식품의약품안전처 **Press Release** 다시 대한민국! 새로운 국민의 나라

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Further Strengthen the Safety of Health Functional Food and Expedite Review Process of Functional Raw Ingredients

- Administrative notice of partial amendments to *Standards and Specifications for Health Functional Foods* (Aug.21)
- Fortify the standards and specifications for functional raw ingredients, incorporating the latest scientific evidence on safety and functionality. Furthermore, refine manufacturing standards
- Rationalize the re-deliberation protocol for functional raw ingredients with a documented review history.

The Ministry of Food and Drug Safety (MFDS) of the Republic of Korea (Minister: Oh Yu-Kyoung) announced an administrative notice implementing partial amendments of the *Standards and Specifications for Health Functional Foods* and *Regulations Concerning Approval of Functional Ingredients and Standards and Specifications for Health Functional Foods* on August 21. Key amendments include the reinforcement of standards and specifications of functional raw ingredients and streamlining of the review process for those with established safety profiles, thereby accelerating approval timelines.

This amendment incorporates 'Precautions for intake' based on the re-evaluation* of 9 functional raw ingredients**, including banaba leaf extract. Moreover, to optimize the review process for functional raw

ingredient re-evaluations, only newly presented data will be subject to deliberate.

* If 10 years have passed since approval as a functional raw ingredient or if any issue related to either safety and functionality arises, re-evaluation has been conducted annually since 2017.

** (2 Nutrients) vitamin B6, vitamin C

(7 Functional raw ingredients) banaba leaf extract, ginkgo leaf extract, octacosanol-containing oil, phosphatidylserine, guar gum/guar gum hydrolyzate, theanine, chlorella

1 **Reinforcement of standards and specifications,** and **Expansion of manufacturing standards** (Amendment of *Standards and Specifications for Health Functional Foods*)

① In order to strengthen the management of adverse event after consuming health functional foods, products containing 8 types of functional raw ingredients are required to label precautions for intake saying "Consult a health care practitioner and stop intake if you are having adverse event." Moreover, for each functional ingredient, information such as targeting age group and precautions for individuals taking medication will be provided to ensure safe public consumption.

* e.g.) Ginkgo leaf extracts :

⑶ Precautions for Intake

(a) Pregnant and lactating women, children shall avoid intake

(b) Consult a health care practitioner prior to intake
if you are taking medicines related to blood coagulation

(c) Consult a health care practitioner and Stop intake
if you are having adverse event

② A re-evaluation of functional raw ingredients and a review of human application test results led to adjustments in the daily intake amounts

of octacosanol, guar gum/guar gum hydrolysate, and chlorella to ensure their safety and functionality. Additionally, considering the daily exposure to heavy metals, the lead specification for guar gum/guar gum hydrolysate is tightened to 1.0 ㎎/㎏ − originally from 2.0 ㎎/㎏.

③ Previously, production of theanine was exclusively reliant upon L-glutamine and ethyl amine. This amendment expands the permissible raw material base to include L-glutamic acid* and ethyl amine, and a new manufacturing method is established accordingly.

* The breakdown of L-glutamine with glutaminase enzyme

▶ Expansion of theanine manufacturing standard

Category	Current	Amendment
Raw materials	①L-Glutamine, Ethyl amine	① L-Glutamine, Ethyl amine ② L-Glutaminc acid, Ethyl amine
Preparation and/or processing	⑴ It shall be in edible from by crystallizing with ethanol after concentrating and purifying ① which reacted with glutaminase. ⑵ It shall meet the standards and specification of food additives when chemical synthesis of ①	⑴ It shall be in edible from by crystallizing with ethanol after concentrating and purifying the ① which reacted with glutaminase. ⑵ It shall be in edible from by crystallizing with ethanol after concentrating and purifying the ② which reacted with glutaminase. ⑶ It shall meet the standards and specification of food additives when chemical synthesis of ①,②

2 Steamlining the re-deliberation procedure of functional raw ingredients

(Amendment of *Regulations Concerning Approval of Functional Ingredients*)

If re-deliberation is requested within two years after a functional raw ingredient review is discontinued (e.g., application denial, voluntary withdrawal), previously reviewed data will be acknowledged, and only

newly submitted will be deliberated to expedite the process.

The MFDS expects this amendment to consolidate the safety management and support the development of the health functional food industry. With public safety as our top priority, we will continue to make resonable adjustments to standards and specifications in response to evolving environment of distribution and consumption.

Details can be found on the MFDS website(http://www.mfds.go.kr > Statutes and Materials > Legislation/Administrative Notice). Public comments on this amendments can be submitted by October 21, 2024.

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