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MOH issues the List of Micronutrients allowed to be added to food

Report Categories:

Food and Agricultural Import Regulations and
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Report Highlights:

This report provides a summary and an unofficial translation of the Circular 44/2015/TT-BYT of the Ministry of Health (MOH) dated November 30, 2015 promulgating the List of micronutrients allowed to be used for food products. This Circular will take effect from March 1, 2016.

Summary:

According to the Law on Food Safety 55/2010/QH12 and Decree 38/2012/ND-CP detailing the implementation of some articles of the Law on Food Safety, MOH is responsible for administration of micronutrients and foods fortified with micronutrients. The Circular 44/2015/TT-BYT is MOH's new regulation implementing their responsibilities for micronutrients. This Circular will take effect from March 1, 2016.

The draft of this Circular was notified as G/SPS/N/VNM67 to the WTO on April 21, 2015. The U.S. Government provided comments on July 13, 2015, but received no official written response to those comments.

This Circular applies for micronutrients used for fortification and supplementation in food. However, it does not apply for formula nutritional products for children, such as infant formula and supplemental formula.

The list of micronutrients is defined in the Appendix of the Circular and includes Part 1- Vitamins and Their Sources and Part 2- Minerals and Their Sources. Nevertheless, the allowed use levels of these vitamins and minerals are not provided. In regard to micronutrients that are not included in the list enclosed with this Circular but listed by Codex Alimentarius (CODEX) or allowed to be used in their producing countries, the Vietnam Food Administration shall consider and propose MOH to amend and supplement this Circular.

The announcement of conformity with technical regulations or food safety regulations for micronutrients is regulated specifically in Article 3 as "The procedures and dossiers for registration of conformity announcement with technical regulations or food safety regulations shall comply with the requirements stipulated in Article 6, Article 7 of Decree 38/2012 and Article 4, 5, 7 and 9 of Circular 19/2012/TT-BYT of the Ministry of Health dated November 9, 2012 guiding the conformity announcement with technical regulations and food safety regulations". Before importing micronutrients as food ingredients for food processing in Vietnam, a registration of conformity announcement needs to be conducted following one of the two processes:

- Announcement on conformity with technical regulations in regard to micronutrients for which MOH already issued technical regulations, such as iodine, magnesium, calcium, iron, zinc and folic acid; or
- Announcement on conformity with food safety regulations for micronutrients which are not yet regulated by technical regulations.

If exporters have questions regarding this registration, Post recommends interested exporters contact the Vietnam Food Administration (VFA) via email: vfa@vfa.gov.vn.

In respect to micronutrients and micronutrient-supplemented food products, which have been issued a receipt of conformity announcement or certification of announcement on conformity with the food safety regulations before the effective date of this Circular, these products can continue to be used until the expiry date of the Receipt or Certification. Following that, these micronutrients and micronutrient-supplemented food products need to be registered for the renewal of the Receipt or Certification as stipulated in Decree 38/2012 and Circular 19/2012/TT-BYT.

The labeling of micronutrients is regulated by Decree 89/2006 and Joint-Circular 34/2014 guiding the labeling of goods with respect to packaged foods, food additives, and food processing aids and other related regulations.

The full Circular 44/2015 in Vietnamese is available at:

<http://vfa.gov.vn/van-ban-phap-luat/thong-tu-so-442015tt-byt-ban-hanh-danh-muc-vi-chat-dinh-duong-su-dung-trong-thuc-pham-241.vfa>

Below is an unofficial translation of Circular 44/2015.

MINISTRY OF HEALTH
No. 44/2015/TT-BYT

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

Hanoi, November 30, 2015

CIRCULAR

promulgating the “List of micronutrients allowed to be added to food”

Pursuant to the Law on Food Safety dated June 17, 2010;

Pursuant to Decree 38/2012/ND-CP dated April 25, 2012 of the Government on making detailed provisions for implementation of some articles of the Law on Food Safety;

Pursuant to Decree 63/2012/ND-CP dated August 31, 2012 of the Government stipulating the functions, duties, power and organizational structure of the Ministry of Health;

At the request of the Director General of Vietnam Food Administration;

Minister of Ministry of Health hereby issues a Circular promulgating the “List of micronutrients allowed to be added to food”:

Article 1. Scope of regulations

1. This Circular provides the List of vitamins and minerals and the requirements on the administration of micronutrients used for supplementation and fortification in food;
2. This Circular does not apply for formula nutritional products for children. The use of micronutrients for these products must comply with relevant national technical regulations and legal requirements on the trading and using of nutritional products for children.

Article 2. The List of vitamins and minerals allowed to be added to food

The List of vitamins and minerals allowed to be added in food is specified in the Annex enclosed with this Circular.

Article 3. Management requirements in respect to micronutrients

1. Micronutrients shall have to be announced to be in conformity with technical regulations or food safety requirements before being circulated in domestic market. The procedure and dossiers for registration of conformity announcement with technical regulations or food safety regulations shall comply with the requirements stipulated in Article 6, Article 7 of Decree 38/2012/ND-CP dated April 25, 2012 of the Government detailing the implementation of some articles of the Law on Food Safety and Article 4, 5, 7 and 9 of Circular 19/2012/TT-BYT of the Ministry of Health dated November 9, 2012 guiding the conformity announcement with technical regulations and food safety regulations.
2. Labeling micronutrients shall comply with Decree 89/2006/ND-CP dated August 30, 2006 of the Government on labeling, Joint-Circular 34/2014/TT-BYT dated October 27, 2014 of the Minister of the Ministry of Health, the Minister of the Ministry of Agriculture and Rural Development, and the Minister of the Ministry of Industry and Trade guiding the labeling of goods in respect to packaged foods, food additives, and food processing aids and other related regulations.
3. The addition of micronutrients into food must comply with national technical regulations and other relevant regulations.
4. Establishments producing and trading micronutrients must completely satisfy the requirements stipulated in Circular 16/2012/TT-BYT dated October 22, 2012 of the Ministry of Health stipulating the safety requirements in respect to establishments producing and trading food, equipment, and materials for packaging and containing food under the management of the Ministry of Health.

Article 4. Transitional provisions

Micronutrients and micronutrient-supplemented food products, which have been issued with Receipt of regulation conformity announcement or Certification of announcement on conformity with the food safety regulations before the effective date of this Circular, shall continue to be used until the expiry of the effective duration specified in the Receipt or Certification.

Article 5. Revision, amendment and supplement

In regard to micronutrients that are not included in the list attached with this Circular but listed by Codex Alimentarius (CODEX) or allowed to be used in their producing countries, the Vietnam Food Administration shall consider and propose the Ministry of Health to issue the amending and supplementing Circular.

Article 6. Terms of reference

In the case where legal normative documents and regulations, which are referred to in this Circular, have amendment, addition or are replaced, the new legal normative documents shall prevail.

Article 7. Implementation provisions

1. This Circular takes effect from March 1, 2016.
2. The Vietnam Food Administration, Ministry of Health is responsible for presiding over and coordinating with relevant authorities to guide the deployment and organization of implementation of this Circular. In the course of implementation, any difficulty or obstacle should be reported to the Vietnam Food Administration for consideration and settlement./.

Recipients:

- Government Office (Culture-Social Affairs, Official Gazette, Government's E-portal);
- The ministries, ministerial-equivalent agencies, agencies belonging the Government;
- Ministry of Justice (Department of Examination of Legal Normative Documents);
- Minister Nguyen Thi Kim Tien (for report);
- People's Committees of provinces and centrally-run cities;
- Health Departments of provinces and centrally-run cities;
- Food Hygiene and Safety Sub-departments of provinces and centrally-run cities;
- Preventive medicine centers of provinces and centrally-run cities;
- The state inspection agencies in respect to import food;
- E-portal of Ministry of Health;
- Kept archives: at Office, Legal, food safety.

**ON BEHALF OF MINISTER
DEPUTY MINISTER**

(signed)

Nguyen Thanh Long

APPENDIX

THE LIST OF MICRONUTRIENTS PERMITTED TO BE USED TO ADD TO FOOD.

(Promulgated in conjunction with Circular 44/2015/TT-BYT dated November 30, 2015)

1. Vitamins:

No.	Name of vitamin	Source of vitamin
1	Vitamin A	- Retinol - Retinyl acetate - Retinyl palmitate - Beta-carotene
2	Vitamin D	- Cholecalciferol - Ergocalciferol
3	Vitamin E	- D-alpha-tocopherol - DL-alpha-tocopherol - D-alpha-tocopheryl acetate - DL-alpha-tocopheryl acetate - D-alpha-tocopheryl acid succinate - DL-alpha-tocopheryl acid succinate - DL-alpha-tocopheryl polyethylene glycol 1000 succinate - Tocopherol mixture - Tocotrienol tocopherol
4	Vitamin K	- Phylloquinone (phytomenadione) - Menaquinone
5	Vitamin B ₁	- Thiamine hydrochloride - Thiamine mononitrate - Thiamine monophosphate chloride - Thiamine pyrophosphate chloride
6	Vitamin B ₂	- Riboflavin - Riboflavin 5'-phosphate sodium
7	Niacin	- Nicotinic acid - Nicotinamid - Inositol hexanicotinate (inositol hexaniacinate)
8	Pantothenic acid	- D-calcium pantothenate - Sodium d-pantothenate - D-panthenol - DL-panthenol - Pantethine
9	Vitamin B ₆	- Pyridoxine hydrochloride - Pyridoxal 5-phosphate - Pyridoxine 5'-phosphate
10	Folic acid (Vitamin B ₉)	- N-Pteroylmonoglutamic - L-methylolate calcium
11	Vitamin B ₁₂	- Cyanocobalamin - Hydroxocobalamin - 5'-deoxyadenosylcobalamin - Methylcobalamin

12	Biotin	- D-biotin
13	Vitamin C	- L-ascorbic acid - Sodium L-ascorbate - Calcium L-ascorbate - Potassium L-ascorbate - Ascorbyl palmitate - Magnesium L-ascorbate - Zinc L-ascorbate

2. Minerals:

No	Name of mineral	Source of mineral
1	Calcium (Ca)	- Calcium carbonate - Calcium chloride - Calcium citrate salts - Calcium gluconate - Calcium glycerophosphate - Calcium lactate - Calcium phosphate salts - Calcium hydroxide - Calcium oxide - Calcium sulfate - Calcium acetate - Calcium L-ascorbate - Calcium bisglycinate - Calcium citrate malate - Calcium pyruvate - Calcium succinate - Calcium L-lysinate - Calcium malate - Calcium L-pidolate - Calcium L-threonate - Calcium Hydroxyapatite
2	Magnesium (Mg)	- Magnesium carbonate - Magnesium chloride - Magnesium citrate salts - Magnesium gluconate - Magnesium glycerophosphate - Magnesium phosphate salts - Magnesium lactate - Magnesium hydroxide - Magnesium oxide - Magnesium sulfate - Magnesium acetate - Magnesium hydroxide carbonate - Magnesium L-ascorbate - Magnesium bisglycinate

		<ul style="list-style-type: none"> - Magnesium L-lysinate - Magnesium malate - Magnesium L-pidolate - Magnesium potassium citrate - Magnesium pyruvate - Magnesium succinate - Magnesium taurate - Magnesium acetyl taurate
3	Iron (Fe)	<ul style="list-style-type: none"> - Iron (II) carbonate - Iron (II) citrate - Iron (III) citrate - Ammonium iron (III) citrate - Iron (II) gluconate - Iron (II) fumarate - Iron (III) sodium diphosphate - Iron (II) lactate - Iron (II) sulfate - Iron (III) diphosphate (Iron (III) pyrophosphate) - Iron (III) saccharate - Iron element (hydrogen-reducing iron, electrolytic iron and carbonyl iron) - Iron (II) succinate - Iron (II) bisglycinate - Iron (III) orthophosphate - Iron (II) L-pidolate - Iron (II) phosphate - Iron (II) taurate - Iron sodium (III) EDTA, trihydrate
4	Copper (Cu)	<ul style="list-style-type: none"> - Copper carbonate - Copper citrate - Copper gluconate - Copper sulfate - Copper-lysine complex - Copper bisglycinate - Copper oxide - Copper L-aspartate
5	Iodine (I)	<ul style="list-style-type: none"> - Sodium iodide - Sodium iodate - Potassium iodide - Potassium iodate - Calcium iodide - Calcium iodate
6	Zinc (Zn)	<ul style="list-style-type: none"> - Zinc acetate - Zinc chloride - Zinc citrate - Zinc gluconate

		<ul style="list-style-type: none"> - Zinc lactate - Zinc oxide - Zinc carbonate - Zinc sulfate - Zinc L-ascorbate - Zinc L-aspartate - Zinc bisglycinate - Zinc L-lysinate - Zinc malate - Zinc mono-L-methionine sulfate - Zinc L-pidolate - Zinc picolinate - Zinc stearate
7	Manganese (Mn)	<ul style="list-style-type: none"> - Manganese carbonate - Manganese chloride - Manganese citrate - Manganese gluconate - Manganese glycerophosphate - Manganese sulfate - Manganese ascorbate - Manganese L-aspartate - Manganese bisglycinate - Manganese pidolate
8	Sodium (4) (Na)	<ul style="list-style-type: none"> - Sodium bicarbonate - Sodium carbonate - Sodium chloride - Sodium citrate - Sodium gluconate - Sodium lactate - Sodium hydroxide - Sodium salts of orthophosphoric acid - Sodium sulfate
9	Potassium (K)	<ul style="list-style-type: none"> - Potassium bicarbonate - Potassium carbonate - Potassium chloride - Potassium citrate - Potassium gluconate - Potassium glycerophosphate - Potassium lactate - Potassium hydroxide - Potassium salts of orthophosphoric acid - Potassium - L-pidolate

		- Potassium malate
10	Selenium (Se)	<ul style="list-style-type: none"> - Sodium selenate - Sodium hydrogen selenite - Sodium selenite - L-selenomethionine - Selenium enriched yeast - Selenious acid
11	Chromium (Cr III)	<ul style="list-style-type: none"> - Chromium chloride and its hexahydrate - Chromium sulfate and its hexahydrate - Chromium lactate trihydrate - Chromium nitrate - Chromium picolinate
12	Molybdenum (Mo VI)	<ul style="list-style-type: none"> - Ammonium molybdate - Sodium molybdate - Potassium molybdate
13	Fluorine (F)	<ul style="list-style-type: none"> - Potassium fluoride - Sodium fluoride - Calcium fluoride - Sodium monofluorophosphate
14	Boron (B)	<ul style="list-style-type: none"> - Boric acid - Sodium borate
15	Silicon (Si)	<ul style="list-style-type: none"> - Silicon dioxide - Silicic acid - Choline-stabilized orthosilicic acid