

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.

Note- This draft amendment should be read with earlier 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 which was uploaded on the on 09.01.2018 website for comments of stakeholders under "Notice For Comments". There are some changes with respect to previous draft, which are as below-

A. (i) the entry "*Areca catechu* L." Listed in Schedule IV revision is proposed to be deleted in view of some safety concern.

(ii) the entries "Glutathione" and "Sterols/Stanol including their esters and cholesterol", is proposed to be replaced with the entries "Glutathione/S-acetyl glutathione" and "Sterols/Stanol including their esters" respectively.

B. In addition to the above, following insertion also proposed 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,-

(i) in regulation 3, after sub-regulation (28), the following sub-regulations shall be inserted, namely,-

(29) For combining ingredients there shall be a rationale based on available scientific and technical evidence which shall be made available to the Food Authority as and when called for.

(ii) in Schedule VF, -

(a) against serial number 18 relating to "Cross carmellose sodium", for the entries in columns (4), the following shall be substituted, namely,-

' 0.5 to 5 %'

(b) after the serial number 83 and the entries relating thereto, the following serial numbers and entries shall be inserted, namely,-

'84	Isopropyl alcohol	Solvent for coating	GMP
85	Dichloromethane	Solvent for coating	GMP
86	Potassium chloride	Gelling agent	GMP'

(iii) In part B,

(a) for serial number 178 relating to "sterol/stanol including their esters and cholesterol" and the entries relating thereto in columns (2), (3) and (4), the following shall be substituted, namely,-

'178.	Sterols/Stanol including their esters '	-
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(b) after the serial number 195, the following serial number and entries shall be inserted, namely,-

'196	Mucopolysaccharides'	
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