Regulatory Insights

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Government Agency
State Administration for Market Regulation

Measures for the Managements of Health Food Raw Materials List and Health Functions List

保健食品原料目录与保健功能目录管理办法

Chapter One General Rules

Article 1. These Measures are formulated in accordance with the Food Safety Law of the People's Republic of China in order to regulate the management of health food raw materials and the list of health functions that allow health foods to be claimed.

Article 2. The Measures apply to the development, adjustment and publication of the raw materials list and health functions list for the production and operation of health foods within China.

Article 3. The health food raw materials list refers to the health food raw materials information chart formulated in accordance with the Measures, including raw materials' name, dosage and corresponding functions.

The health functions list refers to the information chart formulated in accordance with the Measures, with specific evaluation methods and judgement standards .

Article 4. The formulation, adjustment and publication of the health food raw materials list and the health functions list shall be based on the principles of

ensuring food safety and promoting public health, and shall follow the principles of law, science, openness and impartiality.

Article 5. The State Administration for Market Regulation, in conjunction with the National Health Commission and the State Administration of traditional Chinese medicine, formulates, adjusts and publishes the Health Food Raw Materials List and Health Functions List.

Article 6. The review center of The State Administration for Market Regulation(hereinafter referred to as the review center) is responsible for organizing the development of Health Food Raw Materials List and Health Functions List, receiving suggestions for incorporating or adjusting the lists.

Chapter Two The Managements of Health Food Raw Materials List

Article 7. Besides vitamins and minerals, raw materials included in the health food raw materials list shall meet the following requirements:

7.1 Has domestic and foreign edible history, the safety is clear and has been used in registered health foods.

7.2 The health function of the raw material has been included in the health functions list.

7.3 The technical requirements of raw materials, dosage ranges, functions, production processes and testing methods etc can be standardized in order to ensure the consistency of recorded products produced according to the list.

Article 8. In any of the following circumstances, the raw material shall not be included in the list:

8.1 Any food safety risks and the safety of raw materials isn't clear.

8.2 Impossible to formulate technical requirements for standardized management and does not have industrial production conditions;

8.3 The laws and regulations and the relevant departments of the State Council prohibit the use as food, or do not comply with the requirements of the ecological environment and resource laws and regulations, and other prohibitions.

Article 9. On the basis of carrying out relevant research, any agents or individual can submit to the review center a proposal to include or adjust the health food raw materials list.

Article 10. According to the registration and supervision of health foods, the State Administration for Market Regulation may select qualified technical institutions to research raw materials used in approved registered health foods. If the materials meet the requirements, the technical institutions shall propose the proposal to incorporate or adjust the health food raw materials list promptly.

Article 11. Proposals for the inclusion or adjustment of the health food raw materials list should include the following materials:

11.1 The name of the raw material, if necessary, the Latin name, source, original place, used part, specifications etc.

11.2 Dosage range and corresponding function.

11.3 Process requirements, quality standards, functional ingredients or symbolic ingredients and their content range and corresponding testing methods, suitable crowd and unsuitable crowd related instructions, precautions, etc.;

11.4 Adverse reactions in the crowd.

11.5 The basis for inclusion in the list and other related materials

Article 12. The review center shall conduct a technical evaluation on the proposed materials to be included or adjusted for the health food raw materials list, and in conjunction with the use of the raw materials in the registered health foods, make a conclusion to grant or not to include raw materials in the list. The conclusion should be submitted to the State Administration for Market Regulation.

Article 13. The State Administration for Market Regulation shall conduct a preliminary review of the completeness and standardization of the technical evaluation conclusions and other related materials submitted by the review center. If it is proposed to incorporate or adjust the health food raw materials list, it shall publicly solicit opinions and revise and improve the conclusion.

Article 14. The State Administration for Market Regulation shall review the submitted materials from the review center for incorporation or adjustment of the health food raw materials list. If qualified, the incorporated or adjusted health food raw materials list shall be published timely in conjunction with the National Health Commission and the State Administration of Traditional Chinese Medicine.

Article 15. In any of the following circumstances, the State Administration for Market Regulation shall organize a re-evaluation of the raw materials in the health food raw materials list, and according to the re-evaluation results, the list shall be adjusted accordingly with the National Health Commission and the State Administration of Traditional Chinese Medicine.

15.1 Safety risks of the raw materials discovered in new researches.

15.2 Safety risks of the raw materials discovered in food safety supervision or health food supervision.

15.3 The dosage and function are found not scientifically convincing enough in new researches.

15.5 Other conditions which require re-evaluation.

Chapter Three The Managements of Health Functions List

Article 16. The health functions incorporated in the health functions list shall meet the following requirements:

16.1 For the purpose of supplementing dietary nutrients, maintaining the health of the body or reducing the risk factors for disease.

16.2 Having a clear demand of healthy consumption that can be correctly understood and recognized.

16.3 Having sufficient scientific basis, as well as scientific evaluation methods and judgement standards.

16.4 The health care function guided by the traditional health care theory should be in line with the traditional Chinese medicine health care theory;

16.5 The suitable crowd and unsuitable crowd should be clear.

Article 17. The following conditions shall not be included in the health functions list:

17.1 Prevention, treatment and diagnosis of diseases.

17.2 Vulgar or superstitious.

17.3 May mislead consumers and other situations.

Article 18. On the basis of carrying out relevant research, any agents or individual can submit to the review center a proposal to include or adjust the health food functions list.

Article 19. According to the registration and supervision of health foods, the State Administration for Market Regulation may select qualified technical

institutions to research health functions. If the functions are qualified, the technical institutions shall propose the proposal to incorporate or adjust the health food function list promptly

Article 20. Proposals for the inclusion or adjustment of the health food functions list shall include the following materials:

20.1 The name, interpretation, mechanism and basis of the health function.

20.2 Health function research report, including health needs analysis of health function, analysis and review of health function and body health effect, principle basis of function, application scope and other relevant scientific research materials.

20.3 Health function evaluation methods and judgment standards, corresponding functional test reports such as animal experiments or human tests;

20.4 Researches and applications of the same or similar functions domestically or overseas.

20.5 Relevant scientific literature and other materials.

If it is recommended to adjust the health functions list, the reasons, basis and related materials for adjustment are also required.

Article 21. The evaluation agency shall conduct a technical evaluation on the proposed materials for incorporation or adjustment of health food functions list to make comprehensive technical conclusions, and submit them to the State Administration for market regulation.

Article 22. The State Administration for Market Regulation shall conduct a preliminary review of the completeness and standardization of the technical evaluation conclusions and other related materials submitted by the review

center. If it is proposed to incorporate or adjust the health food functions list, it shall publicly solicit opinions and revise and improve the conclusion.

Article 23. The State Administration for Market Regulation shall review the submitted materials from the review center for incorporation or adjustment of the health food functions list. If qualified, the incorporated or adjusted health food functions list shall be published timely in conjunction with the National Health Commission and the State Administration of Traditional Chinese Medicine.

Article 24. In any of the following circumstances, the State Administration for Market Regulation shall organize a re-evaluation of the functions in the health food functions list, and according to the re-evaluation results, the list shall be adjusted accordingly with the National Health Commission and the State Administration of Traditional Chinese Medicine.

24.1 Practical applications and new scientific consensus have found that there are problems in the evaluation methods and criteria of health functions, and need to be re-evaluated and demonstrated.

24.2 Health care functions included in the health functions list lack actual health consumption needs.

24.3 Other situations that need to be re-evaluated.

Chapter Four Supplementary

Article 25. The establishment of the health food raw materials list, the establishment of the list of ingredients traditionally regarded as both food and TCM, the review of new food ingredients should be linked to each other.

Article 26. The measures shall come into force on October 1, 2019.

Original Chinese Document listed Below

保健食品原料目录与保健功能目录管理办法

（2019 年 8 月 2 日国家市场监督管理总局令第 13 号公布）

第一章　总　则

第一条　为了规范保健食品原料目录和允许保健食品声称的保健功能目录的管理工作，根据《中华人民共和国食品安全法》，制定本办法。

第二条　中华人民共和国境内生产经营的保健食品的原料目录和允许保健食品声称的保健功能目录的制定、调整和公布适用本办法。

第三条　保健食品原料目录，是指依照本办法制定的保健食品原料的信息列表，包括原料名称、用量及其对应的功效。

允许保健食品声称的保健功能目录（以下简称保健功能目录），是指依照本办法制定的具有明确评价方法和判定标准的保健功能信息列表。

第四条　保健食品原料目录和保健功能目录的制定、调整和公布，应当以保障食品安全和促进公众健康为宗旨，遵循依法、科学、公开、公正的原则。

第五条　国家市场监督管理总局会同国家卫生健康委员会、国家中医药管理局制定、调整并公布保健食品原料目录和保健功能目录。

第六条　国家市场监督管理总局食品审评机构（以下简称审评机构）负责组织拟订保健食品原料目录和保健功能目录，接收纳入或者调整保健食品原料目录和保健功能目录的建议。

第二章　保健食品原料目录管理

第七条　除维生素、矿物质等营养物质外，纳入保健食品原料目录的原料应当符合下列要求：

（一）具有国内外食用历史，原料安全性确切，在批准注册的保健食品中已经使用；

（二）原料对应的功效已经纳入现行的保健功能目录；

（三）原料及其用量范围、对应的功效、生产工艺、检测方法等产品技术要求可以实现标准化管理，确保依据目录备案的产品质量一致性。

第八条　有下列情形之一的，不得列入保健食品原料目录：

（一）存在食用安全风险以及原料安全性不确切的；

（二）无法制定技术要求进行标准化管理和不具备工业化大生产条件的；

（三）法律法规以及国务院有关部门禁止食用，或者不符合生态环境和资源法律法规要求等其他禁止纳入的情形。

第九条　任何单位或者个人在开展相关研究的基础上，可以向审评机构提出拟纳入或者调整保健食品原料目录的建议。

第十条　国家市场监督管理总局可以根据保健食品注册和监督管理情况，选择具备能力的技术机构对已批准注册的保健食品中使用目录外原料情况进行研究分析。符合要求的，技术机构应当及时提出拟纳入或者调整保健食品原料目录的建议。

第十一条　提出拟纳入或者调整保健食品原料目录的建议应当包括下列材料：

（一）原料名称，必要时提供原料对应的拉丁学名、来源、使用部位以及规格等；

（二）用量范围及其对应的功效；

（三）工艺要求、质量标准、功效成分或者标志性成分及其含量范围和相应的检测方法、适宜人群和不适宜人群相关说明、注意事项等；

（四）人群食用不良反应情况；

（五）纳入目录的依据等其他相关材料。

建议调整保健食品原料目录的，还需要提供调整理由、依据和相关材料。

第十二条　审评机构对拟纳入或者调整保健食品原料目录的建议材料进行技术评价，结合批准注册保健食品中原料使用的情况，作出准予或者不予将原料纳入保健食品原料目录或者调整保健食品原料目录的技术评价结论，并报送国家市场监督管理总局。

第十三条　国家市场监督管理总局对审评机构报送的技术评价结论等相关材料的完整性、规范性进行初步审查，拟纳入或者调整保健食品原料目录的，应当公开征求意见，并修改完善。

第十四条　国家市场监督管理总局对审评机构报送的拟纳入或者调整保健食品原料目录的材料进行审查，符合要求的，会同国家卫生健康委员会、国家中医药管理局及时公布纳入或者调整的保健食品原料目录。

第十五条　有下列情形之一的，国家市场监督管理总局组织对保健食品原料目录中的原料进行再评价，根据再评价结果，会同国家卫生健康委员会、国家中医药管理局对目录进行相应调整：

（一）新的研究发现原料存在食用安全性问题；

（二）食品安全风险监测或者保健食品安全监管中发现原料存在食用安全风险或者问题；

（三）新的研究证实原料每日用量范围与对应功效需要调整的或者功效声称不够科学、严谨；

（四）其他需要再评价的情形。

第三章　保健功能目录管理

第十六条　纳入保健功能目录的保健功能应当符合下列要求：

（一）以补充膳食营养物质、维持改善机体健康状态或者降低疾病发生风险因素为目的；

（二）具有明确的健康消费需求，能够被正确理解和认知；

（三）具有充足的科学依据，以及科学的评价方法和判定标准；

（四）以传统养生保健理论为指导的保健功能，符合传统中医养生保健理论；

（五）具有明确的适宜人群和不适宜人群。

第十七条　有下列情形之一的，不得列入保健功能目录：

（一）涉及疾病的预防、治疗、诊断作用；

（二）庸俗或者带有封建迷信色彩；

（三）可能误导消费者等其他情形。

第十八条　任何单位或者个人在开展相关研究的基础上，可以向审评机构提出拟纳入或者调整保健功能目录的建议。

第十九条　国家市场监督管理总局可以根据保健食品注册和监督管理情况，选择具备能力的技术机构开展保健功能相关研究。符合要求的，技术机构应当及时提出拟纳入或者调整保健功能目录的建议。

第二十条　提出拟纳入或者调整保健功能目录的建议应当提供下列材料：

（一）保健功能名称、解释、机理以及依据；

（二）保健功能研究报告，包括保健功能的人群健康需求分析，保健功能与机体健康效应的分析以及综述，保健功能试验的原理依据、适用范围，以及其他相关科学研究资料；

（三）保健功能评价方法以及判定标准，对应的样品动物实验或者人体试食试验等功能检验报告；

（四）相同或者类似功能在国内外的研究应用情况；

（五）有关科学文献依据以及其他材料。

建议调整保健功能目录的，还需要提供调整的理由、依据和相关材料。

第二十一条　审评机构对拟纳入或者调整保健功能目录的建议材料进行技术评价，综合作出技术评价结论，并报送国家市场监督管理总局：

（一）对保健功能科学、合理、必要性充足，保健功能评价方法和判定标准适用、稳定、可操作的，作出纳入或者调整保健功能目录的技术评价结论；

（二）对保健功能不科学、不合理、必要性不充足，保健功能评价方法和判定标准不适用、不稳定、没有可操作性的，作出不予纳入或者调整的技术评价建议。

第二十二条　国家市场监督管理总局对审评机构报送的技术评价结论等相关材料的完整性、规范性进行初步审查，拟纳入或者调整保健食品功能目录的，应当公开征求意见，并修改完善。

第二十三条　国家市场监督管理总局对审评机构报送的拟纳入或者调整保健功能目录的材料进行审查，符合要求的，会同国家卫生健康委员会、国家中医药管理局，及时公布纳入或者调整的保健功能目录。

第二十四条　有下列情形之一的，国家市场监督管理总局及时组织对保健功能目录中的保健功能进行再评价，根据再评价结果，会同国家卫生健康委员会、国家中医药管理局对目录进行相应调整：

（一）实际应用和新的科学共识发现保健功能评价方法与判定标准存在问题，需要重新进行评价和论证；

（二）列入保健功能目录中的保健功能缺乏实际健康消费需求；

（三）其他需要再评价的情形。

第四章　附　则

第二十五条　保健食品原料目录的制定、按照传统既是食品又是中药材物质目录的制定、新食品原料的审查等工作应当相互衔接。

第二十六条　本办法自 2019 年 10 月 1 日起施行。