

REGULATORY WEBINAR

**HEALTH SUPPLEMENTS,
NUTRACEUTICALS, FSDU, FSMP,
FUNCTIONAL FOODS AND NOVEL
FOODS REGULATIONS**

12TH MARCH 2021

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Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016

- 1. RÉGULATIONS SCOPE AND MAIN REQUIREMENTS**
- 2. DRAFT AMENDEMENTS UPDATE (2020)**
- 3. MAIN CHALLENGES AND WAY FORWARD**
- 4. Q & A**

FOOD SAFETY AND STANDARDS (HEALTH SUPPLEMENTS, NUTRACEUTICALS, FOOD FOR SPECIAL DIETARY USE, FOOD FOR SPECIAL MEDICAL PURPOSE, FUNCTIONAL FOOD AND NOVEL FOOD REGULATIONS, 2016



Ministry of Health & Family Welfare
Government of India

- **PUBLICATION DATE : DEC 2016**

- **IMPLEMENTATION : JANUARY 2018**

- SCOPE OF PRODUCTS:

NUTRACEUTICALS/HEALTH
SUPPLEMENTS (Above 5
Years)

FSDU (FOR CERTAIN
PHYSIOLOGICAL
CONDITIONS) (Intended
for above 24 months of
age)

FSMP (FOOD FOR
SPECIAL MEDICAL
PURPOSE) (Intended
for above 24 months
of age)

Functional Foods, Novel
Foods (above 24 months
of age)



Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016

SCHEDULES MEANS THE SCHEDULES TO THESE REGULATION :

- ☐ **LIST OF VITAMINS AND MINERALS AND THEIR COMPONENTS : SCHEDULE- I**
- ☐ **LIST OF AMINO ACIDS AND OTHER NUTRIENTS : SCHEDULE-II**
- ☐ **VALUES OF VITAMINS AND MINERALS AND TRACE ELEMENTS ALLOWED TO BE USED IN FOOD FOR SPECIAL DIETARY USES AND FSMP:**

SCHEDULE III

- ☐ **LIST OF PLANT OR BOTANICALS : SCHEDULE IV**
- ☐ **LIST OF FOOD ADDITIVES : SCHEDULES V(A) TO V (F)**
- ☐ **LIST OF INGREDIENTS AS NUTRACEUTICALS : SCHEDULE VI, PART A AND PART B**
- ☐ **LIST OF STRAINS AS PROBIOTICS (LIVE MICRO-ORGANISM) : SCHEDULE VII**
- ☐ **LIST OF PREBIOTIC COMPOUND : SCHEDULE VII**

HEALTH SUPPLEMENTS & NUTRACEUTICALS

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REQUIREMENTS

- **Health Supplement** shall contain any of the Ingredients specified in Schedule I or Schedule II or Schedule IV or Schedule VII or Enzymes of Schedule VI.
- May Contain any of the ingredients as specified in these regulation.
- Nutrients can be added up to **1 RDA**.

• Nutraceuticals:

Nutraceuticals.– (1)(i) The nutraceuticals shall provide a physiological benefit and help maintain good health.

A food business operator may extract, isolate and purify nutraceuticals from food or non-food sources, that is preparing amino acids and their derivatives by bacterial fermentation under controlled conditions.

A food business operator may prepare and sell the nutraceuticals in the food-format of granules, powder, tablet, capsule, liquid, jelly or gel, semi-solids and other formats and may be packed in sachet, ampoule, bottle, and in any other format as measured unit quantities except those formats that are meant for parenteral administration.

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- **No restriction of advertisement to general public**


1) CHANNELS/HCP RECOMMENDATIONS

- **No channel restriction and can be sold to OTC and General trade etc.**
- **HCP Recommendation not mandatory .**

FOODS FOR SPECIAL DIETARY USES (FSDU)

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REQUIREMENTS

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- Specially processed or formulated to satisfy particular dietary requirements which may exist or arise because of certain physiological or specific health conditions (**Ex. *Low weight ,Obesity, Diabetes, High blood pressure, Pregnant and lactating women, Geriatric population and other health conditions***)
 - May Contain any of the ingredients as specified in these Regulations.
 - Nutrients can be added **more than the RDA** but shall not exceed the maximum requirements as specified in **Schedule-III** (Nutrient requirements table).



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- **No restriction as on today but under review by Authority (Advertisement restriction to general public notified in Draft regulation)**

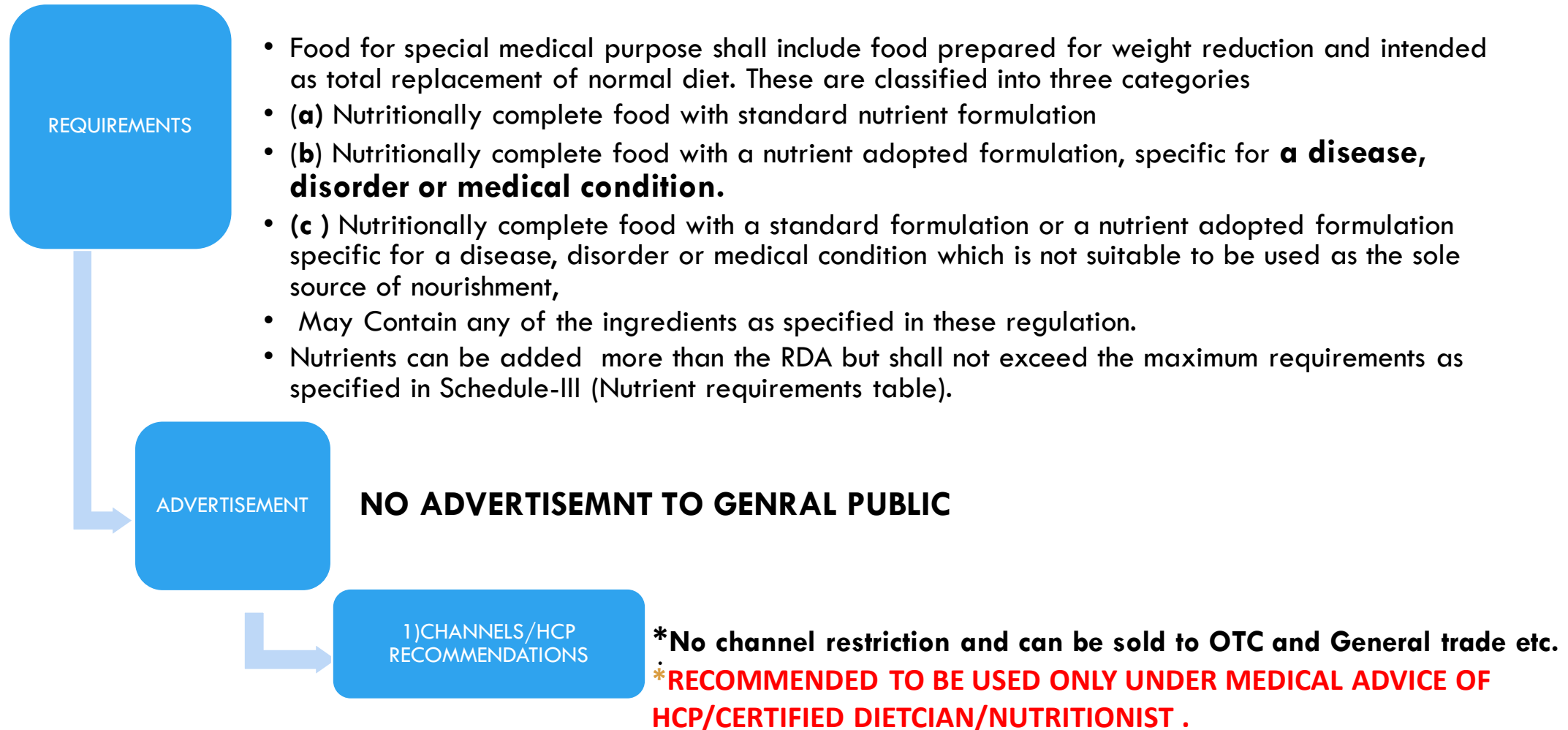


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FOOD FOR SPECIAL MEDICAL PURPOSE (FSMP)

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FOOD SAFETY AND STANDARDS (HEALTH SUPPLEMENTS, NUTRACEUTICALS, FOOD FOR SPECIAL DIETARY USE, FOOD FOR SPECIAL MEDICAL PURPOSE, FUNCTIONAL FOODS AND NOVEL FOODS) AMENDMENT REGULATIONS, 2020

POSITIVE DEVELOPMENTS :

HEALTH SUPPLEMENTS :

- (i) HEALTH SUPPLEMENT SHALL CONTAIN SINGLY OR IN COMBINATION WITH ANY OF THE INGREDIENTS SPECIFIED IN **SCHEDULE I OR SCHEDULE II OR BOTH**. IT MAY ALSO CONTAIN SINGLY OR IN COMBINATION WITH ANY OF THE INGREDIENTS SPECIFIED IN SCHEDULE IV, SCHEDULE VI (PROTEIN AND ENZYMES ONLY), SCHEDULE VII & SCHEDULE VIII.

NUTRACEUTICALS :

- (i) NUTRACEUTICAL SHALL CONTAIN INGREDIENTS SPECIFIED IN **SCHEDULE VI**. IT MAY ALSO CONTAIN SINGLY OR IN COMBINATION WITH ANY OF THE INGREDIENTS SPECIFIED IN SCHEDULE I, SCHEDULE II, SCHEDULE IV, SCHEDULE VII AND SCHEDULE VIII.” SCHEDULE VIII”.



FOODS FOR SPECIAL DIETARY USES : INCLUSION OF **FOOD FOR SPORTSPERSONS**.

GENERAL PROVISIONS:

- ☐ PRODUCTS COVERED UNDER THESE REGULATIONS MAY ALSO CONTAIN SUCH ADDITIONAL INGREDIENTS, OTHER THAN ADDITIVES, WHICH ARE EITHER STANDARDIZED OR PERMITTED FOR USE IN PREPARATION OF THE OTHER STANDARDIZED FOODS AS SPECIFIED IN THE FOOD SAFETY AND STANDARDS (FOOD PRODUCTS STANDARDS AND FOOD ADDITIVES) REGULATIONS, 2011.

POSITIVE DEVELOPMENTS :

- ☐ **CLAIMS APPROVAL** : ANY OTHER CLAIMS IN AN ARTICLE OF FOOD THAT ARE NOT DRUG CLAIMS MAY BE ALLOWED SUBJECT TO PRIOR APPROVAL OF THE FOOD AUTHORITY.

- ☐ THE PRODUCTS COVERED UNDER THESE REGULATIONS INTENDED FOR CHILDREN 2 TO 5 YEARS OF AGE SHALL ONLY BE GIVEN UNDER MEDICAL ADVICE BY PHYSICIAN/ CERTIFIED DIETICIAN/NUTRITIONIST.

- ☐ **COMBINATIONS** OF VITAMINS AND MINERALS, INCLUDING USE OF SINGLE VITAMIN AND MINERAL, IN DOSAGE FORMATS SUCH AS TABLETS, CAPSULES, SYRUPS, AT LEVELS EQUAL TO A MAXIMUM OF ONE RDA OR BELOW SHALL BE COVERED UNDER THESE REGULATIONS.

- ☐ **INCLUSION** OF NEW BOTANICAL INGREDIENTS IN **SCHEDULE IV**
- ☐ **INCLUSION** OF NEW STRAINS (PROBIOTIC) IN **SCHEDULE VII**
- ☐ **INCLUSION** OF NEW PREBIOTIC INGREDIENTS IN **SCHEDULE VIII**

CHALLENGES AND WAY FORWARD

❑ NUTRACEUTICAL REGULATION DRAFT AMENDMENT PROPOSES RESTRICTIONS ON FSDU PRODUCTS ADVERTISEMENT.

RECOMMENDATION: REQUEST TO DELETE THIS REQUIREMENT

RATIONALE :

GLOBALLY, THERE IS NO SUCH RESTRICTION BY ANY COUNTRY ON ADVERTISEMENT OF FSDU TO GENERAL PUBLIC, AND TO THE CONTRARY IN SEVERAL CASES, ONLY THE FSDU CAN USE CERTAIN CLAIMS AND ADVERTISE ACCORDINGLY, TO THE GENERAL PUBLIC, IN ORDER TO ENSURE AND PROVIDE PROPER INFORMATION TO CONSUMERS.

CODEX, AUSTRALIA, NEW ZEALAND, CANADA, EU, USA AND OTHERS.

❑ NUTRIENTS TOLERANCES : MINUS 10 % OF DECLARED VALUE. (FINAL NOTIFICATION 2016)

RECOMMENDATIONS: TOLERANCE VALUES FOR EACH NUTRIENTS SHOULD BE ALIGNED AS PER EU /CODEX PRINCIPLES .

❑ NUTRIENTS ALLOWANCE UP TO MAX 1RDA IN FSDU, FSMP ETC. (EARLIER IT WAS ALLOWED MORE THAN RDA AND MAX UP TO 50% OF TUL AND IN FSMP, IT WAS UP TO MAX VALUE OF SCHEDULE III NUTRIENTS).

RECOMMENDATIONS : THESE PRODUCTS SHOULD BE ALLOWED WITH MORE THAN RDA OF NUTRIENTS AS THESE ARE DESIGNED TO CATER THE SPECIFIC PHYSIOLOGICAL CONDITIONS.

PERMITTED RANGE OF USAGE FOR ADULTS PER DAY (GIVEN IN TERMS OF RAW HERB/ MATERIAL) IN SCHEDULE IV AND MINIMUM VALUES ARE VERY DIFFICULT TO COMPLY .

*Thank
you*

