(Unofficial)

Announcement of the Food and Drug Administration Re: Prescription of Qualities or Standards of Single Food Additives (No.3)

To prescribe qualities or standards of single food additives additional permitted by the Food and Drug Administration.

By the virtue of provisions of (2) of Clause 4 of the Notification of Ministry of Public Health (No.281) Re: Food additives dated 18th August B.E. 2547 (2004) which has been issued by the virtue of provisions of Section 5 and 6 (1) (2) (4) (5) (6) (7) (9) and (10) of the Food Act B.E.2522 (1979) in which contain provisions in relation to the restriction of Rights and Liberties of the Persons, in respect of which Section 29 and in conjunction with Section 33, Section 41, Section 43, and Section 45 of the constitution of the Kingdom of Thailand so permit by virtue of provisions of law; the Food and Drug Administration by the approval of the Food Committee has announced as follows:

The following texts shall be added as (14) of Clause 2 of the announcement of the Food and Drug Administration Re: Prescription of qualities or standards of single food additives dated 24^{th} June B.E.2548 (2005):

"(14) Ice Structuring Protein produced from genetically modified yeast"

Synonyms: - Ice Structuring Protein type III HPLC 12;

- ISP Type III HPLC 12

Formula: consisted of 66 amino acids with 16 varieties in the following sequence:

Asn Gln Ala Ser Val Val Ala Asn Gln Leu Ile Pro Ile Asn Thr Ala Leu Thr Leu Val Met Met Arg Ser Glu Val Val Thr Pro Val Gly Ile Pro Ala Glu Asp Ile Pro Arg Leu Val Ser Met Gln Val Asn Arg Ala Val Leu Gly Pro Thr Thr Leu Met Pro Asp Met Val Lys Gly Tyr Pro Pro Ala

Molecular weight: 7.027 kDa

Acceptable daily intake: 0.2 mg per kg body weight

<u>Description</u>: brown light liquid obtained from fermentation of genetically modified yeast *Saccharomyces cerevisiae* under process control of Ice Structuring Protein produced from genetically modified yeast or Ice Structuring Protein type III HPLC 12 and filtering by Micro filtration technique and passed through Ultra filtration process to obtain concentrated protein.

Characteristics:

- Quantity of Ice Structuring Protein produced from genetically modified yeast; ISP type III HPLC 12, by High performance liquid chromatography (HPLC) is between 4.5 8.5 g/l or total nitrogen not more than 7%
- pH Value is between 2.5 3.5
- Total ash (at 800 $^{\circ}$ C, 1 h) not more than 2 %
- Buffer (calculated as citric acid) not more than 0.2%

Impurity:

- Heavy metal (calculated as Lead) not more than 2 mg/l

Microbiological criteria:

- Total plate count not more than 3,000 colonies/g
- Coliform not more than 10 colonies/g
- E.coli not detected in 25 g
- Listeria not detected in 25 g
- Salmonella not detected in 25 g
- Bacillus cereus not more than 100 colonies/g
- Staphylococcus aureus not more than 10 colonies/g
- Yeast and Molds not more than 100 colonies/g
- Saccharomyces cerevisiae var. genetically modified not detected

Packing and storage: kept in sealed containers at -20 °C

Announced on date 23rd June B.E.2552 (2009)

(Signed) Pipat Yingseree

(Mr. Pipat Yingseree)

Secretary-General of the Food and Drug Administration

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Note: This English version of the notification is translated to meet the need of the non-Thai speaking people. In case of any discrepancy between the Thai original and the English translation, the former will take priority.