European Food Safety Authority

The EFSA Journal (2009) 991, 1-14

SCIENTIFIC OPINION

Safety and efficacy of Yea-Sacc[1026®] (*Saccharomyces cerevisiae*) as feed additive for horses[1]

Scientific Opinion of the Panel on Additives and Products or Substances used in Animal Feed

(Question No EFSA-Q-2008-009)

Adopted on 4 March 2009

PANEL MEMBERS

Georges Bories, Paul Brantom, Joaquim Brufau de Barberà, Andrew Chesson, Pier Sandro Cocconcelli, Bogdan Debski, Noël Dierick, Jürgen Gropp, Ingrid Halle, Christer Hogstrand, Joop de Knecht, Lubomir Leng, Sven Lindgren, Anne-Katrine Lundebye Haldorsen, Alberto Mantovani, Miklós Mézes, Carlo Nebbia, Walter Rambeck, Guido Rychen, Atte von Wright and Pieter Wester

SUMMARY

Following a request from the European Commission, the European Food Safety Authority (EFSA) was asked to deliver a scientific opinion on the safety and efficacy of Yea-Sacc[1026®] (*Saccharomyces cerevisiae*) as a feed additive for horses.

Yea-Sacc[1026®] is the trade name for an additive based on a live preparation of a strain of brewers yeast (*Saccharomyces cerevisiae* CBS 493.94). The product is permanently authorised for use with calves, cattle for fattening and dairy cows. It was also provisionally authorised for use in feed for horses but this authorisation was limited to horses from two months post-weaning onwards at a minimum dose of 4 x 10^9 CFU kg^{-1} complete feed. The applicant is now seeking an extension of use to the whole life of the animal and a reduction of the minimum dose to 4 x 10^8 CFU kg^{-1} complete feed. In addition, the applicant has requested the re-evaluation of the current authorisation, i.e. for horses from two months post-weaning onwards.

In an opinion issued in 2003, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) considered the safety of the product when used in feed for leisure horses and concluded that the product was safe for adult horses but, in the absence of relevant data, could not conclude on its safety for foals. Subsequently, EFSA introduced QPS as an assessment tool. As the species *Saccharomyces cerevisiae* is considered by EFSA to have

[1] For citation purposes: Scientific Opinion of the Panel on Additives and Products or Substances used in Animal Feed on the safety and efficacy of Yea-Sacc[1026®] (*Saccharomyces cerevisiae*) as feed additive for horses. *The EFSA Journal* (2009) 991, 1-14

QPS status, no further assessment of safety is required for the active agent. Consequently, and in the absence of any concerns about the other components, the additive can be presumed as safe for horses of all ages, for consumers of products derived from animals fed the additive, and for the wider environment. The safety for the user was also subject to previous assessments and the FEEDAP Panel is not aware of any additional data which would require its reconsideration.

In its earlier opinion on the use of Yea-Sacc with horses, EFSA considered only the safety of the product and not its potential efficacy. The efficacy of the product and the practical issues pertaining to its use in equine feed are the subject of the present opinion.

The nine trials described provide consistent evidence that YeaSacc[1026®] can have a significant effect on nutrients digestion in horses of all ages. In all the studies, there was a numerical increase in one or more measures of cell wall degradation, reaching significance in seven trials made with mature horses, yearlings and mares. When given to lactating mares, the resulting improvement in fibre digestion is reflected in changes to milk quality, to the benefit of suckling foals which show improved growth compared to foals suckling mares given feed without supplementation. Significant effects on phosphorus metabolism were also seen.

Efficacy was demonstrated in the seven trials over the range 3.0–6.4 x 10^{10} CFU $head^{-1}$ day^{-1}, with a mean value of 4.7 x 10^{10} CFU $head^{-1}$ day^{-1}. Calculations made using these data and the information supplied on intake where this was controlled (six studies on mares and mature horses) gave an approximate range of 1.6–8.2 x 10^{9} CFU per kg complete feed, with a mean of 4.7 x 10^{9} CFU per kg complete feed. This is close to the present minimum recommended dose. The data provided do not support the reduction to a minimum dose of 4.0 x 10^{8} CFU kg^{-1} complete feed as proposed by the applicant.

Because of the difficulties of defining the doses in terms of complete feeds in grazing animals, the FEEDAP Panel recommends the additional provision of doses in terms of CFU $head^{-1}$ day^{-1}.

Key words: zootechnical additive, digestibility enhancers, gut flora stabilisers, Yea-Sacc[1026®], *Saccharomyces cerevisiae*, micro-organism, horses, efficacy.

TABLE OF CONTENTS

BACKGROUND

Regulation (EC) No 1831/2003[2] establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 4(1) of that Regulation lays down that any person seeking an authorisation for a feed additive or for a new use of a feed additive shall submit an application in accordance with Article 7. Article 10(2) of that Regulation also specifies that for existing products within the meaning of Article 10(1), an application shall be submitted in accordance with Article 7, at the latest one year before the expiry date of the authorisation given pursuant to Directive 70/524/EEC for additives with a limited authorisation period, and within a maximum of seven years after the entry into force of this Regulation for additives authorised without time limit or pursuant to Directive 82/471/EEC.

The European Commission received a request from the company Alltech France[3] for the authorisation of the product Yea-Sacc[1026®] to be used as a feed additive for horses (category: zootechnical additives; functional groups: digestibility enhancers, gut flora stabilisers) under the conditions described in Table 1.

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 4(1) (authorisation of a feed additive or new use of a feed additive) and under Article 10(2) (re-evaluation of an authorised additive). EFSA received directly from the applicant the technical dossier in support of this application.[4] According to Article 8 of that Regulation, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. The particulars and documents in support of the application were considered valid by EFSA as of 18 June 2008.

The additive Yea-Sacc[1026®] is a preparation of *Saccharomyces cerevisiae* CBS 493.94. It has been granted permanent authorisation for its use in dairy cows,[5] calves and cattle for fattening.[6] Through the same legal text, it has been provisionally authorised for use in horses, based on a favourable EFSA opinion on the safety of the product 'Yea-Sacc' for leisure horses (EFSA, 2003).

TERMS OF REFERENCE

According to Article 8 of Regulation (EC) No 1831/2003, EFSA shall determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the efficacy and the safety for the target animals, the consumer, user and the environment of the product Yea-Sacc[1026®] which is a preparation of *Saccharomyces cerevisiae* (CBS 493.94), when used under the conditions described in Table 1.

ACKNOWLEDGEMENTS

The European Food Safety Authority wishes to thank the members of the Working Group on Micro-organisms for the preparation of this opinion.

[2] OJ L 268, 18.10.2003, p.29
[3] Alltech France, 14 place Marie-Jeanne Bassot, 92300 Levallois-Perret, France.
[4] Dossier reference : FAD-2007-0048
[5] OJ L 291, 5.11.2005, p.12
[6] OJ L 291, 5.11.2005, p.18

Table 1. **Register entry as proposed by the applicant**

Additive	*Saccharomyces cerevisiae* CBS 493.94
Registration number/EC No/No	EC 5
Category(ies) of additive	Zootechnical additive
Functional group(s) of additive	Digestibility enhancers, gut flora stabilisers

Description			
Composition, description	Chemical formula	Purity criteria	Method of analysis
Preparation of *Saccharomyces cerevisiae* CBS 493.94 containing a minimum of 1 x 10^9 CFU/g of additive	Not appropriate	Not appropriate	Pour plate method following ISO 7954 using chloramphenicol glucose yeast extract (System. Appl. Microbiol. 26, 147-153, 2003)

Trade name	YEA-SACC[1026®]
Name of the holder of authorisation	ALLTECH France

Conditions of use				
Species or category of animal	Maximum Age	Minimum content	Maximum content	Withdrawal period
		CFU kg^{-1} of complete feedingstuffs		
Horses, pre- and post-weaning foal (whole life of the animal)	-	4 x 10^8	2.5 x 10^{10}	Not appropriate

Other provisions and additional requirements for the labelling	
Specific conditions or restrictions for use	In the directions for use of the additive and premixture, indicate the storage temperature, storage life.
Specific conditions or restrictions for handling	Not appropriate
Post market monitoring	Not appropriate No risk associated with the use of Yea-Sacc[1026®] feed additive are pointed out; there is no need for specific requirements for a post-monitoring plan. Such requirement is not applicable to the Yea-Sacc[1026®] feed additive which is composed of a live strain of *Saccharomyces cerevisiae*
Specific conditions for use in complementary feedingstuffs	Do not pellet above 80°C

Maximum Residue Limit (MRL)

Marker residue	Species or category of animal	Target tissue(s) or food products	Maximum content in tissues
Not appropriate	Not appropriate	Not appropriate	Not appropriate

ASSESSMENT

1. Introduction

Yea-Sacc[1026®] is the trade name for an additive based on a live preparation of a strain of brewers yeast (*Saccharomyces cerevisiae* CBS 493.94*),* a yeast species which EFSA recognises as having QPS status (EFSA, 2008). The identity of the active agent has been established and its safety has been previously assessed in conjunction with previous applications for use with cattle. As a result of those assessments, the product was authorised for use with calves, cattle for fattening and dairy cows (see Background).

In addition to cattle, the product was provisionally authorised for use in feed for horses[7] until 20 March 2008. However, this authorisation was limited to horses from two months post-weaning onwards at a minimum dose of 4 x 10^9 CFU kg^{-1} complete feed. The applicant is now seeking an extension of use to the whole life of the animal, and a reduction of the minimum dose to 4 x 10^8 CFU kg^{-1} complete feed. Both applications fall under Article 4 of Regulation (EC) No 1831/2003. In addition, under Art 10(2) of the same Regulation, the applicant has requested the re-evaluation of the current authorisation, i.e. for horses from two months post-weaning onwards, under the category zootechnical additive (functional groups: digestibility enhancers, gut flora stabilisers)

In its previous opinion (EFSA, 2003), EFSA considered the safety of the product when used in feed for leisure horses and concluded that the product was safe for adult horses but, in the absence of relevant data, could not conclude on its safety for foals. Subsequently, EFSA introduced QPS as an assessment tool. As the species *Saccharomyces cerevisiae* is considered by EFSA to have QPS status, no further assessment of safety is required for the active agent. Consequently, and in the absence of any concerns about the other components, the additive can be presumed as safe for horses of all ages, for consumers of products derived from animals fed the additive and for the wider environment. The safety for the user was also subject to previous assessments and the FEEDAP Panel is not aware of any additional data which would require its reconsideration.

In its previous opinion on the use of Yea-Sacc[1026®] with horses, EFSA considered only the safety of the product and not its potential efficacy. The efficacy of the product and the practical issues pertaining to its use in equine feed are the subject of the present opinion.

2. Stability in equine feeds

The stability of the product itself has been previously established at at least 12 months when stored under ambient conditions. In the Register entry, the 'conditions of use' proposed by the applicant carries the warning not to pellet above 80 ^oC (although experimental evidence suggested good stability for 30 minutes at 90 ^oC). This was established for pelleting of complementary feed for cattle but can be applied to the pelleting of equine feed.

Experimental evidence showed that the product could be homogeneously mixed into a typical horse feed (based on 60 samples from three product batches). There appeared to be a 50 % fall in yeast counts after one-month storage of the pelleted feed (four batches) but it is unclear whether this period included losses incurred during the pelleting process. The counts thereafter remained reasonably stable for a further four to six months.

[7] OJ L 291, 5.11.2005, p. 18

2.1. Conditions of use

The product is intended for use in feeds for horses of all ages at a minimum dose of 4 x 10^8 CFU per kg complete feed and a maximum dose of 2.5 x 10^{10} CFU per kg complete feed. This would equate to 0.4 to 25 g additive per kg feed, assuming the minimum declared CFU content of the additive.

2.2. Evaluation of the analytical methods by the Community Reference Laboratory (CRL)

EFSA has verified the CRL report as it relates to the methods used for the control of the active agent in equine feeds. The Executive Summary of the CRL report can be found in the Appendix.

3. Efficacy

The applicant provided the details of nine trials made with horses of different ages and stages of development. They are as follows:

- five trials with mature horses made in three different locations, one of which (study 5) was included to support the application for the lower minimum dose specified in the Register entry;
- two trials with mare and their foals all made at the same location;
- two trials on young horses made in two different locations.

An *in vitro* study on the effect of Yea-Sacc[1026®] supplementation on the rate and extent of microbial breakdown of nutrients was also provided.

The trials made with the mature horses all took the form of a latin square (cross-over) design while those made with mares/foals and young horses were based on a comparison of separate control and treatment groups. The end points focussed on the measurement of apparent digestibility of the major nutrient groups, particularly fibre. In four trials, measures of the apparent digestibility of phosphorus, calcium and other minerals were included.

3.1. Dose

The horses were generally dosed on a unit weight head^{-1} day^{-1} basis and not as specified in the proposed Register Entry. Due to the different weights and intakes of the animals under experiment, the dose calculated in terms of kg feed consumed varied considerably, even within the same study. In four trials with mature horses, a dose of 10 g head^{-1} day^{-1} was used, which, depending on the experimental animal and batch of the product, translated into a calculated dose of approximately 2–8 x 10^9 CFU kg^{-1} feed (Table 2). The lower value for the minimum dose of 10 g in trial 5 resulted from the analysed content of yeast in the batch of additive used being below the presently declared minimum.

3.2. Mature horses

The effects of Yea-Sacc[1026®] supplementation of the diets of mature horses on measures of protein and fibre digestion are summarised in Table 2.

Table 2. **Effect of Yea-Sacc[1026®] on protein and fibre digestion by mature horses**

Trial	No of animals Study design	Dose (CFU head^{-1} day^{-1})	Calculated average dose (CFU kg^{-1} feed)	Crude protein or N digestibility (%)	NDF** digestibility (%)	ADF*** digestibility (%)
1[8]	Eight geldings	0	0	71.7	49.7	41.3
	4 x 4 latin	2.6 x 10^{10}	4.1 x 10^{9}	72.9	52.2	44.8
	square	5.3 x 10^{10}	8.2 x 10^{9}	73.0	54.0*	46.2*
		1.1 x 10^{11}	1.6 x 10^{10}	74.8	53.8*	46.2*
2[9]	Four thoroughbreds 2 x 2 latin square	0	0	67.4	45.3	39.0
		6.6 x 10^{10}	8.0 x 10^{9}	67.7	47.3	42.3
	4 x 4 latin square	0	Inorganic P	66.6	44.3	39.4
		6.4 x 10^{10}	+ 7.0 x 10^{9}	66.8	45.6	41.1*
		0	Organic P	64.1	44.1	37.0
		6.4 x 10^{10}	+ 7.0 x 10^{9}	66.2	47.0	40.3*
3[10]	Six 2-3 year olds 2 x 2 latin square	0	0	73.4	68.2	68.7
		6.4 x 10^{10}	3.8 x 10^{9}	74.3	72.5*	65.5
4[11]	Eight mature stallions 4 x 4 latin square	0	High fibre (HF)	Not determined	33.2	33.3
		4.5 x 10^{10}	HF + 1.6 x 10^{9}		37.6*	37.7
		0	High starch(HS)		38.3	32.3
		4.5 x 10^{10}	HS + 1.6 x 10^{9}		36.2	34.1
5[12]	Four 3 year geldings 4 x 4 latin square		0	67.5	29.5	24.0
		3.8 x 10^{9}	6.4 x 10^{8}	71.8	30.3	26.3
		7.6 x 10^{9}	1.3 x 10^{9}	67.8	27.7	23.8
		1.5x 10^{10}	2.5 x 10^{9}	72.4	27.4	26.1

* Significantly different from the control at $P < 0.05$
** Neutral detergent fibre
*** Acid detergent fibre

There was a general trend in all trials towards increased dry matter digestibility, largely attributable to an increase in apparent fibre digestion. At least one measure relating to fibre digestion was increased significantly ($P < 0.05$) in four of the five trials made with mature horses when given 10 g additive head^{-1} day^{-1}, corresponding to a range of 4.5–6.4 x 10^{10} CFU head^{-1} day^{-1}. The same doses, when expressed in terms of feed consumed, showed a greater range (1.6–8.2 x 10^{9} CFU kg^{-1} feed) because of the differences in weight of the experimental animals and the quantity of feed. A limited microbiological study made in conjunction with Trial 4 showed that although the numbers of cellulolytic organisms were apparently unaffected by supplementation there was a significant increase in total anaerobes and lactate-utilizers in the caecum of supplemented horses compared to their controls. The levels of carboxymethyl cellulase associated with particulate matter were also increased.

[8] Technical dossier/Section III/Annex 4-5
[9] Technical dossier/Section III/Annex 4-6
[10] Technical dossier/Section III/Annex 4-7
[11] Technical dossier/Section III/Annex 4-8
[12] Technical dossier/Section III/Annex 4-4

Phosphorus digestibility, considered in two studies (trials 2 and 3), was found to be significantly increased ($P < 0.01$ and 0.05, respectively). In both cases this was accompanied by a significant increase in calcium digestibility.

3.3. Mares and foals

Two separate trials were made with mares and their foals at the same location. In each case, pregnant mares in the test groups were dosed with 20 g $head^{-1}$ day^{-1} given 'by hand' either as a single dose or as two 10 g doses and compared to a second group of mares fed the unsupplemented feed. Since mares ingested around 10 kg feed and the measured concentration of viable yeast in the additive was ~2.3 x 10^9 CFU g^{-1}, a 20 g dose corresponds to approximately 4 x 10^9 CFU kg^{-1} feed consumed. The effects of supplementation on nutrient digestibility in mares, milk production and nutrient retention in the foals were measured.

In the first study,[13] eight pregnant mares were allotted to one of the two diets four weeks before anticipated foaling and continued for four weeks thereafter. The results were analysed by a one-way ANOVA. In the mares fibre (NDF, ADF, hemicellulose, cellulose), crude protein, calcium and phosphorus digestibility were significantly increased ($P < 0.05$). Milk production was significantly higher ($P < 0.01$) in the treated group, as were the contents of lactose, proteins and lipids. Retention of N ($P < 0.01$), Ca ($P < 0.05$) and P ($P < 0.01$) were considerably higher in foals from treated mares. The foals from treated mares also grew significantly better than those from the control group ($p < 0.01$).

The second study[14] carried out with ten mares with foals, was similar in structure to the first but continued for eight rather than four lactation weeks. The horses were individually housed in the night but had free access to a dirt paddock in daytime. After two weeks, supplemented mares exhibited significantly increased digestibility of dry matter, fibre, nitrogen, calcium and phosphorus ($P < 0.05$). Those increases were also seen when the same parameters were measured four weeks after foaling. The nutrient composition of the milk from mares fed supplemented feed was significantly improved compared to the milk from the untreated controls. Lactose, fat, protein and total amino acids were all significantly elevated throughout the eight-week lactation period ($P < 0.01$). As a consequence, foals nursing supplemented mares showed a significantly greater rate of weight gain after four weeks ($P < 0.02$).

3.4. Young horses

Details of two trials were provided: the first measured the growth of male and female weanlings (28 in total) and the deposition of Ca and P in hooves over a four-month period; the second, carried out in slightly older animals (nine animals), measured the effect of supplementation on nutrient digestibly.

The first study[15] did not show significant differences in bodyweight, chest and cannon circumferences or in the calcium and phosphorus contents in hooves between the test group given 10 g Yea-Sacc[1026®] and the control groups given the unsupplemented diet, although numerical increases were present in all measured parameters. The 10 g provided 3.6 x 10^{10} CFU but in the absence of data on intake it is not possible to relate this to a concentration in complete feed.

[13] Technical dossier/Section III/ Annex 4-9
[14] Technical dossier/Section III/ Annex 4-10 and 4-11
[14] Technical dossier/Section III/ Annex 4-12

In the second study[16] nine yearlings located on three different farms were used in a quasi cross-over study. The digestibility of nutrients was measured prior to and after a three-week supplementation of 8 g head^{-1} day^{-1} Yea-Sacc[1026®]. This delivered 3.0 x 10^{10}CFU day^{-1} but animals were held on pasture and no estimate of daily intake was provided. Consequently, it is not possible to calculate the dose in terms of feed concentration. Significant improvements in the digestibility of dry matter ($P < 0.05$), NDF/hemicellulose ($P < 0.01$), ADF/cellulose ($P < 0.05$) and total nitrogen ($P < 0.05$) were reported.

3.5. *In vitro* study

One *in vitro* dose-response experiment[17] was conducted with three concentrations of Yea-Sacc[1026®] (4.5 x 10^8, 9 x 10^8 and 4.5 x10^9 CFU kg^{-1} DM) on the digestibility of dietary components (organic matter (OM), DM, NDF) and the fermentation patterns (VFA, lactic acid, ammonia and pH). Two methods of assessment were used (gas production and Tilley and Terry) with three diets differing in starch and fibre content. For comparison, the *in vivo* digestibility and pepsin/cellulose digestibility of the three (unsupplemented) diets and their major components were separately measured. Although the diet had the greatest effect on dry matter and NDF digestibility as measured by Tilley and Terry, yeast supplementation at all three dose produced significant increases in OM digestibility ($P < 0.005$) and the digestibility of the NDF fraction ($P < 0.001$). The influence of yeast supplementation was less evident in the gas production system although still significant when measured in terms of total gas produced ($P < 0.05$).

3.6. Conclusion

The nine trials described provide consistent evidence that Yea-Sacc[1026®] can have a significant effect on nutrient digestion in horses of all ages. In all the studies, there was a numerical increase in one or more measures of cell wall degradation (dry matter, NDF/hemicellulose or ADF/cellulose), reaching significance in 4/5 trials with mature horses, 1/1 yearlings and 2/2 mares. When given to lactating mares, the resulting improvement in fibre digestion is reflected in changes to milk quality to the benefit of suckling foals which show improved growth compared to those suckling mares given unsupplemented feed. Significant effects on phosphorus metabolism were also seen.

It is difficult to relate supplementation on a weight of additive head^{-1} day^{-1} basis to the viable count per kg feed basis proposed in the Registry entry. The additive containing the minimum declared content would deliver 1 x 10^{10} CFU head^{-1} day^{-1} (10 g dose) or 2 x 10^{10} CFU head^{-1} day^{-1} (20 g dose). In practice, the various batches of the additive used in the trials contained substantially greater counts than the minimum declared. Efficacy was demonstrated in seven trials over the range 3.0–6.4 x 10^{10} CFU head^{-1} day^{-1}, with a mean value of 4.7 x 10^{10} CFU head^{-1} day^{-1}. Calculations made using these data and the information supplied on intake where this was controlled (six studies on mares and mature horses) gave an approximate range of 1.6–8.2 x 10^9 CFU per kg complete feed with a mean of 4.7 x 10^9 CFU per kg complete feed.

[15] Technical dossier/Section III/ Annex 4-13
[16] Technical dossier/Section III/Annex 4-3

Although *in vitro* studies demonstrated a significant effect on OM and NDF digestibility at 4.5 x 10^8 CFU kg^{-1} feed, evidence from the feeding trials would suggest that this benefit is not seen *in vivo*. No significant effects were found in the dose response study (trial 5).

4. Post-market monitoring

Any risk associated with the use of the product is negligible. It is considered that there is no need for specific requirements for a post-market monitoring plan other than those established in the Feed Hygiene Regulation[18] and Good Manufacturing Practice.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The nine trials described provide consistent evidence that Yea-Sacc[1026®] can have a significant effect on fibre digestion in horses of all ages. When given to lactating mares, the resulting improvement in fibre digestion is reflected in changes to milk quality, to the benefit of suckling foals which show improved growth compared to those suckling mares given unsupplememted feed.

Efficacy was demonstrated in seven trials over the range 3.0–6.4 x 10^{10} CFU $head^{-1}$ day^{-1} with a mean value of 4.7 x 10^{10} CFU $head^{-1}$ day^{-1}. Calculations made using these data and the information supplied on intake where this was controlled (six studies on mares and mature horses) gave an approximate range of 1.6–8.2 x 10^9 CFU per kg complete feed, with a mean of 4.7 x 10^9 CFU per kg complete feed.

The data provided do not support the reduction to a minimum dose of 4.0 x 10^8 CFU kg^{-1} complete feed as proposed by the applicant.

RECOMMENDATIONS

The current requirement for defining doses in terms of complete feedingstuffs may provide only an approximation in the case of grazing animals, including horses. In those cases, additives are usually supplied in the form of a complementary feed or as a top dressing. Unless this forms part of a total mixed ration, the remainder of the feed is given *ad libitum.* Consequently, an unambiguous definition of the target dose can only be given in terms of CFU $head^{-1}$ day^{-1} and this should be provided under 'other provisions' in the Register entry.

This recommendation has already been expressed by the FEEDAP Panel in two opinions (EFSA, 2006a and 2006b) and adopted by Risk Managers in the respective authorisation legislations.[19,20] In the present case, it is recommended that the minimum dose should be set at 4.0 x 10^{10} CFU $head^{-1}$ day^{-1}.

DOCUMENTATION PROVIDED TO EFSA

1. Registration dossier for the product Yea-Sacc[1026®] (Saccharomyces cerevisiae CBS 493.94). December 2007. Submitted by Alltech France.
2. Supplementary information, January 2009. Sent by Alltech France.

[18] OJ L 35, 8.2.2005, p.1
[19] OJ L 57, 24.2.07, p. 3
[20] OJ L 63, 3.2.07, p. 6

3. Evaluation report of the Community Reference Laboratory feed additives authorisation on the methods(s) of analysis for Yea-Sacc[1026®] for horses.
4. Comments from Member States received through the ScienceNet.

REFERENCES

EFSA (European Food Safety Authority), 2008. The maintenance of the list of QPS microorganisms added to food or feed. Scientific Opinion of the Panel on Biological Hazards.

<http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/biohaz_op_ej923_qps_en.pdf?ssbinary=true>

EFSA (European Food Safety Authority), 2003. Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on a request from the Commission on the safety of product "Yea Sacc" for leisure horses

<http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/opinion_amended_feedap_031.pdf?ssbinary=true>

EFSA (European Food Safety Authority), 2006a. Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the safety and efficacy of the product Biosaf Sc 47, a preparation a *Saccharomyces cerevisae*, as a feed additive for dairy small ruminants

<http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/feedap_op_ej379_biosaf_dairy_small_ruminants_en.pdf?ssbinary=true>

EFSA (European Food Safety Authority), 2006b. Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the safety and efficacy of the product Biosaf Sc 47, a preparation a *Saccharomyces cerevisae*, as a feed additive for horses

<http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/feedap_op_ej384_biosaf_sc47_horses_en.pdf?ssbinary=true>

APPENDIX

Executive Summary of the Evaluation Report of the Community Reference Laboratory Feed Additives Authorisation on the Method(s) of Analysis for Yea-Sacc[1026®] for horses

In the current application authorisation is sought for the microbial feed additive Yea-Sacc[1026®] under the category 'zootechnical additives', functional groups 'digestibility enhancers and gut flora stabilisers' according to Annex I of Regulation (EC) No 1831/2003. Specifically, the use of Yea-Sacc[1026®] for horses is requested. Yea-Sacc[1026®] contains a minimum of 1×10^9 viable cells (c.f.u., colony-forming units) of *Saccharomyces cerevisiae* CBS 493.94 (as active agent) per gram. The feed additive is intended to be mixed into complete feedingstuffs at a final concentration of 4.0×10^8 to 2.5×10^{10} c.f.u./kg.

For the determination of the active agent, *Saccharomyces cerevisiae* CBS 493.94, in the feed additive, a pour plate method based on ISO 7954 and a molecular identification method (polymerase chain reaction (PCR)) are proposed by the applicant, which are considered appropriate. For the determination of the active agent *S. cerevisiae* CBS 493.94 in premixtures and feedingstuffs the same methods are proposed by the applicant. The enumeration method was validated in a collaborative study [System. Appl. Microbiol. 2003. 26, 147-153]. The method's performance characteristics of the enumeration method are standard deviations for repeatability (sr) and reproducibility (sR) of around 0.17 – 0.36 $\log_{10}$ and 0.55 – 0.60 $\log_{10}$ calculated from the base 10 logarithms of the measured c.f.u./g in feedingstuffs, respectively. The limits of quantification (LOQ) of this method are 1000 colony forming units (c.f.u) per gram (g) feed additive or premixture and 10^6 c.f.u./kg feedingstuff. These performance characteristics are considered acceptable. This method is recommended for official controls of the active agent expressed in c.f.u. in the feed additive, premixtures and feedingstuffs.

The PCR method for strain identification was ring trial validated and demonstrated a high level of correct identification between laboratories [System. Appl. Microbiol. 2004. 27, 492-500]. It is therefore considered appropriate for official controls.

On the basis of the supplied documentation, no supplementary experimental work (testing or method validation) is required.