

Amendment to the Standards and Specifications for Foods and Food Additives

The government of Japan will revise the current standards for use of Sodium Selenite and Biotin.

Summary

Under Article 10 of the Food Sanitation Act (Act No. 233, 1947) (hereinafter referred to as the “Act”), food additives shall not be used or marketed without authorization by the Minister of Health, Labour and Welfare (hereinafter referred to as “the Minister”). In addition, when specifications or standards are established for food additives based on Article 11 of the Act and stipulated in the Ministry of Health, Labour and Welfare Notification (Ministry of Health and Welfare Notification No. 370, 1959), those additives shall not be used or marketed unless they meet the standards or specifications.

In response to a request from the Minister, the Committee on Food Additives of the Food Sanitation Council that is established under the Pharmaceutical Affairs and Food Sanitation Council has discussed the adequacy of the revision of standards for use of Sodium Selenite and Biotin as a food additive. The conclusion of the committee is outlined below.

Outline of conclusion

The Minister should revise the existing standards for use of Sodium Selenite and Biotin, based on Article 11. (see Attachment).

Attachment

Sodium Selenite 亜セレン酸ナトリウム

Current regulations

Sodium selenite is permitted only in powdered infant formula and formulated breast milk substitutes (excluding those that received the approval of the Minister of Health, Labour and Welfare based on 2, Part 5, Paragraph 6 of Attached Table of the Ministerial Ordinance on Milk and Milk products Concerning Compositional Standards, etc.).

When sodium selenite is used in formulated breast milk substitutes, it shall not be contained at a level exceeding 5.5 µg as Se per 100 kcal for each product.

Revised regulations

Sodium selenite is allowed to be used in liquid infant formula.

Biotin ビオチン

Current regulations

Biotin is permitted only in powdered infant formula and formulated breast milk substitutes (excluding those that received the approval of the Minister of Health, Labour and Welfare based on 2, Part 5, Paragraph 6 of Attached Table of the Ministerial Ordinance on Milk and Milk products Concerning Compositional Standards, etc.), and foods with health claims (foods with nutrient function claims and foods for specified health uses).

When biotin is used in formulated breast milk substitutes, it shall not be contained at a level exceeding 10 µg per 100 kcal in each product.

Revised regulations

Biotin is allowed to be used in liquid infant formula.