

Notice Calling for suggestions, views, comments etc from stakeholders on the Draft Food Safety & Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional food and Novel food) amendment Regulations, 2018.

F. No. Stds./03/Notification-02 (Nutra)/FSSAI-2018.- In the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Foods and Novel Foods) Regulations, 2016,-

(A) in regulation 6,-

(i) in sub-regulation (2), for clause (i), the following shall be substituted, namely;-

“Health supplement shall contain ingredients specified in Schedule I and/or Schedule II. It may also contain ingredients specified in Schedule IV, Schedule VI (enzymes only), Schedule VII and Schedule VIII”.

(B) in regulation 7,-

(i) in sub-regulation (2), for clause (i), the following shall be substituted, namely;-

“Nutraceutical shall contain ingredients specified in Schedule VI. It may also contain ingredients specified in Schedule I, Schedule II, Schedule IV, Schedule VII and Schedule VIII.”

(C) in regulation 8, in sub-regulation (2),-

(i) for clause (i), the following shall be substituted, namely;-

“Food for special dietary use shall contain any of the ingredients specified in Schedule I, Schedule II, Schedule IV, Schedule VI, Schedule VII, and Schedule VIII.”

(ii) for clause (iv), the following shall be substituted, namely;-

“A food business operator may add the quantity of the nutrients up to 50 per cent of tolerable upper limit (TUL) or up to one Recommended Daily Allowance (RDA), whichever is higher”. In case, wherever TUL is not specified, FBOs shall not exceed more than one RDA.

If both RDA and TUL is not available, the addition may be rationalized and justified based on relevant national/international scientific documents for safety and efficacy.”

(D) in regulation 9,-

(i) in sub-regulation (2), for clause (i), the following shall be substituted, namely;-

“Food for special medical purpose shall contain any of the ingredients specified in Schedule I, Schedule II, Schedule IV, Schedule VI (enzymes only), Schedule VII, and Schedule VIII”

(E) after regulation 13, the following shall be inserted, namely,-

“14. Standards for ingredients:

(1) Psyllium (Isabgol) husk: (i) Psyllium (Isabgol) husk means product manufactured from dry seed coats of *Plantago ovate* Forsk. (Fam. *Plantaginaceae*) obtained by crushing the clean seeds and separating the husks by winnowing.

(ii) The product shall be white or translucent, odourless, thin boat shaped structures, 2 to 3 mm long and 0.5 to 1 mm wide. The taste shall be bland and mucilaginous. It should not give any gritty feeling during sensorial (organoleptic) evaluation.

(iii) It shall be free from insect infestation, fungal contamination and fermented, musty or other odours. It shall also be free from any added additives, colours, flavours and harmful foreign materials.

(iv) The product shall conform to the following requirements:

S. No.	Characteristics	Requirements
i)	Moisture, per cent by mass	Not more than 11.5
ii)	Total ash (on dry basis), per cent by mass	Not more than 4.0
iii)	Acid Insoluble Ash (on dry basis), per cent by mass	Not more than 0.45
iv)	Swell Volume, ml/gram	Not less than 40
v)	Organic extraneous matter*, per cent by mass	Not more than 2

*Organic extraneous matter includes broken or entire embryo, fragments of endosperm or capsular wall of fruits belonging to isabgol crop.”

(F) In Schedule III, for the title the following shall be substituted, namely:-

“Schedule – III

[See regulations 3(13), 4(2), 9(2)(i), 9(2)(iv) and 9(2)(v)]

Values for vitamins, minerals and trace elements allowed to be used in Food for Special Medical Purpose (other than those intended for use in Infant Formula)”

(G) In Schedule VA, after serial number 39 and the entries relating thereto, the following serial number and entries shall be inserted, namely,-

“40	172(i), 172(ii), 172(iii)	Iron oxides	7,500 mg/kg (For use in surface treatment only)”
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