EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions
C2 - Management of scientific committees; scientific co-operation and networks

EVALUATION OF THE EFFICACY OF MICRO-ORGANISM PRODUCT BIOSAF SC47

(adopted on 2 December 2002)

1. BACKGROUND

The product "Biosaf SC 47" (*Saccharomyces cerevesiae*), has been provisionally authorised for the use as feed additive for the animal category "cattle for fattening" (Commission Directive 96/7/EC) until 20 February 2001.

The product was assessed by SCAN for safety and is listed in annex of the SCAN report on the use of certain micro-organisms as additives in feedingstuffs (updated 22 March 2001).

The Commission received a request for a permanent Community authorisation for this animal category under the conditions set out in the following table:

Table 1

No.	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions
					CFU/kg of complete feedingstuff		
3	*Saccharomyces cerevisiae* NCYC Sc 47	Preparation of *Saccharomyces cerevisiae* containing a minimum of 5×10^9 CFU/g additive	Cattle for fattening	-	4×10^9	8×10^9	Indicate in the instructions for use: "The quantity of *Saccharomyces cerevisiae* in the daily ration must not exceed 2.5×10^{10} CFU for 100 kg of bodyweight and 0.5×10^{10} CFU for each additional 100 kg of bodyweight."

2. TERMS OF REFERENCE

The Scientific Committee for Animal Nutrition (SCAN) is requested to advise the Commission on the efficacy of the product " Biosaf SC 47" when used as a feed additive in feedingstuffs, under the conditions proposed by the Company (see table 1).

3. OPINION

The product Biosaf SC 47, consisting almost entirely of *Saccharomyces cerevisiae* (strain SC 47), has been previously accepted by the SCAN as safe for use as a feed additive for beef cattle[1]. The SCAN is not aware of any more recent information that would require a re-evaluation of its Opinion on the safety of the product. Consequently the present Opinion deals only with issues related to efficacy.

3.1. Stability of the additive

Data presented on a number of different batches of the product showed that the viability of the additive is maintained for at least one year at ambient temperatures in its commercial packing, provided that this remains unopened. When incorporated into a mineral premix cells retained viability for at least three months at ambient temperatures.

Further studies on the effect of feed processing demonstrated that the initial viability could be maintained with mash diets leaving the conditioning chamber at temperatures <70^{o}C and for pelleted diets leaving the die at temperatures <80^{o}C. Viability was rapidly lost, however, when the temperature at the die exceeded 85^{o}C. Once incorporated into feed (demonstrated with a pelleted protein concentrate), cell viability was maintained for at least a further three months.

In addition to the effect of storage on the viability of the yeast cells, the long-term genetic stability of the strain was confirmed by comparing PFGE patterns from selected batches of the product prepared over a ten year period and comparing these with the deposited strain.

3.2. Effects on rumen fermentation

Reviews of the existing data on the effects of yeast supplementation concluded that the primary site of action of yeast-based additives was the rumen (Newbold *et al*., 1996; Durand-Chaucheyras *et al*., 1997). Consequently a series of experiments were undertaken to investigate the effects of SC47 on rumen fermentation characteristics. These demonstrated a significant increase in total viable bacteria in the present of yeast in an artificial rumen (rustitec), a significant increase in rumen pH (sheep and cows, $P<0.05$) and a significant increase in the production of the fermentation products propionic, butyric and isovaleric acids ($P<0.001$). However, no significant effects were found on the digestibility of dietary components.

3.3. Feeding trials made with cattle for fattening.

The results of a total of ten trials made with cattle for fattening are reported. Four trials (1-4) were previously reported in support of the application for provisional registration. A further six trials (5-10) were completed after provisional application was granted and are now included in support of the present application. All ten studies are summarised in table 2.

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[1] Report on the use of certain micro-organisms as additives in feedingstuffs (expressed, 26 september 1997; updated 30 september 1998)

Table 2. A summary of data from trials investigating the effect of BIOSAF SC 47 on growth performance in cattle for fattening.

Trial Breed (Duration)	Dose (cfu/kg)	No of animals	Mean weight (kg)		ADG[1] (g)	Feed:gain ratio
			Start	Finish		
1	0	27	316	351	690	6.69
Belgium blue	4×10^9	30	311	349	740	6.44
(60 days)	4×10^{10}	30	319	353	660	6.52
Belgium blue	0	16	325	372	800	6.80
Double muscle	4×10^9	16	318	369	820	6.48
(60 days)	4×10^{10}	16	323	373	810	7.33
2						
Montbeliard	0	24	122	244	1092	4.16
(112 days)	7×10^9	25	119	256	1191	3.86
Montbeliard	0	15	108	251	1244	-
(115 days)	7×10^9	20	109	259	1301	-
					Pooled*	
3						
Charolais	0	24	375	689	1360	7.10
(232/228 days)	5×10^9	24	376	692	1395	6.84
4						
Charolais	0	7	500	688	1520	6.32
(142 days)	7×10^9	8	493	699	1630	6.22
Belgian blue	0	8	468	674	1580	-
(142 days)	7×10^9	7	464	659	1440	-
5						
Holsteins	0	27	230	478	1257	5.78
(201, 198 days)	4×10^9	27	230	482	1290	5.79
6						
Holsteins	0	61	322	579	1250	8.22
(223 days)	4×10^9	58	324	583	1291	8.70
7						
Holsteins	0	61	292	535	1220	7.78
(225 days)	4×10^9	60	297	559	1290*	7.43
8						
Charolais	0	64	417	709	1676	-
(180 days)	4×10^9	67	419	714	1719	-
9						
Charolais	0	25	289	530	1439	5.7
(180 days)	4×10^9	25	287	547	1543[2]	5.3[3]
10						
Blonde d'Aquitaine	0	87	320	661	1510	4.75
(252 days)	4×10^9	87	324	672[4]	1590*	4.44**

[1]ADG – average daily gain, [2] P = 0.06, [3,4] P = 0.07
*P <0.05, **P <0.01

Three early trials (1,2 and 4), the first of which was essentially a dose response study, were of a shorter duration than is considered desirable by SCAN for the demonstration of efficacy. However the remaining seven had a minimum duration which varied between 6 and 7 months. In all trials animals were raised in groups of varying size. This led to difficulties in the accurate measurement of the feed intake and the comparison of the feed:gain ratio. Consequently in only one study involving the largest number of animals could a clearly significant improvement in feed:gain ratio be demonstrated ($P<0.01$). However, significant improvements in ADG were seen in two studies (trials 7 and 10) and in a third (Trial 2) when data from two separate experiments at the same location using the same breed of animal with the same application rate were pooled. The small differences in diet in the two pooled studies were considered very unlikely to have confounded the results. Improvement to ADG nearly reached significance ($P = 0.06$) in a fourth study (Trial 9).

Three types of diet considered characteristic of European production systems were tested:

– Cereal-based (maize, barley or wheat, soybean meal plus hay or straw)

– Maize silage (maize silage plus concentrate)

– Sugarbeet pulp (sugarbeet pulp plus concentrate)

There was no convincing evidence that any benefits observed following the addition of the yeast-based additive favoured any particular diet type.

Carcass yield and quality was examined in six of the ten trials, although in one (trial 6), because of the response to BSE, animals were slaughtered at different locations and valid comparisons between control and test animals could not be made. In the remaining studies no significant differences in yield or, when assessed, quality was observed. However, in one trial (trial 8) a significant improvement in conformation (EUROP scale) was observed ($P<0.01$).

3.4. Conclusion

The different feeding experiments reported were performed between 1989 and 2002 and involved a total of 823 fattening cattle (406 in the control groups and 417 in the treated groups). The results obtained showed that inclusion of the additive at the lowest recommended dose range produced a significant improvement in the average daily gain in three different experiments. SCAN also took into account a fourth trial where results were close to significance ($P=0.06$). Numerical improvements to ADG, of the same magnitude observed in the three studies in which significant results were obtained (3.3 to 7.3 %) also were seen in other trials, although in these cases the differences did not reach significance.

On the basis of these results, and on the evidence that SC 47 has always been recovered in the supplemented feed at the recommended level, the SCAN considers that the addition of the yeast product Biosaf SC 47 to the diet of fattening cattle at the levels proposed in Table 1 may result in improved performance.

3.5. References

Durand-Chaucheyras, F., Fonty, G. and Bertin, G. 1997 L'utilisation de levures vivantes, additifs microbiens chez la ruminant: effets sur la microflore et les fermentations ruminales, effets zootechniques. *Bull. GTV* 5-B-576, 35-52.

Newbold C.J., Wallace, R.J. and McIntosh, F.M. 1996 Mode of action of the yeast *Saccharomyces cerevisiae* as a feed additive for ruminants. *Br. J. Nutr.* **76**, 249-261.