COMMISSION IMPLEMENTING REGULATION (EU) No 1018/2012

of 5 November 2012

amending Regulations (EC) No 232/2009, (EC) No 188/2007, (EC) No 186/2007, (EC) No 209/2008, (EC) No 1447/2006, (EC) No 316/2003, (EC) No 1811/2005, (EC) No 1288/2004, (EC) No 2148/2004, (EC) No 1137/2007, (EC) No 1293/2008, (EC) No 226/2007, (EC) No 1444/2006, (EC) No 1876/2006, (EC) No 1847/2003, (EC) No 2036/2005, (EC) No 492/2006, (EC) No 1200/2005, and (EC) No 1520/2007 as regards the maximum content of certain micro-organisms in complete feedingstuffs

(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 [1] and in particular Article 13(1), (2) and (3) thereof,

Whereas:

(1) The use of *Saccharomyces cerevisiae* NCYC Sc 47 belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers' was authorised for 10 years by Commission Regulation (EC) No 232/2009 [2] for dairy buffaloes, by Commission Regulation (EC) No 1447/2006 [3] for lambs for fattening, by Commission Regulation (EC) No 188/2007 [4] for dairy goats and dairy sheep, by Commission Regulation (EC) No 186/2007 [5] for horses, and by Commission Regulation (EC) No 209/2008 [6] for pigs for fattening. It was authorised without a time limit by Commission Regulation (EC) No 316/2003 [7] for cattle for fattening, by Commission Regulation (EC) No 1811/2005 [8] for dairy cows, by Commission Regulation (EC) No 1288/2004 [9] for sows, and by Commission Regulation (EC) No 2148/2004 [10] for weaned piglets.

(2) In accordance with Article 13(3) of Regulation (EC) No 1831/2003, the holder of the authorisations has proposed changing the terms of the authorisations of *Saccharomyces cerevisiae* NCYC Sc 47 as set out in the Regulations referred to in recital 1.

(3) The use of *Bacillus subtilis* DSM 17299 belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers' was authorised for 10 years by Commission Regulation (EC) No 1137/2007 [11] for chickens for fattening.

(4) In accordance with Article 13(3) of Regulation (EC) No 1831/2003, the holder of the authorisation has proposed changing the terms of the authorisation of *Bacillus subtilis* DSM 17299 as set out in the Regulation referred to in recital 3.

(5) The opinions adopted by the European Food Safety Authority ('the Authority') on the use of certain micro-organisms in feed were based on the Qualified Presumption of Safety (QPS) status of the micro-organisms concerned ('Scientific Opinion on the maintenance of the list of QPS biological agents intentionally added to food and feed (2011 update)' [12]). The holders of the authorisations have proposed to delete the limitation concerning the maximum content of the micro-organisms *Saccharomyces cerevisiae* NCYC Sc 47 and *Bacillus subtilis* DSM 17299 in complete feedingstuffs, on the basis that the maximum doses were not consistent with the QPS approach.

(6) In order to avoid market distortions it is appropriate to delete the limitation concerning the maximum content also as regards authorisations of other micro-organisms having the same QPS status.

(7) In accordance with Article 13(1) the Authority was requested to provide an opinion on the possibility to delete the maximum content for other micro-organisms having the same QPS status: *Saccharomyces cerevisiae* CNCM I-1077 authorised for 10 years by Commission Regulation (EC) No 1293/2008 [13] for lambs, by Commission Regulation (EC) No 226/2007 [14] for dairy goats and dairy sheep and without a time limit by Commission Regulation (EC) No 1200/2005 [15] for dairy cows and cattle for fattening; *Saccharomyces cerevisiae* CNCM I-1079 authorised without a time limit by Commission Regulation (EC) No 1847/2003 [16] for piglets and by Commission Regulation (EC) No 2036/2005 [17] for sows; *Saccharomyces cerevisiae* CBS 493.94 authorised without a time limit by Commission

[1] OJ L 268, 18.10.2003, p. 29.
[2] OJ L 74, 20.3.2009, p. 14.
[3] OJ L 271, 30.9.2006, p. 28.
[4] OJ L 57, 24.2.2007, p. 3.
[5] OJ L 63, 1.3.2007, p. 6.
[6] OJ L 63, 7.3.2008, p. 3.
[7] OJ L 46, 20.2.2003, p. 15.
[8] OJ L 291, 5.11.2005, p. 12.
[9] OJ L 243, 15.7.2004, p. 10.
[10] OJ L 370, 17.12.2004, p. 24.
[11] OJ L 256, 2.10.2007, p. 5.
[12] *EFSA Journal 2011*;9(12):2497.
[13] OJ L 340, 19.12.2008, p. 38.
[14] OJ L 64, 2.3.2007, p. 26.
[15] OJ L 195, 27.7.2005, p. 6.
[16] OJ L 269, 21.10.2003, p. 3.
[17] OJ L 328, 15.12.2005, p. 13.

Regulation (EC) No 1288/2004 for cattle for fattening and calves and by Commission Regulation (EC) No 1811/2005 ([1]) for dairy cows; *Saccharomyces cerevisiae* MUCL 39885 authorised without a time limit by Commission Regulation (EC) No 492/2006 ([2]) for cattle for fattening; *Bacillus amyloliquefaciens* CECT 5940 authorised for 10 years by Commission Regulation (EC) No 1292/2008 ([3]) for chickens for fattening; *Lactobacillus farciminis* CNCM MA 67/4R authorised for four years by Commission Regulation (EC) No 1876/2006 ([4]) for chickens and turkeys for fattening and laying hens and without a time limit by Commission Regulation (EC) No 492/2006 for weaned piglets; *Pediococcus acidilactici* CNCM MA18/5M authorised without a time limit by Commission Regulation (EC) No 1200/2005 for chickens for fattening and by Commission Regulation (EC) No 2036/2005 for pigs for fattening; *Lactobacillus acidophilus* D2/CSL CECT4529 authorised without a time limit by Commission Regulation (EC) No 1520/2007 ([5]) for laying hens; *Bacillus subtilis* C-3102 (DSM 15544) authorised for 10 years by Commission Regulation (EC) No 1444/2006 ([6]) for chickens for fattening.

(8) The Authority concluded in its opinion of 24 April 2012 ([7]) that the setting of a maximum content of *Saccharomyces cerevisiae* NCYC Sc 47, *Bacillus subtilis* DSM 17299, *Saccharomyces cerevisiae* CNCM I-1077, *Saccharomyces cerevisiae* CNCM I-1079, *Saccharomyces cerevisiae* CBS 493.94, *Saccharomyces cerevisiae* MUCL 39885, *Bacillus amyloliquefaciens* CECT 5940, *Lactobacillus farciminis* CNCM MA 67/4R, *Pediococcus acidilactici* CNCM MA18/5M, *Lactobacillus acidophilus* D2/CSL CECT4529, and *Bacillus subtilis* C-3102 (DSM 15544) in complete feedingstuff does not offer any additional degree of safety for the target animals and consumers. Therefore, there are no reasons to maintain the maximum content for them.

(9) The conditions provided for in Article 5 of Regulation (EC) No 1831/2003 are satisfied.

(10) Regulations (EC) No 232/2009, (EC) No 188/2007, (EC) No 186/2007, (EC) No 209/2008, (EC) No 1447/2006, (EC) No 316/2003, (EC) No 1811/2005, (EC) No 1288/2004, (EC) No 2148/2004, (EC) No 1137/2007, (EC) No 1293/2008, (EC) No 226/2007, (EC) No 1444/2006, (EC) No 1876/2006, (EC) No 1847/2003, (EC) No 2036/2005, (EC) No 492/2006, (EC) No 1200/2005, and (EC) No 1520/2007 should therefore be amended accordingly.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

([1]) OJ L 291, 5.11.2005, p. 12.
([2]) OJ L 89, 28.3.2006, p. 6.
([3]) OJ L 340, 19.12.2008, p. 36.
([4]) OJ L 360, 19.12.2006, p. 126.
([5]) OJ L 335, 20.12.2007, p. 17.
([6]) OJ L 271, 30.9.2006, p. 19.
([7]) *EFSA Journal 2012*;10(5):2680.

HAS ADOPTED THIS REGULATION:

Article 1

Amendment to Regulation (EC) No 232/2009

In column 8, maximum content, of the entry for 4b1702, *Saccharomyces cerevisiae* NCYC Sc47 in the Annex to Regulation (EC) No 232/2009, the words '$1{,}4 \times 10^9$' are deleted.

Article 2

Amendment to Regulation (EC) No 188/2007

In column 8, maximum content of the entry for 4b1702, *Saccharomyces cerevisiae* NCYC Sc47 in the Annex to Regulation (EC) No 188/2007, the words '$7{,}5 \times 10^9$' are deleted.

Article 3

Amendment to Regulation (EC) No 186/2007

In column 8, maximum content of the entry for 4b1702, *Saccharomyces cerevisiae* NCYC Sc47 in the Annex to Regulation (EC) No 186/2007, the words '7×10^9' are deleted.

Article 4

Amendment to Regulation (EC) No 209/2008

In column 8, maximum content of the entry for 4b1702, *Saccharomyces cerevisiae* NCYC Sc47 in the Annex to Regulation (EC) No 209/2008, the words '$1{,}00 \times 10^{10}$' are deleted.

Article 5

Amendment to Regulation (EC) No 1447/2006

In column 8, maximum content of the entry for E 1702, *Saccharomyces cerevisiae* NCYC Sc47 in the Annex to Regulation (EC) No 1447/2006, the words '$1{,}4 \times 10^{10}$' are deleted.

Article 6

Amendment to Regulation (EC) No 316/2003

In column 7, maximum content of the entry for E 1702, *Saccharomyces cerevisiae* NCYC Sc47 in Annex I to Regulation (EC) No 316/2003, the words '8×10^9' are deleted.

Article 7

Amendment to Regulation (EC) No 1811/2005

Annex III to Regulation (EC) No 1811/2005 is amended as follows:

(1) in column 7, maximum content, of the entry for E 1702, *Saccharomyces cerevisiae* NCYC Sc 47, the words '2×10^9' are deleted;

(2) in column 7, maximum content, of the entry for E 1704, *Saccharomyces cerevisiae* CBS 493.94, the words '$3{,}5 \times 10^8$' are deleted.

Article 8

Amendment to Regulation (EC) No 1288/2004

Annex I to Regulation (EC) No 1288/2004 is amended as follows:

(1) in column 7, maximum content, of the entry for E 1702, *Saccharomyces cerevisiae* NCYC Sc 47, the words '1×10^{10}' are deleted;

(2) in column 7, maximum content, of the entry for E 1704, *Saccharomyces cerevisiae* CBS 493.94, the words '2×10^{9}' and '$1{,}7 \times 10^{8}$' are deleted.

Article 9

Amendment to Regulation (EC) No 2148/2004

In column 7, maximum content of the entry for E 1702, *Saccharomyces cerevisiae* NCYC Sc47 of Annex II to Regulation (EC) No 2148/2004, the words '1×10^{10}' are deleted.

Article 10

Amendment to Regulation (EC) No 1137/2007

In column 8, maximum content of the entry for 4b1821 *Bacillus subtilis* DSM 17299 of the Annex to Regulation (EC) No 1137/2007, the words '$1{,}6 \times 10^{9}$' are deleted.

Article 11

Amendment to Regulation (EC) No 1293/2008

In column 8, maximum content of the entry for 4b1711 *Saccharomyces cerevisiae* CNCM I-1077 of the Annex to Regulation (EC) No 1293/2008, the words '$7{,}3 \times 10^{9}$' are deleted.

Article 12

Amendment to Regulation (EC) No 226/2007

In column 8, maximum content of the entry for 4b1711 *Saccharomyces cerevisiae* CNCM I-1077 of the Annex to Regulation (EC) No 226/2007, the words '3×10^{9}' and '$1{,}2 \times 10^{9}$' are deleted.

Article 13

Amendment to Regulation (EC) No 1444/2006

In column 8, maximum content of the entry for 4b1820 *Bacillus subtilis* DSM 17299 of the Annex to Regulation (EC) No 1444/2006, the words '1×10^{9}' are deleted.

Article 14

Amendment to Regulation (EC) No 1876/2006

In column 7, maximum content of the entry for 12 *Lactobacillus farciminis* CNCM MA 67/4R of Annex I to Regulation (EC) No 1876/2006, the words '1×10^{9}' are deleted.

Article 15

Amendment to Regulation (EC) No 1847/2003

In column 7, maximum content of the entry for E 1703 *Saccharomyces cerevisiae* CNCM I-1079 of Annex II to Regulation (EC) No 1847/2003, the words '6×10^{9}' are deleted.

Article 16

Amendment to Regulation (EC) No 2036/2005

Annex I to Regulation (EC) No 2036/2005 is amended as follows:

(1) in column 7, maximum content, of the entry for E 1703, *Saccharomyces cerevisiae* CNCM I-1079, the words '6×10^{9}' are deleted;

(2) in column 7, maximum content, of the entry for E 1712, *Pediococcus acidilactici* CNCM MA18/5M, the words '1×10^{9}' are deleted.

Article 17

Amendment to Regulation (EC) No 492/2006

Annex II to Regulation (EC) No 492/2006 is amended as follows

(1) in column 7, maximum content, of the entry for E 1710, *Saccharomyces cerevisiae* MUCL 39885, the words '9×10^{9}' are deleted;

(2) in column 7, maximum content, of the entry for E 1714, *Lactobacillus farciminis* CNCM MA 67/4R, the words '1×10^{10}' are deleted.

Article 18

Amendment to Regulation (EC) No 1200/2005

Annex II to Regulation (EC) No 1200/2005 is amended as follows:

(1) in column 7, maximum content, of the entry for E 1711, *Saccharomyces cerevisiae* CNCM I-1077, the words '2×10^{9}' and '$1{,}6 \times 10^{9}$' are deleted;

(2) in column 7, maximum content, of the entry for E 1712, *Pediococcus acidilactici* CNCM MA18/5M, the words '1×10^{10}' are deleted.

Article 19

Amendment to Regulation (EC) No 1520/2007

Annex IV to Regulation (EC) No 1520/2007 is amended as follows:

In column 7, maximum content of the entry for E 1715 *Lactobacillus acidophilus* D2/CSL CECT4529, the words '1×10^{9}' are deleted.

Article 20

Entry into force

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 is binding in its entirety and directly applicable in all Member States.

Done at Brussels, 5 November 2012.

For the Commission
The President
José Manuel BARROSO