China - Peoples Republic of

**Post:** Beijing

**Hygienic Standard for Enzyme Preparations Used in Food Processing**

**Report Categories:**
FAIRS Subject Report

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**Report Highlights:**
On January 5, 2009, the Standardization Administration of China (SAC) notified the World Trade Organization of draft national standard “Hygienic Standard for Enzyme Preparations Used in Food Processing” for public comment. This measure has the WTO reference number G/SPS/N/CHN/112. Interested parties are encouraged to comment on the draft standard before March 6, 2009. This report contains an UNOFFICIAL translation of G/SPS/N/CHN/112.

**Executive Summary:**
On January 5, 2009, the Standardization Administration of China (SAC) and the Ministry of Health (MOH) notified the World Trade Organization of draft national standard “Hygienic Standard for Enzyme preparations Used in Food Processing” for public comment. This measure has the WTO reference number G/SPS/N/CHN/112. The standard specifies the requirements for raw materials, contaminants, micro-organisms, and antimicrobial activity for enzyme preparations in food processing. Upon adoption, this will be a mandatory standard.

Interested parties are encouraged to comment on the draft standard before March 6, 2009. The date of implementation for this measure is April 6, 2009. This report contains an UNOFFICIAL translation of G/SPS/N/CHN/112.
General Information:
BEGIN TRANSLATION

National Standard for Enzyme Preparations Used in Food Processing (Draft)
GB xxxx-xxxx

Jointly issued by the Ministry of Health and the Standardization Administration of China

Preamble

All technical content of the standard is mandatory.

The standard is proposed and managed by the Ministry of Health.

The Ministry of Health is responsible for interpretation of the standard.

The drafting agencies include Nutrition and Food Safety Institute of China CDC and Chinese Institute of Food Fermentation Industry.

Main drafters of the standard: Wang Jun, Luo Xuejuan, Li Xiaoyu, and Cheng Chi.

1. Scope
The standard provides indicator requirements, production processes, packaging, labeling, storage and transportation requirements, as well as testing methods for enzyme preparations used in food processing.

The standard applies to enzyme preparations used in food processing.

2. Standard documents referenced
The clauses in the following documents have been quoted and become part of the standard. For cited documents with dates, all their subsequent modifications (excluding corrections) or revised versions do not apply to this standard. However, parties having reached an agreement based on this standard are encouraged to study whether the latest versions of these documents are applicable. For cited documents without a date, their latest versions apply to this standard.

GB 2760    Hygienic standards for uses of food additives
GB/T 4789.2 Microbiological examination of food hygiene—Detection of aerobic bacterial count
GB/T 4789.3 Microbiological examination of food hygiene—Detection of Coliform bacteria
GB/T 4789.4 Microbiological examination of food hygiene—Examination of Salmonella
GB/T 4789.X Microbiological examination of food hygiene—Examination of E.Coli
GB/T 5009.11 Determination of total arsenic and abio-arsenic in foods
GB/T 5009.12 Determination of lead in foods
3. Terminology and definition
The following terms and definitions apply to the standard.

3.1 Enzyme preparation
Biological products directly extracted from edible or non-edible parts of a plant or animal or fermented and extracted from traditional or genetically modified microorganisms (including but not limited to bacteria, actinomycetes, and fungi) that are used in food processing and have a special catalytic function.

3.2 Antimicrobial activity
Ability to inhibit or eliminate microorganisms

4. Indicator requirements
4.1 Requirements for ingredients
4.1.1 Raw materials for producing enzyme preparations should comply with good manufacture practice (GMP) or relevant requirements and, if used under normal circumstances, should not pose residual contamination that is harmful to health on the final food product.
4.1.2 For enzyme preparations originating from animals, the animal tissues should be consistent with the quarantine requirements for meat.
4.1.3 For enzyme preparations originated from plants, the plant tissues should not be moldy.
4.1.4 Microbial production strains should go through taxonomic and/or genetic identification, and should comply with relevant regulations. Strain preservation methods and conditions should ensure the stability and repeatability between batch fermentation.
4.2 Physical and chemical indicator
The physical and chemical indicators of enzyme preparations should comply with the provisions of Table 1.

Table 1. Physical and Chemical Indicators

<table>
<thead>
<tr>
<th>Item</th>
<th>Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead (mg/kg)</td>
<td>≤ 5</td>
</tr>
<tr>
<td>Abio-arsenic (mg/kg)</td>
<td>≤ 3</td>
</tr>
</tbody>
</table>

4.3 Microbial indicator
The microbial indicator of enzyme preparations should comply with the provisions of Table 2. For enzyme preparations produced from genetically modified microorganisms, the production bacteria should not be detected.

Table 2. Microbial indicator

<table>
<thead>
<tr>
<th>Item</th>
<th>Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aerobic bacterial count cfu/g (mL)</td>
<td>≤ 50,000</td>
</tr>
<tr>
<td>Coliform bacteria MPN/g (mL)</td>
<td>≤ 30</td>
</tr>
<tr>
<td>E. Coli 25g (mL)</td>
<td>No detection</td>
</tr>
<tr>
<td>Salmonella 25g (mL)</td>
<td>No detection</td>
</tr>
</tbody>
</table>

4.4 Antimicrobial activity
Antimicrobial activity should not be detected in enzyme preparations originated from microorganisms.

5. Food additives
5.1 The quality of food additives should comply with corresponding standards and regulations.
5.2 The varieties and dose levels of food additives should comply with the provisions of GB 2760.

6. Production process
Production of enzyme preparations should comply with good manufacture practice (GMP) and relevant regulations.

7. Packaging
Should comply with hygienic requirements for packing containers or materials and the packing container should be clean, dry and sealed.

8. Labeling
Marketing package labels should comply with relevant regulations.

9. Storage and transportation
9.1 Should not be stored with non-food additives and prevent rain, sun and contamination.
9.2 Anti-contamination measures should be taken during transportation and should not be co-mingled with toxic or harmful items.

10. Testing method
10.1 Lead
Determined in accordance with GB/T 5009.12
10.2 Abio-arsenic
Determined in accordance with GB/T 5009.11
10.3 Aerobic bacterial count
Determined in accordance with GB/T 4789.2
10.4 Coliform bacteria
Determined in accordance with GB/T 4789.3
10.5 E. Coli
Determined in accordance with GB/T 4789.X
10.6 Salmonella
Determined in accordance with GB/T 4789.4

END TRANSLATION