Amendments to the Enforcement Ordinance of the Standards of Feed and Feed Additives

The government of Japan will add standards and specifications of *Bacillus subtilis* and Phytase. Major additions are outlined below.

Bacillus subtilis No.5

Specifications for feed additives

Active substance

Compositional specifications

This active substance is a lyophilized or frozen *Bacillus subtilis* JA-ZK strain intended for the use in manufacturing.

Origin The original strain is the *Bacillus subtilis* JA-ZK strain isolated from soil in 2000.

Methods of preservation and criteria for passage

Passage the original strain in culture media containing nutrients such as yeast extract and starch. Preserve the original strain at \leq -70 °C frozen, or at 2 ~ 8 °C after lyophilized.

Grow the original strain using the same media and store the lyophilized or frozen active substance in small quantity. The maximum number of passage of the original strain is 10. This product itself should not be used for passage.

Product

Compositional specifications

This product is in the form of powder. This product is made from mixing bacterial cells collected after cultivation of *Bacillus subtilis* No.5 active substance and starch, then dry and mix excipient substance.

Content 1 g of this product contains 10^{-1} times to 10^{-2} times of live bacteria corresponding to the content on the label.

Standards for methods of manufacture

Culture the original strain of *Bacillus subtilis* No.5. Collect bacterial cells, add starch, dry and mix excipient substance.

Standards for methods of storage

Store the products in airtight containers.

Specifications for methods of manufacture in general

This Bacillus subtilis is allowed to be used in feed for broiler, layer and pig.

Phytase No. 2-3

Specifications for feed additives

Active substance

Compositional specifications

Unit \geq 5000FTU/1g

Physical and chemical properties

1. This active substance is light brown liquid and has characteristic odor.

2. pH of aqueous solution or aqueous suspension $(1 \rightarrow 100)$ is 3.5 to 6.5.

3. This active substance has the best enzyme activity when pH is between pH4.5 and pH6.0.

Ignition residue $\leq 5.0\%$ (0.5g)

Standards for methods of manufacture

Culture genetically modified *Schizosaccharomyces pombe*. Filter the preparation or extract it with water. Then, concentrate the filtrate.

Product 1

Compositional specifications

This product is in the form of liquid and is made from mixing sodium chloride, citric acid and sorbitol to the active substance of Phytase No. 2-3.

Unit This product contains Phytase corresponding to 85 to 170% of the FTU on the label.

Product 2

Compositional specifications

This product is in the form of pieces, powder or particles and is made from mixing or granulating after adding sodium sulfate, excipient substances, and aqueous solution of polyvinyl alcohol if necessary, or pieces, powder or particles made from mixing citric acid, flour and calcium propionate.

Unit This product contains Phytase corresponding to 85 to 170% of the FTU on the label.

Specifications for methods of manufacture in general

This Phytase is allowed to be used in feed for broiler, layer and pig.