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Notice of Modification to the *List of Permitted Sweeteners* to Enable the Use of Monk Fruit Extract (Luo Han Guo) as a Sweetener in Table-Top Sweeteners

Notice of Modification – *Lists of Permitted Food Additives*

Reference Number: [NOM/ADM-0019]

December 2, 2013

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch



Canada

Notice of Modification to the *List of Permitted Sweeteners* to Enable the Use of Monk Fruit Extract (Luo Han Guo) as a Sweetener in Table-Top Sweeteners

Summary

Food additives are regulated in Canada under [Marketing Authorizations](#) (MAs) issued by the Minister of Health and the *Food and Drug Regulations*. Approved food additives and their permitted conditions of use are set out in the [Lists of Permitted Food Additives](#) that are incorporated by reference in the MAs. A petitioner can request that Health Canada approve a new additive or a new condition of use for an already approved food additive by filing a food additive submission with the Department's Food Directorate. Health Canada uses this premarket approval process to determine whether the scientific data support the safety of food additives when used under specified conditions in foods sold in Canada.

Health Canada received a food additive submission seeking approval for the use of monk fruit extract as a sweetener at a maximum level of use of 0.8%, calculated as mogroside V, in table-top sweeteners.

The results of Health Canada's evaluation of available scientific data support the safety and efficacy of monk fruit extract when used as proposed. Since this is a food additive that was not previously permitted for use in Canada, Health Canada published a [Notice of Proposal to Enable the Use of a New Food Additive, Monk Fruit Extract \(Luo Han Guo\), as a Sweetener in Table-Top Sweeteners](#) on March 14, 2013, requesting comments. The comment period was open for 75 days, during which no new scientific information about this additive was submitted to the Department. Since the conclusions of the evaluation remain as described in the Notice of Proposal, Health Canada has modified the [List of Permitted Sweeteners](#) as indicated below.

Modification to the *List of Permitted Sweeteners*

Item No.	Column 1 Additive	Column 2 Permitted in or upon	Column 3 Maximum Level of Use and Other Conditions
M.4	Monk fruit extract	Table-top sweeteners	0.8% calculated as mogroside V

Rationale

Health Canada's Food Directorate has completed its pre-market safety and efficacy assessment of monk fruit extract for use as a sweetener in table-top sweeteners. The assessment considered toxicological, chemical, microbiological, nutritional and technical aspects of the proposal.

No microbiological or nutritional safety concerns have been identified for monk fruit extract when used as proposed and there are no reports indicating a potential association between the ingestion of monk fruit extract and allergies despite a long history of use in other countries, particularly in dietary supplements.

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Based on the results of the safety assessment, Health Canada's Food Directorate considers that the data support the safety of monk fruit extract when used according to conditions set out in the above table. The Department has therefore enabled the use of monk fruit extract as described in the table.

Other Relevant Information

Monk fruit extract used in table-top sweeteners sold in Canada must meet the food-grade specifications set out in the most recent edition of the *Food Chemicals Codex* (FCC). FCC is a compendium of standards for the purity and identity of food ingredients, including food additives, which is published by the United States Pharmacopeial Convention. A key specification of the FCC monograph is that the monk fruit extract contain not less than 30% mogroside V.

In the United States, two Generally Recognized as Safe (GRAS) notices (GRN 000359 and 000301) for monk fruit extract with a mogroside V content of (25%, 45% or 55%) and >30%, respectively, have been submitted to the Food and Drug Administration (FDA) for review since July 2009. The US FDA raised no objections regarding the petitioners' determinations of GRAS (i.e., self-affirmed GRAS) status of the monk fruit extracts for use as a sweetener and flavour enhancer in foods, excluding meat and poultry products, at levels of use consistent with good manufacturing practice.

Australia and New Zealand, and the European Union, do not have food additive provisions for monk fruit extract.

According to published literature, monk fruit extract has been sold as a dietary supplement in Japan, the United States of America, New Zealand and Australia for a number of years.

Monk fruit extract is not listed in the Codex General Standard for Food Additives (GSFA).

Notification – Summary of Comments

In response to the Notice of Proposal to Enable the Use of a New Food Additive, Monk Fruit Extract (Luo Han Guo), as a Sweetener in Table-Top Sweeteners, published on March 14, 2013, Health Canada received four comments during the 75-day comment period.

An industry association requested that consideration be given to allowing monk fruit extract in table-top sweeteners at levels of use consistent with good manufacturing practice (GMP) or, at a minimum, consider a maximum level of 2%, calculated as mogroside V. A food manufacturer also requested that GMP use levels be considered. Health Canada informed both stakeholders that before consideration could be given to changing the maximum level of use for monk fruit extract, scientific data would need to be submitted in support of such a request, as part of a formal food additive submission.

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Another food manufacturer commented that the relative sweetness of mogroside V, when compared to sucrose, should be stated as 200 to 300 times sweeter than sucrose rather than 300 to 400 times as stated in the Notice of Proposal (NOP). The stakeholder was informed that while monk fruit extract itself has been reported to be about 300 times as sweet as sucrose, the value of 300 to 400 stated in the NOP is in reference to the primary sweetening component of monk fruit extract, mogroside V, and not the fruit extract itself.

In addition, support for the proposal was expressed by a food industry association.

Implementation and Enforcement

The above modification came into force on December 2, 2013, the day it was published in the [*List of Permitted Sweeteners*](#).

The Canadian Food Inspection Agency is responsible for the enforcement of the *Food and Drugs Act* and its associated regulations with respect to foods.

Contact Information

Health Canada's Food Directorate is committed to reviewing any new scientific information on the safety in use of any food additive, including monk fruit extract. Anyone wishing to submit new scientific information on the use of this additive or to submit any inquiries may do so in writing, by regular mail or electronically. If you wish to contact the Food Directorate electronically, please use the words "**monk fruit extract**" in the subject line of your e-mail.

[Bureau of Chemical Safety, Food Directorate](#)

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