

## **Regulations for Application and Evaluation of Fungi Health Food (interim)**

**Article 1** With a view to standardizing the appraisal of fungi health food and ensuring the edible safety of fungi health food, the regulations is formulated in accordance with Food Assanation of the People's Republic of China and Provisions for Health Food Registration (interim).

**Article 2** Fungi health food means to make the production with the carp and hyphal body of the edible big fungi and small one. Fungi health food must be safe and reliable, namely edible safety, asepsis and harmless. The character of biology, genetics and ergonomics must be clear and stable, which is used in production.

**Article 3** Except the carp and hyphal body of edible fungi which are used to following an old practice for a long time, the list of fungi strain must be published by the State Food and Drug Administration (SFDA), which is used in health food.

**Article 4** The State Food and Drug Administration (SFDA) determine the institutions for assessment which evaluate the eumycete strain of health food. The list of the institutions for assessment is published by the State Food and Drug Administration (SFDA) .The evaluation of eumycetes health food must be carried out in these institutions.

**Article 5** Except providing documents according to the relevant regulations of health food registration administration, the following documents shall be provided.

1. The formula and formula accordance should contain definite strain generic name, specific name and the order of the strain .The generic name, specific name of the strain should have the corresponding Latin scientific name.
2. The condition of the strain cultivation (nutritive medium, cultivation temperature etc).
3. The source of the strain and the safely edible documents in exterior and interior.
4. The evaluation report of the strain should be issued by the assessment units designated by the State Food and Drug Administration (SFDA).
5. The safety evaluation of the strain (including toxicology test).The strain and its metabolic products must be asepsis and harmless. Poisonous noxious substance and allergenic substance shall not be added into nutrient medium for production. If the strain might produce antibiotic drug, fungal-toxin and other active compounds, the detection report shall be contained, which includes relevant antibiotic dug, fungal-toxin and other active compounds.
6. The strain preservation method、 rejuvenation method and frequency of going down to posterity, preventing variation method of the strain.
7. If the strain goes through acclimatization, mutagenesis, the documents shall be provided, which include the method of acclimatization and mutagenesis, the agent of acclimatization and mutagenesis etc.
8. The technical specification and the technical guarantee for production.

9. The certification documents that production condition meets the Good Manufacturing Practice of Health Food.

10. Applying for utilizing those fungi strain for the development, exploitation and the production of health food, which is not included in the List of Fungi Strain Utilized in Health Food, the documents must be provided, which include research papers and pertinent literature possessing efficacy, the production of the strain and its metabolism having asepsis and harmless.

**Article 6** The applicant purchases the germ powder by fermenting and cultivating, which is used for production of health food. The processing is just a combining and packing procedure. The documents in the fifth regulation may be substituted by the photocopy, which is provided by feed stock suppliers of the strain (covering the official seal of feed stock suppliers), and shall provide the buying and selling certification.

**Article 7** The unit of sample advanced development shall have special section and personnel management seed lot, establishing archive numerical data of the strain. The content includes the source, history, screen, examination, conservation method, quantity, and unsealing utilization of the strain and so on, the record shall be complete.

**Article 8** The place for advanced development fungi health food should be provided with the following conditions:

1. According with the requirements of Good Manufacturing Practice of Health Food (GMP), and establishing hazard analysis critical control point (HACCP) to have the system of quality assurance.
2. The pilot scale production shall be provided with, that is, having the capacity of at least 500L everyday, reporting together with semi-works production.
3. The special factory building or workshop, which is also having special production unit and facilities. There must be applied with eumycete laboratory, having special messenger to administer the strain, having the technologist to take responsibility, who should have technique professional title which is at least medium rank and majors in microbes. Instituting proportionally technological specification and guarantee in detail.

**Article 9** The strain for production and processing cannot be alternated.

**Article 10** Generally health food is produced by hyphal body ferment, for instance, hyphal body can easily obtain encarpium, we can name it by adding encarpium to hyphal body; otherwise, we can name its production (including raw material name) by adding specific name to hyphal body, cannot add the name of its encarpium.

**Article 11** Except nutrient medium, animal 、 plants and other materials, which have usable components, cannot be added to the course of all the fungi strain fermentation.

**Article 12** The strain of gene modification cannot be used in producing health food.

**Article 13** The State Food and Drug Administration (SFDA) take responsibility to interpret the regulations.

**Article 14** The regulations shall go into effect as of July 1st, 2005. If the issued regulations weren't in accordance with the regulations; it shall be subject to this one.

**The list of fungi strain utilized in health food**

*Saccharomyces cerevisiae*

*Candida utilis*

*Kluyveromyces lactis*

*Saccharomyces carlsbergensis*

*Paecilomyces hepiali* Chen et Dai, sp. Nov

*Hirsutella hepiali* Chen et Shen

*Ganoderma lucidum*

*Ganoderma sinensis*

*Ganoderma tsugae*

*Monascus anka*

*Monascus purpureus*