for all animal species, of the maximum content of the additive, from the previously proposed maximum content of 10,000 mg/kg complete feed to 8,000 mg/kg complete feed. The assessment will address the safety for the target species considering the newly submitted data and the data assessed in previous opinions (EFSA FEEDAP Panel, 2015, 2020).

3.1. Safety

3.1.1. Safety for the target species

The applicant provided three new studies, two in dairy cows, and one in rainbow trout to support the safety for target animals.

3.1.1.1. Safety for dairy cows

In a first study with dairy cows, lignosulphonate was incorporated into a concentrate, fed to the animals to provide the intended amount of the additive.[9] The lignosulphonate content in the concentrate was estimated by pellet durability index. However, the intended lignosulphonate content could not be confirmed in all the concentrate feeds prepared, probably due to the use of different equipment and variations in the preparation of the concentrate. Considering this limitation, the study was not further considered for the assessment.

In a second study, 51 dairy cows (Holstein breed, mean body weight 710 kg (range 558–902), age: 41 months (range 24–85), parity 1.8 (range 1–5), 139 days in milk (range 35–293), milk yield 32 kg/day (range 23–47)) were distributed to 4 groups of 13 cows each (control group 12 cows) and fed (partial mixed) diets containing no lignosulphonate (control group), or the diet containing 8,000 (1× the maximum content), 10,000 (1.25×) or 12,000 (1.5×) mg lignosulphonate/kg DM,[10] respectively, for 56 days.[11] Animals were distributed between treatments by parity, days in milk, average milk yield in the

[5] 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, pp. 1–48.
[6] Decision available at: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements.
[7] Available at: https://open.efsa.europa.eu/questions/EFSA-Q-2022-00195.
[8] 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.
[9] Technical dossier/Annex III-26.
[10] Corresponding to 7,040 (1× the maximum content), 8,800 (1.25×) or 10,560 (1.5×) mg lignosulphonate/kg complete feed.
[11] Technical dossier/Annex III-32 to Annex III-38 and Supplementary Information October 2022.

previous week, and body weight. The cows were distributed in three pens, each with four cows of the control group with three electronic feeders, and 13 cows of one treated group with 12 electronic feeders.

The basal diet consisted of roughage (alfalfa silage, corn silage, oat hay) and a concentrate (consisting mainly of barley, soybean and oat meals, providing about 50% of the total daily ration dry matter (DM)) and contained by analysis 51% DM, 15.5% crude protein (CP) and 4.1% EE; energy concentration was calculated as 6.7 MJ NEL/kg. Lignosulphonate was incorporated in the diet added to a supplemented concentrate (at 21,000 mg lignosulphonate/kg), which was mixed with the same concentrate (but not supplemented with lignosulphonate) at different proportions to reach the intended concentration of the additive in the diet for each experimental group. The concentration of lignosulphonate in the concentrate was estimated by the pelleting conditions in the feed mill and pellet durability; the intended concentration was confirmed. A small quantity of soybean meal (0.8 kg daily) was given to all cows in the milking parlour.

The health status of the animals was monitored daily. No animal died during the study. Two control cows, one cow in the 1× group and one the 1.25× group had a mastitis event.

Body weight, milk yield, milk fat and protein and dry matter intake were recorded and analysed daily; fat, lactose, total solids, protein, urea and somatic cell count in milk were recorded and analysed biweekly; blood samples from 12 cows per treatment were collected at study days 1 and 56 to analyse blood biochemistry[12] and haematology.[13] Feed samples were taken weekly for analysis of the nutritional composition.

The statistical analysis was based on a factorial randomised block design using a mixed-effects model for repeated measures using the average of measured parameters during the adaptation period or initial values for blood and milk analysis, parity and initial days in milk as covariate, with the treatment, the week of study and its interaction as fixed effects, and cow as random effect. The experimental unit was the animal. Milk yield was the parameter used to determine sample size.[14]

The results of the zootechnical parameters analysed for which statistical differences observed are summarised in Table 2. No statistical differences between the treatment groups were observed in most of the zootechnical parameters analysed (mean values: total DM intake (TDMI) 24.9 kg; milk yield 32.1 kg/day; milk fat 3.87%; energy corrected milk 33.5 kg/day; fat corrected milk 33.7 kg/day; fat yield 1.23 kg/day; protein yield 1.05 kg/day; lactose yield 1.56 kg/day; feed efficiency (FCM/TDMI) 1.37); body weight increase was significantly lower in the 1× group compared to the control and the 1.5×, and lower in the 1.25× compared to the 1.5× group, while the milk protein content was lower in the 1× and in the 1.25× groups compared to the 1.5×. The modifications are not considered to be related to the treatment or level.

The results of the milk composition analysis from biweekly samples showed that lignosulphonate at 1× and 1.5× increased milk fat percentage compared with the control. In contrast, milk protein percentage was lower in the 1× and the 1.25× groups than in the control. Lactose and non-fat-solids remained unchanged. Milk urea concentration values were within the common range (15–30 mg/dL); mean milk urea concentration in the 1.5× group was greater compared to control and 1.25×. Somatic cell count was lowest in 1.5× group in which no cow had mastitis, in contrast to the other groups.

Table 2: Main results of the zootechnical parameters measured in the tolerance study in dairy cows

Lignosulphonate concentration (mg/kg DM)	Body weight increase (kg)	Daily milk sampling	Biweekly milk sampling		
		Milk protein (%)	Milk fat (%)	Milk protein (%)	Milk urea (mg/dL)
0	32^{ab}	3.30^{ab}	3.69^{b}	3.39^{a}	25.7^{b}
8,000	22^{c}	3.27^{b}	3.96^{a}	3.26^{b}	26.5^{ab}
10,000	27^{bc}	3.29^{b}	3.86^{ab}	3.27^{b}	24.6^{b}
12,000	37^{a}	3.34^{a}	4.08^{a}	3.36^{ab}	28.6^{a}

DM: dry matter.

a,b,c: Mean values within a column with a different superscript are significantly different $p < 0.10$.

[12] Ca, P, Mg, Na, Cl, K, total protein, albumin, globulin, glucose, urea, cholesterol, creatinine, bilirubin, haptoglobin (as an acute phase protein), amylase, GGT, ALP, ALAT, AST, LDH and creatinine kinase.

[13] Red blood cells, packed cell volume, haemoglobin, mean corpuscular volume (MCV), mean corpuscular haemoglobin (MCH), mean corpuscular haemoglobin concentration (MCHC), total and differential counts for leukocytes, platelet counts, prothrombin time and fibrinogen.

[14] Group sample size of 12 achieves 92% power to detect non-inferiority, assuming that the margin of non-inferiority is 10. The significance level (alpha) of the test is 0.15, and the standard deviation of the population of the study is 6.

Regarding blood parameters, no significant differences were found for red blood cells, packed cell volume, haemoglobin, mean corpuscular volume, mean corpuscular haemoglobin, mean corpuscular haemoglobin concentration, neutrophils, monocytes, basophils, fibrinogen and platelet count. The blood parameters, for which a statistical difference among groups was observed, are reported in Table 3. The differences observed did not follow a specific pattern linked to lignosulphonate level in the diet.

Blood biochemical parameters did not show differences between the groups with two exceptions: total protein was lower in the groups 1.25× and 1.5× compared to the control and the 1× group, globulin concentration was lower in the 1.5× group compared to the control and the 1× group. The differences were small and not considered to be of biological relevance.

Table 3: Main results of the blood parameters analysed in the tolerance study in dairy cows

Lignosulphonate concentration (mg/kg DM)	White blood cells (10^9 cells/L)	Lymphocytes (10^9 cells/L)	Eosinophils (cells/μL)	Prothrombin time (s)	Total protein (g/dL)	Globulin (g/dL)
0	8.4^{ab}	3.8b	0.23^{bc}	28.9^{c}	7.31^{a}	3.67^{a}
8,000	7.5^{b}	3.7^{b}	0.32^{ab}	31.0^{b}	7.30^{a}	3.70^{a}
10,000	7.5^{b}	3.8^{b}	0.14^{c}	32.7^{a}	7.04^{b}	3.46^{ab}
12,000	8.6^{a}	4.4^{a}	0.36^{a}	30.5^{bc}	7.07^{b}	3.38^{b}

DM: dry matter.
a,b,c: Mean values within a column with a different superscript are significantly different $p < 0.10$.

3.1.1.1.1. Conclusion on the safety for dairy cows

The results form a 56-day tolerance study with lignosulphonate in dairy cows showed that lignosulphonate is tolerated up to a concentration of 12,000 mg/kg DM. The lowest dose tested (8,000 mg/kg feed DM) is considered safe with a margin of safety of 1.5.

The proposed maximum of 8,000 mg/kg complete feed refers to a standardised complete feed with 88% DM. The corresponding lignosulphonate content would be 9,091 mg/kg DM. This level is also considered safe for dairy cows with a margin of safety of about 1.3.

3.1.1.2. Safety for rainbow trout

A total 700 growing rainbow trout (*Oncorhynchus mykiss*, body weight 51 g) were randomly distributed into 20 experimental tanks (four replicate tanks per experiment group, with 35 fish each) and fed diets containing no lignosulphonate (control group), or the diet containing 500 (0.063x the maximum content), 1,000 (0.125×), 8,000 (1×) or 10,000 (1.25×) mg lignosulphonate/kg complete feed, respectively, for 91 days. A withdrawal period of 31 days followed the end of the supplementation period.[15]

The intended dietary lignosulphonate levels were confirmed by the analysis of a marker ([redacted]), which was premixed with the test item before incorporation into the diet.

The diets, consisting mainly of fishmeal, soy protein concentrate, wheat meal and fish and rapeseed oil, were approximately isonitrogenous (42.7% CP) and isocaloric (22.6 MJ GE/kg). The mixture without the oils were extruded, the pellets afterwards air dried and vacuum-coated with the fish and rapeseed oil mixture. Fish were fed extruded pellets, according to fish size and water temperature of the system, the quantity ranged from 2.02 (at start) to 1.22% body weight per day (at study end). Fish were weighed in 2- to 3-week periods.

Water oxygen (mean oxygen: 8.9 mg/L) and temperature were measured once daily, ammonia, pH, nitrite and nitrate once per week (all remained in the limits recommended for trout).

Zootechnical endpoints measured were: survival, body weight and gain, feed to gain ratio, specific growth rate (SGR)[16] and thermal growth coefficient (TGC).[17] Blood samples were taken at day 91 from 10 fish per tank for haematology[18] and blood chemistry.[19] The same 10 fish per tank were then killed

[15] Technical dossier/annex III-20 to Annex III-25 and Supplementary Information October 2022.
[16] Specific growth rate: {100 × [ln (final BW/initial BW)]} × day^{-1}.
[17] Thermal growth coefficient (TGC): 1,000 × [FBW (1/3) − IBW (1/3) (g)]/[days of growth × mean temperature °C].
[18] Haematocrit (%), haemoglobin (g/dL), neutrophilic granulocytes (%), lymphocytes (%), monocytes (%); and per high power field (1,000 × magnification) neutrophilic granulocytes, lymphocytes, monocytes, white blood cells, anisocytosis, immature neutrophils.
[19] Sodium, chloride, calcium, phosphate, magnesium, glucose, urea, cholesterol, total protein, albumin; creatinine; amylase; aspartate aminotransferase (AST), lactate dehydrogenase (LDH), alkaline phosphatase (ALP), creatine kinase (CK).

for necropsy and body parameters.[20] In addition, due to the lack of results for some blood parameters (potassium, bilirubin, uric acid and AST could not be analysed because of haemolysis and/or measurements below limit of quantification/limit of detection (LOQ/LOD); AST, LDH, ALP and CK were partially affected by haemolysis), histopathological examination of liver, kidney and spleen was made.

The statistical analysis was a non-inferiority test on the key performance parameters (final body weight and SGR), with a pre-specified non-inferiority margin of 5%. For difference testing, an overall ANOVA followed by post hoc pairwise comparison to control (Dunnett) was performed. Occurrence of frequency (percentage) results were analysed using chi-square test. Experimental unit for performance data was the tank, for other parameters – the individual fish.

Only one fish (control group) died during the 91-day experimental phase. No significant inferiority of the treated groups nor any difference in zootechnical parameters between the treatments was observed. Average final weight was 391 g (range: 389–395), average SGR 2.24 (range 2.24–2.26), TGC 2.58 (range 2.58–2.60) and feed/gain 0.70 (range 0.70–0.71).

There were no statistical differences in any of the haematological parameters measured.

Blood glucose showed an interaction with processing time (same day or after overnight storage). However, as the effective role of processing on the glucose level could not be clarified, these data should be considered with caution. If only samples that were processed on the same day (not stored overnight) were considered, a treatment effect was visible with lower glucose levels at higher lignosulphonate doses. Mean glucose concentrations were 2.2 (±1.27), 2.38 (±1.63), 1.21 (±0.96), 1.43 (±1.21), and 1.25 (±0.62) mmol/L for the control group, and the treated groups 0.063×, 0.125×, 1× and 1.25×, respectively. They all were below the 7 to 9 mmol/L range typically seen in trout (Manera and Britti, 2006; Polakof et al., 2011). Sodium was significantly higher in the 0.125× group in comparison to control. There were no statistical differences among groups for chloride, calcium, phosphate, magnesium, total protein, albumin, urea, cholesterol, creatinine, amylase, AST, LDH, ALP and CK.

Body parameters at necropsy (10 fish per tank) were not significantly different among the groups. Length ranged from 31.2 (control) to 31.6 cm (0.063×), mean weight from 394 (1.25×) to 397 g (1×), condition factor from 1.26 (0.063×) to 1.30 (1×) and liver somatic index from 1.25 (1.25×) to 1.36% (control).

Histopathology indicated lipid/glycogen vacuolation of hepatocytes in all fish with a severity that ranged from minimal to moderate. This finding showed a statistical trend ($p < 0.1$) in the two highest doses. With increasing dose, the proportion of mild lipid/glycogen vacuolation increased, while the proportion of moderate lipid/glycogen vacuolation decreased. These findings are in accordance with the lower liver absolute and relative liver weight (and also with the reduced amount of glucose in higher doses). These results, together with the results observed in glucose, may indicate an effect of the indigestible additive on total digestibility of the diet, reducing the intestinal absorption of lipids and glucose. The findings are not considered adverse, affecting the health of fish, since the performance parameters and indices are not impaired by the additive at high doses.

Since no relevant differences between the groups were found in the 91-day period, in which the test substance has been fed, the results of the withdrawal period need not to be considered further.

3.1.1.2.1. Conclusions on the safety for rainbow trout

Based on the absence of adverse effects in the group fed 10,000 mg lignosulphonate/kg feed in all performance endpoints and on haematology and blood chemistry parameters, the FEEDAP Panel considers the highest concentration tested to be tolerated by rainbow trout. Therefore, the maximum recommended content of 8,000 mg lignosulphonate/kg complete feed is considered safe for salmonids, with a margin of safety of 1.25.

3.1.1.3. Discussion and conclusions on the safety for the safety for the target species

In its previous opinions, the FEEDAP Panel assessed several information submitted to support the safety of the additive for all animal species. In particular, in 2015, the FEEDAP Panel evaluated the results reported in several publications and, taking a conservative approach, considered that 10,000 mg lignosulphonate/kg complete feed is safe for pigs for fattening, chickens for fattening, laying hens and cattle for fattening (EFSA FEEDAP Panel, 2015). Since the results of the studies evaluated at that time did not allow to identify a margin of safety, these conclusions could not be extrapolated to other animal species/categories.

[20] Length, weight, liver weight, condition factor (100 × weight/length^3), liver somatic index (%).

In its opinion adopted in 2020, the Panel evaluated (i) three published studies in dairy cows, which were not sufficient to identify a concentration of lignosulphonate in feed that could be considered safe for dairy cows; (ii) a tolerance study in rainbow trout that, considering the shortcomings in study design, did not allow to identify a safe dietary concentration of lignosulphonate for salmonids and (iii) a tolerance study in piglets, from which a safe concentration of 10,000 mg lignosulphonate/kg complete feed was identified, but without a margin of safety. As a result of the assessment of the whole set of information available, the FEEDAP Panel concluded that lignosulphonate is safe at the maximum content of 10,000 mg/kg complete feed for weaned piglets, pigs for fattening, chickens for fattening, laying hens and cattle for fattening (EFSA FEEDAP Panel, 2020).

In the present submission, the applicant is proposing a modification of the conditions of use of the additive, reducing the maximum content of lignosulphonate in feed for all animal species to 8,000 mg/kg. It is noted that in the studies previously evaluated by the Panel, this newly proposed concentration was not systematically tested; however, considering that in all the studies assessed no adverse effect were identified when the animals were fed diets supplemented with up to 10,000 mg lignosulphonate/kg complete feed, the FEEDAP Panel considers that the newly proposed maximum concentration of lignosulphonate of 8,000 mg/kg complete feed can be considered safe for weaned piglets, pigs for fattening, chickens for fattening, laying hens and cattle for fattening, with a margin of safety of 1.25.

In the current application, the results of the two tolerance studies evaluated allowed to conclude that lignosulphonate is safe for dairy cows and for rainbow trout at a maximum content of 8,000 mg/kg complete feed, with a margin of safety of 1.3 for dairy cows and of 1.25 for the rainbow trout.

Taken altogether, the available information allows the FEEDAP Panel to conclude that lignosulphonate is safe in complete feed for weaned piglets, pigs for fattening, chickens for fattening, laying hens, dairy cows, cattle for fattening and salmonids at a maximum content of 8,000 mg/kg, with a margin of safety of at least 1.25. These conclusions are extrapolated to all animal species.

4. Conclusions

The FEEDAP Panel concludes that lignosulphonate is safe for all animal species when used at a maximum content of 8,000 mg/kg complete feed.

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Abbreviations

ALP	alkaline phosphatase
ANOVA	analysis of variance
AST	aspartate aminotransferase (AST)
CK	creatine kinase
CP	crude protein

DM	dry matter
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
LDH	lactate dehydrogenase
LOD	limit of detection
LOQ	limit of quantification
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
SGR	specific growth rate
TDMI	total DM intake
TGC	thermal growth coefficient