

## SCHEDULE 6

Regulation 3

Renewal of authorisation (with modification) of a preparation of *Bacillus velezensis* (ATCC PTA-6737) (formerly *Bacillus subtilis* (ATCC PTA-6737)) (identification number 4b1823) as a feed additive for chickens for fattening, chickens reared for laying, ducks for fattening, quails, pheasants, partridges, guinea fowl, pigeons, geese for fattening and ostriches, and its authorisation as a feed additive extending existing uses to cover all minor poultry species (except for laying), ornamental birds, sporting birds and game birds

The preparation of *Bacillus velezensis* (ATCC PTA-6737), belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers', is authorised as an additive in animal nutrition in accordance with the specifications in the following table(1).

<i>Additive</i>	<i>Bacillus velezensis</i> (ATCC PTA-6737)
<i>Identification number of the additive</i>	4b1823
<i>Authorisation holder</i>	Kemin Europa N.V.
<i>Additive category</i>	Zootechnical additives
<i>Functional group</i>	Gut flora stabilisers
<i>Additive composition</i>	Preparation of <i>Bacillus velezensis</i> (ATCC PTA-6737) containing a minimum of $8 \times 10^{10}$ CFU/g additive
<i>Characterisation of the active substance(s)</i>	Viable spores of <i>Bacillus velezensis</i> (ATCC PTA-6737).
<i>Analytical methods<sup>(1)</sup></i>	For enumeration (colony count) in the feed additive, premixtures, feed materials and compound feed <sup>(2)</sup> : — Spread plate method using tryptone soya agar with pre-heat treatment of feed samples.
	For identification of bacterial strain: — Pulsed-field gel electrophoresis (PFGE).
<i>Species or category of animal</i>	— Chickens for fattening — Chickens reared for laying — Minor poultry species (except for laying) — Ornamental, sporting and game birds
<i>Maximum age</i>	Not applicable
<i>Minimum content<sup>(3)</sup></i>	$1 \times 10^7$ CFU/kg

- (1) Details of the analytical methods set out in the document referenced "D08/FSQ/CVH/SY/Ares(2009)61627" and last updated 6th June 2016. This document is available at the following address: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2008-0039>.
- (2) This method is not suitable for the detection of *Bacillus velezensis* at concentrations below the minimum content level in feed materials and compound feed.
- (3) Content of *Bacillus velezensis* (ATCC PTA-6737): CFU/kg of complete feed with a moisture content of 12%.

(1) This authorisation is a renewal of the authorisations granted under [Commission Regulation \(EU\) No. 107/2010](#) and [Commission Implementing Regulation \(EU\) No. 885/2011](#). Those Regulations are revoked by regulation 11 of these Regulations but see the transitional provision in regulation 8. This feed additive is separately authorised for use in feed for specified other species or categories of animals by [Commission Implementing Regulations \(EU\) No. 306/2013](#), [787/2013](#), [2015/1020](#) and [2017/2276](#).

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

<i>Maximum content</i> <sup>(3)</sup>	No maximum
<i>Other provisions</i>	<ol style="list-style-type: none"> <li>1) In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment must be indicated.</li> <li>2) If <i>Bacillus velezensis</i> (ATCC PTA-6737) is to be used in feed containing coccidiostats, this feed additive is authorised for use with the following coccidiostats only and, in accordance with their individual authorisation criteria for: lasalocid A sodium, maduramicin ammonium, monensin sodium, narasin, narasin/nicarbazin (as combined use only) salinomycin sodium, decoquinate, robenidine hydrochloride or diclazuril.</li> </ol>

- (1) Details of the analytical methods set out in the document referenced “D08/FSQ/CVH/SY/Ares(2009)61627” and last updated 6th June 2016. This document is available at the following address: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2008-0039>.
- (2) This method is not suitable for the detection of *Bacillus velezensis* at concentrations below the minimum content level in feed materials and compound feed.
- (3) Content of *Bacillus velezensis* (ATCC PTA-6737): CFU/kg of complete feed with a moisture content of 12%.