Commission Implementing Regulation (EU) 2020/1398 of 5 October 2020 concerning the renewal of the authorisation of Saccharomyces cerevisiae CBS 493.94 as a feed additive for horses and repealing Regulation (EC) No 886/2009 (holder of authorisation All-Technology Ireland Ltd) (Text with EEA relevance)

# COMMISSION IMPLEMENTING REGULATION (EU) 2020/1398

# of 5 October 2020

concerning the renewal of the authorisation of *Saccharomyces cerevisiae* CBS 493.94 as a feed additive for horses and repealing Regulation (EC) No 886/2009 (holder of authorisation All-Technology Ireland Ltd)

### (Text with EEA relevance)

### THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition<sup>(1)</sup>, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting and renewing such authorisation.
- (2) The preparation of *Saccharomyces cerevisiae* CBS 493.94 was authorised for 10 years as a feed additive for horses by Commission Regulation (EC) No 886/2009<sup>(2)</sup>.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted by the holder of that authorisation for the renewal of the authorisation of *Saccharomyces cerevisiae* CBS 493.94 as a feed additive for horses requesting that additive to be classified in the additive category 'zootechnical additives'. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 12 November 2019<sup>(3)</sup> that, *Saccharomyces cerevisiae* CBS 493.94 does not have an adverse effect under the authorised conditions of use for the animal health, consumer health or the environment. It also concluded that the additive should be considered as a moderate eye irritant and a potential skin and respiratory sensitiser. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. Since the Authority was unable to conclude on the new proposed minimum dose, the previous doses should be maintained.

- (5) The assessment of *Saccharomyces cerevisiae* CBS 493.94 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed as specified in the Annex to this Regulation.
- (6) As a consequence of the renewal of the authorisation of *Saccharomyces cerevisiae* CBS 493.94 as a feed additive under the conditions laid down in the Annex to this Regulation, Regulation (EC) No 886/2009 should be repealed.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The authorisation of the additive specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is renewed subject to the conditions laid down in that Annex.

Article 2

Regulation (EC) No 886/2009 is repealed.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 5 October 2020.

For the Commission

The President

Ursula VON DER LEYEN

#### ANNEX

Identific		Additiv	e CompositSque,cies		unMinimu			End			
number			chemical or	age	content	content	provisio				
of the	holder		formula, category	7	CFU/kg	of		period			
additive	of		description		complete			of			
	authorisation		analyticalanimal		feedings			authorisatio			
			method		with a moisture						
					content						
Categor	v of zoot	echnical a	additives. Function	nal grour			ancer.				
4a1704	y of zootechnical additives. Functional group: digestibility enhancer.All-Saccharo Active Horses1,6 ×26.10.2030										
			composition				1.	26.10.2030 In			
	Ireland	CBS	Preparation		10 <sup>9</sup>			the			
								directions			
	Ltd.	493.94	of Contract					for			
			Saccharomyces					use			
			cerevisae					of			
			CBS					the			
			493.94					additive			
			containing					and			
			a								
			minimum					premixture,			
			of:					the			
			$1 \times 10^{9}$					storage			
			CFU/g					conditions			
			additive					and			
			Powder					stability			
			and					to			
			granulated					heat			
								treatment			
			form					shall			
			Characterisation					be			
			of					indicated.			
			active								
			substance				2.	For			
			Viable					users			
			cells of					of			
								the			
			Saccharomyces					additive			
			<i>cerevisae</i>					and			
			CBS					premixtures			
			493.94					feed			
			Analytical					business			
			method <sup>a</sup>					operators			
			Enumeration:					shall			
								establish			
			pour								
			plate					operational			
			method					procedures			
			using					and			
			chloramphenicol					organisation			
					1			measures			

jrc/en/eurl/feed-additives/evaluation-reports

glucose		to
yeast		address
extract		potential
agar		risks
(ĔN		resulting
15789:20	009)	from
Identific	ation.	their
polymera		use.
chain		Where
reaction		those
(PCR)		risks
method		cannot
(CEN/		be
TS		eliminated
15790:20	108)	or
15790.20		reduced
		to
		a minimum
		by such
		procedures
		and
		measures,
		the
		additive
		and
		premixtures
		shall
		be
		used
		with
		personal
		protective
		equipment,
		including
		eyes,
		skin
		and
		breathing
		protection.

a Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/ jrc/en/eurl/feed-additives/evaluation-reports

#### (**1**) OJ L 268, 18.10.2003, p. 29.

- (2) Commission Regulation (EC) No 886/2009 of 25 September 2009 concerning the authorisation of the preparation of Saccharomyces cerevisiae CBS 493.94 as a feed additive for horses (holder of authorisation Alltech France) (OJ L 254, 26.9.2009, p. 66).
- (**3**) *EFSA Journal* 2019; 17(12):5918.

# Status:

Point in time view as at 31/12/2020.

#### Changes to legislation:

There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1398.