Regulatory Insights

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Government Agency
State Administration Market Regulation (SAMR)

Rules on Declaration and Evaluation of Probiotics Health Foods(Exposure Draft)

益生菌类保健食品申报与审评规定（征求意见稿）

Article 1: In order to strengthen the management of probiotics health foods, standardize the declaration and review work, and ensure the safety, health care functions and quality controllability of probiotics health foods these Regulations are formulated in accordance with the Food Safety Law of People's Republic of China and Measures for the Registration and Filling of Health Food.

Article 2: Probiotics are living microorganisms that are beneficial to the health of the host when ingested in sufficient quantities. Probiotics health food refers to microbial products that use probiotics as the main functional ingredient with necessary excipients and have a beneficial effect on human health when sufficient quantities are ingested. Probiotic health foods must be safe to eat and must not cause acute, subacute or chronic harm to the human body.

Article 3: The biological, genetic, and ergonomic properties of the strains used to produce probiotics health foods should be clear and stable, the strains and their metabolites must be non-toxic and harmless. The strains approved as food ingredients by the national health administrative department can also be used in health food. In addition to safety requirements, the strains should also have sufficient researches and scientific consensus to support their health functions.

Article 4: For the application of probiotics health food, in addition to all dossiers required in Measures for the Registration and Filling of Health Food, below materials should also be provided:

4.1 Use basis of bacteria, the CoA of raw materials etc.

4.2 The genus name, species name and strain number. The genus and species names should mark the corresponding Latin name.

4.3 Culture conditions (Medium, temperature etc.)

4.4 Source of the strain and safety materials domestic and foreign.

4.5 Strain Identification Report (including phenotypic characteristics and identification results of genotype-based strain levels).

4.6 Safety evaluation reports such as pathogenicity test and drug resistance test.

4.7 Preservation method of the strain.

4.8 For domesticated strains, the domestication methods and agents are required.

4.9 Function researches and literature at the strain level.
Where the above materials involve technical and trade secrets, they may be supplied to the relevant national regulatory authorities by the strain manufacturer directly.

Article 5: The strain identification unit of probiotics health foods shall have the inspection and identification qualification of the corresponding strains.

Article 6: The strains used for the production of probiotics health foods shall meet the following conditions:

6.1 The strains used for health food production shall utilize the Seed Lot system. The record, history, source and biological characteristics of primary seed lot shall be verified. The master seed lot should be the seed lot preserved from the passage and amplification of the primary seed lot. The working seed lot should be the seed lot preserved from the passage and amplification of the master seed lot. The biological characteristics of the working seed lot should be consistent with the

primary seed lot. Each batch of master seed lot and working seed lot shall be kept, verified and applied according to the rules. On the suitable medium, the master seed shall not be passaged for more than 10 generations, the working seed lot shall not be passaged for more than 5 generations.

6.2 The trial production unit shall have special departments and staffs to manage the production strains, and establish the strains archives containing source, history, screening, verification, preservation method, quantity and the use of the strains.

6.3 Shall not add toxic or hazardous to the medium.

6.4 The strains used in production and the production process should be consistent with the registration or filing.

Article 7: The place where probiotics health food samples are trial-produced shall meet the following conditions:

7.1 Establish a good quality assurance system such as HACCP, and ensure it is operated effectively.

7.2 Have a pilot production scale or above.

7.3 Must have workshops, facilities for the certain products. Must be equipped with probiotics labs. The strains must be managed by specific personnel, the person in charge should have professional knowledge in production management. Should have detailed technical specifications and technical guarantees.

Article 8: Probiotics health foods shall have a live bacterial count of not less than 10^6 CFU/mL(g) for each strain during their shelf life.

Article 9: The labels and instructions for probiotics health foods shall comply with the relevant provisions of the “Measures for the Registration and Filling of Health Food” and clearly indicate the Chinese name and strain number of the strains.

Article 10: Genetically modified strains and their metabolites shall not be used in health foods.

Article 11: Functional herb or animal ingredients except the medium shouldn't be added to probiotics strains in their fermentation nor in the finished health foods.

Article 12: Production strains must not be changed.

Article 13: Probiotics health foods, when applying for renewal, should be provided with safety evaluation data such as post-marketing crowd evaluation and after-sales monitoring reports.

Article 14: The regulation is interpreted by the SAMR.

Article 15: These Provisions shall be implemented from XXXX/XX/XX. Where the provisions issued in the past are inconsistent with these provisions, these provisions shall prevail.

Supplementary

The health foods produced with the inactivated bacteria or metabolites, should be named with the actual active ingredients' name rather than Probiotics. In addition, the naming should also follow Article 50 in Measures for the Registration and Filling of Health Food.

Original Chinese Document listed Below

益生菌类保健食品申报与审评规定

（征求意见稿）

第一条　为加强对益生菌类保健食品的管理，规范申报与审评工作，确保益生菌类保健食品的安全性、保健功能及质量可控性，根据《中华人民共和国食品安全法》《保健食品注册与备案管理办法》，制定本规定。

第二条　益生菌系指活的微生物，当摄取足够数量时，对宿主健康有益。益生菌类保健食品系指以益生菌为主要功效成分，添加必要的辅料制成，当摄入足够数量时对人体健康起有益作用的微生物产品。益生菌类保健食品必须食用安全，不得对人体产生急性、亚急性或者慢性危害。

第三条 生产益生菌类保健食品所用菌种（株）的生物学、遗传学、功效学特性应明确和稳定，菌种（株）及其代谢产物必须无毒无害。国家卫生行政部门发布的可用于食品的菌种（株）可用于益生菌类保健食品，菌种（株）除符合安全性的要求外，还应具有充足的研究数据和科学共识支持其具有保健功能。

第四条　申请益生菌类保健食品，除按照《保健食品注册与备案管理办法》等有关规定提交申报资料外，还应提供以下资料：

（一）菌种的使用依据、原料检验报告等。

（二）菌种属名、种名及菌株号。菌种的属名、种名应有对应的拉丁学名。

（三）菌种的培养条件（培养基、培养温度等）。

（四）菌株来源及国内外安全食用资料。

（五）菌种鉴定报告（包括表型特征和基于基因分型的菌株水平的鉴定结果）。

（六）菌种（株）的致病性试验、耐药性试验等安全性评价报告。

（七）菌种的保藏方法。

（八）对经过驯化菌种，应提供驯化的方法及驯化剂等资料。

（九）菌种在株水平上具有功能作用的研究报告、科学文献等。

上述材料涉及技术及商业秘密的，可由菌种生产商直接提供给国家相关管理部门。

第五条 益生菌类保健食品的菌种鉴定单位应具有相应菌种鉴定、检测法定资质的检验机构。

第六条 用于益生菌类保健食品生产的菌种应满足以下条件：

（一）保健食品生产用菌种应采用种子批系统。原始种子批应验明其记录、历史、来源和生物学特性。从原始种子批传代、扩增后保存的为主种子批。从主种子传代、扩增后保存的为工作种子批。工作种子批的生物学特性应与原始种子批一致，每批主种子批和工作种子批均应按规程要求保管、检定和使用。在适宜的培养基上主种子传代不超过 10 代，工作种子传代不超过 5 代。

（二）试制单位应有专门的部门和人员管理生产菌种，建立菌种档案资料，内容包括菌种的来源、历史、筛选、检定、保存方法、数量、开启使用等完整的记录。

（三）不得在生产用培养基内加入有毒有害物质。

（四）生产使用的菌株及生产工艺应当与注册或备案的一致。

第七条 益生菌类保健食品样品试制的场所应具备以下条件：

（一）建立危害分析关键控制点(HACCP)等良好质量保证体系，并保证有效运行。

（二）具备中试或中试以上生产规模。

（三）必须有适用于该产品生产的厂房或车间、生产设备和设施；必须配备益生菌实验室，菌种必须有专人管理，应由具有与生产

管理相适应的相关专业技术人员负责；制定相应的详细技术规范和技术保证。

第八条　益生菌类保健食品在其保质期内每种菌的活菌数目不得少于 10^6CFU/mL(g)。

第九条 益生菌类保健食品标签及说明书应符合《保健食品注册与备案管理办法》等相关规定，并明确标示菌种中文名称及菌株号。

第十条　经过基因改造的菌种及其代谢产物不得用于保健食品。

第十一条 所用益生菌菌种在其发酵过程及生产的保健食品，除培养基外，不得加入具有功效成分的动植物及其它物质。

第十二条 生产用菌株不得变更。

第十三条 益生菌类保健食品申请延续注册时应提供产品上市后人群评价和售后监测报告等安全性评价资料。

第十四条　本规定由国家市场监督管理总局负责解释。

第十五条　本规定自××年×月×日起实施。以往发布的规定，与本规定不符的，以本规定为准。

附 则

利用微生物菌种的死菌及代谢产物生产的保健食品，其产品名称除应符合《保健食品注册与备案管理办法》第五十六条的相关规定外，应以其实际功效成分作通用名，不得以益生菌命名。